IAQG 9101:2016
(Rev. F)

Ballot Draft
Changes Overview

Prepared by the IAQG 9101 team

December 2015
13 members on the 9101 Team Representing:

- Americas, Europe, and Asia-Pacific IAQG sectors
- 8 IAQG member companies
- 6 Different countries
- 4 Certification Body members
- 1 Dedicated Scribe
9101 Stakeholders

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

FAQ’s arising from current version

Feedback through OASIS and from stakeholders

Lessons learned from OPMT oversight of CB audit reports

Support of the OASIS Next Generation (NextGen) project
Simplified forms to avoid duplication and improve reporting flow


Rationalized content of clauses relating to Stage 1 audit to align with changes to Form 1.

Recognized the OASIS NextGen project with Form modifications

Changed process effectiveness levels from 4 to 5 and simplified definitions

Changed PEAR application from current 9100-series:2014 clause 7 (Product Realization) to revised 9100-series:2016 clause 8 (Operation)
Updated Process Evaluation Matrix (PEM)

- Simplified process realization wording:
  - “Defined and implemented” becomes “determined” to align to 9100-series terminology
- Assessment levels revised from 4 to 5 and redistributed to provide more balance in relation to the effectiveness result
- Clarified the issuing of NCRs relating to the audit findings:

**Process Results**

“The audit team shall issue an NCR against the relevant 9100-series standard clause when the process is not delivering the planned results and appropriate action is not being taken”.

**Process Realization**

“The audit team shall issue an NCR against the relevant 9100-series standard clause when planned activities of a process are not realized, or not fully realized”.

Level 2 here means that the process is determined and planned activities are partly or fully realized. The process however is not delivering the planned results and appropriate action is not being taken.

Level 1 means that the process is not determined and planned activities are not realized. Furthermore the process is not delivering the planned results and appropriate action is not being taken.

Level 2 here means that the process is not determined and planned activities are not realized. The process however is delivering the planned results or if not, appropriate action is being taken.
### Updated PEM Assessment Levels 3 & 4

<table>
<thead>
<tr>
<th>Process Realization (a)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planned activities fully realized</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Planned activities not fully realized</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Process Results (b)

<table>
<thead>
<tr>
<th>Planned results not achieved and appropriate action is not taken</th>
<th>Planned results not achieved, but appropriate action is being taken</th>
<th>Planned results are achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

**Level 3** means that the process is determined but planned activities are *not* fully realized. The process however is *not* delivering the planned results but appropriate action is being taken.

**Level 4** here means that the process is determined and planned activities are fully realized. The process however is *not* delivering the planned results but appropriate action is being taken.

**Level 4** here means that the process is determined but planned activities are *not* fully realized. The process however is *delivering* the planned results.
Level 5 means that the process is determined and planned activities are fully realized. Furthermore the process is delivering the planned results and there are no nonconformities identified.

<table>
<thead>
<tr>
<th>Process Realization (a)</th>
<th>Planned activities fully realized</th>
<th>Planned activities not fully realized</th>
<th>Planned activities not realized</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>3</td>
<td>2</td>
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<tr>
<td></td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

**Process Results (b)**

- Planned results not achieved and appropriate action is not taken
- Planned results not achieved, but appropriate action is being taken
- Planned results are achieved
Level 1 means that the process is not determined and planned activities are not realized. Furthermore the process is not delivering the planned results and appropriate action is not being taken.

Level 2 here means that the process is determined and planned activities are partly or fully realized. The process however is not delivering the planned results and appropriate action is not being taken.

Level 3 means that the process is determined but planned activities are not fully realized. The process however is not delivering the planned results but appropriate action is being taken.

Level 4 here means that the process is determined and planned activities are fully realized. The process however is not delivering the planned results but appropriate action is being taken.

Level 5 means that the process is determined and planned activities are fully realized. Furthermore the process is delivering the planned results and there are no nonconformities identified.

Level 4 here means that the process is determined but planned activities are not fully realized. The process however is delivering the planned results.

Level 2 here means that the process is determined and planned activities are partly or fully realized. The process however is not delivering the planned results and appropriate action is being taken.

Level 1 means that the process is not determined and planned activities are not realized. Furthermore the process is not delivering the planned results and appropriate action is not being taken.

Level 2 here means that the process is determined but planned activities are not fully realized. The process however is delivering the planned results or if not, appropriate action is being taken.

Level 3 means that the process is determined but planned activities are not fully realized. The process however is not delivering the planned results but appropriate action is being taken.

Level 4 here means that the process is determined and planned activities are fully realized. The process however is not delivering the planned results but appropriate action is being taken.
Mandatory ‘Audit Approaches’ (9101E clause 4.1.2)
- Requirements for using specific ‘Audit Approaches’ to be moved into updated 9101:2016 (Rev. F) “Auditor Guidance Material”.
- Relocated auditing of Special Processes for clarity, now included in clause 4.2.2.4.1 in 9101:2016 (Rev. F).

Major / Minor nonconformity definition
- ISO17021-1:2015 definitions added

Special Audit
- Revised to clarify reason(s) for conducting a Special Audit
Forms continue to be referenced in Appendix B

- Electronic versions of the Forms will remain accessible via the IAQG website together with supporting instructions.

http://www.sae.org/iaqg/
9101 Key Revision Summary - Forms

General:
- Simplified/clarified form entries to support audit reporting using OASIS NextGen
- Revised nomenclature to align with ISO 17021-1:2015 and revised 9100-series:2016
- Disclaimer statements added in accordance with ISO 17021-1:2015
- Clarified form instructions to improve process flow
Form 1 (Stage 1 Audit Report):

- Alignment to 9100-series:2016 including:
  - “Exclusions” box changed to “Requirements determined as ‘not applicable’”, “Justification” box added and “Quality Manual” changed to “QMS Documented Information”
  - “Key Requirements” replaced with “Confirmation of Requirements” to align with the QMS Process Matrix Report
  - “Key Information” reduced in scope and renamed “Other Information”
Form 2 (QMS Process Matrix Report):

- Clause numbers & titles changed to align with revised 9100-series:2016
- Clarified when “N/A” and ‘empty boxes’ can be utilized in populating the matrix
- Changed to accommodate Summary of Objective Evidence for clauses 4, 5, 6, 7, 9 and 10
- Changed to accommodate reporting (5) PEAR levels
- Changed to identify common process application across multiple sites, several site, campus, or complex organizations.
Form 3 (PEAR):

- Added the box “Responsibility/Authority” for the process to align with revised 9100-series:2016
- Assessment levels revised from 4 to 5 and redistributed to provide more balance in relation to the effectiveness result
- Copied the PEM image from 9101:2016 Table 3 into the Form to help with PEAR level determination
Form 4 (NCR):

- Added “Cause Code” box to accommodate the allocation of a suitable code from the IAQG listing and to support future IAQG data collection.
- Deleted “Signature” boxes to support OASIS NextGen.

<table>
<thead>
<tr>
<th>C��Name</th>
<th>NONCONFORMITY REPORT (NCR)</th>
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</tbody>
</table>

**SECTION 1 — NONCONFORMITY DETAILS**

- **AQRS Standard/Revision**: 9120 Rev 9120 Rev 9120 Rev
- **Applicable 9100/9110/9120 requirements/cases**:
- **Process/Func/Department**: Classification (M&R)
- **Statement of Nonconformity**:
- **Objective Evidence**:
  - Containment Required? □ Yes □ No
  - Auditor: "Organization Representative"

**SECTION 2 — ORGANIZATION’S PLANNED ACTIONS**

- **Corrective Action(s)**: "Planned Completion Date:"
  - Actual Completion Date:
  - Root Cause:
- **Organizational Representative**: "Data:"
- **Auditor**: "Data:"

**SECTION 3 — AUDITOR VERIFICATION AND NCR CLOSURE**

- **Details**:
  - Auditor:
  - Audit Team Leader:
- **Date**:

**DISCLAIMER STATEMENT**

This audit was conducted based on a sampling process of the available information.
Form 5 (Audit Report):

- Audit Type expanded to include reason for “Special Audit”
- Improved/Clarified statement for the audit team leader’s certification recommendation
- Changed to accommodate reporting (5) PEAR levels
- Deleted “Signature” boxes to support OASIS NextGen
- Alignment to 9100-series:2016 including:
  - “Exclusions” box changed to “Requirements determined as ‘not applicable’”, “Justification” box added and “Quality Manual” changed to “QMS Documented Information”
  - Improved to include a statement regarding the verification of effectiveness of corrective actions taken for nonconformities identified during the previous audit.
- Box added to signify Integrated Audit (Yes/No)
### 9101 Key Revision Summary - Forms

#### Form 5 (Audit Report) continued:

<table>
<thead>
<tr>
<th>Audit Details</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Audit Objective</td>
<td></td>
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<tr>
<td>Audit Scope</td>
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<tr>
<td>Requirements Statement</td>
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<tr>
<td>Audit Plan</td>
<td></td>
</tr>
<tr>
<td>Audit Results</td>
<td></td>
</tr>
<tr>
<td>Nonconformities identified and corrective actions taken</td>
<td></td>
</tr>
</tbody>
</table>

**NOCOMFORMITY**

- An individual number of nonconformities identified during the audit.
- Major nonconformities.
- Minor nonconformities.

**PROCESS EFFECTIVENESS ASSESSMENT REPORTS (PEAR)**

- Number of nonconformities identified during the audit.
- Process Effectiveness Level Result.

**AUDIT CONCLUSION**

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Brief Description</th>
<th>DSM Document Reference</th>
<th>DSM Document Reference</th>
<th>DSM Document Reference</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**AUDIT TEAM LEADER RECOMMENDATIONS**

- Based on the Stage 1 audit Result.
- Based on the Surveillance Audit Result.
- Based on the Reassessment Audit Result.
- Based on the Initial Audit Result.
- Based on the Reexamination Audit Result.
- Based on the Reexamination Audit Result.

**ORGANIZATION OF CONFIRMATION**

- An individual number of nonconformities identified during the audit.
- Process Effectiveness Level Result.
- Process Effectiveness Level Result.
- Process Effectiveness Level Result.
- Process Effectiveness Level Result.
- Process Effectiveness Level Result.
Form 6 (Supplemental Audit Report):

- Audit Type expanded to include reason for “Special Audit”
- Changed to accommodate reporting (5) PEAR levels
- Deleted “Signature” boxes to support OASIS NextGen
- Box added to signify Integrated Audit (Yes/No)
9101 revision scheduled in parallel with 9100-series revision