EVIDENCE PRODUCT CHECKLIST

For the FDA Document
"Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices"
September 9, 1999
As Amended by *"Guidance for Industry, FDA Reviewers and Compliance on Cybersecurity for Networked Medical Devices Containing Off-the Shelf (OTS) Software*
January 14, 2005

Author Stan Magee, CCP

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SEPT Product 34

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Produced by Software Engineering Process Technology (SEPT)
2725 NW Pine Cone Drive
Issaquah, WA. 98027
Tel. 425-391-2344
E-mail: Stanmagee@smartwire.net

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Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices

EVIDENCE PRODUCT CHECKLIST

Introduction

The process of defining what is necessary for compliance with a software engineering process guidance document such as “Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices” is sometimes confusing and laborious because the directions contained in the document may be unclear or ambiguous. To aid in determining what is actually “required” by the document 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 policies, 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 document calls out the procedure review. In this checklist “manuals, reports, scripts and specifications” are included in the document category. When the subject document references another document for physical evidence, the checklist does call out the requirements of the referenced document, such as “Compliance on Cybersecurity for Networked Medical Devices Containing Off-the Shelf (OTS) Software”.

The Author has carefully reviewed the document “Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices” and defined the physical evidence required based upon this classification scheme. SEPT has conducted a second review of the complete list to ensure that the documents’ 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 document did not call it out then it is not required; 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 document, though not specifically called out in the document, and they are designated by an asterisk (*) throughout this checklist. 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.

- There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the “OTS Testing Plan “could be a part of the "OTS Verification and Validation Plan ". 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 statement reflecting that this physical evidence is not required and why. The reasons for the evidence not being required 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.

"Off-the-Shelf Software (OTS) Use in Medical Devices" Checklist

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

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

This checklist specifies evidence that is unique. After reviewing the completed document, the second review was conducted from a common sense "reasonable man" approach. If a document or other piece of evidence appeared to be required, but was not called out in the document, 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. Required items are denoted by an underline to aid use of the checklist.

Using the Checklist

When a company is planning to use " Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices" document, the company should review the evidence checklist. If the company's present process does not address "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices" product, then this question should be asked: Is the evidence product required for the type of business of the company? If in the view of the company the evidence is not required, 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 required, 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) *agrees* 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) *disagrees* 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 *combined* 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) *is not planned* 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 checklis*t* (document, etc*) is not planned* by the organization and *should be* 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 8 sections:

- Section 1. Introduction
- Section 2. Composites of all required and suggested "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices" evidence products.
- Sections 3-7. Individual checklists for each evidence type.
- Section 8. "About the Author"

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 document.

Section 2
Product Checklist for "Guidance For Industry, FDA Reviewers and Compliance On Off-the-Shelf Software Use in Medical Devices," Checklist by Clause

FDA Off-the-Shelf (OTS) Document Clause Number and Name	**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
2.0 OTS SOFTWARE USE					
2.1 Basic Documentation for OTS Software	• Evaluating and Using OTS in a Medical Device Procedure* • OTS Basic Requirements Document Procedure* • OTS Configuration Management Plan Procedure* • OTS Customer Support Plan Procedure* • OTS Installation Plan Procedure* • OTS Interface Document Procedure*	• OTS Configuration Management Plan • OTS Customer Support Plan • OTS Installation Plan • OTS Maintenance Plan • OTS Storage Plan • OTS Testing Plan • OTS Verification and Validation Plan	• OTS Current "Bug" List Records • OTS Patches List Records • OTS Test Records • OTS Verification and Validation Records	• OTS Basic Requirements Document • OTS Interface Document • OTS Test Scripts* • OTS User Manual	• Completion of Each Life Cycle Phase OTS Review* • OTS Basic Requirements Document Review * • OTS Configuration Management Plan Review * • OTS Customer Support Plan Review * • OTS Installation Plan Review* • OTS Interface Document Review * • OTS Maintenance Plan Review *

*Recommended Item

Section 2
Product Checklist for "Guidance For Industry, FDA Reviewers and Compliance On Off-the-Shelf Software Use in Medical Devices," Checklist by Clause

FDA Off-the-Shelf (OTS) Document Clause Number and Name	**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
2.1 Basic Documentation for OTS Software (Cont.)	• OTS Maintenance Plan Procedure* • **OTS Policy*** • OTS Storage Plan Procedure* • OTS Test Scripts Procedure* • OTS Testing Plan Procedure* • OTS User Manual Procedure* • OTS Verification and Validation Plan Procedure*				• OTS Storage Plan Review * • OTS Test Scripts Review* • OTS Testing Plan Review * • OTS User Manual Review * • OTS Verification and Validation Plan Review *

*Recommended Item

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Product Checklist for "Guidance For Industry, FDA Reviewers and Compliance On Off-the-Shelf Software Use in Medical Devices," Checklist by Clause

FDA Off-the-Shelf (OTS) Document Clause Number and Name	**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
2.2 OTS Software Hazard Analysis	• OTS Hazards Analysis Document Procedure* • OTS Hazards List, Severity, and Cause List Document Procedure*			• OTS Hazards Analysis Document • OTS Hazards List, Severity, and Cause List Document	• OTS Hazards Analysis Document Review* • OTS Hazards List, Severity, and Cause List Document Review*
2.3 OTS Software Hazards Mitigation	• OTS Hazards Mitigation Plan Procedure*	• OTS Hazards Mitigation Plan	• Residual Hazards List Records		• OTS Hazards Mitigation Plan Review* • Residual Hazards List Records Review*
2.4 Describe and Justify Residual Risk	• Remaining Hazards (In depth) Report Document Procedure*			• Remaining Hazards (In depth) Report Document	Remaining Hazards (In depth) Report Document Review*

*Recommended Item