BS EN 9101:2015

BSI Standards Publication

Quality Management Systems — Audit Requirements for Aviation, Space, and Defence Organisations

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National foreword

This British Standard is the UK implementation of EN 9101:2015. It supersedes BS EN 9101:2011 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee ACE/1, International and European Aerospace Policy and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

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

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

This European Standard was approved by CEN on 20 March 2015.

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European foreword

This document (EN 9101:2015) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

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

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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

This document supersedes EN 9101:2011.

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

RATIONALE

This European standard has been revised to incorporate the requirements for accredited Certification Bodies (CBs) introduced by International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) ISO/IEC 17021:2011, EN 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 defence organisations 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. Organisations 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 standardises the requirements for conducting and reporting of Quality Management System (QMS) audits. It can be used by aviation, space, and defence organisations at all levels throughout the global supply chain.

It provides requirements for an audit and reporting process, based on:

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

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

0 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 European Standard focuses on the evaluation of effectiveness (see ISO 9000, subclause 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 European Standard takes into account the new requirements presented in the 2009 revisions of the EN 9100-series standards [e.g. critical items, special requirements, On-time Delivery (OTD) performance, risk management, project management].

0.2 Auditing approach

This European Standard supports the engagement and evaluation of an organization's QMS process approach, as required by the EN 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 European 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.

1 Scope

1.1 General

This European 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 EN 9100-series standards, the organization's QMS documentation, and customer and statutory/regulatory requirements.

The requirements in this European 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 EN 9101 standard shall take precedence.

NOTE 1 In this European Standard, the term "EN 9100-series standards" comprises the following Aerospace Quality Management System (AQMS) standards: EN 9100, EN 9110, and EN 9120; developed by the IAQG and published by various national standards bodies.

NOTE 2 In addition to this European 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 European Standard shall be used for audits of EN 9100-series standards by CBs for certification of organisations, under the auspices of the aviation, space, and defence industry certification scheme [also known as Industry Controlled Other Party (ICOP) scheme]. The ICOP scheme requirements are defined in the EN 9104-series standards (i.e. EN 9104/1, EN 9104/2, EN 9104/3).

NOTE Relevant parts of this European 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

EN 9102[1)], *Aerospace series — Quality systems — First article inspection*

EN 9104-001[1)], *Aerospace series — Quality management systems — Part 001: Requirements for Aviation, Space, and Defence Quality Management System Certification Programs*

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

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

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

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

EN 9115[1)], *Quality Management Systems — Requirements for Aviation, Space and Defence Organisations — Deliverable Software (Supplement to EN 9100)*

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

EN 9131[1)], *Aerospace series — Quality Management Systems — Nonconformance Data Definition and Documentation*

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 European Standard, the terms and definitions provided in ISO 9000, ISO/IEC 17000, EN 9100-series standards, EN 9104/1 standard, and the following apply. Furthermore, an acronym log for this European 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 organisation 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 organisation's progress towards achieving its goals

3.3
major nonconformity
a non-fulfilment 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 EN 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-fulfilment 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 EN 9100-series standard requirement;
- a customer QMS requirement; or
- a procedure associated to the organization's QMS.

Note 1 to entry: 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 organisation 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 organisation. Planned results include product conformity and OTD to meet customer requirements, and may include other elements related to the process, as defined by the organisation

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 EN 9100-series standards, shall meet the requirements of ISO/IEC 17021, as stated in each relevant clause of this European Standard. Additional audit requirements for the aviation, space, and defence industry are invoked by this European Standard.

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

4.1 General

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

The audit process requirements consist of three main parts:

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

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

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

4.1.1 Audit process

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

a) Pre-audit activities (see subclause 4.3.1);

b) Stage 1 audit (see subclause 4.3.2);

c) Stage 2 audit (see subclause 4.3.3);

d) Surveillance audit (see subclause 4.3.4); and

e) Recertification audit (see subclause 4.3.5).

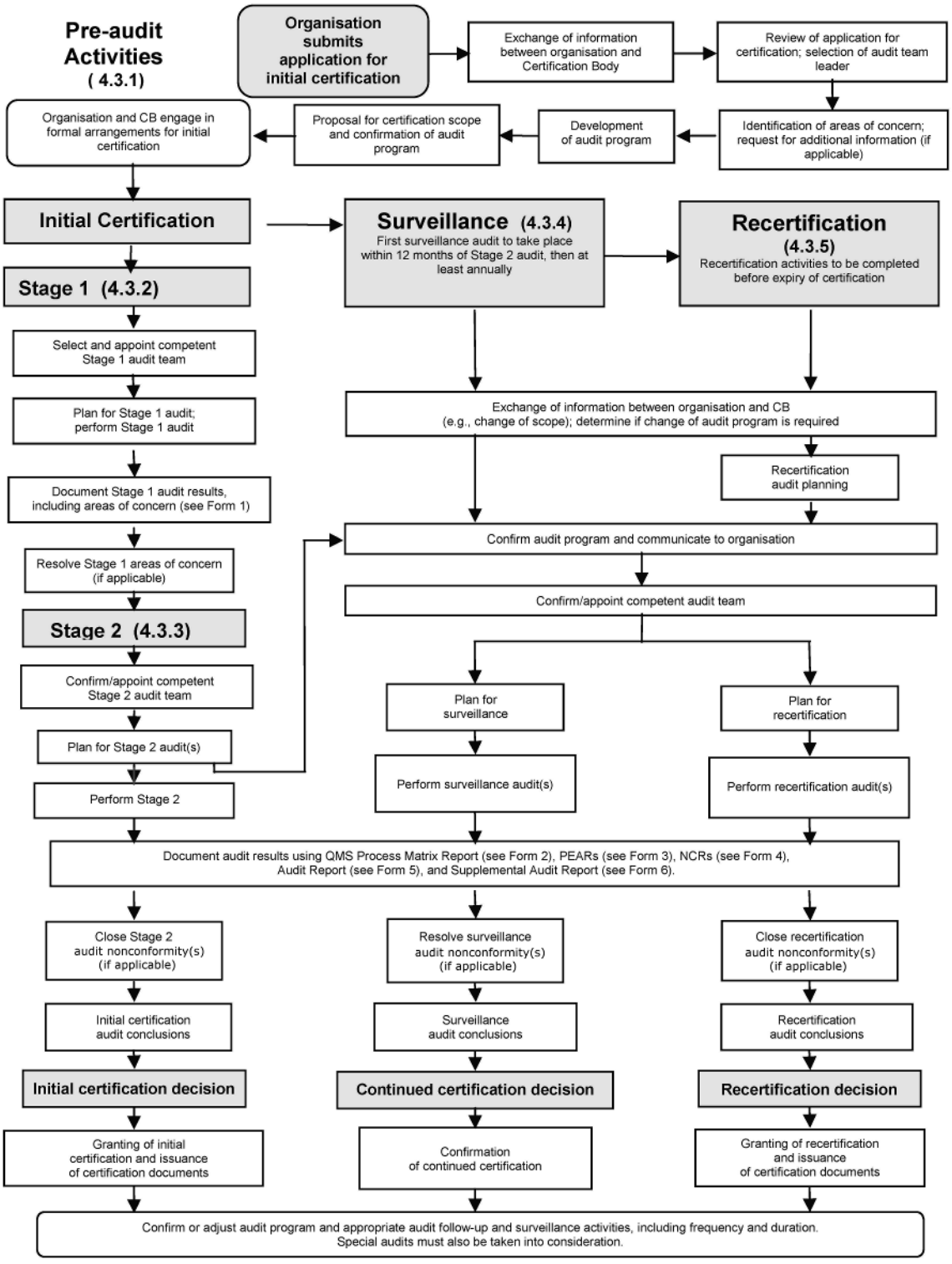


Figure 1 — Overview of audit process flow

(see ISO/IEC 17021:—, Figure E.1)

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 subclause 4.3.6.

NOTE 2 The requirements for certification are defined by the EN 9104/1 standard.

4.1.2 Audit approaches

The following approaches (see subclauses 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).

4.1.2.2 Organisational 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 analysed 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 EN 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 EN 9100-series standards subclause 4.2); resource management (see EN 9100-series standards Clause 6); and measurement, analysis, and improvement (see EN 9100-series standards, Clause 8).

4.1.2.5 Special processes

When special processes (see EN 9100/EN 9110, subclause 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 organisations 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 EN 9104/1, subclause 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
Stage 1 Audit	• Stage 1 Audit Report (Form 1)				
Stage 2 Audit **Surveillance** **Recertification**	• QMS Process Matrix Report (Form 2); per site • PEAR (Form 3); per site or combined, as appropriate • Nonconformity Report (NCR) (Form 4); as applicable • Audit Report (Form 5) • Supplemental Audit Report (Form 6); optional				
Special Audit	• PEAR (Form 3); per site or combined, as appropriate • NCR (Form 4); as applicable • Audit Report (Form 5)				

Recording of process information may be combined into a single PEAR for multiple sites, several site, campus, or complex organisations, 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 EN 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

Audit Phase / Common Activity	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, subclauses 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 EN 9104/1, subclause 14.2), to assist with audit planning for surveillance and recertification audits. The audit activities shall be prioritised 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:

a) the sequence and interactions of the organization's processes;

b) the criticality of products and processes, including special processes;

c) the risks associated with product or process maturity (e.g. new product introduction, new process equipment or facilities);

d) product related safety issues (e.g. airworthiness issues, reporting to customer and/or authorities);

e) results of internal audits;

f) previous audit findings (e.g. CBs, customers, regulatory authorities);

g) 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 EN 9104/1)];

m) integrated and/or combined audits (see EN 9104/1, subclause 8.2.3);

n) use of Advanced Surveillance and Recertification Procedures (ASRP) (see EN 9104/1, subclause 8.9);

o) use of CAAT (see EN 9104/1, subclause 8.10); and

p) the proportion of aviation, space, and defence 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 defence 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, subclause 9.1.9 apply.

In addition, each on-site audit, except for nonconformity follow-up (see subclause 4.2.4) and special audits (see subclause 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 defence customers, since the last audit;

c) a review of customer satisfaction information and requested corrective actions and associated responses (see subclause 4.1.2.1);

d) an interview with top management (see subclause 4.1.2.2);

e) an audit of the organization's processes, including their performance and effectiveness (see subclauses 4.1.2.3, 4.1.2.4, and 4.1.2.5), as identified in the audit plan (see subclause 4.2.1);

f) an audit of the continual improvement of the QMS (see subclause 4.1.2.6);

g) an audit of follow-up actions from previous audits; and

h) an audit of the purchasing process (see EN 9104/1, subclause 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, subclause 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 familiarise audit team members with the organization's activities.

4.2.2.4 Audit conduct

The requirements of ISO/IEC 17021, subclauses 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 subclause 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, subclause 9.1.9.6 apply.

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

NOTE 1 If objective evidence for Clause 4, 5, Clause 6, and Clause 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 European 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 EN 9100-series standards, subclause 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 EN 9100-series standards, Clause 7) on the PEAR (see Form 3 - section 2), taking into account the confidentiality of information (see ISO/IEC 17021, subclause 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 categorised as 'major' or 'minor', and issued against the relevant EN 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 EN 9100-series standards, Clause 7) on the PEAR (see Form 3 - section 3).

Nonconformities determined from the evaluation of process realization shall be categorised as 'major' or 'minor', and issued against the relevant EN 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 EN 9100-series standards, Clause 7) considering:

a) process realization – the extent to which planned activities are realized (see subclause 3.7); and

b) process results – the extent to which planned results are achieved (see subclause 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 EN 9100-series standard, subclause 4.1.c and/or subclause 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 EN 9100-series standard subclauses 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, subclause 9.1.9.7 apply.

Table 3 — PROCESS EVALUATION MATRIX

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

4.2.2.7 Conducting the closing meeting

The requirements of ISO/IEC 17021, subclauses 9.1.9.8 and EN 9104/1, subclause 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, subclause 9.1.10 apply.

In addition, at the conclusion of the Stage 1 audit (see subclause 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 EN 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, subclauses 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 analyse 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 EN 9104/1, subclause 8.4.

4.3 Audit phase specific requirements

The requirements of ISO/IEC 17021, subclause 8.5 apply.

Additionally, organisations 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, subclauses 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 EN 9100-series standards [see guidance on applicability (e.g. EN 9100, subclause 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, subclause 9.2.1 apply.

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

a) percentage of revenue for aviation, space, and defence industry business, as a proportion of the organization's total revenue;

b) number of employees associated to aviation, space, and defence 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 defence customers.

4.3.1.2 Application Review

The requirements of ISO/IEC 17021, subclause 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 EN 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, subclause 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 EN 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 organisations 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 EN 9104/1, subclause 8.2.3), is as claimed by the organization during the application review phase;

- 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:

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 judgement on performance and trends.

d) evidence that the requirements of the applicable EN 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 defence and any other customers requiring EN 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. EN 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. EN 9115, EN 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 subclause 4.3.2.2, plus the following items, shall be addressed, as applicable:

a) percentage of revenue for aviation, space, and defence industry business, as a proportion of the organization's total revenue;

b) number of employees associated to aviation, space, and defence 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 EN 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 EN 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 EN 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 defence 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) adjust the composition of the audit team for the Stage 2 audit, including the addition of any technical experts or translators that are needed;

e) verify the information used for determination of the certification structure; and

f) 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, subclauses 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 subclause 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 subclause 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, subclause 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 subclause 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 subclause 4.2.2.1) may be spread over these audits.

4.3.5 Recertification audit

The requirements of ISO/IEC 17021, subclause 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 subclause 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, subclause 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

A change bar (|) 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
(informative)

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

Appendix B
(normative)

FORMS

EN 9101 **FORM 1: STAGE 1 AUDIT REPORT**

[1] *CB Name*	**STAGE 1 AUDIT REPORT**					[2] *CB Logo*
[3] **Audit Date(s):**		[4] **Audit Duration** (auditor days)	On-site:		[5] **Report No.:**	
			Off-site:		[5] **Report Date:**	

Organization	
[6] **Name:**	[7] **Contact Details**
Address:	Representative:
	Title:
	Telephone:
Subsidiary of:	E-mail:
Website:	OASIS Administrator:

[8] **Preferred Language for Stage 2 Audit:**		[9] Interpreter Needed? (Yes/No):	
[10] Proposed Certification Scope:			
[11] Permitted Exclusions (clauses):			
[12] **Audit Team Leader:**			

Audit Criterion					
[13] **AQMS Standard:**	EN 9100☐	EN 9110☐	EN 9120☐	[14] **Revision(s):**	
[15] **Quality Manual:**				[16] **Revision:**	

[17] **Online Aerospace Supplier Information System (OASIS) Data**					
OIN	**Site**	**Central Function** (yes/no)	**Number of Employees**	**Audit Duration** (Auditor Days)	**Audited** (yes/no)

Business	[18] **Organization Revenue**	[19] **Personnel Numbers**		[20] **Organization Shift Patterns**
	% of Total Revenue	**F/P/T***	**% of Total Workforce**	**Number of Employees E/D/L/N****
Aviation, Space, and Defence				
Other				
**F* = Full Time, *P* = Part Time, T = Temporary **E = Early Shift, D = Day Shift, L = Late Shift, *N* = Night Shift				

[21] **List of Current (C) / Potential (P) – Aviation, Space, and Defence Key Customers**			
Customer	**Address**	**Contact**	**% of Business**

EN 9101 **FORM 1: STAGE 1 AUDIT REPORT**

[22] **HIGH LEVEL REQUIREMENTS CONFIRMATION:** (S = Satisfactory, U = Unsatisfactory)				
Requirement (associated EN 9100-series standard clause)	**Reference**	**S**	**U**	**Comments**
Evidence of the description, interaction, and sequence of processes (4.1), included in the quality manual (on-site or remote) (4.2.2 c).				
Evidence of the identification of outsourced processes (4.1).				
Evidence and applicability of a quality manual (4.2.2).				
Evidence of a **documented procedure** covering control of documents (4.2.3).				
Evidence of a **documented proce**dure covering control of records (4.2.4).				
Evidence of management review planning and results from the previous review(s) (5.6).				
Evidence of a **documented procedure** covering internal audit (8.2.2).				
Evidence of internal audit planning and results of the processes/procedures of the QMS (8.2.2).				
Evidence of a **documented procedure** covering control of nonconforming product (8.3).				
Evidence of a **documented procedure** covering corrective action (8.5.2).				
Evidence of a **documented procedure** covering preventive action (8.5.3).				
Evidence that all the requirements of EN 9100-series standards are addressed by the organization's processes.				

[23] **Comments** *(summary of above, if unsatisfactory)*

EN 9101 FORM 1: STAGE 1 AUDIT REPORT

[24] **KEY CUSTOMER PERFORMANCE:**				
Customer	**Trend of Product Conformity Performance**		**Trend of On-time Delivery Performance**	
	Satisfactory	**Unsatisfactory**	**Satisfactory**	**Unsatisfactory**

[25] **Comments** *(collective summary of above trends, plus any other customer performance information gathered):*

[26] **Customer Quality Management System Approval Status:**	
Customer	**Approval Status**

[27] **ADDITIONAL AVIATION, SPACE, AND DEFENCE CUSTOMER QUALITY MANAGEMENT SYSTEM REQUIREMENTS:**		
Customer	**Description of Additional Requirements**	**Document Reference**

[28] **Comments:**

EN 9101 **FORM 1: STAGE 1 AUDIT REPORT**

[29] **KEY INFORMATION:** (*specific information obtained from the organization, including summary comments)*	
Processes / Activities / Subjects	**Comments**
Process Sequence and Interaction (e.g. process maps, flowcharts)	
High Risk Processes/Products	
Risk Management	
Special Processes (e.g. metal joining, coating, thermal processing, bonding, chemical treatment)	
Regulatory Requirements / Authority Approval / Recognitions	
Configuration Management	
Project Management	
Continual Improvement Activities	
Special Requirements / Critical Items (including key characteristics)	
Product Process Verification (e.g. EN 9102)	
Foreign Object Debris / Damage (FOD) Programs	
Special Work Environment [e.g. Electrostatic Discharge Sensitive (ESDS), clean room, temperature/humidity controls]	
Customer Presence in Organization (e.g. on-site representatives, regular meetings, reason)	
Restricted Areas / Proprietary Information / Confidentiality	
Export Limitations / Controls	
Customer Delegated Inspection	
Nonconforming Product Management [e.g. delegated Materials Review Board (MRB)]	
Evaluation of Certification Structure Applicability [If certification structure is complex, verify Certification Structure Oversight Committee (CSOC) concurrence.]	
Evaluation of Quality Management System – when a combined certification audit is requested	
Customer Satisfaction and Complaints Status	
Customer Authorized Direct Ship / Direct Delivery	

EN 9101 **FORM 1: STAGE 1 AUDIT REPORT**

[30] **Areas of Concern:**

Audit Team Leader Recommendations:				
[31] **The Organization is Ready to Proceed with the Stage 2 Audit:**				Yes / No
[32] **If No, Enter Reason(s):**				
[33] **Proposed Stage 2 Auditor-days Required:**				___ Days
[34] **Proposed Date(s) of the Stage 2 Audit:**				
[35] **Composition/Competency of the Audit Team for the Stage 2 Audit:**				
[36] **Certification Structure Verified:**				
Single ☐	Multiple ☐	Campus ☐	Several ☐	Complex ☐
[37] **Level of QMS Integration:**				
Fully Integrated ☐	Partially Integrated ☐	Not Integrated ☐	Not Applicable ☐	
Comments:				

Organization Confirmation	
[38] Upon mutual agreement with customers / potential customers, the organization will make available all results of this audit including the report, findings, checklists, etc.	
[39] **Organization Representative Name:**	

[40] **Audit Team Leader Approval**	
Name:	
Date:	
[41] **Report Distribution:**	

EN 9101 **Form 2: QMS Process Matrix Report**

1 ***CB Name***	**QMS PROCESS MATRIX REPORT**			2 ***CB Logo***
3 **Organization:**			5 **Audit Report Number:**	
4 **Site/OIN:**			6 **Issue Date:**	
7 **Type of Certification Structure:** **Single ☐ Multiple ☐ Campus ☐ Several ☐ Complex ☐**				
8 **AQMS Standard:** EN 9100 ☐ EN 9110 ☐ EN 9120 ☐				

		ORGANIZATION QMS PROCESSES											
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
9 **Process Name**													
10 **Related Process Effectiveness Assessment Report (PEAR) Identification**													
11 **Process Effectiveness Level**	**1**												
	2												
	3												
	4												

EN 9101 **Form 2: QMS Process Matrix Report**

Clauses (* = not applicable for EN 9120**)**		[12] **Conformity**												[13] **NCR Number**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	
4.	**Quality Management System**													
4.1	General Requirements													
4.2	Documentation Requirements													
4.2.1	Documentation Requirements – General													
4.2.2	Quality Manual													
4.2.3	Control of Documents													
4.2.4	Control of Records													
[14] **Summary of Objective Evidence:**														
5.	**Management Responsibility**													
5.1	Management Commitment													
5.2	Customer Focus													
5.3	Quality Policy													
5.4	Planning													
5.4.1	Quality objectives													
5.4.2	Quality Management System Planning													
5.4.3	Safety Objectives (EN 9110 only)													
5.5	Responsibility, Authority, and Communication													
5.5.1	Responsibility and Authority													
5.5.1.1	Accountable Manager (EN 9110 only)													
5.5.1.2	Maintenance Manager(s) (EN 9110 only)													
5.5.2	Management Responsibility													
5.5.3	Internal Communication													

EN 9101 **Form 2: QMS Process Matrix Report**

Clauses (* = not applicable for EN 9120**)**		[12] **Conformity**												[13] **NCR Number**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	
5.6	Management Review													
5.6.1	General													
5.6.2	Review Input													
5.6.3	Review Output													
5.7	Safety Policy (EN 9110 only)													
[14] **Summary of Objective Evidence:**														
6.	**Resource Management**													
6.1	Provision of Resources													
6.2	Human Resources													
6.2.1	General													
6.2.2	Competence, Training and Awareness													
6.3	Infrastructure													
6.4	Work Environment													
[14] **Summary of Objective Evidence:**														
7.	**Product Realization**													
7.1	Planning of Product Realization													
7.1.1	Project Management *													
7.1.2	Risk Management *													
7.1.3	Configuration Management (7.1.1 for EN 9120)													

EN 9101 **Form 2: QMS Process Matrix Report**

Clauses (* = not applicable for EN 9120**)**		[12] **Conformity**												[13] **NCR Number**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	
7.1.4	Control of Work Transfers (7.1.2 for EN 9120)													
7.2	Customer-Related Processes													
7.2.1	Determination of Requirements Related to the Product													
7.2.2	Review of Requirements Related to the Product													
7.2.3	Customer Communication													
7.3	Design and Development *													
7.3.1	Design and Development Planning *													
7.3.2	Design and Development Inputs *													
7.3.3	Design and Development Outputs *													
7.3.4	Design and Development Review *													
7.3.5	Design and Development Verification *													
7.3.6	Design and Development Validation *													
7.3.6.1	Design and Development Verification and Validation Testing *													
7.3.6.2	Design and Development Verification and Validation Documentation *													
7.3.7	Control of Design and Development Changes *													
7.4	Purchasing													
7.4.1	Purchasing Process													
7.4.2	Purchasing Information													
7.4.3	Verification of Purchased Product													
7.5	Production and Service Provision													

EN 9101 **Form 2: QMS Process Matrix Report**

Clauses (* = not applicable for EN 9120**)**		[12] **Conformity**												[13] **NCR Number**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	
7.5.1	Control of Production and Service Provision													
7.5.1.1	Production Process Verification * ***(Maintenance Process Verification -*** EN 9110***)***													
7.5.1.2	Control of Production Process Changes * ***(Control of Maintenance Process Changes -*** EN 9110***)***													
7.5.1.3	Control of Production Equipment, Tools, and Software Programs * ***(Control of Maintenance Equipment, Tools, and Software Programs -*** EN 9110***)***													
7.5.1.4	Post-Delivery Support *													
7.5.2	Validation of Processes for Production and Service Provision *													
7.5.3	Identification and Traceability													
7.5.4	Customer Property													
7.5.5	Preservation of Product													
7.6	Control of Monitoring and Measuring Equipment													
8.	**Measurement, Analysis, and Improvement**													
8.1	General													
8.2	Monitoring and Measurement													
8.2.1	Customer Satisfaction													
8.2.2	Internal Audit													

EN 9101 Form 2: QMS Process Matrix Report

Clauses (* = not applicable for EN 9120)		[12] Conformity												[13] NCR Number
		1	2	3	4	5	6	7	8	9	10	11	12	
8.2.3	Monitoring and Measurement of Processes													
8.2.4	Monitoring and Measurement of Product													
8.2.5	Evidence of Conformity (EN 9120 only)													
8.3	Control of Nonconforming Product													
8.4	Analysis of Data													
8.5	Improvement													
8.5.1	Continual Improvement													
8.5.2	Corrective Action													
8.5.3	Preventive Action													
[14] **Summary of Objective Evidence:**														

[15] **Auditor Name(s):**	

EN 9101 **Form 3: Process Effectiveness Assessment Report**

1 ***CB Name***	**PROCESS EFFECTIVENESS ASSESSMENT REPORT**	2 ***CB Logo***

3 **Organization:**	4 **Site(s):**	5 **OIN(s):**
6 **PEAR Number:**	7 **Audit Report Number:**	8 **Issue Date:**

Section 1 – Process Details

9 **Process Name:**

10 **AQMS Standard(s):** EN 9100 ☐ EN 9110 ☐ EN 9120 ☐	**Applicable** EN 9100/EN 9110/EN 9120 **clause(s):**

11 **Inputs:**

12 **Activities:**

13 **Outputs:**

14 **Interactions:**

Section 2 – Process Results

15 **Organization's method for determining process results:**

16 **Performance Measures:**

KPI 1:	
KPI 2:	
KPI 3:	

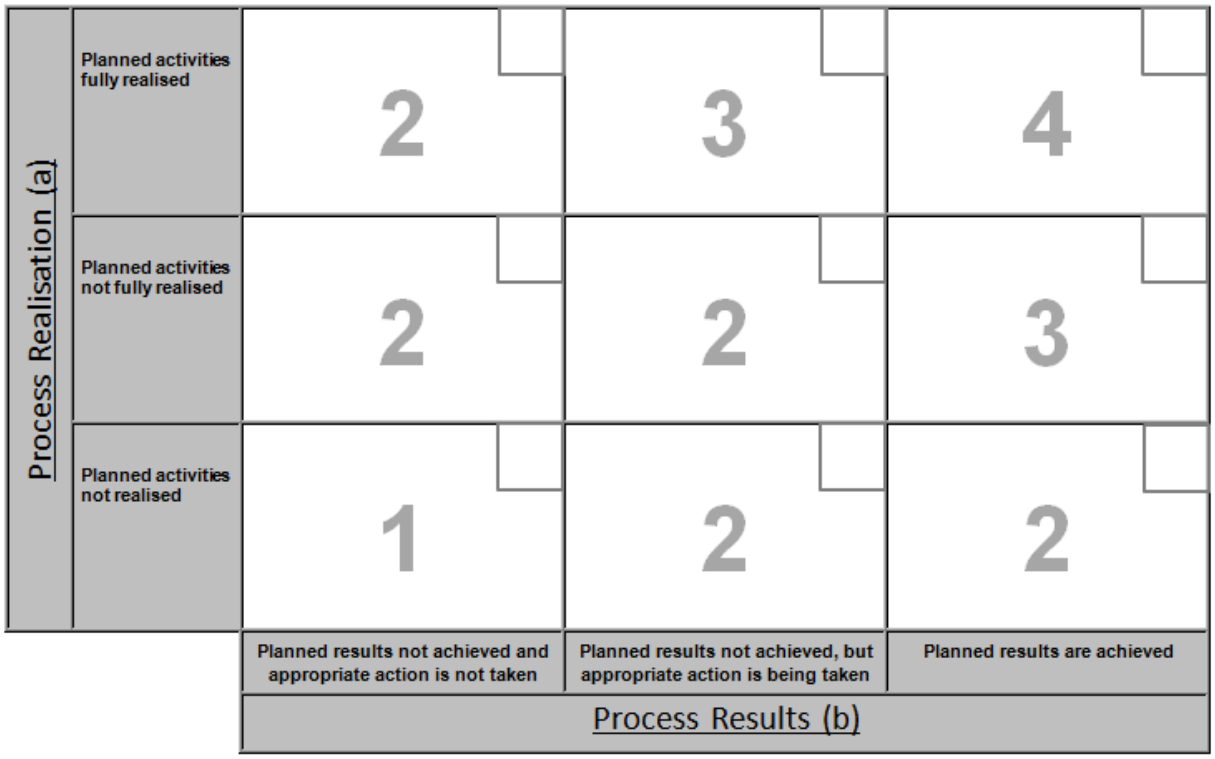
17 **Auditor observations and comments supporting process result determination:**

Reference	Target for Audited Period	Value Measured for Audited Period	Comments
KPI 1:			
KPI 2:			
KPI 3:			

EN 9101 **Form 3: Process Effectiveness Assessment Report**

Section 3 – Process Realization
[18] **Summary of audit trails and sources of evidence:**

Section 4 – Process Effectiveness
[19] **Process Effectiveness Level**



[20] **Auditor Name(s):**	[21] **Organization Representative Name:**

EN 9101 **Form 4: Nonconformity Report (NCR)**

[1] **CB Name**	**NONCONFORMITY REPORT (NCR)**		[2] **CB Logo**
[3] **Organization:**		[5] **Audit Report Number:**	
		[6] **NCR Number:**	2
[4] **Site/OIN:**		[7] **Issue Date:**	2

Section 1 – Nonconformity Details			
[8] **AQMS Standard(s):** EN 9100 ☐ EN 9110 ☐ EN 9120 ☐		[8] **Applicable** EN 9100/EN 9110/EN 9120 **requirement/clause:**	
[9] **Process/Area/Department:**		[10] **Classification (Ma / Mi):**	
[11] **Statement of Nonconformity:**			
[12] **Objective Evidence:**			
[13] **Immediate Containment Required? Yes ☐ No ☐**			**Due Date:**
[14] **Auditor**		[15] **Organization Representative Acknowledgement**	
Name:	**Signature:**	**Name:**	**Signature:**

[16] **SECTION 2 – ORGANIZATION'S PLANNED ACTIONS** [Attach continuation of response(s) on separate sheet, as needed.]	**Response Due Date:**
[17] **Containment Action(s):**	
[18] **Correction(s):**	[19] **Planned Completion Date:**
[20] **Root Cause:**	
[21] **Corrective Action(s):**	[22] **Planned Completion Date:**
[23] **Organization Representative:**	**Date:**
[24] **Auditor Acceptance:**	**Date:**
Section 3 – Auditor Verification and NCR Closure	
[25] **Details:**	

[26] **Auditor Name(s):**		[27] **Audit Team Leader:**	
Signature:	**Date:**	**Signature:**	**Date:**

EN 9101 **Form 5: Audit Report**

[1] ***CB Name***	**AUDIT REPORT**			[2] ***CB Logo***
[3] **Audit Type:**	Stage 2 ☐	Surveillance ☐	Recertification ☐	Special ☐
[4] **Audit date(s):**	[5] **Audit Duration** (Auditor Days)		[6] **Report No.:**	
	On-site:		[6] **Report Date:**	
	Off-site:			

Organization					
[7] **Name:**		[8] **Contact Details:**			
Address:		Representative:			
		Title:			
		Telephone:			
Subsidiary of:		E-mail:			
Website:		OASIS Administrator:			
[9] **Certification Structure:**	Single: ☐	Multiple: Cat 1: ☐ Cat 2: ☐	Several: ☐	Campus: ☐	Complex: ☐
[10] **ASRP:** Yes ☐ No ☐		[11] **CAAT:** Yes ☐ No ☐			
[12] **Certificate Number:**		[13] **Expiration Date:**			
Audit Team					
[14] **Audit Team Leader:**					
[15] **Audit Team Members:**					
[16] **Observers/Translators/Technical Experts:**					
Audit Criterion					
[17] **AQMS Standard:**	EN 9100 ☐	EN 9110 ☐	EN 9120 ☐	[18] **Revision:**	
[19] **Quality Manual:**				[20] **Revision:**	
Audit Details					
[21] **Audit Objectives:**					
[22] **Audit Scope:**					
[23] **Permitted Exclusions:**					
Nonconformity					
[24] **Total Number of Nonconformities** (issued during the audit)**:**					
[25] **Major Nonconformities:**		[26] **Minor Nonconformities:**			
Process Effectiveness Assessment Report					
[27] **Total Number of PEARs** (issued during the audit)**:**					
[28] **Process Effectiveness Level Results:**					
Level 1:		Level 2:		Level 3:	Level 4:
Report Issue					
[29] **Report Distribution:**					

EN 9101 **Form 5: Audit Report**

AUDIT CONCLUSIONS

[30] **Audit Summary:**

[31] **Key Issues/Concerns Requiring Top Management Attention:**

[32] **Strengths and Good Practices:**

[33] **Opportunities for Improvement:**

[34] **Previous Surveillance Audit Nonconformity Status:**		
NCRs Issued: (during last audit)	**NCRs Closed:**	**NCRs Open:**

EN 9101 **Form 5: Audit Report**

[35] **OASIS DATA**						
OIN	**Site**	**Supplemental Report No.**	**Central Function** (yes/no)	**Number of Employees**	**Audit Duration** (Auditor Days)	**Audited** (yes/no)

[36] **CHANGES TO ORGANIZATION / FACILITIES / QUALITY MANAGEMENT SYSTEM / SCOPE (since last visit)**			
Reference Number:	**Brief Description:**	(as applicable)	
		Organization Document Reference	EN 9100 / EN 9110 / EN 9120 Clause Reference

[37] **AGREED FOLLOW-UP ARRANGEMENTS:**

EN 9101 **Form 5: Audit Report**

[38] **AUDIT TEAM LEADER RECOMMENDS:**
☐ Initial Certification ☐ Recertification ☐ Initial Certification / Recertification (Subject to closure of all nonconformities)
☐ Continued Certification ☐ Continued Certification (Subject to completion of all containment action for associated NCRs)
☐ Suspension of Certification ☐ Withdrawal of Certification

ORGANIZATION CONFIRMATION	
Upon mutual agreement with customers / potential customers, the organization will make available all results of this audit, including the report, findings, corrective actions, checklists, etc.	
[39] **Organization Representative Name:**	
Signature:	
Date:	

[40] **Audit Team Leader Approval**	
Name:	
Signature:	
Date:	

EN 9101 **FORM 6: SUPPLEMENTAL AUDIT REPORT**

1 ***CB Name***	**SUPPLEMENTAL AUDIT REPORT**			2 ***CB Logo***
3 **Audit Type:**	Stage 2 ☐	Surveillance ☐	Recertification ☐	Special ☐
4 **Audit date(s):**	5 **Audit Duration** (Auditor Days)		6 **Report No.:**	
	On-site:		6 **Report Date:**	
	Off-site:			

Organization					
7 **Name:**		8 **Contact Details:**			
Address:		Representative:			
		Title:			
		Telephone:			
Subsidiary of:		E-mail:			
Website:		OASIS Administrator:			
9 **Certification Structure:**	Single: ☐	Multiple: Cat 1: ☐ Cat 2: ☐	Several: ☐	Campus: ☐	Complex: ☐
10 **ASRP:** Yes ☐ No ☐		11 **CAAT:** Yes ☐ No ☐			
12 **Certificate Number:**		13 **Expiration Date:**			
Audit Team					
12 **Audit Team Leader:**					
13 **Audit Team Members:**					
14 **Observers/Translators/Technical Experts:**					
Audit Criterion					
15 **AQMS Standard:**	EN 9100 ☐	EN 9110 ☐	EN 9120 ☐	16 **Revision:**	
Audit Details:					
17 **Audit Scope:**					
Nonconformity					
18 **Total Number of Nonconformities** (issued during the audit)**:**					
19 **Major Nonconformities:**		20 **Minor Nonconformities:**			
Process Effectiveness Assessment Report					
21 **Total Number of PEARs** (issued during the audit)**:**					
22 **Process Effectiveness Level Results:**					
Level 1:		Level 2:		Level 3:	Level 4:
AUDIT CONCLUSIONS					
23 **Audit Summary:**					

EN 9101 **FORM 6: SUPPLEMENTAL AUDIT REPORT**

[24] **Key Issues/Concerns Requiring Top Management Attention:**

[25] **Strengths and Good Practices:**

[26] **Opportunities for Improvement:**

[27] **CHANGES TO ORGANIZATION / FACILITIES / QUALITY MANAGEMENT SYSTEM / SCOPE (since last visit)**			
Reference Number:	**Brief Description:**	(as applicable)	
		Organization Document Reference	EN 9100 / EN 9110 / EN 9120 Clause Reference

[28] **OASIS DATA**					
OIN	**Site**	**Supplemental Report No.**	**Central Function** (yes/no)	**Number of Employees**	**Audit Duration** (Auditor, days)

ORGANIZATION CONFIRMATION	
Upon mutual agreement with customers / potential customers, the organization will make valuable all results of this audit, including the report, findings, connective actions, checklists, etc.	
[29] **Organization Representative Name:**	
Signature:	**Date:**

[30] **Audit Team Leader / Auditor**	
Name:	
Signature:	**Date:**

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