

IEC 62304:2006 Mapping of Requirements to Documents

This table maps all requirements of the IEC 62304:2006 (by section) to the relevant documents (here: OpenRegulatory templates).

Note that the document names in the “Fulfilled in Document” column are based on the OpenRegulatory templates. You’ll probably have a different system for assigning document names, so feel free to rename them.

Class	Section	Title	Fulfilled in Document	Comment
(General)	4.1	Quality management system	Quality Management Manual	
	4.2	Risk management	SOP Integrated Software Development	
	4.3	Software Safety Classification	Risk Management Report	
	4.4	Legacy Software	(Not applicable)	<i>Not applicable unless you have legacy software.</i>
A, B, C	5.1.1	Software development plan	Software Development and Maintenance Plan	
A, B, C	5.1.2	Keep software development plan update	SOP Integrated Software Development	
A, B, C	5.1.3	Software development plan reference to system design and development	Software Development and Maintenance Plan	
C	5.1.4	Software development standards, methods and tool planning	Software Development and Maintenance Plan	
B, C	5.1.5	Software integration and integration test planning	Software Development and Maintenance Plan	
A, B, C	5.1.6	Software verification planning	Software Development and Maintenance Plan	

Classes	Section	Title	Fulfilled in Document	Comment
A, B, C	5.1.7	Software risk management planning	Software Development and Maintenance Plan	
A, B, C	5.1.8	Documentation planning	Software Development and Maintenance Plan	
A, B, C	5.1.9	Software configuration management planning	Software Development and Maintenance Plan	
B, C	5.1.10	Supporting items to be controlled	Software Development and Maintenance Plan	
B, C	5.1.11	Software configuration item control before verification	Software Development and Maintenance Plan	
B, C	5.1.12	Identification and avoidance of common software defects	Software Development and Maintenance Plan	
A, B, C	5.2.1	Define and document software requirements from system requirements	SOP Integrated Software Development; Software Requirements List	
A, B, C	5.2.2	Software requirements content	Software Requirements List	
B, C	5.2.3	Include risk control measures in software requirements	Software Requirements List	
A, B, C	5.2.4	Re-evaluate medical device risk analysis	SOP Integrated Software Development	
A, B, C	5.2.5	Update requirements	SOP Integrated Software Development	
A, B, C	5.2.6	Verify software requirements	SOP Integrated Software Development; Checklist Software Requirements	
B, C	5.3.1	Transform software requirements into an architecture	SOP Integrated Software Development; (Software architecture diagrams, interface documentation)	

Classes	Section	Title	Fulfilled in Document	Comment
B, C	5.3.2	Develop an architecture for the interfaces of software items	SOP Integrated Software Development; (Software architecture diagrams, interface documentation)	
B, C	5.3.3	Specify functional and performance requirements of SOUP item	SOUP list	
B, C	5.3.4	Specify system hardware and software required by SOUP item	SOUP list	
C	5.3.5	Identify segregation necessary for risk control	SOP Integrated Software Development	
B, C	5.3.6	Verify software architecture	SOP Integrated Software Development; Checklist Software Architecture	
B, C	5.4.1	Subdivide software into software units	SOP Integrated Software Development; (Software architecture diagrams)	
C	5.4.2	Develop detailed design for each software unit	SOP Integrated Software Development	
C	5.4.3	Develop detailed design for interfaces	SOP Integrated Software Development	
C	5.4.4	Verify detailed design	SOP Integrated Software Development	
A, B, C	5.5.1	Implement each software unit	SOP Integrated Software Development; (GitHub Pull Requests / GitLab Merge Requests)	
B, C	5.5.2	Establish software unit verification process	SOP Integrated Software Development	
B, C	5.5.3	Software unit acceptance criteria	SOP Integrated Software Development	
C	5.5.4	Additional software unit acceptance criteria	SOP Integrated Software Development	
B, C	5.5.5	Software unit verification	SOP Integrated Software Development; (CI/CD in GitHub Pull Requests / GitLab Merge Requests)	

Classes	Section	Title	Fulfilled in Document	Comment
B, C	5.6.1	Integrate software units	SOP Integrated Software Development; (Merge in GitHub / GitLab)	
B, C	5.6.2	Verify software integration	SOP Integrated Software Development; (Merge in GitHub / GitLab)	
B, C	5.6.3	Software integration testing	SOP Integrated Software Development; (Merge in GitHub / GitLab, CI/CD)	
B, C	5.6.4	Software integration testing content	SOP Integrated Software Development; (CI/CD in GitHub Pull Requests / GitLab Merge Requests)	
B, C	5.6.5	Evaluate software integration test procedures	SOP Integrated Software Development	
B, C	5.6.6	Conduct regression tests	SOP Integrated Software Development; (CI/CD in GitHub Pull Requests / GitLab Merge Requests)	
B, C	5.6.7	Integration test record contents	SOP Integrated Software Development; (CI/CD in GitHub Pull Requests / GitLab Merge Requests)	
B, C	5.6.8	Use software problem resolution process	SOP Software Problem Resolution	
A, B, C	5.7.3	Retest after changes	SOP Integrated Software Development	
A, B, C	5.7.4	Evaluate software system testing	SOP Integrated Software Development; Software System Test Plan	
A, B, C	5.7.5	Software system test record contents	SOP Integrated Software Development; Software System Test Protocol	
A, B, C	5.8.1	Ensure software verification is complete	SOP Integrated Software Development; Checklist Software Release	
A, B, C	5.8.2	Document known residual anomalies	SOP Integrated Software Development; (Release notes / changelog)	
B, C	5.8.3	Evaluate known residual anomalies	Risk table; (Release notes / changelog)	

Classes	Section	Title	Fulfilled in Document	Comment
A, B, C	5.8.4	Document released versions	SOP Integrated Software Development; (Release notes / changelog)	
B, C	5.8.5	Document how released software was created	SOP Integrated Software Development; (Release notes / changelog)	
B, C	5.8.6	Ensure activities and tasks are complete	SOP Integrated Software Development; Checklist Software Release	
A, B, C	5.8.7	Archive software	SOP Integrated Software Development; (Tagged commit in git)	
A, B, C	5.8.8	Assure reliable delivery of released software	SOP Integrated Software Development	
A, B, C	6.1	Establish a software maintenance plan	Software Development and Maintenance Plan	
A, B, C	6.2.1	Monitor feedback		
A, B, C	6.2.1	Document and evaluate feedback		
A, B, C	6.2.1	Evaluate problem report's affects on safety	SOP Problem Resolution	
A, B, C	6.2.2	Use software problem resolution process	SOP Problem Resolution	
A, B, C	6.2.3	Analyse change requests	SOP Change Management	
A, B, C	6.2.4	Change request approval	SOP Change Management	
A, B, C	6.2.5	Communicate to users and regulators	SOP Change Management	
A, B, C	6.3.1	Use established process to implement modification	SOP Change Management	

Classes	Section	Title	Fulfilled in Document	Comment
A, B, C	6.3.2	Re-release modified software system	SOP Change Management	
B, C	7.1.1	Identify software items that could contribute to a hazardous situation	SOP Integrated Software Development	
B, C	7.1.2	Identify potential causes of contribution to a hazardous situation	SOP Integrated Software Development	
B, C	7.1.3	Evaluate published SOUP anomaly lists	SOP Integrated Software Development	
B, C	7.1.4	Document potential causes	SOP Integrated Software Development	
B, C	7.2.1	Define risk control measures	SOP Integrated Software Development	
B, C	7.2.2	Risk control measures implemented in software	SOP Integrated Software Development	
B, C	7.3.1	Verify risk control measures	SOP Integrated Software Development	
	7.3.2	(Not used)		
B, C	7.3.3	Document traceability	SOP Integrated Software Development; Software Requirements List	
A, B, C	7.4.1	Analyse changes to medical device software with respect to safety	SOP Change Management	
B, C	7.4.2	Analyse impact of software changes on existing risk control measures	SOP Change Management	
B, C	7.4.3	Perform risk management activities based on analyses	SOP Change Management	
A, B, C	8.1.1	Establish means to identify configuration items	Software Development and Maintenance Plan	

Classes	Section	Title	Fulfilled in Document	Comment
A, B, C	8.1.2	Identify SOUP	SOP Integrated Software Development	
A, B, C	8.1.3	Identify system configuration documentation	SOP Integrated Software Development	
A, B, C	8.2.1	Approve change requests	SOP Change Management	
A, B, C	8.2.2	Implement changes	SOP Change Management	
A, B, C	8.2.3	Verify changes	SOP Change Management	
A, B, C	8.2.4	Provide means for traceability of change	SOP Change Management	
A, B, C	8.3	Configuration status accounting	Software Development and Maintenance Plan	
A, B, C	9.1	Prepare problem reports	SOP Software Problem Resolution	
A, B, C	9.2	Investigate the problem	SOP Software Problem Resolution	
A, B, C	9.3	Advise relevant parties	SOP Software Problem Resolution; SOP Incident Reporting	
A, B, C	9.4	Use change control process	SOP Change Management	
A, B, C	9.5	Maintain records	SOP Software Problem Resolution	
A, B, C	9.6	Analyse problems for trends	SOP Software Problem Resolution	
A, B, C	9.7	Verify software problem resolution	SOP Software Problem Resolution	

Classes	Section	Title	Fulfilled in Document	Comment
A, B, C	9.8	Test documentation contents	SOP Integrated Software Development	

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