

# checklist

## Evidence Product Checklist

For IEC Standard 60601-1-4

Edition 1.1 2000-04

*IEC 60601-1-4: Medical Electrical Equipment  
Part 1: General Requirements for Safety.  
Part 4, Programmable Electrical Medical Systems*

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**SEPT Product Number 15**

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# **EVIDENCE PRODUCT CHECKLIST**

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### ***IEC 60601-1-4: Medical Electrical Equipment Part 1: General Requirements for Safety. Part 4, Programmable Electrical Medical Systems***

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# IEC 60601-1-4 EVIDENCE CHECKLIST

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## Introduction

The process of defining what is necessary for compliance with a software engineering process standard such as IEC 60601-1-4 “*Medical Electrical Equipment Part 1: General Requirements for Safety. Part 4. Programmable Electrical Medical Systems*” is sometimes confusing and laborious because the directions contained in the standard may be unclear or ambiguous. To aid in determining what is actually “required” by the standard 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. SEPT has carefully reviewed IEC 60601-1-4 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 standard’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 document did not call it out then it is not required; however if the standard were used by an enterprise to improve its software process, then it would make sense to recognize missing documents. Therefore, there are documents specified in this checklist that are implied by the standard, though not specifically called out in the standard, 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.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the Software Detail Specification Document could be a subset of Software Design Specification. SEPT 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 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 software project or business requirements.

Even though IEC 60601-1-4 does not reference ISO/IEC Standard 12207—“*Software Life Cycle Processes*”, the summary requirements of this document are called out in the checklist. This important software engineering standard should be employed if an enterprise wants to gain the full benefits of applying IEC 60601-1-4 to producing medical

electrical equipment containing software. The user of this checklist should also be aware of the definitions of risk management called out in ISO Guide73—“*Risk Management–Vocabulary--Guidelines for Use in Standards*” when applying IEC 60601-1-4.

**IEC 60601-1-4 Checklist**

This checklist was prepared by analyzing each clause of IEC 60601-1-4 for the key words that signify a:

- Procedure
- Plan
- Records
- Document
- Review
- Audit

This checklist specifies evidence that is software 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.

**Using the Checklist**

When a company is planning to use IEC 60601-1-4 as their software development standard for a project the company should review the IEC 60601-1-4 evidence checklist. If the company’s present process does not address an IEC 60601-1-4 evidence product, then this question should be asked: “Is the evidence product required for the type of software the business is producing?” If in the view of the company, the evidence is not required, the rationale should be documented and inserted in the quality manual. This rationale should pass “*the reasonable person rule.*” If the evidence is required, plans should be prepared to address the missing items.

**Detail Steps**

An enterprise should compare the proposed output of their software project or 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.

<b>Condition</b>	<b>Action Required</b>
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 enterprise.	Record in checklist that the enterprise is compliant.

<b>Condition</b>	<b>Action Required</b>
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 enterprise but the content is the <i>same</i> .	Record in the checklist the evidence title the enterprise uses and record that the enterprise 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) where this information is contained.
4. The title of the documented evidence specified by the checklist (document, etc) is <i>not</i> planned by the enterprise because it is <i>not</i> 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) is <i>not</i> planned by the enterprise 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 9 sections:

- Section 1. Introduction
- Section 2. Composite of all recommended IEC 60601-1-4 evidence products.
- Section 3-8. Individual checklists for each evidence type.
- Section 9. 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.

### **Author's Qualifications**

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 convener of WG 7 (Life Cycle Management) for ISO/IEC JTC1 SC 7 (Software and Systems Engineering) standards group. He has been a U.S. delegate to the International Plenary meetings since 1986. 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 Specification Documents*, Artech House Publishers, 1997, ISBN 0-89006-919-0 and *Guide to Standards and Specification Documents for Designing Web Software*, Artech House Publishers, 1998, ISBN 0-89006-819-4. 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 international software standards for medical device firms. Mr. Magee has over 35 years experience in the software field and is considered an expert in the area of software life cycle methodology. He is active 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.

### **WARRANTIES AND LIABILITY**

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**Section 2**  
**60601-1-4 EVIDENCE PRODUCTS CHECKLIST BY CLAUSE**

<b>IEC 60601-1-4 CLAUSE NUMBER and NAME</b>	<b>PROCEDURES</b>	<b>PLANS</b>	<b>RECORDS</b>	<b>DOCUMENTS</b>	<b>AUDITS and REVIEWS</b>
<b>1.203 Relationship to Other Standards</b>					
1.203.3	<ul style="list-style-type: none"> <li>• ISO 9000-3-1997 Requirements for Procedures</li> <li>• ISO/IEC 12207 Requirements for Procedures*</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 9000-3-1997 Requirements for Plans</li> <li>• ISO/IEC 12207 Requirements for Plans*</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 9000-3-1997 Requirements for Records</li> <li>• ISO/IEC 12207 Requirements for Records*</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 9000-3-1997 Requirements for Documents</li> <li>• ISO/IEC 12207 Requirements for Documents*</li> </ul>	<ul style="list-style-type: none"> <li>• <b>ISO 9000-3-1997 Requirements for Audits</b></li> <li>• ISO 9000-3-1997 Requirements for Reviews</li> <li>• <b>ISO/IEC 12207 Requirements for Audits*</b></li> <li>• ISO/IEC 12207 Requirements for Reviews*</li> </ul>
<b>6.0 Identification, Marking and Documents</b>					
6.8.201	<ul style="list-style-type: none"> <li>• Risk Management Procedure*</li> <li>• User Manual Procedure*</li> </ul>		<ul style="list-style-type: none"> <li>• Residual Risk Records</li> </ul>	<ul style="list-style-type: none"> <li>• User Manuals</li> </ul>	<ul style="list-style-type: none"> <li>• Risk Management Procedure Review*</li> <li>• User Manual Procedure Review*</li> <li>• User Manuals Review*</li> </ul>

**Section 2**  
**60601-1-4 EVIDENCE PRODUCTS CHECKLIST BY CLAUSE**

IEC 60601-1-4 CLAUSE NUMBER and NAME	PROCEDURES	PLANS	RECORDS	DOCUMENTS	AUDITS and REVIEWS
6.8.202			<ul style="list-style-type: none"> <li>• Configuration Management Record</li> </ul>		
<b>52.201 Documentation</b>					
52.201.1	<ul style="list-style-type: none"> <li>• Documentation Procedure</li> </ul>	<ul style="list-style-type: none"> <li>• Documentation Plan</li> </ul>	<ul style="list-style-type: none"> <li>• Documentation Records</li> </ul>		<ul style="list-style-type: none"> <li>• Documentation Plan Review</li> <li>• Documentation Procedure Review</li> </ul>
52.201.2					