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Standards Organizations; 6. Potential Procedures, Checklists, and Documents; 7. Review of Procedures and Processes; 7.1. Difference between Procedures and Processes
7.2. Why Review Procedures and Processes?7.3. Types of Review; 7.4. Frequency of Review; 7.5. Review Content; 7.6. Course of Action, Changes, and Updates Following Review; 7.7. Review Responsibilities; 8. Configuration Management; 8.1. Rationale for Configuration Management; 8.2. Configuration Management Coverage; 8.3. Records Responsibility; 8.4. System and Location; 8.5. Version Control; 8.6. Design Repository; 8.7. File Structure; 8.8. Obsolete Documents; 8.9. Training for Use of the System; 9. Documentation; 9.1. Rationale for Documentation
9.2. Coverage and Responsibility for Documentation9.3. Types of Documentation; 9.4. Best Practices for Documentation; References; Appendix A: Example Document Outlines; Work Order (WO); Minutes; Problem Report/Corrective Action (PRCA); Engineering Change Request (ECR); Engineering Change Notice (ECN); Project Management Plan (PMP); Interface Control Documents (ICDs); Development Plans; Requirements; Risk Management Plan; Configuration Management Plan; Documentation Plan; Analysis Reports; Design Description; Test Plan; Operation Plan; Metrology Concerns and Procedures
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Sommario/riassunto

This handbook provides a consolidated, comprehensive information resource for engineers working with mission and safety critical systems. Principles, regulations, and processes common to all critical design projects are introduced in the opening chapters. Expert contributors then offer development models, process templates, and documentation guidelines from their own core critical applications fields: medical, aerospace, and military. Readers will gain in-depth knowledge of how to avoid common pitfalls and meet even the strictest certification standards. Particular emphasis is placed