

**Quality Management Systems
Audit Requirements for Aviation, Space, and Defense Organizations**

RATIONALE

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, EN9101:2006, EN9111:2005, EN9121:2005, SJAC 9101C).

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FOREWORD

To assure customer satisfaction, aviation, space, and defense 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 defense 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 International 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.

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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:

- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the processes implemented and maintained?
- 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 appendices and shall be used to fulfill the reporting requirements.

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

REQUIREMENTS

1. SCOPE

1.1 General

This 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., clauses 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 appendices]. 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 standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- 9100* Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
- 9110* Quality Management Systems – Requirements for Aviation Maintenance Organizations
- 9120* Quality Management Systems – Requirements for Aviation, Space and Defense Distributors
- 9104* Requirements for Aerospace Quality Management System Certification / Registrations Programs
- 9104/2* Requirements for Oversight of Aerospace Quality Management System Registration / Certification Programs
- 9104/3* Requirements for Aerospace Auditor Competency and Training Courses

- 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

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

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, 9104/2, 9104/3), 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-fulfillment 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/services; it can be one or more of the following situations:

- a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
- 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;
- any nonconformity that would result in the probable shipment of nonconforming product; and/or
- 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-fulfillment 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/services; it can be either one of the following situations:

- a single system failure or lapse in conformance with a 9100-series standard or customer quality management system requirement; or
- 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 clause 4.1.1) shall be followed when auditing and certifying quality management systems in the aviation, space, and defense 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 clause 4.1.1);
- b) information on the common activities (see clause 4.2) that shall be used to support the audit phases; and
- c) the specific requirements for each audit phase (see clause 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 clause 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 Figure 1):

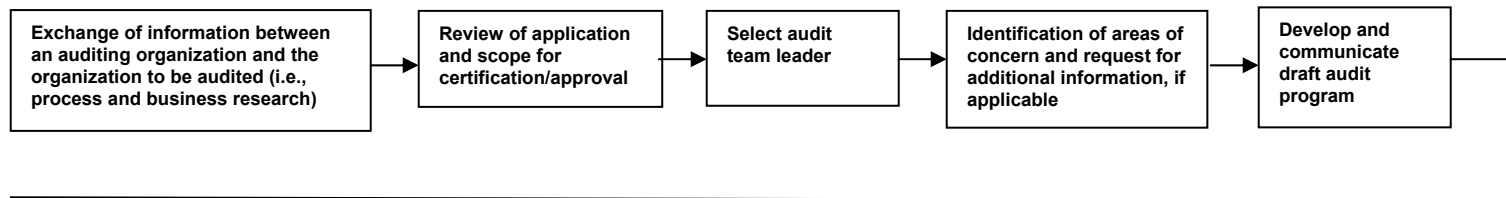
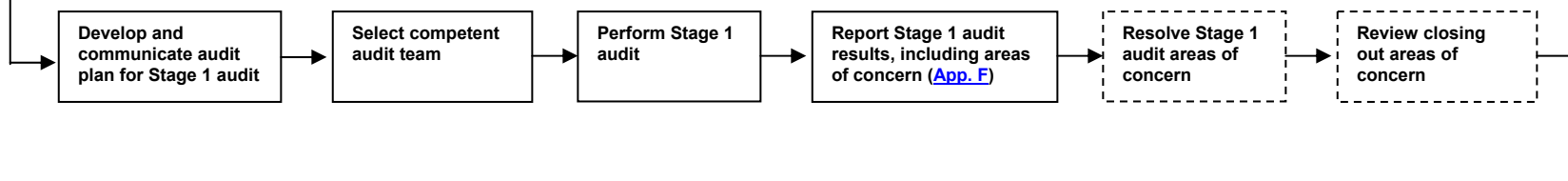
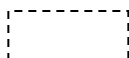
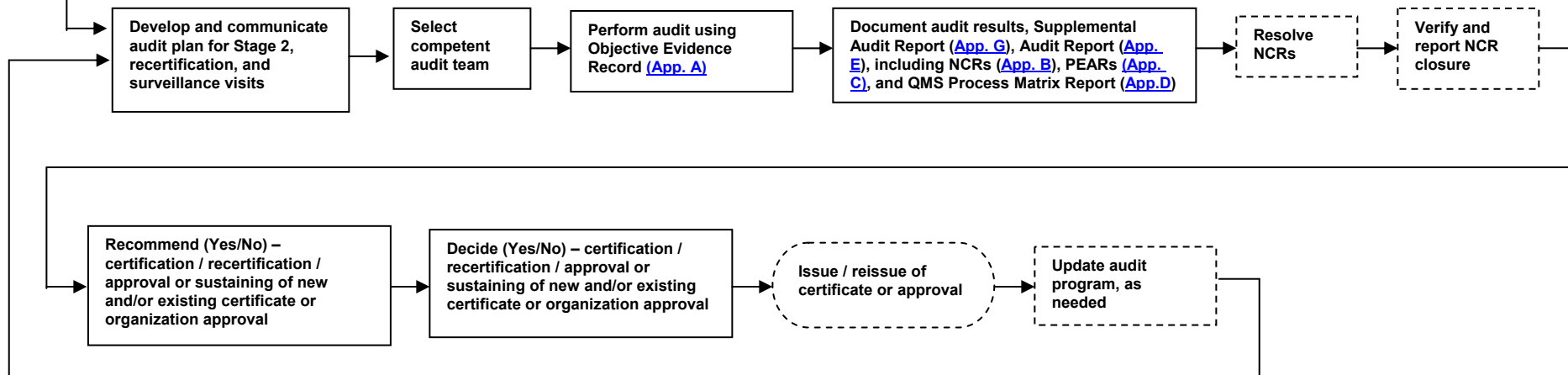
- Pre-audit activities (see clause 4.3.1);
- Stage 1 audit (see clause 4.3.2);

- Stage 2 audit (see clause 4.3.3);
- Surveillance audit (see clause 4.3.4); and
- Recertification audit (see clause 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 clause 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 clause 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.

Pre-audit Activities (clause 4.3.1)**Stage 1 Audit (clause 4.3.2)****Stage 2 Audit (clause 4.3.3) / Surveillance (clause 4.3.4) / Recertification Audit – (clause 4.3.5)**

= as required

App. = Appendix

FIGURE 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 Figure 2.

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

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

FIGURE 2: RELATIONSHIPS BETWEEN AUDIT PHASES AND COMMON AUDIT ACTIVITIES

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), including performance information 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 clause 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, clause 4.1.b);

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

- 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);
- g) have actions implemented to achieve planned results and to promote continual improvement; and
- h) are effective in achieving the desired results (e.g., verify performance information available - percentage of nonconforming parts/products, percentage OTD).

NOTE 3: Planned results can be related to process outputs or the associated activities.



Documents

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4.1.2.6 Continual Improvement

The audit team should evaluate the organization's interrelated processes and activities for continual improvement of the quality management system, its processes, their conformity, and effectiveness in order to:

- ensure focus on issues that are important to the organization, their customers, and regulatory authorities; and
- determine the effectiveness of an organization's approach to continually improving process performance.

NOTE: The organization should be able to demonstrate that they have a structured approach to achieve continual improvement of the quality management system and its processes.

The audit team should develop audit trails from actual situations (e.g., corrective action from an internal audit, response to a customer complaint, management review action item) associated to the following interconnected activities, as applicable:

- a) quality policy and objectives used to reflect the organization's commitment;
- b) identified improvement actions using various inputs, such as:
 - results of internal and external audits;
 - customer satisfaction data, including product quality, OTD performance, and complaints;
 - process performance;
 - aggregate information on corrective and preventive actions;
 - problem resolutions and lessons learned; and
 - benchmarking and sharing of best practices.
- c) management review used to evaluate the status of an improvement action;
- d) availability and management of resources;
- e) continual improvement implementation plan(s);
- f) monitoring and measurement of continual improvement activities, including processes for:
 - monitoring and measurement of continual improvement actions and results;
 - evaluating effectiveness of actions taken and associated results; and
 - initiating modified/additional actions (see b and c above), if results are not satisfactory or effective.

4.2 Common Audit Activities

4.2.1 Audit Planning

[ISO/IEC 17021 clauses 9.1.2 and 9.1.3; ISO 19011 clause 6.4.1]

The audit team shall be appointed before the audit.

The audit planning should take into account:

- a) the scope and complexity of the organization's quality management system;
- b) the processes of the organization, including their sequence and interactions;
- c) the criticality of products and processes, including special processes;
- d) product related safety issues (e.g., airworthiness issues, reporting to customer and/or authorities);
- e) results of internal audits;
- f) previous audit findings;
- g) performance measures and trends for quality and OTD;
- h) previous management review results;
- i) customer satisfaction and complaints log, including feedback requests received by the CB (e.g., items identified through OASIS feedback process);
- j) customer specific, statutory, and regulatory quality management system requirements;
- k) performance data available from customers;
- l) changes to organization (e.g., structure; facilities; business strategy; processes; technologies; a review of requirements from new aviation, space, and defense customers); and
- m) the audit team member's required background/experience and desired competencies.

The audit team leader shall use the organization's customer feedback requests, including those received through OASIS, to assist with audit planning for surveillance and recertification audits. The audit activities shall be prioritized based upon performance data for business risks that can impact the customer (i.e., customer concerns, customer special statuses) and on low performing processes.

As an input into the audit planning process, the audit team leader shall obtain information from the organization regarding their customers on the proportion of aviation, space, and defense business each customer represents, based on their approximate percentage of business. The audit team leader shall ensure that the amount of audit time planned on auditing any one customer's specific quality management system requirements is consistent (approximately) with the proportion of aviation, space, and defense business each customer represents (e.g., customer X may only have 20% of the business so do not spend 80% of the time verifying customer X's specific quality management system requirements).

NOTE: The need to use translators can impact the audit plan/planning and defined audit duration.

4.2.2 On-site Audits

[ISO/IEC 17021 clause 9.1.9]

4.2.2.1 General

Each on-site audit, except for nonconformity follow-up (see clause 4.2.4) and special audits (see clause 4.3.6) shall include the following, as applicable:

- a) a review of the changes to the quality management system, since the last audit;
- b) a review of requirements from new aviation, space, and defense customers, since the last audit;
- c) a review of customer satisfaction information and requested corrective actions and associated responses;
- d) an interview with top management (see clause 4.1.2.2);
- e) an audit of the quality management system performance and effectiveness (see clause 4.1.2.3);
- f) an audit of the organization's processes (their performance and effectiveness, see clauses 4.1.2.4 and 4.1.2.5), as identified in the audit plan (see clause 4.2.1);
- g) an audit of the continual improvement of the quality management system (see clause 4.1.2.6);
- h) an audit of special processes (see clause 4.2.2.8), as identified in the audit plan (see clause 4.2.1);
- i) an audit of follow-up actions from previous audits.

During the audit, the use of relevant audit methods, as described in clause 4.1.2, shall be considered.

NOTE: If there is more than one surveillance audit during a year (e.g., every six months), the activities and items mentioned above can be spread over these audits.

4.2.2.2 Opening Meeting

[ISO 19011 clause 6.5.1]

The opening meeting shall be conducted by the audit team leader. Attendance to the opening meeting shall be recorded. In addition to the criteria mentioned in ISO 19011, the following items shall be addressed, as applicable:

- a) introduce the participants, purpose, and roles of Accreditation Body (AB), Other Party (OP) assessors, or National Aviation Authorities (NAAs), if the certification audit is subject to a witness audit activity;
- b) confirmation of the status of nonconformities from the previous review or audit; and
- c) reconfirmation of any access restrictions for security reasons.

4.2.2.3 Site Tour

The audit team leader may conduct a site tour to address any changes in scope or facilities since the last visit, or to familiarize audit team members with the organizations' activities.

4.2.2.4 Audit Conduct

[ISO 19011 clause 6.5.2]

The audit should be conducted through the use of various auditing methods (see clause 4.1.2), as defined by the audit plan. Furthermore, the audit team should pursue relevant audit trails to assist in the determination of quality management system conformity and effectiveness.

Objective evidence on audit findings shall be recorded in accordance with clause 4.2.2.5.

4.2.2.5 Identifying and Recording of Audit Findings

[ISO/IEC 17021 clauses 9.2, 9.3, and 9.4; ISO 19011 clause 6.5.5]

The audit team shall record detailed objective evidence (e.g., reviewed procedures, shop orders, training records, products, verification records). The objective evidence shall be recorded on a standardized form [i.e., OER (see Appendix A)] or on the CB's own documentation. In this case, the CB document shall meet the intent of the OER. The completed form(s) shall be included in the audit records maintained by the CB.

NOTE 1: Population of the OER may start during the Stage 1 audit to record the documents reviewed.

NOTE 2: If clause 7 of the 9100-series standards and its' sub-clauses are associated with processes that are addressed by PEARs, the objective evidence is only required to be documented on the PEAR. In such case, the PEAR number should be referenced in the OER.

In addition to recording conformity/nonconformity, the audit team may identify opportunities for improvement.

The NCR (see Appendix B) shall be used to record nonconformities; each NCR shall contain only one nonconformity. When nonconformities are identified, the audit team shall categorize the nonconformity as 'major' or 'minor', according to the definitions provided in this standard. The need for containment in accordance with the organization's corrective action process shall be reviewed by the audit team.

Recurrence of the same or similar nonconformity found during consecutive audits at a particular site/location shall be considered as a failure of the corrective action process (see 9100-series standards clause 8.5.2) and shall result in a major nonconformity being issued.

NOTE 3: If there is no evidence of non-fulfillment of a requirement, the auditor cannot issue a nonconformity. If the auditor found evidence of non-fulfillment of a requirement, the auditor determines the nonconformity classification (major/minor). Soft grading of nonconformities and/or identifying them as an observation, opportunity for improvement, or recommendation does not benefit the organization, its customers, or the CB. Furthermore, there is risk that the nonconformity be given a lower priority for correction and/or corrective action or that no action will be taken, and the conditions will expand and/or continue to exist.

The results of effectiveness shall be recorded on the PEAR (see Appendix C) for each audited product realization process. The level of effectiveness for each recorded process shall be recorded on the PEAR (statement of effectiveness level). If the level of effectiveness has been classified as a '2' or a '1', this shall result in a nonconformity being issued against 9100-series standards clauses 4.1.c and f (see clause 4.2.4).

NOTE 4: At the discretion of the auditing organization, other processes can be recorded on a PEAR.

4.2.2.6 Preparing Audit Conclusions

[ISO/IEC 17021 clauses 9.2.4, 9.3, and 9.4; ISO 19011 clause 6.5.6]

Prior to the closing meeting, the audit team shall identify any changes that may be required to the audit program (e.g., scope, audit time or timing, surveillance frequency, audit team competence).

4.2.2.7 Closing Meeting

[ISO 19011 clause 6.5.7]

The closing meeting shall include the following, as a minimum:

- a) an explanation to the organization that audit evidence collected during the audit was a sample and not considered to be all encompassing of the organization's quality management system;
- b) an explanation of the audit team's method for reporting audit findings, including any grading of nonconformities (i.e., major, minor);
- c) an explanation of the process used by the audit team for handling and closing nonconformities, if applicable, and what consequences, if any, there are in relation to the organization's certification or approval status;
- d) the communication to the organization of required time frames for nonconformity correction and corrective action plans, as applicable;
- e) the communication of any audit team activities taking place after completion of the audit (e.g., follow-up on corrective action plans, submittal of audit report);
- f) the communication of the audit team leader's certification recommendation based, upon the completed audit; and
- g) the communication to the organization of how any complaints or appeals pertaining to the audit are to be processed.

4.2.2.8 Special Processes

When special processes (see 9100/9110 clause 7.5.2) are identified in the audit plan, the audit team shall evaluate process validation, as well as, the monitoring, measuring, and control of these processes.

NOTE 1: When an organization declares that special processes are excluded from the scope of certification, the audit team should evaluate the justification of this exclusion during Stage 1 of the initial audit.

a) Verification of Validation of Special Processes

The process records shall be reviewed for each audited special process, including a comparison between actual/planned results and the established arrangements (see 9100 clause 7.5.2).

b) Monitoring, Measurement, and Control of Special Processes

The audit team shall identify process requirements, including customer requirements, for special processes and select a sample of the processes. For the selected process(es), the audit team shall audit the monitoring and measuring equipment used (e.g., calibration, accuracy) and the method for recording the results. If required, the traceability between the process (e.g., batch or load charge identification) and the resulting products shall be verified.

For outsourced special processes, the audit team shall verify that the organization's supplier control process addresses these items accordingly. In addition, the audit team shall review the use of customer-designated sources, as required.

NOTE 2: Special processes are managed by using personnel qualified, as required by organization and/or customer requirements, and by controlling physical or chemical process characteristics [e.g., temperature, time (process duration), pressure, chemical composition of product or process treatment material (surface treatment solution)].

NOTE 3: If an audit(s) has been performed by a customer or by a specialized independent 3rd party, the audit team can take the audit by these organizations into account.

4.2.3 Audit Reporting

[ISO/IEC 17021 clause 9.1.10; ISO 19011 clause 6.6]

The QMS Process Matrix Report (see Appendix D) shall be completed by the audit team for each visited site to demonstrate which processes and quality management system clauses have been audited. The form can be pre-populated prior to on-site activity and easily modified/revised, as appropriate, during each visit. The completed report shall be part of the audit record.

NOTE 1: This form has multiple applications, it can be used:

- after the Stage 1 audit, for preparation of the audit plan for the initial Stage 2 audit;
- after the certification/recertification audit, to prepare the audit plan for the certification cycle surveillance audits; or
- to assist in visibly presenting the cross-references between the standard requirements and the organization's processes.

Exclusions, as justified by the organization and accepted by the audit team, shall be documented in the audit report (see Appendices E and F). Use of "Not Evaluated" (N/E) shall not be used in an initial or recertification audit.

At the conclusion of the Stage 1 audit (see clause 4.3.2.4), the audit report defined in Appendix F shall be compiled and issued. At the conclusion of each certification, surveillance, and recertification audit, audit results shall be recorded and issued containing the information and using the standard templates as defined in Appendices B (if applicable), C, and D. In addition, the Supplemental Audit Report (see Appendix G) shall be used to record results for individual sites, if the audit report (see Appendix E) does not include audit details of the individual sites.

The content in the audit report, including findings, shall give a true and independent view of the conformity status and determination of effectiveness of the quality management system in order to give confidence to customers or potential customers; enabling them to draw appropriate conclusions in their supplier selection and surveillance processes. The audit summary shall reflect the seriousness of the nonconformities (i.e., number, criticality, impact).

NOTE 2: The audit data, including required audit documents/records, needs to be uploaded to OASIS within the time frame specified in 9104.

4.2.4 Nonconformity Management

[ISO/IEC 17021 clauses 9.1. thru 9.4; ISO 19011 clause 6.8]

After issuance of a nonconformity the CB shall:

- a) when the nature of the nonconformity needs immediate containment action, require the organization to determine and report (see Appendix B) the specific containment actions, including correction within 7 calendar days after the audit and reach agreement with the audit team leader within the next 14 calendar days;
- b) require the organization to analyze and report on the NCR (see Appendix B): the root cause and specific correction and corrective actions taken, or planned to be taken, to eliminate the detected nonconformities within a defined time;
- c) agree with the organization on corrective action(s) and corrective action plans within a maximum of 30 days from the end of the on-site audit.
- d) document details of evidence supporting the closure of nonconformities; and
- e) report to the organization after verification of corrective actions is complete.

The NCR (see Appendix B) shall be used to document verification and nonconformity closure.

Evaluation and closing of the corrective action plan and associated corrective actions relating to a nonconformity shall not be performed during the audit in which the nonconformity was issued.

NOTE: Any containment action and correction can be reviewed during the audit.

Verification activities shall be carried out as determined by the audit team leader. Verification shall be carried out on-site, if the verification of the corrective action cannot be carried out based on a review of the documentation and supporting objective evidence provided by the organization.

4.2.5 Audit Records

[ISO/IEC 17021 clauses 9.9]

Information pertaining to the audit (e.g., checklists, questionnaires, auditor notes, records of objective evidence) shall become part of the audit records.

4.3 Audit Phase Specific Requirements

4.3.1 Pre-audit Activities

[ISO/IEC 17021 clauses 8.6, 9.1.1 thru 9.1.9, 9.2.1, and 9.2.2; ISO 19011 clause 6.2]

All activities to be included in the scope of certification shall be relevant to the scope of the applicable 9100-series standards for aviation, space, and defense customers [see guidance on applicability (e.g., 9100 clause 1.2)].

4.3.1.1 General

In addition to the information defined in ISO/IEC 17021 [see clause 9.2.1], the CB shall require the organization to provide the following:

- the revenue for aviation, space, and defense industry, as a proportion of the total revenue;
- the number of employees working for aviation, space, and defense and the total workforce; and
- identification of the major (e.g., top five) aviation, space, and defense customers.

4.3.1.2 Requirements for the Certification Body

Before scheduling the Stage 1 visit, the CB shall:

- appoint an audit team leader that has sufficient knowledge of the activities and the intended scope of certification to determine auditor required competences and/or whether technical experts are needed;
- take into account any additional requirements/requests from the organization and/or the organization's customer(s), as long as they are not in conflict with the provisions of ISO/IEC 17021, to optimize the benefit of the certification audit program; and
- ensure that audit time is identified in accordance with ISO/IEC 17021 [see clause 9.1.4] and 9104.

NOTE: These items can have influence on the audit duration throughout the certification cycle.

Organizations can deny auditors access to proprietary or classified information, and/or areas due to the competitive sensitivity or national security regulations invoked in customer contracts. The CB shall require the organization to provide information if any activities, programs, specifications, and/or areas are not accessible because of restrictive or confidential nature. The scope of certification shall not include processes that were not audited to sufficient depth to verify an organization's conformity, including the determination of effectiveness.

However, they may be included if the processes can be proven to be similar to processes that were assessed and the same quality management system procedures and controls are invoked. In the audit report, exclusions for these programs, customers, and/or activities shall be stated with supporting justification provided.

4.3.1.3 Requirements for the Audit Team Leader

Before scheduling the Stage 1 audit, the audit team leader shall:

- determine if information received during this pre-audit activity phase is sufficient to proceed to the Stage 1 audit; and
- verify the audit duration for the Stage 1 and Stage 2 audits.

4.3.2 Stage 1 Audit

[ISO/IEC 17021 clause 9.2.3.1]

4.3.2.1 General

Before the Stage 1 audit, the audit team leader shall be confirmed and possible audit team members shall be identified. After the Stage 1 audit, the team composition for the Stage 2 audit shall be reviewed based on information received and observed during the Stage 1 audit; followed by the final appointment of the team members.

The Stage 1 audit shall:

- be performed by the audit team leader appointed for the initial audit with audit team assistance if needed; and
- include an on-site visit.

NOTE: For 9120, the Stage 1 audit can be conducted off-site, based on organization considerations (e.g., size, location, risk, previous audit team knowledge).

For organizations with more than one site that have a single quality management system, the Stage 1 audit shall also include an evaluation of the identified central function with the authority for administration, control, audit, review, and maintenance of the quality management system. Additionally, a relevant number of representative sites, including all sites with different technologies and dissimilar activities, shall be included. This will give the audit team sufficient information in order to identify the complexity, risk, and scale of the activities covered by the quality management system subject to certification; any differences between sites; and to what extent each site produce or provide substantially the same kind of products/services according to the same procedures and methods.

The Stage 1 audit shall include a tour of the site facilities. This will enable the audit team to gain a greater understanding of the organization's processes, equipment, areas, products, and state of readiness in preparation for the Stage 2 audit.

4.3.2.2 Collection of Information

During the Stage 1 audit the audit team shall collect sufficient information that allows the CB to:

- confirm the audit program;
- review the need for additional technical experts and/or auditors to compose a competent audit team;
- determine any additional audit activities, as needed, for the fulfilment of the requirements for initial certification; and
- schedule the Stage 2 audit activities.

The audit team leader shall require the organization to provide the necessary information and documentation for review, including the following:

- quality manual;
- description of processes showing their sequence and interactions, including the identification of any outsourced processes;
NOTE 1: The processes can be depicted in various ways [e.g., process maps, turtle diagrams, SIPOC method (breakdown of supplier, inputs, process steps/tasks, outputs, customer), octopus].
- performance measures and trends for the previous 12 months;
- evidence that the requirements of the applicable 9100-series standards are addressed by the organization's documented procedures established for the quality management system (e.g., by referencing them in the quality manual or by using a cross reference);
- interactions with support functions on-site or at remote locations/sites;
- evidence of internal audits of processes/procedures, including internal and external quality management system requirements;
- the latest management review results;
- list of all major (e.g., top five) aviation, space, and/or defense and any other customers requiring 9100-series standard compliance, including an indication of how much business each customer represents and their customer specific quality management system requirements, if applicable; and
- evidence of customer satisfaction and complaint summaries, including verification of customer reports, scorecards, and special status or equivalent.

NOTE 2: Examples of customer specific quality management system requirements are: product process verification, including First Article Inspection (FAI) requirements (e.g., 9102); quality records to be created and maintained by the organization; coordination of document changes; defined special requirements/critical items/key characteristics; approval of design changes by the customer; flow down of requirements to sub-tiers; customer notification of production process changes; traceability; handling of nonconformities; and applicability of other IAQG quality management system standards in contracts (e.g., 9115, 9131).

4.3.2.3 Review of the Organization

During the Stage 1 audit, the subjects listed in clause 4.3.2.2 plus the following items shall be addressed, as applicable:

- number of employees (i.e., full time, part time, contract, temporary) dedicated to aviation, space, and defense;
- number of shifts and shift patterns specific to production and/or maintenance;
- evaluation of multiple site eligibility for determination of audit time and sampling;
- identification of high risk associated with processes and products;
- risk management and associated tools [e.g., Failure Mode and Effect Analysis (FMEA)];
- identification of special processes performed or subcontracted;
- regulatory requirements and authority approvals/recognitions;

- additional requirements on configuration management;
- project/program management;
- continual improvement activities;
- OTD and quality performance measures;
- identification of special requirements/critical items, including key characteristics;
- production process verification [i.e., production readiness, production planning verification, FAI requirements (e.g., 9102)], as invoked in contracts;
- prevention programs [e.g., Foreign Object Debris/Damage (FOD)];
- special work environments [e.g., Electrostatic Discharge Sensitive (ESDS), clean room];
- customer presence at organization [e.g., resident representatives, regular meetings, reason(s) for presence];
- customer satisfaction and complaints status, including customer reports and scorecards;
- any customer specific organization approval statuses, e.g., limited approval, probation, suspension, withdrawal;
- customer restricted areas or proprietary information/confidentiality;
- exclusions from 9100-series standards (exclusions must be limited to clause 7) and supporting justification;
- export limitations/controls [e.g., International Traffic in Arms Regulations (ITAR), Export Administration Regulation (EAR)];
- customer delegated verifications and Materials Review Board (MRB) authority; and
- customer authorized direct ship/direct delivery.

NOTE: The audit team can begin recording objective evidence related to the quality manual, quality management system process documentation, and the applicable process and procedural conformity results to the requirements of the applicable 9100-series standards.

4.3.2.4 Stage 1 Conclusions

The audit team leader shall use the results of the above review and any additional information obtained from the site tour to:

- determine the quality management system implementation status;
- determine the organization's readiness for the Stage 2 audit;
- identify any areas of concern that would be classified as a nonconformity, if not resolved before the Stage 2 audit;
- develop a plan for the Stage 2 audit, that includes any additional quality management system requirements from the organization's aviation, space, and defense customers;
- verify the proposed scope of certification and its applicability to the IAQG scheme and, where necessary, communicate to the organization why the proposed scope should be modified;
- verify the information used for and recommend/revise, as needed, the audit day calculation.



- review the audit time for the Stage 2 audit and update the audit plan accordingly;
- adjust the composition of the audit team for the Stage 2 audit, including the addition of any technical experts or translators that are needed; and
- identify any changes required to the contract and communicate those revisions to the organization and CB.

The audit findings shall be recorded in the Stage 1 Audit Report (see Appendix F). A copy of the audit report shall be given to the organization after completion of the Stage 1 audit.

The CB shall review the status of the areas of concerns to determine preparedness for the Stage 2 audit.

4.3.3 Stage 2 Audit

[ISO/IEC 17021 clause 9.2.3.2]

Stage 1 and Stage 2 audits shall not be performed on the same day or on consecutive days (back to back).

During the on-site activities for the Stage 2 audit, the elements of the quality management system and the associated organization's processes shall be audited for conformity (see Appendix D), including determination of effectiveness. Detailed audit findings, including reference to the audited processes, process documentation, and associated records, shall be documented (see clause 4.2.2.5).

During the opening meeting, the audit team leader shall reconfirm with the organization the issues identified during the Stage 1 audit (see clause 4.3.2).

After the opening meeting, the audit team leader shall:

- a) decide on conducting a facility tour to review substantial changes in scope or facilities, since the last visit; and
- b) revise planning, as needed, due to organization changes since the Stage 1 audit (e.g., personnel changes, department/business unit reorganization, new customer complaint) or any objections from the organization that impact the audit.

All nonconformities shall be closed and verified by the audit team before a recommendation for certification can be made.

NOTE: Requirements for closure of nonconformities are contained in 9104.

4.3.4 Surveillance

[ISO/IEC 17021 clause 9.3]

All clauses of the applicable quality management system standard (except exclusions) and the organization's processes that are part of the quality management system shall be audited during the surveillance audits within one certification cycle. The audit method(s) to be used (e.g., audits on specific problems, areas, products, or sub-processes) shall be based on the outcome of the audit team's review of quality management system performance data.

The audit plan for the surveillance audit shall take consideration of changes in the organization (see clause 4.2.1). The composition of the audit team shall be determined, based on the audit plan for the surveillance audit. Audit plans for surveillance shall be based on continuing operational control of process and on product performance indicators and trends for the previous 12 months (both for quality and OTD).

Detailed audit findings, including reference to the audited processes, process documentation, and associated records, shall be documented (see clause 4.2.2.5).

For surveillance audits, the audit team leader shall advise within the audit report (see Appendix E) whether the recorded nonconformities should be reason for suspension of the certificate. Failure by the organization to demonstrate effective corrective action to deal with repeat nonconformities, the lack of actual performance data, or lack of operational control shall warrant suspension of the certification.

NOTE 1: If there is more than one surveillance audit during a year (e.g., every six months), the activities and items mentioned under clause 4.2.2.1 can be spread over these audits.

NOTE 2: Requirements for closure of nonconformities are contained in 9104.

4.3.5 Recertification

[ISO/IEC 17021 clause 9.4]

The recertification audit should be planned a minimum of three months before the expiry date of the current certificate. The 'scope of certification' shall be verified prior to each recertification audit. Any change of customer approval status shall be reviewed by the audit team to determine the impact on the certification status. During on-site activities for recertification, the elements of the quality management system and the associated organization's processes (see Appendix D) shall be audited for conformity, including determination of effectiveness.

The organization's quality manual and quality management system process documentation shall be reviewed for changes. Detailed audit findings, including reference to the audited processes, process documentation, and associated records, shall be documented (see clause 4.2.2.5).

All nonconformities shall be closed and verified by the audit team before a recommendation for recertification can be made.

NOTE 1: Requirements for closure of nonconformities are contained in 9104.

NOTE 2: Appointment of a new audit team could be a justification for a full or partial Stage 1 audit, including an on-site visit by the audit team.

4.3.6 Special Audits

[ISO/IEC 17021 clause 9.5]

Special audits can be performed anytime during the certification cycle in response to one of the following situations:

- a) in response to a customer or other interested party request, when a serious issue (supported by objective evidence) has been identified;

NOTE: In this case, the requester shall be notified in advance of the audit dates and made aware of the audit results.

- b) in response to an organization's request to change their scope of certification (commonly known as extensions to scope) or revise the listing of certified sites; or

- c) when transferring certification from one CB to another.

NOTE: In this case, the pre-transfer review of the existing certification (see IAF MD 2) shall include an audit of the prospective organization site(s) by an AEA. Items listed in clause 4.2.1 shall be evaluated, including a review of previous certification audits performed by their prior CB (see requirements for transfer of certifications defined in 9104).

These audits shall be coordinated with the organization prior to the visit. The organization shall be given information about the specific reason and subject of the visit.

An audit plan shall be completed and submitted to the organization prior to arrival. The results for special audits shall be documented on the applicable appendices (e.g., Appendices A, B, C, and E).