FAQ 9101:2016 / 9101F

Rev. 2 – 05 Mar 2018

Note 1: These FAQs correspond to 9101:2016 (9101F).
Note 2: The item number corresponds with the order of submittal of the questions. This will support traceability. The questions and answers are located in this document in order of the clauses of the 9101 standard, in order to facilitate searching. New questions/adjustments since the previous issue are indicated in red.
Note 3: This is a 'living' document that will be updated regularly and published on the IAQG website.

#	FAQ# Rev.E	Clause	Question	Answer
1	6	1.2	Can an organization that does not have ASD business be certified to 9100?	Yes, this is possible: see 'IAQG ICOP and OASIS resolutions log' under help/guidance on the OASIS website: www.iaqg.org/oasis, resolution #127.
2	9	3.3	Can you give an example of a major nonconformity that it is judged to be detrimental to the integrity of the product or service?	Example: Evidence of a missed heat-treat operation found during an audit of special process control. Example: Dimensional nonconformance found in an inspection report that has not been dispositioned by the appropriate authority.
3	10	3.3	Can you give an example of major nonconformity that could result in failure or reduce the usability of the product or service?	Example: Evidence that the Test Verification/Validation procedure does not meet customer requirements. Example: Evidence of an unauthorized rework/repair without customer approval.
4	11	3.3	Can you give an example of major nonconformity that results in the total breakdown of a system to meet a 9100 requirement?	Example: Evidence that no internal audits had been performed during the last year and no planning for the next year. Example: Evidence that there is no register of external providers to show their approval status and their scope of approval.
5	86	3.3	What is meant by the term "probable" relating to "any nonconformity that can result in the probable delivery of nonconforming product or service"?	The auditor makes an assessment (based on objective evidence) as to whether the nonconformity would have been detected by the organization during subsequent activity, to prevent delivery of nonconforming product or service to the customer.
6	14	3.3 3.4	Is there a direct relationship between the major and minor nonconformity definitions and the effectiveness measurements defined in 9101?	No. See 9101 clause 4.2.2.5.3 for evaluation of effectiveness.

7	87	3.8	Is a performance metric required for both quality and timeliness for every process covered in 9100-series clause 8?	No, performance metrics for operational processes are defined by the organization in relation to each identified operational process. Determination of Quality and OTD performance also needs to be measured by the organization to demonstrate fulfillment of customer requirements, but this is not related to every process.
8	20	4.2.1	Is the verification of customer specific performance targets the task of a CB audit, as this is not a defined requirement in 9100-series standards?	The auditor should establish with the organization if a customer has specified performance targets and if "yes", review performance against those targets.
9	21	4.2.1	How shall an audit address 'customer concerns'?	Audit planning should include evaluating actions taken to address 'customer concerns' such as customer complaints and OASIS feedback. These are inputs that can influence the audit plan. These can be audited at the (next) surveillance/recertification audit or by a special audit (see 9101 clause 4.3.6)
10	23	4.2.1	Why customer specific QMS requirements shall be audited?	9100-series clause 4.4.1 states 'The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements. The aim is that the QMS requirements of customers are included in the audit, to reduce the need for additional QMS audits by the customers.
11	24	4.2.1	Can you give examples of customer specific requirements?	Requirements related to: the use of 9102, traceability, nonconformity management, role of the MRB, use of customer approved external providers, retained documented information, flow down to external providers, etc.
12	25	4.2.1	How has an auditor access to customer specific requirements?	Pre-audit information, contract files and/or purchase order notes all provide insight into customer specific requirements. The audit team has the right of access to files related to contracts.
13	27	4.2.1	Shall statutory/regulatory requirements be audited?	The applicable statutory and regulatory quality management system requirements shall be addressed (See 9100-series clause 4.4.1) during the audit. Results of statutory and regulatory audits can be used to evaluate parts of the QMS such as corrective action, internal audit and management review.
14	30	4.2.2.2	How do you conduct an opening meeting on a site when the site is not visited by the audit team leader but by an AEA only?	In most cases the team leader would expect the AEA at each site to conduct a site specific opening meeting. Site specific personnel need to be informed of the important issues covered by clause 4.2.2.2. Audit team still need to ascertain important specific information about the site. e.g. Health & Safety issues etc.

15	32	4.2.2.5	What is the level of detail for processes to be recorded on the PEAR form?	The process (e.g. Design, Manufacturing, Purchasing) is determined by the organization and recorded on the PEAR. All processes are assessed at an appropriate level, and audit trails and audit evidence are summarized in sufficient detail within Section 3 of the PEAR to provide adequate visibility of the process audited.
16	33	4.2.2.5	Why is objective evidence for conforming situations recorded in addition to nonconforming situations?	To provide objective evidence of the audit findings and to meet the requirements of ISO17021-1 9.4.5 that requires conformity and nonconformity to be identified, classified and recorded.
17	34	4.2.2.5	When would the recurrence of a nonconformity during a consecutive audit lead to a major nonconformity?	When the same or similar nonconformity is identified at the same site/location during one audit and the following audit to indicate that the corrective action process is not effective.
18	36	4.2.2.5	Do I have to raise a major NCR against clause 4.4.1.c and/or 4.4.1.g when the effectiveness level of the process is rated a “1”?	A major NCR would be raised against 9100-series standards 4.4.1.c and /or 4.4.1.g if the nonconformity was related to the effective operation and control of the QMS processes and met the definition for a major nonconformity (9101 clause 3.3). NCRs are the result of nonconformities identified during the audit in relation to process realization and/or process results (see 9101 standard clause 4.2.2.5.1 and 4.2.2.5.2). NCRs are not the result of the process effectiveness level.
19	37	4.2.2.5	If a regulatory audit (or customer audit or other) has taken place and NCRs have been written, should the same NCR be written by the certification body auditor if the corrective action has not yet taken place?	Yes, the CB auditor shall write NCRs if the corrective action has not taken place as scheduled.
20	42	4.2.4	Do I have to be onsite to verify and close the NCR?	Not always needed, dependent upon the documented information provided by the organization. See also ISO 17021-1 9.4.10.
21	46	4.2.4 b	Why do nonconformities have to be corrected within 30 days from the end of the on-site audit, while systemic issues typically take longer than 30 days?	Correction, corrective action(s) and corrective action plans have to be agreed between the CB and the organization within a maximum of 30 days after the end of the on-site audit. It is recognized that implementation of the defined action(s) can in some cases take longer.
22	48	4.2.4 b	If agreement is not reached within 30 days from the issuance of the nonconformity although the organization is adequately reacting, can the CB allow the organization some extra time?	Agreement within 30 days is a "requirement", but the CB may allow the organization some extra time in exceptional circumstances, providing the agreement is being actively managed.

23	47	4.2.4	Why the “Evaluation and closing of the corrective action plan and associated corrective actions relating to a nonconformity shall not be performed during the audit in which the nonconformity was issued”?	Because the organization would need sufficient time to undertake a review of the identified nonconformity including correction, root cause analysis and corrective action. Furthermore the audit plan would not accommodate additional time to undertake a review of the organizations response and objective evidence.
24	89	4.2.4	Does the auditor need to create a new (or updated) audit report (Form 5) following an on-site NCR verification follow up visit?	There is no requirement to create a new (or updated) audit report following an on-site NCR verification visit. Section 3 of the NCR (Form 4) is used to document verification of the corrective action and effectiveness of actions taken to prevent recurrence.
25	13	4.3 4.3.1	Clause 4.3 states "the CB shall require the organization to provide information if any activities, programs, specifications and/or areas are not accessible because of restrictive or confidential nature” and in 4.3.1 “the scope of certification shall not include processes that were not audited to sufficient depth to verify the organization's conformity, including the determination of effectiveness. However they may be included if the processes can be proven to be similar to processes that were assessed and the same QMS documented information and controls are invoked.” Therefore how can I determine effectiveness and that they are truly using the same documented information, etc. if I do not have access to the information?	If access is not permissible, it will be up to the auditor to determine similarity by interviewing personnel and assessing maintained and retained documented information that is available to draw this conclusion. If the auditor cannot make such a conclusion then coordinate with the CB not to include the program or processes in the scope of certification. Note: Audit planning may include access permission or security clearances arranged prior to Stage 2 or any onsite audit. Proprietary Information Agreement (PIA’s) may also be included between the CB and the organization.
26	53	4.3.1.1 a	What is the purpose to record revenue for aviation, space and defense industry business as a proportion of the organization’s total revenue?	The information is used as an input to Audit Planning (see 4.2.1 p) in order to determine the amount of audit time proportional to the level of business each customer represents.

27	55	4.3.2	Is there a limit to the number of Stage 1 audits that could be conducted?	There is no limit to the number of Stage 1 audits, however one Stage 1 audit should be sufficient. If during the (scheduled) audit days for the stage 1 audit, time is not sufficient, additional days should be added. The CB shall consider the need to repeat all, or part of the Stage 1 audit if any significant changes occur that would impact the management system (see ISO17021-1 9.3.1.2.4). In the event the time period between Stage 1 and Stage 2 exceeds 6 months, an additional Stage 1 audit shall be conducted (9101 4.3.3).
28	58	4.3.2.3 e	Why do 'export limitations/controls [e.g., International Traffic in Arms Regulations (ITAR), Export Administration Regulation (EAR)]' have to be reviewed by the audit team?	In order to provide an understanding to the CB regarding product or service information, processes and documentation that may impact the audit and subsequent reporting.
29	59	4.3.2.3 a	Can an organization claim Design as "Not Applicable" within their certification scope if they undertake design activity that in turn is passed to their customer who has overall design responsibility for the product?	No, the justification shall not be accepted by the CB for organizations that perform design activity needed to fulfill aviation, space and defense customer contracts.
30	60	4.3.2.3 f	What is the difference between 'direct ship' and 'direct delivery'?	It depends on the Airworthiness Authorities (FAA/EASA). See ARP/EN/SJAC 9107 and 9114 and the IAQG dictionary, available via the IAQG website.
31	63	4.3.3	Why the Stage 1 and Stage 2 audit cannot be performed on the same day or consecutive days?	Because it cannot be foreseen before the Stage 1 audit that the organization is ready for the Stage 2 audit. So, the Stage 2 audit can only be scheduled after the Stage 1, in order to ensure that there is sufficient time for the organization to take appropriate action to eliminate possible areas of concern.
32	90	4.3.4	Can you clarify what is meant by "repeat nonconformities" and how that may lead to suspension of the certification?	The audit team leader may recommend suspension of the certification if the audit result identifies a trend of repeat nonconformity to indicate that previous corrective action defined and implemented by the organization is deemed to be ineffective.
33	68	4.3.5 NOTE	If it is justified to conduct a full or partial Stage 1 audit during recertification due to the appointment of a new audit team are these days included in the 9104/1 tables?	If a Stage 1 audit is determined to be necessary during recertification, additional audit days shall be added to the required audit duration defined in Table 2 (see 9104/1 8.2.2 h).

34	74	Form 1	What is the reason for the detailed information on “Aviation, Space and Defense” and “other” business as well as the separate call out of the workforce?	Information is needed to support audit planning including calculation of the audit duration, coverage of shift patterns and to determine the amount of audit time proportional to the level of business each customer represents.