Three new aspects of IEC 60601-1:2005 (3\textsuperscript{rd} Edition)

- Risk Management
- Software (PEMS)
- Usability
Specific Collateral Standards

- Risk Management: ISO 14971
- 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

IEC 60601-1 3rd Edition
General Standard

IEC 60601-1-6
Usability

IEC 62366
Usability

IEC 60601-1-4
PEMS

ISO 14971
Risk Management

IEC 62304
Software
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
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!

- Bob Duffy, Bob Duffy Associates
  - 858-487-1859
  - bduffy@BobDuffyAssociates.com
  - www.BobDuffyAssociates.com