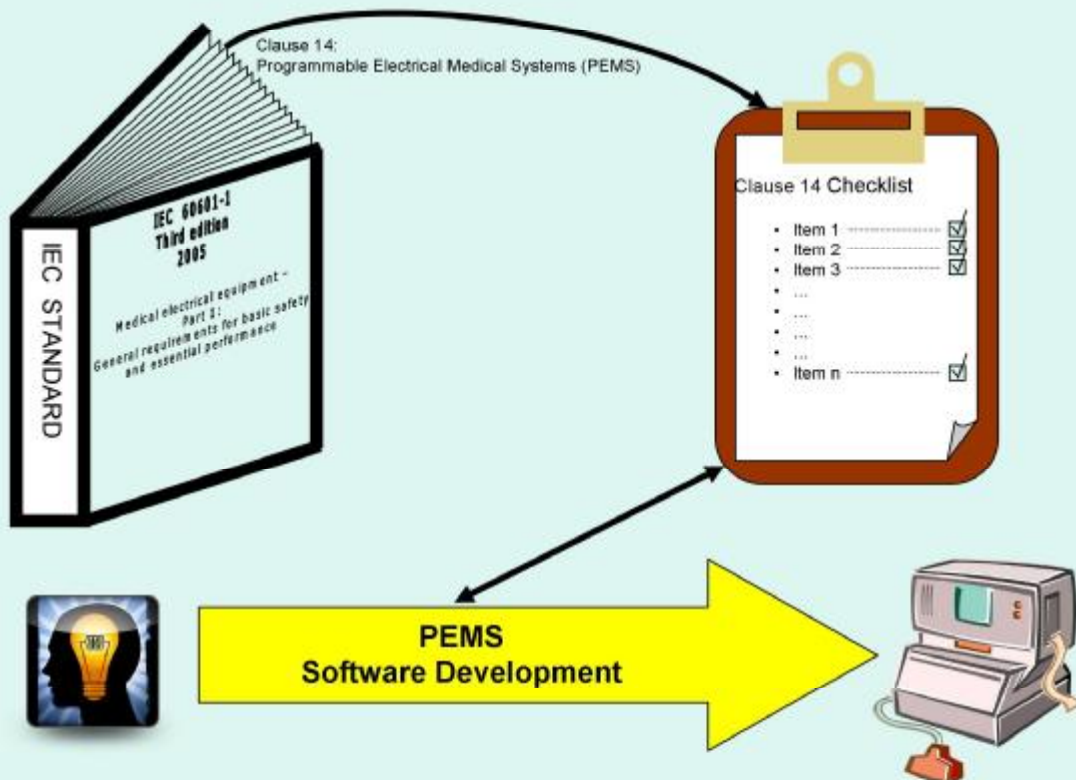


# A Checklist for Programmable Electrical Medical Systems As Defined In Clause 14 Of IEC 60601-1 Third Edition 2005



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**For Standard IEC 60601-1 Ed. 3.0 b:2005**  
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## **Evidence Product Checklist**

For Standard **IEC 60601-1 Ed. 3.0 b: 2005**

### **Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Clause 14 Programmable Electrical Medical Systems (PEMS)**

#### **Introduction: Overview of the Standard IEC 60601-1 Ed. 3.0 b: 2005, Clause 14 Electrical Medical Systems (PEMS).**

This standard contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. For certain types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone. Clause 14 is the software related section of this standard.

#### **Introduction to the checklist**

Since SEPT only produces checklists for software standards, (its core competence), SEPT has just produced a checklist for clause 14 (software). In the rest of this document this standard and project will just be referred to as "Clause 14 Programmable Electrical Medical Systems (PEMS)".

The process of defining what is necessary for compliance with a document for software such as "Clause 14 Programmable Electrical Medical Systems (PEMS)" is often confusing and laborious because the directions contained in the standard are unclear or ambiguous. To aid in determining what is actually "required" by the standard in the way of physical evidence for compliance with the standard, 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. 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 standard calls out for a procedure review. In this checklist "manuals, reports, scripts and specifications" are included in the document category.

The author has carefully reviewed "Clause 14 Programmable Electrical Medical Systems (PEMS)" of the standard 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 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 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 standard, though not specifically called out in the document, 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 3-8 of the checklist.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another 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 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 of the organization.

### **Method of preparation**

The checklist for, “Clause 14 Programmable Electrical Medical Systems (PEMS)” was prepared by analyzing each clause for the key words that signify a:

- Policy
- Procedure
- Plan
- Records
- Document ( Including Lists, 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 suggested, 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 a checklist tables, based on the type of product or evidence.

### **Using the Checklist**

When a company is planning to use “Clause 14 Programmable Electrical Medical Systems (PEMS)” document, the company should review the evidence checklist. If the company’s present process does not address a “Clause 14 Programmable Electrical Medical Systems (PEMS)” 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 and no further action is required.
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 by the business of the organization.	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> completed by at a date in the future.	Record in the checklist when this evidence will be planned and completed and reference a plan for accomplishing the task and a date.

### Components of the Checklist

This checklist is composed of 9 sections:

- Section 1. Introduction
- Section 2. Composites of all recommended and suggested, Clause 14 Programmable Electrical Medical Systems (PEMS) artifacts
- Sections 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. You may reach our help desk 9AM till 5 PM. Our help desk may be reached at 425-391-2344 or, Email [Stanmagee@smartwire.net](mailto:Stanmagee@smartwire.net)

## **Warranties and Liability**

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## Section 2

### “Clause 14 Programmable Electrical Medical System (PEMS)” Evidence Products Checklist By Clause

<b>Clause 14 Programmable Electrical Medical Systems (PEMS)</b>	<b>Policies and Procedures</b>	<b>Plans</b>	<b>Records</b>	<b>Documents</b>	<b>Audits and Reviews</b>
<b>14 Programmable Electrical Medical Systems (PEMS)</b>					

Sample

## Section 2

### “Clause 14 Programmable Electrical Medical System (PEMS)” Evidence Products Checklist By Clause

Clause 14 Programmable Electrical Medical Systems (PEMS)	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
14.1 General	<ul style="list-style-type: none"> <li>• <b>ISO 14971 Polices*</b></li> <li>• ISO 14971 Required Procedures</li> <li>• Legacy Devices Systems Used Procedure*</li> <li>• OTS ( Off the Shelf) Software Used Procedure*</li> <li>• Risk Management File Procedure*</li> <li>• Subsystems of Non-Medical Origin Used Procedure*</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 14971 Required Plans</li> </ul>	<ul style="list-style-type: none"> <li>• Essential Performance Process Used Records</li> <li>• ISO 14971 Required Records</li> <li>• PEMS Development Life Cycle Process Used Records*</li> <li>• Risk Management Process Used Records*</li> <li>• Safety Process Used Records</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 14971 Required Documents</li> <li>• Legacy Devices Systems Used Documents*</li> <li>• OTS (Off the Shelf) Software Used Document*</li> <li>• Risk Management File Document*</li> <li>• Subsystems of Non-Medical Origin Used Document*</li> </ul>	<ul style="list-style-type: none"> <li>• <b>ISO 14971 Audits*</b></li> <li>• ISO 14971 Reviews*</li> <li>• Legacy Devices Systems Used Review*</li> <li>• OTS ( Off the Shelf) Software Used Review*</li> <li>• <b>Risk Management File and Assessment of the Process Cited in Clause 14.2 and 14.13 Audits*</b></li> <li>• Risk Management File Review*</li> <li>• Subsystems of Non-Medical Origin Used Review*</li> </ul>