9101

REQUIREMENTS FOR CONDUCTING AUDITS OF AVIATION, SPACE, AND DEFENSE QUALITY MANAGEMENT SYSTEMS

Change Overview
9101:2016 versus 9101:2022

Issue: 1

Team members

- Brian Geer – Lockheed Martin (IDR/SDR)
- Conny Flink – GKN Aerospace (SDR)
- Masayuki Kogusuri – IHI Corporation (SDR)
- Wilfried Weber – Hutchinson PFW Aerospace
- Romuald Thimon – Safran
- Mark Heaton-Watts – Rolls-Royce
- Ron Liew – Collins
- Jeanette Preston - Smithers Quality Assessments
- Paul Dionne – ABS-QE
- Gary Procter – Lloyds Register
- Hiroshi Terao – Bureau Veritas
- Stuart Anthony – Scribe

9101 Team coverage

12 members on the 9101 team representing:

- Americas, Europe and Asia Pacific sectors
- Across 6 international countries
- Including:
  - 7 IAQG industry member companies
  - 4 Certification Body (CB) members
  - 1 dedicated scribe

9101 Interested parties

- Aviation, Space and Defense supply chain
- IAQG member companies
- IAQG community and working groups
- Accreditation and Certification Bodies
- Aviation, Space and Defense authorities
- AQMS auditors

9101 Key reasons for change

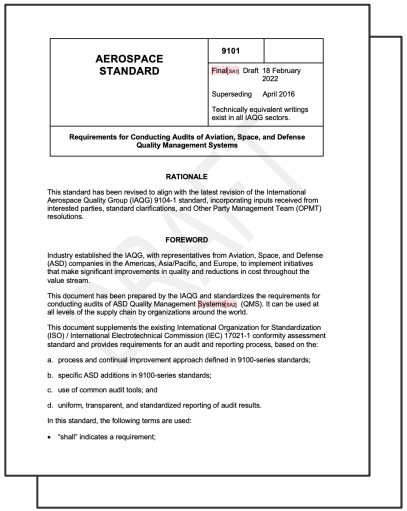
- Update of requirements to align with planned changes to 9104/1
- Improvement to audit report forms based on 9101 survey feedback
- Incorporation of current clarifications and resolutions
- Integration of OASIS feedbacks
- Clause renumbering to improve the document flow

Date Revision Initiated: *15-05-2019*

IAQG Issued Standard Number:	*9101*	**Current Issue (letter and date):**	**AAQG**	*Rev F, 2016-10*
			APAQG	*Rev F, 2016-10*
			EAQG	*Rev 2016-07*
IAQG Issued Standard Title:	*Quality Management Systems - Audit Requirements for Aviation, Space, and Defense Organizations*			
IAQG Issued Standard Scope:	*Requirements for the preparation and execution of the audit process, together with 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.*			
IAQG Document Representative (IDR):	*Brian Geer - Lockheed Martin*			
Strategy Focus Stream Leader (SFSL):	*Alan Daniels - Boeing*			
AAQG Sector Document Representative (SDR):	*Brian Geer - Lockheed Martin*			
APAQG Sector Document Representative (SDR):	*Masayuki Kogusuri - IHI*			
EAQG Sector Document Representative (SDR):	*Conny Flink - GKN Aerospace*			
Reason(s) for Revision:	*Main reason: Update of requirements to align with the changes to 9104/1. Supplementary reasons: Improvements to audit report forms based on 9101 survey feedback (May 2019) and incorporation of current clarifications and resolutions.*			
Initiative Deliverables:	*Revised 9101 standard, updated audit report forms, change presentation and updated FAQs.*			
Standard Interdependencies: *Critical interdependency: 9104/1 updated standard and on-time deliverables (CD, Ballot Draft, Final Draft). Other interdependencies: Budget for OASIS update (2020/21). Potential auditor training (key changes).*				
Estimated Publication Date: *Q2 2022* *NOTE: This date is a trigger for a Key Performance Indicator (KPI); see KPI item #2.*				
Date the Requirements Team (or RSFSL) Reviewed and Approved this Form/Data: *15-05-2019*				

Document structure

- Rationale, Forward, Table of Contents
- Introduction, Scope, References, Terms and Definitions
- Auditing and Reporting
  - General, Audit Program, Audit Reporting
- Common Audit Activities
  - General, Audit Planning, Conducting Audits,
  - Audit Report, Nonconformity Management
- Audit Phase Specific Requirements
  - General, Pre-audit Activities, Stage 1 Audit, Stage 2 Audit,
  - Surveillance Audit, Recertification Audit, Special Audit
- Appendices
  - Acronym Log, Form Images



AEROSPACE STANDARD

9101

Final(SAE) Draft 18 February 2022

Superseding April 2016

Technically equivalent writings exist in all IAQG sectors.

Requirements for Conducting Audits of Aviation, Space, and Defense Quality Management Systems

RATIONALE

This standard has been revised to align with the latest revision of the International Aerospace Quality Group (IAQG) 9104-1 standard, incorporating inputs received from interested parties, standard clarifications, and Other Party Management Team (OPMT) resolutions.

FOREWORD

Industry established the IAQG, with representatives from Aviation, Space, and Defense (ASD) 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 audits of ASD Quality Management Systems(QMS). It can be used at all levels of the supply chain by organizations around the world.

This document supplements the existing International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 17021-1 conformity assessment standard and provides requirements for an audit and reporting process, based on the:

a. process and continual improvement approach defined in 9100-series standards;

b. specific ASD additions in 9100-series standards;

c. use of common audit tools; and

d. uniform, transparent, and standardized reporting of audit results.

In this standard, the following terms are used:

- "shall" indicates a requirement;

9101

Key Changes

Clarified definitions

- **Containment:**
  - Action to control and mitigate the impact of a nonconformity to protect the customer, organization, or product (i.e., stop the problem from getting worse); includes immediate action, immediate communication, and verification to ensure that the nonconforming situation does not further degrade.
- **Repeat Nonconformity:**
  - A trend of identical nonconformities reported against the same requirement, indicating that previous corrective action attempt(s) failed to prevent recurrence of the nonconforming situation.

Rationale: To provide clarification and harmonize with IAQG dictionary entries

General

- Reference to proposed 9104/1 clause numbers updated to link complementary audit requirements
- All references to “several-site, campus and complex organizations” have been removed (single-site and multi-site certification structures remain)
- The term “Advanced Surveillance and Recertification Procedures (ASRP)” has been replaced by “Performance Based Surveillance/Recertification Process (PBS/RP)”
- The term “Computer Assisted Auditing Techniques (CAAT)” has been replaced by “Information and Communication Technology (ICT)”
- Reference to “Integrated/Combined audits” has been replaced by “Integrated Management System (IMS) audits”

Rationale: To align with 9104/1:2022

General

- The requirement to audit the Purchasing process during each on-site audit (annually) has been removed
- Existing requirement adjusted to state that all Stage 1 (9100, 9110 and 9120) audits include an on-site evaluation
- The requirement to take organization performance into account to support risk analysis during audit planning has been strengthened
- A statement that all audit reporting is managed electronically using the OASIS database has been added

Rationale: To align with 9104/1:2022 and/or adopt current resolutions

General

- Text has been clarified to state that process names need to be consistent in the Audit Plan, QMS Process Matrix (Form 2) and PEAR (Form 3) and need to correspond to the process names defined by the organization
- A requirement that organizations need to provide Organization Certification Analysis Process (OCAP) data to the Certification Body (CB) a minimum of 90 days prior to each initial, surveillance and recertification audit has been added
- Additional requirements added to ensure that each on-site audit verifies the:
  - Scope of certification
  - OCAP data provided

Rationale: To capture current 9101 clarifications and/or adjust 9101 requirements

General

- A requirement for the CB and audit team leader to set up the audit in OASIS prior to each audit has been added
- Clarified that a single audit report may be issued for integrated AQMS audits
- Clarification added to state that all requirements of the applicable AQMS standard and the organizations processes are audited during the Stage 2 audit, the recertification audit and across the surveillance audits.

Rationale: To clarify/adjust 9101 requirements

General

- Stage 1 audits:
  - The requirement for the organization to provide the percentage of revenue for Aviation, Space and Defense (ASD) industry business audit has been removed
  - Requirement adjusted to state that any customer and/or regulator specific approvals and their requirements are collected
  - The requirement to determine customer presence at the organization has been removed
  - The requirement to review customer delegated inspection and/or authorized direct ship/direct delivery has been removed
  - Requirement expanded to state that evidence of customer performance, process performance and performance of quality objectives needs to be reviewed

Rationale: To adjust 9101 requirements

Tables

TABLE 1 – AUDIT REPORTING REQUIREMENTS

<table>
<tr><th>Audit Phase / Audit Report(s)</th><th>Stage 1 (see 6.3)</th><th>Stage 2 (see 6.4)</th><th>Surveillance (see 6.5)</th><th>Recertification (see 6.6)</th><th>Special (see 6.7)</th></tr>
<tr><td>Stage 1 Audit Report (see Form 1)</td><td>Required</td><td colspan="4"></td></tr>
<tr><td>QMS Process Matrix Report (see Form 2)</td><td rowspan="4"></td><td colspan="3" rowspan="2">Required; per site or combined, as appropriate (see 4.3.3)</td><td rowspan="2">See 4.3.2</td></tr>
<tr><td>Process Effectiveness Assessment Report (PEAR) (see Form 3)</td></tr>
<tr><td>Nonconformity Report (NCR) (see Form 4)</td><td colspan="4">Required (as applicable)</td></tr>
<tr><td>Audit Report (see Form 5)</td><td colspan="4">Required</td></tr>
</table>

- Existing Table 1 improved to clarify the audit reporting requirements relating to each audit phase

Rationale: To improve clarification and remove audit reporting relating to previous 9104/1 certification structures

Tables continued…..

TABLE 2 – SPECIAL AUDIT REPORTING REQUIREMENTS

Reason for Special Audit	QMS Process Matrix Report (see Form 2)	Process Effectiveness Assessment Report (PEAR) (see Form 3)
Transferring certification from one CB to another	Not required	
Reducing an organization's certification scope, or number of sites and/or locations		
Verification of evidence to support application of Performance Based Surveillance/Recertification Process (PBS/RP)		
Change to an organization's certification structure	Required	Required, if special audit activity is conducted against 9100-series standard clause 8
Investigate a complaint or serious issue		
Follow up from an organization's suspension		
Expanding an organization's certification scope, or number of sites and/or locations		

- New Table 2 introduced to clarify the specific reporting requirements for Special audits

Rationale: To incorporate existing 9101 clarification #1

Tables continued…….

TABLE 5 – NONCONFORMITY REPORT MANAGEMENT TIME FRAMES

Item	Who	What	When
1	Auditor	Issue NCR	Site closing meeting (see 5.3.11)
2	Organization	Response to containment	Within a maximum of 7 days of NCR issuance
3	Auditor and Organization	Reach agreement on containment action	Within a maximum of 21 days of NCR issuance
4	Organization	Response to root cause, correction, and corrective action plan	Within a maximum of 30 days of NCR issuance
4	Auditor	Review and accept correction(s), root cause(s), corrective action, and supporting corrective action plan	
5	Organization	Re-establish conformity	Within a maximum of 90 days of NCR issuance (see 9104-1 clause 8.5.11.1)
6	Auditor	Verify implementation of correction and corrective action	In accordance with the dates accepted in the correction and supporting corrective action plans
7	Auditor	Verify effectiveness of corrective action	During the next programed audit

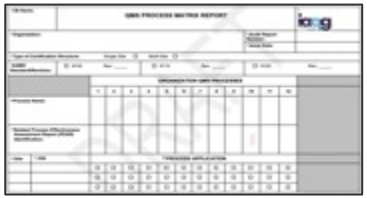
- New Table 5 introduced to clarify the specific requirements for managing NCRs, including timeframes

Rationale: To improve clarification relating to the management of NCRs

Audit report forms

- Stage 1 Audit Report (Form 1)
  - Fields adjusted to reflect changes in the 9101 standard
  - Fields added to enable the capture of ICT use and comments
  - Individual AQMS clause numbers combined to a high-level to ease the entry of “confirmation of requirements”

- QMS Process Matrix Report (Form 2)
  - Fields adjusted to reflect changes in the 9101 standard
  - Some AQMS clause numbers combined to ease the entry of “conformity” information



Rationale: To improve form content based on survey feedback and maintain reporting requirements based on 9101 and ISO17021-1 requirements

Audit report forms

- PEAR (Form 3)
  - Fields adjusted to reflect changes in the 9101 standard
  - Non value-added fields removed

- NCR (Form 4)
  - Additional fields added to expand the capture of containment date, ownership and acknowledgement

Rationale: To improve form content based on survey feedback, maintain reporting requirements based on 9101 and ISO17021-1 requirements and improve OASIS work flow

Audit report forms

- Audit Report (Form 5)
  - Fields adjusted to reflect changes in the 9101 standard

- Supplemental Audit Report (Form 6)
  - This optional audit report form has been removed

NOTE: Manual versions of all audit report forms, together with instructions will continue to remain accessible via the IAQG website

Rationale: To improve form content based on survey feedback and maintain reporting requirements based on 9101 and ISO17021-1 requirements