FAQ 9101:2010 / 9101D

Rev. 7.0 20140626

Note 1: This FAQ is corresponding to 9101:2010 (9101D).
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 chapters of the 9101 standard, in order to facilitate searching. New questions 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.

#	Clause	Question	Answer
1	General	Why are there no recommended practices included in the standard?	Recommended practices are, generally speaking, not included in standards developed by IAQG. When needed, IAQG will publish recommended practices and guidance material as separate documents.
2	General	What is the relation between the 9101 and the 17021-2 after publication, as there is some duplication with the new ISO17021-2 as now underdevelopment?	The leading principle is that there should not be duplication in standards as developed by IAQG and published ISO standards. As a consequence, IAQG 9101:2009/2010 will be modified after 17021-2 comes into force to eliminate duplications.
3	General	Is it mandatory for an organization to submit information on finances and manpower?	Finance: Yes - Financial information shall be used to prioritize the audit time for the various customers and activities. When actual financial data cannot be disclosed, proportion of aviation, space & defense business is mandatory for auditing planning purposes. Reporting of EBIT, revenue information, etc in the audit report is optional, subject to approval of the audited organization. Manpower: Yes - This information should be submitted to the CB. Reason for this is that the audit duration is linked with the manpower.
4	General	Can the standard be used for 1st and 2nd party auditing?	Yes, the standard can be used in support of internal and external audits, as appropriate, see note 2 in clause 1.2.
5	General	Is the verification complying with the fulfillment of the requirements of airworthiness regulations of the regulatory authorities, e.g., FAA, EASA, for an approvable QM-system addressed in the standard?	The 9100 series is covering various airworthiness regulation issues in the requirements, e.g. the requirements as in 21G.139b. Also the 9100-series standards makes a statement in 4.1 on fulfilling the applicable statutory and regulatory quality management system requirements . The auditors have to audit these requirement, where applicable. Also there is no change to the approach as in the old 9101

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
6	General	Why there are no longer separate 9101,9111 and 9121 standards?	The reason for this is that the common part of the clauses and reports are is much bigger than the specific parts for 9110 and 9120. By integrating the specifics into one document, a considerable cost reduction and efficiency improvement can be achieved.
7	General	Why are there so much additional requirements, in comparison with the previous version?	The main reason for this is to reduce variation in application and interpretation between the various users of the standard, e.g., between CBs and /or individual auditors. This will increase the reliability and robustness of the Aerospace Certification scheme as controlled by industry, which is part of the IAQG strategy. This standard will eliminate the guesswork.
9	General	Why there is no definition of "Top Management" in 9101?	Top Management" is defined in ISO 9000 §3.2.7
10	General	Shall exclusions be reported?	Yes, on the OER (see box 9 of the instructions) and in the audit reports E and F (box 12).
11	General	Where can I find the allowed time period for distribution of the audit report?	See 9104-1 8.5 a.
12	General	Why is the use of the report formats mandatory?	The use of the specified formats is mandatory because they can be used by customers of the organization. The standard format will provide for the efficient reading and access to the data and prevent misinterpretation.
13	General	Why the standard considers the possible use of the certification body as an extension of the customer (or other interested parties) of the organization?	Aerospace industry considers this as an important requirement in order to reduce the need for additional QMS audits by the customers and associated cost. This should be provisioned in CB contract. From the beginning IAQG has seen the OP Certification as an alternative for customer QMS audits at supplier.
14	General	Do the standard and the forms adequately address the assessment of multiple site organizations? As written it only has one minor reference in Stage 1.	Yes, multi-site reporting is addressed in chapter 4.2.3. The stage 1 for multi-sites is addressed in clause 4.3.2. Appendix A, D and G can be used per individual site.
15	General	Why so many forms have to be completed?	The forms are just reflecting the type of activities that auditors have to perform. Completion of these forms is considered as objective evidence
16	General	Does 9101 contain additional requirements to the QMS of an organization?	No, there are no additional requirements to the QMS of an organization in 9101.
17	General	Have the requirements in 9101 been tested before publication?	Yes, a draft version of requirements has been tested in pilots. The feedback from these pilots have been taken into account when modifying the draft text into the final version.
18	General	Has the text of the standard exposed to external comments before publication?	Yes, 4 drafts have been published for comments. Around 600 comments have been addressed and incorporated where appropriate.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
19	General	Does the new 9101 contain duplication with ISO 17021 and/or 19011?	The new 9101 does no contain any duplication. The 17021 requirements are all applicable, unless 'overruled' by 9101. By the 9101 standard, the guidelines of 19011 are now worldwide to be applied mandatory by CB's as requirements, as already earlier implemented in the Americas sector by ANAB thru Heads Up 36.
20	General	Why 9101 is written as a set of requirements for the certification bodies on how to conduct, perform and document audits instead of a guidance?	It is written as requirements and not as guidance as it is our experience that if it is not a requirements, variations do occur. The standard is a contribution to making the ICOP scheme more robust.
21	General	Why 9101 is written knowing that ISO is working on 17021-2 containing many similar or even duplicate requirements?	It will take some time before 17021-2 comes into force. IAQG did not want to wait. As soon as 17021-2 is applied by the CBs, 9101 will be rewritten to eliminate duplications.
22	General	Can all the 9101 required forms be completed within the audit days as required by IAF MD 5 EMS and QMS audit duration?	No, but recording the objective evidence using the relevant sections of the OER is permitted during the on-site audit time as per 9104-1 8.2.2 d).
23	General	Why scoring is deleted from the new 9101 version?	The feedback that we received indicated that scoring was hardly used or misused (e.g. personal evaluation), but that it took considerable time to do the scoring and include it in OASIS. Based on this, the decision was taken not to continue with scoring.
113	General	When do the CBs have to start using 9101D/2009/2010?	CB's have to start using 9101D/2009/2010) when they are going to audit and certify against the new 91xx:2009 standards, after fulfilling Supplemental Rule 001 – Rules for 9100/9110/9120:2009 Transition, as published by IAQG on the OASIS main page. The 2 most important rules are: 1) Auditors have to go through and successfully pass the IAQG Sanctioned Auditor training and authentication for the new standards with their respective AAB. 2) CB's will have to support a review by the AB to demonstrate conformance to this SR
124	1.2	Can an organization that does not have ASD business be registered to 9100?? This question arose during a discussion about companies that want to get ASD business but can't because they are nor registered 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 # 29..
24	3	Why there is no definition of 'Opportunities for Improvement'?	It is commonly used, see a.o. § 3.2.13 in ISO9000, not appropriate to define in 9101, as it is also used in ISO standards. It should be in 9000.
25	3	Why there is no definition of 'Key Performance Indicator' or 'KPI'?	Key Performance Indicator is a commonly used term in the ASD industry. Although KPI is not defined within the Standard; clarification can be found in Note 1 of 4.1.2.5
26	3	Where is the definition for "nonconformity" located?	The definition for Nonconformity is in ISO 9000:2005. 9101 does NOT include definitions that are covered in other reference documents.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
97	3.1	Is containment action needed for both major and minor NC?	Yes, when applicable, see NCR instruction 16
98	3.2	Can you give an example of a major NC that it is judged to be detrimental to the integrity of the product?	Example : NC in special process control that result in reduction of reliability of the product e.g. missed heat treating operation.
99	3.2	Can you give an example of major NC that could resulting in failure or reduce the usability of the product or service?	Example : a) NC in design verification process that result in non fulfillment of a product performance requirement b) not completing a rework/repair prior to shipment without customer awareness.
100	3.2	Can you give an example of major NC that resulting of total breakdown of a system to meet 9100 requirement?	Example: No internal audit performed during the last year and no planning for the next year.
27	3.3	Can you give examples of 'similar nonconformities associated to different sites or different departments/functions/processes within a single site'?	Multiple site examples: Document control issues such as documents not readily available all sites; nonconformities issued at one site not evaluated as closed at all sites; internal audits not performed in accordance with audit plan at all sites. Single site examples: : Measuring equipment found out of calibration in various departments, internal audits not performed in accordance with the internal audit plan at different sites, performance information not up to date in various processes, customer complaints not addressed in relevant functions. Major Nonconformities are defined in 3.2. Classification of NCs will be based on auditor judgment; observed conditions shall take into consideration if the issue is an isolated incident or is a systemic issue..
28	3.7	When is the OER is to be initiated and populated with information?	The OER may be used during Stage 1 to record appropriate OE; it shall further be used during appropriate audit activities (see note 1 in clause 4.2.2.5; also reference clause 4.3.2.2/3).
29	4.1.1	What is the difference between an audit program and an audit plan?	An audit program is intended to address the full certification cycle: which sites/ processes/departments are to be audited in each individual audit and surveillance visit; an audit plan is addressing the detailed activities within one (surveillance) audit. See also ISO9000 and 19011.
30	4.1.1	Why the selection of the audit team is placed before the stage 1 and not after this stage when more information is available?	Stage 1 is part of the Initial Audit; the audit team may need more than one person and must be selected based on the information provided.
123	4.1.1	Questions are being raised about the flowcharts "not making sense the way they are written" - some believe some of the boxes on the Stage 2 section should belong at the end of the Stage 1 Audit. Could you comment on the intent of this flow?	The flowchart is just a navigation aid and a high level summary of the process flow as described in detail in 9101. The flowchart is not a requirement in itself, the text of the standard is binding.
32	4.1.2	Is there is a direct relationship between the major and minor nonconformity definitions and the effectiveness measurements defined in the document?	Yes there is a relationship, see 4.2.2.5 and the instructions in appendix C.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
33	4.1.2	Why 'Configurations audits' are not one of the approaches as defined in section 4.1.2?	9101 standard is the requirements for auditing, regardless of the audit scope. Configuration audit is a specific audit scope undertaken by the organization per 9100 standard.
34	4.1.2	Why there is no verbiage or defined approaches associated with the 'Risk Approach to Auditing' in section 4.1.2	Risk is just one element of the auditing approach. The approach to risk is covered throughout the 9101 standard with particular emphasis on audit planning and audit execution.
35	4.1.2	Do all 6 different audit approaches have to be used during each audit phase?	No, audit approaches can be used as appropriate to conduct each on-site audit. These approaches are foundational to the objectives of transforming the 9101 from a checklist to a process based auditing requirements document.
36	4.1.2.1	How shall the audit team document whether customer satisfaction is adequately evaluated and appropriate actions are taken by the organization	Objective Evidence should be recorded on the OER (Clause 8.2.1); any findings that are classified as nonconformity shall be documented on the Appendix B NCR and followed up as appropriate.
125	4.1.2.1 and others	Can an auditor access performance data for an organization in OASIS?? This question came up during a discussion of what they should be reviewing in preparation for an audit.	No. OASIS does not contain performance data. Performance data would have to be obtained from the organization during Stage 1 or surveillance/recertification audit planning and/or on-site audit phases.
37	4.1.2.2	Is the top management interview required at each audit? Or once a year? Or once a registration cycle?	Minimum is once a year. See section 4.2.2.1 and Note and section 4 .3.4 NOTE 1.
38	4.1.2.3	Is the verification of customer specific targets the task of a CB audit, as this is not a defined requirements in 9100 series standards?	The auditor should be inquiring with the organization if a customer has imposed specific performance targets and if "yes", review performance against those targets in order to determine if there is conformance with the following requirements of 9100 series standards : a. monitoring and control of processes is effective (4.1), b. there is a focus on the customer (5.2), c. monitoring of customer satisfaction (8.2.1), and d. continually improve the effectiveness of the quality management system (4.1, 8.4).
39	4.1.2.3	Can effectiveness be determined based on a sample process per visit as effectiveness is typically determined over time?	Yes - effectiveness can be determined based on performance indicators. These should cover at least a certain period. Therefore it is important to audit during the stage 1 if these PIs are in place. If they are not in place, the organization is not ready for the stage 2.
40	4.1.2.4 & 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 a (next) surveillance/recertification audit or by a special audit (see 9101 4.3.6)

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
41	4.2.1	Why customer specific QMS requirements shall be audited?	9100-series (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.
42	4.2.1	Can you give examples of customer specific requirements?	Requirements related to: the use of 9102, traceability, NC management, role MRB, use of customer approved suppliers, record retention, requirements flow down to suppliers, etc.
43	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.
44	4.2.1	Shall the audit team check the customer related percentage of the companies' activities?	No, the audit team shall use the customer related amount of work/activities to prioritize the audit activities 'pro rata'.
45	4.2.1	Shall requirements from the authorities be audited?	The applicable statutory and regulatory quality management system requirements shall be addressed (See 9100 4.1). If audit trails lead the audit down that path, the results of "authorities" audits can be used to evaluate other parts of the QMS such as corrective action, Internal audits and management review. If a company is approved by an aviation authority, the CB audit shall not duplicate the authorities audit.
143	4.2.1	Does the (lead) auditor need all information as indicated before each surveillance audit?	No. The information listed in the 9101 standard is referred as "should" (recommendation), not "shall" (requirement). The (lead) auditor can also use the previous information.
127	4.2.2.1	4.2.2.1 h) 9101 Does this mean each special process has to be audited annually?	No. Only those special processes as identified in the audit plan.
144	4.2.2.2	Opening meeting by team leader (TL)? What to do with an opening meeting on a site when the site is not visited by the TL but by an AEA only?	In most cases, TL would expect AEA at each site to conduct a site specific opening meeting. Site specific personnel need to be informed of the important issues covered by 4.2.2.2. Audit team still need to ascertain important site specific information about the site. E.g. Health & Safety issues etc.
145	4.2.2.4	Where and how various auditing approaches should be defined in the audit plan? Can you give examples?	The audit shall be conducted in accordance to the audit plan, but there is no requirement to define the audit approaches in the audit plan, Use appropriate audit approaches (see clause 4.1.2.1 through 4.1.2.6 for examples).
46	4.2.2.5	Is the use of the OER (Appendix A) mandatory?	The use of the OER is not mandatory, as long as objective evidence is recorded on documents that meet the intent of the OER, e.g., CBs may use their own forms.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
47	4.2.2.5	What is the intent of the OER?	The intent is to record the objective evidence from the clauses that have been addressed during the audit. Objective evidence may include documents, procedures, records etc, including the related identification of the department(s), process(es).
48	4.2.2.5	Can a nonconformity be written during the stage 1 audit?	No, see ISO17021, only areas of concern are to be recorded , on Stage 1 report (box 30). During the stage 2 audit, these might become NC's if not properly addressed/resolved by the organization prior to the stage 2.
49	4.2.2.5	Why Process Effectiveness Assessment is limited to the product realization process only?	The process of effectiveness assessments is introduced for the first time in history. Therefore it was decided to do this at a manageable level. In the future it might be expanded as evaluation of effectiveness matures. Note that other processes can be recorded on a PEAR.
50	4.2.2.5	What are 'Product Realization Processes?	The concept of product realization processes is described in section 0.2 of 9100-series. See also 7.1.
52	4.2.2.5	What is the level of detail for processes to be recorded on the PEAR form?	It should be the processes determined by the organization and covered within the audit plan. On all organization processes sampling is allowed: not to deep level, not to high level; examples: purchasing, production planning, design, assembly of a specific product line, etc.
53	4.2.2.5	Why also record objective evidence for conforming situations, and not only for nonconforming situations?	For 2 reasons: 1. To have objective evidence that the situation was audited, 2. To fulfill the requirements of 17021, a.o. 9.2.3.1 and 2, in a standardized way.
101	4.2.2.5	When recurrence of NC during consecutive audit should lead to major NC?	When the same or similar NC is identified at the same location during one audit and the following audit. Repeat of issue demonstrating the corrective action and/or continual improvement processes are not effective.
102	4.2.2.5	If I have multiple PEARs that are 1 or 2, do I have to issue an NCR against 4.1 c or f for every PEAR or can I roll up multiple PEARs into one NCR against 4.1 c or f.?	Multiple PEARs that are level 1 or 2 can be rolled up into one NCR against clause 4.1 c and f if the auditor determines the Management System to be ineffective . If this is not the case then individual NCRs should be raised for each PEAR that is determined level 1 or 2 for each respective process.
141	4.2.2.5	Do I have to raise a second NCR against clause 4.1.c and f if I find a non-conforming condition against the AQMS standard requirements?	No, a NCR raised due to a non-conforming condition against the AQMS standard requirements does not mean a second NCR must be written against clause 4.1 c and f. The only time a second NCR is required to be written against 4.1 c and f is if a PEAR rating of 1 or 2 is noted against the respective process (see also FAQ #102).

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
116	4.2.2.5	If a regulatory audit (or customer audit or others) has taken place and NCR's have been written, we go out to audit and discover the same issue - should a NCR be written by us as the certification body auditors (if the corrective action has not taken place)?	Yes, the CB auditor shall write NCR's if the corrective action has not taken place as scheduled.
118	4.2.2.5	Do we have to complete an OER & QMS matrix for each site (for instance several sites are under one scope - site A, B, C, D....) If they have a process that covers all of the sites, do we have to complete a QMS matrix for each of just one)?	Objective evidence gathered during the assessment and included in the audit report must be traceable to where it was found (e.g. site, project, document, record etc). This could be achieved by producing one composite OER & QMS matrix for all sites provided that traceability is maintained, or separate OER's/QMS matrices for each site. So, flexible use, up to the CB.
119	4.2.2.5	Who will approve that our OER meets the intent of the requirements if we modify it?	If there is doubt at the CB, the RMC/national CBMC should be asked for advice. There is no formal requirement that the CB's OER needs formal approval. In the end, it is the oversight assessor who will have a judgment on the OER used by the CB.
129	4.2.2.5	PEAR is to be completed and entered into OASIS in what language? English?	In the national language, as used with the other forms
146	4.2.2.5	Where do we have to record the objective evidence on the (non) fulfillment of the customer requirements on the QMS? On the OER? The OER gives no indication for that. Can you give further instructions on this?	Expectations are that you incorporate into your process based audits samples of the relevant customer specific requirements and record objective evidence of fulfillment against the applicable clause on the OER (or PEAR as appropriate).
54	4.2.2.7	Why this paragraph does not instruct the lead auditor/auditor to report safety issues or airworthiness nonconformities	If a company is approved by an aviation authority, the CB audit shall not duplicate the authorities audit. If requirements from the authorities to the customer have been 'passed through' to the organization, they shall be considered as customer requirements. These shall be audited. It is for the organization to inform the customer and to determine together with the customer if there are safety issues. See also 9100-series 8.3.
55	4.2.2.7	Why is not included in this section that auditors should discuss the findings issued during the closing meeting?	This is already addressed in 19011 6.5.7. There is no duplication in 9101. Note that application of 19011 guidelines is mandatory when using 9101.
56	4.2.2.8	Where are the special processes as operated by an organization recorded?	Special processes shall be identified during the stage 1 and recorded on the Stage 1 audit report. See Appendix F of the new 9101 standard (ref. Box 29) and for surveillance and recertification audits, audit planning activities (see 4.2.1) require that any change in processes shall be identified and recorded on the Audit Report (ref. Appendix E box 36). Audited special processes have to be recorded in OER.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
57	4.2.2.8	Can existing special processes being excluded from the audit?	Yes - Special processes (7.5.2) is an excludable clause (ref. ISO9001 and 9100 1.2 “exclusions are limited to requirements within Clause 7”). Naturally, the exclusion shall not be accepted by the CB as justifiable for production organizations that operate special processes needed to fulfill aerospace customer contracts.
58	4.2.2.8	Do for each special process, the validation records have to be verified, specially in cases where organizations run many special processes, this can not be fulfilled within the timeframe of the audit plan?	The extent of coverage of special processes will be taken into account during the audit planning process. Sampling is allowed.
59	4.2.2.8	How should an audit team perform audits on special processes?	It is not intended for a QMS auditor to conduct a detailed process evaluation of special process characteristics. It is expected however that the auditor will verify the validation of special processes (using appropriate records) as required by 9100-series 7.5.2.
128	4.2.2.8	Note 3: If a customer audit or other party i.e. NADCAP has performed an audit do I still have to audit the special process also? Pertaining to "can take the audit by.....into account"	Not completely; a review of the audit results, sampling on some of the findings and verification if any reported nonconformities have been adequately solved , i.e. no recurrences, would be sufficient.
60	4.2.3	When the QMS Process Matrix Report (Appendix D) shall be completed?	This form has multiple applications, see note 1 in clause 4.2.3.
61	4.2.3	Why "Not Evaluated"(N/E) shall not be used in an initial or recertification audit?	The N/E requirement is related to Appendix A only. The reason is that all clauses shall be audited during the initial or recertification audit, except those clauses of chapter 7 that have been excluded . In this case the exclusion must be clearly indicated with ‘EX’ in the OER: see box 9 of the OER. Note: if there are QMS processes excluded, this must clearly follow from the ’scope of certification’ description.
62	4.2.3	What is the value of the QMS Process Matrix as the OER already provides evidence of which clauses have been audited and whether they are acceptable?	The OER is a very detailed level of recording audit results. Most customers are interested in an overview, and a check on completeness of the audit and a list of NCRs related to chapters.
120	4.2.3	Where are the "rules" for the OASIS database? Is there somewhere that gives good clear directions for the Certification Body Administrative folks about OASIS?	The ‘rules’ for OASIS uploads are in 9104-1. OASIS itself provides Help files and guidance. Also there is a detailed training package for data entry personnel available. This is posted under Help/Guidance.
63	4.2.3 & 4.3.3	Do ‘findings’ include only nonconformities?	No, findings are both conformities and nonconformities , see ISO9000, definition 3.9.5 Note: Audit findings can indicate either conformity or nonconformity with audit criteria, and opportunities for improvement

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
64	4.2.4	Do I have to be onsite to verify the corrective action has to be verified for its effectiveness?	Not always needed, e.g. in case of a document change that can be done off site. See also see 17021 9.1.12 & 13 and 9.3.2.1 b).
65	4.2.4	Is there a difference of Nonconformity Management between "Major nonconformity" and "Minor nonconformity"?	No, Major and minor Nonconformities are managed the same. Classification of NC's assists the organization to prioritize issues to be addressed.
66	4.2.4	Clarify the impact of "Major nonconformity" to the assessed organization.	The impact should be mainly on the containment action, as the definition of a major NC indicates 'to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products . This possible impact should be mitigated as soon as possible by the containment action. It is the audit team leader's responsibility to determine the possible consequences of the NC's, e.g. on certification status, see 4.3.4.
67	4.2.4	Why there is no indication as to the amount of days that the corrective action needs to be available to the Lead Auditor when there is no containment actions required?	See 4.2.4 c) "The organization is required for correction, corrective action(s), and corrective action plans within a maximum of 30 calendar days from the end of the on-site audit." See FAQ #81
68	4.2.4	Why non conformities have to be corrected within 30 days from the end of the on-site audit while systemic issues typically take longer than 30 day?	Systemic issues don't have to be corrected within 30 days. Only the **corrective action(s) and corrective action plans** have to be agreed between CB and organization. In some cases implementation can take longer.
69	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."	The time needed for **root** cause analysis etc. normally takes a thorough analysis by the audited organization and implementation time. Also, review by the auditor of corrective action, root cause an implementation would take away time from the audit itself.
112	4.2.4	4.2.4 c) …a maximum of 30 days… Is this calendar days?	It is calendar days
132	4.2.4	4.2.4 c) If agreement is not reached within 30 days from the end of the on-site audit although the organization is adequately reacting, can the CB allow the organization for 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.
126	4.2.4	If agreement is not reached (within 30 day per 4.2.4c) will the CB be noncompliant?	If the organization is not or not adequately reacting and the CB is actively pursuing agreement with the organization, the CB would be considered in conformance.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
147	4.2.4	See Note: why also the 'correction' on a nonconformity may be reviewed during the audit? This should be removed.	This NOTE (Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement) is not a requirement. Verification of containment or correction is at the discretion of the audit team. It is an opportunity for the audit team to observe how quickly the organization reacts should immediate containment or correction be necessary.
148	4.2.4	When NCR's are raised, a follow-up is conducted to verify the effectiveness of corrective actions taken and close the NCR's. How are the outcomes of the follow-up to be reported and what is required to be uploaded into OASIS when all NCR's are closed?	Outcomes of the follow-up will be completed in Box #'s 25, 26 and 27 of each NCR, and the completed NCR upload into OASIS.
70	4.2.5	Is there a requirement for the auditor to make copies of company forms and documents as objective evidence?	No, 9101 does not require copies of company documents, but the reference should be recorded on the OER. So, permission for copies is only an issue between audit team leader and organization where the leader needs copies in order to prepare the report off site.
71	4.2.5	Why the Audit Records paragraph does not include that all information pertaining to the audit is to be available to the audited organization at the conclusion of the audit?	The documents as indicated may need some cleaning up after the audit. Audit report needs to be written AFTER the audit. Audit information availability is addressed in 9104, 8.4
121	4.2.5	It states "auditor notes become part of the audit record - usually stays with the CB, isn't given to the client. But Form F - Stage 1 Audit Report states "upon mutual agreement with customers, the organization will make available all results of this audit including the .....auditor notes"... if the CB is not giving the auditor notes to the organization (and they don't - just capture the information in the audit report) - how would the organization make those available to their customer?	Upon mutual agreement with customers/potential customers, the organization will make available all results of the audit. Notes not included in the audit report but part of the client file may be made available upon request if they exist. Reference to the auditor notes will be deleted in the next revision as pertinent information from these notes are transposed to the final audit report.
103	4.3.1	Pre audit clarification: what pre-audit activities can be done on-site during the stage 1?	Pre-audit activities as defined in 9101, Figure 1 and ISO 17021, are performed prior to Stage 1 audit, otherwise the Stage 1 audit can not be adequately prepared and conducted.
72	4.3.1 & 4.3.2	Who is paying for the CB pre-audit activities and stage 1 activities?	This is normally the client, as negotiated between CB and client. Stage 1 is an integral part of the certification activities as described in 17021 and therefore not specific for 9101.
73	4.3.1.1	What is the purpose to record revenue as a proportion of total revenue-for what purpose?	Although there is an option to record the actual revenue, the information is used to formulate the percentage of business as an input to the time spent by the audit team in proportion to the level of business. See linkage to 4.2.1 Audit Planning.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
115	4.3.1.2	The second sentence (under the note) 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 natures. 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". The next paragraph states "they may be included if the processes can be proven to be similar to processes that were assessed and the same QMS procedures and controls are invoked." The main question is "how can I determine effectiveness and that they are truly using the same procedures, etc. if I do not have access to see them or the records"?	If access is not permissible, it will be up to the auditor to determine similarity by interviewing personnel, available records, and or procedures to draw this conclusion. If the auditor can not make such a conclusion coordinate with the CB not to include the program or processes in the scope of the audit. Note: Audit planning may include access permission or security clearances arranged prior to Stage two or any onsite audit. Proprietary Information Agreement (PIA's) may also be included between the CB and the client
74	4.3.2	Does the verification of the readiness of the system for certification include the review of the organizational structure and the responsibilities/accountabilities?	Yes, see also 4.3.2.2 on collection of sufficient information.
134	4.3.2	Is there a limit to the number of Stage 1 audits that could be conducted? We thought, "No" as each Stage 1 audit is a beginning to the process of certification and each is a start from the beginning.	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 used. Postponement of the Stage 1 audit by the organization or CB (for whatever reason) may also result in a completely new Stage 1 audit.
75	4.3.2.2	Should there be evidence of internal audits of all procedures, including all internal and external QMS requirements as the internal audits are normally based on status and importance of the company's processes?	No, only the "processes"(e.g. 4.1 a). and 'procedures' as meant in 9100:2009. There should be evidence of the internal audit program and fulfillment of these planned activities to satisfy this aspect of Stage 1 planning.
76	4.3.2.2	Why the requirement "evidence that the requirements of the applicable 9100-series standards are addressed by the organization's documented procedures established for the quality management system (e.g., by referencing them in the quality manual or by using a cross reference) is now in 9101 since it was removed from 9100:2009? Unless they mean only those sections that require a procedure.	It is removed from the 9100:2009 but it is now in 9101:2009, as an 'e.g.' to facilitate the work of the audit team. 9101 writing team's opinion is that it would take too much time for the audit team to find this out (time to be paid by the client).

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
117	4.3.2.2	Performance metrics for prior 12 months - what to do if this is not available? And does it have to be "new" data after a QMS was set up to the new version of 9100?	The standard is very explicit on this. So, if there is no performance metrics available for the previous 12 month there should be no stage 2 audit. There is no requirement that it has to be 'new' data after the QMS was set up to the new 9100. Should be performance measures and trends supporting 'Quality' and 'On time delivery' See Appendix F, block 24 Key Customer Performance.
149	4.3.2.2	As part of the Stage 1 audit, clause 4.3.2.2.requires the organisation to provide the audit team leader with performance measures and trends for the previous 12 month period. What if an existing multi-site AQMS approval wants to add a new site to their approval or an existing single site AQMS approval relocates to a new location, would they have to wait until 12 months of operational data had been generated before they could achieve a AQMS approval for their new site?	It is acceptable for the CB to use data from other sites or the old site to establish the baseline for the new site or location. Process Measures for the new site or location could be compared to the existing baseline for comparative data analysis and indicators of established process performance. Note: This requirement was added to prevent audit and certification of new facilities (i.e. those with no previous manufacturing history) until sufficient evidence of AQMS implementation and data was available.
77	4.3.2.3	Why 'export limitations/controls [e.g., International Traffic in Arms Regulations (ITAR), Export Administration Regulation (EAR)]' have to be reviewed by the audit team?	These don't have to be reviewed but only addressed, in how far they would limit access by the audit team to certain areas, processes or documents.
135	4.3.2.3	A lot of discussion continues to be generated on "Design Responsible," vs. "Not Design Responsible." Largest concerns centered on the situation where the customer is design responsible however the organization has some design processes that feed information to the customer. In that case can the organization exclude design even though they have process performing design tasks?	No, the exclusion shall not be accepted by the CB as justifiable for organizations that perform design tasks needed to fulfill aviation, space and defense customer contracts.
150	4.3.2.3	bullet m: Why 'production process verification' should be limited to 'as invoked in contracts'?	9101 could be more clear and should be read as "Production process verification including production readiness, production planning verification, FAI requirements, etc." Production process verification is not limited to customer contract requirements. This is a 9100 requirement 7.5.1.1, however a customer may further define expectations of Production process verification in their contracts.
151	4.3.2.3	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.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
152	4.3.2.4	Must there be a formal statement recorded on the readiness of the organization, after the organization has addressed all areas of concerns from the stage 1?	No, the 9101 standard doesn't require a formal statement to be recorded however the auditor needs to confirm and document if the organization is ready to proceed to Stage 2 by responding (Yes/No) in Box 31 of Appendix F – Audit Report (Stage 1).
153	4.3.2.4	Why the CB has to determine preparedness for the stage 2 and not the lead-auditor? It is after all his responsibility, or not?	The audit team leader has the responsibility to recommend the readiness for the stage 2 audit. The CB determines preparedness for the stage 2 audit based on the recommendation by the audit team leader as stated on Appendix F Box #31.
78	4.3.3	Why the stage 1 and stage 2 audit shall not be performed on the same day or consecutive days?	The reason is that it cannot be foreseen before the stage 1 audit that the organization is ready for the stage 2 audit, i.e. there might be areas of concern. So, the stage 2 visit 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.
142	4.3.3	While 9101 stated at paragraph 4.3.3 that "Stage 1 and Stage 2 audits shall not be performed on the same day or on consecutive days (back to back)" there are no specific requirements of the maximum timeframe between a Stage 1 and a Stage 2 Audit. This, in my opinion, could leave CB to do what they want. For your information in the automotive scheme, there is a requirement set to 90 days maximum.	Appendix F Form instruction block 35 provides guidance on this: "Note: The elapsed time should normally be between six weeks and three months from the Stage 1 audit". However, this may be impacted by business conditions and or the amount of time for the organization to address areas of concern(s) raised during the Stage 1 Audit.
114	4.3.3	Is there a rule that the organization has to do Stage 2 within 6 months from the date of the Stage 1 or they have to start over with stage 1? If so, where is it found?	There is no such rule.
130	4.3.3	What if it is not possible for the same lead auditor to do the stage 2 audit (e.g. sickness, travel day and cost- Europe back to Asia for instance) - can it be done by another Lead Auditor?	The standard does not state that the stage 2 Lead auditor should be the same as the stage 1. See 9104-1 clause 8.3.2 "… The individual fulfilling the team leader role may change during the certification cycle."
79	4.3.3, 4.3.4 & 4.3.5	"Should all elements of the quality management system and all organization's processes that are needed for the quality management system shall be audited for conformity (see Appendix D), including determination of effectiveness."? This is impossible to do for large organizations	There should be a sufficient sample of processes/procedures be audited covering all requirements of the QM standard to assess sufficient objective evidence upon which to base a certification/approval decision. See also 17021. Note: use of the PEAR is mandated per 4.2.2.5.
80	4.3.4	Why this clause does not include a requirement on the time period that the Lead Auditor will make the Audit Plan available to the audited organization, e.g. no later than 30 calendar days before the audit start date?	The timeframe is to be agreed between client and CB. 9101 should not to be too detailed, therefore the standard only indicates that the audit plan should be there before the audit starts.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
140	4.3.4	During transition from 9100 Rev B to Rev C what happens if an existing certified organization does not have 12 months quality and OTD performance measures available at the next surveillance visit?	During the transition, it can happen that 12 months data is not available and this is acceptable. However, an NCR may be raised against available data if planned results are not being achieved and/or appropriate action is not being taken.
81	4.3.4 & 4.3.5	What is the indication as to the timeframe to respond and implement corrective actions for NCR closure.	This is addressed in some detail in 4.2.4
107	4.3.5	If it is necessary to do a stage 1 on a recertification, i.e. with a new audit team , are these days included in 9104-1 tables for 9101 4.3.5 note 2 ?	Appointment of a new audit team could be a justification for a full or partial Stage 1 audit, including an on-site visit by the audit team. Reference 9101 4.3.5 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. Reference 9104-1 8.2.2 h.
82	4.3.6	What is the meaning of the word “Customer” : a certified organization or a customer of the organization?	‘Customer' means here 'customer of the certified organization'. ‘Client’ is used to indicate the customer of the CB, as in 17021.
83	4.3.6	Who pays for the additional special audit days to have the CB come in?	Should be part of the contract between CB and client, client should pay. There is an example of an OEM that has made it a contractual requirement with their suppliers that in the event the approval status has been downgraded from approved, the supplier is to make arrangements with their CB for a special audit.
84	4.3.6	Why "objective evidence" here, as there may be situations the case for CB to conduct special audits to investigate complaints, etc. without firm objective evidence?	Certification Bodies should have some form of objective evidence such as factual data to justify the visit.
133	4.3.6	4.3.6 c) When transferring certification from one CB to another, is the NOTE below the text applicable as mandatory or just as reference because the NOTE is "shall statement" (the pre-transfer review of the existing certification shall include an audit of the prospective organization site by AEA)?	This NOTE refers the proposed 9104-1 (under development), and it will become a "requirement" when the new 9104-1 is published, but until publication this remains in 9101 as a guidance note.
87	App. A	Why the OER does not list the requirements as question (questionnaire) as in the previous issue of the standard?	The intention of the new 9101 is to move away from clause based conformity auditing towards auditing of processes, performance and effectiveness

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
88	App. A	Who is determining the effectiveness of a process?	Basically, this is a top management and organization responsibility, as in 9100 4.1, 5.1, 5.3, 5.5.3, 5.6, 6.1, 8.1, 8.2.3 and 8.4. The audit team shall audit if these requirements have been fulfilled in a correct way(conformity assessment). 9101 requires from the audit team to have an independent evaluation if the effectiveness of the QMS main processes are satisfactory. Assessment of effectiveness is based on the audit team' s observations and conclusions.
89	App. A	What if there are no statutory/regulatory requirements (line 159)?	The audit team shall audit if the organization has determined the statutory and regulatory requirements applicable to the product. If there are no statutory and regulatory requirements, this can be excluded from the audit or classified as N/A (not applicable)].
104	App. A	How to address exclusions in OER: Not applicable?	Record "EX" in "C" column on OER per Instruction 9 when the auditor agrees with the exclusion , record on an NCR when auditor determines exclusion to be invalid and an unfulfilled requirement.
105	App. A	How to use OER in surveillance (see 4.3.1 or 4?): implied need, be more clear on this.	OER to be completed for those clauses audited during the surveillance audit. Clauses not evaluated will be identified as "N/E".
109	App. A	On the OER, does every row in column 11 need to be filled out?	Requirements are clear with respect to NA, NE or recording of the PEAR only. However, there is an expectation to record what was observed for things audited. The standard does not prevent the ability to group OER line items under one entry of objective evidence. It is understood that this can be the case and would allow the use of , for example "ditto" marks, a line drawn through those OER line items associated with one objective evidence entry, or referencing other applicable OER row numbers where the objective evidence is the same e.g. "See OER item #232".
110	App. A/B/C/D	For an initial audit, the organization does not have a OIN, what should be done?	OASIS generates an OIN when the client starts entering his supplier data in OASIS. This can start before the stage 2, after the CB starts entering audit data, e.g. the stage 1 report. So, the OIN can be available before the stage 2 audit starts. Note that the stage 1 report does not ask for an OIN. But if not available when completing the forms, leave blank, until the Stage 2 report is uploaded to OASIS. The CB can add the missing OIN at that moment.
90	App. B	Why the Nonconformity Report Appendix "B" item 13 "Due Dates" does not give any instruction related to the amount of days (Form Instruction)?	Clause 4.2.4 Nonconformity Management provides instruction regarding due dates for containment and corrective action due dates requirements.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
122	App. B	Note in box 14 &15: if the CB just types the person's name in (that is what they are doing now - because the Corrective Action information is sent from the client organization to them) - is that acceptable?	There are various ways to do this, e.g. by putting statements such as 'original signature on file' when typing in names, or scanning signed documents. Finally, the method should be verified during an office assessment by the NAB/industry assessor.
131	App. B	There are 2 #15's - one towards the top and one towards the bottom of the form. Could this be different persons although it didn't appear that way in the instructions?	Yes, It could be different persons.
154	App. B	Does section 2 of the NCR in Appendix B need to be completed by the auditee in full or can they refer to and attach another document?	It is not permissible to simply say "see attached". Containment, root cause and corrective action should be described in section 2 on the form in full, (expanding the form as required). It is however permissible to describe the containment, 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 OASIS together with the associated NCR.
91	App. C	Why note 2 of block 13 indicates that a Major or Minor NCR is to be issued when the effectiveness level of the process is rated at "2" as there is no indication of the criteria's that would lead the auditor in making the decision to raise the NCR as a Major or Minor.	The criteria is in the definition of a MA or mi in chapter 3, see 3.2 second bullet. If a process is not implemented and planned results are not achieved, this is considered as 'reduce its ability to assure controlled processes or compliant products'.
106	App. C	Effectiveness level 3 ->may write NCR?	Yes you may write a NCR when planned results are not achieved and not fulfilling the requirements of the standard e.g. use of non calibrated equipment for product verification.
155	App. C	I have just audited a Purchasing process. It is clearly defined and includes all interactions shown within the Process Manual. KPI's have been established, data analysis shows that the targets set are being achieved. (It looks a 'perfect 4'). However during further audit I found that supplier evaluation records were missing for two suppliers and decided to raise an NCR against supplier evaluation. How should I grade the PEAR; 1, 2, 3 or 4?	This should be graded as '4'. The NCR that you raised is a 'conformity' issue against 7.4.1 and not an 'effectiveness' issue against 4.1.c. and f.
92	App. C & 4.2.2.5	Do we have to write one PEAR form for each process?	No, the standard requires in 4.2.2.5 one PEAR form for each product realization process (those processes as related to chapter 7 of 9100-series). For other processes, e.g., training, continual improvement, measuring of product, internal auditing, the PEAR form might be used.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
136	App. C & 4.2.2.5	In completing the PEAR is it required to do a PEAR for each site of a multi site?	There is no requirement for a PEAR to be raised at each site. Process effectiveness may be documented on a single PEAR that covers more than one site where the processes are substantially the same and/or sequentially linked within the overall product realization process.
156	App. C & 4.2.2.5	Is it required for an Organization to assist in the completion of the PEAR(s) or OER?	Under 9101 Section 1.2 "Application", the 9101 standard shall be used by the CB for certification audits of 9100-series standards. There is no requirement in 9101 for an organization to assist in the completion of the PEAR(s) or OER, with the exception of the acknowledgement signature box on the PEAR form. Throughout the audit process the CB auditor will engage with the organization to facilitate the collection of information in order to complete the audit reports. The CB auditor is ultimately responsible for completing audit evidentiary records, and whilst there is no requirement placed upon an organization to provide recording assistance, the auditor may request such support.
111	App. D	Can the QMS Matrix be added to as long as nothing is taken away, e.g. by adding a column to the QMS matrix for additional information?	No change to form is allowed. If the auditor has additional information to record about a specific process, then the OER was designed to capture that information.
137	App. D	Appendix D (QMS process matrix report) instruction box 8 refers to manufacturing processes such as machining, painting, assembly (processes/sub-processes/value added activities). Is it a requirement that a PEAR is raised at this level of detail?	The use of the PEAR is linked to those product realization process determined by the organization and covered within the audit plan and hence may be at any level (see also FAQ 52).
93	App. E	What is the definition of a „Key Issues / Concerns“ (see box 32), as also non-conformances and opportunities for improvement are enquired?	These are those issues or concerns as determined by the audit team that needs top management attention. Note: not all NCs, e.g., minor or OFI need top management attention.
108	App. E	Choices 4 and 5 in box 38 seem contradictory. The organization must close all open nonconformities before… is the fourth choice, but the fifth choice says “is ready…. after NCRs closing out verification. When would you choose the fifth option if the fourth option should be selected with any open NCRs? This was linked also to a question about **4.3.3.b, the sentence after 4.3.3 b… recommendations for certification cannot be made until all nonconformities are closed.** This would seem to contradict the fifth choice in Box 38 of the Stage 2 Report.	Box 4 shall be ticked if there are any ‘open’ NCRs at the publication of the audit report and recommendation to the CB. Box 5 can be ticked if at the moment of publication/recommendation all NCRs have been closed out. This includes verification.

FAQ 9101:2010 / 9101D

#	Clause	Question	Answer
139	App. E	There is no check box for granting recertification when NCRs have not been raised (Box: Audit Team Leader Recommendations).	This is an error in the form. In this instance Option 1 “is ready for granting certification/approval” should be ticked and read as “is ready for granting certification/ recertification/approval”.
94	App. F	What is the reason for the detailed information on Aviation / Space / Defense / Other as well as the separate call out of workforce (middle block)?	Information is needed for audit planning (including calculation of audit duration). Stakeholders and IAQG member companies have declared interest to have this information.
95	App. F	Do I have to give all audit results to my customers/potential customers? That should be handled by customer - supplier agreements and discussions.	No, this should only be done '*upon mutual agreement*'**?** It should be handled by customer - supplier agreements and discussions.
96	App. F	Why OTD, quality performance metrics, latest management review …requirements of 4.3.2.1 - 4.3.2.3 are not listed on the Appendix F list?	They are addressed in boxes 22 and 24 of Appendix F.
138	App. F	Stage 1 Appendix F indicates that completion of box 18 on % of the total revenue for aviation, space and defense business. The text of clause 4.3.2.2 only indicates the level of business for each customer, please clarify?	In 4.3.1.1 it is clearly indicated that the CB shall require the organization to provide the revenue for aviation, space, and defense industry, as a proportion of the total revenue.
85	Appendices	Are the report format appendices published as separate documents?	Yes, they are available as editable templates in PDF format on the IAQG website. Translated report formats will become available on national level, e.g., the websites of the national ASD Trade Associations In Europe an SJAC in Japan.
86	Appendices	Is the use of all the forms required?	Appendix G is the only optional form.