# 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.

| Classes | 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) | *Not applicable unless you have legacy software.* |
| 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 |  |
| 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) |  |
| 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) |  |
| 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) |  |
| 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 | 6.2.1.1 | Monitor feedback |  |  |
| A, B, C | 6.2.1.2 | Document and evaluate feedback |  |  |
| A, B, C | 6.2.1.3 | 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 |  |
| 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 |  |
| 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 |  |
| A, B, C | 9.8 | Test documentation contents | SOP Integrated Software Development |  |

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