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Client Alert

FDA and Life Sciences

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FDA Makes First Significant Changes to Premarket Medical Device Software Guidance in 16 Years

On November 4, 2021, FDA released a draft guidance for public comment entitled "Content of Premarket Submissions for Device Software Functions" (the "2021 Draft Guidance"). In its final form, this guidance will replace the 2005 guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (the "2005 Final Guidance"). FDA is accepting comments on the Draft Guidance until February 2, 2021, filed to docket FDA-2021-D-0775.

The 2021 Draft Guidance makes significant changes to the previously issued 2005 Final Guidance and has the potential to alter software development processes and documents expected of manufacturers of software in a medical device (SiMD) or software as a medical device (SaMD).

I. Comparison of the 2021 Draft Guidance and the 2005 Final Guidance

Below are seven areas we have identified that distinguish the 2005 Final Guidance from the 2021 Draft Guidance that deserve special attention from manufacturers:

2021 Draft Guidance	2005 Final Guidance
Title: Content of Premarket Submissions for Device Software Functions	Title: Content of Premarket Submissions for Software Contained in Medical Devices
Overall Implications: As with the recently updated guidance for Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices and the policy and considerations for Multiple Function Device Products, the focus has shifted from establishing expectations for an entire system based on its highest level of risk to treating each function independently.	
Referenced Standards: ANSI/AAMI/ISO 14971, ANSI/AAMI/IEC 62304, and ANSI/AAMI SW91	Referenced Standards: ISO 14971 and AAMI SW68:2001
Implications: AAMI SW68:2001 (Medical device software – Software life cycle processes) was the source document for the 2005 Final Guidance and the international standard ANSI/AAMI/IEC 62304 (Medical device software – Software life cycle processes). The 2021 Draft Guidance updates the standards reference to the current standards and defers to ANSI/AAMI/IEC 62304, with some modification. The 2021 Draft Guidance retains references to ANSI/AAMI/ISO 14971 and utilizes the standard more extensively than the 2005 Final Guidance did. ANSI/AAMI SW91 (Classification of defects in health software) is a new addition in the 2021 Draft Guidance and provides a uniform hierarchical scheme for classifying software anomalies, which has benefits both in terms of harmonization (e.g. across projects within a single manufacturer, across manufacturers within the industry) and defect trending, which is an ANSI/AAMI/IEC 62304 requirement.	
Documentation Level: Basic, Enhanced	Level of Concern: Major, Moderate, Minor
Implications: FDA's categorization of software Level of Concern was always at odds with the software safety classification (A, B, or C) described in ANSI/AAMI/IEC 62304 and it often was not used by FDA or SaMD/SiMD developers beyond inclusion in a submission. The new "basic" and "enhanced" documentation categories provided in the 2021 Draft Guidance will provide clarity by specifying enhanced documentation for device components of combination products, three categories of blood products, class III devices, or functions that would "present a probable risk of death or serious injury." This latter factor would include Class C software, as defined by ANSI/AAMI/IEC 62304, but with a probability / likelihood component that may reduce the number of Class C software items falling into this bucket. Although FDA has indeed introduced another classification scheme beyond one established in a recognized consensus standard, the 2021 Draft Guidance provides a structure more easily mapped to ANSI/AAMI/IEC 62304 than the questionnaire-driven Minor, Moderate, Major Level of Concern described in the 2005 Final Guidance.	
System and Software Architecture Design Chart	Architecture Design Chart
Implications: This critical component of software design useful in both change management and risk management was not required in the 2005 Final Guidance for Minor Level of Concern Software.	

<table>
<tr><td colspan="2">If finalized, the 2021 Draft Guidance would require software architecture for all SiMD / SaMD premarket submissions. It also provides much more extensive guidance for the contents of software architecture and dedicates Appendix B to examples of well-constructed architectural diagrams.</td></tr>
<tr><td>Risk Management File</td><td>Device Hazard Analysis</td></tr>
<tr><td colspan="2">Implications: Where the 2005 Final Guidance asked for only the hazard analysis (i.e., risk analysis) as a requirement for product submissions, the 2021 Draft Guidance proposes submission of the complete risk management file described in ANSI/AAMI/ISO 14971, which includes a risk management plan, risk assessment (including risk-benefit analysis, where applicable), and risk management report. Firms conforming to ANSI/AAMI/ISO 14971 have always established these records as part of their risk management file, but their inclusion in product submissions was previously restricted to the risk analysis.</td></tr>
<tr><td>Software Development and Maintenance Practices</td><td>N/A</td></tr>
<tr><td colspan="2">Implications: Describing how software would be maintained and changes managed was not a requirement for submissions based on the 2005 Final Guidance.

Under the 2021 Draft Guidance manufacturers could address this requirement by either declaring conformity to ANSI/AAMI IEC 62304 or providing a summary description of the development and maintenance lifecycle in the premarket submission.</td></tr>
<tr><td>Unresolved Anomalies (e.g., Bugs, Defects, or Errors)</td><td>Unresolved Anomalies (Bugs or Defects)</td></tr>
<tr><td colspan="2">Implications: Including a listing of unresolved anomalies (defined in both 2005 and 2021 as deviations from the expected – consistent with ANSI/AAMI/IEC 62304), with appropriate rationale, impacts, and timelines for resolution was not a requirement for Minor Level of Concern software in the 2005 Final Guidance.

The 2021 Draft Guidance would require this information for all medical device software functions and further recommend use of ANSI/AAMI SW91 for classifying software defects in a uniform manner.</td></tr>
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II. Take-Aways

The 2021 Draft Guidance does not wholly deviate from the 2005 Final Guidance, but rather provides more clarifying detail and, if finalized, could potentially require more structured documentation for inclusion in premarket submissions for SaMD and SiMD.

Although documentation categories would be simplified and clarified under the 2021 Draft Guidance, the documentation requirements themselves may be more extensive (especially for low-risk devices). Similarly, the deeper alignment with ANSI/AAMI/IEC 62304 and ANSI/AAMI/IEC 14971 may impose documentation requirements reflected in those standards even beyond what is described in the 2021 Draft Guidance. That said, if this Draft Guidance is finalized, certain manufacturers (e.g., manufacturers of Class I or Class II devices not in combination products or certain blood-related devices) may be able to partially mitigate increased documentation requirements by using well-structured software architecture, which can segregate

low-risk functions from high-risk functions, thus expanding the use of the Basic Documentation Level in submissions.

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