



Changes Overview

'Conformity plus Performance Equals Effectiveness'

Prepared by the IAQG 9101 team

Presentation Objectives



Part One:

- Provide Overview of 9101:2014 (Rev. E)
 - Team Membership
 - Stakeholders
 - Revision Why?
 - Process Approach
 - Key Changes

Part Two:

- Provide Details of:
 - 9101:2014 (Rev. E)

Part Three:

- Provide Overview of:
 - 9101:2014 (Rev. E) Forms





Part One

Overview of 9101:2014 (Rev. E)

9101 Team Membership



- 14 members on the 9101 Team Representing:
 - Americas, Europe, and Asia-Pacific IAQG sectors
 - 6 different countries
 - 9 IAQG member companies
 - Certification Body community (5 members)



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



9101 Revision - Why?



- Revisions of ISO 17021:2011, 19011:2011 and release of 9104/1:2012 had influence triggering the need for change
- Large number of FAQ's arising from current version
- Some requirements lost in appendix instructions
- Feedback from Aerospace Auditor Transition Training (AATT)
- Lessons learned from OPMT oversight of CB audit reports
- Stakeholder feedback



9101 Process Approach



- > An enhanced audit approach for evaluating "process based management systems"
- Definition of the audit process phases with audit planning, execution, analysis and reporting: (Preaudit activities, Stage 1, Stage 2, Surveillance, Re-Certification)
- Audit of the organization's processes and continual improvement approach, as required in 9100-series standards
- Improvement of performance-based, process-oriented audit methods, techniques and reporting
- Balanced recording of objective evidence for planned arrangements and planned results
- Reporting of audit results in a uniform, transparent and standardized way

9101 Key Revision Summary



- New Process Evaluation Matrix (PEM)
 - Clear definitions to assist auditors when determining process effectiveness levels / numerical conclusions when documenting PEARs
- 'Audit Methodologies' are mandatory as 'Audit Approaches'
 - Audit Methodologies are renamed Audit Approaches and become mandatory... "should" now becomes "shall"



9101 Key Revision Summary



Consolidation and Improvements of the Forms:

- Improvements on "QMS Process Matrix Report", "NCR" and "Audit Report"
- Incorporation of 9104/1 including Certification Structure
- Improvement of Forms to reflect OASIS entry requirements
- The OER form is withdrawn but the principle of recording objective evidence remains.
- Objective evidence will now be captured in the updated PEAR form (for 9100 series standards clause 7), QMS Process Matrix Report (for other than clause 7) and summarized on the Audit Report form
- The CB may use additional audit tools, such as checklists or questionnaires, to help auditors in the collection of objective evidence during the audit process



9101 Key Revision Summary

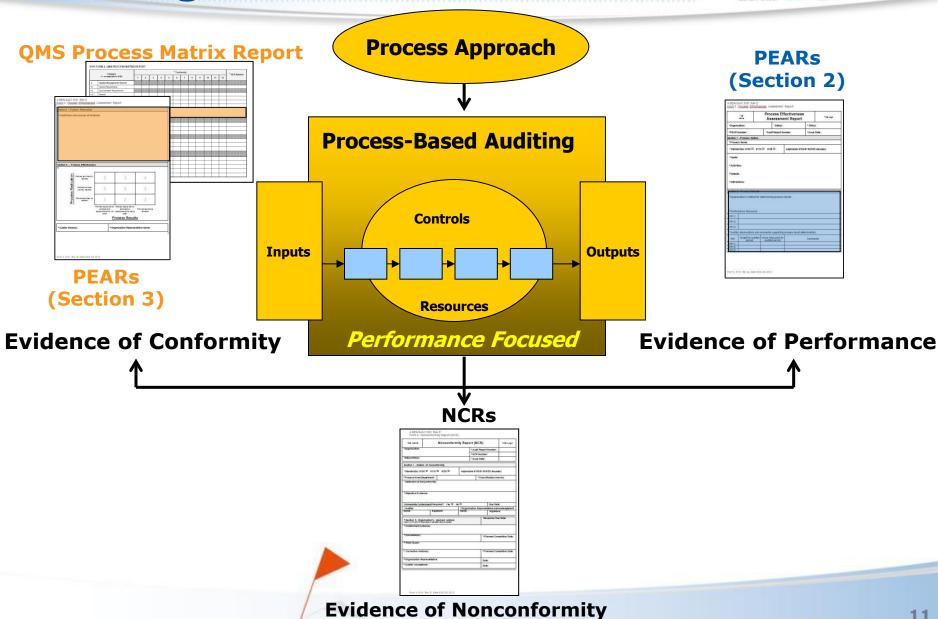


- ➤ Appendices are referenced as forms and will be available for use online
 - 9101 will only include a representation of forms as a part of the standard (these copies are not intended to be used for audits)
 - URL link will be referenced to access the forms from the IAQG website http://www.sae.org/iaqg/
 - Forms managed in accordance with IAQG Procedure 119



Model for Process Based Auditing - 9101









Part Two

Details of 9101:2014 (Rev. E)

9101: Introduction and Scope



Clause 0 and 1 Introduction and Scope:

Deleted ISO 19011 reference and include 9104/1

References:

- Updated 9104/1
- Added IAF MD 3 Mandatory document for Advanced Surveillance and Recertification Procedures (ASRP)
- Added IAF MD 4 Mandatory document for the use of Computer Assisted Auditing Techniques (CAAT) for Accredited Certification of Management Systems
- Added IAQG Procedure 119 Forms Management

Rationale:

■ The incorporation of updated reference documents such as ISO/IEC 17021, 9104/1, IAF MD3 & MD4 and IAQG procedure 119 for forms management.

3. Terms and definitions



Definitions added or updated for:

Key Performance Indicators (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

Rationale:

- To add definitions for the phrase "Key Performance Indicators" and for the elements of effectiveness: "Planned Activities" and "Planned Results".
- Key Performance Indicators (KPI) were defined due to their use throughout this revision of 9101 and their addition to the new PEAR form.

3. Terms and definitions



Definitions added or updated for:

Process Effectiveness Assessment Report (PEAR)

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

Rationale:

The definition of the PEAR was expanded to help achieve the balance of conformity, results and effectiveness, and to align the PEAR for collection of additional objective evidence that was previously collected on the OER.



3. Terms and definitions



Definitions added or updated for:

Planned Activities

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

Planned Results

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

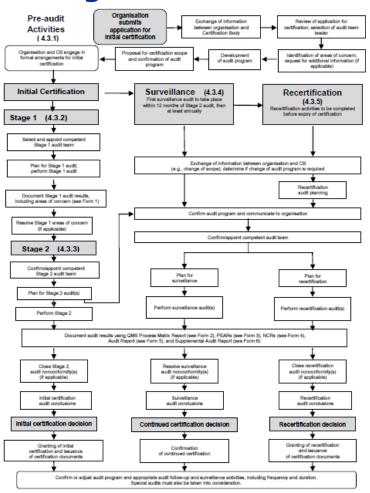
Rationale:

 The new terms were added to further define the term effectiveness as found in ISO 9000 3.2.14.

4.1.1 Audit process



Aligned Audit Process Flow with ISO 17021



Rationale:

The process flow has additional information unique to Aviation, Space and Defense (ASD) that is not found in ISO17021 while maintaining all of the ISO17021 content.

FIGURE 1 – OVERVIEW OF AUDIT PROCESS FLOW

(see ISO/IEC 17021 - Figure E.1)

4.1.2 Audit Approaches



- Audit Approaches now a "shall" and repositioned "Special Processes"
 - The following approaches shall be used, as appropriate, to conduct each on-site audit:
 - Customer Focus
 - Organizational Leadership
 - Quality Management System Performance and Effectiveness
 - Process Management
 - Special Processes
 - Continual Improvement



4.1.2 Audit Approaches



Rationale:

- The Audit Approaches introduced by clause 4.1.2 are linked to several principles that are promoted by the 9100 series standards.
- Each Audit Approach is described by the 9101 standard through a list of requirements that auditors can easily recognize. These are all 9100 series requirements, presented in a different order than they are in the 9100 series standards.
- These approaches provide more effective audit trails than clause by clause auditing.
- The "shall" statements have replaced the previous "should" statements, to emphasize that auditors are required to use these approaches, that are directly linked to the 9100 series standards in order to promote process based auditing.



4.1.3 Reporting:



➤ The names of the audit documents have changed from 'Appendices' to 'Forms':

9101 D Appendices (previous version)	9101 E Forms (updated version)
Appendix A (OER)	Form 3 (PEAR) Section 3 & Form 2
	(QMS Process Matrix Report)
Appendix B (Nonconformity Report)	Form 4 (Nonconformity Report)
Appendix C (PEAR)	Form 3 (PEAR)
Appendix D (QMS Process Matrix)	Form 2 (QMS Process Matrix Report)
Appendix E (Audit Report)	Form 5 (Audit Report)
Appendix F (Stage 1 Audit Report)	Form 1 (Stage 1 Audit Report)
Appendix G (Supplemental Audit Report)	Form 6 (Supplemental Audit Report)

Rationale:

The change from appendices to forms is in alignment with other ASD standards. As mentioned before, the forms are separated from the standard and are available on the IAQG websites.

4.1.3 Reporting continued:



▶ Added certification structure reporting requirements:

TABLE 1 - CERTIFICATION STRUCTURE REPORTING MATRIX

Type of Certification Structure Audit Phase	Single Site	Multiple Sites	Campus	Several Sites	Complex Organisation
Stage 1 Audit	• Sta	age 1 Audit Re	port (Form 1)		
Stage 2 Audit Surveillance Recertification	• PE • No • Au	AR (Form 3); ponconformity Right (For dit Report (For	atrix Report (Fo per site or com eport (NCR) (Fo m 5) idit Report (For	bined, as appro orm 4); as app	opriate
Special Audit	• NC	AR (Form 3); p CR (Form 4); as ditReport (For		bined, as appro	opriate

> Rationale:

 To illustrate what forms are required for each audit stage and each of the new certification structures described in 9104/1.

4.2.1 Audit planning (Common)



Added the following to be taken into account:

- Certification structure (single site, multiple site, campus, several sites, complex) (see 9104/1 clause 3.1.1)
- Integrated and/or combined audits (see 9104/1 clause 8.2.3)
- Use of Advanced Surveillance and Recertification Procedures (ASRP) (see 9104/1 clause 8.9).
- Use of Computer Aided Auditing Techniques (CAAT) (see 9104/1 clause 8.10).

> Rationale:

 To require the auditing organization and auditor to incorporate the requirements from the 9104/1 standard during the audit planning process.



- **>4.2.2.1**
 - h. an audit of the purchasing process (see 9104/1 clause 8.2.2.n).
- **▶**4.2.2.2 Conducting the Opening Meeting
 - The requirements of 17021:2011 clauses 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., netmeeting, Webex, Meet-me).

> Rationale:

- To include an audit of the Purchasing process as required by 9104/1.
- To clarify the need to have the AEA conduct site specific opening meetings for those organizations who have a non-single site structure, or choose an alternative to hold a central opening meeting with site representatives, either in person or by virtual means.



> 4.2.2.5 Identifying and Recording of Audit Findings

- The audit team shall record measures, targets, and values of KPIs related to each audited product realization process (see 9100-series standards clause 7) on the PEAR (section 2)
- Objective evidence for Product Realization processes (9100 series clause 7) shall be recorded on the PEAR (section 3)
- Objective evidence for processes outside of Product Realization processes (9100 series clauses 4, 5, 6, 8) shall be recorded on the QMS Matrix (The organization and CB may agree to utilize the PEAR for these processes, in this case the objective evidence shall be recorded on the PEAR)

Rationale:

 To clarify how to record objective evidence using the updated QMS Process Matrix and the PEAR. This has changed as a result of withdrawing the requirement to complete an Objective Evidence Report.



- > Evaluation of effectiveness now includes:
 - Process realization the extent to which planned activities are realized and
 - Process results the extent to which planned results are achieved
 - Added Table 3, Process Evaluation Matrix to be used to determine the level of process effectiveness

Effectiveness (extent to which planned activities are realised and planned results achieved)

Planned activities fully realised	a) The process is defined implemented and planned activities fully realised however b) The process is not delivering the planned results and appropriate action is not being taken	a) The process is defined, implemented and planned activities fully realised however b) The process is not delivering the planned results, but appropriate action is being taken	a) The process is defined, implemented and planned activities fully realised and b) The process is delivering the planned results
Planned activities not fully realised	a) The process is defined and implemented, but planned activities not fully realised and b) The process is not delivering the planned results and appropriate action is not being taken	a) The process is defined implemented but planned activities not fully realised and b) The process is not delivering the planned results but appropriate action is being taken	The process is defined and implemented but planned activities not fully realised however The process is delivering the planned results
Planned activities not realised	The process is not defined implemented, and planned activities not realised and The process is not delivering the planned results and appropriate action is not being taken	a) The process is not defined implemented, and planned activities not realised and b) The process is not delivering the planned results but appropriate action is being taken	a) The process is not defined implemented, and planned activities not realised however b) The process is delivering the planned results
	Planned results not achieved and appropriate action is not taken	Planned results not achieved, but appropriate action is being taken	Planned results are achieved
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Rationale:

- To ensure that the determination of effectiveness is based upon process realization and process results, in line with the new definitions.
- The idea behind the PEM is to create a more consistent way of determining the process effectiveness level, using a two axis model aligned to the definition of effectiveness.
- The PEM provides a logical set of criteria that the auditor can select from, in order to determine and visualize the effectiveness level.



4.2.3 Audit report



- Defined reporting requirements for "combined" and "integrated" audits
 - For combined and integrated audits, separate reports shall be issued for each audit performed for each standard. Where appropriate, processes common between the standards may be reported on the same PEAR and the same QMS Process Matrix Report. Each report for combined and integrated audits shall be linked to all other reports from the audit

Rationale:

- To incorporate the new requirements for Combined and Integrated audits.
- To provide improved and accurate audit reporting when auditing more than one ASD standard, individual audit reports are required. When processes are identical among multiple standards, it is permissible to issue one PEAR report and QMS Process Matrix Report for both standards.

4.2.4 Nonconformity management



- Clarified Containment actions requirements: 'Fix Now'
 - 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: Containment action and correction can be reviewed during the audit.
- Rationale:
 - To clarify what is expected for containment

4.3.2 Stage 1 Audit



- ➤ Revised Collection of Information and clarified Stage 1 audit offsite provisions for 9120.
 - c. product conformity and OTD performance measures and trends;
 - NOTE 2: The data should be sufficient to allow team leader to make a judgment on performance and trends.
 - b. include an on-site visit; however, for 9120 the Stage 1 audit can be conducted off-site based on consideration of various organization factors (e.g., size, location, risk, previous audit team knowledge).

Rationale:

- To assure organizations that did not previously have an AQMS are not penalized or eliminated from attempting certification, the 12 month data requirement was removed.
- In response to a 9101D FAQ. Notes should not be used to supersede requirements. Note changed to a requirement 4.3.2.1 b.

4.3.3 STAGE 2 AUDIT



- Clarified timeframe for between Stage 1 and Stage 2 Audits
 - In the event the time period between Stage 1 and Stage 2 exceeds
 6 months, an additional Stage 1 audit shall be conducted

Rationale:

There was no prior requirement of how much time could transpire between the completion of a Stage 1 audit and the start of Stage 2. Questions were asked if there was a time limitation before a complete Stage 1 audit would have to restarted because the risks of significant changes that could impact the Stage 2 audit. International consensus determined 6 months as an acceptable time limit.





Part Three

Overview of 9101:2014 (Rev. E) Forms

9101:2014 Form Revision



Revision Highlights

Common Changes:

- "Appendices" changed to "Forms".
- "Shall" requirements moved from instructions to appropriate text of the standard.
- Incorporated 9104/1 requirements.
- Forms are not part of the standard and are managed according to IAQG procedure 119.
- Forms are available in English on the IAQG website



Form 1: Stage 1 Audit Report





- Deleted 12 months"Data" requirement.
- Includes verification of "Certification Structure" type.
- Includes evaluation of "Level of QMS Integration".
 Instructions define % of integration per 9104/1.
- Removed signature line.

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Configuration Management	
Project/Program Management	
Continual Improvement Activities	
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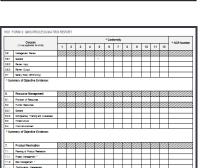


Form 2: QMS Process Matrix Report



- Support evidence of "Conformity" to 9100 series standards clauses 4, 5, 6 and 8 for an organization's QMS processes.
- 9110 clauses updated.





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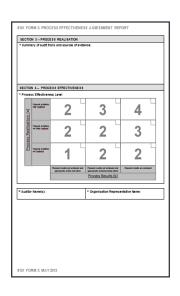


Form 3: Process Effectiveness Assessment Report (PEAR)



- Section 1: structured recording of process details
- Section 2: structured recording of process results (performance).
- Section 3: recording of process realization (objective evidence formerly recorded on the OER).
- Section 4: Added Evaluation matrix (to be used after a process has been assessed).
- Signature line removed.







Form 4: Nonconformity Report (NCR)



- Can be used for combined and integrated audits if a nonconformance is common across AQMS standards.
- Identifies if containment is required.
- Recording of containment information separated from correction requirements.
- Where detail is provided via an attachment, it is not permissible to simply say "see attached". It is permissible to describe the containment, correction, root cause and corrective action in summary format provided that the full detail is annotated to the NCR via an attachment, that is also subsequently uploaded to the OASIS with the associated NCR.

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Form 5: Audit Report



- Certification Structure reporting
- ASRP or CAAT reporting
- Includes OASIS data requirements
 - Central function
 - Associated Locations/OIN
 - Supplemental report traceability

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audit, including the report, findings, corrective actions, checklists, etc.:								
*Organization Representative Name:								
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Form 6: Supplemental Audit Report



- Certification Structure reporting.
- ASRP or CAAT reporting.
- OASIS data requirements:
 - Central function
 - Associated Locations/OIN
- Shall be used to record results for individual sites, if the Audit Report (Form 5) does not include audit details of the individual sites/locations.

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