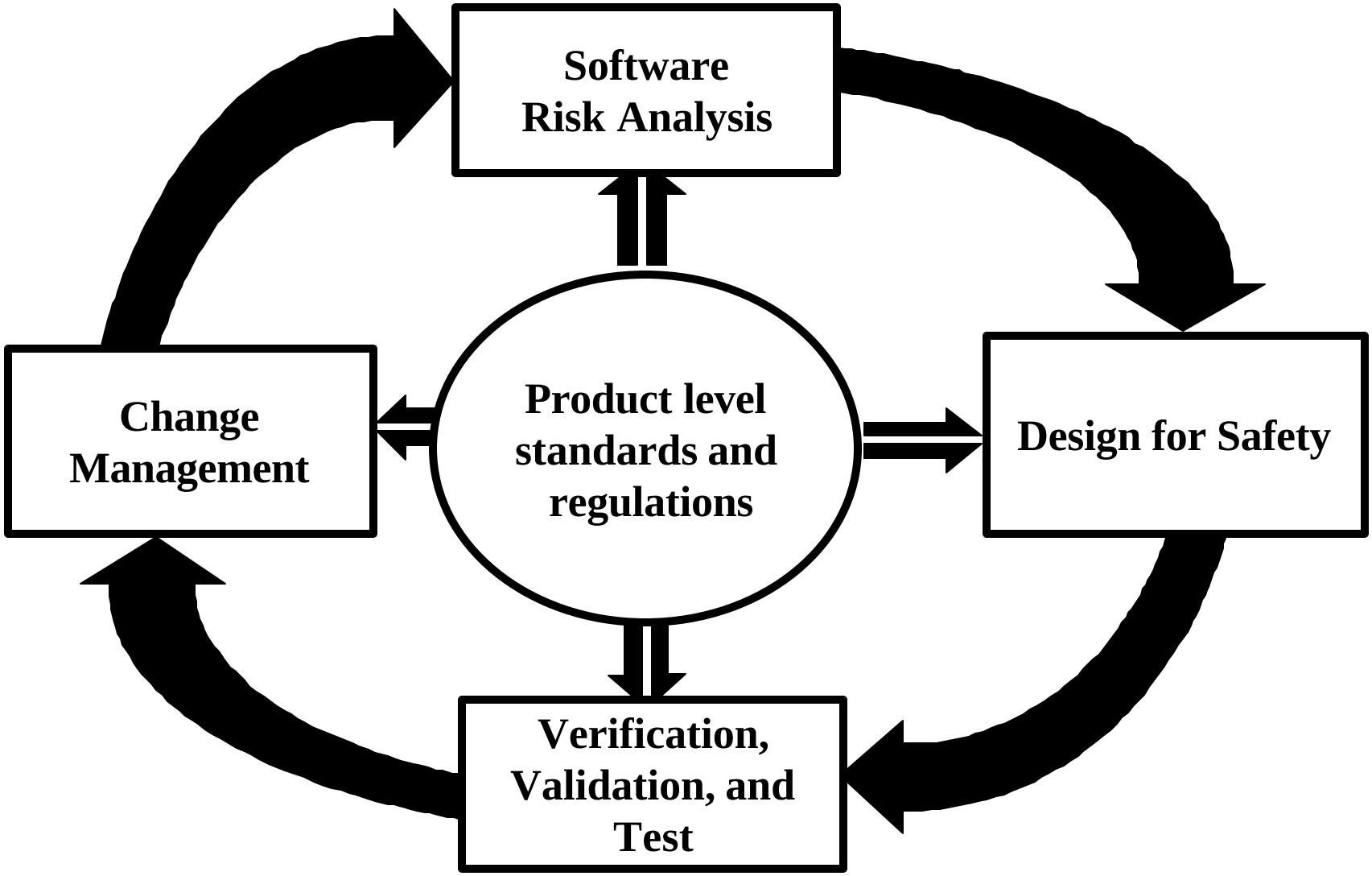
ANSI / UL 1998
Safety of Software in Programmable Components

UL 1998 CORE REQUIREMENTS



Software Risk Analysis

UL 1998, Section 3

- **Risk Identification**
- **Initiating causes**
- **Software risk management**
- **Traceability**

ISO/IEC DIS 14971:

Medical Devices – Application of risk management to medical devices

Process Definition

UL 1998, Section 4

- **Defined inputs and outputs**
- **Integrated risk management**
- **Traceability**
- **Verification**

ISO/IEC 12207: Information technology – Software life cycle processes

Design for Software Safety
UL 1998

- **Software Design**
- **Critical and Supervisory Sections**
- **Measures to Address Microelectronic Failure Modes**
- **Product Interfaces**
- **User Interfaces**

Design for Software Safety
UL 1998

- **Traceable**
- **Verifiable, testable, maintainable**
- **Defined interfaces**
- **Partitioning**
- **Initialization of variables to non-hazardous state**
- **Risk-addressed states and state transitions**

Design for Software Safety
UL 1998

- **Fault-handling**
- **Redundant software**
- **Redundant hardware**
- **Self diagnostic routines**
- **Data integrity**

Verification
UL 1998, Section 11

- **Software Analysis**
- **Software Testing**
- **Failure Modes and Stress Testing**

Software Testing

- **Development & Post-release testing**
- **Test Cases traceable to Risk Analysis**
- **Traceable to the safety requirements**

Failure Mode & Stress Testing

- **Operator errors**
- **Microelectronic Hardware failure**
- **Error in data received from other sources**
- **Negative condition branch**
- **Out-of-range**
- **Boundary condition**
- **Type mismatched values for parameters**

Software Validation

FDA/CDRH's Guidance for Industry: General Principles of Software Validation

"establishing [define, document, implement] by objective evidence that all software requirements have been implemented correctly and completely and are traceable to system requirements."

Documentation

- **Software Safety Plan**
- **Risk Analysis Approach and Results**
- **Configuration Management Plan**
- **Product Summary and User Documents**
- **System Architecture**

Documentation

- **System and Software Requirements Specification**
- **System and Software Design Specification**
- **Verification, Validation and Test Plans**
- **Verification, Validation and Test Results**
- **Software Safety Reference Manual**

Change Management
UL 1998, Section 14

- **Software shall contain a unique identifier.**

- **Changes or patches to a programmable electronic system shall not increase risk.**

- **Each time a change or patch is incorporated in the software, a new identifier shall be assigned.**

Off-The-Shelf (OTS) Software

UL 1998, Section 13

- **Risks addressed**
- **Identification of Version Release number**
- **List of known anomalies**
- **Evidence of verification**
- **Configuration Management plan**

UL 1998
FDA Standards Recognition

- **All medical devices containing software**
- **510(k), IDE, PMA, HDE**

FDA Submissions

Software Documents	MINOR	MODERATE	MAJOR
Software Description	SUBMIT	SUBMIT	SUBMIT
Device Hazard Analysis	SUBMIT	SUBMIT	SUBMIT
SRS	SUBMIT	SUBMIT	SUBMIT
Release Version No.	SUBMIT	SUBMIT	SUBMIT

FDA Submissions
Minor / Moderate LOC

SUBMIT

- **UL 1998 compliance**

DON'T SUBMIT

- **Architectural Design***
- **Design Specification***
- **Traceability**
- **Validation**
- **Development***
- **Revision History***

Global Engineering Documents

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THANK YOU FOR ATTENDING

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