SLOVENSKI STANDARD
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Sistemi vodenja kakovosti - Zahteve za presojo organizacij zračnega prometa, vesoljskih poletov in obrambe

Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organizations

Qualitätsmanagementsysteme - Audit-Anforderungen für Organisationen der Luftfahrt, Raumfahrt und Verteidigung

Systèmes de management de la Qualité - Exigences d'audit pour les Organismes de l'Aéronautique, l'Espace et la Défense

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Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organizations

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This European Standard was approved by CEN on 28 March 2011.

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Foreword

This document (EN 9101:2011) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2012, and conflicting national standards shall be withdrawn at the latest by January 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 9101:2008.

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This standard was reviewed by the Domain Technical Coordinator of ASD-STAN's Quality Domain.

To assure customer satisfaction, aviation, space, and defence organizations must produce and continually improve, safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.

This document standardizes the requirements for conducting and reporting of quality management system audits. It provides requirements for an audit and reporting process based on:

- the process and continual improvement approach defined in 9100-series standards;
- the specific aviation, space, and defence additions in 9100-series standards;
- the use of common audit tools; and
- the uniform, transparent, and standardized reporting of audit results.

It can be used by aviation, space, and defense organizations at all levels throughout the global supply chain.

In this European Standard, the word "shall" indicates a requirement and the word "should" a recommendation to meet the intent of the standard. Words "typical", "example", or "e.g." indicate suggestions given for guidance. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This standard has been completely rewritten to incorporate the 2009 changes to IAQG 9100-series standard quality management system requirements, the requirements for accredited Certification Bodies (CBs) introduced by International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 17021, and inputs received from industry stakeholders associated to process based auditing methods

and the evaluation of process effectiveness. It replaces the existing versions of 9101, 9111, and 9121 (e.g., AS9101C, AS9111, AS9121, EN 9101:2006, EN 9111:2005, EN 9121:2005, SJAC 9101C).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

0 Introduction

0.1 General

Auditing is a basic tool to assess effective implementation of and conformity to quality management system requirements. In addition to the determination of conformity, this standard focuses on the evaluation of effectiveness of the quality management system and its associated processes.

An organization is not only required to be in conformity with quality management system requirements, but to be effective in meeting customer expectations and delivering products that meet those expectations. In other words, an organization must not only meet the requirements of the quality management system standard, but at the same time deliver products that satisfy customer expectations.

Additionally, this standard takes into account the new requirements presented in the 2009 revisions of the 9100-series standards [e.g., critical items, special requirements, On-time Delivery (OTD) performance, risk management, project management].

0.2 Auditing Approach

This standard supports the engagement and evaluation of an organization's quality management system process approach, as required by the 9100-series standards. When evaluating an organization's quality management system, there are basic questions that should be asked of every process, for example:

a) Is the process identified and appropriately defined?

b) Are responsibilities assigned?

c) Are the processes implemented and maintained?

d) Is the process effective in achieving the desired results?

The collective answers to these and other associated questions will contribute to the evaluation results.

Additionally, product quality (as delivered), customer satisfaction, and quality management system effectiveness can be considered as interrelated. This relationship should be reflected in the audit process and associated results.

0.3 Audit Records and Reports

This standard defines the audit records and reports to be generated and maintained. They are critical in providing objective evidence on the conformity and effectiveness of the quality management system (including process effectiveness), and reporting the audit results. They can be used to inform the organization and its customers in a standard format/structure.

Records and reports to be generated are identified within this standard as annexes and shall be used to fulfill the reporting requirements.

NOTE Electronic templates of these documents will be made available by the IAQG.

1 Scope

1.1 General

This European standard defines requirements for the preparation and execution of the audit process. Additionally, it defines the content and composition for the audit reporting of conformity and process effectiveness to the 9100-series standards, the organization's quality management system documentation, and customer/regulatory requirements.

The requirements in this standard are additions or represent changes to the requirements and guidelines in the standards for conformity assessment, auditing, and certification as published by ISO/IEC (i.e., ISO/IEC 17000, ISO 19011, ISO/IEC 17021). When there is conflict with these standards, the requirements of the 9101 standard shall take precedence.

NOTE 1 In this standard, the term "9100-series standards" comprises the following quality management system standards: 9100, 9110, and 9120; developed by the IAQG and published by various national standards bodies.

NOTE 2 In addition to this standard, IAQG publishes recommended practices that can be used by audit teams when executing the audit process.

1.2 Application

This standard shall be used for audits of 9100-series standards by CBs for certification of organizations, under the auspices of the aviation, space, and defense industry certification scheme [also known as Industry Controlled Other Party (ICOP) scheme]. The ICOP scheme requirements are defined in the 9104-series standards.

NOTE 1 Conflicts between 9104-series standards and this standard will be escalated to IAQG and resolved by an IAQG decision(s).

NOTE 2 Relevant parts of this standard (e.g., 4.2.1, 4.2.2, 4.2.3, and 4.2.4) can be used by an organization in support of internal audits (1st party) and external audits at suppliers (2nd party). This includes the audit methodology, guidance material, and document formats [e.g., audit reports, Nonconformity Reports (NCRs), other documents described in the Annexes]. In such case, the words "Certification Body" or "CB" should be read as "auditor" or "auditing organization" as appropriate.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 9100, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*[1)]

EN 9110, *Quality Management Systems — Requirements for Aviation Maintenance Organizations*[1)]

EN 9120, *Quality Management Systems — Requirements for Aviation Space and Defence Distributors*[1)]

EN 9104, *Aerospace series — Quality management systems — Requirements for Aerospace Quality Management System Certification/Registrations Programs*[1)]

1) As developed under the auspice of the IAQG and published by various standards bodies (e.g., ASD-STAN, SAE, CEN, JSA/SJAC, ABNT).

EN 9104-002, *Aerospace series — Quality management systems — Part 002: Requirements for Oversight of Aerospace Quality Management System Certification/Registrations Programs*[1)]

EN 9104-003, *Aerospace series — Quality management systems — Part 003: Requirements for Aerospace Quality Management System (AQMS) Auditor Training and Qualification*[1)]

IAF MD 2:2007, *IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems*

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17021:2006, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*

3 Terms and definitions

For the purpose of this standard, the terms and definitions provided in ISO 9000, ISO/IEC 17000, 9100-series standards, 9104-series standards (i.e., 9104, 9104-002, 9104-003), and the following apply.

3.1
containment

action to control and mitigate the impact of a nonconformity and protect the customer's operation (stop the problem from getting worse); includes correction, immediate corrective action, immediate communication, and verification that the nonconforming situation does not further degrade

3.2
major nonconformity

a non-fulfilment of a requirement which is likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products; it can be one or more of the following situations:

a) a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;

b) the absence of or total breakdown of a system to meet a 9100-series standard requirement, an organization procedure, or customer quality management system requirement;

c) any nonconformity that would result in the probable shipment of nonconforming product; and/or

d) a condition that could result in the failure or reduce the usability of the product or service and its intended purpose

3.3
minor nonconformity
a non-fulfilment of a requirement which is not likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products; it can be either one of the following situations:

a) a single system failure or lapse in conformance with a 9100-series standard or customer quality management system requirement; or

b) a single system failure or lapse in conformance with a procedure associated to the organization's quality management system

NOTE A number of minor nonconformities against one requirement (e.g., similar nonconformities associated to different sites or different departments/functions/processes within a single site) can represent a total breakdown of the system and thus be considered a major nonconformity.

3.4
Nonconformity Report (NCR)
a document stating results and providing objective evidence of nonconformity against audit criteria, including the following information: containment, correction, root cause, corrective action implementation, and closure

3.5
Objective Evidence Record (OER)
a document recording objective evidence of the audit findings, including reference to the reviewed or observed procedures, records, products, processes, and associated NCRs and opportunities for improvement

3.6
Online Aerospace Supplier Information System (OASIS)
web-based IAQG database containing information on participating IAQG member companies, National Aerospace Industry Associations (NAIAs), National Accreditation Bodies (NABs), accredited CBs, authenticated Aerospace Experience Auditors (AEAs), certified suppliers, certificates, and assessment results

3.7
Process Effectiveness Assessment Report (PEAR)
a document stating results and providing evidence of determination on the effectiveness of a process

4 Auditing and reporting

Referenced ISO/IEC 17021 and ISO 19011 clauses shall be invoked as requirements, including the associated 'practical help' text in applicable ISO 19011 clauses.

4.1 General

Audit Process

The audit process and associated activities (see 4.1.1) shall be followed when auditing and certifying quality management systems in the aviation, space, and defence industry.

The audit process established to assess conformity, including the determination of effectiveness, of quality management systems to the 9100-series standards shall meet the requirements of ISO/IEC 17021 and the additional requirements defined by this standard.

The audit process requirements consist of three main parts:

a) the phases of the audit process (see 4.1.1);

b) information on the common activities (see 4.2) that shall be used to support the audit phases; and

c) the specific requirements for each audit phase (see 4.3).

Audit Methodology

The audit can be conducted through the use of various auditing methods to determine the quality management system conformity, including the determination of effectiveness. The methodologies defined in 4.1.2 are complementary to audit practices of ISO 19011 and can be employed to establish audit trails and facilitate information collection.

4.1.1 Audit Process

The audit process consists of the following phases (see Table 1):

a) Pre-audit activities (see 4.3.1);

b) Stage 1 audit (see 4.3.2);

c) Stage 2 audit (see 4.3.3);

d) Surveillance audit (see 4.3.4); and

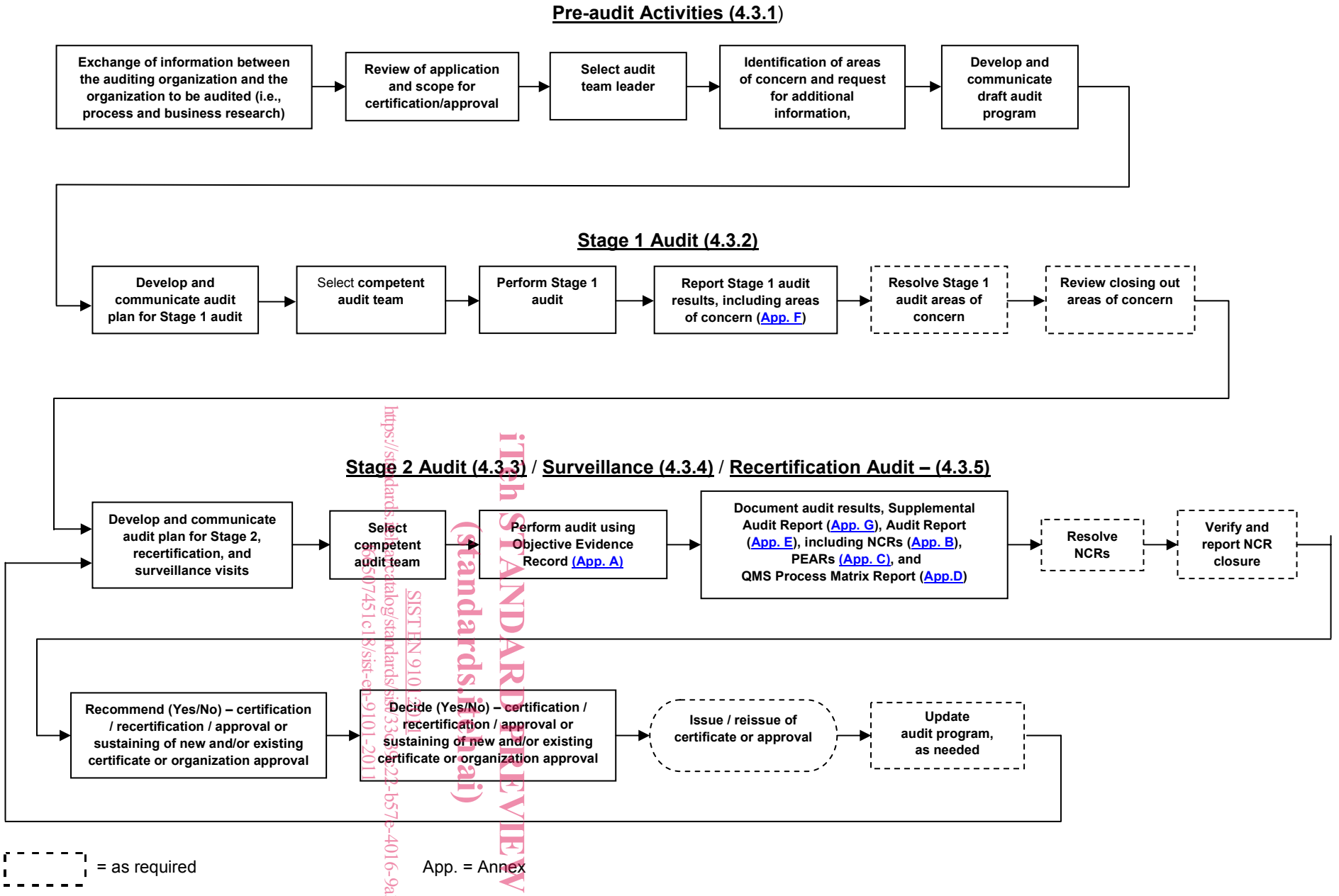
e) Recertification audit (see 4.3.5).

Pre-audit activities, Stage 1, and Stage 2 are applicable for initial certification. Stage 1 audit can be utilized for recertification [see ISO/IEC 17021, 9.4].

NOTE 1 Although 'Special Audit' is not listed as a part of the audit program, it can be applicable after initial certification when directed by special request. The requirements for special audits are addressed in 4.3.6.

NOTE 2 Although certification is formally part of the audit process, the requirements for certification are defined by the 9104-series standards.

Table 1 — Overview of audit process flow



Common Activities

Audit planning, on-site auditing, and audit reporting are common activities linked with Stage 1, Stage 2, surveillance, and recertification audits. Nonconformity management is common for Stage 2, surveillance, and recertification audits.

The requirements for activities and/or common activities that apply to each phase of the audit program are referenced in Table 2.

The Stage 1, Stage 2, surveillance, and recertification activities shall be described in the audit program established during the 'Pre-audit Activities' phase.

Table 2 — Relationships between audit phases and common audit activities

		Audit Phase (4.3)				
			Audit Program			
		Pre-audit Activities (4.3.1)	Stage 1 (4.3.2)	Stage 2 (4.3.3)	Surveillance (4.3.4)	Recertification (4.3.5)
Common Activity (4.2)	Audit Planning (4.2.1)	√	√	√	√	√
	On-site Auditing (4.2.2)	—	√	√	√	√
	Audit Reporting (4.2.3)	—	√	√	√	√
	Nonconformity Management (4.2.4)	—	—	√	√	√

4.1.2 Audit Methodology

The following approaches identify different audit methods that can be used, as appropriate, to conduct audits.

NOTE The identified methods are not intended to be a complete listing, but represent a significant contribution for auditors to evaluate quality management system conformity and effectiveness. Use of these methods will help transition from clause based auditing and put focus on the actual processes, their effectiveness, and their ability to meet the quality objectives.

4.1.2.1 Customer Focus

The audit team should assess whether customer satisfaction is adequately evaluated and appropriate actions are taken by the organization based on available performance information (e.g., nonconformity data, corrective action requests, results of satisfaction surveys, complaints regarding product quality, OTD, service provision, responsiveness to customer and internal requests) provided by the organization's customers (e.g., scorecards, report cards). In addition, organization related 'feedback requests' received through OASIS should be evaluated to confirm they have been adequately addressed.

Customer feedback is a process and should be audited as a process; not audited as a clause of the standard. An evaluation should be performed in how this process is managed and its ability to provide meaningful information in order to assess the overall effectiveness of the quality management system.

4.1.2.2 Organizational Leadership

There should be an interview(s) with top management to evaluate the:

a) establishment and continued relevance of the organization's quality policy and objectives;

b) establishment of performance measures aligned to quality objectives;

c) quality management system development, implementation, and continual improvement;

d) top management commitment;

e) quality management system performance and effectiveness;

f) performance to customer expectations (e.g., supplier rating, scorecard, audit results); and

g) actions taken to address issues that are not meeting customer performance expectations.

4.1.2.3 Quality Management System Performance and Effectiveness

The audit of quality management system performance and effectiveness should include a review of the following:

a) the processing and handling of customer complaints, customer feedback data (e.g., periodic performance reports received from customers), and other relevant customer data (e.g., results of customer surveys);

b) results and actions from internal and external audits of the quality management system, including their associated records;

c) stakeholder feedback (e.g., feedback from regulatory authorities or other interested parties);

d) the process and handling of process/product nonconformities, including review of associated corrective actions and evaluation on the effectiveness of actions taken;

e) the process and handling of preventive actions, including evaluation on the effectiveness of actions taken;

f) management review conduct, including review of associated records (e.g., process inputs/outputs, actions taken);

g) internal performance monitoring, measurement, reporting, and reviews against stakeholder and internal performance objectives and targets, including the review of continual improvement activities and associated records;

h) the organization's current performance against targets, including customer specific targets and associated records of applicable corrective actions taken where targets are not being met; and

i) the status and effectiveness of the organization's process performance improvement activities and their outcomes related to product quality.

NOTE Evaluation of the effectiveness of the quality management system should consider how well the system is deployed, as demonstrated by the measures defined by the organization to meet customer satisfaction and organization quality objectives.

4.1.2.4 Process Management

The audit team should conduct quality management system audits using a method that focuses on process performance and effectiveness; this ensures that priority is given to the following:

a) reviewing the organization's processes, their sequence and interactions, and performance against requirements and defined measures, with focus on processes that directly impact the customer;

b) reviewing the process based management techniques, including the examination of process controls (e.g., quality, takt time, cycle time, output effectiveness, control limits, process capability determination);

c) reviewing the process objectives/targets, with focus on areas where objectives/targets have not been achieved and on issues that have the greatest impact on the customer(s);

d) reviewing plans in place to ensure performance objectives/targets are met;

e) reviewing applicable corrective action plans in place where objectives/targets are not met; and

f) pursuing audit trails addressing customer concerns or requests for corrective actions, performance against objectives, and relevant process controls.

The audit team should pursue process based audit trails by following actual products, customer orders, and related documents (e.g., customer contracts, drawings, shop orders, inspection records) through the organization's product realization and associated processes; verifying the interfaces between processes and the linked documentation requirements (see 9100-series standards, 4.2); resource management (see 9100-series standards Clause 6); and measurement, analysis, and improvement (see 9100-series standards Clause 8).

4.1.2.5 Process Performance and Effectiveness

The audit team should audit processes to sufficient depth and detail to evaluate if the organization's processes are capable of meeting planned results and performance levels, including applicable customer specific targets.

NOTE 1 Key Performance Indicators (KPIs) are often used to identify organizational emphasis areas and acceptable performance levels.

The audit team should evaluate, as appropriate, that processes:

a) are identified and appropriately defined;

b) are sequenced and interactions are defined (see 9100-series standards, 4.1.b);

NOTE 2 Often the output from one process directly forms the input to the next (see 0.2 Process Approach in 9100-series standards).

c) have responsibilities assigned and responsible functions identified;

d) have relevant process controls defined;

e) have the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel;

f) are monitored, measured, and analyzed against planned results (determination of process effectiveness);