



EVIDENCE PRODUCT CHECKLIST

For Standard ISO 9001:2015

Quality management systems – Requirements

A checklist prepared by analyzing each clause of ISO 9001:2015



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SEPT Evidence Product Checklist

For ISO 9001:2015 *Quality management systems - Requirements*

2015 Edition

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ISO 9001:2015 Quality management systems: Requirements – SEPT Evidence Product Checklist

Overview of the Standard ISO 9001:2015 Quality management systems: Requirements

ISO 9001:2015 specifies requirements for a quality management system where an organization:

- Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
- All requirements of ISO 9001:2015 are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.
- In clause 4.3 of the 2015 edition it defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. In this case an organization should document the decision to exclude a requirement of ISO9001:2015 in its' Quality management system (QMS). In layman's term this means that in order to become 9001 certified an organizations' QMS must comply with all facets of the standard unless the product or services that they produce does not require, use or depend on that clause. An example of that would be a TV station that did only broad casting. They would not have to comply with those sections of the standard that dealt with manufacturing. However they would have to document this situation by clauses.

Major Changes in ISO 9001:2015 from the 2008 Version

- Format changed to fit common structure for all ISO Management System Standards
- Greater compatibility with services and non-manufacturing users
- Clearer presentation of the “Organization”
- Process approach introduced in 2008 version strengthened
- Preventive Action addressed as Risk identification and mitigation
- Documented information replaces documents and records
- Control of externally provided products and services replaces purchasing/outsourcing
- Greater emphasis on seeking opportunities for improvement of an organization’s processes, products and services
- **Other Beneficial Changes**
- Enhanced leadership involvement in the management system

- Risk-based thinking
- Simplified language, common structure and terms
- Aligning QMS policy and objectives with the strategy of the organization

The Meaning of Documented Information in ISO 9001:2015 Version and how it is applied in the checklist

The 2015 edition of this International Standard defines requirements to “maintain documented information” whereas the ISO 9001:2008 version used specific terminology such as “document” or “documented procedures”, “quality manual” or “quality plan”.

Similarly, there is now a requirement to “retain documented information” where ISO 9001:2008 used the term “records” to denote documents needed to provide evidence of conformity with requirements. The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to “maintain” documented information does not exclude the possibility that the organization might also need to “retain” that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where ISO9001:2015 refers to “information” rather than “documented information” (e.g. in 4.1: “The organization shall monitor and review the information about these external and internal issues”), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

Purpose and Objectives of the Checklist

The purpose of this checklist is to ensure that an organization does not overlook any facet of physical evidence that is called out or implied in ISO9001:2015.

The process of defining what is necessary for compliance with a quality management process standard such as “ISO Standard 9001:2015” is often confusing and laborious because the directions contained in the standards are 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 standard calls out the procedure review.** In this checklist “manuals, reports, scripts and specifications” are included in the document category. When the subject standard references another standard for physical evidence, the checklist does not call out the requirements of the referenced standard.

The Author has carefully reviewed the document “ISO Standard 9001:2015 Quality management systems – Requirements” 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 standard 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. 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 "Design and Development Verification Plan" could be a part of the "Design and Development 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.

General Principles of SEPT Checklist for the ISO Standard 9001:2015 Quality management systems - Requirements

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, 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 a required artefact, but was not called out in the document, then it is added with an asterisk (*) - suggested artefacts) after its notation in the checklist. The information was transferred into checklist tables, based on the type of product or evidence.

In total there are 77 required artefacts and 433 suggested artefacts included in the SEPT checklist.

Terminology in 2015 Version and its Interpretation in this Checklist

The following table defines how the wording in ISO9001:2015 has been interpreted by the author, eg, if the word in the standard is “Communicating” the author interprets this as a plan type artefact but since the word “Plan” is not used it’s a suggested item, rather than a required item. Note: R=Required in ISO9001:2015 version, S=Suggested in ISO9001:2015 version

ISO 9001:2015 word	Suggested Artefact title in Checklist (as proof that a requirement of the standard has been met)
Address	Document or Procedure as S
Apply	Plan or Record as S
Assign	Document as S
Audit	Audit as R
Communicating	Plan as S
Continually Improve/ Improve	Procedure as S
Control	Procedure as S
Demonstrate	Record as R, sometimes a Review as R
Determine	Plan or Document or both as S
Ensure	Plan as S
Establish	Document as S
Evaluate	Review as S
Implement	Procedure as S
Maintain	Document as S
Maintain Documented Information	Document as R
Monitor	Procedure as S
Plan	Plan as R
Policy	Policy as R
Process	Procedure as S
Promoting	Plan as S
Provide	Procedure or Plan or both as S
Retain	Record as R
Retain Documented Information	Record as R
Review	Review as R

Using the SEPT Checklist

When an organization is planning to use "ISO 9001:2015 Quality management systems – Requirements" standard, the organization should review the evidence checklist. If the organization's present process does not address an ISO 9001:2015 standard product, then this 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.) <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.) is <i>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.
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Sections of the Checklist

This checklist is composed of 10 sections:

- Section 1. Overview of ISO 9001:2015 and to the SEPT checklist.
- Section 2. Composites of all required and suggested “ISO 9001:2015 Quality management systems - Requirements” evidence products.
- Sections 3-8. Individual checklists for each evidence type.
- Section 9 – ISO 9001:2008 items no longer called out in ISO 9001:2015 version
- Section 10. “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

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Versions of the SEPT Checklist

1. Original edition: Checklist for ISO 9001:2000
2. 2008 Edition of the checklist:
3. 2015 Edition of the checklist: This checklist replaces the previous version, providing alignment with the 2015 standard.

Section 2

ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4 Context of the organization					
4.1 Understanding the organization and its context	<ul style="list-style-type: none"> • External and Internal Issues Monitoring Plan Procedure* • Strategic External and Internal Issues Document Procedure* 	<ul style="list-style-type: none"> • External and Internal Issues Monitoring Plan* 		<ul style="list-style-type: none"> • Strategic External and Internal Issues Document* 	<ul style="list-style-type: none"> • External and Internal Issues Monitoring Plan Review* • External and Internal Issues Monitoring Review • Strategic External and Internal Issues Document Review*

Section 2

ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2 Understanding the needs and expectations of interested parties	<ul style="list-style-type: none"> • QMS Customer Requirements Document Procedure* • QMS Interested Parties Document Procedure* • QMS Interested Parties Requirements Document Procedure* • QMS Interested Parties Requirements Monitoring Plan Procedure* • QMS Statutory and Regulatory Requirements Document Procedure* 	<ul style="list-style-type: none"> • QMS Interested Parties Requirements Monitoring Plan* 		<ul style="list-style-type: none"> • QMS Customer Requirements Document* • QMS Interested Parties Document* • QMS Interested Parties Requirements Document* • QMS Statutory and Regulatory Requirements Document* 	<ul style="list-style-type: none"> • QMS Customer Requirements Document Review* • QMS Customer Requirements Information Review • QMS Interested Parties Information Review • QMS Interested Parties Requirements Document Review* • QMS Interested Parties Requirements Monitoring Plan Review* • QMS Statutory and Regulatory Requirements Document Review*

Section 2

ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.3 Determining the scope of the quality management system (QMS)	<ul style="list-style-type: none"> • Products and Services Document Procedure* • QMS Application Plan Procedure* • QMS Non-Applicable ISO 9001 Requirements Document Procedure* • QMS Scope Document Procedure* 	<ul style="list-style-type: none"> • QMS Application Plan* 		<ul style="list-style-type: none"> • Products and Services Document • QMS Non-Applicable ISO 9001 Requirements Document • QMS Scope Document 	<ul style="list-style-type: none"> • Products and Services Document Review* • QMS Application Plan Review* • QMS Non-Applicable ISO 9001 Requirements Document Review* • QMS Scope Document Review*