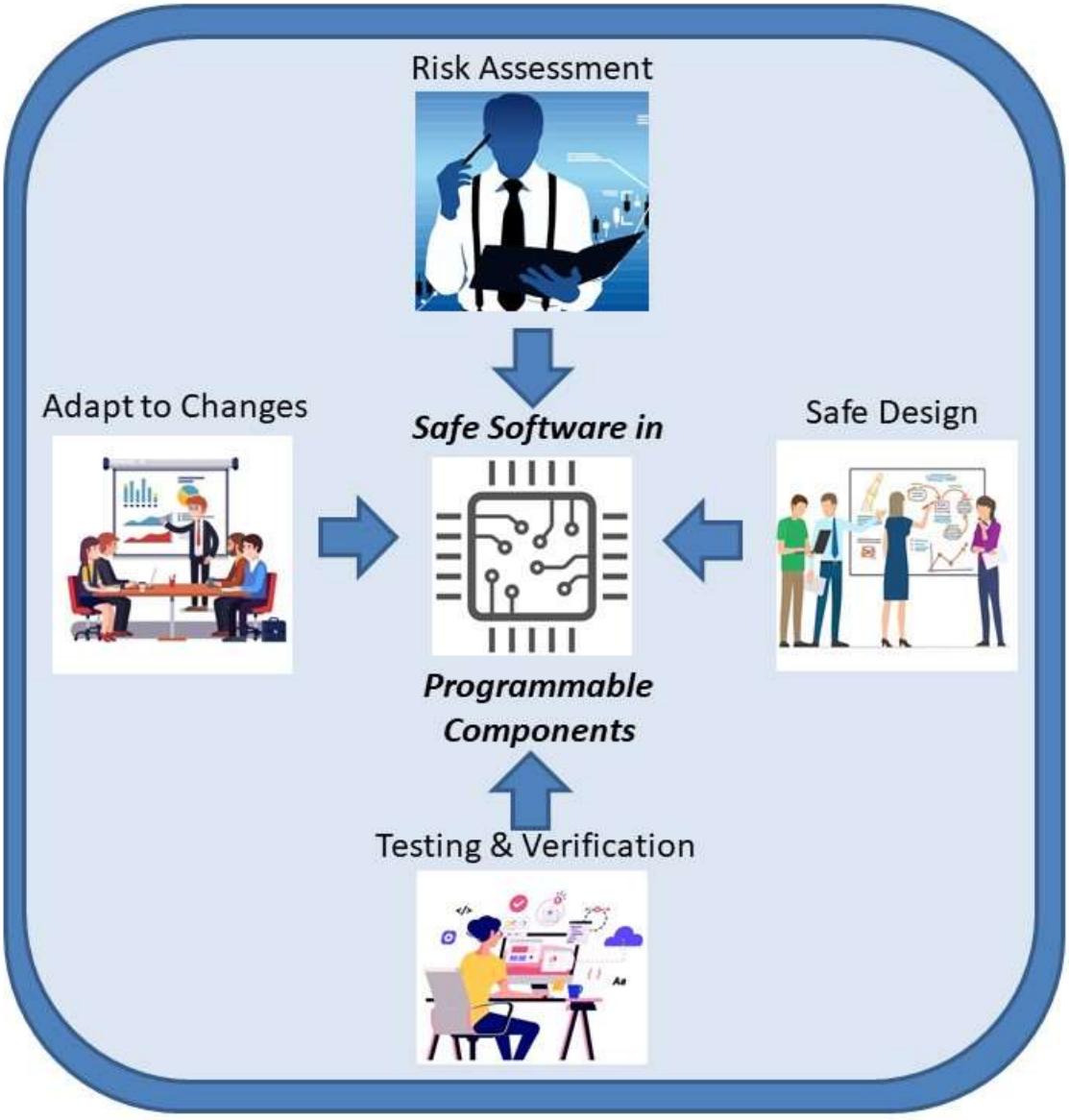
SEPT Evidence Product Checklist for

UL 1998 - Standard for Safety -
Software in Programmable Components



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Evidence Product Checklist

For

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Edition 3

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UL 1998 Checklist Revision Page

Changes to the Standard	Date	Description of Change		Change to the Checklist
Edition 1	May 2004	The first edition of UL 1998.		Version 1 of checklist based on 2004 Edition 1.
Edition 2	Dec-2013	Various changes based on usage of Edition 1		No update to checklist
Edition 3	Sept 2018	Adoption by ANSI of 2013 version of UL 1998 which substantially meets requirements proposed in 2018 with various small changes as described in the history page		Version 2 of checklist with 80% items changed to give artifact names used in UL1998 edition 3

Contents

Section 1 Foreword

If a company produces products that have software in a programmable component that possibly could cause bodily harm, they need to adhere to Safety Standard UL 1998. They need this checklist, to ensure that the required artifacts (procedures, plans, records, documents and reviews) have been produced to meet the requirements of UL 1998. This checklist will save time and money for the organization.

Sections of the Checklist

This checklist is composed of 6 sections:

- Section 1. Foreword
- Section 2. Checklist of all required and suggested UL1998:2018 (Edition 3) artifacts, by clause.
- Sections 3-7. Individual checklists for each type of artifact (procedures, plans, records, documents and reviews)
- Section 8. About the author

Overview of the Standard UL1998

The UL 1998 standard is focused on **application-specific, non-networked software** in a **programmable component** that is embedded in a product for which a failure may result in injury to persons. In addition, UL 1998 is a reference software standard intended to be used in conjunction with any product specific safety standards that address safety requirements for the identified programmable component and the product hardware. The software configuration of a microprocessor based programmable component typically includes the operating system or executive software, communication software, micro-controller, input/output hardware, and any generic software libraries, database management or user interface software.

Relationship to other key Standards

There is no bibliography and there are no referenced standards in UL 1998.

Background of the SEPT Checklists

For 25 + years Software Engineering Process Technology (SEPT) has produced checklists for international and national process standards. They have been produced for Medical Devices, Quality, Security and Software processes. Organizations buy and use these checklists to:

1. Perform a gap analysis - Standard requirements versus what the organization does;
2. Ensuring that all the artifacts that are cited in the standard are addressed;
3. Providing the traceability by artifact from the standard to a process step;
4. Demonstrate that the organization was following a “best of practice standard” in case of litigation;

5. Reduce cost by procuring an “Off the Shelf” checklist rather than developing one internally.
6. Insurance that they have a checklist that is compiled by a company experienced in deciphering standards and verified by domain experts.

How the UL 1998 SEPT Checklist was Constructed

The first step in construction of the checklist was to define clearly all the artifacts (procedures, plans, records, documents, or reviews) that the underlying standard calls out. Furthermore, what constitutes physical evidence (artifacts) to meet the guidance outlined in UL1998 is sometimes difficult to identify. To bridge this gap the author and SEPT experts have identified items of physical evidence called out in the standard based on their knowledge of the document and their experience in the standards field. Each item of physical evidence that was identified by these experts is listed in the checklist as an artifact (procedures, plans, records, documents, or reviews). If an artifact is required by UL1998, it appears in the checklist without an appended symbol. Sometimes we call out an artifact that is not expressly identified but we think it should be included. If that is the case, we flag it with an * as suggested.

There must be an accompanying record of some type when a review has been accomplished. This record would define the findings of the review and any corrective action to be taken. For the sake of brevity this checklist does not call out a separate record for each review. All procedures should be reviewed but the checklist does not call out a review for each procedure unless the standard calls out the procedure to be reviewed. Where records are cited as artifacts, reviews of the records are not included, but we would expect a review to be held.

The author has carefully reviewed the Standard UL1998 and defined the physical evidence required based upon this classification scheme. SEPT’s engineering department has conducted a second review of the complete list and baseline standard to ensure that the documents’ producers did not leave out a physical piece of evidence that a “reasonable person” would expect to find. If an artifact 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 Design Operation and Safety Features Document” could be a part of the “Software Design 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 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.
The information was transferred into checklist tables, based on the type of product or evidence. In total, there are 208 artifacts identified by SEPT in the checklist, of which 69 are required and 139 suggested.

Using the Checklist

When a company is planning to use UL1998 standard, the company should review the evidence checklist. If the company's present process does not address a UL1998 standard product, then the following question should be asked: "Is the evidence product required for the type of business of the organization?" If, in the view of the organization, 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 titles 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.

Product Support

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

Guarantees and Liability

Software Engineering Process Technology (SEPT) makes no guarantees 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
UL 1998 Evidence Products Checklist By Clause

UL 1998 CLAUSE NUMBER and NAME		PROCEDURES	PLANS	RECORDS	DOCUMENTS	REVIEWS
3	**Risk Analysis**					
3.1	Risk Analysis	• Risk Analysis Procedure*		• Risk Analysis Records* • Software Addresses Identified Risks Records*		• Risk Analysis Review*
3.2	Risk Analysis			• Risk Analysis Based Upon Safety Requirements for the Programmable Component Records*		
3.3	Risk Analysis			• Analysis of Critical, Non-critical and Supervisory Software Sections Records*		• Analysis of Critical, Non-critical and Supervisory Software Sections Review*
3.4	Risk Analysis			• Analysis of States or Transitions Capable of Resulting in a Risk Records*		• Analysis of States or Transitions Capable of Resulting in a Risk Review*

* Suggested item

Section 2
UL 1998 Evidence Products Checklist By Clause

UL 1998 CLAUSE NUMBER and NAME		PROCEDURES	PLANS	RECORDS	DOCUMENTS	REVIEWS
4	**Process Definition**					
4.1	Process Definition	• Software Process Activities Procedure				
4.2	Process Definition					
4.3	Process Definition			• Traceability of Risk Analysis to Programmable Component and Software Requirements Specification Records		

* Suggested item

Section 2
UL 1998 Evidence Products Checklist By Clause

UL 1998 CLAUSE NUMBER and NAME		PROCEDURES	PLANS	RECORDS	DOCUMENTS	REVIEWS
4.4	Process Definition	• Software Process Activity Transition in Consideration of Safety Related Requirements for the Programmable Component Procedure*		• Software Process Activity Transition in Consideration of Safety-Related Requirements for the Programmable Component Records		
4.5	Process Definition			• Software Process Activities Work Products List Records		
4.6	Process Definition			• Software Process Activity Supporting Communication of Issues Impacting Safety-Related Functioning for the Programmable Component Records		

* Suggested item

Section 2
UL 1998 Evidence Products Checklist By Clause

UL 1998 CLAUSE NUMBER and NAME		PROCEDURES	PLANS	RECORDS	DOCUMENTS	REVIEWS
4.7	Process Definition			• Safety Related Requirements Traceability Matrix (Throughout Processes) Report Records		
4.8	Process Definition	• Software Verification, Validation and Testing Activities (Addressing Errors at their Source) Procedure*				

* Suggested item

Section 2
UL 1998 Evidence Products Checklist By Clause

UL 1998 CLAUSE NUMBER and NAME		PROCEDURES	PLANS	RECORDS	DOCUMENTS	REVIEWS
5	**Qualification of Design, Implementation and Verification Tools**					
5.1	Qualification of Design, Implementation and Verification Tools			• Software Tool Calibration, Verification and Validation Activity Records* • Software Tool Qualification Records • Software Tool Third Party Certification Program Records*		

* Suggested item