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FDA-62304 Summary Comparison Training Aide

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The table on the next pages provides a high level comparison of FDA expectations and requirements with IEC 62304 requirements for medical device software. There are many details and fine points to be considered that cannot be comprehensively presented in a generic and summary manner so keep this in mind. There are also a number of changing subtleties to FDA's interpretations, submission requirements, and enforcement that change over time.

The table provided uses the information from Appendix A of the 2015 Amendment to 62304 *AAMI/IEC 62304:2006/AMD1 issued July 2015*.

The first added column indicates the Sections of 62304 that align with FDA's *General Principles of Software Validation* (GPSV) guidance requirements. It is important to note that this guidance, while allowing more or less rigor based on safety and effectiveness risk, essentially requires all elements of software validation regardless of risk, unlike 62304 which requires fewer elements for lower Safety Classes (Safety Class is a term defined in 62304 not used in FDA regulations and guidance's) as defined internal to this standard.

Three other columns have been added one alongside each 62304 Safety Class column to indicate Sections of 62304 are relevant to information in premarket submissions requested by FDA for each of its Levels of Concerns defined in the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Keep in mind that this guidance only indicates a sampling of information that FDA normally requires for each Level of Concern to be provided in premarket. FDA is clear that other information is required to be on file, as indicated in the GPSV and other FDA documents, and can be requested if they deem it necessary.

Nothing provided in this document is intended to identify situations in which software might be considered outside the scope of regulation by FDA (either is not considered to be a medical device or where FDA is exercising enforcement discretion and not actively regulating the specific type of device).

Note that this table is presented at a summary level based on sections of 62304. Details in each section may be requirements for more or less or different things or formality at a low level in terms of what FDA requires or in terms of terminology used.

Note also that 62304 allows differentiation of requirements for different portions of the software in a medical device if different software components have different Safety Classes. FDA, although it allows for differing rigor and evidence based on risk, does not provide exemptions for basic requirements for information or elements of validation for different software components.

Finally, keep in mind that FDA has specific guidance for off-the-shelf software information in premarket submissions as well as cybersecurity guidance and usability in more specific detail then is included in 62304 so for this and other reasons mentioned above no inference should be made that if one meets 62304 requirements, even for Class C software, that one automatically complies with FDA requirements.

Summary of requirements by 62304 Safety Class Versus FDA Requirements
(See important notes on previous page)

Clauses and subclauses ***The comparison of FDA requirements to 62304 Sections is to the general intent of the section not each detail of what is stated in 62304.***	**FDA* GPSV**	**62304 Class A**	**FDA* LOC MINOR**	**62304 Class B**	**FDA* LOC MODERATE**	**62304 Class C**	**FDA* LOC MAJOR**
Clause 4 All requirements	All except 4.3 4.2 Not necessarily 14971	X	All except 4.3 4.2 Not necessarily 14971	X	All except 4.3 4.2 Not necessarily 14971	X	All except 4.3 4.2 Not necessarily 14971
Planning 5.1 5.1.1, 5.1.2, 5.1.3, 5.1.6, 5.1.8, 5.1.9, 5.1.10	X	X		X	Summary only	X	Summary with list of documents & CM & Maintenance Plan
5.1.5, 5.1.7, 5.1.11, 5.1.12	X			X		X	
5.1.4	X					X	
Requirements Analysis 5.2 5.2.1, 5.2.2, 5.2.4, 5.2.5, 5.2.6	X	X	Summary only	X	X	X	X
5.2.3	X			X	X	X	X
Architectural Design 5.3 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.6	X			X	X	X	X
5.3.5	X				X	X	X
Detailed Design 5.4 5.4.1	X			X	X	X	X
5.4.2, 5.4.3, 5.4.4	X				X	X	X
Unit Imp. & Verification 5.5 5.5.1	X	X		X	Summary Only	X	X
5.5.2, 5.5.3, 5.5.5	X			X	Summary Only	X	X
5.5.4	X				Summary Only	X	X
Integration & Int. Test 5.6 All requirements	X			X	Summary Only	X	X

System Testing 5.7 All requirements	X	X	X	X	X	X	X
SW Release 5.8 5.8.1, 5.8.2, 5.8.4, 5.8.7, 5.8.8	X	X	5.8.1, 5.8.2, 5.8.4	X	5.8.1, 5.8.2, 5.8.4	X	5.8.1, 5.8.2, 5.8.4
5.8.3, 5.8.5, 5.8.6	X		5.8.3, 5.8.6	X	5.8.3, 5.8.6	X	5.8.3, 5.8.6
Maintenance Clause 6 All requirements	X	X	X	X	Summary Only	X	X
Risk Analysis 7.1 All requirements	X		X	X	X	X	X
Risk Control 7.2 All requirements	X		X	X	X	X	X
RCM Verification 7.3 All requirements	X		X	X	X	X	X
Risk Mgmt of Changes 7.4 7.4.1	X	X	X	X	X	X	X
7.4.2, 7.4.3	X		X	X	X	X	X
Configuration Mgmt. Clause 8 All reqs.	X	X		X	Summary Only	X	X
Problem Resolution Clause 9 All reqs.	X	X	9.3	X	Summary Only	X	X
	Trace and OTSS/SOUP and security info is spread throughout 62304 sections		Trace and OTSS/SOUP and security info is spread throughout 62304 sections		Trace and OTSS/SOUP and security info is spread throughout 62304 sections		Trace and OTSS/SOUP and security info is spread throughout 62304 sections
	Also see FDA Cybersecurity guidances.and OTSS guidances		Also see FDA Cybersecurity & OTSS guidances.		Also see FDA Cybersecurity & OTSS guidances.		Also see FDA Cybersecurity & OTSS guidances.

* FDA LOCs are used to identify the information FDA wants submitted in premarket submissions and does not indicate all information FDA requires for compliance and might request during the submission process or check during inspections or as part of field issue investigations. The FDA's GPSV guidance is the correct primary reference for all items FDA suggests be available for compliance purposes and this is indicated in the 2nd column and is not related to Level of Concern (LOC).

The risk model utilized in 62304 is not the same as the risk model used for FDA device classification and or pre-market software review. Each model was created at a different time and for a different purpose.