

IEC60601-1 3RD EDITION KEY COLLATERAL STANDARDS INTEGRATION

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Three new aspects of IEC 60601-1:2005 (3rd Edition)

- Risk Management
- Software (PEMS)
- Usability

Specific Collateral Standards

- Risk Management: ISO 14971
- Software (PEMS): IEC 60601-1-4 (4/2000)
- Usability: IEC 60601-1-6

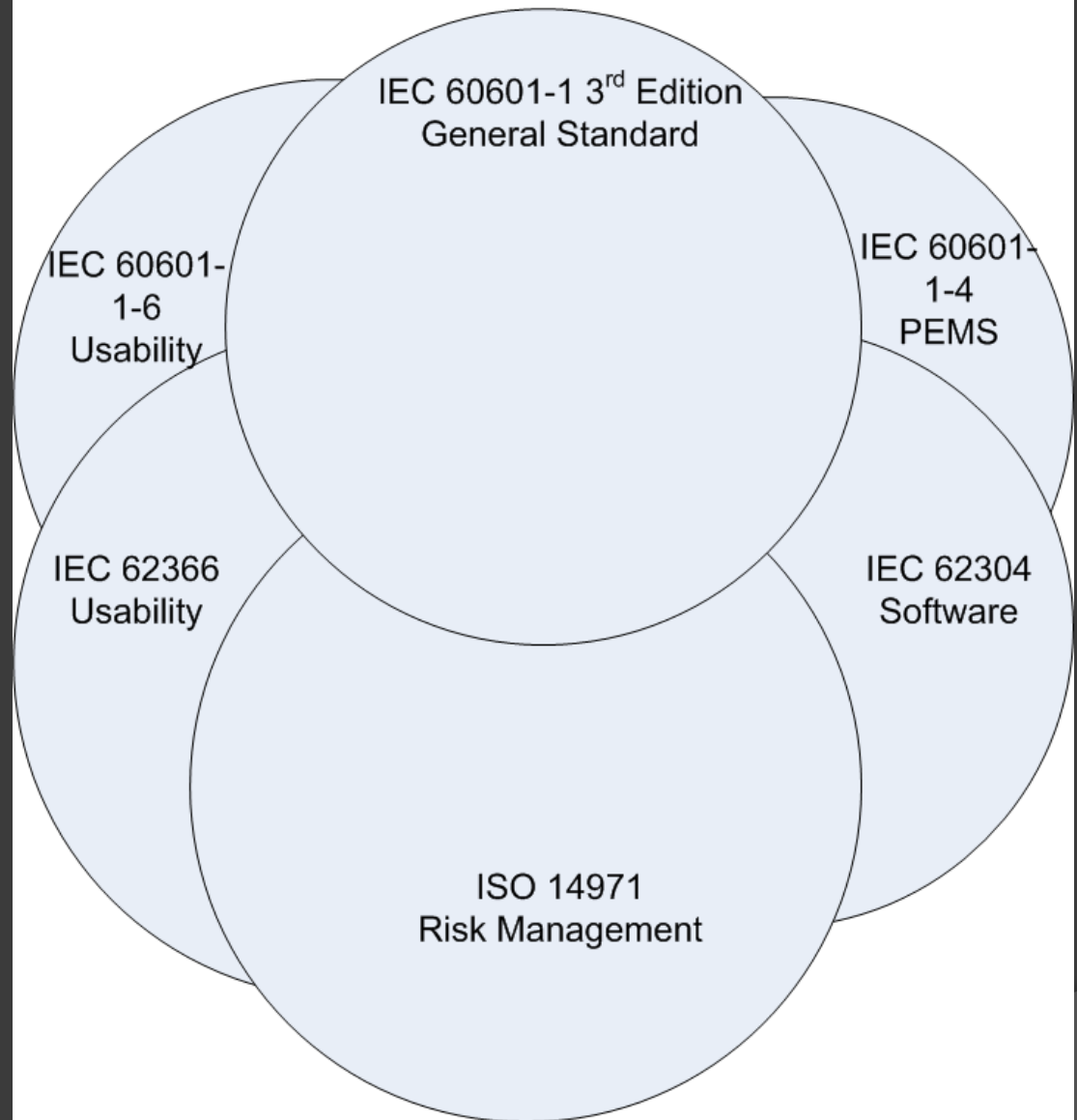
Additional/Replacement Collateral Standards

- Software (PEMS): IEC 62304
- Usability: IEC 62366

Key Aspects of The (3) Collateral Standards

- Process Standards
- Not testable
- Require document (“objective evidence”) review
- Common focus on Risk Management

IEC 60601-1 3rd Edition (3) Collateral Standards Framework



Key Links to the General Standard

- Risk Management – Sections 4.2, 4.3 and 13
- Software (PEMS) – Section 14
- Usability – Section 12.2

Key Elements of each Collateral Standard – Risk Management

- ◎ Risk Management (ISO 14971)
 - Risk Management Planning
 - Essential Performance
 - Risk Analysis process
 - Risk Evaluation process
 - Risk Control process
 - Evaluation of overall Risk Acceptability
 - Risk Management Report
 - Production and Post-Production Information

Key Elements of each Collateral Standard – Software/PEMS

- ◎ Software (PEMS) – IEC 62304
 - Software Development Planning
 - Software Safety Classification
 - Software Risk Management Process
 - Software Requirements Specification (SRS) and analysis
 - System Interface Specification(s)
 - Software Architecture design
 - Software Detailed Design

Key Elements of each Collateral Standard – Software/PEMS (cont.)

- ◎ Software (PEMS) – IEC 62304 (continued)
 - Software Verification
 - Unit Level
 - Integration Level
 - System Level
 - Software Validation
 - Software Configuration Management Process
 - Software Maintenance process
 - Post-production Software Problem Resolution process

Key Elements of each Collateral Standard - Usability

- ◎ Usability – IEC 62366
 - Usability Engineering process
 - Usability Specification
 - Application Specification
 - Frequently Used Functions
 - Usability Hazards and Hazardous Situations
 - Primary Operating Functions

Key Elements of each Collateral Standard – Usability (cont.)

- ◎ Usability – IEC 62366 (continued)
 - User Interface Design and Implementation
 - Usability Validation Plan
 - Usability Verification
 - Usability Validation
 - Post-production Usability process
 - Accompanying Documents

Design and Development Lifecycle – ISO 13485/FDA QSR

- ◎ Design & Development (D&D) Planning (7.3.1)
- ◎ Design Input (7.3.2)
- ◎ Risk Analysis (7.1)
- ◎ Design Output (7.3.3)
 - Design
 - Implementation

Design and Development Lifecycle – ISO 13485/FDA QSR (cont.)

- Design Reviews (7.3.4)
- Design Verification (7.3.5)
- Design Validation (7.3.6)
- Design Transfer (7.3.1, 7.3.3)
- Post-Production Monitoring (8)

Basic 3-Collaterals Design and Development Framework

- For each step of the Design & Development Lifecycle, address the 3-Collaterals in addition to the basic product design:
 - Risk Management
 - Usability
 - Software (PEMS)

Design and Development Lifecycle with 3-Collaterals Integration

- ◎ Design Planning
 - Overall D&D Plan
 - Software Development Plan
 - Usability Engineering Plan
 - Risk Management Plan

Design and Development Lifecycle with 3-Collaterals Integration

◎ Design Input

- Overall Product Requirements
- Software Requirements
- Usability Requirements
- Risk Mitigations

Design and Development Lifecycle with 3-Collaterals Integration

- ◎ Design Output
 - Detailed Design
 - Overall Design
 - Software Design
 - User Interface Design
 - Risk Mitigation Design

Design and Development Lifecycle with 3-Collaterals Integration

◎ Design Output

- Design Implementation
 - Overall Implementation
 - Software Implementation
 - User Interface Implementation
 - Risk Mitigation Implementation

Design and Development Lifecycle with 3-Collaterals Integration

◎ Design Review

- Overall Design Reviews
- Software Design Reviews
- User Interface Design Reviews
- Risk Mitigation Design Reviews
- Traceability Reviews

Design and Development Lifecycle with 3-Collaterals Integration

⦿ Risk Management

- Risk Analysis

- Hazard identification
- Initial Risk Estimation
- Risk Reduction specification
- Residual Risk Estimation
- Transferring Mitigations to Requirements

Design and Development Lifecycle with 3-Collaterals Integration

- ◎ Design Verification
 - Overall Design Verification
 - Software Design Verification
 - User Interface Design Verification
 - Risk Mitigation Verification

Design and Development Lifecycle with 3-Collaterals Integration

- ◎ Design Validation
 - Overall Design Validation
 - Software Validation
 - User Interface Validation
 - Risk Mitigation Validation

Design and Development Lifecycle with 3-Collaterals Integration

- ◎ Post-Production Monitoring
 - Overall Post-Production Monitoring
 - Post-Production Software Monitoring
 - Post-Production User Interface Monitoring
 - Post-Production Risk Monitoring

Summary – Framework for 3-Collaterals Integration

- ⦿ Since the 3-Collaterals are Process Standards, integrate the 3-Collaterals' requirements to the D&D process
- ⦿ Generate the required documents as part of the D&D documents
- ⦿ Integrate Risk Management throughout the D&D process
- ⦿ Integrate the 3-Collaterals to post-production monitoring

Summary – Framework for 3-Collaterals Integration (cont.)

- ① When analyzing information from post-production monitoring, address the 3-Collaterals:
 - Does the information suggest anything about Risk?
 - Does the information suggest anything about Software (PEMS) ?
 - Does the information suggest anything about Usability?

Conclusion

- The 3-Collateral Standards to IEC 60601-1 3rd Edition can be easily integrated in the Design & Development (D&D) process under ISO 13485 and the FDA QSR

Thank You!

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