SierraLabs

# IEC 62304

| Reference | Software Lifecycle Process | Applicable for | | |
|---|---|---|---|---|
| | | Class A | Class B | Class C |
| | **PRIMARY LIFECYCLE PROCESESS** | | | |
| **5** | **SOFTWARE DEVELOPMENT Process** | | | |
| **5.1** | **Development Planning Activity** | | | |
| 5.1.1 | Software development plan task | X | X | X |
| 5.1.2 | Software development plan reference to SYSTEM requirements task | X | X | X |
| 5.1.3 | SOUP management planning task | | X | X |
| 5.1.4 | Software development measures planning task | | X | X |
| 5.1.5 | Software integration and integration testing planning task | | X | X |
| 5.1.6 | Software VERIFICATION planning task | X | X | X |
| 5.1.7 | Software VERIFICATION requirements coverage planning task | | X | X |
| 5.1.8 | Software RISK MANAGEMENT planning task | X | X | X |
| 5.1.9 | Documentation planning task | X | X | X |
| 5.1.10 | Software configuration management planning task | X | X | X |
| 5.1.11 | Software configuration control planning task | | X | X |
| 5.1.12 | Software problem resolution planning task | | | X |
| **5.2** | **Requirements Analysis Activity** | | | |
| 5.2.1 | Define software requirements from SYSTEM requirements task | X | X | X |
| 5.2.2 | Establish software requirements task | X | X | X |
| 5.2.3 | Software requirements content task | X | X | X |
| 5.2.4 | Include RISK CONTROL measures in software requirements task | | X | X |
| 5.2.5 | Update RISK ANALYSIS task | X | X | X |
| 5.2.6 | Ensure compliance with SYSTEM requirements task | X | X | X |
| 5.2.7 | Uniquely identify software requirements task | X | X | X |
| 5.2.8 | Update SYSTEM requirements task | X | X | X |
| 5.2.9 | Verify software requirements task | X | X | X |
| 5.2.10 | Document software requirements VERIFICATION task | X | X | X |
| **5.3** | **Architectural Design Activity** | | | |
| 5.3.1 | Transform software requirements into an ARCHITECTURE task | X | X | X |
| 5.3.2 | Document software ARCHITECTURE task | X | X | X |
| 5.3.3 | Document software safety classification of each SOFTWARE ITEM task | X | X | X |
| 5.3.4 | Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS task | | X | X |
| 5.3.5 | Specify SYSTEM hardware and software required by SOUP item task | | X | X |
| 5.3.6 | Specify functional and performance requirements of SOUP item task | | X | X |
| 5.3.7 | Identify segregation necessary for SAFETY task | | X | X |
| 5.3.8 | Verify software ARCHITECTURE task | | X | X |
| 5.3.9 | Verify appropriateness of software development plan task | | X | X |
| 5.3.10 | Document results of software ARCHITECTURE VERIFICATION task | | X | X |
| **5.4** | **Detailed Design Activity** | | | |
| 5.4.1 | Refine SOFTWARE ITEMS into SOFTWARE UNITS task | | X | X |
| 5.4.2 | Inheritance of software safety classification task | | X | X |
| 5.4.3 | Develop detailed design for each SOFTWARE UNIT task | | | X |
| 5.4.4 | Develop detailed design for interfaces task | | | X |
| 5.4.5 | Verify detailed design task | | X | X |
| 5.4.6 | Additional detailed design VERIFICATION task | | | X |
| 5.4.7 | Document results of design VERIFICATION task | | X | X |
| **5.5** | **Software Coding Activity** | | | |
| 5.5.1 | Implement each SOFTWARE UNIT task | | X | X |
| 5.5.2 | Establish SOFTWARE UNIT VERIFICATION PROCESS task | | X | X |
| 5.5.3 | Verify software code task | | X | X |
| 5.5.4 | Additional software code VERIFICATION task | | X | X |
| 5.5.5 | Document the results of software code VERIFICATION task | | X | X |
| **5.6** | **Integration and Testing Activity** | | | |

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| 5.6.1 | Integrate SOFTWARE UNITS task | | X | X |
| 5.6.2 | Verify software integration task | | X | X |
| 5.6.3 | Document the results of software integration task | | X | X |
| 5.5.4 | Additional software code VERIFICATION task | | X | X |
| 5.6.5 | Integration testing content task | | X | X |
| 5.6.6 | Include integration testing for non-normal cases task | | | X |
| 5.6.7 | Conduct regression tests task | | X | X |
| 5.6.8 | Document results of software integration tests task | | X | X |
| 5.6.9 | Integration test documentation contents task | | X | X |
| 5.6.10 | Use formal software problem resolution PROCESS task | | X | X |
| **5.7** | **System Testing Activity** | | | |
| 5.7.1 | Establish tests for each software requirement task | | X | X |
| 5.7.2 | Use formal software problem resolution PROCESS task | | X | X |
| 5.7.3 | Repeat tests and conduct regression tests task | | X | X |
| 5.7.4 | Verify SOFTWARE SYSTEM testing task | | X | X |
| 5.7.5 | Record data for each test task | | X | X |
| **5.8** | **Release Activity** | | | |
| 5.8.1 | Ensure software VERIFICATION is complete | | X | X |
| 5.8.2 | Ensure documentation is complete | | X | X |
| 5.8.3 | Document known residual anomalies | | X | X |
| 5.8.4 | Evaluate known residual anomalies | | X | X |
| 5.8.5 | Document released VERSIONS | | X | X |
| 5.8.6 | Document how released software was created | | X | X |
| 5.8.7 | Archive master copies | | X | X |
| 5.8.8 | Use established procedures for software release | | X | X |
| **6** | **SOFTWARE MAINTENANCE Process** | | | |
| **6.1** | **Establish software maintenance plan Activity** | | | |
| 6.1.1 | Establish software maintenance plan task | X | X | X |
| **6.2** | **Problem and Modification Analysis Activity** | | | |
| 6.2.1 | Record and evaluate feedback task | X | X | X |
| 6.2.2 | Use software problem resolution PROCESS task | X | X | X |
| 6.2.3 | Analyse modification requests task | X | X | X |
| 6.2.4 | Conduct analysis of changes implied by modification request task | X | X | X |
| 6.2.5 | Document new, modified and deleted item task | X | X | X |
| 6.2.6 | Review and approve modification task | X | X | X |
| 6.2.7 | Document modification task | | X | X |
| **6.3** | **Modification Implementation Activity** | | | |
| 6.3.1 | Use established PROCESS to implement modification task | X | X | X |
| 6.3.2 | Define criteria for testing modifications task | | X | X |
| 6.3.3 | Verify modifications task | | X | X |
| 6.3.4 | Conduct regression testing task | | X | X |
| 6.3.5 | Demonstrate software RISK CONTROL measures remain effective task | | X | X |
| 6.3.6 | Document the test results task | | X | X |
| **see 5.3** | **Architectural Design Activity** | | | |
| **see 5.4** | **Detailed Design Activity** | | | |
| **see 5.5** | **Software Coding Activity** | | | |
| **see 5.6** | **Integration and Testing Activity** | | | |
| **see 5.7** | **System Testing Activity** | | | |
| **see 5.8** | **Release Activity** | | | |
| | **SUPPORTING PROCESSES** | | | |
| **7** | **SOFTWARE RISK MANAGEMENT Process (referenced ISO 14971)** | | | |
| **7.1** | **Analysis of software contributing to HAZARDS Activity** | | | |
| 7.1.1 | Identify SOFTWARE ITEMS that could contribute to a HAZARD task | | X | X |
| 7.1.2 | Identify potential causes of contribution to a HAZARD task | | X | X |
| 7.1.3 | Consider specific potential causes task | | X | X |

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| 7.1.4 | Review published SOUP anomaly lists task | | X | X |
| 7.1.5 | Document potential causes task | | X | X |
| 7.1.6 | Document sequences of events task | | X | X |
| **7.2** | **RISK CONTROL measures Activity** | | | |
| 7.2.1 | Define RISK CONTROL measures task | | X | X |
| 7.2.2 | RISK CONTROL measures implemented in software task | | X | X |
| **7.3** | **VERIFICATION of RISK CONTROL measures Activity** | | | |
| 7.3.1 | Verify RISK CONTROL measures task | | X | X |
| 7.3.2 | Document any new sequences of events task | | X | X |
| 7.3.3 | Document TRACEABILITY task | | X | X |
| **7.4** | **RISK MANAGEMENT of software changes Activity** | | | |
| 7.4.1 | Analyse changes TO MEDICAL DEVICE SOFTWARE with respect to safety task | X | X | X |
| 7.4.2 | Analyse impact software changes on existing RISK CONTROL measures task | | X | X |
| 7.4.3 | Perform RISK MANAGEMENT ACTIVITIES based on analyses task | | X | X |
| **8** | **SOFTWARE CONFIGURATION MANAGEMENT Process** | | | |
| **8.1** | **Configuration identification Activity** | | | |
| 8.1.1 | Establish means to identify CONFIGURATION ITEMS task | X | X | X |
| 8.1.2 | Identify SOUP task | X | X | X |
| 8.1.3 | Document SOUP designator task | X | X | X |
| 8.1.4 | Identify SYSTEM configuration documentation task | X | X | X |
| **8.2** | **Configuration control Activity** | | | |
| 8.2.1 | Identify and record change requests task | X | X | X |
| 8.2.2 | Approve requests prior to implementation task | X | X | X |
| 8.2.3 | Implement changes task | X | X | X |
| 8.2.4 | Provide means for TRACEABILITY of change task | X | X | X |
| **8.3** | **Configuration status accounting Activity** | | | |
| 8.3.1 | Configuration status accounting task | X | X | X |
| **9** | **SOFTWARE PROBLEM RESOLUTION Process** | | | |
| | **SOFTWARE PROBLEM RESOLUTION Activity** | | | |
| 9.1.1 | Prepare problem reports task | X | X | X |
| 9.1.2 | Advise relevant parties task | X | X | X |
| 9.1.3 | Investigate the problem task | X | X | X |
| 9.1.4 | Evaluate the problem's relevance to safety task | X | X | X |
| 9.1.5 | Track and report status task | X | X | X |
| 9.1.6 | Resolve the problem task | X | X | X |
| 9.1.7 | Maintain a record of the problem task | X | X | X |
| 9.1.8 | Analyse problems for trends task | X | X | X |
| 9.1.9 | Verify task | X | X | X |