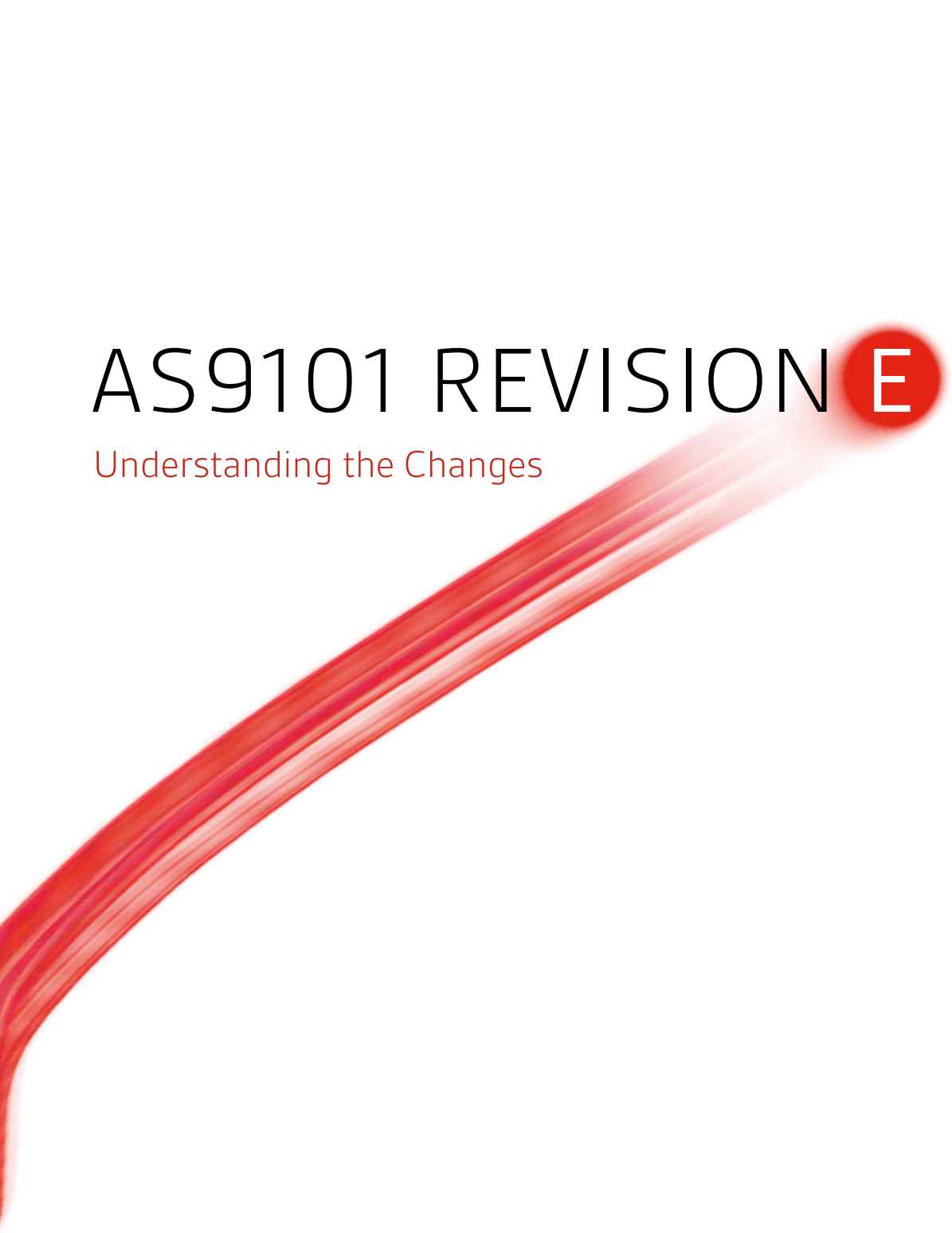
AS9101 REVISION E

Understanding the Changes



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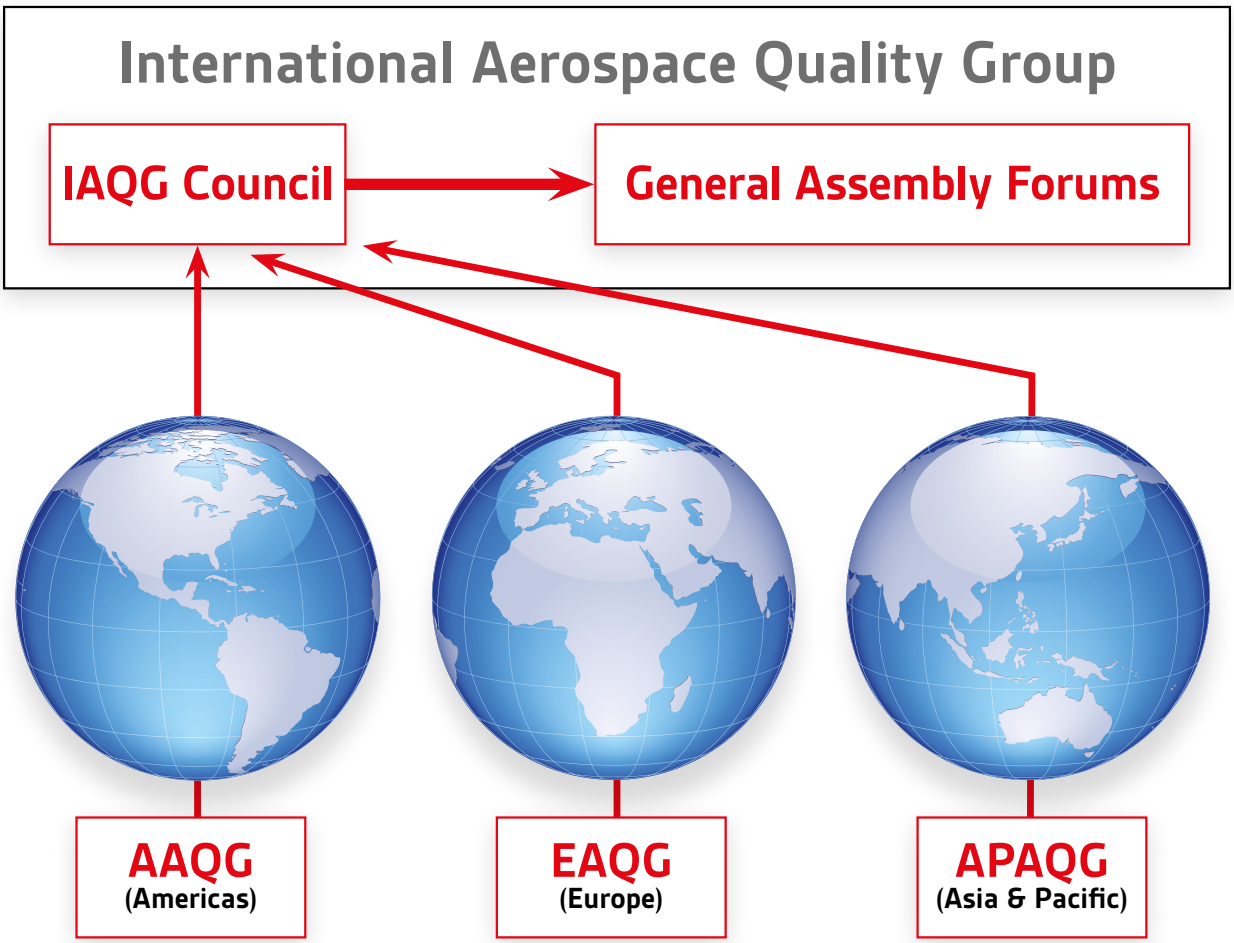
Introduction

Aviation, space and defense (ASD) organizations are highly regulated to ensure their products are safe and reliable, conform to statutory and regulatory requirements, and meet or exceed customer expectations. The extensive globalization of the industry and its supply chain complicates compliance and creates challenges to the supplier as well as the end user.

The International Aerospace Quality Group (IAQG) was formed to help address and improve issues around quality, delivery and cost to protect the integrity of the product and processes in the ASD sector.

Comprised of representatives from companies across the globe, the IAQG's mission is to implement initiatives that contribute to the improvement in the quality and cost efficiency throughout the value stream. Through certification to standards in the AS9100 series, companies demonstrate their efforts to bring continual improvement to the quality of their products and services.



* Source: IAQG 9101 team (2014) *IAQG 9101:2014 (Rev. E) Changes Overview 'Conformity plus Performance Equals Effectiveness'* [PowerPoint slides]. Retrieved from http://www.sae.org/iaqg/projects/9101E_changes.pdf

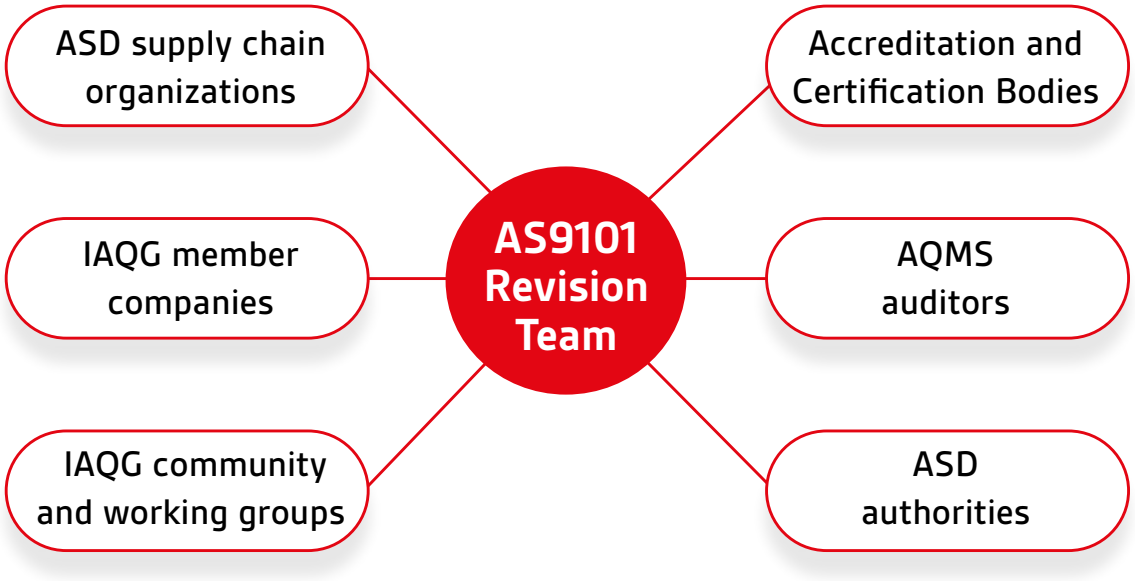
AS9101 is the standard that governs how certification bodies conduct audits in the ASD sector. While the changes to this standard directly impact CBs, there is an indirect aspect of this standard that holders of certificates in the AS9100 series need to understand.

As the certification body of choice for many of the world's ASD companies, it is important that we share the changes this revision will bring to our activities and how we believe they may affect future audits.

Overview of AS9101 Rev. E

AS9101 provides Quality Management Systems Audit Requirements for ASD organizations. The Standard has been revised by IAQG to incorporate the requirements for Certification Bodies (CBs) such as BSI, that are introduced by ISO/IEC 17021 Conformity Assessment – Requirements for bodies providing audit and certification of management systems, ISO 19011 Guidelines for auditing management systems, AS9104/1 – Aviation, Space and Defense Quality Management System Certification Program as well as inputs from industry stakeholders associated with process-based auditing methods and the evaluation of process effectiveness.

With Standards in the ASD sector, every revision brings together a working group of representatives from across the IAQG world to ensure the changes incorporate the needs of each region. The AS9101 Team was represented by the Americas, Asia/Pacific and Europe sectors with team members from 6 countries, 9 IAQG companies and 5 certification bodies. The stakeholders include:



The revisions of ISO 17021:2011 and 19011:2011 as well as the release of AS9104/1:2012 triggered the need for changing AS9101. There were a number of other factors that underscored this decision. The previous version, AS9101D, generated over 19 pages of questions, suggesting a significant need for clarification. Requirements were often lost in the appendix instructions, leading to misunderstandings. This revision is also a reflection of feedback from various ASD stakeholders as well as those comments that were received during the Aerospace Auditor Transition Training (AATT).

Highlights

The revised Standard reinforces the importance of the process approach for evaluating "process-based management systems" with the basic questions that the auditor will need to understand about every process to include:

- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the processes adequately implemented and maintained?
- Is the process effective in achieving the desired results?

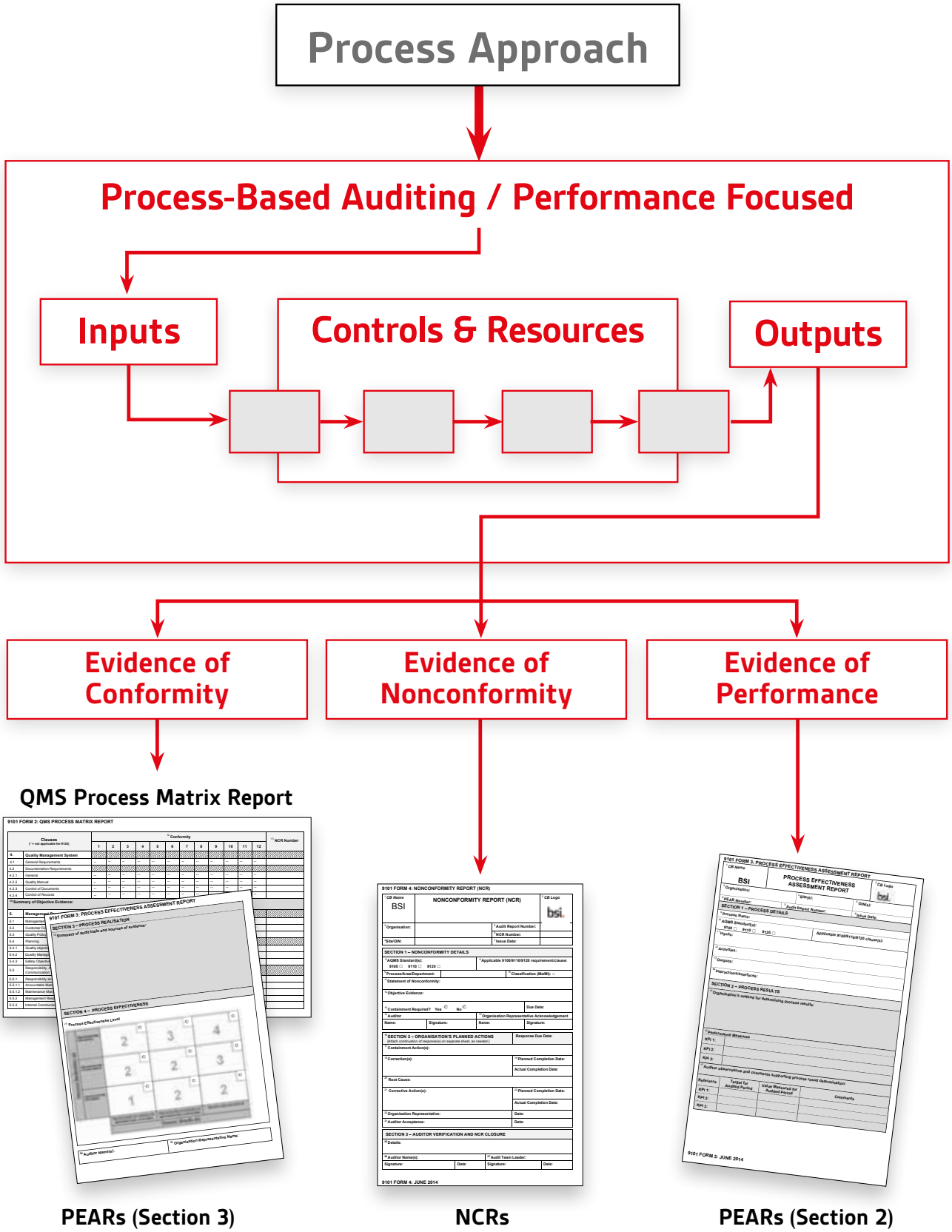
A new Process Evaluation Matrix (PEM) was developed to provide clear definitions to assist auditors in determining process effectiveness levels. The PEM guides the auditor through numerical conclusions when documenting Process Effectiveness Assessment Reports (PEARs).

Audit Methodologies previously defined as audit methods that can be used have been renamed as Audit Approaches and are now mandatory. In short, "should" statements have become "shall" statements.

Forms have been consolidated, improved and moved out of the appendices. They are now available for download on www.sae.org/iaqg. There are other changes to the forms, which include:

- Improving the forms including "QMS Process Matrix Report", "NCR" and "Audit Report"
- Incorporating AS9104/1 requirements including Certification Structure
- Improving the forms to reflect OASIS database entry requirements, including
  - Central function
  - Associated locations/OIN
  - Supplemental report number for traceability
  - Number of employees
  - Audit duration (auditor days)
  - Audited (yes/no)
- Withdrawing the OER form, but keeping the principle of recording objective evidence.
  - Capturing objective evidence in the updated PEAR form (for AS9100 series standards clause 7) and QMS Process Matrix Report (for other than clause 7) and summarized on the Audit Report form
  - Allowing the CB to use additional audit tools such as checklists or questionnaires, to help auditors in the collection of objective evidence during the audit process

This chart provides a picture of the Process Approach and where Evidence of Conformity, Evidence of Nonconformity and Evidence of Performance are recorded on the new forms.



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Details of AS9101 Rev. E

The Reference documents incorporated in developing this Standard, including ISO/IEC 17021, AS9104/1, IAF MD 3, IAF MD 4 as well as IAQG Procedure 105.6. have been updated. These changes brought about a shift in focus to the evaluation of effectiveness and its associated processes as well as increased attention to meeting the needs and expectations of the customer. The specific changes include:

Introduction

0.1 General

- Reference to ISO 19011 has been removed and replaced with AS9104/1
- Effectiveness is defined as "extent to which planned activities are realized and planned results achieved" drawing directly from the definitions in ISO 9000 clause 3.2.14.

Requirements

1. **Scope** – Reference to ISO 19011 has been removed and replaced with AS9104/1

2. Normative References:

- Provides for the updated AS9104/1
- Adds IAF MD 3 – Mandatory Document for Advanced Surveillance and Recertification Procedures (ASRP)
- Adds IAD MD 4 – Mandatory Document for Computer Assisted Auditing Techniques (CAAT)
- Adds IAQG Procedure 105.6 – Forms Management

3. Terms and Definitions

Revision E clarified a number of terms and definitions as indicated below, that are used throughout the audit process as well as those terms that appear on the revised PEAR form. ISO 9000 is the standard for all Quality Management Systems fundamentals and vocabulary; revising the terms in the AS9100 series brings the language into conformity.

3.2 Key Performance Indicators (KPIs) are those measures associated with goals or targets showing how well an organization 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 organization's progress toward achieving its goals. KPIs are used throughout this revision and have been added to the new PEAR form.

The new terms "Planned Activities" and "Planned Results" were added to further define the term effectiveness as found in ISO 9000 3.2.14.

3.7 Planned Activities are defined as 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.

3.8 Planned Results are the intended performance of a process as defined and measured by the organization. Planned results include product conformity and on-time-delivery (OTD) to meet customer requirements and may include other elements related to the process as defined by the organization.

3.9 Process Effectiveness Assessment Report has been 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.

4. Auditing and Reporting

4.1.1 Audit Process The overview of the Audit Process Flow (Figure 1) has been revised to include additional information unique to ASD that is not found in ISO 17021, while maintaining all of the ISO 17021 content.

Note: In Rev. E, Audit Methodologies have been replaced by Audit Approaches that the auditor must use (as appropriate) and Special Processes have been repositioned under Audit Approaches.

4.1.2 Audit Approaches are linked to several principles that are promoted by the AS9100 series standards. Each Audit Approach is described by the AS9101 Standard through a list of requirements that auditors can easily recognize; however, they are presented in a different order than they are in the AS9100 series standards. These approaches provide for a more effective audit trail than clause-by-clause auditing. These approaches focus on several areas, including:

- Customer Focus
- Organizational Leadership
- QMS Performance and Effectiveness
- Process Management
- Special Processes
- Continual Improvement

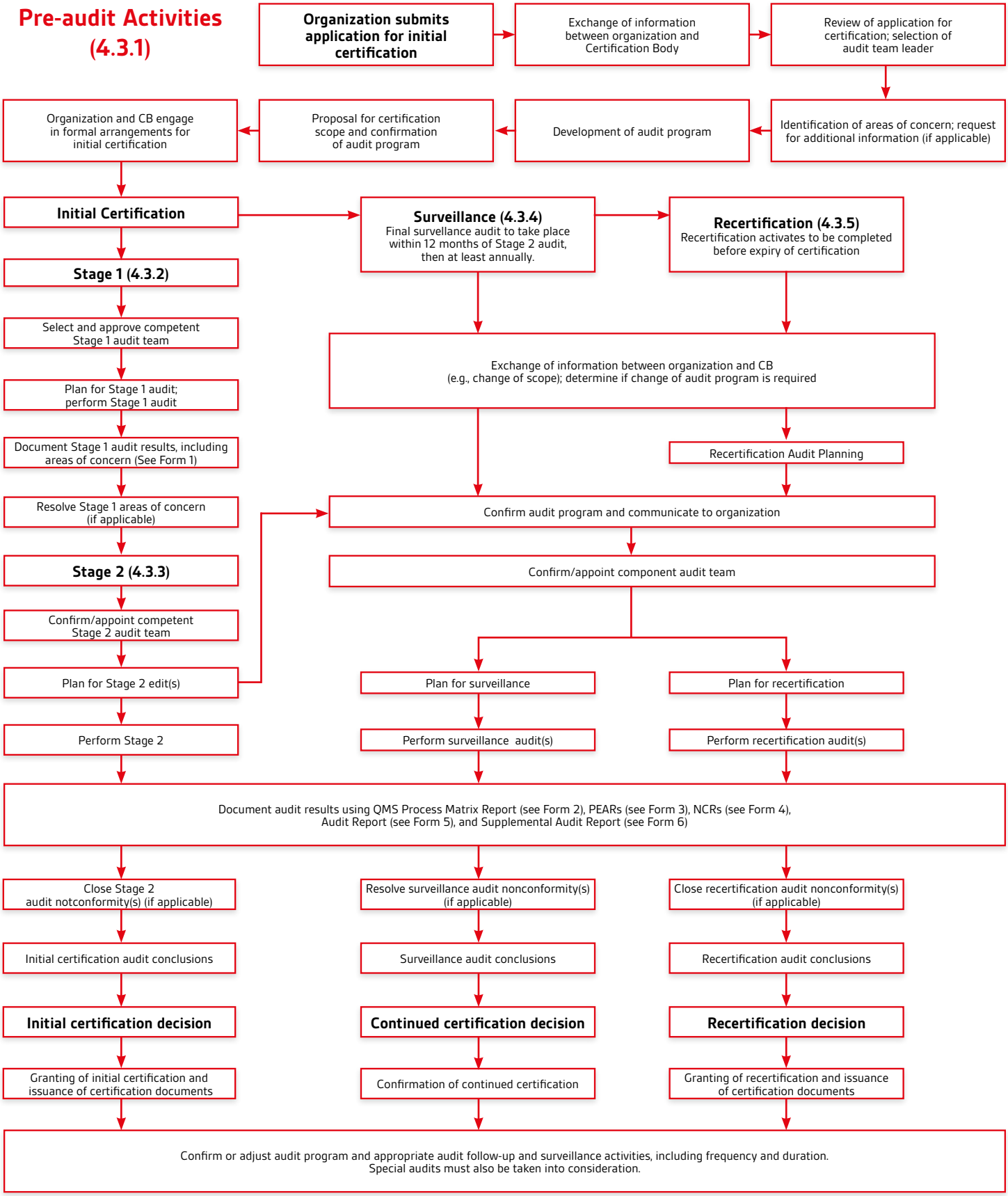

Figure 1- Overview of Audit Process Flow

(see ISO/IEC 17021 – Figure E.1)

* Source: IAQG 9101 team (2014) *IAQG 9101:2014 (Rev. E) Changes Overview 'Conformity plus Performance Equals Effectiveness'* [PowerPoint slides]. Retrieved from http://www.sae.org/iaqg/projects/9101E_changes.pdf

In order to align the reporting with other AS Standards, the audit documents have been renamed and moved from the Appendices to Forms and are now available online at www.SAE.org/IAQG. The Certification Structure Reporting Requirements have been also added. The following tables indicate the changes in the revised version. The Certification Structure Reporting requirements have been added to illustrate which forms are required for each audit stage of the new Certification Structures as defined in AS9104/1.

AS9101 D Appendices (previous version)	AS9101 E Forms (updated version)
Appendix A (Objective Evidence Report)	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)

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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 • 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)				

* Source: IAQG 9101 team (2014) *IAQG 9101:2014 (Rev. E) Changes Overview 'Conformity plus Performance Equals Effectiveness'* [PowerPoint slides]. Retrieved from http://www.sae.org/iaqg/projects/9101E_changes.pdf

4.2 Common Audit Activities have been expanded to provide that audit planning, on-site auditing, and audit reporting are common activities linked with Stage 1, Stage 2, surveillance, recertification as well as the new provision for special audits. Nonconformity management is common for Stage 2, surveillance and recertification audits.

Revision E has expanded a number of sections under Common Audit Activities.

4.2.1 Audit Planning has been expanded to incorporate the requirements from the AS9104/1 Standard. These changes include the following to be considered when establishing the audit plan:

- (l.) Certification Structure [i.e single site, multiple site, campus, several sites, complex organization]
- (m.) Integrated and/or Combined Audits
- (n.) Use of Advanced Surveillance and Recertification Procedures (ASRP)
- (o.) Use of Computer Assisted Auditing Techniques (CAAT)

4.2.2 Conducting On-Site Audits has been changed to ensure that the organization's purchasing process is audited at least annually as defined by AS9104/1 clause 8.2.2n, and has brought about specific requirements for conducting the Opening Meeting.

4.2.2.1 General repositions 'an audit of special processes' to 4.1.2 Audit Approaches, and adds the requirement for (h.) an audit of the purchasing process at least annually.

4.2.2.2 Conducting the Opening Meeting has been changed 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 option to hold a central opening meeting with site representatives, either in person or by virtual means.

4.2.2.5 Identifying and Recording Audit Findings was changed 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 Objective Evidence Report.

- The audit team shall record measures, targets, and values of KPIs related to each audited product realization process (see AS9100-series Standards clause 7) on the PEAR (section 2)
- Objective evidence for Product Realization processes (AS9100 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.)

Under this section, Revision E also introduces Process Results and Process Realization to be used in the determination of effectiveness and to align with the new definitions of Planned Activities and Planned Results.

– Process realization – the extent to which planned activities are realized and

– Process results – the extent to which planned results are achieved

It introduces the Process Evaluation Matrix (PEM) (Table 3). The purpose of 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. This is one of the more important sections in this revision.

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 results 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, however b) The process is not delivering the planned results 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 results 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)		

* Source: IAQG 9101 team (2014) *IAQG 9101:2014 (Rev. E) Changes Overview 'Conformity plus Performance Equals Effectiveness'* [PowerPoint slides]. Retrieved from http://www.sae.org/iaqg/projects/9101E_changes.pdf

4.2.3 Audit Report in Revision E has been changed to define the reporting requirements for "combined" and "integrated" audits. The CB shall now issue separate reports 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. This will provide improved and more accurate audit reporting when auditing to more than one ASD Standard as each individual audit reports are now required. When processes are identical among multiple Standards, it is now permissible to issue one PEAR report and QMS Process Matrix Report for both Standards.

4.2.4 Nonconformity Management Revision E clarifies what is expected for a nonconformity that requires containment. It clarifies Containment Action as ("fix now") and directs the Audit Team Leader to require the organization as a means of addressing the nonconformity to:

- Describe the immediate actions "fix now" taken to contain the nonconforming situation/conditions and to control any identified nonconforming products
- Record all corrections
- 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
- Review containment action and correction during the audit, as appropriate

4.3.2 Stage 1 Audit changes clarify some requirements for AS9120 audits as well as the collection of information.

- **4.3.2.1 General** clarifies Stage 1 Off-Site provision for AS9120 by moving it from a NOTE into 4.3.2.1(b) which can be conducted off-site based on consideration of various organization factors (e.g., size, location, risk, previous audit team knowledge).
- **4.3.2.2 Collection of Information** replaces the 12 month Data Collection requirement with (c.) Product Conformity and OTD Performance measures and records. It does require that the data be sufficient to allow the audit team leader to make a judgement on performance and trends

These changes have been made to assure organizations are not penalized if they did not previously have an AQMS, nor are they eliminated from attempting certification if they do not have 12 months of data. Changes to this section are also in response to FAQs on the previous versions the committee received reinforcing the direction that notes should not be used to supersede requirements.

4.3.3 Stage 2 Audit is clarified to clearly determine the timeframe between Stage 1 and Stage 2 Audits as well as what will be required if that timeframe is exceeded. Revision E states, "in the event the time period between Stage 1 and Stage 2 exceeds 6 months, an additional Stage 1 audit shall be conducted." 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. Numerous questions were asked about if there will be a time limitation before a complete Stage 1 audit would have to be restarted, because of the risks of significant changes that could impact the Stage 2 audit. International consensus determined 6 months as an acceptable time limit.

Overview of AS9101 Rev. E Forms

A number of changes have been made to the forms required under AS9101. Some forms, like the OER have been withdrawn, while others have been developed to better document the audit process as well as the effectiveness of an organization's processes.

- **General**
  - The OER is withdrawn
  - "Appendices" are changed to "Forms"
  - "Shall" requirements are moved from instructions to the appropriate text in the standard
  - Incorporated AS9104/1 requirements
  - Forms are no longer part of the Standard and are managed according to IAQG Procedure 105.6
  - Forms are available on the IAQG website at: http://www.sae.org/iaqg/forms/index.htm
- **Form 1 Stage 1 Audit Report**
  - Deletes the 12-month "Data" requirement
  - Adds the verification of the Certification Structure
  - Adds the evaluation of the 'level of QMS Integration' (ref: AS9104/1 8.2.3)
  - Deletes the signature line
- **Form 2 QMS Process Matrix**
  - Supports evidence of Conformity to the 9100 series standards for clauses 4, 5, 6 & 8
  - The AS9110 clauses were updated

- **Form 3 Process Effectiveness Assessment Report (PEAR)**
  - Section 1 provides for a structured recording of Process Details
  - Section 2 provides for a structured recording of Process Results (Performance)
  - Section 3 provides for the recording of Process Realization (Objective Evidence)
    - Note that Objective Evidence was formally recorded on the OER
  - Section 4 provides for the recording of Process Effectiveness. (Numerical Value)
  - Deletes the signature line
- **Form 4 Nonconformity Report (NCR)**
  - Use for a Combined / Integrated Audit when a nonconformity is common across the AQMS standards
  - Identifies when Containment is required and separates Containment information from Correction
  - Establishes 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, which is also subsequently uploaded to the OASIS with the associated NCR.
- **Form 5 Audit Report**
  - Adds the reporting of the Certification Structure
  - Adds provision for ASRP and CAAT reporting
  - Adds provisions for OASIS Data
- **Form 6 Supplemental Audit Report**
  - Adds the reporting of the Certification Structure
  - Adds provision for ASRP and CAAT reporting
  - Adds provisions for OASIS Data
  - Shall be used to record results for individual sites, when the (Form 5) Audit Report does not include audit details of the individual sites/locations

Next Steps

According to IAQG OPMT ICOP Resolutions Log, Resolution #117:

"Certification Bodies (CBs) shall implement the AS9101E / 9101:2014 audit requirements standard no later than July 01, 2015. This timeline may be accelerated and implementation can occur upon completion of the following:

1. CB procedures and processes shall be updated to address conformance and to the requirements of the revised standard, including access to the approved 9101 Forms on the IAQG Forms Management System website or other approved 9101 forms in other languages as may be provided by the IAQG sectors. CB clients shall be notified when the revised standard will be used for AQMS audits.
2. Authenticated Aerospace Auditors and Aerospace Experienced Auditors using the revised standard and associated forms shall have completed the web based IAQG OPMT sanctioned "IAQG 9AS101E/ AS9101:2014 Online Update Training Module" course. The CB shall maintain records of each AQMS Auditor's successful completion of the AS9101E / AS9101:2014 training module.
3. CB's support personnel (e.g.; management, administrative) shall complete internal awareness training on any changes that impact audit support processes.
4. Each CB shall advise their respective Accreditation Body (AB) and SMS (or CBMC) in writing that they have established conformance to the revised standard and this resolution.

All prior versions of the AS9101 "Quality Management Systems Audit Requirements for Aviation, Space, and Defense Organization" standard (e.g.; AS9101D / AS9101:2011) and associated forms shall no longer be used to record AS9100/AS9110/AS9120 audits after July 1, 2015.

ABs, OP Assessors and CBs shall coordinate prior to all witness and office assessments of CBs to ensure that the issue or version of 9101 is known by all parties prior to the conduct of a witness or office assessment."

While IAQG requires all CBs implement these changes no later than July 1, 2015, BSI intends for its auditors to begin using AS9101 Revision E starting March 1, 2015. Prior to any changes in our auditing procedures, BSI will notify our customers as to when these changes will take place.

Bibliography:

IAQG 9101 team (2014) *IAQG 9101:2014 (Rev. E) Changes Overview 'Conformity plus Performance Equals Effectiveness'* [PowerPoint slides]. Retrieved from http://www.sae.org/iaqg/projects/9101E_changes.pdf

"Aerospace Standard" SAE Aerospace AS9101 Rev. D 2010.

"Aerospace Standard" SAE Aerospace AS9101 Rev. E 2014.

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