SEPT EVIDENCE PRODUCT CHECKLIST

For ISO Standard 9004:2009 Managing for the sustained success of an organization – A quality management approach

2009 Version

ISBN 978-0-9819522-6-0 ISBN 0-9819522-6-7

SEPT EVIDENCE PRODUCT CHECKLIST

For ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach

2009 Version

Author: Andy Coster, CCP

ISBN 978-0-9819522-6-0

ISBN 0-9819522-6-7

Produced by
Software Engineering Process Technology
(SEPT)
2725 NW Pine Cone Drive
Issaquah, WA. 98027
Tel. 425-391-2344

E-mail: <u>Stanmagee@smartwire.net</u>
Web Site: www.12207.com

© 2003- 2010, V17 Software Engineering Process Technology (SEPT) All rights reserved.

SEPT Evidence Product Checklist for Standard--ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach

Overview of the Standard ISO 9004:2009

The 2009 edition of ISO 9004 *Managing for the sustained success of an organization* – *A quality management approach* - is the third edition of the standard first published in 1987. This standard provides organizations with a model for "sustained success" in today's complex, demanding, and ever-changing environment based on the following key concepts:

- 1. **Sustainability** to support the achievement of sustained success by any organization, regardless of size, type or activity, by a quality management approach.
- Continual Improvement of an organization's overall performance, efficiency
 and effectiveness based on a process-based approach. It focuses on meeting the
 needs and expectations of customers and other relevant parties, over the long
 term, and in a balanced way.
- 3. **Performance Improvement** providing a broader perspective of quality management than ISO 9001:2008. This is particularly useful for performance improvement. It will prove useful to organizations whose top management wishes to move beyond ISO 9001, in pursuit of ongoing improvement, measured through the satisfaction of customers and other stakeholders.
- 4. **Self Assessment** -ISO 9004:2009 allows organizations to enhance the quality of product and service delivery to their customers by promoting self-assessment as an important tool to enable organizations to:

Benchmark their level of maturity, covering leadership, strategy, management system, resources and processes

Identify their strengths and weaknesses

Identify opportunities for either improvements or innovation, or both.

5. **Independence** - although ISO 9004:2009 complements ISO 9001:2008 (and vice versa), it can also be used independently. It is not intended for third-party certification, regulatory, or contractual use, nor as a guide to the implementation of ISO 9001:2008. To help users get the best out of the standard, an annex gives a clause-by-clause correspondence between ISO 9001:2008 and ISO 9004:2009.

The structure of the standard is shown in Fig 1below, including the relationship to ISO 9001:2008.

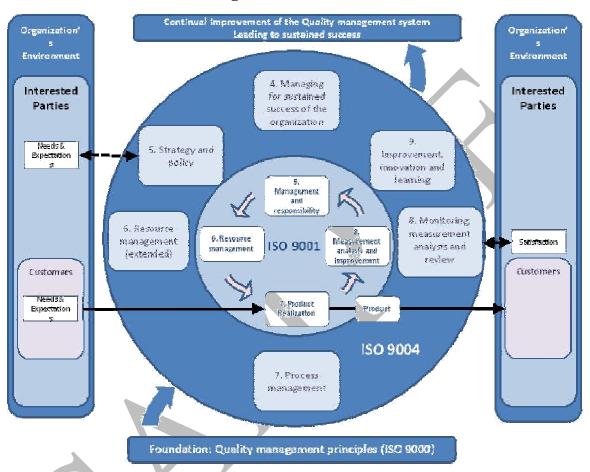


Fig 1 ISO 9004:2009

Introduction to the SEPT Checklist for ISO 9004

ISO 9004 will provide your organization with guidance and support to achieve sustained success by a quality management approach. It can be used by any organization, regardless of size, type and activity. However, what constitutes physical evidence 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.

11/10/2010 4

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. This assigning of maturity level was based on the expert knowledge of the standard and their experience in the quality field.

ISO 9004 provides a wider focus on quality management than ISO 9001. It addresses the needs and expectations of all relevant interested parties. It also provides guidance for the systematic and continual improvement of your organization's overall performance. The checklist is an implementation tool that complements the use of ISO 9004 within your organization.

To support the use of ISO 9004:2009 this checklist is constructed around a classification scheme of physical evidence comprised of policies, procedures, plans, records, documents, and reviews. In this checklist "manuals, reports, scripts and specifications" are included in the document category.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the "Recognition and Reward Plan" could be a part of the "People Motivation 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.

Revision History

New checklist – but see Sept Checklist (ISBN: 9780981952208) for ISO 9001:2008 as a companion document

11/10/2010 5

Using the Checklist

When a company is planning to use "ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach" standard, the company should review the evidence checklist. If the company's present process does not address an ISO 9004:2009 standard product, then this question should be asked: Is the evidence product required for the type of business and maturity level of the company? If in the view of the company 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 six conditions that exist for each item listed in the checklist. The following six conditions and the actions required by these conditions are listed in the table below.

Condition	Action Required
• 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 meeting the expectation of ISO 9004.
• The title of the documented evidence specified by the checklist (document, plan, etc.) disagrees 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 meeting the expectation of ISO 9004, and the evidence is the same although the title is different.
• The title of the documented evidence specified by the checklist (document, plan, etc.) is <i>combined</i> with another piece of evidence.	Record in the checklist the title of the evidence (document, plan, etc.) in which this information is contained. Record that the organization is meeting the expectation of ISO 9004

11/10/2010 6

• The title of the documented evidence specified by the checklist (document, plan, 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.
• The title of the documented evidence specified by the checklist (document, plan, etc.)) is not appropriate for the organization because of the perceived maturity level or business plan.	Record in the checklist that the evidence is not required and the rationale for this decision.
• The title of the documented evidence called out by the checklist (document, plan, etc.) is not planned by the organization and should be planned by it as the organization matures or as the document is needed.	Record in the checklist when this evidence will be planned and reference a plan for accomplishing the task and date.

Components of the Checklist

This checklist is composed of 8 sections:

- Section 1. Introduction
- Section 2. Composites of all suggested ISO 9004:2009 evidence products.
- Sections 3-7. Individual checklists for each evidence type.
- Section 8. "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.

Section 2
ISO 9004:2009 EVIDENCE PRODUCTS CHECKLIST BY CLAUSE

ISO 9	004:2009 Clause Number	Policies and	Plans	Records	Documents	Reviews
	and Name	Procedures				
	Managing for the sustaining uccess of an organization					
4.1 0	General		 Customer Satisfaction and Stakeholder Plan (3) Decision Strategy Plan (3) Resource Utilization Plan (3) 		 Quality Management System Document (3) Quality Management System Processes Used Document (3) 	



Section 2
ISO 9004:2009 EVIDENCE PRODUCTS CHECKLIST BY CLAUSE

ISO 9004:2009 Clause Number	Policies and	Plans	Records	Documents	Reviews
and Name	Procedures				
4.2 Sustained success		 Environment Monitoring and Analysis Plan (4) Innovation and Continual Improvement Plan (4) Interested Parties Engagement Plan (4) Interested Parties Needs Plan (5) Learning Opportunity Plan (4) Long Term Plan (5) Relationship Management Plan (4) Resource Management Plan (3) Risk Management Plan (3) 			
4.3 The organization's environment	 Organization Change Management Procedure (3) 	 Interested Party Risk Management Plan (3) 			

Section 2
ISO 9004:2009 EVIDENCE PRODUCTS CHECKLIST BY CLAUSE

ISO 9004:2009 Clause Number	Policies and	Plans	Records	Documents	Reviews
and Name	Procedures				
4.4 Interested parties, needs and expectations	• Interest Parties Definition, Needs and Expectation Procedure (4)				
5 Strategy and policy					
5.1 General		Mission, Vision and Values Communication Plan (3)		Mission, Vision and Values Document (3)	
5.2 Strategy and policy formulation	 Environment Monitoring Procedure (4) Future Resource and Technology Needs Procedure (3) Organization Strategy Formulation and Review Procedure (4) Process Capability Assessment Procedure (4) Strategy and Policy Change Procedure (3) 	 Product Strategy Plan (3) Regulatory Requirements Strategy Plan (3) Organization Strengths, Weaknesses, Opportunities, and Threats Plan 		Organization Strategy and Policies Document (4)	
5.3 Strategy and policy deployment					