# Purpose

*Use this form to report on the development of a new Software System. Incremental improvements, bug fixes and enhancements to an existing system should be reported on SSI-QF-10H.*

This report summarizes the software development activities that were performed on the *<Software System>* in accordance with **SSI-SOP-20 Software Development and Verification.** Maintenance activities are reported annually in **SSI-QF-20H Software Maintenance Report**.

# Software and Operational Environment Description

*<Per FDA Moderate Level of Concern, a comprehensive overview of the device features that are controlled by software, and the intended operational environment is required for the FDA submission. The information should be provided in paragraph format, highlighting major or operationally significant software features. The software description should include information on the following:*

* *programming language*
* *hardware platform*
* *operating system (if applicable)*
* *use of Off-the-Shelf software (if applicable).*

*If the device uses Off-the Shelf software, please refer to the FDA guidance document “Guidance for Off-the-Shelf Software Use in Medical Devices.”*

*If this information is included in another document, such as the Software Requirements Specification, the submission should contain an annotation and a reference to the document in the submission where this information is located.*

# Software Risk Assessment/ Device Hazard Analysis

*<Per FDA Guidance, a Device Hazard Analysis for all Software Devices is required. The Device Hazard Analysis should take into account all device hazards associated with the device’s intended use, including both hardware and software hazards. It is recommended that this information is presented in tabular form with a line item for each identified hazard. This document can be in the form of an extract of the software-related items from a comprehensive risk management document, such as the Risk Management Summary described in ISO 14971. In this format, each line item should include:*

*identification of the hazardous event*

*severity of the hazard*

*cause(s) of the hazard*

*method of control (e.g., alarm, hardware design)*

*corrective measures taken, including an explanation of the aspects of the device design/requirements, that eliminate, reduce, or warn of a hazardous event; and*

*verification that the method of control was implemented correctly.*

*When performing a hazard analysis, it is recommended that all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the device are covered.>*

# Software Requirements Specification

*<Provide overview and refer to the Software Requirements Specification and Traceability Matrix document. See also below.>*

# Software Architecture and Architecture Design Chart

*<Provide overview and refer to the Software Architecture Diagram document>*

# Software Design Specification

*<Per FDA Guidance, the Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The Software Requirements Specification (SRS) describes what the Software Device will do and the SDS describes how the requirements in the SRS are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the Software Device was clear and unambiguous, with minimal ad hoc design decisions. The SDS may contain references to other documents, such as detailed software specifications. However, the document you submit should, in and of itself, provide adequate information to allow for review of the implementation plan for the software requirements in terms of intended use, functionality, safety, and effectiveness.*

*Either a separate document for SDS should be produced or the SDS covered in the Software Requirements Specification and Traceability Matrix document>*

# Traceability Analysis

*<Provide overview and refer to the Software Requirements Specification and Traceability Matrix document. See also below.>*

# Software Development Environment Description

*<Per FDA Moderate Level of Concern, the submission should include a summary of the software development life cycle plan. This summary should describe the sponsor’s software development life cycle and the processes that are in place to manage the various life cycle activities.*

*For a Moderate Level of Concern device, is it recommended that a summary of the configuration management and maintenance plans is provided.>*

# Verification and Validation

*<Per FDA Moderate Level of Concern, the submission should include a summary list of validation and verification activities and the results of these activities, including the pass/fail criteria. The Traceability Analysis should effectively link these activities and results to the design requirements and specifications.>*

# Software Revision History

*<Refer to the Software Revision History Document and/or provide a summary below>*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Software Version** | **Software Release Review Meeting Minutes**  **(includes residual anomalies and their acceptability evaluation)**  **(only applicable for software systems)** | **Software Development Plan** | **Software Requirements Specification and Traceability Matrix**  **(only applicable for software systems)** | **Software Periodic Review Report (if applicable)** |
|  |  |  |  |  |

# Unresolved Anomalies (Bugs or Defects)

*<Per FDA Moderate Level of Concern, the submission should include a list of all unresolved software anomalies. For each anomaly, it is recommend that the following is indicated:*

* *Problem*
* *impact on device performance*
* *any plans or timeframes for correcting the problem (where appropriate).*

*It is recommended that each item is annotated with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. Typically, this list can be generated as an output of a change control board or similar mechanism for evaluation and disposition of unresolved software anomalies. It is recommended that this list is communicated to the end user as appropriate to assist in the proper operation of the device. In all instances where it is practical to do so, you should include any mitigations or possible work-arounds for unresolved anomalies.*

*If list of anomalies were captured as part of a formal design review meeting for software release, these should be referenced here>*

# Conclusion

*<Adjust as necessary>*

*Objective evidence is provided that the implemented software requirements specification conforms to the user needs and intended uses identified by the system Design Traceability Matrix via the ProjectName Software Requirements Traceability Matrix. The verification activities provide objective evidence that the requirements implemented through software can be consistently fulfilled.*

*The open software anomalies have been reviewed and documented as being at an acceptable risk.*

*It is concluded that ProjectName Software Version xxx is suitable to be released into production.>*

# Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **Date** |
| **Software Engineer** |  |  |  |
| **Project Lead** |  |  |  |

# Document Change Control

|  |  |  |  |
| --- | --- | --- | --- |
| **Version umber** | **Date** | **Author(s)** | **Brief Description of Change** |
| <<###>> | <<###>> | <<###>> | <<###-###>> |