Medical Device Software Validation

ESTIMATING LEVEL OF EFFORT FOR SOFTWARE VALIDATION

The US FDA requires that medical devices of all classes automated with computer software comply with the Design Control regulation (21 CFR 820.30(a)(2)(i)). Validation is an element of design controls. Software validation differs from both software verification and device validation! Software validation is the empirical demonstration that the executable code:

- successfully fulfills the documented device software design inputs (also known as the Software Requirements Specification or SRS)
- successfully mitigates the targeted software risks identified in the software risk management file (often known as the Software Hazard Analysis or SHA).

Software validation requires creation of a software validation protocol, execution of that protocol, and generation of an independent software validation report. The complexity and extent of the software validation protocol depends, in part, upon the FDA's designation of software Level of Concern (LoC). Please refer to the decision flowchart on the backside of this page.

Executing the final software validation protocol requires the current version of the code running on the device or a production prototype of the device. Creating the software validation protocol requires the following documents for all LoC software:

1. Software Description (including language, identification of commercial libraries, identification of applied risk mitigations, and specification of intended operational environment)
2. Device Hazard Analysis (or at least that portion that addresses software risks and mitigation verifications)
3. Software Design Inputs (also known as the SRS)
4. Architectural Design Chart (for minor LoC code, this is just a block diagram)
5. Software Design Outputs (also known as the SDD)
6. Revision Level History & Unresolved Defects List

In addition, for LoC Moderate & Major, the configuration management documentation is required for protocol development.

One of our principals (GMS) is one of a very small number of individuals (in the US and globally) licensed as a professional software engineer. In order to estimate the level of effort to create the final protocol, the aforementioned documents are required. Missing or poorly constructed documents require correction or completion prior to creating the protocol and increase the estimated level of effort. The level of effort required for protocol execution and generation of the final report depends upon the complexity and extent of the required software validation protocol. Poorly designed or improperly executed "validation" studies negate the value of validation, providing the manufacturer with little or no benefit. One important result of a software validation is that the software design or implementation (code) may have to be changed. The following are a few useful references for medical device software development; you should familiarize yourself and your development team with these FDA Guidance documents PRIOR TO BEGINNING your software development efforts:

1. Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
2. Guidance for Industry, FDA Reviewers, and Compliance on Off-the-Shelf Software Use in Medical Devices, September 9, 1999
3. General Principles of Software Validations; Final Guidance for Industry and FDA Staff, January 11, 2002
4. Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 14, 2005
5. Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff, April 3, 2016
6. Guidance for Industry and FDA Staff: RadioFrequency Wireless Technology in Medical Devices, January 3, 2007

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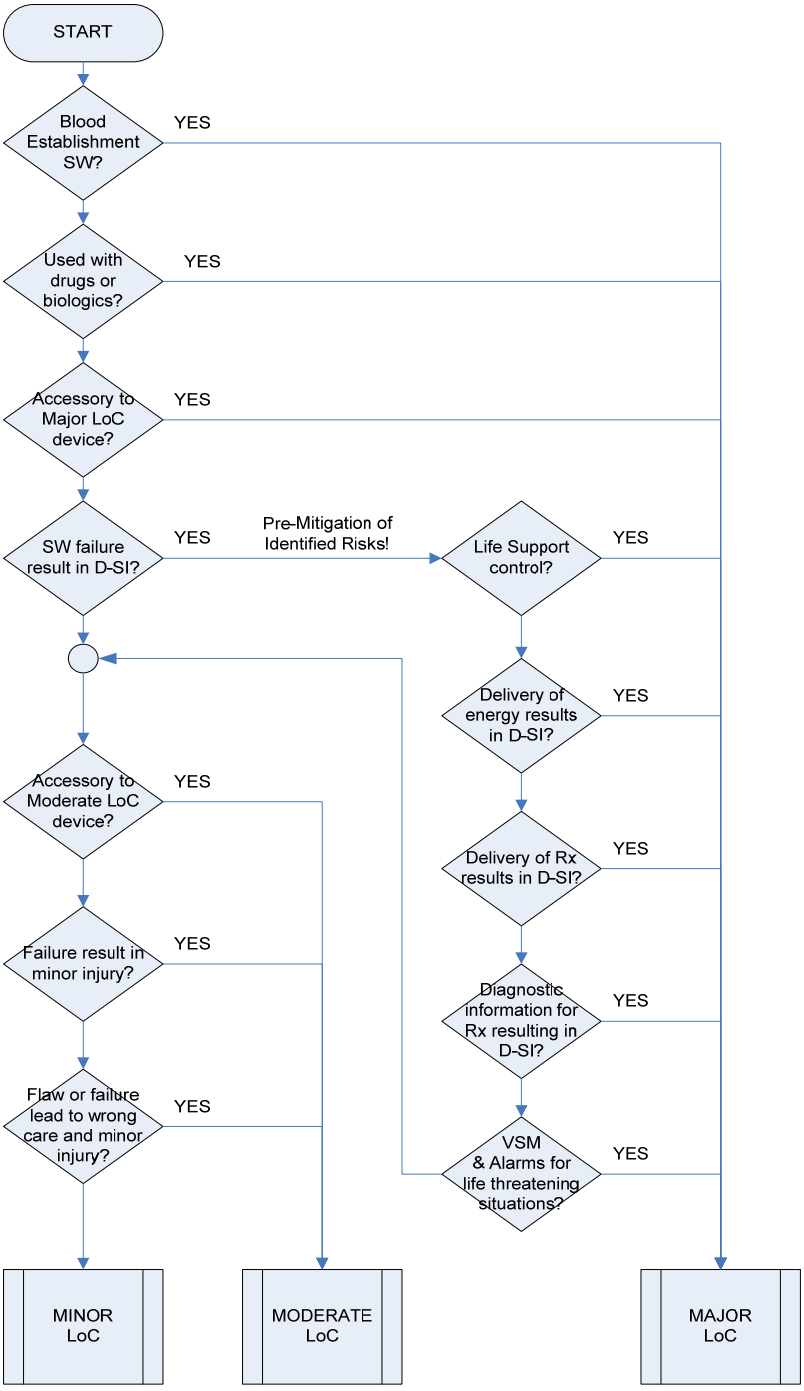
Determining your medical device software's Level of Concern (LoC):

(please refer to reference 1 on backside for further information)



KEY:

SW=software; LoC=Level of Concern; D-SI=death or serious injury; Rx=treatment; VSM=vital signs monitor

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