

System Safety Requirements Review

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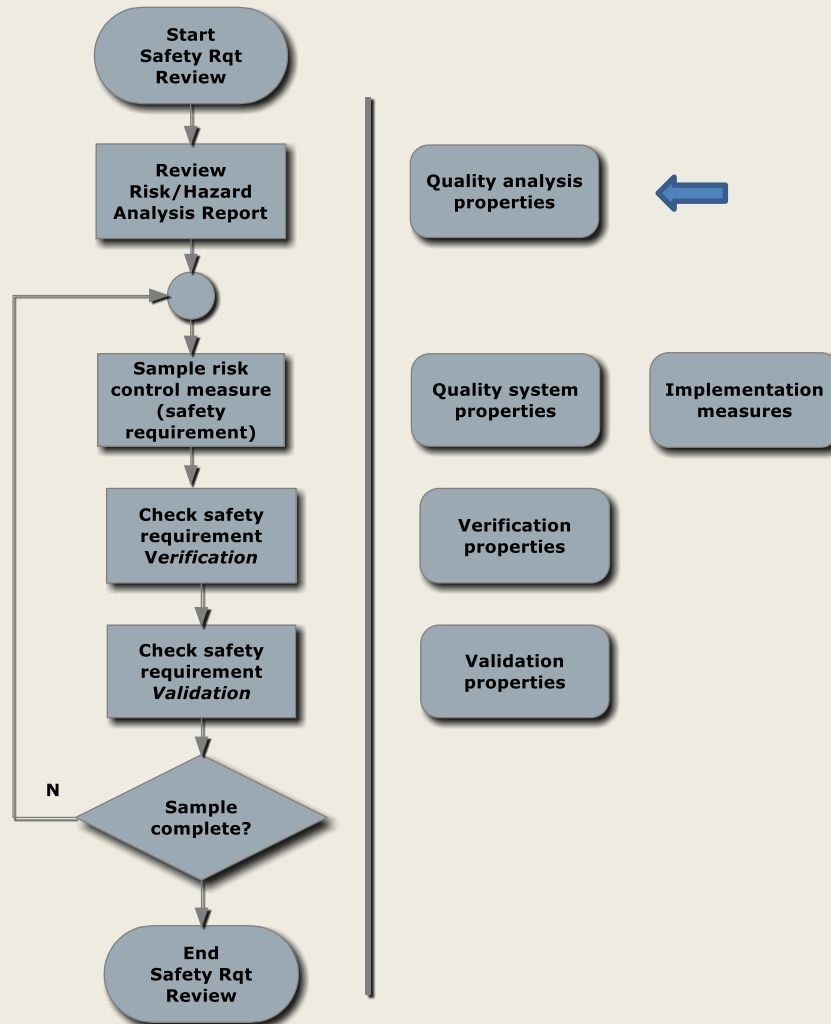
Review Environment

- Thousands of device manufacturers
- No presentation standard
- Tight time constraints
- Technology revolution/evolution
 - Discrete to interoperable (autonomous) systems
 - Mobile apps
 - Cloud based platforms & information aggregation

Core Safety Standards

- Context
 - IEC 60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
 - IEC 60601-X Particular standards
 - ISO 14971: *Medical devices -- Application of risk management to medical devices*

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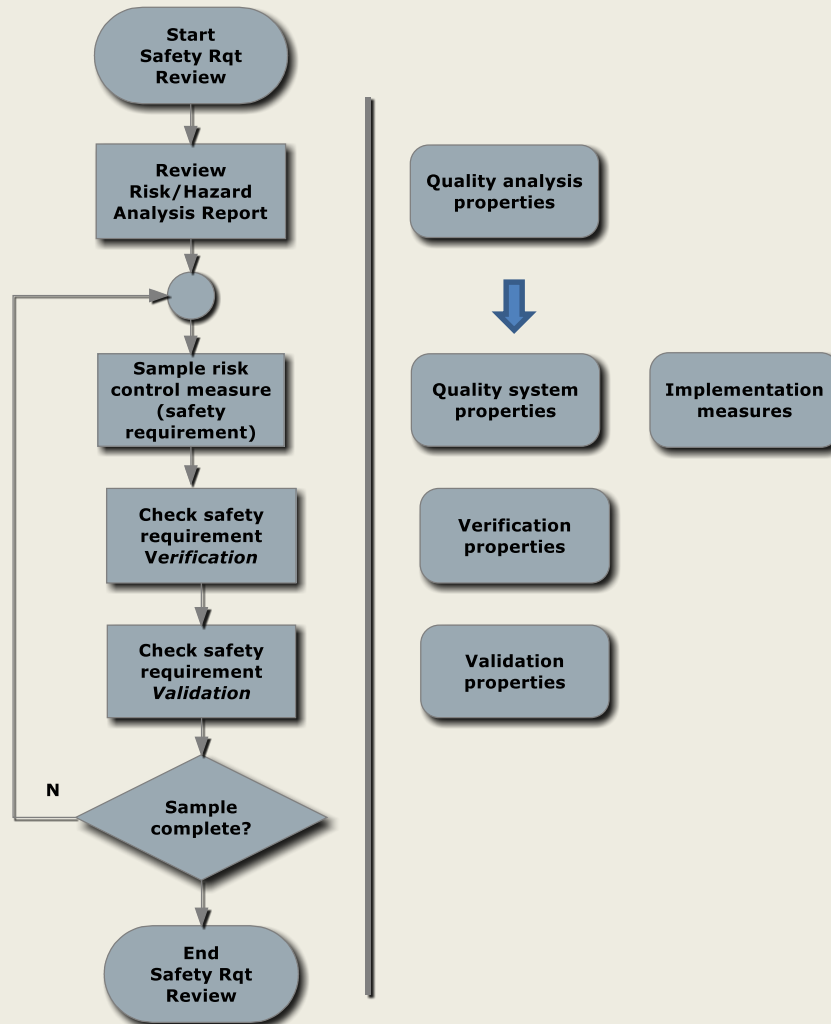


Review Risk/Hazard Analysis Report

Quality Analysis Properties

- Identification of hazardous situations and their causes on which safety reqts are based are reasonable
- Known device issues are addressed
- Analysis uses best practices
- Risk acceptability criteria is established

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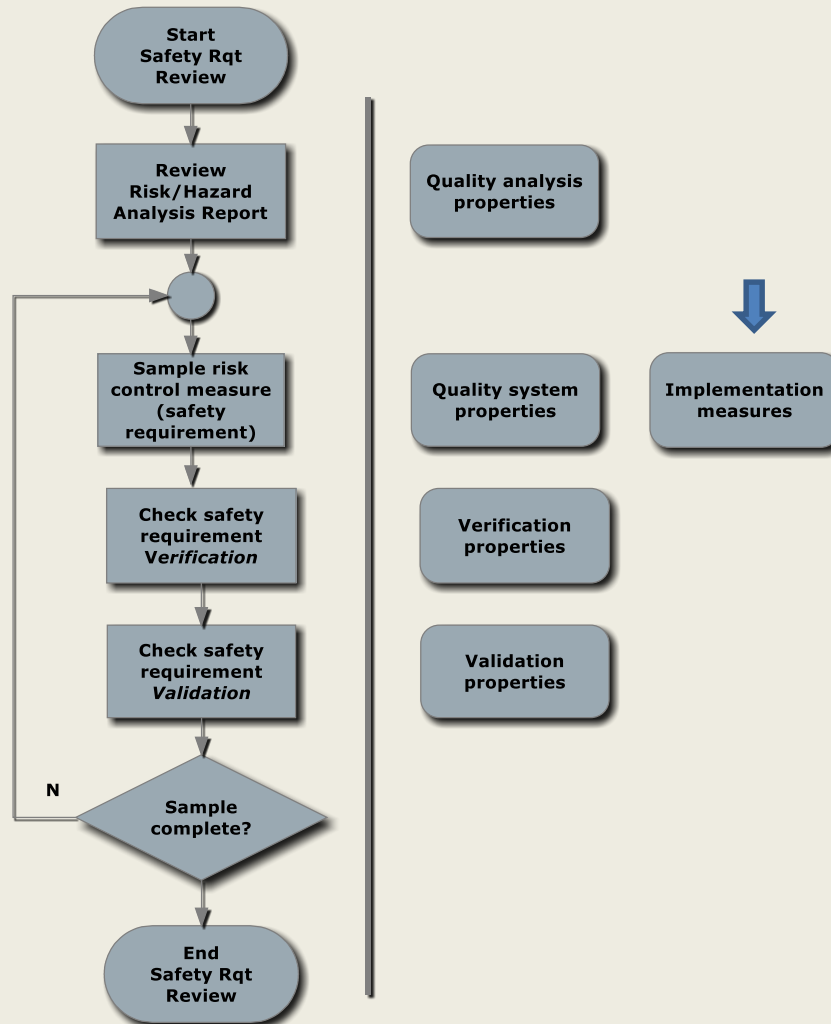


Sample Safety Requirement(s)

Quality System Properties

- Consistent
- Complete (in the context of the identified hazardous situation)
- Unambiguous
- Requirement identifiers suitable for versioning & **traceability**

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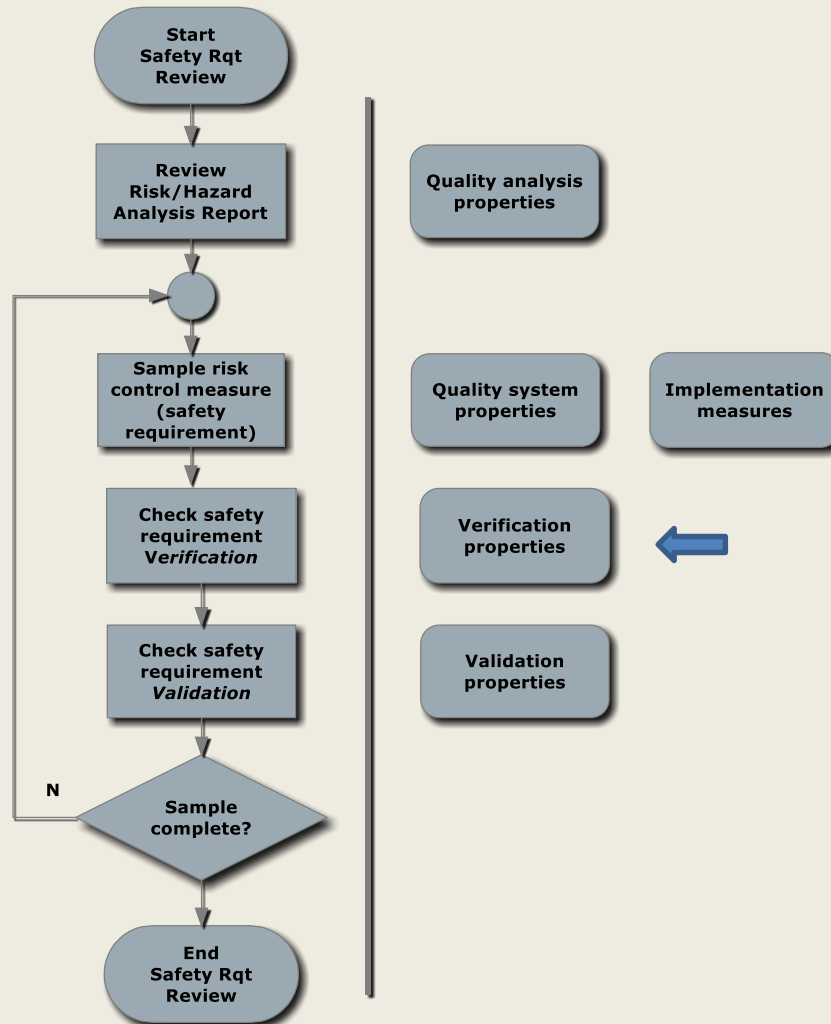


Sample Safety Requirement(s)

Implementation Technology

- Best engineering practices
- Proven in use
- Model driven design
- Formal methods based
- Static analysis

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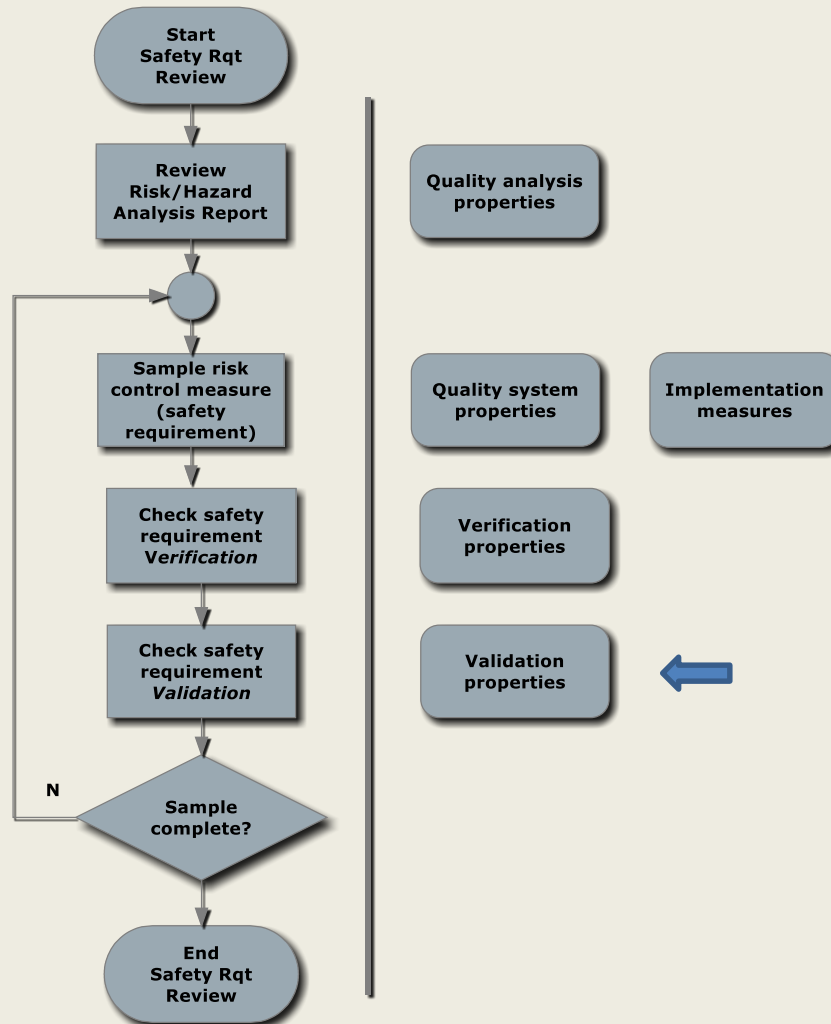


Check Safety Requirement Verification

Verification Properties

- Test cases are reasonable e.g. challenge boundary conditions as well as function, unambiguous
- Results demonstrate that safety requirement is effective
- Test cases and results **trace** to safety requirement

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Check Safety Requirement Validation

Validation Properties

- Test cases are reasonable e.g. challenge boundary conditions as well as function
- Results demonstrate that (implemented) safety requirement is effective in use environment
- Test cases and results **trace** to safety requirement

