IAQG 9101:2016 Clarifications

According to IAQG Procedure 105.2, clarifications are provided by the IAQG and Sector Document Representatives and summarized below. Please contact the applicable Sector Document Representative if you have any questions. Sector Document Representatives names and contact information can be found on the IAQG website.

Furthermore the IAQG have developed Deployment Support Materials and Frequently Asked Questions (FAQs) to help interested parties understand the 9101:2016 changes that can also be found on the IAQG website.

#	9101	Clarification Request	Clarification
1	9101 Clause 4.1.2 Table 1	Can you give examples of when a QMS Process Matrix Report (Form 2) and a PEAR (Form 3) is/is not required during a special audit to clarify the NOTE below Table 1?	1. There is no requirement to issue a QMS Process Matrix Report or PEAR during a Special Audit when certification is transferred from one CB to another, unless the existing certificate expires within the next 12 months, in which case a Stage 1 and Stage 2 audit is required (See/9104/1 clause 8.8 c). 2. A QMS Process Matrix Report is required during a Special Audit when there is a: a. A change to an organizations certification structure b. A complaint investigation or serious issue c. A follow up from an organization suspension d. An expansion in the certification scope, number of sites and/or locations And a PEAR is required in the above circumstances (a-d) when the Special Audit activity is conducted against 9100-series clause 8.
			3. There is no requirement to issue a QMS Process Matrix Report or PEAR during a Special Audit if the scope of certification is reduced, or there is a reduction to the number of sites and/or locations
			See summary table below:

Reason for Special Audit	QMS Matrix Report	PEAR	
Transferring certification from one CB to another	No, unless the existing certificate expires within the next 12 months, in which case a Stage 1 and Stage 2 audit is required (see 9104/1 clause 8.8c)		
Change to an organizations certification structure		Yes, if special audit activity is conducted against 9100-series clause 8	
Investigate complaint or serious issue	Yes		
Follow up from organization suspension			
Expanding an organizations certification scope, number of sites and/or locations			
Reducing an organizations certification scope, number of sites and/or locations	No		

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2 4.2.1 Regarding the clause requirement "the audit 1	The intent of the 0404 standard is to secure the soldit
plan shall be based on the processes defined by the organization and documented in the QMS Process Matrix Report". Does the "based on" wording require the audit plan to match the processes defined in the organizations documented information?	The intent of the 9101 standard is to assure the audit is planned and carried out according to the processes identified by the organization, so therefore the process/activities identified on the audit plan would need to be equivalent to the process names stated on the QMS Process Matrix Report (Form 2) Box 8. For example, Design and Development is equivalent to Development and Design, Product Design and Development, Des and Dev, but not equivalent to Engineering. Equivalence means not only in name but also in content.