IAQG 9101:2016 (REV F)

CHANGE OVERVIEW

PREPARED BY THE IAQG 9101 TEAM

16 Oct 2017

Presentation Objectives

Part One:

➤ Overview of 9101:2016 (Rev F)
- Team Membership
- Team Coverage
- Stakeholders
- Key Reasons for Change
- Key Revision Summary
- Revision Schedule

Part Two:

➤ Key Revision Detail
- 9101:2016 (Rev F) Standard

Part Three:

➤ Key Revision Detail
- 9101:2016 (Rev F) Forms

Part One

Overview of 9101:2016 (Rev F)

9101 Team Membership

Hiroshi Terao (APAQG)
9101 CB Representative
BUREAU VERITAS JAPAN

Gary Procter
9101 CB Representative
LRQA

Francois Dumesnil
9101 CB Representative
CQFD

Paul Dionne
9101 CB Representative
ABS-QE

Jeanette Preston
9101 CB Representative
SMITHERS QUALITY ASSESSMENT

Bob Keys
9101 CB Representative
DNV GL EMERITUS

Brian Geer
9101 IDR – Team Leader
LOCKHEED MARTIN

Conny Flink
9101 EAQG SDR
GKN AEROSPACE

Tom Gallagher
9101 AAQG SDR
UNITED TECHNOLOGIES

Masayuki Kogusuri
9101 APAQG SDR
IHI CORPORATION

Wilfried Weber
9101 EAQG Representative
PFW AERO

Romuald Thimon
9101 EAQG Representative
SAFRAN

Mark Heaton-Watts
9101 EAQG Representative
ROLLS-ROYCE

Michel Jacquaniello
9101 EAQG Representative
ZODIAC AEROSPACE

Stuart Anthony
9101 Scribe
IAQG

9101 Team Coverage

➢ 15 members on the 9101 team representing:

- Americas, Europe, and Asia-Pacific IAQG sectors

- 8 IAQG member companies

- 6 different countries

- 6 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

9101 Key Reasons for Change

➢ Publication of ISO17021-1:2015, ISO9001:2015 and 9100–series:2016 standards

➢ FAQs arising from 9101:2014 (Rev E)

➢ OASIS feedback requests

➢ Stakeholder feedback

➢ Lessons learned from OPMT oversight of CB audit reports

➢ Support of the OASIS Next Generation (NextGen) project

Key Revision Summary

➢ Incorporated updated requirements and revised terminology from new revisions of ISO9001:2015, ISO17021-1:2015 and 9100–series:2016 standards

➢ Changed PEAR application from previous 9100-series clause 7 (Product Realization) to new 9100-series clause 8 (Operation)

➢ Changed process effectiveness levels from 4 to 5 and simplified Process Evaluation Matrix (PEM) definitions

➢ Clarified raising of NCRs in relation to nonconformities

➢ Audit approaches moved from the 9101 standard into Auditor Guidance Material
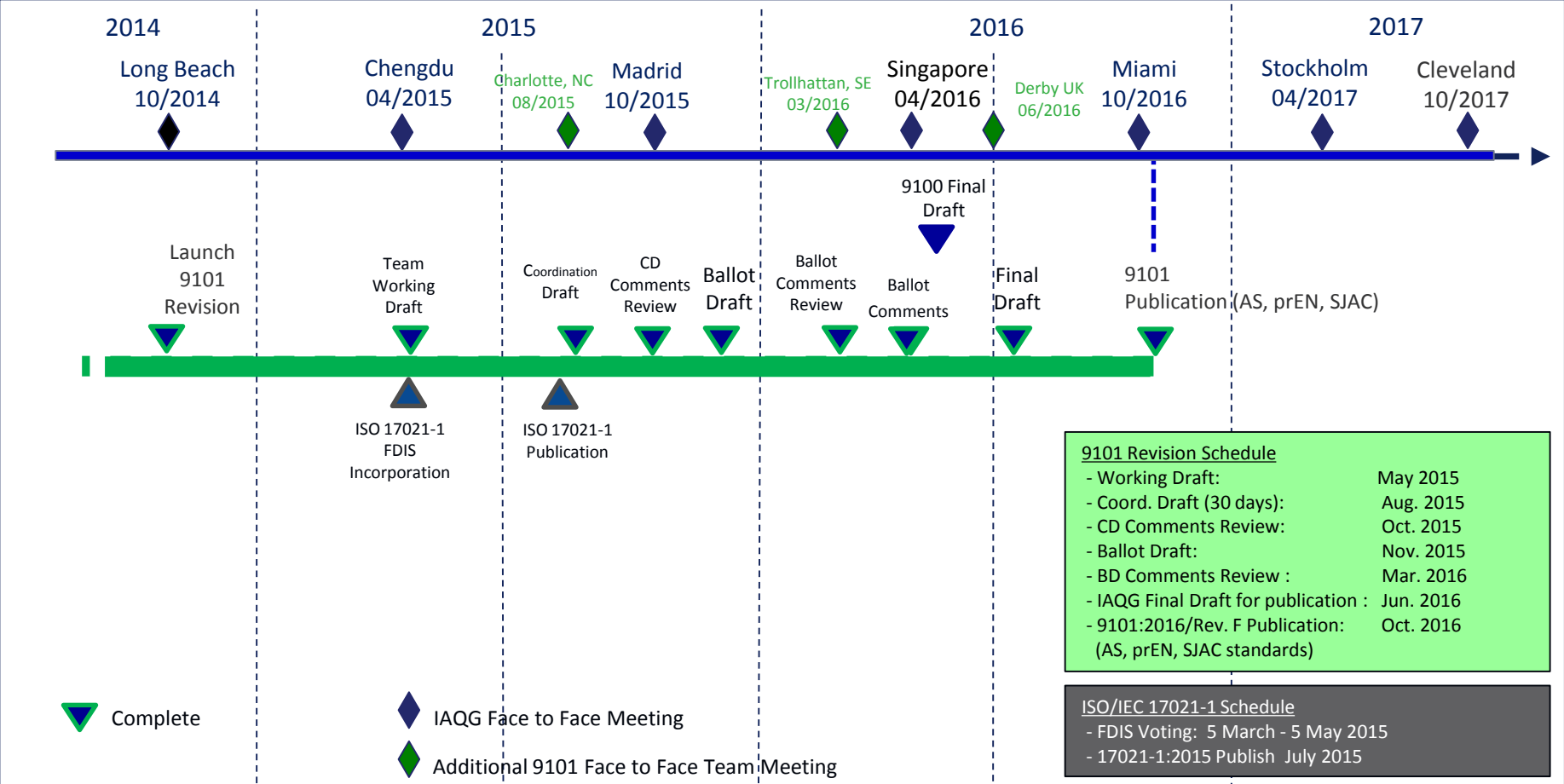
➢ ………..continued

Key Revision Summary continued…

➢ Simplified the content of 9101 clauses relating to Stage 1 audit to align with changes to Form 1

➢ Simplified/clarified Form entries and instructions to support audit reporting using OASIS NextGen

9101:2016 Revision Schedule

2014	2015		2016	2017

Long Beach 10/2014

Chengdu 04/2015

Charlotte, NC 08/2015

Madrid 10/2015

Trollhattan, SE 03/2016

Singapore 04/2016

Derby UK 06/2016

Miami 10/2016

Stockholm 04/2017

Cleveland 10/2017

9100 Final Draft

Launch 9101 Revision

Team Working Draft

Coordination Draft

CD Comments Review

Ballot Draft

Ballot Comments Review

Ballot Comments

Final Draft

9101 Publication (AS, prEN, SJAC)

ISO 17021-1 FDIS Incorporation

ISO 17021-1 Publication

9101 Revision Schedule
- Working Draft: May 2015
- Coord. Draft (30 days): Aug. 2015
- CD Comments Review: Oct. 2015
- Ballot Draft: Nov. 2015
- BD Comments Review : Mar. 2016
- IAQG Final Draft for publication : Jun. 2016
- 9101:2016/Rev. F Publication: Oct. 2016
  (AS, prEN, SJAC standards)

ISO/IEC 17021-1 Schedule
- FDIS Voting: 5 March - 5 May 2015
- 17021-1:2015 Publish July 2015

▽ Complete

◆ IAQG Face to Face Meeting

◆ Additional 9101 Face to Face Team Meeting

Part Two

Key Revision Detail
9101:2016 (Rev F) Standard

9101 Key Revision Detail

➤ Updated Major / Minor nonconformity definitions (clauses 3.3 and 3.4)

- ISO17021-1:2015 definitions have been linked as a requirement
- Additional 9101 definitions continue to be included

➤ Rationale:

- Definitions rationalized to include each respective definition from ISO17021-1

9101 Key Revision Detail

➢ Removed 'Audit Approaches' [9101:2014 (Rev E) clause 4.1.2]

- ▪ Requirements for using specific 'Audit Approaches' moved into updated "Evaluation Guidance Material".

- ▪ Requirements for conducting an audit of Special Processes has been moved to clause 4.2.2.4.1

➢Rationale:

- ▪ To build upon the maturity developed by auditors in their approach towards conducting process based audits, and to provide additional flexibility in the audit approach

- ▪ Special process audit requirements was part of 'audit approaches' and since those have been moved into guidance material the need to retain specific requirements has been relocated

9101 Key Revision Detail

➢ Clarified audit reporting requirements (clause 4.1.2)

- ▪ Updated to allow the recording of process information into one QMS Process Matrix Report
- ▪ Table 1 updated to align Special audit reporting with other audit phases
- ▪ Note added to Table 1 to provide guidance on the use of Forms 2 and 3 for Special audits

➢ Rationale:

- ▪ To provide more flexibility when common processes exist across multiple sites, campus, several sites or complex organization
- ▪ To provide a more unified audit reporting approach for all audit phases
- ▪ Note added to show that the reason for a special audit (clause 4.3.6) may have an impact on the use of Forms 2 and 3

9101 Key Revision Detail

➢ Clarified the issuing of NCRs relating to Operational processes (9100-series clause 8):

▪ Process Results (clause 4.2.2.5.1):

▪ "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 (clause 4.2.2.5.2):

▪ "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"

➢Rationale:

▪ To emphasize the requirement when to issue NCRs in relation to Process Results and Process Realization

9101 Key Revision Detail

Audit of Operational processes (9100-series clause 8)

9101 clause 4.2.2.5.1

Record process performance results on the PEAR (Section 2)

Issue an NCR when the process is not delivering the planned results and appropriate action is not being taken

9101 clause 4.2.2.5.2

Record process realization results on the PEAR (Section 3)

Issue an NCR when planned activities of a process are not realized or not fully realized

Evaluate the audit evidence from the PEAR and select the corresponding effectiveness value from the PEM
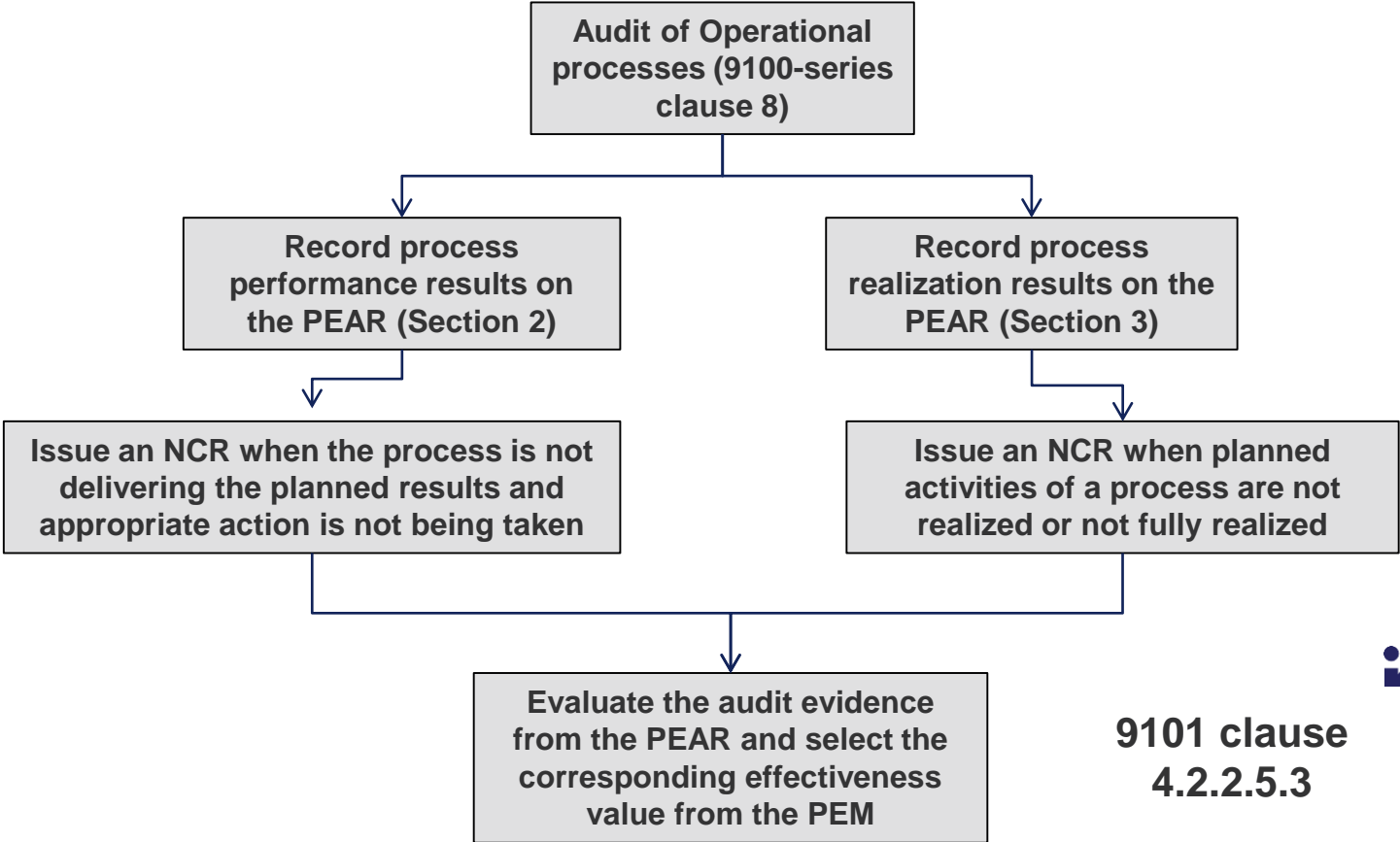
9101 clause 4.2.2.5.3

9101 Key Revision Detail

Audit findings and resultant effectiveness level

Process Realization (a)	Planned results not achieved and appropriate action is not taken	Planned results not achieved, but appropriate action is being taken	Planned results are achieved
Planned activities fully realized	2	4	5
Planned activities not fully realized	2	3	4
Planned activities not realized	1	2	2

Process Results (b)

Legend:
- NCR(s) have not been issued
- NCR(s) have been issued related to Process Realization
- NCR(s) have been issued related to Process Results
- NCR(s) have been issued related to Process Realization and Process Results

Reminder……
The process effectiveness level is determined from the audit results (conformity and nonconformity)

9101 Key Revision Detail

➢ Updated PEM (clause 4.2.2.5.3 Table 3)

- Simplified Process Realization wording "defined and implemented" becomes "determined"
- Assessment levels revised from 4 to 5 and redistributed within the matrix

➢ Rationale:

- To align the text with 9100-series terminology
- To provide more balance relating to the effectiveness result
- To improve the visual representation of process risk

9101 Key Revision Detail

Updated PEM Assessment Levels 1 & 2

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.

Process Realization (a)		Process Results (b)		
	Planned activities fully realized	2	4	5
	Planned activities not fully realized	2	3	4
	Planned activities not realized	1	2	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

9101 Key Revision Detail

Updated PEM Assessment Levels 3 & 4

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 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.

Process Realization (a)		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
	Planned activities fully realized	2	**4**	5
	Planned activities not fully realized	2	**3**	**4**
	Planned activities not realized	1	2	2

9101 Key Revision Detail

Updated PEM Assessment Level 5

Process Realization (a)		Planned results not achieved and appropriate action is not taken	Planned results not achieved, but appropriate action is being taken	Planned results are achieved
	Planned activities fully realized	2	4	(5)
	Planned activities not fully realized	2	3	4
	Planned activities not realized	1	2	2
		Process Results (b)		

Level 5 means that the process is determined and planned activities are fully realized. Furthermore the process is delivering the planned results.

9101 Key Revision Detail

➢ Clarified the requirement for the audit team leader to provide the organization with applicable NCR(s) and PEAR(s) <u>associated with those NCRs</u> (clause 4.2.2.7)

➢ Rationale:

▪ To show that only PEARs associated with the respective NCR(s) need to be provided at the closing meeting

9101 Key Revision Detail

➢ Removed the requirement to issue a separate audit report for integrated audits (clause 4.2.3)

➢ Rationale:

- Allow a single report for integrated audits by indicating Yes/No on Forms 5 and 6
- The requirement for separate reports for a combined audit is retained in accordance with IAQG OPMT ICOP Resolutions Log #105

9101 Key Revision Detail

➢ New requirement to verify the effectiveness of corrective actions taken for nonconformities (if applicable) identified during the previous audit (clauses 4.3.4 and 4.3.5)

➢Rationale:

▪ To strengthen the verification of corrective action effectiveness during subsequent audits (if applicable) and to align with a new requirement in ISO17021-1 clause 9.4.8.2 r

9101 Key Revision Detail

- Clarified the reasons for conducting a Special Audit (clause 4.3.6 a & b)
  - An organization's request to revise their existing:
    - Certification scope
    - Certification structure
    - Number of site(s) and/or location(s)
  - Transfer of certification from one CB to another (see 9104/1 clause 8.8)
- Rationale:
  - To accommodate other reasons for conducting a Special Audit, in particular an increase or reduction to the certification scope, certification structure, number of sites or number of locations

TRANSITION TOGETHER

Part Three

Key Revision Detail
9101:2016 (Rev F) Forms

9101 Key Revision Detail

➢ Form 1 (Stage 1 Audit Report):

- "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" and now includes 9100-series clause numbers & titles, reference to documented information and "Yes/No" indicator

- "Key Information" reduced in scope and renamed "Other Information"

- Removed "Website" and "Subsidiary of" boxes

- NOTE added to instructions to allow the use of attachments

9101 Key Revision Detail

➢ Form 1 (Stage 1 Audit Report) continued:

▪ Disclaimer statement added

➢Rationale:

▪ To align with updated 9101 & ISO17021-1 requirements and 9100-series clauses and terminology

▪ To provide more consistency when confirming requirements against the 9100-series standards

▪ To support OASIS NextGen

9101 Key Revision Detail

➢ Form 2 (QMS Process Matrix Report):

- 9100-series clause numbers & titles changed

- Clarified when "N/A" and 'empty boxes' can be utilized in populating the matrix

- Changed to accommodate Summary of Objective Evidence for 9100-series clauses 4,5,6,7,9 and 10

- Changed to accommodate reporting (5) PEAR levels

- Changed to identify common process application across multiple sites, campus, several sites or complex organizations

- NOTE added to instructions to allow the use of attachments

………..continued

9101 Key Revision Detail

➤ Form 2 (QMS Process Matrix Report) continued:

- Disclaimer statement added

➤ Rationale:

- To align with updated 9101 & ISO17021-1 requirements and 9100-series clauses and terminology

- To allow one report when common processes exist across multiple sites, campus, several sites or complex organizations

- To support OASIS NextGen

9101 Key Revision Detail

➢ Form 3 (PEAR):

- Added the box "Responsibility/Authority" for the process

- Assessment levels revised from 4 to 5 and redistributed

- Updated the PEM image

- NOTE added to instructions to allow the use of attachments

- Disclaimer statement added

➢Rationale:

- To align with updated 9101 & ISO17021-1 requirements and 9100-series terminology

- To provide more balance in relation to the effectiveness result

- To help with PEAR level determination when using the Form

- To support OASIS NextGen

9101 Key Revision Detail

➢ Form 4 (NCR):

- ▪ Added "Cause Code" box
- ▪ Deleted "Signature" boxes
- ▪ Instructions updated to include Annex A (List of Cause Codes)
- ▪ NOTE added to instructions allowing the use of attachments
- ▪ Disclaimer statement added

➢ Rationale:

- ▪ To align with updated ISO17021-1 requirements
- ▪ To accommodate the allocation of a suitable Cause Code from the IAQG listing in order to support future data collection.
- ▪ To support OASIS NextGen

9101 Key Revision Detail

➤ Form 5 (Audit Report):

- Audit type expanded to include reason for "Special Audit"

- Removed "Website" and "Subsidiary of" boxes

- Box added to signify Integrated Audit (Yes/No)

- "Exclusions" box changed to "Requirements determined as not applicable", "Justification" box added and "Quality Manual" changed to "QMS Documented Information"

- Changed to accommodate reporting (5) PEAR levels

- Inclusion of a statement to verify the effectiveness of corrective actions taken for nonconformities identified during the previous audit

9101 Key Revision Detail

➢ Form 5 (Audit Report) continued:

- Clarified statement for the audit team leader's certification recommendation
- Deleted "Signature" boxes
- NOTE added to instructions allowing the use of attachments
- Disclaimer statement added

➢ Rationale:

- To align with updated 9101 & ISO17021-1 requirements and 9100-series terminology
- To provide more consistency when recommending the certification decision
- To support OASIS NextGen

9101 Key Revision Detail

➢ Form 6 (Supplemental Audit Report):

- Audit type expanded to include reason for "Special Audit"
- Changed to accommodate reporting (5) PEAR levels
- Deleted "Signature" boxes
- Box added to signify Integrated Audit (Yes/No)
- NOTE added to instructions to allow the use of attachments
- Disclaimer statement added

➢ Rationale:

- To align with updated 9101 & ISO17021-1 requirements and 9100-series terminology
- To support OASIS NextGen

9101 Key Revision Detail

➤ 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/