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(R) Quality Management Systems Audit Requirements for Aviation, Space, and Defense Organizations		

#### RATIONALE

This standard has been revised to incorporate the requirements for accredited Certification Bodies (CBs) introduced by International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17021:2011, 9104/1:2012, and inputs received from industry stakeholders associated to process-based auditing methods and the evaluation of process effectiveness.

#### 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/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, at all levels of the supply chain, throughout the world. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

Industry 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 document has been prepared by the IAQG and standardizes the requirements for conducting and reporting of Quality Management System (QMS) audits. It can be used by aviation, space, and defense organizations at all levels throughout the global supply chain.

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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.

In this 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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## TABLE OF CONTENTS

INTRODUCTION.....	4
0.1 General .....	4
0.2 Auditing Approach.....	4
0.3 Audit Records and Reports.....	4
REQUIREMENTS .....	5
1. SCOPE.....	5
1.1 General .....	5
1.2 Application.....	5
2. NORMATIVE REFERENCES.....	5
3. TERMS AND DEFINITIONS .....	6
3.1 Containment.....	6
3.2 Key Performance Indicator (KPI) .....	6
3.3 Major Nonconformity .....	6
3.4 Minor Nonconformity .....	7
3.5 Nonconformity Report (NCR).....	7
3.6 Online Aerospace Supplier Information System (OASIS) .....	7
3.7 Planned Activities.....	7
3.8 Planned Results.....	7
3.9 Process Effectiveness Assessment Report (PEAR).....	7
4. AUDITING AND REPORTING.....	7
4.1 General .....	8
4.1.1 Audit Process .....	8
4.1.2 Audit Approaches.....	8
4.1.3 Reporting.....	12
4.2 Common Audit Activities .....	13
4.2.1 Audit Planning .....	13
4.2.2 Conducting On-site Audits .....	14
4.2.3 Audit Report .....	17
4.2.4 Nonconformity Management.....	18
4.3 Audit Phase Specific Requirements .....	19
4.3.1 Pre-audit Activities.....	19
4.3.2 Stage 1 Audit.....	20
4.3.3 Stage 2 Audit.....	23
4.3.4 Surveillance Audit .....	23
4.3.5 Recertification Audit .....	24
4.3.6 Special Audit .....	24
5. NOTES.....	24
APPENDIX A ACRONYM LOG .....	25
APPENDIX B FORMS .....	26
FIGURE 1 OVERVIEW OF AUDIT PROCESS FLOW.....	9
TABLE 1 CERTIFICATION STRUCTURE REPORTING MATRIX.....	12
TABLE 2 RELATIONSHIP BETWEEN COMMON ACTIVITIES AND AUDIT PHASES.....	13
TABLE 3 PROCESS EVALUATION MATRIX.....	17

## INTRODUCTION

### 0.1 General

Auditing is a basic tool to assess effective implementation of and conformity to QMS requirements. In addition to the determination of conformity, this standard focuses on the evaluation of effectiveness (see ISO 9000 clause 3.2.14) of the QMS and its associated processes.

An organization is not only required to be in conformity with QMS requirements, but to be effective in meeting customer expectations and delivering products that meet those 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 QMS process approach, as required by the 9100-series standards. When evaluating an organization's QMS, 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 adequately 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.

In addition, product quality (as delivered), customer satisfaction, and QMS 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, during the audit process. They are critical in providing the organization and its customers with objective evidence on the conformity and effectiveness of the QMS (including process effectiveness), and reporting the audit results in a standard format/structure.

## REQUIREMENTS

### 1. SCOPE

#### 1.1 General

This standard defines requirements for the preparation and execution of the audit process. In addition, it defines the content and composition for the audit reporting of conformity and process effectiveness to the 9100-series standards, the organization's QMS documentation, and customer and statutory/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/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 Aerospace Quality Management System (AQMS) standards: 9100, 9110, and 9120; developed by the IAQG and published by various national standards bodies.

NOTE 2: In addition to this standard, the IAQG publishes deployment support material on the IAQG website (see <http://www.sae.org/iaqg/>) 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 (i.e., 9104/1, 9104/2, 9104/3).

NOTE: Relevant parts of this standard can be used by an organization in support of internal audits (1st party) and external audits at suppliers (2nd party).

### 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
9102*	Aerospace First Article Inspection Requirements
9104/1*	Requirements for Aviation, Space, and Defense Quality Management System Certification Programs
9104/2*	Requirements for Oversight of Aerospace Quality Management System Registration/Certification Programs
9104/3*	Requirements for Aerospace Auditor Competency and Training Courses
9115*	Quality Management Systems - Requirements for Aviation, Space and Defense Organizations - Deliverable Software (Supplement to 9100)
9131*	Quality Management Systems - Nonconformance Data Definition and Documentation

\*As developed under the auspice of the IAQG and published by various standards bodies [e.g., SAE International, European Committee for Standardization (CEN), Japanese Standards Association/Society of Japanese Aerospace Companies (JSA/SJAC), Brazilian Association for Technical Norms (ABNT)].

IAF MD 2:2007	IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
IAF MD 3:2008	IAF Mandatory Document for Advanced Surveillance and Recertification Procedures
IAF MD 4:2008	IAF Mandatory Document for the Use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems
IAQG Procedure 119	Forms Management
ISO 9000:2005	Quality management systems - Fundamentals and vocabulary
ISO/IEC 17000:2004	Conformity assessment - Vocabulary and general principles
ISO/IEC 17021:2011	Conformity assessment - Requirements for bodies providing audit and certification of management systems

### 3. TERMS AND DEFINITIONS

For the purpose of this standard, the terms and definitions provided in ISO 9000, ISO/IEC 17000, 9100-series standards, 9104/1 standard, and the following apply. Furthermore, an acronym log for this standard is presented in Appendix A.

#### 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 Key Performance Indicator (KPI)

Measures associated with goals or targets showing how well an organization is achieving its objectives or critical success factors for a particular project. KPIs are used to objectively define a quantifiable and measurable indication of the organization's progress towards achieving its goals.

#### 3.3 Major Nonconformity

A non-fulfillment of a requirement which is likely to result in the failure of the QMS 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 QMS requirement;
- any nonconformity that would result in the probable shipment of nonconforming product; and
- a condition that could result in the failure or reduce the usability of the product or service and its intended purpose.

### 3.4 Minor Nonconformity

A non-fulfillment of a requirement which is not likely to result in the failure of the QMS or reduce its ability to assure controlled processes or compliant products/services; it can be a single system failure or lapse in conformance with one of the following conditions:

- a 9100-series standard requirement;
- a customer QMS requirement; or
- a procedure associated to the organization's QMS.

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.

### 3.5 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.

### 3.6 Online Aerospace Supplier Information System (OASIS)

Web-based IAQG database containing information on participating IAQG member companies, National Aerospace Industry Associations (NAIA), National Accreditation Bodies (NAB), accredited CBs, authenticated Aerospace Experience Auditors (AEAs), Aerospace Auditors (AAs) certified suppliers, certificates, and audit results.

### 3.7 Planned Activities

The means, methods, and internal requirements by which the organization intends to achieve planned results of a given process to meet customer requirements. Planned activities include conformity to process requirements and procedures.

### 3.8 Planned Results

The intended performance of a process, as defined and measured by the organization. Planned results include product conformity and OTD to meet customer requirements, and may include other elements related to the process, as defined by the organization.

### 3.9 Process Effectiveness Assessment Report (PEAR)

A document stating process evaluation results; providing evidence of conformity to requirements and process effectiveness.

## 4. AUDITING AND REPORTING

The audit and reporting process established to assess conformity, including the determination of QMS effectiveness to the 9100-series standards, shall meet the requirements of ISO/IEC 17021, as stated in each relevant clause of this standard. Additional audit requirements for the aviation, space, and defense industry are invoked by this standard.

For combined and integrated audits, the requirements of 9104/1 clause 8.2.3 apply.

#### 4.1 General

The audit process and associated activities (see clause 4.1.1) shall be followed when auditing and certifying organizations to AQMS standards in the aviation, space, and defense industry.

The audit process requirements consist of three main parts:

- a. the phases of the audit process (see clause 4.1.1);
- b. 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).

##### 4.1.1 Audit Process

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

- a. Pre-audit activities (see clause 4.3.1);
- b. Stage 1 audit (see clause 4.3.2);
- c. Stage 2 audit (see clause 4.3.3);
- d. Surveillance audit (see clause 4.3.4); and
- e. Recertification audit (see clause 4.3.5).

Pre-audit activities and Stage 1/Stage 2 audits are applicable for initial certification. A Stage 1 audit can also be utilized for recertification audits and during CB transfer.

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: The requirements for certification are defined by the 9104/1 standard.

##### 4.1.2 Audit Approaches

The following approaches (see clauses 4.1.2.1 thru 4.1.2.6) shall be used, as appropriate, to conduct each on-site audit.

###### 4.1.2.1 Customer Focus

The audit team shall determine that customer satisfaction is being 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).

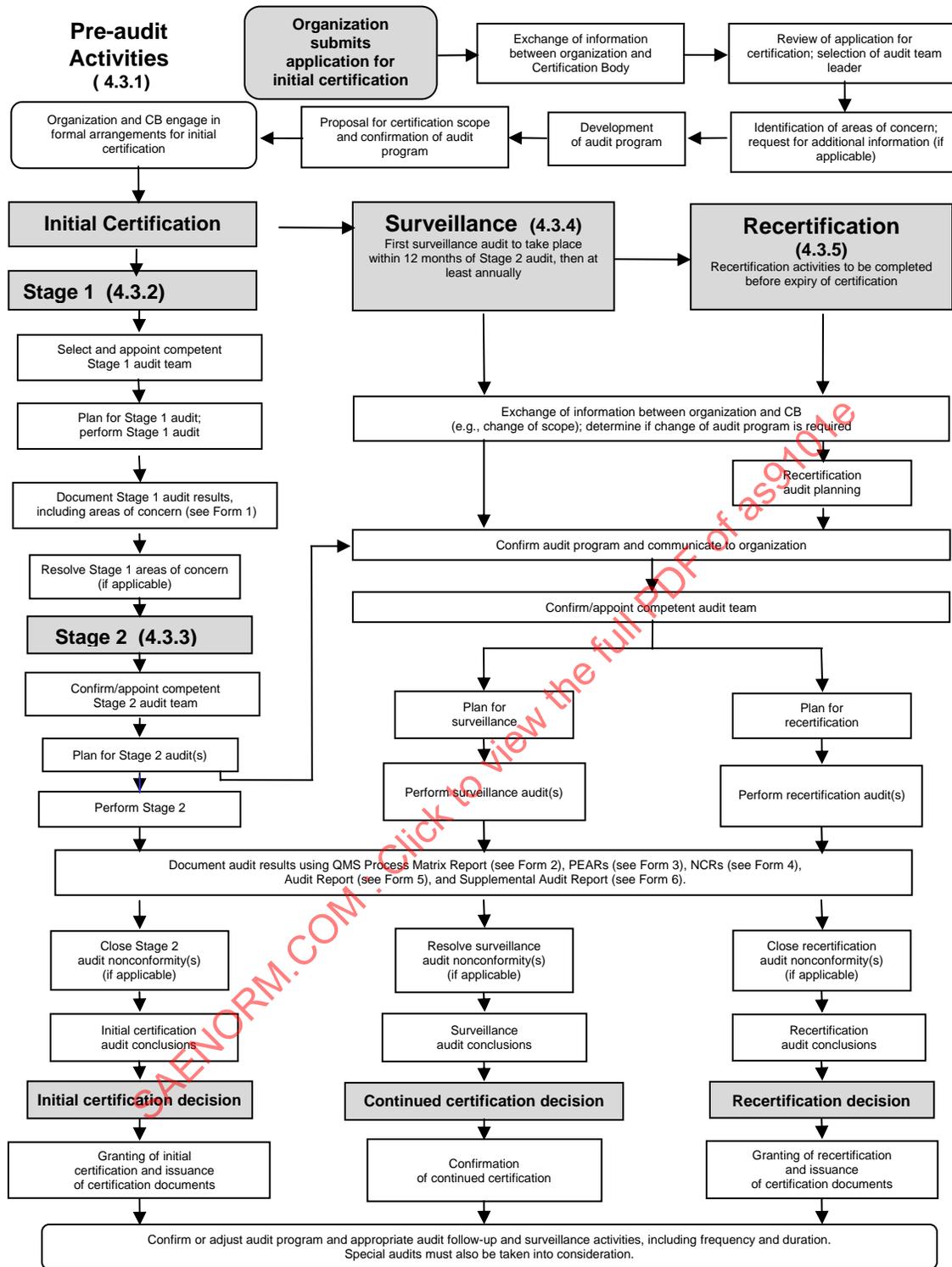


FIGURE 1 - OVERVIEW OF AUDIT PROCESS FLOW (SEE ISO/IEC 17021 - FIGURE E.1)

#### 4.1.2.2 Organizational Leadership

There shall 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. QMS development, implementation, and continual improvement;
- d. top management commitment;
- e. QMS 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 QMS performance and effectiveness shall include a review of the following:

- a. the processing 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 QMS, including their associated records;
- c. stakeholder feedback (e.g., feedback from regulatory authorities or other interested parties);
- d. the processing of process/product nonconformities, including review of associated corrective actions and evaluation on the effectiveness of actions taken;
- e. the processing of preventive actions, including evaluation on the effectiveness of actions taken;
- f. management review conduct, including 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 continual improvement activities and associated records;
- h. the organization's current performance against targets, including customer specific targets and associated records of applicable 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.

#### 4.1.2.4 Process Management

The audit team shall conduct QMS 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, the identification of functions and assignment of responsibilities, and performance against requirements and defined measures, with focus on processes that directly impact the customer;
- b. reviewing the process for validation and approval of processes and process changes;

- c. reviewing the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel;
- d. reviewing the process-based management techniques, including the examination of process measures (e.g., quality, takt time, cycle time, output effectiveness, control limits, process capability determination);
- e. reviewing plans in place to ensure performance objectives/targets are monitored, measured, and analyzed in order to realize the planned activities and achieve the planned results (e.g., verify performance information availability, percentage of nonconforming parts/products, percentage OTD);
- f. reviewing applicable action taken when objectives/targets are not met to promote continual improvement; and
- g. pursuing audit trails addressing customer concerns or requests for corrective actions, performance against objectives, and relevant process controls.

The audit team shall 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: KPIs are used to identify an organization's progress towards achieving its performance goals.

NOTE 2: KPIs relating to financial information are not in the scope of the 9101 standard.

NOTE 3: 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 Special Processes

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

- a. The process records shall be reviewed for each audited special process, including the established arrangements and a comparison between actual and planned results.
- b. The audit team shall identify and select a sample of special processes, including those defined by the customer. For the selected special processes, 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.
- c. In the case of 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 1: 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 2: 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. This can include audit results, sampling of the findings, and verification of any reported nonconformities to determine adequate resolution (i.e., no recurrence).

#### 4.1.2.6 Continual Improvement

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

- a. ensure focus on issues that are important to the organization, their customers, and regulatory authorities; and
- b. 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 QMS and its processes.

#### 4.1.3 Reporting

Reporting requirements associated with AQMS certification structures (see 9104/1 clause 3.11) are included in Table 1.

TABLE 1 - CERTIFICATION STRUCTURE REPORTING MATRIX

Type of Certification Structure \ Audit Phase	Single Site	Multiple Sites	Campus	Several Sites	Complex Organization
<b>Stage 1 Audit</b>	<ul style="list-style-type: none"> <li>• Stage 1 Audit Report (Form 1)</li> </ul>				
<b>Stage 2 Audit</b> <b>Surveillance</b> <b>Recertification</b>	<ul style="list-style-type: none"> <li>• QMS Process Matrix Report (Form 2); per site</li> <li>• PEAR (Form 3); per site or combined, as appropriate</li> <li>• Nonconformity Report (NCR) (Form 4); as applicable</li> <li>• Audit Report (Form 5)</li> <li>• Supplemental Audit Report (Form 6); optional</li> </ul>				
<b>Special Audit</b>	<ul style="list-style-type: none"> <li>• PEAR (Form 3); per site or combined, as appropriate</li> <li>• NCR (Form 4); as applicable</li> <li>• Audit Report (Form 5)</li> </ul>				

Recording of process information may be combined into a single PEAR for multiple sites, several site, campus, or complex organizations, provided that the process is common across sites/structures. Information recorded shall reflect each site included in the PEAR. The process effectiveness level shall reflect the lowest value of the various sites assessed.

In accordance with IAQG Procedure 119, representations of the 9101 forms are presented in Appendix B for reference only. Electronic versions of these forms, with supporting instructions, are available via the forms section of the IAQG website: <http://www.sae.org/iaqg/>. Use of these electronic forms is mandatory and variations are not permissible; however, expanding the fields to accommodate the recording of information is permissible.

## 4.2 Common Audit Activities

Audit planning, on-site auditing, and audit reporting are common activities linked with Stage 1, Stage 2, surveillance, recertification, and special audits. Nonconformity management is common for Stage 2, surveillance, and recertification audits. The requirements for activities and common activities that apply to each phase of the audit program are referenced in Table 2.

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

**TABLE 2 - RELATIONSHIP BETWEEN COMMON ACTIVITIES AND AUDIT PHASES**

Common Activity \ Audit Phase	Pre-audit Activities (4.3.1)	Stage 1 (4.3.2)	Stage 2 (4.3.3)	Surveillance (4.3.4)	Recertification (4.3.5)	Special (4.3.6)
Audit Planning (4.2.1)	X	X	X	X	X	X
On-site Auditing (4.2.2)		X	X	X	X	X
Audit Reporting (4.2.3)		X	X	X	X	X
Nonconformity Management (4.2.4)			X	X	X	X

### 4.2.1 Audit Planning

The requirements of ISO/IEC 17021 clauses 9.1.2 thru 9.1.8 apply.

In addition, the audit plan shall be based on the processes defined by the organization and documented in the QMS Process Matrix Report (see Form 2).

The audit team leader shall use the organization's customer feedback requests, including those received through the OASIS database (see 9104/1 clause 14.2), to assist with audit planning for surveillance and recertification audits. The audit activities shall be prioritized based upon performance data for business risks that could impact the customer (i.e., customer concerns, customer special statuses) and on processes that are not achieving planned results.

Audit planning shall take into account:

- the sequence and interactions of the organization's processes;
- the criticality of products and processes, including special processes;
- the risks associated with product or process maturity (e.g., new product introduction, new process equipment or facilities);
- product related safety issues (e.g., airworthiness issues, reporting to customer and/or authorities);
- results of internal audits;
- previous audit findings (e.g., CBs, customers, regulatory authorities);
- performance measures and trends for quality and OTD (e.g., KPIs, scorecards, dashboards);

- h. previous management review results;
- i. customer requirements;
- j. statutory/regulatory requirements;
- k. customer satisfaction/performance data;
- l. certification structure [i.e., single site, multiple site, campus, several sites, complex organization (see 9104/1)];
- m. integrated and/or combined audits (see 9104/1 clause 8.2.3);
- n. use of Advanced Surveillance and Recertification Procedures (ASRP) (see 9104/1 clause 8.9);
- o. use of CAAT (see 9104/1 clause 8.10); and
- p. the proportion of aviation, space, and defense business each customer represents.

NOTE: The audit team leader should ensure that the amount of audit time planned on auditing any one customer's specific QMS requirements is consistent (approximately) with the proportion of aviation, space, and defense business each customer represents (e.g., if customer X has 20% of the business, the audit team should not spend 80% of their time verifying customer X's specific QMS requirements).

#### 4.2.2 Conducting On-site Audits

##### 4.2.2.1 General

The requirements of ISO/IEC 17021 clause 9.1.9 apply.

In addition, 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 QMS, since the last audit (including certification structure);
- 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 (see clause 4.1.2.1);
- d. an interview with top management (see clause 4.1.2.2);
- e. an audit of the organization's processes, including their performance and effectiveness (see clauses 4.1.2.3, 4.1.2.4, and 4.1.2.5), as identified in the audit plan (see clause 4.2.1);
- f. an audit of the continual improvement of the QMS (see clause 4.1.2.6);
- g. an audit of follow-up actions from previous audits; and
- h. an audit of the purchasing process (see 9104/1 clause 8.2.2.n).

NOTE: If there is more than one surveillance audit during a year (e.g., every six months), some activities (e.g., interview with top management) may be spread over these audits.

#### 4.2.2.2 Conducting the Opening Meeting

The requirements of ISO/IEC 17021 clause 9.1.9.2 apply.

In addition, in case of a non-single site certification structure:

- a. the AEA shall conduct site specific opening meetings; or
- b. a central opening meeting shall be conducted with representatives from all sites, either physically or by means of electronic/distance meeting methods (e.g., net-meeting, Webex, Meet-me).

#### 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 organization's activities.

#### 4.2.2.4 Audit Conduct

The requirements of ISO/IEC 17021 clauses 9.1.9.3 thru 9.1.9.5 apply.

In addition, the audit shall be conducted through the use of various auditing approaches (see clause 4.1.2). The audit team shall pursue relevant audit trails to assist in the determination of QMS conformity and effectiveness.

NOTE: Audit tools may be developed (e.g., check sheets, questionnaires) to help auditors in the collection of objective evidence during the audit process.

#### 4.2.2.5 Identifying and Recording of Audit Findings

The requirements of ISO/IEC 17021 clause 9.1.9.6 apply.

The audit team shall complete the QMS Process Matrix Report (see Form 2) to demonstrate which processes and 9100-series standard clauses have been audited, including a summary of objective evidence related to each 9100-series standard clauses 4, 5, 6, and 8. For recording a summary of objective evidence related to the product realization process, see clause 4.2.2.5.2.

NOTE 1: If objective evidence for clauses 4, 5, 6, and 8 are recorded on PEAR(s), there is no need repeat these details on the QMS Process Matrix Report. Reference to the applicable PEAR(s) should be stated in the respective QMS Process Matrix Report objective evidence field.

NOTE 2: Form 2 has multiple applications, it can be:

- Pre-populated, prior to on-site activity, and easily modified/revised, as appropriate, during each visit.
- Used after the Stage 1 audit, for preparation of the audit plan for the initial Stage 2 audit.
- Used after the certification/recertification audit, to prepare the audit plan for the certification cycle surveillance audits.
- Used to assist in visibly presenting the cross-references between the AQMS standard requirements and the organization's processes.

The NCR (see Form 4) 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 immediate containment shall be identified 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 major nonconformity against the corrective action process (see 9100-series standards clause 8.5.2).

NOTE 3: 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 would be given a lower priority for correction and/or corrective action, or that no action would be taken and the conditions will expand and/or continue to exist.

#### 4.2.2.5.1 Process Results

The audit team shall record measures, targets, and values of KPIs related to each audited product realization process (see 9100-series standards clause 7) on the PEAR (see Form 3 - section 2), taking into account the confidentiality of information (see ISO/IEC 17021 clause 8.5 requirements).

NOTE: Upon mutual agreement between the organization and the CB, other processes can be recorded on a PEAR.

Nonconformities determined from the evaluation of the process results shall be categorized as 'major' or 'minor', and issued against the relevant 9100-series standard clause.

#### 4.2.2.5.2 Process Realization

The audit team shall record a summary of audit trails and audit evidence related to each audited product realization process (see 9100-series standards clause 7) on the PEAR (see Form 3 - section 3).

Nonconformities determined from the evaluation of process realization shall be categorized as 'major' or 'minor', and issued against the relevant 9100-series standard clause.

NOTE: Population of the PEAR may start during the Stage 1 audit to record information (e.g., documents, procedures, records) reviewed.

#### 4.2.2.5.3 Process Effectiveness

The audit team shall evaluate the effectiveness of each audited product realization process (see 9100-series standards clause 7) considering:

- a. process realization - the extent to which planned activities are realized (see clause 3.7); and
- b. process results - the extent to which planned results are achieved (see clause 3.8).

In order to determine the effectiveness level of the audited process, the audit team shall evaluate the audit evidence arising from the PEAR (see Form 3 - sections 2 and 3) and select the corresponding value based upon the descriptions given in the Process Evaluation Matrix (see Table 3). The process effectiveness level derived from the evaluation shall be recorded in the PEAR (see Form 3 - section 4) and documented on the QMS Process Matrix Report (see Form 2).

The audit team shall verify that a 'major' NCR (see Form 4) has been issued against 9100-series standard clause 4.1.c and/or 4.1.f, when the effectiveness level of the process is rated a "1".

An effectiveness level of "4" shall only be determined, if the audited process is delivering planned results and no nonconformities were identified.

NOTE: NCRs issued against 9100-series standard clauses 4.1.c or 4.1.f, resulting from multiple PEARS, may be combined into a single NCR.

#### 4.2.2.6 Preparing Audit Conclusions

The requirements of ISO/IEC 17021 clause 9.1.9.7 apply.

TABLE 3 - PROCESS EVALUATION MATRIX

<b>Process Realization (a)</b>	<b>Planned activities fully realized</b>	a) The process is defined, implemented, and planned activities fully realized; however, b) The process is not delivering the planned results and appropriate action is not being taken. <b>2</b>	a) The process is defined, implemented, and planned activities fully realized; however, b) The process is not delivering the planned results, but appropriate action is being taken. <b>3</b>	a) The process is defined, implemented, and planned activities fully realized; and b) The process is delivering the planned results. <b>4</b>
	<b>Planned activities not fully realized</b>	a) The process is defined and implemented, but planned activities not fully realized; and b) The process is not delivering the planned results and appropriate action is not being taken. <b>2</b>	a) The process is defined and implemented, but planned activities not fully realized; and b) The process is not delivering the planned results, but appropriate action is being taken. <b>2</b>	a) The process is defined and implemented, but planned activities not fully realized; however, b) The process is delivering the planned results. <b>3</b>
	<b>Planned activities not realized</b>	a) The process is not defined, implemented, and planned activities not realized; and b) The process is not delivering the planned results and appropriate action is not being taken. <b>1</b>	a) The process is not defined, implemented, and planned activities not realized; and b) The process is not delivering the planned results, but appropriate action is being taken. <b>2</b>	a) The process is not defined, implemented, and planned activities not realized; however b) The process is delivering the planned results. <b>2</b>
		<b>Planned results not achieved and appropriate action is not taken</b>	<b>Planned results not achieved, but appropriate action is being taken</b>	<b>Planned results are achieved</b>
<b>Process Results (b)</b>				

#### 4.2.2.7 Conducting the Closing Meeting

The requirements of ISO/IEC 17021 clause 9.1.9.8 and 9104/1 clause 8.5 apply.

In addition, at the closing meeting, the audit team leader shall, at a minimum, provide the organization with any applicable NCRs (see Form 4) and associated PEARs (see Form 3).

#### 4.2.3 Audit Report

The requirements of ISO/IEC 17021 clause 9.1.10 apply.

In addition, at the conclusion of the Stage 1 audit (see clause 4.3.2.4), the Stage 1 Audit Report (see Form 1) shall be compiled and issued. At the conclusion of each certification, surveillance, and recertification audit, the audit results shall be recorded and issued including the standard forms [i.e., QMS Process Matrix Report (see Form 2); PEAR (see Form 3); NCR (see Form 4), if applicable; Audit Report (see Form 5)]. The Supplemental Audit Report (see Form 6) shall be used to record results for individual sites, if the Audit Report (see Form 5) does not include audit details of the individual sites.

Exclusions, as justified by the organization and accepted by the audit team, shall be documented in the Audit Report [see Stage 1 Audit Report (Form 1), QMS Process Matrix Report (Form 2), and Audit Report (Form 5)].

The content in the Audit Report (see Form 5), including findings, shall give a true and independent view of the conformity status and determination of effectiveness of the QMS in order to give confidence to customers or potential customers; enabling them to draw appropriate conclusions in their supplier selection and surveillance processes.

NOTE 1: The audit data, including required audit documents/records, needs to be uploaded to the OASIS database within the time frame specified (see 9104/1 Appendix C).

For combined and integrated audits, separate reports shall be issued (i.e., one for each audit performed for each standard). Where appropriate, processes common between the standards may be reported on the same PEAR (see Form 3) and QMS Process Matrix Report (see Form 2). Each report for combined and integrated audits shall be linked to all other reports from the audit.

NOTE 2: When copies of the organization's records/documents are used in audit report preparation (e.g., by the team leader off-site), all associated documentation should be returned to the audited organization.

#### 4.2.4 Nonconformity Management

The requirements of ISO/IEC 17021 clauses 9.1.11 thru 9.1.13 apply.

In addition, after issuance of a nonconformity the audit team leader shall:

- a. require the organization to analyze the root cause and report the specific correction and corrective actions taken, or planned to be taken, to eliminate the detected nonconformities on the NCR (see Form 4); and
- b. agree with the organization on correction, corrective action(s), and corrective action plans within a maximum of 30 calendar days from the end of the on-site audit.

When the nature of the nonconformity needs immediate containment action, the audit team leader shall require the organization to:

- describe the immediate actions ('fix now') taken to contain the nonconforming situation/conditions and to control any identified nonconforming products. Correction shall always be recorded; and
- report within 7 calendar days, after the audit, the specific containment actions, including correction, and reach agreement on those actions with the audit team leader within the next 14 calendar days.

NOTE 1: Containment action and correction can be reviewed during the audit.

The NCR shall be used to document verification of the corrective action. 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.

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. A completed NCR shall be uploaded into the OASIS database, after verification.

For combined and integrated audits, where a nonconformity has been determined in a common process, a single NCR shall be issued referencing the requirements for each AQMS standard. NCRs issued on common processes shall be referenced in both reports.

NOTE 2: Requirements for the closure of identified nonconformities is defined in 9104/1 clause 8.4.

### 4.3 Audit Phase Specific Requirements

The requirements of ISO/IEC 17021 clause 8.5 apply.

Additionally, 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.

Any information considered confidential by the organization's customers and/or authorities, or the organization itself shall not be reported, unless approved by the audited organization.

#### 4.3.1 Pre-audit Activities

The requirements of ISO/IEC 17021 clauses 8.6 and 9.1.1 apply.

Additionally, all activities to be included in the scope of certification shall be relevant to the scope of the applicable 9100-series standards [see guidance on applicability (e.g., 9100 clause 1.2)].

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 QMS procedures and controls are invoked. In the audit report, exclusions for these programs, customers, and/or activities shall be stated with supporting justification provided.

##### 4.3.1.1 Application

The requirements of ISO/IEC 17021 clause 9.2.1 apply.

In addition, the CB shall require the organization to provide the following:

- a. percentage of revenue for aviation, space, and defense industry business, as a proportion of the organization's total revenue;
- b. number of employees associated to aviation, space, and defense business (i.e., full time, part time, temporary) and percentage of the total workforce; and
- c. identification of the major (e.g., top five) aviation, space, and defense customers.

##### 4.3.1.2 Application Review

The requirements of ISO/IEC 17021 clause 9.2.2 apply.

###### 4.3.1.2.1 Requirements for the Certification Body

Before scheduling the Stage 1 visit, the CB shall:

- a. 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;
- b. 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
- c. ensure that audit time is identified in accordance with 9104/1 and, if applicable, ASRP and/or CAAT criteria defined in IAF MD 3 and/or IAF MD 4 respectively.

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

#### 4.3.1.2.2 Requirements for the Audit Team Leader

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

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

#### 4.3.2 Stage 1 Audit

The requirements of ISO/IEC 17021 clause 9.2.3.1 apply, with the following additions:

##### 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:

- a. be performed by the audit team leader appointed for the initial audit with audit team assistance, if needed; and
- b. include an on-site visit; however, for 9120 the Stage 1 audit can be conducted off-site based on consideration of various organization factors (e.g., size, location, risk, previous audit team knowledge).

For organizations with more than one site that have a single QMS, 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 QMS. 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 QMS 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;
- verify that the level of QMS integration, for combined and/or integrated audits (see 9104/1 clause 8.2.3), is as claimed by the organisation during the application review phase;
- determine any additional audit activities, as needed, for the fulfillment 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:

- a. quality manual;
- b. description of processes showing their sequence and interactions, including the identification of any outsourced processes;

NOTE 1: The processes can be documented in various ways, including but not limited to process maps, turtle diagrams, SIPOC method (breakdown of Supplier, Inputs, Process steps/tasks, Outputs, and Customer), and octopus.

- c. product conformity and OTD performance measures and trends;

NOTE 2: The data should be sufficient to allow the audit team leader to make a judgment on performance and trends.

- d. evidence that the requirements of the applicable 9100-series standards are addressed by the organization's documented procedures established for the QMS (e.g., by referencing them in the quality manual or by using a cross reference);
- e. interactions with support functions on-site or at remote locations/sites;
- f. evidence of internal audits of processes/procedures, including internal and external QMS requirements;
- g. management review results;
- h. 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 QMS requirements, if applicable; and

NOTE 3: Examples of customer specific QMS 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 AQMS standards in contracts (e.g., 9115, 9131).

- i. evidence of customer satisfaction and complaint summaries, including verification of customer reports, scorecards, and special status or equivalent.

#### 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:

- a. percentage of revenue for aviation, space, and defense industry business, as a proportion of the organization's total revenue;
- b. number of employees associated to aviation, space, and defense industry business (i.e., full time, part time, temporary) and percentage of total work force;
- c. number of shifts and shift patterns specific to production and/or maintenance;
- d. evaluation of certification structure (i.e., single site, multiple site, campus, several site, complex organization) eligibility for determination of audit time and sampling (see 9104/1);
- e. identification of high risk associated with processes and products;

- f. risk management and associated tools [e.g., Failure Mode and Effect Analysis (FMEA)];
- g. identification of special processes performed or subcontracted;
- h. regulatory requirements and authority approvals/recognitions;
- i. additional requirements associated to configuration management;
- j. project/program management;
- k. continual improvement activities;
- l. OTD and quality performance measures;
- m. identification of special requirements/critical items, including key characteristics;
- n. production process verification, including production readiness, production planning verification, FAI requirements, etc.;
- o. prevention programs [e.g., Foreign Object Debris/Damage (FOD)];
- p. special work environments [e.g., Electrostatic Discharge Sensitive (ESDS), clean room];
- q. customer presence at the organization [e.g., resident representatives, regular meetings, reason(s) for presence];
- r. customer satisfaction and complaints status, including customer reports and scorecards;
- s. customer specific organization approval statuses (e.g., limited approval, probation, suspension, withdrawal);
- t. customer restricted areas or proprietary information/confidentiality;
- u. exclusions from 9100-series standards (exclusions shall be limited to clause 7) and supporting justification;
- v. export limitations/controls [e.g., International Traffic in Arms Regulations (ITAR), Export Administration Regulation (EAR)];
- w. customer delegated verifications and Materials Review Board (MRB) authority; and
- x. customer authorized direct ship/direct delivery.

NOTE: The audit team can begin recording objective evidence related to the quality manual, QMS 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 organization review and additional information obtained from the site tour to:

- a. develop a plan for the Stage 2 audit, that includes any additional QMS requirements from the organization's aviation, space, and defense customers;
- b. 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;
- c. verify the information used for audit day calculation and recommend/revise, as needed;

- d. review the audit time for the Stage 2 audit and update the audit plan accordingly;
- e. adjust the composition of the audit team for the Stage 2 audit, including the addition of any technical experts or translators that are needed;
- f. verify the information used for determination of the certification structure; and
- g. identify any changes required to the contract and communicate those revisions to the organization and CB.

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

The requirements of ISO/IEC 17021 clauses 9.2.3.2, 9.2.4, and 9.2.5 apply.

In addition, Stage 1 and Stage 2 audits shall not be performed on the same day or on consecutive days (back to back). In the event the time period between Stage 1 and Stage 2 exceeds six months, an additional Stage 1 audit shall be conducted.

During the on-site activities for the Stage 2 audit, the elements of the QMS and the associated organization's processes shall be audited for conformity, 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.

#### 4.3.4 Surveillance Audit

The requirements of ISO/IEC 17021 clause 9.3 apply.

In addition, all clauses of the applicable AQMS standard (except exclusions) and the organization's processes that are part of the QMS 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 QMS performance data, including product conformity 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 Form 5) whether the recorded nonconformities should be reason for suspension or withdrawal 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: If there is more than one surveillance audit during a year (e.g., every six months), some activities (reference clause 4.2.2.1) may be spread over these audits.

#### 4.3.5 Recertification Audit

The requirements of ISO/IEC 17021 clause 9.4 apply.

In addition, 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 the recertification, the QMS and the organization's processes that are needed for the QMS shall be audited for conformity (see QMS Process Matrix Report - Form 2), including determination of effectiveness.

The organization's quality manual and QMS 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).

NOTE: 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 Audit

The requirements of ISO/IEC 17021 clause 9.5 apply.

In addition, 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. 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 increase the listing of certified sites.
- c. When transferring certification from one CB to another.

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.

The results for special audits shall be documented on Form 3 (PEAR); Form 4 (NCR), as applicable; and Form 5 (Audit Report).

### 5. NOTES

- 5.1 A change bar (I) located in the left margin is for the convenience of the user in locating areas where technical revisions, not editorial changes, have been made to the previous issue of this document. An (R) symbol to the left of the document title indicates a complete revision of the document, including technical revisions. Change bars and (R) are not used in original publications, nor in documents that contain editorial changes only.

## APPENDIX A - ACRONYM LOG

AA	Aerospace Auditor
AEA	Aerospace Experience Auditor
AQMS	Aerospace Quality Management System
ASRP	Advanced Surveillance and Recertification Procedures
CAAT	Computer Assisted Auditing Techniques
CB	Certification Body
CSOC	Certification Structure Oversight Committee
EAR	Export Administration Regulation
ESDS	Electrostatic Discharge Sensitive
FAI	First Article Inspection
FMEA	Failure Mode and Effect Analysis
FOD	Foreign Object Debris/Damage
IAQG	International Aerospace Quality Group
ICOP	Industry Controlled Other Party
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ITAR	International Traffic in Arms Regulations
KPI	Key Performance Indicator
MRB	Materials Review Board
NAB	National Accreditation Bodies
NAIA	National Aerospace Industry Association
NCR	Nonconformity Report
OASIS	Online Aerospace Supplier Information System
OIN	OASIS Identification Number
OTD	On-time Delivery
PEAR	Process Effectiveness Assessment Report
QMS	Quality Management System
SIPOC	Supplier, Inputs, Process steps/tasks, Outputs, and Customer



## 9101 FORM 1: STAGE 1 AUDIT REPORT (CONTINUED)

9101 FORM 1: STAGE 1 AUDIT REPORT	
# Areas of Concern:  	
<b>AUDIT TEAM LEADER RECOMMENDATION:</b>	
# The Organisation is Ready to Proceed with the Stage 2 Audit:	Yes / No
# If No, Enter Reason(s):  	
# Proposed Stage 2 Auditor days Required:	___ Days
# Proposed Date(s) of the Stage 2 Audit:	
# Composition/Competency of the Audit Team for the Stage 2 Audit:	
<b># Certification Structure Verified:</b>	
Single <input type="checkbox"/>	Multiple <input type="checkbox"/>
Campus <input type="checkbox"/>	Several <input type="checkbox"/>
Complex <input type="checkbox"/>	
<b># Level of GM 8 Integration:</b>	
Fully Integrated <input type="checkbox"/>	Partially Integrated <input type="checkbox"/>
Not Integrated <input type="checkbox"/>	Not Applicable <input type="checkbox"/>
Comments:  	
<b>ORGANISATION CONFIRMATION</b>	
# Upon mutual agreement with customers / potential customers, the organisation will make available all results of this audit including the report, findings, checklists, etc.	
# Organisation Representative Name:	
<b># Audit Team Leader Approval</b>	
Name:	
Date:	
# Report Distribution:	

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