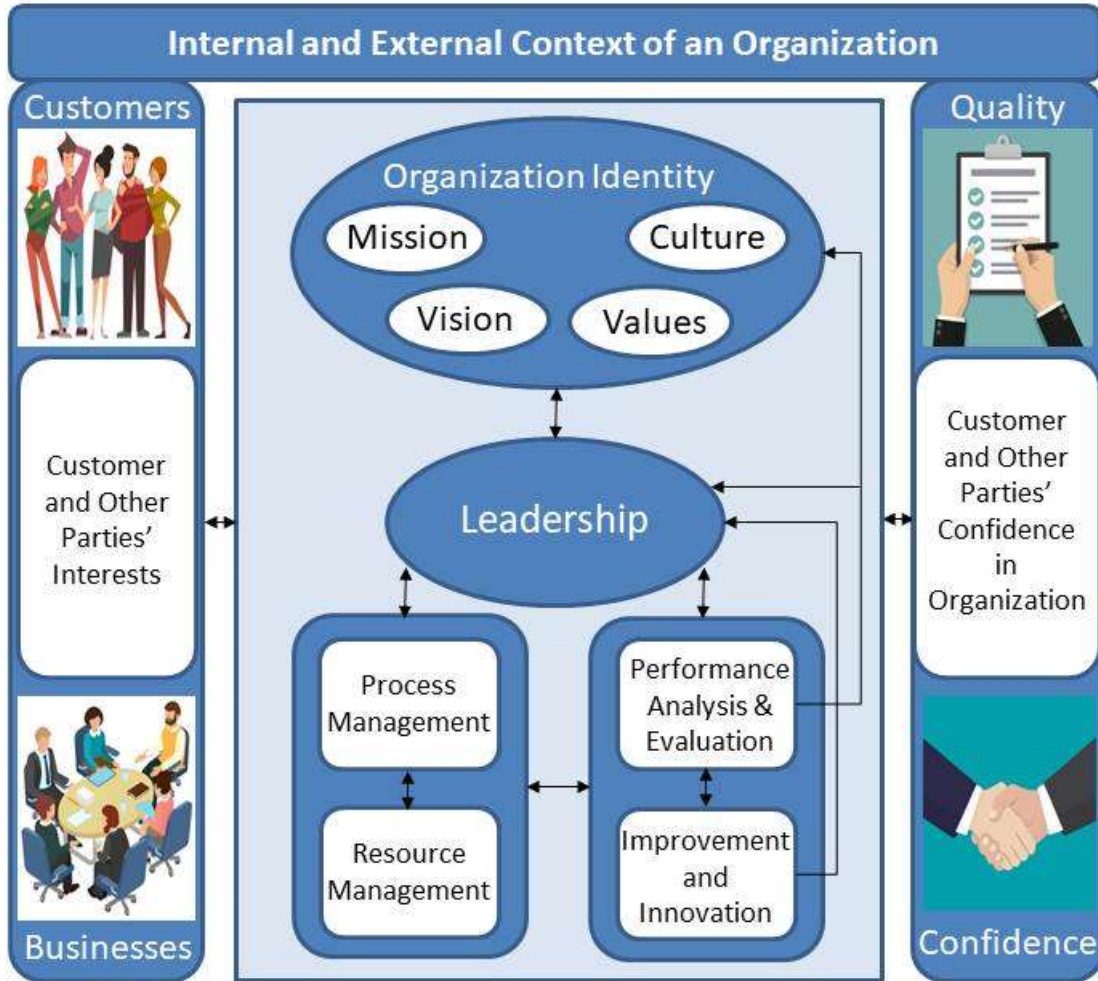


SEPT Evidence Product Checklist

For Standard ISO 9004:2018

*Quality management — Quality of an organization —
Guidance to achieve sustained success*



By: Andrew Coster

SEPT Product 96

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Checklist for Standard ISO 9004:2018 –

**Quality management — Quality of
an organization — Guidance to
achieve sustained success**

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Change Page History

Date	Change	Reason
10-19-2010	First Version	Rewrite of ISO 9004 published in 2009 for 2008 version of ISO 9001
08-08-2018	Second Version	Incorporated the new requirements defined in ISO 9004:2018 Mapped artifacts to quality maturity levels and depicted them by section in the checklist

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Note –Links for Sections 2-14 above were manually generated.

Section 1

Introduction

Components of the Checklist

This checklist is composed of 9 sections:

- Section 1. Introduction
- Section 2. Composites of all required and suggested “ISO 9004:2018 artifacts.
- Sections 3-8. Individual checklists for each type of artifact (policies & procedures, plans, records, documents, audits and reviews)
- Sections 9-13 Individual checklists for each maturity level artifact (policies & procedures, plans, records, documents, audits and reviews)
- Sections 14. About the authors

Overview of the Standard ISO 9004:2018

- ISO 9004:2018 provides guidelines for enhancing an organization's ability to achieve sustained success. This guidance is consistent with the quality management principles given in ISO 9000:2015
- ISO 9004:2018 provides a self-assessment tool to review the extent to which the organization has adopted the concepts in the standard
- ISO 9004:2018 is applicable to any organization, regardless of its size, type and activity.

Relationship to other key Standards

ISO 9004:2018 is a companion document and is harmonized with ISO 9001:2015, and ISO 9004:2015.

Introduction to the SEPT Checklist for ISO 9004

This checklist defines all the artifacts defined in the ISO 9004:2018 standard. It also assigns a maturity level to each artifact that can be used to assess the maturity level of an organization. In this “guidance” standard there are no “required” artefacts (no “shalls”) only “suggested” items.

For 20 + years Software Engineering Process Technology (SEPT) has produced checklists for standards that address software issues. To reduce the fog surrounding these types of standards SEPT has produced checklists for standards since 1994. This is another checklist related to quality standards.

ISO 9004 will provide your organization with guidance and support to achieve sustained success by using a quality management approach. This approach can be used by any organization, regardless of size, type and activity. To document that an organization has achieved a certain quality maturity level the standard recommends that the organization produce and use certain quality artifacts (Procedure, Policy, Plan, Records, Document, Audits and Review) at each maturity level. However, what constitutes physical evidence (Artifacts) to meet the guidance outlined in ISO 9004 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 quality field. Each item of physical evidence that was identified by these experts is listed in the checklist as; policy, procedure, plan, records, document or reviews.

ISO 9004 promotes self-assessment as an important tool for the review of the maturity level of an organization. This self-assessment can provide an overall view of the performance of an organization and degree of maturity of their management system. To aid in this transition from physical evidence to maturity level, the checklist identifies the maturity level associated with each piece of physical evidence called out in the checklist. Since the standard does not assign a maturity level to an item of physical evidence the author and SEPT experts have assigned a maturity level to each piece of physical evidence listed. The maturity level is marked in brackets () after the artefact in each checklist. This assigning of maturity level was based on the expert knowledge of the standard and their experience in the quality field.

The SEPT checklists are 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. In the procedure category, guidelines are included when the subject standard references another standard for physical evidence. The checklist does not call out the requirements of the referenced standard.

The authors have carefully reviewed the Standard ISO 9004:2018 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 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 "Process Control Procedure" could be a part of the "Process Planning and Control Procedure". The authors have 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.

General Principles of the Checklist for ISO Standard 9004:2018

This checklist was prepared by analyzing each clause of the Standard for the key words that signify a:

- Policy
- Procedure (Including Guidelines)
- Plan
- Records
- Document (Including 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 person” approach.

In total, there are 309 artefacts identified by SEPT in the checklist.

This includes:

- | | |
|--------------------|-----|
| • Maturity level 1 | 0 |
| • Maturity level 2 | 20 |
| • Maturity level 3 | 117 |
| • Maturity level 4 | 96 |
| • Maturity level 5 | 76 |

Using the Checklist

When a company is planning to use ISO 9004:2018 standard, the company should review the evidence checklist. If the company’s present process does not address an ISO 9004:2018 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.) <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.

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 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
ISO 9004:2018 Evidence Products Checklist by Clause

ISO 9004:2018 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4 Quality of an organization and sustained success					
4.1 Quality of an organization	<ul style="list-style-type: none"> • Customer Focus Procedure (3) • Organization's Customers and Interested Parties Needs and Expectations Procedure (2) • Organization's Interested Parties Satisfaction Enhancement and Overall Experience Procedure (4) • Organization's Sustained Success (Applying Quality Management Principles) Procedure (4) • Relationship Management Procedure (2) 				

Section 2
ISO 9004:2018 Evidence Products Checklist by Clause

ISO 9004:2018 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2 Managing for the sustained success of an organization					
4.2.1 Managing for the sustained success of an organization	<ul style="list-style-type: none"> • Improvement, Learning and Innovation to Support Changes in Organizational Context (by Top Management) Procedure (5) • Organization's Context Monitoring, Analysis, Evaluation and Review (by Top Management) to Identify All Interested Parties Needs and Expectations Procedure (2) 	<ul style="list-style-type: none"> • Top Management Short and Long Term Risks and Opportunities Plan (4) 			<ul style="list-style-type: none"> • Top Management Short and Long Term Risks and Opportunities Plan Review (4)

Section 2
ISO 9004:2018 Evidence Products Checklist by Clause

ISO 9004:2018 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2.1 Managing for the sustained success of an organization (Cont.1)	<ul style="list-style-type: none"> • Organization's Mission, Vision and Values Determination, Implementation and Communication (by Top Management) to Promote an Aligned Culture Procedure (3) • Organization's Performance Monitoring, Analysis, Evaluation and Review (by Top Management) Procedure (3) • Organization's Policies, Strategies and Objectives Determination, Implementation and Communication (by Top Management) Procedure (2) 				

Section 2
ISO 9004:2018 Evidence Products Checklist by Clause

ISO 9004:2018 Clause Number and Name	Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2.1 Managing for the sustained success of an organization (Cont. 2)	<ul style="list-style-type: none"> • Organization's Relevant Process Determination and Management (by Top Management) Within a Coherent System Procedure (2) • Organization's Resources Management to Achieve Intended Results (by Top Management) Procedure (2) • Top Management Short and Long Term Risks and Opportunities Plan Procedure (4) 				
4.2.2 Managing for the sustained success of an organization	<ul style="list-style-type: none"> • Consideration of Needs and Expectations of the Organization's Interested Parties Procedure (3) 				