



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

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- 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

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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.

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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.) <i>is 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

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.

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.

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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	• External and Internal Issues Monitoring Plan Procedure* • Strategic External and Internal Issues Document Procedure*	• External and Internal Issues Monitoring Plan*		• Strategic External and Internal Issues Document*	• External and Internal Issues Monitoring Plan Review* • External and Internal Issues Monitoring Review • Strategic External and Internal Issues Document Review*

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* Suggested item QMS = Quality Management System

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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	• 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*	• QMS Interested Parties Requirements Monitoring Plan*		• QMS Customer Requirements Document* • QMS Interested Parties Document* • QMS Interested Parties Requirements Document* • QMS Statutory and Regulatory Requirements Document*	• 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*

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* Suggested item QMS = Quality Management System

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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)	• Products and Services Document Procedure* • QMS Application Plan Procedure* • QMS Non-Applicable ISO 9001 Requirements Document Procedure* • QMS Scope Document Procedure*	• QMS Application Plan*		• Products and Services Document • QMS Non-Applicable ISO 9001 Requirements Document • QMS Scope Document	• Products and Services Document Review* • QMS Application Plan Review* • QMS Non-Applicable ISO 9001 Requirements Document Review* • QMS Scope Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.4	Quality management system and its processes					
4.4.1	Quality management system and its processes	• QMS Improvement Plan Procedure* • QMS Operation and Control Plan Procedure* • QMS Process Change Plan Procedure* • QMS Process Evaluation Plan Procedure* • QMS Processes Inputs and Outputs Document Procedure* • QMS Processes Plan Procedure* • QMS Processes Sequence and Interaction Document Procedure* • QMS Resource Plan Procedure*	• QMS Improvement Plan* • QMS Operation and Control Plan* • QMS Process Change Plan* • QMS Process Evaluation Plan* • QMS Processes Plan* • QMS Resource Plan* • QMS Risks and Opportunities Plan*		• QMS Processes Inputs and Outputs Document* • QMS Processes Sequence and Interaction Document* • QMS Responsibilities and Authorities Document • QMS Risks and Opportunities Document*	• QMS Improvement Plan Review* • QMS Operation and Control Plan Review* • QMS Process Change Plan Review • QMS Process Evaluation Plan Review* • QMS Processes Inputs and Outputs Document Review* • QMS Processes Plan Review* • QMS Processes Sequence and Interaction Document Review* • QMS Resource Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.4	Quality management system and its processes					
4.4.1	Quality management system and its processes (Cont. 1)	• QMS Responsibilities and Authorities Document Procedure* • QMS Risks and Opportunities Document Procedure* • QMS Risks and Opportunities Plan Procedure*				• QMS Responsibilities and Authorities Document Review* • QMS Risks and Opportunities Document Review* • QMS Risks and Opportunities Plan Review*
4.4.2	Quality management system and its processes	• QMS Process Operation Document(s) Procedure*		• QMS Process Operation Records	• QMS Process Operation Document(s)	• QMS Process Operation Document(s) Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5 Leadership						
5.1	Leadership and Commitment					
5.1.1	General	• Business Process Plan Procedure* • Quality Objectives Document Procedure* • Quality Policy • Quality Policy Procedure*	• Business Process Plan*		• Quality Objectives Document	• Business Process Plan Review* • Context and Strategic Direction Review* • QMS Results Review* • Quality Objectives Document Review* • Quality Policy Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5.1.2	Customer focus	- Customer Focus Requirements Document Procedure* - Customer Satisfaction Enhancement Plan Procedure* - Risks and Opportunities Document Procedure* - Statutory and Regulatory Requirement Document Procedure*	Customer Satisfaction Enhancement Plan*		- Customer Focus Requirements Document* - Risks and Opportunities Document* - Statutory and Regulatory Requirement Document*	- Customer Focus Requirements Document Review* - Customer Satisfaction Enhancement Plan Review* - Risks and Opportunities Document Review* - Statutory and Regulatory Requirement Document Review*
5.2	Policy					
5.2.1	Developing the quality policy	QMS Continual Improvement Plan Procedure*	QMS Continual Improvement Plan*			QMS Continual Improvement Plan Review*
5.2.2	Communicating the quality policy	Quality Policy Communication Plan Procedure*	Quality Policy Communication Plan*			Quality Policy Communication Plan Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5.3	Organizational roles, responsibilities and authorities	- Customer Focus Plan Procedure* - Organizational Responsibilities and Authorities Document Procedure* - QMS Change Plan Procedure* - QMS Performance Report Document Procedure*	- Customer Focus Plan* - QMS Change Plan*		- Organizational Responsibilities and Authorities Document* - QMS Performance Report Document	- Customer Focus Plan Review* - Organizational Process Output Review* - Organizational Responsibilities and Authorities Document Review* - QMS Change Plan Review* - QMS Integrity Review* - QMS Performance Report Document Review* - Quality Management System Compliance Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
6 Planning						
6.1	Actions to address risks and opportunities	• QMS Results Assurance Plan Procedure* • QMS Risks and Opportunities Action Effectiveness Evaluation Plan Procedure* • QMS Risks and Opportunities Action Plan Procedure*	• QMS Results Assurance Plan* • QMS Risks and Opportunities Action Effectiveness Evaluation Plan* • QMS Risks and Opportunities Action Plan			• QMS Results Assurance Plan Review* • QMS Risks and Opportunities Action Effectiveness Evaluation Plan Review* • QMS Risks and Opportunities Action Plan Review*
6.2	Quality objectives and planning to achieve them	• Quality Objective Resource Plan Procedure*	• Quality Objective Resource Plan*			• Quality Objective Resource Plan Review* • Quality Objectives Evaluation Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7	Support					
7.1	Resources					
7.1.1	General	- QMS External Providers Acquisition Plan Procedure* - QMS Internal Resource Constraints Plan Procedure*	- QMS External Providers Acquisition Plan* - QMS Internal Resource Constraints Plan*			- QMS External Providers Acquisition Plan Review* - QMS Internal Resource Constraints Plan Review*
7.1.2	People	- QMS Implantation Resource Plan Procedure* - QMS Process Operation and Control Resource Plan Procedure*	- QMS Implantation Resource Plan* - QMS Process Operation and Control Resource Plan*			- QMS Implantation Resource Plan Review* - QMS Process Operation and Control Resource Plan Review*
7.1.3	Infrastructure.	Organizational Infrastructure Plan Procedure*	Organizational Infrastructure Plan*			Organizational Infrastructure Plan Review*
7.1.4	Environment for the operation of processes	Organizational Environment Plan Procedure*	Organizational Environment Plan*			Organizational Environment Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.1.5	Monitoring and measuring resources					
7.1.5.1	General	- Product and Service Conformity Verification Resource Plan Procedure* - Product and Service Monitoring and Measurement Resource Maintenance Plan Procedure*	- Product and Service Conformity Verification Resource Plan* - Product and Service Monitoring and Measurement Resource Maintenance Plan*	Product and Service Monitoring and Measurement Resource Records		- Product and Service Conformity Verification Resource Plan Review* - Product and Service Monitoring and Measurement Resource Maintenance Plan Review* - Product and Service Monitoring and Measurement Resource Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.1.5.2	Measurement traceability	- Product and Service Measuring Equipment Calibration Plan Procedure* - Product and Service Measuring Equipment Identification Plan Procedure* - Product and Service Measuring Equipment Maintenance Plan Procedure* - Product and Service Measuring Equipment Results Qualification Procedure*	- Product and Service Measuring Equipment Calibration Plan* - Product and Service Measuring Equipment Identification Plan* - Product and Service Measuring Equipment Maintenance Plan*	Measurement Traceability Calibration or Verification Records		- Product and Service Measuring Equipment Calibration Plan Review* - Product and Service Measuring Equipment Identification Plan Review* - Product and Service Measuring Equipment Maintenance Plan Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.1.6	Organizational knowledge	- Organizational Change Additional Knowledge Acquisition Plan Procedure* - Organizational Process Operation Knowledge Plan Procedure* - Product and Service Conformity Knowledge Plan Procedure*	- Organizational Change Additional Knowledge Acquisition Plan* - Organizational Process Operation Knowledge Plan* - Product and Service Conformity Knowledge Plan*			- Organizational Change Additional Knowledge Acquisition Plan Review* - Organizational Process Operation Knowledge Plan Review* - Product and Service Conformity Knowledge Plan Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.2	Competence	QMS People Acquisition Plan Procedure*	QMS People Acquisition Plan*	QMS People Competence Records		- QMS People Acquisition Effectiveness Review* - QMS People Acquisition Plan Review* - QMS People Competence Review* - QMS People Education, Training and Experience Review*
7.3	Awareness	People QMS Awareness Plan Procedure*	People QMS Awareness Plan*			People QMS Awareness Plan Review*
7.4	Communication	QMS Internal and External Communication Plan Procedure*	QMS Internal and External Communication Plan*			QMS Internal and External Communication Plan Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5	Documented information					
7.5.1	General	- QMS Effectiveness Documents Procedure* - QMS ISO 9001 Required Documents Procedure*			- QMS Effectiveness Documents - QMS ISO 9001 Required Documents	- QMS Effectiveness Documents Review* - QMS ISO 9001 Required Documents Review*
7.5.2	Creating and updating	- Document Creation and Updating Procedure* - Document Review and Approval Procedure*				
7.5.3	Control of documented information					
7.5.3.1	Control of documented information	Document Control Procedure*				

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.3.2	Control of documented information	• External Document Control Procedure* • Product and Service Conformity Records Protection Procedure*		• Product and Service Conformity Records		

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8 Operation						
8.1	Operation planning and control	• Organization Operational Planning and Control Plan Procedure* • Organization Operational Planning and Control Procedure* • Organization Outsourced Process Control Procedure* • Organization Process Change Control Procedure* • Product and Service Acceptance Criteria Document Procedure*	• Organization Operational Planning and Control Plan • Product and Service Requirements Conformity Achievement Resource Plan*	• Organizational Process Execution Records • Product and Service Requirements Conformity Records	• Product and Service Acceptance Criteria Document* • Product and Service Requirements Document*	• Organization Operational Planning and Control Plan Review* • Product and Service Acceptance Criteria Document Review* • Product and Service Requirements Conformity Achievement Resource Plan Review* • Product and Service Requirements Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.1	Operation planning and control (Cont. 1)	- Product and Service Requirements Conformity Achievement Resource Plan Procedure* - Product and Service Requirements Document Procedure*				

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.2	Requirements for products and services					
8.2.1	Customer communication	• Customer Communication Contingency Action Plan Procedure* • Customer Property Control Procedure* • Product and Service Information Document Procedure*	• Customer Communication Contingency Action Plan*	• Product and Service Customer Complaint Records* • Product and Service Customer Feedback Records*	• Product and Service Information Document*	• Customer Communication Contingency Action Plan Review* • Customer Enquiry, Contract or Order Change Review* • Customer Enquiry, Contract or Order Review* • Product and Service Information Document Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.2.2	Determining the requirements related to products and services	- Organization Product and Service Requirements Document Procedure* - Product and Service Statutory and Regulatory Requirements Document Procedure*			- Organization Product and Service Requirements Document* - Product and Service Statutory and Regulatory Requirements Document*	- Organization Product and Service Requirements Document Review* - Product and Service Statutory and Regulatory Requirements Document Review*
8.2.3	Review of requirements related to products and services					
8.2.3.1	Review of requirements related to products and services					Product and Service Customer Requirements Review
8.2.3.2	Review of requirements related to products and services			- Product and Service Customer Requirements Review Records - Product and Service New Customer Requirements Records		

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.2.4	Changes to requirements for products and services	- Product and Service Requirements Change Document Procedure* - Product and Service Requirements Change Notification Procedure*		Product and Service Requirements Change Notification Record*	Product and Service Requirements Change Document	Product and Service Requirements Change Document Review*
8.3	Design and development of products and services					
8.3.1	General	Design and Development Procedure*				

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

8.3.2	Design and development planning	• Design and Development Customer and User Involvement Plan Procedure* • Design and Development Interface Control Plan Procedure* • Design and Development Internal and External Resource Plan Procedure* • Design and Development Process Complexity and Duration Process Document Procedure* • Design and Development Process Stage Plan Procedure*	• Design and Development Customer and User Involvement Plan* • Design and Development Interface Control Plan* • Design and Development Internal and External Resource Plan* • Design and Development Process Stage Plan* • Design and Development Responsibilities and Authorities Plan* • Design and Development Verification and Validation Plan* • Product and Service Provision Plan*	• Design and Development Requirements Demonstration Records	• Design and Development Process Complexity and Duration Process Document*	• Design and Development Customer and User Involvement Plan Review* • Design and Development Interface Control Plan Review* • Design and Development Internal and External Resource Plan Review* • Design and Development Process Complexity and Duration Process Document Review* • Design and Development Process Stage Plan Review*
8.3.2.	Design and development planning	• Design and Development				• Design and Development

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
	(Cont. 1)	Responsibilities and Authorities Plan Procedure* • Design and Development Verification and Validation Plan Procedure* • Product and Service Provision Plan Procedure*				Responsibilities and Authorities Plan Review* • Design and Development Review* • Design and Development Verification and Validation Plan Review* • Product and Service Provision Plan Review*

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* Suggested item QMS = Quality Management System

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.3.3	Design and development inputs	- Design and Development Standards and Codes of Practice Document Procedure* - Product and Service Functional and Performance Requirements Document Procedure* - Product and Service Potential Consequences of Failure Document Procedure*		- Design and Development Input Records - Design and Development Previous Similar Information Records*	- Design and Development Standards and Codes of Practice Document* - Product and Service Functional and Performance Requirements Document* - Product and Service Potential Consequences of Failure Document*	- Design and Development Standards and Codes of Practice Document Review* - Product and Service Functional and Performance Requirements Document Review* - Product and Service Potential Consequences of Failure Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.3.4	Design and development controls	• Design and Development Problem Action Procedure* • Design and Development Process Results Document Procedure* • Design and Development Validation Procedure* • Design and Development Verification Procedure*		• Design and Development Process Control Records • Design and Development Review Action Records • Design and Development Validation Records • Design and Development Verification Records	• Design and Development Process Results Document	• Design and Development Process Results Document Review* • Design and Development Results Review

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.3.5	Design and development outputs	Product and Service Characteristics Document Procedure*		Design and Development Output Records	Product and Service Characteristics Document	- Design and Development Output Acceptance Criteria Review* - Design and Development Output Adequacy Review* - Design and Development Output Meets Input Requirements Review* - Design and Development Output Monitoring and Measurement Requirements Review* - Product and Service Characteristics Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.3.6	Design and development changes	Design and Development Change Procedure*		- Design and Development Change Adverse Impact Action Records - Design and Development Change Authorization Records - Design and Development Change Records - Design and Development Change Review Records		

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.4	Control of externally provided processes, products and services					
8.4.1	General	• External Process, Product and Service Provider Evaluation, Selection, Monitoring and Re-evaluation Plan Procedure* • External Process, Product and Service Control Plan Procedure* • External Product and Service Provider Evaluation, Selection, Monitoring and Re-evaluation Criteria Document Procedure*	• External Process, Product and Service Provider Evaluation, Selection, Monitoring and Re-evaluation Plan* • External Process, Product and Service Control Plan*	• External Provider Evaluation and Action Records	• External Product and Service Provider Evaluation, Selection, Monitoring and Re-evaluation Criteria Document*	• External Process, Product and Service Provider Evaluation, Selection, Monitoring and Re-evaluation Plan Review* • External Process, Product and Service Conformance Review* • External Process, Product and Service Control Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.4.1	General (Cont. 1)					External Product and Service Provider Evaluation, Selection, Monitoring and Re-evaluation Criteria Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.4.2	Type and extent of control	• External Provider Control Plan Procedure* • External Provider Output Control Plan Procedure* • Externally Provided Process, Product and Service Verification Plan Procedure* • QMS Externally Provided Process Control Procedure*	• External Provider Control Plan* • External Provider Output Control Plan* • Externally Provided Process, Product and Service Verification Plan*			• External Provider Control Effectiveness Review* • External Provider Control Plan Review* • External Provider Output Control Plan Review* • Externally Provided Process, Product and Service Statutory and Regulatory Impact Review* • Externally Provided Process, Product and Service Verification Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.4.3	Information for external providers	• External Provider Control and Monitoring Requirements Document Procedure* • External Provider Interaction Requirements Document Procedure* • External Provider Methods, Processes and Equipment Approval Procedure* • External Provider Onsite Verification and Validation Requirements Document Procedure*			• External Provider Control and Monitoring Requirements Document* • External Provider Interaction Requirements Document* • External Provider Onsite Verification and Validation Requirements Document* • External Provider People Competence and Qualification Requirements Document* • External Provider Process Product and Service Requirements Document*	• External Provider Control and Monitoring Requirements Document Review* • External Provider Interaction Requirements Document Review* • External Provider Onsite Verification and Validation Requirements Document Review* • External Provider People Competence and Qualification Requirements Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.4.3	Information for external providers (Cont. 1)	- External Provider People Competence and Qualification Requirements Document Procedure* - External Provider Process Product and Service Requirements Document Procedure* - External Provider Product and Service Approval Procedure* - External Provider Product and Service Release Approval Procedure*				- External Provider Process Product and Service Requirements Document Review* - External Provider Requirements Adequacy Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5	Production and service provision					
8.5.1	Control of production and service provision	• Product and Service Provision Competent and Qualified Persons Plan Procedure* • Product and Service Provision Control Procedure* • Product and Service Provision Human Error Prevention Action Plan Procedure* • Product and Service Provision Monitoring and Measuring Procedure*	• Product and Service Provision Competent and Qualified Persons Plan* • Product and Service Provision Human Error Prevention Action Plan* • Product and Service Provision Monitoring and Measuring Resource Plan* • Product and Service Provision Process Infrastructure and Environment Plan*	• Unverified Product and Service Provision Results Records	• Product, Service or Activity Characteristics Document*	• Product and Service Provision Competent and Qualified Persons Plan Review* • Product and Service Provision Human Error Prevention Action Plan Review* • Product and Service Provision Monitoring and Measuring Resource Plan Review* • Product and Service Provision Process Infrastructure and Environment Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5.1	Control of production and service provision (Cont. 1)	- Product and Service Provision Monitoring and Measuring Resource Plan Procedure* - Product and Service Provision Process Infrastructure and Environment Plan Procedure* - Product and Service Provision Release, Delivery and Post-delivery Procedure* - Product and Service Provision Validation and Revalidation of Planned Results Procedure*				Product, Service or Activity Characteristics Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5.1	Control of production and service provision (Cont. 2)	Product, Service or Activity Characteristics Document Procedure*				
8.5.2	Identification and traceability	- Product and Service Output Identification Plan Procedure* - Product and Service Provision Monitoring and Measurement Output Status Identification Plan Procedure*	- Product and Service Output Identification Plan* - Product and Service Provision Monitoring and Measurement Output Status Identification Plan*	Product and Service Output Traceability Records		- Product and Service Output Identification Plan Review* - Product and Service Provision Monitoring and Measurement Output Status Identification Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5.3	Property belonging to customers or external providers	- Customer and External Provider Property Care Procedure* - Customer or External Provider Property Lost, Damaged or Unsuitability Report Document Procedure* - Customer or External Provider Property Unsuitability Report Document Procedure* - Product or Service Customer and External Provider Incorporated Property Care Procedure*		Customer or External Provider Property Lost, Damaged or Unsuitability Report Records	- Customer or External Provider Property Lost, Damaged or Unsuitability Report Document - Customer or External Provider Property Unsuitability Report Document*	- Customer or External Provider Property Lost, Damaged or Unsuitability Report Document Review* - Customer or External Provider Property Unsuitability Report Document Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5.4	Preservation			Product and Service Provision Conformity to Requirements Output Records*		

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5.5	Post-delivery activities	- Product and Service Post-delivery Potential Undesired Consequences Plan Procedure* - Product and Service Post-delivery Customer Feedback Plan Procedure* - Product and Service Post-delivery Customer Requirements Plan Procedure* - Product and Service Post-delivery Nature, Use and Intended Lifetime Plan Procedure* - Product and Service Post-delivery Procedure*	- Product and Service Post-delivery Potential Undesired Consequences Plan* - Product and Service Post-delivery Customer Feedback Plan* - Product and Service Post-delivery Customer Requirements Plan* - Product and Service Post-delivery Nature, Use and Intended Lifetime Plan*		Product and Service Post-delivery Statutory and Regulatory Requirements Document*	- Product and Service Post-delivery Potential Undesired Consequences Plan Review* - Product and Service Post-delivery Customer Feedback Plan Review* - Product and Service Post-delivery Customer Requirements Plan Review* - Product and Service Post-delivery Nature, Use and Intended Lifetime Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.5.5	Post-delivery activities (Cont.1)	Product and Service Post-delivery Statutory and Regulatory Requirements Document Procedure*				Product and Service Post-delivery Statutory and Regulatory Requirements Document Review*
8.5.6	Control of changes	Product and Service Provision Change Control Procedure*		Product and Service Provision Change Control Authorization, Review and Action Taken Records		
8.6	Release of products and services	- Product and Service Release Procedure* - Product and Service Requirements Implementation Plan Procedure*	Product and Service Requirements Implementation Plan	- Product and Service Authorization Traceability Records - Product and Service Conformity to Acceptance Criteria Records - Product and Service Release Records		Product and Service Requirements Implementation Plan Review*

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.7	Control of nonconforming outputs					
8.7.1	Control of nonconforming outputs	• Nonconforming Product and Service Action Procedure* • Nonconforming Product and Service Concession Authorization Procedure* • Nonconforming Product and Service Identification and Control Procedure* • Nonconforming Product and Service Output Correction Procedure* • Nonconforming Product and Service Output Customer Information Procedure*				

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
8.7.1	Control of nonconforming outputs (Cont. 1)	Nonconforming Product and Service Output Segregation, Containment, Return or Suspension Procedure*				
8.7.2	Control of nonconforming outputs			- Product and Service Concession Record - Product and Service Nonconformity Action Record - Product and Service Nonconformity Authorization Record - Product and Service Nonconformity Record		

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ISO 9001:2015 Evidence Products Checklist by Clause

ISO 9001:2015 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
9	Performance evaluation.					
9.1	Monitoring, measurement, analysis and evaluation					
9.1.1	General	• Product and Service Monitoring and Measurement Plan Procedure* • Product and Service Monitoring and Measurement Review Plan Procedure* • Product and Service Monitoring, Measurement, Analysis and Evaluation Procedure* • QMS Monitoring and Measurement Plan Procedure*	• Product and Service Monitoring and Measurement Plan* • Product and Service Monitoring and Measurement Review Plan* • QMS Monitoring and Measurement Plan*	• Product and Service Monitoring and Measurement Results Records • QMS Monitoring and Measurement Results Records		• Product and Service Monitoring and Measurement Plan Review* • Product and Service Monitoring and Measurement Review Plan Review* • QMS Monitoring and Measurement Plan Review* • QMS Performance and Effectiveness Review

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