

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



Applicable to 9104-001:

[Click 'here' to go to the end of the log](#)

FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
1	<p>9104-001 clause 5.2.c and clause 6.4.</p> <p>What does "continuing" mean in both of these clauses? Does "continuing" mean the person is currently working? Are both full time and part time persons allowed from an organization related to aviation, space, or defense industry? If "continuing" allows for a retired person, what is the criteria for "continuing"?</p>	<p>Continuing means full time employment with no break in service in either the private (e.g. IAQG Member) or public (e.g. Government, Military) aviation, space and defense sector.</p> <p>It should be recognized that this is an advisory position (in accordance with ISO 17011, clause 4.3.2 for Abs, ISO 17021, clause 6.2.1 and ISO/IEC 17021-1 clause 5.2.3 regarding "appropriate interested parties" for CBs).</p> <p>The intent is to have a person that is actively employed in the aviation, space or defense industry on a full time basis. This full time employment should demonstrate the person's active engagement, involvement and continued awareness of activities in the Aviation, Space and Defense sector.</p>	X	
2	<p>9104-001 clause 8.3.3.</p> <p>In this clause what does "the entire audit" mean? Is it required that an AEA is required to participate at the on-site audit at each site during scheduled audit? For example, when one AEA and one AA perform audit at site "A" on the first day, and only the AA performs the audit at site "A" on the 2nd day, would this case satisfy with the requirement of clause 8.3.3? Does "the entire audit" mean that the AEA will participate all times during audit at each site?</p>	<p>The entire audit is from opening meeting until closing meeting and includes any associated preparation and report writing. This may also include several locations and sites for various certification structures (e.g. several site or Campus).</p> <p>The intent of the requirement is to have the AEA audit team leader actively involved in the entire audit and an AEA at each site during the audit. There should be no case (like the example given) where an AA will audit independently with no AEA on site.</p> <p>Also, please see 9104-001, clause 8.3.2 for further clarification.</p> <p>This issue is also addressed in 9104-001 FAQs, Question Number 17.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
3	<p>9104-001 clause 8.3.8.</p> <p>In this clause of the requirement "The same auditor shall be limited to no more than two certification cycles...." Is this retroactive?</p> <p>For example: An auditor has been auditing a client for the last six years and has just conducted the re-certification audit in 2012. Does the auditor have to give up this client to another auditor? Or, can the auditor be the lead auditor for this client for this certification cycle and the next certification cycle?</p> <p>Does the requirement "The same auditor shall be limited to no more than two certification cycles...." apply if a certificated client transfers between certification bodies and the same auditor is used by both certification bodies?</p>	<p>Yes, it is retroactive.</p> <p>Since you just conducted the recertification audit, you must give up this client as the AEA audit team leader at the next recertification audit.</p> <p>No, you cannot be the audit team leader for the next certification cycle.</p> <p>We encourage rotation of the audit team leader in this scenario but the requirement is linked to certification cycles.</p> <p>Yes. This requirement applies if a certificated organization transfers between certification bodies and the same auditor works for both certification bodies. It also applies if the auditor works for the previous certification body before the transfer and the new certification body after the transfer.</p>	X	
4	<p>9104-001 clause 8.4.d.</p> <p>In this clause what does "re-established" mean?</p> <p>For example, clause 8.4 b) states 'No certificates to AQMS standards or any combination of AQMS standards requiring a certification decision shall be issued, unless all major and minor nonconformities have been contained; satisfactorily corrected with root cause analysis; and the corrective action has been implemented, reviewed, accepted, and verified by the CB.</p> <p>Does " re-established " mean "closure of nonconformities" as stated in clause 8.4 b) i.e. that all nonconformities have been contained; satisfactorily corrected with root cause analysis; and the corrective action has been implemented, reviewed, accepted, and verified by the CB?</p>	<p>The term "re-established" does not mean closure of the nonconformity. The root cause analysis and corrective action to prevent recurrence may not have been accomplished in the 60-day timeframe. However, the intent is to ensure all "containment" actions are complete. Containment actions will include taking the necessary action to ensure conformance to the existing QMS requirements. Additional root cause and corrective action (to prevent recurrence) may take more than 60 days to complete but all steps and actions to be taken must be documented within the corrective action response.</p> <p>The term "days" are represented in calendar days.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
5	<p>9104-001 clause 14.3.d and 9104-002 clause 9</p> <p>What is the "escalation process" referred to in this clause?</p>	<p>The escalation process is explained in the 9104-002 standard at clause 9.4 and in Table 2</p> <p>"9.4 If any issues cannot be resolved between affected parties, then the matter shall be escalated to the next level of authority within the ICOP scheme."</p>	X	
6	<p>9104-001 clauses 3.23 and 6.7.k)</p> <p>Is the meaning of "pre-audit" in 9101 clause 4.3.1 the same as the meaning of "pre-audit" in 9104-001 clause 3.23 and 6.7 k)?</p>	<p>No. 'Pre-audit' in 9104-001 refers to activities that occur before the start of the initial certification audit and may include an on-site audit to evaluate the suppliers' quality management system before the beginning of the initial certification audit in addition to other activities that involve the CB contacting its client. 'Pre-Audit Activities' in 9101 section 4.3.1 refers to the activities that take place after the start of the certification process as part of the preparation for an AQMS certification audit (primarily initial audit, but may refer to surveillance or recertification audits). 9101 section 4.3 refers to 'Audit Phase Specific Requirements'.</p> <p>It is expected that an accredited CB would document any services they provide to a client that occur before the start of the initial certification audit so that the CB's processes involving ISO/IEC 17021 or ISO/IEC 17021-1 and 9104-001 requirements on impartiality and avoidance of consultancy can be assessed by the accrediting AB or during oversight. It is recognized that discussions requiring client contact to be able to make an informed application for AQMS certification may occur more than once. Specifically, no more than one on-site audit event before the start of the initial certification audit is permitted by the requirement.</p>	X	
7	<p>9104-001 clause 6.11</p> <p>What does "CBs shall ensure that classified material or export control requirements, related to CB auditor access, are disclosed to their aviation, space, and defense clients" mean in clause 6.11?</p> <p>Can a CB disclose classified material or export control requirements, related to CB auditor access, to their aviation, space, and defense clients?</p>	<p>The intent of this requirement is that the CB and their client need to have a discussion to determine whether some classified, or proprietary areas of client's facility may have restricted access, may be subject to export control restrictions or may require to be excluded from the audit in order to meet local or national laws, and/or preserve confidentiality throughout the audit and certification process. As a result of this discussion, it is expected that agreements are reached about where the audit can and will take place, who the auditors will be and establish their legal ability to audit the client's management system, products and processes.</p> <p>Arrangements may include limitations on citizenship, access, security clearance or similar and may include the signing of legally binding documents such as confidentiality arrangements or NDA's (Non-Disclosure Agreements) in order to preserve the confidentiality of the products and processes audited.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
8	<p>9104-001 clause 8.2.1.3 b) and 8.9.b)</p> <p>Does "the defined audit duration" in clause 8.2.1.3 b) mean the audit duration after adding a minimum of 10% from clause 8.2.1.3.c) to the total duration defined by Table 2?</p> <p>Clause 8.9 b) "The ASRP process outlined in IAF MD 3 shall not reduce the Table 2 required on-site audit duration by more than 30% for single, campus, several, and ---.",</p>	<p>Yes. In clause 8.2.1.3.b) "the defined audit duration" means the calculated audit duration after adding a minimum of 10% to the total duration defined by Table 2.</p> <p>The same expectation is required for clause 8.9 b) and "the Table 2 required on-site audit duration". In clause 8.9 b) "the Table 2 required on-site audit duration" shall be deemed to be replaced with "the defined audit duration" for a Campus structure. Where applicable, a permissible reduction for ASRP may be applied after the increase of 10% required by clause 8.2.1.3.c) for a Campus certification structure.</p>	X	X
9	<p>9104-001 clauses 5.3.5, 9.c) and 10.4 c)</p> <p>Within these clauses the terms 'may' and 'shall' are both used in relation to the results of oversight witnessed assessments being shared with the applicable AAB in the event that AQMS auditor competency issues are identified. Which is correct?</p>	<p>In 9104-001 clauses 5.3.5 and 9.c) the word "shall" is made optional by the term "when deemed appropriate" which precedes the "shall" in each requirement. In clause 10.4.c) a different term, "may" is used. When the whole of each requirement is read together, although different words are used, each requirement is actually the same. Identifying an AQMS Auditor Competency issue to the applicable AAB is optional and is to be decided by the entities conducting the oversight at the time a competency issue is determined. The decision to advise the AAB should be based on the severity of the competency issue identified and the impact on the effectiveness of the audit as witnessed to be able to correctly determine the conformance and effectiveness of the management system being audited.</p>	X	
10	<p>9104-001 clause 8.2.1.2 and Table 2</p> <p>For multiple site certification structures, if 100% of sites are sampled in the first surveillance year, is it acceptable that only the site containing the central function is audited in second surveillance year?</p>	<p>No. The intent is that the site containing the central function and approximately 50% of the sites are audited each surveillance year for category 1, and approximately 33% of the sites are audited each surveillance year for category 2. Auditing 100% of the sites in one year does not comply with the requirement to audit approximately 50% or 33% of the sites (according to established category) and does not remove the site sampling requirement for the other surveillance year. Auditing 100% of the sites in one surveillance year and none in the second surveillance year would not be a conforming practice within IAF MD 5 and it is not a conforming practice under 9104-001 requirements.</p>	X	X
11	<p>9104-001 clause 5.3.1 c) and 5.3.2 a)</p> <p>Does "complete" mean "all clauses" of 9100 or 9110 standard?</p>	<p>It may not be possible for an AB to witness all clauses and sub-clauses being actively audited during a witness assessment due to the scope of the applicant CB's client and where there may only be one or a very small number of clients available for the assessment. In such cases the intent of witnessing the 'complete' standard means the AB witness assesses the whole of the CB's AQMS audit for stage 1 and stage 2 and the auditing of the applicability of any permissible exclusions. In this way the AB is able to witness assess all clauses of the applicable AQMS standard, i.e. the 'complete' AQMS standard.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
12	<p>9104-001 clause 13.5 and IAQG OPMT Certification Structure Oversight Committee (CSOC) Application Guidance and Guidance Materials</p> <p>Clarify the term 'Audit Program'</p>	<p>An audit program (from ISO 9000) is a set of one or more audits planned for a specific time frame and directed towards a specific purpose</p> <ul style="list-style-type: none"> ISO/IEC 17021 and ISO/IEC 17021-1 clause 9.1.1 states: <ul style="list-style-type: none"> An audit program for the full certification cycle shall be developed to clearly identify the audit activity required to demonstrate that the client's management system fulfils the requirements for certification to the selected standard The audit program shall include a two-stage initial audit, surveillance audits in the first and second years following a certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision. The determination of the audit program and any subsequent adjustments shall consider the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits. ISO/IEC17021 Appendix F and ISO 17021-1 Note 2 under clause 9.1.3.2 also provide some guidelines about the items to take into consideration when building an audit program <p>The ICOP certification process identifies a three-year certification cycle. A detailed audit plan is not necessary for CSOC applications however an audit program for the three-year certification cycle is required.</p>	X	X
13	<p>9104-001 clause 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>What level of product descriptions is required?</p>	<p>Simple but clear (not 10 pages) but sufficient to provide understanding to industry professionals that may not be familiar with the specific product(s)</p> <p>The intent is to validate whether the certification structures are fitting the products and their associated value stream(s).</p>		X
14	<p>9104-001 clause 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>How do I attach more than two files to the CSOC feedback request?</p>	<p>Use Win Zip or embed files as objects within a collector file e.g. a Word file. Software other than Win Zip should not be used as the CSOC may not be able to open the files.</p>		X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
15	<p>9104-001 clause 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>Can a site be split between different certification structures, and the headcount split accordingly?</p>	<p>A site within a complex certification structure may contain one or more value streams. As a result of there being more than one value stream, one or more departments that may be administrative or service related in nature (e.g. human resources, office staff, facilities) may support one or more value streams. Where a site supports more than one value stream the following allocation rules for determining the number of effective personnel / employees shall apply:</p> <ul style="list-style-type: none"> • Where personnel / employees on a site can be clearly identified as allocated to a specific value stream, only the number personnel / employees permanently allocated to that specific value stream require to be taken into account in determining the effective number of personnel / employees; • In all other cases, where personnel / employees on a site are allocated to more than one value stream simultaneously the total number of employees for a specific site shall be taken into account for each and every value stream they are involved in supporting. <p>Note 1: It is possible that a site may contain a mix of these conditions e.g. centralized design and centralized purchasing but distinctly separated manufacturing. In this case the effective number of employees shall be allocated according to the established rules.'</p> <p>Note 2: It should also be recognized that additional audit time is needed for this certification structure because each value stream should be audited for conformance, including its support processes (e.g., objective evidence gathered, specific to each value stream).</p>	X	X
16	<p>9104-001 clauses 8.2.e), 8.2.1.5.b), 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>What is meant by a 'justification' in the application file? (e.g. audit days)</p> <p>Is it required that a CB creates a record, document or a form to support objective evidence of conformance?</p>	<p>A 'Justification' is something that shows an action to be reasonable or necessary; e.g. records that show that the audit time determined by the CB is appropriate for a specific client at a particular time</p> <ul style="list-style-type: none"> • See also ISO/IEC 17021 clause 9.1.4.1 and ISO/IEC 17021-1 clause 9.1.4.2 for detailed items to be analyzed for the justification of audit duration ISO/IEC 17021 clauses 9.1.4.1 and 9.9.2.d) and ISO/IEC 17021-1 clauses 9.1.4.3 and 9.9.2.d) require the CB to maintain records of the justification of the determination of the audit time. The format of that record is defined by the particular CB as part of their management system. All CB records regarding the audit and other certification activities for all organizations that submitted applications, were audited, certificated, suspended or withdrawn are to be maintained in accordance with ISO/IEC 17021 clause 9.9.4 and ISO/IEC 17021-1 clause 9.9.4 	X	X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
17	<p>9104-001 clauses 8.3.3), 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>Does the requirement 8.3.3 for a lead auditor to be on site at one site during all audit activity apply to complex structures, as it may be difficult in case of worldwide spread audits?</p>	<p>This requirement has been written to ensure that when an audit is spread all over the world in more than one time zone access by the AEAs and AAs to the lead auditor for review of findings, clarification, consultation or escalation of questions is ensured. It is understood that the lead auditor may not be available at all times while an audit is performed and a local audit team leader may be temporarily in charge of this role for a local site. In all cases, the lead auditor shall perform a significant part of the total audit and access for co-ordination shall be ensured, to meet the intent of the requirement. This may be achieved through daily synthesis meetings or teleconferences, e-mail exchanges, daily reports from auditors, etc. as required to ensure an effective audit is conducted.</p> <p>The 9104-001 clause 8.3.7 remains valid. The audit team leader shall be responsible for ensuring the completeness of the audit and the accuracy of the audit report, findings, and conclusions for the whole audit.</p> <p>It is recognized that over the course of the audit program the lead auditor may change.</p>	X	X
18	<p>9104-001 clauses 3.27, 8.1.1, 13.5, Appendix B and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>What does "single" of "a single value stream" mean? For example, in the case of a big company composed of more than one site which delivers Aircraft to the customer, can a "value stream" be considered as a "single value stream" for single campus?</p> <p>If the company composed of some sites provide three kinds of aerospace products (not substantially (i.e., <80 %) the same, but through to the same methods and procedures), can "value stream" be considered as "triple value stream" for triple campus?</p>	<p>A value stream is defined in 9104-001 clause 3.27 as: 'An end-to-end business process which delivers a product or service to a customer. The process steps may use and produce intermediate goods, services, and information to achieve the end product or service.'</p> <p>Yes. A 'single value stream' would therefore using the above definition would mean one end-to-end business process which delivers a product or service to a customer.</p> <p>No. A triple value stream is not a single value stream.</p> <p>Reference 9104-001 Appendix B for Campus eligibility criteria.</p>	X	X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
19	<p>9104-001 clauses 3.8, 3.11, 8.1.1, 13.5, Appendix B and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>What is the Central Office or Central Function for a certification structure?</p> <p>Is there a difference between the central function and the controlling address required for the certification document?</p>	<p>There is only one overall Central Office (or Central Function) for each certification structure:</p> <ul style="list-style-type: none"> The definition for Central Office is located in 9104-001 at clause 3.8 and is 'the organization location/activity that controls the 'common' quality management system for the organization under a single AQMS standard certificate.' 9104-001 clause 8.1.1.c requires that the central function / office: <ul style="list-style-type: none"> Controls the common management system Conducts the common management review Controls the internal audit program Has the authority to require all sites to implement corrective action as needed Collects and analyses data from all sites Has the authority and ability to initiate organizational change in regard to system documentation, system changes, management review, complaints, evaluation of corrective actions, internal audit planning and review of associated results and legal requirements. 9104-001 Appendix B always describes the central office in a singular context. <p>The controlling address is used in campus structure only to identify a single location to be listed on the certificate and in OASIS. It is up to the certificated organization to decide if this is the same address as the central office or central function.</p>	X	X
20	<p>9104-001 clauses 13.5, 18.1 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>Can a client with a certification structure other than single site segregate access to tier 2 audit report data in OASIS on a site by site basis?</p>	<p>An organizations' personnel must recognize that data from all sites is equally available when access to tier 2 data is granted by the certified organization. One audit report is written for all sites under a single certification. This audit report is uploaded into OASIS and can be seen as tier 2 data for all of the sites under the certification.</p> <p>The audit results for a particular site may be recorded on a 9101 Form 6. 9101 Clause 4.2.3 states 'The Supplemental Audit Report (Form 6) shall be used to record results for individual sites, if the Audit Report (Form 5) does not include audit details of the individual sites.'</p>	X	X
21	<p>9104-001 clauses 8.2.1.4, 8.9, 8.10, 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>At what step in the audit duration calculation process should allowable reductions (ASRP and Table 4 for Several Sites certification structure) be taken? Prior to or after the expected ISO 17021 additions?</p>	<p>The intent of 9104-001 is that any permissible reductions should be made prior to the expected additions of ISO/IEC 17021 or ISO/IEC 17021-1 clause 9.1.4 and IAF MD 5 additions. For reductions use Table 2 audit days as the denominator when calculating percent reduction except for campus which should use table 2 audit days plus the mandatory 10% increase.</p> <p>Agreed reductions are only permissible under certain specific conditions as specified in 9104-001. CAAT does not allow a reduction only a transfer from on-site audit duration to off-site audit duration.</p>	X	X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
22	<p>9104-001 clauses 8.2.1.5, 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>Within a complex certification structure, is the mixing of sub-categories within the sub-structures allowed e.g. may a several sites reduction be applied to a multiple site or campus sub-structure, or multiple site sampling be applied to more than one campus?</p>	<p>No. The mixing or co-mingling of sub-categories including the on-site audit duration calculation or site sampling is not permissible. The intent is that each sub-structure established within a complex structure uses the requirements only for that identified sub-structure including the on-site audit duration calculation e.g. a multiple site sub-structure would use the on-site audit calculation methodology from 9104-001 clause 8.2.1.2 or a campus sub-structure would use the calculation methodology from 9104-001 clause 8.2.1.3. Similarly, the site sampling requirements are to apply to each sub-structure e.g. all sites within a campus sub-structure must be visited every year.</p>	X	X
23	<p>9104-001 clauses 8.2.1.5, 13.5 and IAQG OPMT CSOC Application Guidance and Guidance Materials</p> <p>How should a CB provide evidence of compliance to the eligibility criteria for the overall complex structure and the sub-structures within the complex certification structure?</p>	<p>9104-001 clause 8.1 sets out the eligibility criteria for all certification structures in two parts; a general description of eligibility criteria for all certification structures at 8.1.1 and in addition eligibility criteria for each certification structure type at 8.1.2. This also points at 9104-001 Appendix B that has a detailed description of the eligibility criteria in the second row of the table beneath the header row.</p> <p>Whilst it is not appropriate for the CSOC to describe how a CB provides evidence of compliance to the eligibility criteria for the overall complex structure and the sub-structures within the complex certification structure, the CSOC can advise that the voting members are looking for evidence of the evaluation and determination of the overall complex certification structure and each of the sub-structures within the complex structure. Part of evaluation is the demonstration that all the applicable eligibility criteria have been met. It is only through the detailed analysis and development of such a record that it can be demonstrated that a client really fits a particular certification structure. The CSOC is looking to see that the applicant CB and the client have achieved that understanding and can demonstrate the fit of the correct certification structure.</p> <p>As part of 9104-001 clause 8.1.3, it is a requirement for all CB's to maintain evidence of the review and determination of certification structures for all clients. The CSOC expects that CB's have a process in place to satisfy this as part of the accreditation to achieve compliance with this requirement.</p>	X	X
24	<p>9104-001 clause 5.3.8</p> <p>If a CB applies to the IAQG 9104-001 IDR and / or SDR's for a clarification of 9104-001 requirement as a result of a nonconformity being raised does the 90 calendar day period before the suspension process is started by the AB continue?</p>	<p>Where a CB co-ordinates with an AB and applies to the IAQG 9104-001 IDR and / or SDR's for a clarification of 9104-001 using the OASIS feedback process the the AB will give consideration to the appropriateness and validity of the submission of the clarification to the IDR/SDR process in deciding if the calendar days from the submission of the request through OASIS to the date of receipt of an answer contribute to the 90 calendar day period before the initiation of the suspension process (i.e. if 'clock' shall stop). A repeated clarification on the same issue will not stop the 90 calendar day period elapsing. Refer also to FAQ #25.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
25	<p>9104-001 clause 5.3.8</p> <p>What happens with regard to suspension if a CB is genuinely unable to have a nonconformity verified and closed within 90 calendar days as the corrective action planned to be implemented will take longer than 90 calendar days to implement e.g. in the event of a major computer system change?</p>	<p>Should a CB require more than 90 calendar days to have corrective action verified and the nonconformity closed following the raising of a nonconformity, the accrediting AB is required to start the suspension process in accordance with 9104-001 but may not necessarily make a decision to suspend the CB. The intent is to ensure that the AB considers the reasons and situation for the suspension, the re-establishment of conformance by the CB, including any corrective action that may be underway and make an accreditation decision based on the realised situation.</p>	X	
26	<p>9104-001 clause 3.25 and Appendix B</p> <p>What is the relationship between address and site?</p> <p>What is the relationship between site and distance?</p> <p>Why does Appendix B reference one address for eligibility criteria for a single site?</p>	<p>As per 9104-001 clause 3.25 a site is a permanent location where an organization carries out work or a service. This is the same definition as used by IAF MD1.</p> <p>There is no direct relationship between a site and an address.</p> <p>A site may have one or more addresses depending on the nature of the site. There may be multiple buildings and addresses on a single site or more than one address in single building.</p> <p>There is no relationship between site and distance. A single site may be small or large. Normally a single site is contiguous. A site would normally be considered contiguous even if natural or man-made features (e.g. roads, rivers, canals, railroads) may happen to cross the site.</p> <p>Where another feature such as a building, location or site owned or operated by another entity separates the work locations the separated locations would not be considered a single site except under the following conditions:</p> <ul style="list-style-type: none"> • where there is multiple business operating in the same building, or • where the work locations are linked via a series of buildings or units around one central car park on one single industrial park. <p>The organization must be able to sustain their business relationships with aviation, space and defense customers using one address to be eligible as a single site.</p>	X	X
27	<p>9104-001 clause 8.2.1.2 and Table 3</p> <p>How do the eligibility criteria associated with IAF MD 1 clause 3 apply to Multiple-Site Certification structures?</p>	<p>IAF MD1 clause 3 applies to all Multiple Site certification structures under 9104-001 regardless of the sampling process used. Sampling in accordance with IAF MD1 is allowed for 9120 certifications. In all other cases the site auditing frequency for multiple site certification structures is defined in Table 3.</p>	X	X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
28	<p>9104-001 clause 8.2.2 and Table 2</p> <p>How do you calculate audit duration for an organization with more than one site when the overall scope includes design and/or development but one or more of the sites do not carry out design or development activity?</p>	<p>For 9100 or 9110 scoped organizations with a campus certification structures that include design and development activities in their scope the '9100/9110' columns in 9104-001 Table 2 are to be used based on the total population in order to calculate on-site audit duration i.e. do not use the columns that are '9100/9110 less design'.</p> <p>For all other certification structures that include design and development activities in their scope and involve more than one site:</p> <ul style="list-style-type: none"> • For sites within the scope that do not include design or development activities the 9104-001 Table 2 '9110/9110 less design' columns are to be used to calculate on-site audit duration. • For sites within the scope that include design or development activities the 9104-001 Table 2 '9110/9110' columns are to be used to calculate on-site audit duration. <p>Where design and/or development activities occur at any site, the site containing the central function shall use the 9104-001 Table 2 columns '9100/9110' to calculate on-site audit duration.</p>	X	X
29	<p>9104-001 clause 18.1</p> <p>9104-001 clause 18.1.c) requires certificated organizations to notify their clients when they 'lose' their certification. Are certified organizations required to notify their aviation, space and defense customers if the certification is suspended?</p>	<p>No, there is no requirement to notify a customer when a certificate is suspended. Organizations shall notify their aviation, space and defense customers when the certificate is withdrawn by their CB and removed from OASIS.</p>	X	
30	<p>9104-001 clause 8.2.1</p> <p>What does 9104-001 require for sites that are used for overflow of work away from a main certificated site?</p> <p>What does 9104-001 require for the auditing of remote workers operating away from a main site?</p>	<p>Sites supporting overflow work must be added to the certificate in order for the work to be considered within the scope the certification. Overflow sites are temporary sites per IAF MD1 clauses 1.3 and 2.2 and should be treated as such.</p> <p>A single employee located at a remote location (e.g. a virtual or home office worker) may not be considered a site. Remote workers are normally tied to an office (or site) as part of the overall structure and should be counted within the headcount of the site. Additional audit duration may have to be added due to the additional complexity associated with ensuring that the activities of remote workers can be audited as part of the scope of the certification. At times remote working locations may need to be treated as temporary sites if multiple workers are at a given location.</p>	X	X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
31	<p>9104-001 clause 8.1 and Appendix B</p> <p>Can an organization that has differentiated product lines be considered as a Campus?</p>	Yes, providing there is only one single value stream (all products are substantially the same i.e. by made methods and processes that are greater than or equal to 80% the same for all products or services realized through the Campus certification structure) for all of the different customers' products.	X	X
32	<p>9104-001 clause 8.1 and Appendix B</p> <p>For multiple site certification structures how much commonality of the activities on each site is enough?</p>	All processes and methods on each site should be substantially (i.e. by made methods and processes that are greater than or equal to 80% the same) the same for all products or services realised (see Appendix B multiple site). There can be less processes on one or more of the sites.	X	X
	<p>Is an organization eligible for a multiple site certification structure when 80% of the sites have similar processes and methods, yet 20% of sites do not e.g. 8 out of 10 sites are common and 2 are not?</p> <p>Can an organization that conducts their business through linked processes in different locations be eligible for a multi-site structure?</p>	<p>No, they are not eligible for a multiple site certification structure. The 80% or greater commonality requirement applies to the processes at each site. Each site must be performing at least 80% of the same processes as every other site.</p> <p>No. This would indicate a value stream that operates across more than one site and is likely to be associated with a campus structure.</p>		
33	<p>9104-001 clause 8.6.o) and Appendix B</p> <p>9104-001 states that a Campus certification structure shall have only one controlling address and OIN however OASIS requires each site within a campus structure to be established and have an active site supplier administrator, why?</p>	OASIS follows the structure established on a certificate i.e. a controlling address and a series of sites that form the campus to realize the product or service. When initially implementing a campus structure within OASIS, there will be an OIN established for each site certificated and an associated site administrator is required because OASIS used OIN's as the means to identify each entity within OASIS. The organization may use the same supplier administrator across all of the sites. When the certificate is published in OASIS only the address and OIN of the site designated as the controlling address is visible in the Certified Suppliers Directory (CSD). It is necessary to have site administrators in case an address or other certification details are required to be amended in OASIS.	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
34	<p>9104-001 clause 8.4.b)</p> <p>9104-001 requires that a certification decision can only be taken and a certificate issued after a nonconformity unless 'all major and minor nonconformities have been contained; satisfactorily corrected with root cause analysis; and the corrective action has been implemented, reviewed, accepted, and verified by the CB'.</p> <p>What is required for verification in this context; does the CB require to verify implementation or to verify as effectively implemented? Can the verification be after the certification decision?</p>	<p>No, verification that corrective has been implemented is required before the certification decision.</p> <p>'Verified' in 9104-001 is in line in with ISO/IEC 17021 clause 9.1.12 and 9.1.15.b) or ISO/IEC 17021-1 clause 9.4.10 and 9.5.2.b) i.e. ' ... the certification body shall verify the effectiveness of any correction and corrective actions taken.'</p>	X	
35	<p>9104-001 clause 8.1</p> <p>Is the central function linked to a site or is it an activity?</p> <p>For a multiple site certification structure, what are the requirements for auditing the central function and how is the on-site audit duration determined?</p>	<p>The central function is linked to the site that is identified as the central office. The central office site for multiple site certification structures shall be audited every year as it contains the central function. It is recognised that remote workers i.e. employees located at other sites or locations, may report directly to the central function or may manage or control the process operated by the central function. These employees shall be included in the headcount of the site containing the central function.</p> <p>What is required to be audited in the central function is defined in 9104-001 8.1.1.c). The audit duration for the central function is not specifically identified however the site containing the central function is to be identified. IAF MD1 ties the central function to a site and uses the audit duration for the site. As the ICOP scheme aligns with the IAF Mandatory Documents correspondingly the audit duration to be applied for auditing the central function is the audit duration for the site containing the central function. The site containing the central function and the central function activities are to be audited every year.</p> <p>Where design and/or development activities occur at any site, the site containing the central function shall use the 9104-001 Table 2 columns '9100/9110' to calculate on-site audit duration.</p>	X	X
37	<p>9104-001 clauses 6.7.c), 8.3 and 8.2.3b)</p> <p>Can the competent audit team criteria utilized for the audit of combined and integrated AQMS audits be applied to non-combined or integrated audits?</p>	<p>No. For certification audits with a single AQMS standard it is expected and required from 9104-001 and 9104-003 (clause 5.3) that all of the audit team members shall at a minimum be authenticated as an AA for the specific AQMS standard and one or more of the audit team shall be authenticated as an AEA for the specific AQMS standard.</p>	X	X

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
38	9104-001 clause 8.2 What are the requirements for calculating audit duration if a CB decides to implement an audit frequency that is more than once per year e.g. at 9 monthly intervals?	Regardless of the surveillance frequency adopted by a CB, the minimum on-site audit durations are required to be met by the end of each surveillance year. A recertification audit is also to be conducted with a single audit report based on the requirements set out in 9104-001 and any applicable IAQG OPMT resolutions.	X	X
39	9104-001 clause 8.8.c) and 8.8.d) If a certified client transfers its certificate to another CB within 12 months of the expiration date of the current certification whereby a stage 1 and stage 2 audit is required, does the stage 1 and stage 2 audit requirement mean an initial certification audit is required? When undertaking the onsite transfer stage 2 audit, what audit duration tables should be used, initial, surveillance or recertification? Does the stage 2 audit meet the expectation and criteria for a special audit?	<p>No. An initial certification audit is not a transfer audit.</p> <p>An initial certification audit may be required if the pre-transfer review (as per IAF MD 2 clause 2.2) cannot validate the adequacy and validity of the existing certification for transfer and then the client may need to become subject to an initial certification audit as per IAF MD 2 section 2.3.5.</p> <p>The on-site audit duration is not specified by 9104-001 as the on-site audit(s) required for transfer are special audits and not regularly planned audits within the certification cycle.</p> <p>Yes. The process to transfer a certificate is described in 9104-001 clause 8.8 and IAF MD2. The process requires the accepting CB to start with a pre-transfer review and follow the requirements of IAF MD 2. In addition to a pre-transfer review, an on-site special audit is required as per 9104-001 clause 8.8.d). In the 12 months before expiry of the certification the on-site special audit is required to have two parts:</p> <ul style="list-style-type: none"> • A stage 1 on-site audit which includes validation of the adequacy and validity of the existing certification as described in ISO/IEC 17021 and ISO 17021-1 which allows the new CB to gain an understanding of the transferring client's management system and site operations. • A special on-site audit described in 9104-001 clause 8.8.c) as a 'stage 2 audit' which is used to validate the implementation, including effectiveness, of the management system including the items listed in 9101 clause 4.2.1 as well as any areas of concern highlighted the pre-transfer review and the on-site stage 1 audit. <p>Two audit reports are required (Stage 1 and Special) in order to provide objective evidence of conformance.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
39 continued	What are the special audit requirements that support the certification transfer process during the surveillance cycle and when certificates expire within 12 months?	<p>In addition to the requirements IAF MD 2 “IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems” for:</p> <p>Certification Transfer during the Surveillance cycle:</p> <p>Special Audit – Cert Decision – Cert Issuance = Transfer Complete – Surveillance</p> <p>Special audit scope = Verify that the QMS conforms to the standard and existing certification is valid. Audit to sufficient depth to validate the integrity of the existing certificate.</p> <p>The accepting certification body shall take the decision on certification before any surveillance audits are initiated. (Refs: IAF MD 2, Section 2.3.5)</p> <p>Certification Transfer when certificates are expiring within the next 12 Months (Refs: 9104-001, clause 8.8.c):</p> <p>Special Audit (Stage 1 and Stage 2 audit activities and reporting) – Cert Decision – Cert Issuance = Transfer Complete – Recertification</p> <p>Stage 1 = 17021-1; Section 9.3.1.2 and 9101:2016 Criteria (must be on site) Stage 2 = Special audit scope = Verify that the QMS conforms to the standard and existing certification is valid. Audit to sufficient depth to validate the integrity of the existing certificate.</p> <p>The Audit Phase requirements of 9101:2016, Section 4.3.3 should not apply to the transfer process since the transfer special audit occurs post initial certification. The Stage 1 and Stage 2 audit activities supporting the Transfer Special Audit may occur on consecutive days.</p> <p>The accepting certification body shall take the decision on certification before any recertification audits are initiated. (Refs IAF MD 2, Section 2.3.5)</p> <p>Audit Duration: The CB must ensure that sufficient audit duration is utilized to meet the audit objectives and the justification for the determined audit duration shall be documented and a record maintained (Refs: 9104-001, 8.2.e).</p>		
40	Audit Duration FAQ cancelled.			

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
41	<p>9104-001 clause 8.2</p> <p>What are the requirements for adding an additional site to an existing AQMS certification?</p>	<p>Prior to adding an additional site to an existing AQMS certification, the site must be audited in accordance with 9104-001.</p> <p>The additional new site is required to be audited to all of the applicable clauses of the AQMS and for the effective processes at the site (refer to ISO/IEC 17021 clauses 8.6.3 and 9.5.1 or ISO/IEC 17021-1 clause 8.5.3 and 9.6.4.1).</p> <p>9104-001 Table 2 audit durations are based on the establishment of a certification structure to enable effective audit. As part of the application review and documented justification the CB will be expected to evaluate any impact the new additional site has on the existing certification structure and established on-site audit duration. For the audit where the new additional site is added, the on-site audit duration for the new site would be expected to be determined by the CB using the initial audit duration for the new additional site in accordance with the established certification structure.</p> <p>Where the determined certification structure is a campus it would be a justifiable approach to use the initial audit duration for a site (new site) within a several sites structure.</p>	X	X
42	<p>9104-001 clause 8.5.c) and 8.6.d) and ISO/IEC 17021-1 clause 8.2.2.b)</p> <p>9104-001 clause 8.5.c) and 8.6 d) refers to the "Certificate issue date" while ISO/IEC 17021-1 8.2.2 b) refers to "the effective dates of granting, extending or renewing certification". Are these the same date?</p> <p>When OASIS refers to the 'Certificate Issue Date' what date is it referring to?</p>	<p>This FAQ should be read in conjunction with IAQG OPMT Resolution #125</p> <p>Yes, these are the same dates. ISO/IEC 17021-1 clause 8.2.2.b) is also referring to certification decision date which may be earlier than the effective date. 9104-001 clause 8.6.d) is referring to the effective date when the certificate was issued following a certification decision.</p> <p>When OASIS uses 'Certificate Issue Date' it means the start date of the valid "effective" period of the certificate. OASIS does not currently record the certification decision date or the actual date a certificate was physically issued.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
43	<p>9104-001 clause 8.2.1.b) and IAF MD 5 section 3.9</p> <p>Do the limitations on reduction of audit duration mandated by IAF MD5 section 3.9 mean that for some sites within a Campus certification structure that there will be insufficient on-site audit duration with the result that a CB cannot use AQMS audit durations to issue an ISO 9001 certificate of the same scope?</p>	<p>No. The minimum audit durations mandated by 9104-001 should meet the minimum on-site audit duration requirements required by the IAF for ISO 9001 certification.</p> <p>Where there may be concern that the minimum on-site audit duration mandated by 9104-001 is insufficient when taking into account a large number of employees at a given site, complexity of the quality management system, and the number and/or variety of activities in accordance with 9104-001 section 8.2 the required audit duration from Table 2 shall be increased, as appropriate. A CB should fully document their justification to their approach to calculating on-site audit duration and demonstrate that it meets all applicable requirements. Where a CB has audit duration concerns then they will need to add to the on-site audit duration.</p>	X	X
44	<p>9104-001 clause 8.6.o)</p> <p>If the certification structure of the supplier is a Campus, does the organization need to identify the 'controlling address' in addition to 'central function'?</p>	<p>The 'controlling address' and the 'central function' are often at the same site, however the controlling address of a Campus certification structure may be different from the 'central function' address. All certification structures may only have one controlling address and one central function. Also, if the controlling address is not the same as the central function address; the scope of the activities at the central function must clearly be stated within the published certificate in accordance with 9104-001 clause 8.6.m) and n).</p> <p>For the purpose of 9104-001 the controlling address is the address listed on the face of the issued certificate.</p>	X	X
45	<p>9104-001 clause 8.6 and ISO/IEC 17021 and ISO/IEC 17021-1 clause 8.2</p> <p>When an AQMS certification document is issued to a supplier that contains more than one site, is it acceptable to issue more than one version of the certificate so that each site certificated can be shown more visibly at the home site location?</p>	<p>No. Each site within a certificate that contains more than one site is dependent on other sites for at least some of the functioning of the quality management system e.g. the controlling address or the central function. Any one site is therefore part of the overall certification and the certification document issued should always be the same wherever it is seen i.e. on a site or in the OASIS database to ensure that there is no misunderstanding or misrepresentation of the issued AQMS certificate.</p> <p>Where a site needs a standalone certificate and chooses to be certified as a single site, the supplier shall ensure that all of the criteria are met for that site to be certificated as a single site organisation.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
46	<p>9104-001 Clause 5.3.4 and Table 1)</p> <p>When an AB is conducting the annual requirement for witnessed assessments from Table 1), does the AB require to assess all sites within an AQMS certification or can the AB select one site from an AQMS certification in order to be able to meet the requirement?</p>	<p>An audit of a suppliers' AQMS certification includes all sites on the certificate in accordance with the requirements of 9104-001. In witnessing the AQMS audit of a supplier, an AB assessment team is required to be present for the whole duration of the CB audit, from the opening meeting to the closing meeting (9104-001 clause 5.3.4.c) and this would include the supplier sites that are being audited for that audit event (initial, surveillance or recertification).</p> <p>It is recognised that an AB may not witness every part of every audit particularly where there is more than one auditor involved or where there is audit activity on more than one site simultaneously. It is the intent of the standard that the AB witness the entire audit from opening meeting to closing meeting. This is in order to achieve the required demonstration of the CB's competence to carry out specific conformity assessment tasks, which should include attendance at more than one site or on more than one occasion depending on the certification structure and organisation of the audit being witnessed.</p>	X	
47	<p>9104-001 Clause 8.2.2.d) and the associated Note</p> <p>The Note under 9104-001 clause 8.2.2.d) allowed the completion of objective evidence on the OER during the Table 2 minimum audit duration however there is no OER in the 9101 forms associated with the standard. Can the objective evidence be recorded on the QMS Matrix and PEAR forms during Table 2 minimum audit duration?</p>	<p>9104-001 Table 2 represents the "minimum audit duration". Additional time shall be added to address required 9101 report writing in accordance with 9104-001 clause 8.2.2.d). Although it is recognized that 9101 requires forms to be completed during the audit, additional time shall be added to the minimum Table 2 audit duration (based on the size and complexity of the organization) to address completion of the required 9101 forms.</p> <p>The recording of objective evidence on the 9101 forms can occur during the audit conduct but the minimum audit duration shall be increased to account for completion of these forms.</p>	X	X
48	FAQ Cancelled.			

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
49 Replaces FAQ#36	<p>9104-001 clause 8.2</p> <p>Are increases to the minimum on site audit duration mandatory?</p>	<p>9104-001 states that on-site audit duration requires a documented justification and shall be increased, as appropriate, based on:</p> <ul style="list-style-type: none"> • On site audit report writing and completion of all required 9101 forms during the audit. • The complexity of the quality management system, • The number and/or variety of activities • Audit activity for corrective action verification • The use of translators, and • The need use on site time for audit planning with the CB's client <p>Based on the 9104-001 requirements including the need for completion of 9101 forms on-site it is extremely unlikely that a CB does not increase the required 9104-001 minimum on-site audit duration. In all cases there shall be documented justification for the calculated on-site audit time in accordance with ISO/IEC 17021 and 9104-001 requirements. The justification shall also be included in the 9104-001 Audit Calc report.</p>	X	X
50	<p>NCR Upload FAQ cancelled due to OASIS NG release.</p>			
51	<p>9104-001 clause 8.5.c) Use of the Audit Calc tool for the pdf report to upload to the OASIS database.</p> <p>Is there a protocol (i.e. selection of a certification cycle stage) for using the Audit Calc tool to record Special Audits, such as transfers?</p>	<p>The WSU audit calc tool became obsolete upon release and use of the OASIS NG functionality. Please refer to the help/guidance within OASIS for use of the new audit calc functionality.</p>	X	
52	<p>9104-001 clause 8.6</p> <p>Is it a requirement that a certification document issued for an AQMS standard(s) include a listing of all clauses or sub-clauses that are deemed not applicable and outside of the scope of the organization's QMS?</p>	<p>No. There is no requirement to reference specific clauses that are not applicable on the certificate. The scope of certification should provide clarity of the scope of certification with respect to the type of activities, products and services that will be offered to the organization's customers without being misleading or ambiguous.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
53	<p>9104-001 clause 8.8</p> <p>Is an on-site transfer audit required at each site for multiple-site, several site, campus and complex certification structures or is an on-site special audit at the site containing the central function only?</p>	<p>An on-site special audit is required at a minimum at the site containing the central function and the special audit should be extended to audit at the remote sites if issues are identified during either the pre-transfer review or the central function special audit. As stated in IAF MD 2, Section 2.3.5 “The decision as to the action required will depend upon the nature and extent of any problems found and shall be explained to the organization and the justification for the decision shall be documented and the records maintained by the certification body.” The term “action” in this sentence is understood to mean the extent of audit activity required.</p>	X	
54	<p>9104-001 clause 6.6, ISO/IEC 17021 clause 9.1.1.2 and ISO/IEC 17021-1 clause 9.1.3.2</p> <p>If there is a surveillance audit scheduled in the last month of the surveillance year e.g. December, and the auditor gets sick or becomes unavailable for any reason, is it acceptable to re-schedule the surveillance audit into the first part of the next surveillance year e.g. January, without any consequences?</p>	<p>If the annual surveillance requirement is not met, the certification cannot be maintained and the CB is required to initiate the suspension process. Where a situation would reasonably represent a special circumstance, such as the example given, the special circumstance may contribute to the final decision made by the CB. Documentation of the situation and the associated certification decision is required to be made available for assessment or oversight and coordination with the AB would be expected prior to the final certification decision on the suspension.</p>	X	
55	<p>9104-001 clause 8.8, ISO/IEC 17021 clauses 8.6.3 and 9.5 and ISO/IEC 17021-1 clauses 8.5.3 and 9.6.4</p> <p>Is there a requirement for a special audit at the central function and a new site when a request is received to remove a site from an existing AQMS standard certified organization (and structure) and then add that site to another existing AQMS certified organization (and structure)?</p>	<p>Please also refer to FAQ#41 on adding a site to an existing AQMS Certification</p> <p>Yes. Adding a site to an existing certification would represent a significant change to the scope of certification and may cause the applicable certification structure to change. The CB is required to verify through special audit that the added site’s QMS has been updated and aligned to include the certified organization’s common processes and the central function of the certified organization has updated their processes to address the added site and can demonstrate conformance with applicable AQMS standard(s) and 9104-001 and requirements.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
56	<p>9104-001 clause 8.8, ISO/IEC 17021 clauses 8.6.3 and 9.5 and ISO/IEC 17021-1 clauses 8.5.3 and 9.6.4</p> <p>Is there a requirement for an on-site special audit of the central function when a request is received by a CB to remove a site from the existing scope of certification and associated certification structure is received?</p>	<p>No. Removing a site from an existing certification may or may not represent a significant change for the central function of the certified organization. The CB is required to ensure that sufficient documentation is available that describes the change and actions taken by the certified organization to ensure conformance. The CB is required to evaluate those changes and take action as appropriate to the impact of the changes. Should the request represent a significant change (e.g. changes or movement in the existing scope of operations, change of the site containing the central function or major changes to the management system and/or processes) an on-site special audit is required. A significant change would be a change that may affect the capability of the certificated management system to continue to fulfil the requirements of the applicable AQMS standard(s) or 9104-001.</p>	X	
57	<p>9104-001 clause 8.2, 8.2.e and 8.2.1.a</p> <p>What are the minimum audit duration requirements (i.e., initial, annual surveillance, and recertification audits) for the 9120:2016 standard when an organization has determined that requirements within 9120:2016, Section 8.3 Design and Development of Products and Services are applicable to the scope of the Quality Management System (QMS)?</p>	<p>The CB shall utilize the 9104-001 Table 2, audit duration requirements for 9120 as the starting point for duration calculations and it should be increased based on the following 9104-001 requirements: 9104-001, clause 8.2: "the required audit duration from Table 2 shall be increased, as appropriate, taking into account the complexity of the quality management system, and the number and/or variety of activities." 9104-001 clause 8.2.1.a: "No reductions from the audit duration defined in Table 2 are allowed, except as specifically defined in this standard for the individual certification structures. Increases to the required audit duration are expected for areas with identified risk, complexity, or increased scope."</p> <p>The justification for the determined audit duration shall be documented and a record maintained. (Refs: 9104-001, 8.2.e).</p>	X	
58	<p>9104-001, clause 8.3.8</p> <p>When should a lead auditor be changed to comply with the lead auditor rotation requirement?</p> <p>Can the removed lead auditor still support the audit team?</p>	<p>Once an auditor has served as the audit team leader for a specific client for two full consecutive certification cycles and has been removed from the team leader role they shall not be assigned as the audit team leader again, for the specific client, until after the next re-certification audit (i.e. after one full certification cycle of 3 years).</p> <p>The auditor may serve as a team member after removal.</p>	X	

9104-001 Frequently Asked Questions (FAQ) Log

Revision: 20 Nov 2018



FAQ Number	9104-001 Clause and Question	Answer	Applicability	
			9104-001	CSOC
59	<p>9104-001 8.2.n & all 9104-001 references to annual or annually</p> <p>When the standard uses the term “annual” or “annually” does it imply calendar year (i.e., Jan – Dec, 20xx) or 12 months since last occurrence (i.e., 5 June 20xx to 5 June 20xy)?</p>	The requirement refers to any time in the calendar year (i.e., Jan – Dec, 20xx).	X	
60	<p>9104-001, clause 8.8.d</p> <p>Does the 9104-001 standard require a special onsite audit for each client to support the MD 2 transfer process; when a CB acquisition occurs that creates a mass transfer of clients from an existing CB entity to the new CB structure?</p>	<p>The onsite special audit requirement is associated with the risks of a single supplier changing CB’s and the potential reasons behind such a transfer.</p> <p>The reasons for mass transfer and the associated risks may be unique to each occurrence and therefore CB’s should provide a plan for management of these transfers to their respective AB. The AB should respond to the applicable SMS with their recommendations and obtain plan concurrence.</p>	X	
61	<p>9104-1, clause 8.2.2.n</p> <p>When a certified organization has three purchasing processes, can the annual requirement to audit purchasing be met if the CB audits at least one of these purchasing process per year?</p>	Yes, the intent is to ensure that a process which demonstrates conformance to 9100/9110/9120 clause 8.4 Control of Externally Provided Processes, Products, and Services is audited at least annually, to sufficient depth, to determine process effectiveness and conformance.	X	

[Click 'here' to go to the start of the log](#)

End of the 9104-001 FAQ Log