On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

FDA notes that in particular, the QMSR does not utilize certain terms, such as "Design Controls," and "Design Validation." The elements that comprise these terms are described in ISO 13485:2016, Clause 7.3 and its subclauses, which are incorporated by reference in the QMSR.

Contains Nonbinding Recommendations

Content of Premarket Submissions for Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 14, 2023.

The draft of this document was issued on November 4, 2021.

This document supersedes Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005.

For questions about this document regarding CDRH-regulated devices, contact the Digital Health Center of Excellence at digitalhealth@fda.hhs.gov. For questions about this document regarding CBER regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2021-D-0775. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00000337 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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Content of Premarket Submissions for Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

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

I. Introduction

This guidance document is intended to provide information regarding the recommended documentation for premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions, which 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).[1] This document replaces FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

The recommendations in this guidance are intended to facilitate FDA's premarket review. This guidance describes information that would be typically generated and documented[2] during software development, verification, and validation. The least burdensome approach was applied to identify the minimum amount of information that, based on our experience, would generally be needed to support a premarket submission for a device that uses software. During premarket review, FDA may request additional information that is needed to evaluate the submission. For example, in order to demonstrate a reasonable assurance of safety and effectiveness for devices

[1] The term "device" is defined in 201(h)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act to include an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man ... or intended to affect the structure or any function of the body of man..." and "does not include software functions excluded pursuant to section 520(o)" of the FD&C Act.

[2] As a reminder, manufacturers of device software must create and maintain software-related documentation in accordance with the requirements of the Quality System (QS) Regulation (21 CFR 820.30 Subpart C – Design Controls of the Quality System Regulation).

that use software, documentation related to the requirements of the Quality System Regulation (QSR) (21 CFR Part 820) is often a necessary part of the premarket submission. As part of QSR design controls, a manufacturer must "establish and maintain procedures for validating the device design," which "shall include software validation and risk analysis, where appropriate" (21 CFR 820.30(g)).

The documentation recommended in this guidance is based on FDA's experience evaluating the safety and effectiveness of device software. However, sponsors may use alternative approaches and provide different documentation so long as their approach and documentation satisfy premarket submission requirements in applicable statutory provisions and regulations. For the current edition(s) of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[3] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices[4] and Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research.[5]

As stated above, this guidance identifies the software information FDA considers to generally be necessary to support a premarket submission. The recommendations in this guidance are also intended to facilitate FDA's premarket review. FDA anticipates that the Agency and industry will need up to 60 days after the publication of this guidance to operationalize the recommendations discussed. However, CDRH intends to review any such information if submitted at any time.

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

II. Background

The purpose of this guidance is to describe FDA's thinking on the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions. This thinking recognizes recent changes to the FD&C Act made by the 21st Century Cures Act (Cures Act), which amended section 520 of the FD&C Act and excludes certain software functions from the device definition. It also considers the rapidly evolving nature of digital health and recent FDA-recognized consensus standards related to software. This guidance, as described in Section III (Scope), is intended to complement other existing guidance documents that provide recommendations related to software, including the

[3] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.
[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation.

guidance documents listed below. The following guidance documents represent a subset of FDA guidances with digital health content[6] relevant to premarket software documentation activities. Please note the list is not exhaustive and is subject to change:

- Multiple Function Device Products: Policy and Considerations[7]
- Off-The-Shelf Software Use in Medical Devices[8]
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices[9]
- General Principles of Software Validation[10]
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices[11]
- Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software[12]
- Applying Human Factors and Usability Engineering to Medical Devices[13]

FDA encourages the consideration of these guidances when developing device software functions and preparing premarket software documentation.

The emergence of consensus standards related to software has helped to improve the consistency and quality of software development and documentation, particularly with respect to activities such as risk assessment and management. When possible, FDA harmonized the terminology and recommendations in this guidance with software-related consensus standards, such as the following examples. The following standards are not intended to represent an exhaustive list and are subject to change:[14]

- ANSI/AAMI/ISO 14971: *Medical devices - Applications of risk management to medical devices*
- ANSI/AAMI/IEC 62304: *Medical Device Software - Software Life Cycle Processes*
- ANSI/AAMI SW91: *Classification of defects in health software*

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[6] Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content.
[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations.
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.
[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-premarket-submission-recommendations-interoperable-medical-devices.
[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation.
[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices.
[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software.
[13] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices.
[14] The most up-to-date list of voluntary FDA-recognized consensus standards is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

The Agency encourages the consideration of these FDA-recognized consensus standards when developing device software functions and preparing premarket software documentation. When assessing the appropriate Documentation Level for the device and the overall recommended documentation for inclusion in a premarket submission, please refer to Section V (Documentation Level) and Section VI (Recommended Documentation) of this guidance.

Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 ("FDORA"), enacted on December 29, 2022, added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act (section 515C). Under section 515C, FDA can approve or clear a predetermined change control plan (PCCP) for a device that describes planned changes that may be made to the device and that would otherwise require a supplemental premarket approval application or premarket notification. For example, section 515C provides that a supplemental premarket approval application (section 515C(a)) or a premarket notification (section 515C(b)) is not required for a change to a device if the change is consistent with a PCCP that is approved or cleared by FDA. Section 515C also provides that FDA may require that a PCCP include labeling for safe and effective use of a device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan. If you are interested in proposing a PCCP in your marketing submission, we encourage you to submit a Pre-Submission to engage in further discussion with CDRH. See FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

III. Scope

For the purposes of this document, FDA refers to a software function that meets the definition of a device as a device software function. For any given product, 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.[15] For example, a product with an intended use to analyze data has one function: analysis. A product with an intended use to store, transfer, and analyze data has three functions: (1) storage, (2) transfer, and (3) analysis. As this example illustrates, a product may contain multiple functions.

This guidance is intended to cover device software functions. Examples include, but are not limited to, firmware and other means for software-based control of medical devices, software accessories to medical devices, and software only[16] function(s) that meet the definition of a device.

[15] For details, see "Multiple Function Device Products: Policy and Considerations," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations.

[16] "Software only" functions include device software functions intended to be operated on commercial OTS computing platforms.

This guidance recommends the information to provide in a premarket submission that includes a device software function(s). For the purposes of this guidance, the term premarket submission includes, but is not limited to, premarket notification (510(k)) submission, De Novo classification request, Premarket Approval (PMA) application, Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE), or Biologics License Application (BLA). Certain devices are subject to premarket review through a BLA under section 351 of the Public Health Service Act.

This guidance does not apply to automated manufacturing and Quality System software[17] or software that is not a device. For further information or to clarify the documentation expectations, please contact the responsible FDA review division.

Generally, the recommendations in this guidance apply to the device constituent part of a combination product[18] (such as drug-device and biologic-device combination products) when the device constituent part[19] includes a device software function, including combination products assigned to CDER and CBER regulated under drug or biological product market submission types. For more information, contact the FDA review Division that will have the lead review for the combination product.[20]

Other FDA guidance documents may recommend additional software-related documentation for inclusion in a premarket submission. For example, recommendations regarding cybersecurity information to include in a device premarket submission can be found in the guidances "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and "Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."[21] Section II (Background) references other relevant guidance documents that supplement the recommendations contained in this guidance.

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[17] As part of Quality System Regulation production and process controls, 21 CFR 820.70(i) states, "When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented."

[18] 21 CFR 3.2(e).

[19] 21 CFR 4.2.

[20] Sponsors may request in writing the participation of representatives of the Office of Combination Products (OCP) in meetings regarding their combination products, or to have OCP otherwise engage on regulatory matters concerning the product (section 503(g)(1)(A) of the FD&C Act). In addition, if you are uncertain whether your product is a combination product or a constituent part of a combination product, or which center has primary jurisdiction, you may request engagement by the Office of Combination Products. For more information on requesting engagement on regulation of combination products, please see FDA's guidance "Requesting FDA Feedback on Combination Products," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.

[21] For example, as part of the software validation and risk analysis required by 21 CFR 820.30(g), software device manufacturers may need to establish a cybersecurity risk management process that encompasses the total product lifecycle in order to address cybersecurity risks and emerging vulnerabilities.

Device software functions subject to specific special controls[22] may require additional software-related documentation in a premarket submission. As applicable, please refer to the relevant special controls for the device.

This guidance does not apply to the software-related documentation that may be needed to evaluate postmarket software device issues, including corrections and removals.[23]

While this guidance identifies the documentation sponsors should include in premarket submissions, this guidance is not meant to provide recommendations regarding how device software should be developed, verified, and validated. This guidance does not recommend the use of any specific software life cycle model or development methodology (such as waterfall model or other variations thereof, spiral model, Agile model, etc.). Sponsors should establish a software life cycle model that is appropriate for their product and organization, and meets the applicable regulatory requirements. The software life cycle model that is selected should cover the software throughout its total product life cycle. Regardless of the software lifecycle model being utilized, sponsors should ensure that the establishment of their design history file (DHF)[24] documentation is synchronized with their software development, verification, and validation efforts. DHF documentation that is created retrospectively or following a prolonged period of time after actual software development, verification, and validation efforts could raise concerns regarding whether a developer has adequate control of their design process. For recommendations on device software development, verification, and validation, please consult software-related FDA-recognized voluntary consensus standards and other software-related FDA guidance documents referenced in this guidance (e.g., "General Principles of Software Validation"[25]).

IV. Definitions

The following terms are used for the purposes of this guidance:

Device Software Function - Software function that meets the device definition in section 201(h) of the FD&C Act. As discussed above, 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.

[22] For more information regarding special controls, please see FDA's Regulatory Controls webpage, available at https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.
[23] See 21 CFR Part 806.
[24] Each manufacturer shall establish and maintain a DHF for each type of device. 21 CFR 820.30(j). A DHF is a compilation of records which describes the design history of a finished device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of 21 CFR 820. See 21 CFR 820.30(j).
[25] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation.

Off-the-Shelf (OTS) Software[26] - A generally available software component used by a device manufacturer for which the manufacturer cannot claim complete software life cycle control (e.g., operating system, printer/display libraries).

Serious Injury[27] - An injury or illness that:

1) Is life threatening,
2) Results in permanent impairment of a body function or permanent damage to a body structure, or
3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent is defined as irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

Software Verification and Software Validation - This guidance uses the terms "software verification" and "software validation," which are described in further detail below.

- For the purposes of this guidance, software verification is confirmation by objective evidence that the output of a particular phase of development meets all the input requirements for that phase. Software verification involves evaluating the consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. Software testing is one of several verification activities intended to confirm that the software development output meets its input requirements. Other verification activities include source code evaluations (e.g., code inspections and walkthroughs), document inspections, design reviews, technical evaluations (e.g., software architecture, software detailed design, etc.) and traceability analyses (e.g., software requirements specification to software design specification (and vice versa), source code to software design specification (and vice versa), and test cases to source code and to software design specification). For example, the input and output of the design phase are known as Software Requirements Specification (SRS) and Software Design Specification (SDS), respectively. In this case, software verification would involve confirming by objective evidence (e.g., reviews, traceability analysis) that the software design as documented in the SDS (i.e., output) correctly and completely implements all the requirements of the SRS (i.e., input).

- For the purposes of this guidance, software validation refers to establishing, by objective evidence, that the software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled. Software validation is a part of design validation of the finished device. It involves checking for proper operation of the software in its actual or simulated use environment, including integration into the final device where appropriate. Software validation is highly dependent upon comprehensive software testing and other

[26] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.
[27] *Serious injury* as defined in 21 CFR 803.3(w).

verification tasks previously completed at each stage of the software development life cycle. Planning, requirements, traceability, testing, risk assessment, design reviews, change management, and many other aspects of good software engineering are important activities that together help to support a conclusion that software is validated.

The above descriptions of software verification and software validation are consistent with FDA's thinking as described in the guidance "General Principles of Software Validation."

V. Documentation Level

The recommended documentation for a premarket submission depends on the device's risk to a patient, a user of a device, or others in the environment of use. FDA intends to take a risk-based approach to help determine the device's Documentation Level, which is either **Basic** or **Enhanced**. The purpose of the Documentation Level is to help identify the minimum amount of information that would support a premarket submission that includes device software functions.

The Documentation Level of a device is based on the risks of its device software function(s) in the context of the device's intended use,[28] such that the documentation level reflects the device as a whole.

For the purpose of this guidance:

> **Enhanced Documentation** should be provided for any premarket submission that includes device software function(s) where a failure or flaw of any device software function(s) could present a hazardous situation with a probable[29] risk of death or serious injury,[30] either to a patient, user of the device, or others in the environment of use. These risks should be assessed prior to implementation of risk control measures. Sponsors should consider the risks in the context of the device's intended use (e.g., impacts to safety, treatment, and/or diagnosis), and other relevant considerations.
>
> **Basic Documentation** should be provided for any premarket submission that includes device software function(s) where Enhanced Documentation does not apply.

When determining the Documentation Level, sponsors should consider all known or foreseeable software hazards and hazardous situations associated with the device, including those resulting from reasonably foreseeable misuse, whether intentional or unintentional, prior to the implementation of risk control measures. This also includes the likelihood that device functionality is intentionally or unintentionally compromised by inadequate device cybersecurity.

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[28] See 21 CFR 801.4 ("…[I]ntended uses…refer to the objective intent of the persons legally responsible for the labeling of an article. The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article.").
[29] The term "probable" is intended to exclude the consideration of purely hypothetical risks.
[30] See 21 CFR 803.3(w).

It is the sponsor's responsibility to proactively and comprehensively consider risks as part of the device's risk assessment.[31]

While devices within the scope of this guidance should be individually assessed to determine the appropriate Documentation levels, there are certain categories of devices for which we recommend that Enhanced Documentation be provided in a premarket submission. Specifically, we recommend that Enhanced Documentation should be provided in a premarket submission for devices intended to test blood donations for transfusion-transmitted infections, devices used to determine blood donor and recipient compatibility, automated blood cell separator devices intended for collection of blood and blood components for transfusion or further manufacturing use, and blood establishment computer software (BECS).[32]

There are other categories of device for which we generally recommend Enhanced Documentation be provided in a premarket submission. FDA believes that given the nature of these products and their intended uses, these products may have unique risks that require further documentation to ensure that FDA is able to evaluate the safety and effectiveness of the device. These include devices that are a constituent part of a combination product (i.e., drug/device, biologic/device, or drug/device/biologic)[33] and Class III devices. In the course of evaluating the appropriate Documentation Level for a device that is a constituent part of a combination product or a Class III device, a sponsor may determine that an Enhanced Documentation level does not apply. In such cases, the sponsor should provide an appropriately detailed rationale as to why Basic Documentation instead of Enhanced Documentation is appropriate for the premarket submission. As previously discussed, during the course of submission review, FDA may request additional information if needed to evaluate the safety and effectiveness of the device.

Sponsors may submit a Pre-Submission to obtain FDA feedback about a device's Documentation Level and recommended documentation prior to a premarket submission, as described in the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[34] For additional information on how to engage with a particular Center with regard to a combination product, including best practices for doing so, please see the final guidance "Requesting FDA Feedback on Combination Products."[35]

For additional information and examples of devices that demonstrate the implementation of the Documentation Level risk-based approach, please refer to Appendix A of this guidance.

VI. Recommended Documentation

This section reflects FDA's recommendations for information to be included in premarket submissions for Basic and Enhanced Documentation Levels. This recommended information

[31] For information on risk assessment refer to Section VI.C of this guidance.
[32] See Appendix A for rationale on enhanced documentation level for BECS.
[33] 21 CFR 3.2(e).
[34] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.
[35] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.

should demonstrate that planning, requirements, risk assessment, design reviews, traceability, change management, testing plans and results, and other aspects of good software engineering for device software functions were employed, to support a conclusion that the device software function was appropriately designed, verified, and validated.

If the device is a multiple function device product and includes software function(s) that are considered "other functions," as that term is used in the guidance "Multiple Function Device Product: Policy and Considerations," the recommendations described in the aforementioned guidance should be considered when preparing the software documentation for a premarket submission.

Table 1 below provides an outline of the recommended documentation for each software documentation element and corresponding Documentation Level. Please refer to subsections A-J in this section of the guidance (VI) for more detail.

Table 1. Outline of Recommended Documentation

Software Documentation Elements	Basic Documentation Level	Enhanced Documentation Level
Documentation Level Evaluation (Section VI.A)	A statement indicating the Documentation Level and a description of the rationale for that level.	
Software Description (Section VI.B)	Software description, including overview of significant software features, functions, analyses, inputs, outputs, and hardware platforms.	
Risk Management File (Section VI.C)	Risk management plan, risk assessment demonstrating that risks have been appropriately mitigated, and risk management report.	
Software Requirements Specification (SRS) (Section VI.D)	SRS documentation, describing the needs or expectations for a system or software, presented in an organized format, at the software system level or subsystem level, as appropriate, and with sufficient information to understand the traceability of the information with respect to the other software documentation elements (e.g., risk management file, software design specification, system and software architecture design chart, software testing).	

Software Documentation Elements	Basic Documentation Level	Enhanced Documentation Level
System and Software Architecture Design (Section VI.E)	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 information technology (IT) infrastructure and peripherals) interact with the system and software.	
Software Design Specification (SDS) (Section VI.F)	FDA is not recommending the SDS as part of the premarket submission. Sponsor should document this information on the design via the DHF for the device. During premarket review, FDA may request additional information, if needed, to evaluate the safety and effectiveness of the device.	SDS documentation, including sufficient information that would allow FDA to understand 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.
Software Development, Configuration Management, and Maintenance Practices (Section VI.G)	A summary of the life cycle development plan and a summary of configuration management and maintenance activities; **OR** A Declaration of Conformity[36] to the FDA-recognized version of IEC 62304, including subclauses 5.1.1-5.1.3, 5.1.6-5.1.9, clause 6 (Software maintenance process), and clause 8 (Software configuration management process), among others as applicable.	**Basic Documentation Level, PLUS** complete configuration management and maintenance plan document(s); **OR** A Declaration of Conformity[37] to the FDA-recognized version of IEC 62304, including subclause 5.1 (Software development planning), clause 6 (software maintenance process), and clause 8 (software configuration management process), among others as applicable.

[36] For more information, please see Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

[37] For more information, please see Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

Software Documentation Elements	Basic Documentation Level	Enhanced Documentation Level
Software Testing as Part of Verification and Validation (Section VI.H)	A summary description of the testing activities at the unit, integration and system levels; **AND** System level test protocol including expected results, observed results, pass/fail determination, and system level test report.	**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.
Software Version History (Section VI.I)	A history of tested software versions including the date, version number, and a brief description of all changes relative to the previously tested software version.	
Unresolved Software Anomalies (Section VI.J)	List of remaining unresolved software anomalies with an evaluation of the impact of each unresolved software anomaly on the device's safety and effectiveness.	

A. Documentation Level Evaluation

A statement indicating the Documentation Level for the device and a description of the rationale for such Documentation Level. The rationale should account for the device's intended use, and include references, where appropriate, from the submission documentation (such as Risk Management File, Software Description, etc.) to support the indicated Documentation Level.

B. Software Description

An overview of significant software features and functions, including images, flow charts, and state diagrams as needed to adequately explain the software functionality[38] should be provided. If the premarket submission is for a modified device, provide the document number of the previous submission and highlight pertinent software changes (e.g., changes that affect safety and effectiveness) since the last FDA approval or clearance.

[38] FDA may request additional architecture diagrams to address the cybersecurity risks associated with a device. For more information, please refer to the guidance document, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

Consider and, as applicable, provide information to address the questions below when preparing the software description. However, FDA recognizes that these questions and examples may not capture all the unique aspects of device software and encourages the inclusion of additional information that will further FDA's understanding of the device's functionality to facilitate the review of a submission.

If the device is a multiple function device product and includes software function(s) that are considered "other functions," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations," the recommendations described in the aforementioned guidance should be considered when preparing the software description information.

- Software Operation
    - What is the role of the software as it relates to the intended use of the device? *Examples: software-only device, software that controls the device hardware, software application that accompanies the device for data processing.*
    - Who is the intended user of the software? *Examples*: *the patient, a caregiver, a healthcare professional, or a combination thereof*
    - What is the intended patient population?
        - Does the software function focus on a specific disease, condition, patient characteristic or demographic?
        - Does the software provide information that is directly applicable to a specific disease or condition?
    - If the software performs analysis of signals/patterns or images, what is the analysis methodology? *Examples: rule-based calculations, online test administration, artificial intelligence and machine learning (AI/ML), neural networks, fixed (locked) or adaptive (iterative, continuously learning) algorithms*.
    - If the device software function uses ML models trained through ML methods (i.e., is AI/ML-enabled, such as AI, ML, adaptive models, natural language processing (NLP), neural networks, and related approaches):
        - What methods, models, frameworks, and/or platforms were used?
        - What data (populations, samples) informed the model(s)? How, when, and where was the data collected?
        - What steps were taken to identify and address potential biases and limitations of the model(s)?
        - What materials, mechanisms, and/or approaches are used to provide transparency about the model's development, performance, and limitation(s)?

- Software Specifics[39]
  - What hardware platforms are used?
  - What software platforms are used?
    - If applicable, what hosting environments are used (e.g., hospital networks, cloud infrastructures) and for what functions (e.g., processing, storage)?
  - Does the device use OTS software?[40]
  - What is the final release version (i.e., version intended to be released to end users)? If this version is different from the documentation's version, explain the differences.

- Software Inputs and Outputs
  - What are the inputs and their format? *Examples: signals, images (specify modality), measurements (specify units), reports, questionnaires, other device data/results*.
  - Who or what provides the inputs? *Examples: patients, caregivers, healthcare professionals, technicians, sensors/attachments, signal acquisition systems, in vitro diagnostic devices, other medical devices, other non-medical products or software.*
  - What are the outputs and their format? *Examples: diagnostic information, treatment information, control signals for device hardware, images (specify modality), measurements (specify units), alarms, alerts, or reports.*
  - Who or what receives the outputs? *Examples: patients, caregivers, healthcare professionals, technicians, health records, device hardware, other medical devices, interoperable systems.*
  - Does the software impact or replace any action(s) otherwise performed manually by a health care professional, patient, caregiver, or other operator? What are the clinical workflow steps and assumptions (from beginning to end state)? *Examples: automates steps, triages patients, provides a definite diagnosis or suggests likely diagnosis for further confirmation by physician, performs or recommends specific treatment, identifies a region of interest for further review.*

[39] One example approach for providing some of the identified software specifics is by providing a Software Bill of Materials (SBOM) that lists and provide details on software components including, but not limited to, commercial, open source, OTS, and manufacturer-developed software components. For some devices, information related to an SBOM may be required part of a premarket submission.

[40] If a device uses OTS software, FDA may request additional information in premarket submissions. For more information, please refer to the guidance document "Guidance for Off-The-Shelf Software Use in Medical Devices."

- Is the device designed to be interoperable?[41] In other words, does the device transmit, exchange, and/or use information through an electronic interface (e.g., network, wireless) with another medical/non-medical product, system, or device? If yes, what other products does the device interface with, and what methods, standards, and specifications are used to interact and/or communicate with other medical/non-medical product, system, or device? Are the medical/non-medical products, systems, or devices networked?

If any of the information requested above is included in another document, such as the Software Requirements Specification (SRS), an annotation and a reference to the document in the submission where this information is located should be provided.

C. Risk Management File

The risk management file should be provided as part of the premarket submission and include the following documentation. FDA recommends sponsors refer to an FDA-recognized version of ISO 14971 for additional information on the development and application of a risk management file.

(1) Risk Management Plan

FDA recommends sponsors submit a risk management plan to support the effectiveness of the risk management activities and processes for a particular medical device.[42] In FDA's review of the risk management plan, the Agency intends to primarily focus on:

- Individual risk acceptability criteria including the need for risk reduction (control).
- Method to evaluate the acceptability of the overall residual risk for all residual risks after all risk control measures have been implemented and verified.

The risk acceptability criteria should be based on the sponsor's process for determining acceptable risk. The acceptability criteria should be documented in the risk management plan before an initial risk evaluation is performed for the device software under review.

It should be clear in the risk management plan how the sponsor plans to evaluate the overall residual risk against the benefits of the intended use of the device.

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[41] More information on interoperable medical devices is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.

[42] For combination products that include device software functions, a 14971-based risk management framework that incorporates relevant considerations from International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q9 Quality Risk Management is recommended. For further information, see, for example, AAMI TIR 105 Risk Management Guidance for Combination Products.

(2) Risk Assessment

A risk assessment that includes a risk analysis, risk evaluation, risk control and a benefit-risk analysis (where applicable) should be provided for all device software. For software that is part of a system, a risk assessment should be performed on the system comprising the software and its whole hardware environment. If this information is covered in the system risk assessment documentation, this should be noted in the software documentation with reference to the particular section of the premarket submission.

For multiple function device products, the risk assessment should include the results of a risk-based analysis of any potential adverse impact or labeled positive impact of "other function(s)," as that term is used in the guidance "Multiple Function Device Product: Policy and Considerations," to the safety or effectiveness of the device function(s)-under-review.

A risk assessment should document the following items (e.g., in tabular format):

- Risk Analysis
  - Identification of known or foreseeable hazards[43] (and their causes) associated with the device based on the intended use; reasonably foreseeable misuse whether intentional or unintentional; and the impacts to safety, treatment, and/or diagnosis. For each identified hazard, the sponsor should consider the reasonably foreseeable sequences or combinations of events that can result in a hazardous situation,[44] and should identify and document the resulting hazardous situation(s).
  - Estimation of the risk of each hazard and hazardous situation.[45]
  - Severity of the harm[46] resulting from the hazardous situation.
- Initial Risk Evaluation of the Hazardous Situation
  - This includes assessment of acceptability (e.g., acceptable, not acceptable) and need for risk reduction (control) measures as defined in the risk management plan.
- Risk Control Measures
  - This should include the following risk control measures listed in descending order from highest to lowest priority:

[43] For the purposes of this guidance, hazard refers to a potential source of harm.
[44] For the purposes of this guidance, hazardous situation refers to a circumstance in which people, property or the environment is/are exposed to one or more hazards.
[45] It is often difficult to adequately estimate the probability of software failures that could contribute to a hazardous situation. Applying unrealistically low probability estimates to software failures could result in unrealistic risk evaluation and subsequently lead to inappropriate risk control measures. As a result, in some instances it may be prudent to focus on the identification of potential software functionality and failures that could result in hazardous situations instead of estimating probability. In such cases, considering a worse case probability is appropriate, the probability for the software failure occurring should be set to 1.
[46] For the purposes of this guidance, harm refers to injury or damage to the health of people, or damage to property or the environment.

  - Design (e.g., eliminating or reducing unnecessary features, modifying the software architecture to prevent hazardous situations, modifying the user interface to prevent usability errors)
  - Protective measures (e.g., defensive programming checks that detect unexpected faults followed by automatic intervention to halt the delivery of results or therapy, alarms allowing user intervention to prevent a hazardous situation)
  - Information for safety (e.g., written warnings, on-screen warnings, training)

- There should be verification of the implementation of the risk control measures and verification of the effectiveness of the implemented risk control measures (i.e., the implemented risk control measure reduces risk). This can be accomplished by tracing the identified hazard to the verified specific risk control measures (e.g., a requirement ID in the SRS and SDS, a test name and identifier in the testing documentation that shows pass/fail results, a user manual name and identifier, a training manual name and identifier). For example, given an identified hazard (e.g., HAZ-XXX[47]), the following could be listed for traceability: a design related risk control measure that is documented in a software requirement specification (e.g., SRS-XXX) and software design specification (e.g., SDS-XXX), and tested as part of a unit test case (e.g., UT-XXX), integration test case (e.g., INT-XXX) and system test case (e.g., SYS-XXX). FDA recognizes that there may be instances where a specific hazard traces to several requirements/specifications and tests, thereby making the presentation of information cumbersome in the risk assessment document. Therefore, sponsors may choose to present this traceability in a separate document linking together software requirements specifications, software design specifications, testing and identified hazards derived from the risk assessment.

- There should be an assessment of whether risk control measures introduce new hazards or hazardous situations or impact the initial risk evaluation.

- Document any risk control measures employed to mitigate increased risk or adverse effect on performance due to the combination of "other function(s)," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations," with the device function-under-review.

- Residual Risk Evaluation of the Hazardous Situation after implemented Risk Control Measures.
  - This includes assessment of acceptability (e.g., acceptable, not acceptable) as defined in the risk management plan.

[47] "XXX" denotes a unique number identifier for a specific hazard, software requirement specification, software design specification, unit test case, integration test case or system test case.

- Benefit-Risk
  - If a residual risk is deemed not acceptable according to the acceptability criteria in the risk management plan and further risk control is not possible, the sponsor should provide documented benefit-risk analysis to demonstrate that the benefits of the intended use outweigh the residual risk, which may be referenced in other benefit-risk assessment documentation.

(3) Risk Management Report

A risk management report should be provided to:

- Show how the risk management plan has been appropriately implemented.
- Demonstrate that the risk management file has been assessed by the appropriate personnel and the overall residual risk is acceptable.
- Demonstrate appropriate methods are established for the collection and assessment of relevant production and post-production information.

D. Software Requirements Specification (SRS)

The SRS documents the requirements[48] for the software which typically specifies inputs and outputs, functions that the software will perform, hardware,[49] performance,[50] interfaces,[51] user interaction, error definition and handling, intended operating environment, safety related requirements derived from a risk assessment (Refer to Section VI.C Risk Management File) and all ranges, limits, defaults, and specific values that the software will accept. For additional details on what should be included in the software requirements specification, refer to the guidance, "General Principles of Software Validation."

[48] The term "requirements" is used in this section as part of the term "Software Requirements Specification," and does not refer to a regulatory requirement.
[49] Hardware requirements generally include, but are not limited to, requirements related to: microprocessors, memory devices, sensors, energy sources, safety features, and communications.
[50] Software performance and functional requirements generally include, but are not limited to, requirements related to algorithms or control characteristics for therapy, diagnosis, monitoring, alarms, analysis, and interpretation with full text references or supporting clinical data, if necessary. Software performance and functional requirements may also include: device limitations due to software, internal software tests and checks, error and interrupt handling, fault detection, tolerance, and recovery characteristics, safety requirements, and timing and memory requirements.
[51] Interface requirements (e.g., external, user, internal) generally include, but are not limited to, both communication between system components and communication with the user such as: printers, monitors, keyboard, mouse, cloud servers, peripheral medical devices, mobile technology platforms.

The QSR requires "a mechanism for addressing incomplete, ambiguous, or conflicting requirements."[52] Each requirement identified in the software requirements specification should be traceable and we recommend that the SRS be evaluated for accuracy, completeness, consistency, testability, correctness, and clarity.

A singular SRS document or set of multiple SRS documents should be provided. The documentation should include a description of the software requirement identification and tracking methodology used to support the traceability of the requirements. For example, in a device that includes multiple functions, components, and/or accessories, where each has its own individual SRS document and associated software device functions, the set of individual SRS documents would comprise the complete SRS.

FDA acknowledges that modern development practices may employ incremental or evolutionary software development practices. Additional forms of software requirements might be included in the submission, such as well elaborated stories, use cases, textual descriptions, screen mockups, and data flows.

In order to facilitate a timely premarket review, the following recommendations should be considered in preparing SRS documentation:

- Format the SRS to be well-organized, easily navigable and readable with the labeling and/or grouping of requirements (such as by modules or units of a function).

- Note any relevant traceability between requirements listed in the SRS and information related to those requirements in other software documentation (such as the SDS, System and Software Architecture Diagram, etc.).

- If the premarket submission involves a modification to an existing approved or cleared device, highlight all pertinent differences in software requirements.

- Identify the requirements the sponsor believes are most critical (i.e., could have the most significant impact) to the device's safety and effectiveness. These requirements could be highlighted within the SRS document and/or consolidated in a supplemental document that includes these requirements of interest in a summarized format. This technique may help facilitate the presentation of those requirements that most critically affect clinical functionality or performance specifications that are directly associated with the intended use of the device, or would otherwise impact the device's safety and effectiveness.

[52] See 21 CFR 820.30(c) ("Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.").

- If any of the information requested above is included in another document, an annotation and a reference to the document in the submission where this information is located should be provided.

Documentation of requirements included in the premarket submission for the device function-under-review should include adequate detail to describe any expected relationship, utility, reliance, or interoperability with any "other function," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations."

E. System and Software Architecture Diagram

The purpose of the system and software architecture diagram is to present a roadmap of the device design to facilitate a clear understanding of:

- The modules and layers that make up the system and software;
- The relationships among the modules and layers;
- The data inputs/outputs and flow of data among the modules and layers; and
- How users or external products, including IT infrastructure and peripherals (e.g., wirelessly connected medical devices) interact with the system and software.

For purposes of the system and software architecture diagram, this guidance considers a module to be a discrete unit or architectural item within the system or software. A module could represent, for example, a finished hardware device within a system of hardware and software products, a hardware component within a finished hardware device, a finished software product within a system of software products, or a software function within a finished software product. A module is not specifically meant to describe code-level software functions, although such code-level software functions could be considered modules if appropriate. The sponsor should determine what constitutes a module in the context of its system and software.

Sponsors should provide the appropriate level of detail in the system and software architecture diagram to convey the information in a manner that can facilitate an efficient premarket review, including descriptive text (in the diagram or in an accompanying document) to explain the architecture diagram where appropriate. A system and software architecture diagram that is not appropriately tailored (e.g., too high-level, too detailed, or overly confusing) or that is illegible (e.g., cropped diagrams, inadequate font size, unreadable without high magnification) could lead to requests for additional information from the FDA review division. To the extent appropriate, the system and software architecture diagram can be communicated in one or more diagrams and in one or more formats, and may convey different dimensions of the system and software. The system and software architecture diagram may comprise multiple static diagrams (e.g., those illustrated in Appendix B), dynamic diagrams (e.g., state diagrams), cybersecurity architecture diagrams, and others as needed for adequate detail. If more than one diagram is used, the sponsor

should provide a high-level diagram that communicates the overview and points to the other diagrams that provide additional detail. The relationship between diagrams should also be clearly communicated. In general, the sponsor should take note of the following visual, language, and reference considerations when developing an effective system and software architecture diagram:

- Visual Considerations
    - The diagram and the means for communicating information in the diagram should be visually consistent (e.g., a solid arrow should convey a specific meaning as compared to a dashed arrow; icons should be used consistently; lines that intersect should clearly communicate whether the intersection is a crossing or connection) and the meaning ascribed should be clearly communicated (e.g., through the use of standard symbols and notation).
    - The level of detail provided in the diagram should be consistent throughout unless areas of less detail are clearly explained (e.g., in the case of functions, within the system or software, that are not under review).
    - Modules should be grouped in a logical and obvious manner.
    - Use of color or other visual means (e.g., dashed boxes within solid boxes) should be used to convey layering within the system, software, or module.
    - Visual clutter should be avoided, and the diagram should be scaled according to the complexity and amount of information presented.
- Language Considerations
    - Annotations should be used to provide additional information about a particular module or data element (e.g., a plain language explanation of the module purpose or a pointer to a document or requirement within the premarket submission).
    - Use of terminology and naming conventions should be consistent within the diagram and the remainder of the premarket submission materials.
    - Use of acronyms, jargon, or terms that are not defined in the diagram itself should be avoided.
- Reference Considerations
    - The diagram should reference other documents in the submission (e.g., Software Description, Software Requirements Specification), as appropriate.
    - For submissions related to modification(s) to a previously cleared or approved device, the diagram should identify and reference the modules that are affected by the modification(s).

The above considerations are intended to serve as a guide and may not apply in every case or may apply differently for different diagrams. When developing the system and software

architecture diagram, sponsors are encouraged to leverage industry best practices within and outside the medical device industry. OTS modeling languages or platforms may be used to develop the system and software architecture diagram. Any modeling language- or platform-specific terminology should be defined or supported by reference to a publicly-available consensus standard or specification. The resulting architecture diagram should be provided in a form that aligns with eCopy guidelines recommended in the guidance "eCopy Program for Medical Device Submissions."[53]

For multiple function device products, the system and software architecture diagram should clearly delineate between the device functions-under-review and the "other functions," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations." The system and software architecture diagram should include adequate detail to understand how or if the "other function(s)" interact with or impact the device function-under-review.

Example system and software architecture diagrams are provided in Appendix B of this guidance, illustrating approaches to effectively convey the recommended information to facilitate an efficient premarket review. These simplified examples demonstrate how the considerations described in this section can be implemented into a system and software architecture diagram. The modules in the example are intended for illustration purposes only and are not intended to document or represent a comprehensive or complete system and software architecture diagram for a specific medical device or system. The illustrated approach does not prescribe any specific modeling languages or platforms to allow for flexibility in development and documentation. The approaches illustrated can be applied to any system and software architecture diagram.

F. Software Design Specification (SDS)

The Software Design Specification (SDS) may contain both a high level summary of the design and detailed design information. In terms of the relationship between the Software Requirement Specification (SRS) and the SDS, the SRS describes what the software function will do and the SDS describes how the requirements in the SRS are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the device software function was clear and unambiguous, with minimal ad hoc design decisions. The use of minimal ad hoc design decisions reflects the general principle that the creation of SDS should occur as a prospective activity rather than documented retrospectively after the software design has been implemented by ad hoc design methods. Documentation of specifications included in the premarket submission for the device function-under-review should include adequate detail to describe any expected relationship, utility, reliance, or interoperability with any "other function," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations."

[53] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.

(1) Basic Documentation Level

FDA is not recommending the SDS as part of the premarket submission. Sponsors should document this information on the design internally via the DHF for the device. During premarket review, FDA may request additional information on the design, if needed, to evaluate the safety and effectiveness of the device.

(2) Enhanced Documentation Level

A 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. The software functional units or modules along with the interfaces among them identified in the architectural (i.e., high-level) design should be documented with the corresponding detailed (i.e., low-level) design information in the SDS. The information provided for review should be sufficient to ensure that the work performed in developing the software functional units or modules and their interfaces was clear and unambiguous, with minimal ad hoc design decisions. For example, the creation of the SDS is expected to have occurred as a prospective activity where the SDS was used to guide the design, development and testing of the software rather than documented retrospectively after the software design has been implemented by ad hoc design methods.

For additional details on what should be included in the software design specification, refer to the guidance, "General Principles of Software Validation."

G. Software Development, Configuration Management, and Maintenance Practices

One way a sponsor could address this documentation element of a premarket submission is to provide the recommended information on related software development, configuration management, and maintenance practices and procedures. In another approach, a sponsor could provide a Declaration of Conformity to specific clauses of the FDA-recognized version of ANSI/AAMI/IEC 62304 *Medical Device Software - Software Life Cycle Processes* or the FDA-recognized version of IEC 62304 *Medical device software - Software life cycle processes* (hereafter referred to collectively as ANSI/AAMI/IEC 62304). A sponsor could also provide a Declaration of Conformity to the complete ANSI/AAMI/IEC 62304 standard. However, a Declaration of Conformity to the complete ANSI/AAMI/IEC 62304 standard is not needed due to known differences in categorization of device software functions and other recommended documentation.

(1) Basic Documentation Level

A summary of the processes and procedures that are in place to manage the software life cycle development, software configuration and change management, and software maintenance activities should be provided. This summary information should include an adequate description of:

- Processes and procedures used in software development, verification, and validation.
- Software coding standards, methods, and tools used in software development.
- Main deliverables of the typical activities and tasks involved in software development, verification, and validation.
- Processes, procedures, and tools used to link user needs, system requirements, software requirements, software design specifications, software testing and implemented risk control measures (i.e., traceability).
- Processes and procedures used in software configuration and change management.
- Processes and procedures used in software maintenance that includes risk assessment of software changes, initial testing that evaluates the correctness of the implemented software change(s), and regression analysis and testing.

Alternatively, to address the recommendations for this documentation element, a sponsor may provide a Declaration of Conformity to the FDA-recognized version of ANSI/AAMI/IEC 62304 *Medical Device Software - Software Life Cycle Processes*, including subclauses 5.1.1 ("Software development plan"), 5.1.2 ("Keep software development plan updated"), 5.1.3 ("Software development plan reference to system design and development"), 5.1.6 ("Software verification planning"), 5.1.7 ("Software risk management planning"), 5.1.8 ("Documentation planning"), 5.1.9 ("Software configuration management planning"), clause 6 ("Software maintenance process"), and clause 8 ("Software configuration management process"),[54] among others as applicable.

(2) Enhanced Documentation Level

Documents implementing the configuration management and maintenance plans should be provided in addition to the summary documentation requested for the Basic Documentation Level, as described above.

Alternatively, to address the recommendations for this documentation element, a sponsor may provide a Declaration of Conformity to the FDA-recognized version of ANSI/AAMI/IEC 62304

[54] References to clauses and subclauses based on ANSI/AAMI/IEC 62304:2006 & A1:2016.

Medical Device Software – Software Life Cycle Processes, including subclause 5.1 (Software development planning), clause 6 ("Software maintenance process"), and clause 8 ("Software configuration management process"),[55] among others as applicable.

H. Software Testing as part of Verification and Validation

Refer to Section IV (Definitions) for important information pertaining to FDA's thinking on verification and validation, as it relates to this guidance. Additionally, please refer to guidance "General Principles of Software Validation" for additional details regarding FDA's thinking regarding software testing, particularly unit level (module or component) testing, integration level (internal and external interfaces) testing, and system level (functional) testing.

The recommendations in this guidance do not address other forms of testing, such as non-clinical bench, animal, or clinical testing. For more information regarding other forms of device performance testing, sponsors should refer to relevant special controls,[56] FDA-recognized voluntary consensus standards,[57] and device-specific guidances. If the premarket submission leverages information from other device performance testing section(s) to address software verification and validation, the sponsor is encouraged to appropriately reference the other performance testing material to facilitate the navigation between submission sections, reduce instances of duplication, and improve readability.

(1) Basic Documentation Level

The following software testing documentation should be provided:

- A summary description of the testing activities at the unit, integration, and system levels. The summary description should include the software version tested and the overall pass/fail test results for all test protocols (i.e., collection of test procedures for specific software functionality) executed. If the device is a modified version of a previously cleared or approved device, provide a summary of the modifications compared with the previous cleared or approved version along with a summary description of the additional testing activities performed at the unit, integration, and system levels as compared with the previously cleared or approved version.

- Any intentional changes made in response to failed tests and documentation of test results demonstrating that the intentional changes were implemented correctly.

- A regression analysis and regression testing with pass/fail test results (where applicable) to account for unintended effects of a software change.

[55] References to clauses and subclauses based on ANSI/AAMI/IEC 62304:2006 & A1:2016.
[56] For more information regarding special controls, please see FDA's Regulatory Controls webpage, available at https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.
[57] The most up-to-date list of voluntary FDA- recognized consensus standards is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

- Regression analysis is a documented evaluation of the impact of a software change based on review of the relevant documentation (e.g., software requirements specification, software design specification, source code, test plans, test cases, test scripts, etc.) to determine whether regression testing is needed. If regression testing is needed as determined by the regression analysis, the sponsor should identify the necessary regression tests to be run. Regression testing is the rerunning of test cases that a program has previously executed correctly and comparing the current result to the previous result in order to detect unintended effects of a software change.

- System level test protocol including expected results derived from software requirements, actual results that are observed and recorded, objective pass/fail determination (i.e., actual results are acceptably equivalent to expected results) and a system level test report. The system level test report should demonstrate that the protocol has been acceptably executed with passing test results and any unresolved anomalies have been acceptably deferred based on a risk assessment for the candidate release version.

(2) Enhanced Documentation Level

In addition to the documentation requested for the Basic Documentation Level, all unit and integration level test protocols and reports should be provided, including expected results derived from software requirements and design, actual results that are observed and recorded, and objective pass/fail determination (i.e., actual results are acceptably equivalent to expected results). The unit and integration level test reports should demonstrate that the protocols have been acceptably executed with passing testing results and any unresolved anomalies have been acceptably deferred based on a risk assessment for the candidate release version.

I. Software Version History

The documentation should include the history of software versions that were tested and documented at the unit, integration, and system levels as part of verification and validation activities, beginning with the version that became subject to the design controls, as described in 21 CFR 820.30. This typically takes the form of a line-item tabulation including the date, version number that was tested (including, if applicable, bench, animal, and clinical testing) and a brief description of all changes in the version relative to the previously tested version.

The last entry in a line-item tabulation should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

If the software version history includes a version(s) that corresponds to a previously released cleared or approved version of the software, the sponsor should highlight in the version history document each prior released cleared or approved version and the premarket submission number(s) associated with that release.

If the device is a multiple function device product and includes software function(s) that are considered "other functions," as that term is used in the guidance "Multiple Function Device Products: Policy and Considerations," the recommendations described in the aforementioned guidance should be considered when preparing the software version history.

J. Unresolved Software Anomalies

An anomaly is any condition that deviates from the expected behavior based on user needs, requirements, specifications, design documents, or standards. Anomalies may be found during the review, test, analysis, compilation, or use of the software (whether before or after release, or whether inside a sponsor's organization or outside it) or at other times. An unresolved software anomaly is a defect that still resides in the software because a sponsor deemed it appropriate not to correct or fix the anomaly, according to a risk-based rationale about its impact to the device's safety and effectiveness.

A list of unresolved anomalies should document the following items (e.g., in tabular format) for each unresolved anomaly present in the software:

- A description of the anomaly;
- Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly;
- Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations;
- Outcome of the evaluation; and
- Risk-based rationale for not correcting or fixing the anomaly in alignment with the sponsor's risk management plan or procedure(s).

Additionally, the Agency recommends considering the utilization of a defect classification system, or taxonomy, for each anomaly, such as ANSI/AAMI SW91's *Classification of defects in health software*.[58] Regardless of the defect classification system used, the sponsor should evaluate the impact of an unresolved anomaly on the device's safety and effectiveness based on the software's intended use.

Where appropriate, a sponsor should communicate to end users any mitigations or possible work-arounds for unresolved anomalies to assist in the proper operation of the device to fulfill its intended use. FDA recommends that any planned or already distributed communication

[58] As stated in ANSI/AAMI SW91, a defect classification system, or taxonomy, is used to classify or categorize the types of defects that might exist in software. A defect classification system is neutral with respect to programming language, methodology, product, intended use, risk (severity of anomalies), and regulatory status.

(customer notification, labeling, etc.) to end users regarding unresolved anomalies is referenced in the premarket submission.

VII. Additional Information - Regulatory Considerations for Software Functions

Section 3060(a) of the Cures Act amended section 520 of the FD&C Act on December 13, 2016, removing certain software functions from the definition of device in section 201(h) of the FD&C Act. Sponsors should consider the following reference materials to learn more about FDA's regulatory considerations for software functions:

- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act[59]
- General Wellness: Policy for Low Risk Devices[60]
- Policy for Device Software Functions and Mobile Medical Applications[61]
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices[62]
- How to Determine if Your Product is a Medical Device[63]
- Clinical Decision Support Software[64]

Appendix A: Documentation Level Examples

The following list of example devices is intended to demonstrate the implementation of the Documentation Level risk-based approach. Please note that 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 do or do not require a certain Documentation Level. These examples do not define the appropriate Documentation Level for a particular device type. As such, the Documentation Level should be uniquely considered for each particular device or device modification and in consideration of the device's intended use. The rationales in the examples below are abbreviated and FDA encourages sponsors to provide a detailed assessment that accounts for the specifics of their device (such as the device's risk assessment,[65] software description, etc.) when addressing the recommendations in Sections V and VI.A of this guidance.

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[59] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act.
[60] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.
[61] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.
[62] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.
[63] Available at https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device.
[64] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software.
[65] For more information on risk assessment refer to Section VI.C of this guidance.

1. A hardware-only non-patient-matched hip prosthesis.

   Description: The device is a non-patient-matched hip prosthesis that contains no firmware or other means for software-based control.

   Rationale: The device does not contain software.

   Outcome: No Documentation Level

2. A non-contact infrared thermometer intended for intermittent measurement of body temperature from the forehead.

   Description: The device is intended to measure body temperature from the forehead using an infrared sensor. The device is a hand-held, battery powered, reusable device for home and professional healthcare facility use.

   Rationale: In general, a failure or latent flaw of the device software function(s) would not present a hazardous situation with 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.

   Outcome: Basic Documentation Level

3. A non-invasive blood pressure monitor with inflatable cuff.

   Description: The device is intended to measure a person's systolic and diastolic blood pressure in units of mmHg through software-controlled inflation and deflation of the cuff. The device is a battery powered, reusable device for home and professional healthcare facility use.

   Rationale: In general, a failure or latent flaw of the device software function(s) would not present a hazardous situation with 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.

   Outcome: Basic Documentation Level

4. A device software function for optical camera-based measurement of pulse rate and breathing rate.

   Description: The device is intended for non-contact, periodic, spot measurement of pulse rate and breathing rate when the subject is at rest. The software analyzes compatible video signals of subjects in single occupancy rooms of subjects that do not require continuous vital signs monitoring or critical care. The device is

intended for use by trained staff and is not intended to be the sole method of checking the physical health of a subject.

Rationale: A failure or latent flaw of the device software function(s) would not present a hazardous situation with 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.

Outcome: Basic Documentation Level

5. A computerized behavioral therapy device to treat psychiatric disorders.

   Description: The device is a prescription software device intended to provide a computerized version of condition-specific cognitive behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients who have been previously diagnosed with a psychiatric condition. It is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes. It is not intended to substitute for routine in-person therapy sessions.

   Rationale: A failure or latent flaw of the device software function(s) would not present a hazardous situation with 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.

   Outcome: Basic Documentation Level

6. A traumatic brain injury (TBI) eye movement assessment aid.

   Description: The device is a prescription device that is intended to track a patient's eye movements using a commercial OTS mobile phone and camera and analyze the tracked eye movements to aid in the assessment of mild TBI, commonly known as "concussion." The device provides a positive or negative indicator about the presence of eye movements that are consistent with mild TBI.

   Rationale: A failure or latent flaw of the device software function(s) would not present a hazardous situation with 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. The device is intended for use as an aid in the assessment of mild (non-severe) injury and is not intended as a standalone diagnostic.

   Outcome: Basic Documentation Level

7. An implantable sensor for measuring pulmonary artery (PA) pressure.

Description: The device is a system comprising a permanent implant that is placed in the PA and an external software-controlled reader that retrieves and transmits PA pressure measurements. The PA hemodynamic data are used by the physician for heart failure management and with the goal of reducing heart failure hospitalizations. There are no device software functions located on the implant.

Rationale: While the device is a class III device, a failure or latent flaw of the device software function(s) would not present a hazardous situation with 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. Risks of death or serious injury to the patient in this scenario are due to the implantable nature of the device and failure of the hardware or implant procedure itself, not the device software function(s).

Outcome: Basic Documentation Level

8. Over-the-counter (OTC) application for identification of irregular heart rhythms.

   Description: The software application is intended for analysis of photoplethysmograh data, identification of episodes of irregular heart rhythms suggestive of Atrial Fibrillation (AF), and providing notification to the user of the irregular rhythm episodes. It is intended to opportunistically provide a notification of possible AF and the absence of a notification is not intended to indicate that no disease is present. It is intended for OTC use and it is not intended to replace traditional methods of diagnosis or treatment.

   Rationale: A failure or latent flaw of the device software function(s) would not present a hazardous situation with 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.

   Outcome: Basic Documentation Level

9. An *in vitro* nucleic acid test for the qualitative detection of Human Papillomavirus (HPV) DNA in human cervical specimens.

   Description: The test is intended for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US (atypical squamous cells of undetermined significance) cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with professional medical guidelines, results from prior screening, medical history, and other risk factors.

Rationale: While the test is classified as a class III device, a failure or latent flaw of the device software function(s) 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. There are several alternatives for the detection of cervical cancer precursors including testing by cytology alone, co-testing with HPV alongside or as a follow-up to cytology or HPV testing as a first line screening test for cervical cancer. The patient's age, medical history, and thorough physical examination will provide further information on the risk of cervical disease, as well as the need for referral to colposcopy. The test should only be used in conjunction with this clinical information in accordance with professional clinical patient management guidelines.

Outcome: Basic Documentation Level

10. An *in vitro* nucleic acid test for the qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors.

    Description: The test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.

    Rationale: A failure or latent flaw of the device software function(s) would not present a hazardous situation with 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.

    Outcome: Basic Documentation Level

11. A device software function on a commercial OTS head-mounted display (e.g., augmented reality/virtual reality/mixed reality (AR/VR/MR)) that superimposes pre-surgical images on a patient's body.

    Description: The device is intended to provide real-time superimposition of medical images on the patient during a surgical procedure, but is neither intended to directly guide surgical planning or procedures nor be worn by the lead surgeon.

    Rationale: A failure or latent flaw of the device software function(s) would not present a hazardous situation with 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, since the device is neither intended to directly guide surgical planning or procedures nor be worn by the lead surgeon.

Outcome: Basic Documentation Level

12. A laser system for the treatment of acne vulgaris.

Description: The device is a laser system used in dermatology offices used to treat acne vulgaris through heating of dermal tissue. The device software only operates the laser engine. Delivery of therapy requires the operator to depress a physical switch on the handpiece.

Rationale: A failure or latent flaw of the device software functions(s), such as not delivering the laser energy when directed, would not present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

Outcome: Basic Documentation Level

13. A radiological display device.

Description: The device is intended for displaying clinical radiology images for review, analysis, and diagnosis by trained medical practitioners. The software contained in the device is limited to the following functionalities: display controls, ambient light sensing, luminance calibration tools, and quality-control software.

Rationale: A failure or latent flaw of the device software function(s), such as inadequate quality of displayed images, would not present a hazardous situation with 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.

Outcome: Basic Documentation Level

14. An electric breast pump.

Description: The device is intended to be used by lactating women to express and collect milk from their breasts. The device uses a DC-powered motor driving the vacuum pump which is controlled electronically to provide a range of user-selected suction levels at specified cycle frequencies. The device display provides the user with information on the pumping mode, timer, battery level, and suction.

Rationale: A failure or latent flaw of the device software function(s) (e.g., software fails to properly control the suction level) would not present a hazardous situation with 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.

Outcome: Basic Documentation Level

15. An implantable cardiac pacemaker used to treat bradycardia.

    Description: The device is an implanted, programmable dual-chamber pulse generator intended to provide rate-adaptive bradycardia therapy as well as other therapeutic and diagnostic functionality. It senses the heart's electrical activity and generates electrical impulses to cause the heart to contract or beat according to the programmed patient's needs. It communicates with a programmer and the patient's home monitoring device.

    Rationale: A failure or latent flaw of the device software function(s), such as failure to pace or a latent flaw leading to incorrect sensing of an ectopic beat, would lead to a hazardous situation that would present a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    Outcome: Enhanced Documentation Level

16. A facility use continuous ventilator.

    Description: The device is intended to provide continuous ventilation for adult, pediatric, and neonatal patients who require invasive or noninvasive respiratory support. It allows clinicians to set ventilator control parameters, set alarm limits, and view monitored values and waveforms for patient management. It includes respiratory monitoring as well as both mandatory and spontaneous ventilation modes. It is intended for use in professional healthcare facilities.

    Rationale: A failure or latent flaw of the device software function(s), such as failure to provide appropriately timed ventilation, would present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.

    Outcome: Enhanced Documentation Level

17. A multi-parameter patient monitor for use in a professional healthcare facility.

    Description: The device is a multi-parameter monitor intended for use on adult, pediatric, and neonatal patients in a professional healthcare facility. It is used for monitoring of various hemodynamic and respiratory vital signs and parameters, including central venous oxygen saturation, electrocardiogram (ECG), arrhythmia detection, invasive and non-invasive blood pressure, temperature, cardiac output, hemoglobin concentration, pulse oximetry, spirometry, airway gases, and gas exchange. It is designed to detect alarm conditions and generate alarm signals. It can be connected to the hospital network and other monitors to allow for remote viewing and management of patients.

Rationale: A failure or latent flaw of the device software function(s), such as incorrect calculation of parameters or an exploited cybersecurity vulnerability that compromises its ability to provide life-threatening arrhythmia detection and alarms, would present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.

Outcome: Enhanced Documentation Level

18. A Blood Establishment Computer Software (BECS) or BECS accessory.

    Description: The device is used in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions. A BECS accessory is a device intended for use with BECS to augment the performance of the BECS or to expand or modify its indications for use.

    Rationale: A failure or latent flaw of the device software function(s), such as a failure to prevent the release of unsuitable blood and blood components, would present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.

    Outcome: Enhanced Documentation Level

19. A qualitative *in vitro* nucleic acid screening test for the direct detection of Babesia DNA and RNA in whole blood samples from individual human donors.

    Description: The device is a screening test that includes device software for detection of Babesia DNA and RNA in whole blood samples to prevent the release of unsuitable blood and blood components.

    Rationale: A failure or latent flaw of the device software function(s), such as an inaccurate result in the identification of a transfusion-transmitted infection, would present a hazardous situation with a probable risk of death or serious injury to a patient, or serious injury, prior to the implementation of risk control measures.

    Outcome: Enhanced Documentation Level

20. An infusion pump intended for use in a health care facility to pump fluids and medications into a patient.

    Description: The device is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of fluids, medications, blood, and blood

products through clinically accepted routes of administration (intravenous, intra-arterial, subcutaneous, epidural, and enteral). It is intended for use by trained health care professionals in healthcare facilities.

Rationale: A failure or latent flaw of the device software function(s), such as providing the incorrect flow rate or failing to deliver fluids/medications, would present a hazardous situation with 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.

Outcome: Enhanced Documentation Level

21. An *in vitro* nucleic acid test for the quantitative measurement of Cytomegalovirus (CMV) DNA in human plasma or whole blood.

    Description: The test is intended for use as an aid in the management of CMV in solid organ transplant patients and in hematopoietic stem cell transplant patients. In patients receiving anti-CMV therapy, DNA measurements can be used to assess viral response to treatment. The results from the test must be interpreted within the context of all relevant clinical and laboratory findings and is not intended for use as a screening test for blood or blood products

    Rationale: The test is classified as a class III device. Furthermore, a failure or latent flaw of the device software function(s), such as failure to provide correct test results, would present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

    Outcome: Enhanced Documentation Level

22. A device software function that provides a sepsis alarm to a healthcare provider in a critical care environment.

    Description: Software intended to analyze patient demographics, vital signs, and lab results from an electronic medical record to provide asepsis alarm identifying patients with sepsis or at risk of developing sepsis earlier than a healthcare provider would otherwise. The patient clinical data used as an input for the software is part of ongoing or active monitoring of the patient's current health state in a critical care environment.

    Rationale: A failure or latent flaw of the device software function(s), such as failure to provide a sepsis alarm) would present a hazardous situation with 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.

    Outcome: Enhanced Documentation Level

23. A continuous glucose monitoring system.

Description: The device is intended to provide real time, continuous glucose monitoring for the management of diabetes in persons 2 years of age and older. It is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. It aids in the detection of episodes of hyperglycemia and hypoglycemia and facilitates both acute and chronic therapy adjustments.

Rationale: A failure or latent flaw of the device software function(s), such as failure to provide correct blood glucose measurement or detection of hypoglycemia, would present a hazardous situation with 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.

Outcome: Enhanced Documentation Level

24. Powered Lower Extremity Exoskeleton.

Description: A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.

Rationale: A failure or latent flaw of the device software function(s), such as loss of remote control or movement signal processing, could present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

Outcome: Enhanced Documentation Level

25. A retinal diagnostic software device.

Description: The device is limited to prescription use and incorporates an AI/ML-enabled algorithm that is intended to evaluate images for diagnostic screening to identify retinal diseases or conditions.

Rationale: A failure or latent flaw of the device software function(s), such as a diagnostic algorithm failure that provides a false result, could present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

Outcome: Enhanced Documentation Level

26. A radiation therapy treatment system (e.g., Linear accelerator).

Description: The device is intended to noninvasively deliver a focal dose of radiation to a specified volume of a patient's anatomy while sparing the surrounding normal tissues and structures.

Rationale: A failure or latent flaw of the device software function(s), such as under- or overdose to a target volume or delivery to the wrong volume, could present a hazardous situation with a probable risk of death or serious injury to the patient prior to the implementation of risk control measures.

Outcome: Enhanced Documentation Level

27. A drug-device combination, with the device constituent part detecting ingestion of the drug component to prevent treatment failure.

Description: The product is a combination product comprised of two regulated components (drug and device). The "primary mode of action"[66] is the drug component, provided as a tablet. The device constituent part detects ingestion of the tablet component to monitor adherence to the drug regimen. A missed dose greatly increases the likelihood of treatment failure for a life-threatening condition. The device constituent part includes hardware (sensors) and software (signal processing).

Rationale: A failure or latent flaw of the device software function(s), such as a false detection of tablet ingestion, would present a hazardous situation with a probable risk of death or serious injury to either a patient (through worsening of the life-threatening disease), user of the device, or others in the environment of use, prior to the implementation of risk control measures.

Outcome: Enhanced Documentation Level

[66] Section 503(g)(1)(C) of the FD&C Act states that the term "primary mode of action" means "the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product."

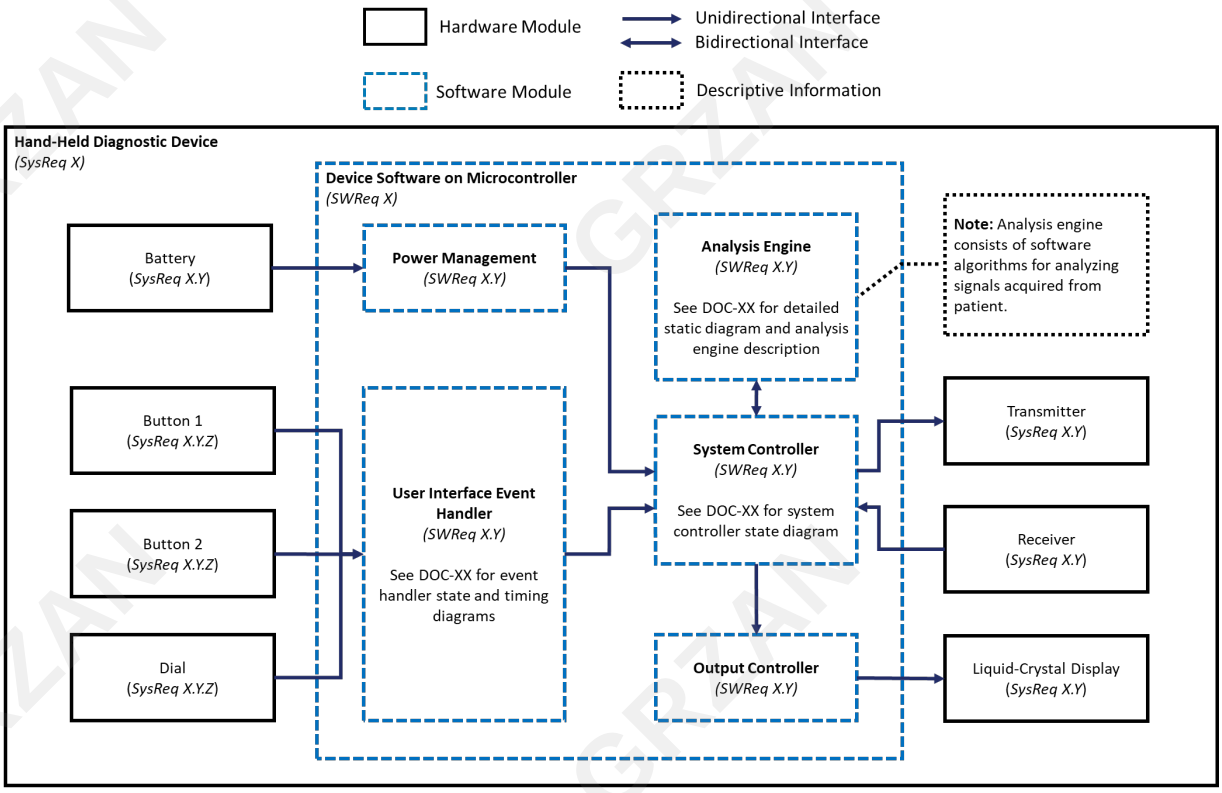
Appendix B: System and Software Architecture Diagram Examples

The three example diagrams below are simplified for the purpose of demonstrating how the considerations described in Section VI.E (System and Software Architecture Diagram) could be implemented into diagrams that facilitate a clear understanding of the system and software. Each diagram is supported by descriptive text and a brief discussion on notable features. The examples are intended for illustration purposes only and do not describe a complete and comprehensive system and software architecture diagram.

The illustrative diagrams are based on the following distinct example devices:

1. A hand-held diagnostic device
2. An implantable therapeutic device with patient- and provider-facing applications
3. A cloud-based device algorithm for analyzing previously captured medical images

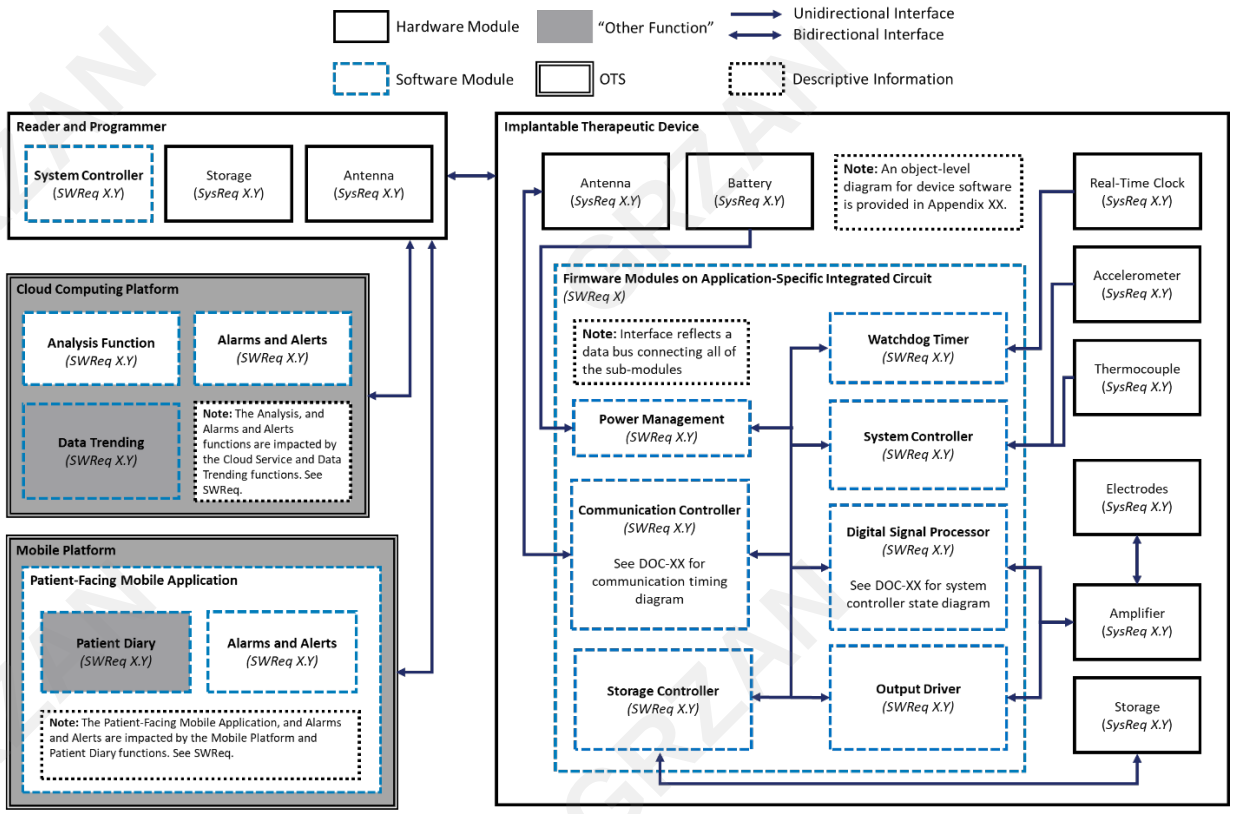
The diagrams are largely static diagrams with high-level identification of interfaces between system and software components. The use of any specific design or formatting features is only provided as a suggestion and does not preclude the use of alternative approaches and/or OTS modeling languages or platforms.



SysReq refers to the system requirement(s). Refer to the *System Requirements Document* (SysRS-XX Rev. X) for detailed information.
SWReq refers to the software requirement(s). Refer to the *Software Requirements Document* (SRS-XX Rev. X) for detailed information.

Figure 1: Example System and Software Architecture Diagram – Hand-Held Diagnostic Device

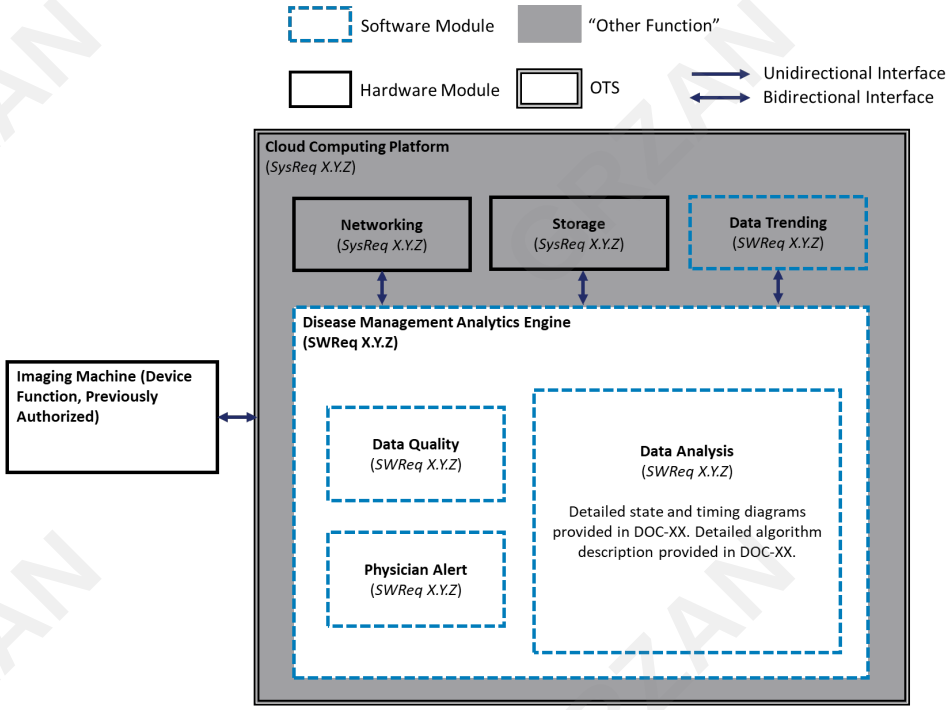
Figure 1 depicts a static, high-level system and software architecture diagram of the modules in a fictional hand-held diagnostic device. A legend is provided to describe visual features used to identify different components. References are provided to documents containing more information, including other static diagrams, dynamic diagrams, and detailed descriptions. An annotation is provided to improve clarity on the purpose of one module. Text is provided with adequate clarity and font size for readability.



SysReq refers to the system requirement(s). Refer to the *System Requirements Document* (SysRS-XX Rev. X) for detailed information.
SWReq refers to the software requirement(s). Refer to the *Software Requirements Document* (SRS-XX Rev. X) for detailed information.

Figure 2: Example System and Software Architecture Diagram – Implantable Therapeutic Device with Patient- and Provider-Facing Applications

Figure 2 depicts a static, high-level system and software architecture diagram of the modules in a fictional implantable therapeutic device. The example depicts the implementation of device software functions on OTS platforms, including a cloud computing platform and a smartphone application.



SysReq refers to the system requirement(s). Refer to the *System Requirements Document* (SysRS-XX Rev. X) for detailed information.
SWReq refers to the software requirement(s). Refer to the *Software Requirements Document* (SRS-XX Rev. X) for detailed information.

Figure 3: Example System and Software Architecture Diagram - Cloud-based Device Algorithm for Analyzing Previously Captured Medical Images

Figure 3 depicts a static, high-level system and software architecture diagram of the modules in a fictional cloud-based algorithm for analyzing previously captured medical images. The example shows how a software-only function can be described from a platform-level perspective.