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
Document structure

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

<table>
<thead>
<tr>
<th>Audit Phase</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>
</thead>
<tbody>
<tr>
<td>Stage 1 Audit Report (see Form 1)</td>
<td>Required</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QMS Process Matrix Report (see Form 2)</td>
<td></td>
<td></td>
<td>Required; per site or combined, as appropriate (see 4.3.3)</td>
<td></td>
<td>See 4.3.2</td>
</tr>
<tr>
<td>Process Effectiveness Assessment Report (PEAR) (see Form 3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonconformity Report (NCR) (see Form 4)</td>
<td></td>
<td></td>
<td>Required (as applicable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit Report (see Form 5)</td>
<td></td>
<td></td>
<td></td>
<td>Required</td>
<td></td>
</tr>
</tbody>
</table>

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

- **Existing Table 1 improved to clarify the audit reporting requirements relating to each audit phase**
### TABLE 2 – SPECIAL AUDIT REPORTING REQUIREMENTS

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

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

Rationale: To incorporate existing 9101 clarification #1
New Table 5 introduced to clarify the specific requirements for managing NCRs, including timeframes.

### TABLE 5 – NONCONFORMITY REPORT MANAGEMENT TIME FRAMES

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

**Rationale:** To improve clarification relating to the management of NCRs.
Audit report forms

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

• QMS Process Matrix Report (Form 2)
  o Fields adjusted to reflect changes in the 9101 standard
  o 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)
  o Fields adjusted to reflect changes in the 9101 standard

• Supplemental Audit Report (Form 6)
  o 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