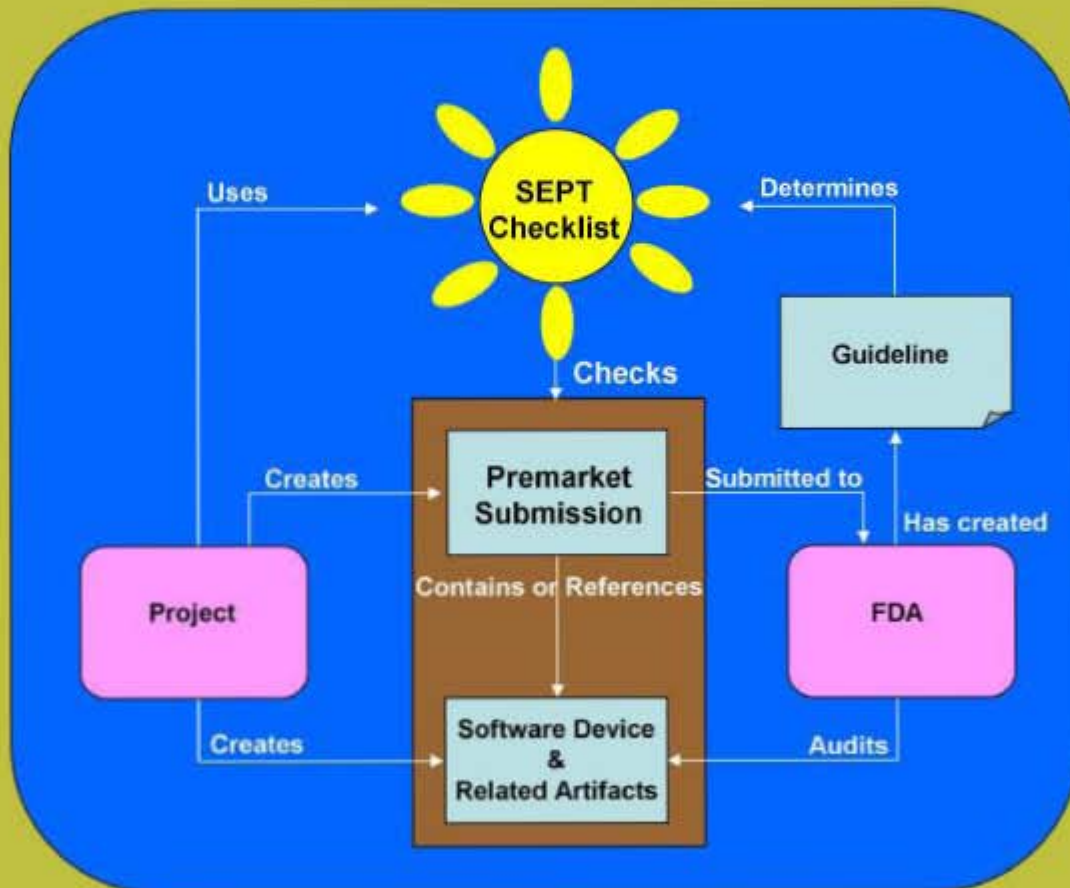




Evidence Product Checklist for Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005

SEPT Product Number 57
Author Stan Magee



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Introduction

The process of defining what is necessary for compliance with a guideline such as “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” is often confusing and laborious because the directions contained in the guidelines are unclear or ambiguous. To aid in determining what is actually “recommended” by the guideline in the way of physical evidence of compliance, the experts at SEPT have produced this checklist. This checklist is constructed around a classification scheme of physical evidence comprised of procedures, plans, records, documents, audits, and reviews. There must be an accompanying record of some type when an audit or review has been accomplished. This record would define the findings of the review or audit and any corrective action to be taken. For the sake of brevity this checklist does not call out a separate record for each review or audit. All procedures should be reviewed but the checklist does not call out a review for each procedure, unless the guideline calls out the procedure review. In this checklist “manuals, reports, scripts and specifications” are included in the document category.

The author has carefully reviewed the guideline “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and defined the physical evidence recommended based upon this classification scheme. SEPT has conducted a second review of the complete list to ensure that the guideline’s producers did not leave out a physical piece of evidence that a “reasonable person” would expect to find. It could certainly be argued that if the guideline did not call it out then it is not recommended; however, if the document was used by an organization to improve its process, then it would make sense to recognize missing documents. Therefore, there are documents specified in this checklist that are implied by the guideline, though not specifically called out in the guideline, and they are designated by an asterisk (*) throughout this checklist. These items are classified as suggested. If a document is called out more than one time, only the first reference is stipulated. If there are no new requirements or suggestions in a particular clause or sub-clause then the clause or sub-clause is omitted throughout sections 2-7.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the “Data Base Requirements Document” could be a part of the Software Requirements Document”. The author has called out these individual items separately to ensure that the organization does not overlook any facet of physical evidence. If the organization does not require a separate document, and an item can be a subset of another document or record, then this fact should be denoted in the detail section of the checklist for that item. This should be done in the form of a statement reflecting that the information for this document may be found in section XX of Document XYZ. If the organizational requirements do not call for this physical evidence for a particular project, this should also be denoted with a

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statement reflecting that this physical evidence is not recommended and why. The reasons for the evidence not being recommended should be clearly presented in this statement. Further details on this step are provided in the Detail Steps section of the introduction. The size of these documents could vary from paragraphs to volumes depending upon the size and complexity of the project or business requirements.

General Principles

General Principles of the checklist for “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

This checklist was prepared by analyzing each clause of this guideline for the key words that signify a:

- Procedure
- Plan
- Records
- Document (Including Lists, Manuals, Reports, Scripts and Specifications)
- Audit
- Review

This checklist specifies evidence that is unique. After reviewing the completed guideline, the second review was conducted from a common sense “reasonable man” approach. If a document or other piece of evidence appeared to be recommended, but was not called out in the guideline, then it is added with an asterisk (*) after its notation in the checklist. The information was transferred into checklist tables, based on the type of product or evidence.

Using the Checklist

When a company is planning to use “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, the company should review the evidence checklist. If the company’s present process does not address an “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” product, then this question should be asked: Is the evidence product recommended for the type of business of the company? If in the view of the company the evidence is not recommended, the rationale should be documented and inserted in the checklist and quality manual. This rationale should pass “*the reasonable person rule.*” If the evidence is recommended, plans should be prepared to address the missing item(s).

Detail Steps

An organization should compare the proposed output of their organization against the checklist. In doing this, they will find one of five conditions that exist for each item listed in the checklist. The following five conditions and the actions required by these conditions are listed in the table below.

Condition	Action Required
1. The title of the documented evidence specified by the checklist (document, plan, etc) <i>agrees</i> with the title of the evidence being planned by the organization.	Record in checklist that the organization is compliant.
2. The title of the documented evidence specified by the checklist (document, etc) <i>disagrees</i> with the title of the evidence planned by the organization but the content is the same.	Record in the checklist the evidence title the organization uses and record that the organization is compliant, and the evidence is the same although the title is different.
3. The title of the documented evidence specified by the checklist (document, etc) is <i>combined</i> with another piece of evidence.	Record in the checklist the title of the evidence (document, etc) in which this information is contained.
4. The title of the documented evidence specified by the checklist (document, etc) <i>is not planned</i> by the organization because it is not required.	Record in the checklist that the evidence is not required and the rationale for this decision.
5. The title of the documented evidence called out by the checklist (document, etc) <i>is not planned</i> by the organization and <i>should be</i> planned by it.	Record in the checklist when this evidence will be planned and reference a plan for accomplishing the task.

Components of the Checklist

This checklist is composed of 7 sections:

- Section 1. Introduction
- Section 2. Composites of all recommended and suggested “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.
- Sections 3-7. Individual checklists for each evidence type.

Product Support

All reasonable questions concerning this checklist or its use will be addressed free of charge for 60 days from time of purchase, up to a maximum of 4 hours consultation time.

Warranties and Liability

Software Engineering Process Technology (SEPT) makes no warranties implied or stated with respect to this checklist, and it is provided on an “as is” basis. SEPT will have no liability for any indirect, incidental, special or consequential damages or any loss of revenue or profits arising under, or with respect to the use of this checklist.

About the Author - Stan Magee

Stan Magee is president of Software Engineering Process Technology Company, a firm specializing in the implementation of software process technology for U.S. and international corporations and organizations.

Mr. Magee is past convener (1999-2002) of WG 7 (Life Cycle Management) for ISO/IEC JTC1 SC 7 (Systems and Software Engineering) standards group. During his tenure the standard ISO/IEC Standard 15288-System Engineering-System Life Cycle Processes, was developed. He was a U.S. delegate to the International Plenary meetings from 1986 - 2002. In 1995 he was elected to the IEEE Computer Society Golden Core of 500 people who have significantly served the IEEE Society in standards development over its 50 year history.

Mr. Magee is co-author of the books, *Guide to Software Engineering Standards and Specifications*, Artech House Publishers, 1997, ISBN 0-89006-919-0 and *Guide to Standards and Specifications for Designing Web Software*, 1998, Artech House Publishers ISBN 0-89006-819-4. He has authored many technical reports relating to software engineering standards issues. In 1997 Mr. Magee was part of a “People to People” quality mission to China and lectured at Shanghai University on software quality standards. He gives seminars on meeting the requirements of ISO 9001/9003 for medical device firms. In 1994 he established a software business and quality system plan, for VNIPI Sport of Moscow, Russia for obtaining ISO 9001 certification. VNIPI is the privatized MIS section of the Russian Olympic Committee. In 2002, Mr. Magee established a plan for the Thailand Government to be in the upper quartile producers of software in the world market place by 2010. Mr. Magee has over 42 years experience in the software field and is considered an expert in the area of software life cycle methodology.

He has served on many governmental, educational and professional boards, and holds BS from the School of Engineering from Oregon State University and an MBA in International Business from the University of Puget Sound.

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph

FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 9 Table 3					
Page 9 Table 3 Row 1-Level of Concern Level of concern A, B, and C	Level of Concern Document Procedure*			Level of Concern Document	Level of Concern Document Review*
Page 9 Table 3 Row 2-Software Description Level of concern A, B, and C	Software Description Document Procedure*			Software Description Document	Software Description Document Review*
Page 9 Table 3 Row 3-Device Hazard Analysis Level of concern A, B, and C	Device Hazard Analysis Document Procedure*			Device Hazard Analysis Document	Device Hazard Analysis Document Review*
Page 9 Table 3 Row 4-1-Software Requirements Specification (SRS) Level of concern A	Summary of Functional Requirements Specification (SRS) Document Procedure* (Summary of functional requirements only)			Summary of Functional Requirements Specification (SRS) Document (Summary of functional requirements only)	Summary of Functional Requirements Specification (SRS) Document Review * (Summary of functional requirements only)

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 9 Table 3 Row 4-2- Software Requirements Specification (SRS) Level of concern B and C	- Software Requirements Specification (SRS) Document Procedure* (Complete document)			Software Requirements Specification (SRS) Document (Complete document)	Software Requirements Specification (SRS) Document Review* (Complete document)
Page 9 Table 3 Row 5- Architecture Design Chart Level of concern B, and C	Architecture Design Chart Document Procedure*			Architecture Design Chart Document	Architecture Design Chart Document Review*
Page 9 Table 3 Row 6- Software Design Specification (SDS) Level of concern B, and C	Software Design Specification (SDS) Document Procedure*			Software Design Specification (SDS) Document	Software Design Specification (SDS) Document Review*
Page 9 Table 3 Row 7- Traceability Analysis Level of concern A, B, and C	Traceability Analysis Document Procedure*			Traceability Analysis Document	Traceability Analysis Document Review*

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 9 Table 3 Row 8-2-Software Development Environment Description Level of concern B	Software Development Environment Description Document Procedure* (Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities)			Software Development Environment Description Document (Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities)	Software Development Environment Description Document Review * (Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities)

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Page 9 Table 3 Row 8-3-Software Development Environment Description Level of concern C	Software Development Environment Description Document Procedure* (Summary of software life cycle development plan, Annotated list of control documents generated during development process. Include the configuration management and maintenance plan.)			Software Development Environment Description Document (Summary of software life cycle development plan, Annotated list of control documents generated during development process. Include the configuration management and maintenance plan.)	Software Development Environment Description Document Review* (Summary of software life cycle development plan, Annotated list of control documents generated during development process. Include the configuration management and maintenance plan.)

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Page 10 Table 3 Row 9-1-Verification and Validation Documentation Level of concern A	Verification and Validation Document Procedure * (Software functional test plan, pass/fail criteria, and results.)			Verification and Validation Documentation (Software functional test plan, pass/fail criteria, and results.)	Verification and Validation Document Review* (Software functional test plan, pass/fail criteria, and results.)
Page 10 Table 3 Row 9-2-Verification and Validation Documentation Level of concern B	Verification and Validation Document Procedure * (Description of V&V activities at the unit, integration and system level. System level test protocol including pass/fail criteria and test results.)			Verification and Validation Document (Description of V&V activities at the unit, integration and system level. System level test protocol including pass/fail criteria and test results.)	Verification and Validation Document Review* (Description of V&V activities at the unit, integration and system level. System level test protocol including pass/fail criteria and test results.)

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Page 10 Table 3 Row 9-3-Verification and Validation Documentation Level of concern C	Verification and Validation Document Procedure* (Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.)			Verification and Validation Document (Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.)	Verification and Validation Document Review* (Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.)
Page 10 Table 3 Row 10 Revision Level History Level of concern A, B and C	Revision Level History Document Procedure*			Revision Level History Document	Revision Level History Document Review*

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Checklist by Page and Paragraph

FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 10 Table 3 Row 11- Unresolved Anomalies (Bug or Defects) Level of concern B and C	Unresolved Anomalies (Bugs or Defects) Document Procedure*			Unresolved Anomalies (Bugs or Defects) Document	Unresolved Anomalies (Bugs or Defects) Document Review*
Page 10 Level of Concern Level of concern A, B, and C	Rationale for the Decision On the Level Of Concern Document Procedure*			Rationale for the Decision On the Level Of Concern Document	Rationale for the Decision On the Level Of Concern Document Review*
Page 10 Software Description Level of concern A, B, and C	Off-the Shelf Software Document Procedure*			Off-the Shelf Software Document	Off-the Shelf Software Document Review*

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 11 Device Hazard Analysis Level of concern A, B, and C	ISO 14971 Requirements for Procedures*	ISO 14971 Requirements for Plans*	- Hazard Analysis Report that Address All Foreseeable Hazards Including Those Resulting From Inadvertent Misuse of the Device Record - ISO 14971 Requirements for Records*	ISO 14971 Requirements for Documents*	ISO 14971 Requirements for Audits - ISO 14971 Requirements for Reviews*
Page 11 Software Requirements Specification (SRS)					
Page 12 (SRS) Hardware Requirements Level of concern B and C	Detail Description of the Hardware Requirements Document Procedure*			Detail Description of the Hardware Requirements Document	Detail Description of the Hardware Requirements Document Review*

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 12 (SRS) Programming Language Requirements Level of concern B and C	Detail Description of the Programming Language Requirements Document Procedure*			Detail Description of the Programming Language Requirements Document	Detail Description of the Programming Language Requirements Document Review*
Page 12 (SRS) Interface Requirements Level of concern B and C	Detail Description of the Interface Requirements Document Procedure*			Detail Description of the Interface Requirements Document	Detail Description of the Interface Requirements Document Review*
Page 12 (SRS) Software Performance and Functional Requirements Level of concern B and C	Detail Software Performance and Functional Requirements Document Procedure*			Detail Software Performance and Functional Requirements Document	Detail Software Performance and Functional Requirements Document Review*
Page 13 Architecture Design Chart Level of concern B and C	State Diagram Document Procedure*			State Diagram Document	State Diagram Document Review*

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Page 13 Software Design Specification Level of concern B and C	Software Design Specification References to Detail Software Specifications Document Procedure*			Software Design Specification References to Detail Software Specifications Document	Software Design Specification References to Detail Software Specifications Document Review*
Page 13 Traceability Analysis Level of concern A, B, and C	Matrix of Traceability Within the Life Cycle Document Procedure*			Matrix of Traceability Within the Life Cycle Document	Matrix of Traceability Within the Life Cycle Document Review*

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 14 Environment Description Level of concern C	- List or Description of Software Coding Standards Document Procedure* - Software Life Cycle Control/ Baseline Documents Procedure*			- List or Description of Software Coding Standards Document - Software Life Cycle Control/ Baseline Documents	- List or Description of Software Coding Standards Document Review* - Software Life Cycle Control/ Baseline Documents Review*
Page 14 Verification and Validation Documentation					
Page 14 Verification and Minor level of Concern Devices					
Page 14 Moderate Level of Concern Devices					

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Page 15 Major Level of Concern Devices Level of concern C	- Software Modification Because of Failed Test Documents Procedure* - Software Modification Test Results Documents Procedure*			- Software Modification Because of Failed Test Documents - Software Modification Test Results Documents	- Software Modification Because of Failed Test Documents Review* - Software Modification Test Results Documents Review*

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Page 15 Revision Level History Level of concern A, B, and C	- Assessment of the Potential Effect of the Difference between the Tested Version and the Release Version on the Safety and Effectiveness of the Software Document Procedure* - Differences Between Tested Version of the Software and Released Version Document Procedure*			- Assessment of the Potential Effect of the Difference between the Tested Version and the Release Version on the Safety and Effectiveness of the Software Document - Differences Between Tested Version of the Software and Released Version Document	- Assessment of the Potential Effect of the Difference between the Tested Version and the Release Version on the Safety and Effectiveness of the Software Document Review* - Differences Between Tested Version of the Software and Released Version Document Review*

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Page 15 Unresolved Anomalies (Bugs or Defects) Level of concern B and C	- Impact of Any Unresolved Anomaly on Device Safety or Effectiveness Document Procedure* - Mitigation or Workaround for Unresolved Anomalies Document Procedure*			- Impact of Any Unresolved Anomaly on Device Safety or Effectiveness Document - Mitigation or Workaround for Unresolved Anomalies Document	- Impact of Any Unresolved Anomaly on Device Safety or Effectiveness Document Review* - Mitigation or Workaround for Unresolved Anomalies Document Review*
Page 15 The Special 510(k) Program Level of concern A,B, and C (If Applicable)	Special 510(k)Program Device Regression Testing Results to Verify and Validate the Software Modification Document Procedure*			Special 510(k)Program Device Regression Testing Results to Verify and Validate the Software Modification Document	Special 510(k)Program Device Regression Testing Results to Verify and Validate the Software Modification Document Review*

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Page 16 The Abbreviated 510(k) Program Level of concern A,B, and C (If Applicable)	• Declaration of Conformance, Test Results, and Pass /Fail Criteria Document Procedure* • Deviation From the Tests and Test Methods as Specified in the Standard Document Procedure* • Deviations Impact on Safety and Effectiveness of the Software Device Document Procedure*		• Abbreviate 510 (k) Program Statement that Testing Will be Conducted and Meet Specified Acceptance Criteria Record • Declaration of Conformance to the Standard as Defined in Page 19 Note IX Record	• Declaration of Conformance, Test Results, and Pass /Fail Criteria Document • Deviation From the Tests and Test Methods as Specified in the Standard Document • Deviations Impact on Safety and Effectiveness of the Software Device Document	• Declaration of Conformance, Test Results, and Pass /Fail Criteria Document Review* • Deviation From the Tests and Test Methods as Specified in the Standard Document Review* • Deviations Impact on Safety and Effectiveness of the Software Device Document Review*

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Page 17 Additional Topic Risk Assessment and Management					
Page 17 Background Level of concern A,B, and C					Risks Associated with Potential Failures or Design Flaws Software Device Review
Page 17 Risk Assessment and Level Of Concern Level of concern A,B, and C	Rational Why The Device Has a Different Level of Concern Than Other Like Devices Document Procedure*			Rational Why The Device Has a Different Level of Concern Than Other Like Devices Document	Rational Why The Device Has a Different Level of Concern Than Other Like Devices Document Review*

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FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Checklist by Page and Paragraph	Procedures	Plans	Records	Documents	Audits & Reviews
Page 17 Risk Management	Estimate of Risk on Severity of the Hazard Resulting From Failure of the Software Device Document Procedure*			Estimate of Risk on Severity of the Hazard Resulting From Failure of the Software Device Document	Estimate of Risk on Severity of the Hazard Resulting From Failure of the Software Device Document Review*
Page 17 Software Change Management					

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Page 18 Blood Establishment Computer Software Level of concern A,B, and C	- Blood Establishment Computer Software User Manual Document Procedure* - Outstanding Anomalies or Software Defects with Corresponding Workarounds for Blood Establishment Computer Software Document Procedure*			- Blood Establishment Computer Software User Manual Document - Outstanding Anomalies or Software Defects with Corresponding Workarounds for Blood Establishment Computer Software Document	- Blood Establishment Computer Software User Manual Document Review* - Outstanding Anomalies or Software Defects with Corresponding Workarounds for Blood Establishment Computer Software Document Review*

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Page 18 Software of Unknown Pedigree (SOUP) Level of concern A, B, and C	- Documentation on the Origination of the SOUP Software Document Procedure* - Risk Associated With the Missing or Incomplete Documentation of Prior Testing for “SOUP” Software Document Procedure*			- Documentation on the Origination of the SOUP Software Document - Risk Associated With the Missing or Incomplete Documentation of Prior Testing for “SOUP” Software Document	- Documentation on the Origination of the SOUP Software Document Review* - Risk Associated With the Missing or Incomplete Documentation of Prior Testing for “SOUP” Software Document Review*
Page 18 Virus Protection Software Level of concern A,B, and C	Virus Protection Software Document Procedure*			Virus Protection Software Document	Virus Protection Software Document Review*

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Page 18 Interface, Networking, and Network Infrastructure Level of concern A,B, and C	Capabilities and Liabilities on the Design and Hazard Analysis Affecting the Medical Device Due to Interfaces, Networking and Network Infrastructure Document Procedure*			Capabilities and Liabilities on the Design and Hazard Analysis Affecting the Medical Device Due to Interfaces, Networking and Network Infrastructure Document	Capabilities and Liabilities on the Design and Hazard Analysis Affecting the Medical Device Due to Interfaces, Networking and Network Infrastructure Document Review*
Page 19 Combination Products					

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