

## Subject: Conducting AS91XX:2009 Assessments

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- 1.0 PURPOSE:** To provide the controls necessary to assure that the assessment and certification processes AS91XX:2009 complies with all applicable rules and regulations of the applicable accreditation or approval body and these management system requirements.

**Note:** The requirements of this CQAM are in addition to the requirements of CQAM-102/103. If there are any conflicts this procedure takes precedence.

- 2.0 SCOPE:** This procedure is to be used by all Smithers Quality Assessments, Inc. (SQA) auditors in the evaluation of a client's AS quality related activities.

**Note:** Auditors are required to be authenticated through the AATT process and identified in the OASIS database.

*Organizations that do not have aviation, space or defense products or services within the scope of their documented management system may apply for and be certified to AS91XX provided they are operating within the scope of application of the applicable AQMS standard and comply with all the applicable provisions of the ICOP scheme (See IAQG resolution #127).*

- 3.0 RESPONSIBILITY:** *The General Manager is responsible to the SQA President for ensuring all AS91XX related audits are conducted in accordance with this CQAM. The SQA Office at 121 S. Main St. Suite #300 Akron, OH 44308 has as the overall responsibility for the implementation of the 9104-series standards requirements. The design, development and maintenance of the implementation of the 9104-series standards will be through employees of Smithers Quality Assessments.*

- 4.0 AUTHORITY:** *The General Manager is authorized by the SQA President to take appropriate actions to assure the proper and complete implementation of this CQAM.*

### **5.0 Definitions**

**Planned activities-** *The means, method, and internal requirements by which the organization intends to achieve planned results of a given process to meet customer requirements. Planned activities include conformity to process requirement and procedures.*

**Planned Results-** *The intended performance of a process, as defined and measured by the organization. Planed results include product conformity and OTD to meet customer requirements, and may include other elements related to the process, as defined by the organization.*

**Special audits-** *although not listed as a part of the audit program, it can be applicable after initial certification, when directed by special request.*

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### **5.0 PROCEDURES:** (Ref: CQAM-102, Procedure for Conducting Quality System Assessment.)

#### **5.1 Resolving consultancy conflicts:** Prior to conducting an assessment to AS91XX, the President shall assure that the following actions are taken to assure the absence of consultancy (see SQA-74):

**5.1.1** SQA is not permitted to provide any training outside of public training open to and attended by 2 or more companies or conduct internal audits.

#### **5.2 Extent of assessment activity:** It shall be the policy of SQA that assessments conducted to AS shall not be limited to the system's basic system processes or requirements but shall also include:

- a) products supplied to customers subscribing to the certification to AS91XX and;
- b) applicable customer specific requirements in effect at the time of the assessment. The accepted practice is to identify these extended requirements during the Stage 1 assessment; however, they may also be discovered during the initial assessment activity or subsequent assessments. Identifying newly added aerospace customers when auditing AS91XX. Also, the initial assessment shall include all remote sites, e.g., engineering, purchasing, warehouses.

**5.2.1 Limitations on pre-assessments:** No more than one pre-assessment per site of the same company is permitted and its duration cannot exceed 80% of the required Stage-2 assessment.

**5.2.2 SQA does not provide combined or integrated AQMS audits.**

#### **5.3 Organizational Leadership:** *There will be an interview(s) with Top Management to evaluate the:*

- a. *establishment and continued relevance of the organizations quality policy and objectives;*
- b. *establishment of performance measures aligned to quality objectives;*
- c. *QMS development, implementation, and continual improvement;*
- d. *Top management commitment;*
- e. *QMS performance and effectiveness;*
- f. *Performance to customer expectations (e.g. supplier rating, scorecard, audit results);*

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*g. Actions taken to address issues that are not meeting customer performance expectations.*

### **5.4 Quality Management System Performance and Effectiveness-** *the audit of the QMS performance and effectiveness will include a review of the following:*

- a) The processing of customer complaints, customer feedback data (e.g. periodic performance reports received from customers), and other relevant customer data (e.g. results of customer surveys).*
- b) Results and actions from internal and external audits of the QMS, including their associated records*
- c) Stakeholder feedback (e.g. feedback from regulatory authorities and other interested parties).*
- d) The processing of process/product nonconformities, including review of associated corrective actions and on the effectiveness of actions taken*
- e) The processing of preventive actions, including evaluation on the effectiveness of actions taken*
- f) Management review conduct, including associated records (e.g. process inputs/outputs, actions taken)*
- g) Internal performance monitoring, measurement, reporting, and reviews against stakeholder and internal performance objectives and targets, including continual improvement activities and associated records;*
- h) The organization's current performance against targets, including customer specific targets and associated records of applicable actions taken where targets are not being met*
- i) The status and effectiveness of the organization's process performance improvement activities and their outcomes related to product quality*

### **5.5 Process Management:** *The audit team will conduct QMS audits using a method that focuses on process performance and effectiveness which ensures priority is given to:*

- a. Reviewing the organizations processes, their sequence and interactions, the identification of functions and assignment of responsibilities and performance against requirements and defined measures, with focus on processes that directly impact the customer.*
- b. Reviewing the process for validation and approval of processes and*

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- process change.*
- c. Reviewing the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel.*
- d. Reviewing the process-based management techniques, including the examination of process measures (e.g. quality, cycle time, output effectiveness, control limits, process capability determination)*
- e. Reviewing plans in place to ensure performance objectives/targets are monitored, measured, and analyzed in order to realize the planned activities and achieve the planned results (e.g. verify performance information availability, percentage of nonconforming parts/products, percentage OTD)*
- f. Reviewing applicable action taken when objectives/targets are not met to promote continual improvement*
- g. Pursuing audit trails addressing customer concerns or requests for corrective action, performance against objectives, and relevant process controls.*

*The audit team will audit processes to sufficient depth and detail to evaluate if the organizations processes are capable of meeting planned results and performance levels, including applicable customer specific targets*

*NOTE1: KPIs are used to identify an organizations progress towards achieving its performance goals.*

*NOTE2: KPIs relating to financial information are not in the scope of the 9101 standard and therefore is not auditable.*

*NOTE3: Process based audit trails should be pursued by following actual products, customer orders and related documents such as customer contracts, drawings, shop orders, and inspection records through the organizations product realization and associated processes. The process audit will verify the interfaces between processes and the linked documentation requirements, resource management and measurement, analysis and improvement.*

**5.6** *Special Processes: When included in the audit plan, the audit team shall evaluate the process validation as well as the monitoring, measuring and control of these processes.*

- a. Process records shall be reviewed for each audited special processes.*
- b. Audit team shall identify and select a sample of special processes; the audit team shall audit the monitoring and measuring equipment used and the method of recording results. If required, the traceability between the process and the resulting product shall be verified.*

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- c. *In case that the processes is outsourced, the audit team shall verify that the organization's supplier control process addresses these items accordingly; the audit team shall review of customer designated sources.*

*Note 1: Special processes are managed by using qualified personnel as required by the client or client's customer requirements, and by controlling physical or chemical process characteristics.*

*Note 2: If an audit is conducted by a customer or a specialized independent 3<sup>rd</sup> party, the audit team can take that into account; this can include audit results, sampling of the findings and verification of any reported non-conformities to determine adequate resolution. It is recommended that the audit team audits special processes independently of the results of the customer or 3<sup>rd</sup> party.*

**5.7 Continual Improvement:** *The audit team shall evaluate the organization's interrelated processes and activities for continual improvement of the QMS, its' processes, their conformity and effectiveness in order to:*

- a. *Focus on issues that are important to our client, their customers and regulatory authorities and*
- b. *Determine the effectiveness of the clients approach to continually improve their process performance.*

*Note: The client should demonstrate they have a structured approach to continual improvement.*

### 5.8 Reporting

Certification Structure Reporting Matrix					
Structure type AUDIT PHASE	Single Site	Multiple Sites	Campus	Several Sites	Complex
STAGE 1	Stage 1 Audit Report (Form 1) SQA-90				
STAGE 2 SURVEILLANCE RE-CERTIFICATION	<ul style="list-style-type: none"> <li>QMS Process Matrix (Form 2) per site</li> <li>PEAR (Form 3); per site or combined, as appropriate</li> <li>Nonconformity Report – NCR (Form 4) as applicable</li> <li>Audit Report (Form 5)</li> <li>Supplemental Audit Report (Form 6); optional</li> </ul>				
SPECIAL AUDIT	<ul style="list-style-type: none"> <li>PEAR (Form 3); per site or combined, as appropriate</li> <li>Nonconformity Report – NCR (Form 4) as applicable</li> <li>Audit Report (Form 5)</li> </ul>				

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*Recording of process information may be combined in a single PEAR for multiple sites, several sites, campus or complex organizations provided that the process is common across sites/structures. Information recorded shall reflect each site included in the PEAR, and the effectiveness rating shall reflect the lowest value of the various sites assessed.*

*Use of the 9101E forms are mandatory and variations of the forms is not allowed. Expanding the fields to accommodate recording information is acceptable. In addition, audit guidance notes in the forms is also acceptable.*

### 5.9 Common Audit Activities

Relationship between common activities and audit phases						
AUDIT PHASE COMMON ACTIVITY	Pre-audit activities (4.3.1)	Stage 1 (4.3.2)	Stage 2 (4.3.3)	Surveillance (4.3.4)	Recertification (4.3.5)	Special (4.3.6)
AUDIT PLANNING (4.2.1)	X	X	X	X	X	X
ON-SITE AUDITING (4.2.2)		X	X	X	X	X
AUDIT REPORTING (4.2.3)		X	X	X	X	X
NONCONFORMITY MANAGEMENT (4.2.4)			X	X	X	X

#### 5.9.1 AUDIT PLANNING

*The plan shall be based on the processes identified by the organization and documented in the QMS.*

*The audit team leader shall use the organization's customer feedback requests including those in OASIS to assist with planning for surveillance and re-certification audits. The audit activities shall be prioritized on performance data for the business risks that could impact the customer and on processes not achieving planned results.*

*Pre-Audit planning data is required for all audits and is required prior to going on-site and assist in creating the audit plan and shall take into account:*

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- a) the scope and complexity of the organization's quality management system;
- b) the processes of the organization, including their sequence and interactions;
- c) the criticality of products and processes, including special processes;
- d) *risks associated with the product or process maturity*
- e) product related safety issues (e.g., airworthiness issues, reporting to customer and/or authorities);
- f) results of internal audits;
- g) previous audit findings;
- h) performance measures and trends for quality and OTD;
- i) previous management review results;
- j) customer satisfaction and complaints log, including feedback requests received by the CB (e.g., items identified through OASIS feedback process);
- k) customer specific, statutory, and regulatory quality management system requirements;
- l) performance data available from customers;
- m) *certification structure*
- n) changes to organization (e.g., structure; facilities; business strategy; processes; technologies; a review of requirements from new aviation, space, and defense customers); and
- o) the audit team member's required background/experience and desired competencies.
- p) *Proportion of aviation, space and defense business (amount of audit time planned on auditing any one customer should be proportionate the to % business)*
- q) *Use of CAAT or ASRP*

The review of this information in conjunction with SQA-78 will be utilized to

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develop the audit plan demonstrating the prioritization of assessment activities and planned assessment time proportion of aviation, space, and defense business each customer represents. This review also ensures that any significant changes that impact the organization's audit duration are reviewed each year prior to developing the audit plan.

**Note 1:** Consideration shall be given to timing of activities over consecutive days to give a sequence which avoids unnecessary duplication of visits to one process.

**Note 2:** The duration of an auditor day is normally 8 hours and may or may not include travel time or lunch depending upon local legislation.

**Note 3:** SQA-78 (Comprehensive Requirements Workbook) contains the proportion of aviation, space, and defense business each customer represents, based on their approximate percentage of business. Also contained in this file are Business Conditions which can affect the audit duration.

**5.9.2** Each on-site assessment (excluding on-site CAR follow-up) and special audits utilizing the process approach shall address the following:

- a) a review of the changes to the quality management system, since the last audit;
- b) a review of requirements from new aviation, space, and defense customers, since the last audit;
- c) *A review of customer satisfaction information; customer complaints, customer feedback data (e.g. periodic performance reports received from customers), and other relevant customer data (e.g. results of customer surveys).*
- d) *Results and actions from internal and external audits of the QMS, including their associated records*
- e) *Stakeholder feedback (e.g. feedback from regulatory authorities and other interested parties).*
- f) *The processing of process/product nonconformities, including review of associated corrective actions and on the effectiveness of actions taken*
- g) *The processing of preventive actions, including evaluation on the effectiveness of actions taken;*

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- h) *Management review conduct, including associated records (e.g. process inputs/outputs, actions taken)*
- j) *an interview(s) with top management to evaluate the (see clause 4.1.2.2);*
  - 1. *establishment and continued relevance of the organizations quality policy and objectives;*
  - 2. *establishment of performance measures aligned to quality objectives;*
  - 3. *QMS development, implementation, and continual improvement;*
  - 4. *Top management commitment;*
  - 5. *QMS performance and effectiveness;*
  - 6. *Performance to customer expectations (e.g. supplier rating, scorecard, audit results);*
  - 7. *Actions taken to address issues that are not meeting customer performance expectations.*
- k) *Internal performance monitoring, measurement, reporting, and reviews against stakeholder and internal performance objectives and targets, including continual improvement activities and associated records;*
- l) *The organization's current performance against targets, including customer specific targets and associated records of applicable actions taken where targets are not being met*
- m) *The status and effectiveness of the organization's process performance improvement activities and their outcomes related to product quality*
- n) *An audit of continual improvement*
- o) *an audit of special processes (see clause 4.2.2.8), as identified in the audit plan (see clause 4.2.1);*
- p) *an audit of follow-up actions from previous audits.*
- q) *Verification of the organization's OASIS database administrator*
- r) *Verification of Certification Structure*

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**NOTE1:** If there is more than one surveillance audit during a year (e.g., every six months), the activities and items mentioned above can be spread over these audits.

**NOTE2:** All processes in product realization shall require the completion of a PEAR which documents the effectiveness of the process. It is encourage that the auditor utilize a PEAR for each of the organizations defined process on the SQA-78.

**NOTE3:** All remote locations must be audited prior to the Stage 2 assessment, once during the surveillance cycle and the prior to the recertification assessment at a minimum.

**NOTE4:** The design function whether on-site or remote must be audited at least once within each consecutive 24 month period.

**NOTE 5:** Design Process- When the client is product design responsible, verify they have a completed design package or a Mock Design package available for review during the audit.

**NOTE6:** Customer satisfaction data (report cards and complaints), client's internal performance data internal audit and management review are required to be scheduled and audited day-1 (first) to adequately plan and prioritize the assessment. The audit plan may need to be modified during the assessment to accommodate audit trails identified during this activity. This also includes an interview of top management.

**NOTE 7:** The organization's Purchasing process shall be audited at least annually.

*5.9.3 Conducting the opening meeting: The AEA shall conduct site specific opening meetings or a central opening meeting shall be conducted with representatives from all sites (physically or by means of electronic meeting methods). Use the SQA opening/closing meeting checklist as part of SQA-67.*

*5.9.4 Site Tour: The audit team leader may conduct a site tour to address any changes in the scope or facilities since the last visit or to familiarize team members with the site/organization.*

*5.9.5 Audit Conduct: The audit shall be conducted using various auditing approaches. The team shall pursue relevant audit trails to assist in determining conformity and effectiveness.*

*5.9.5.1 SQA has developed detail sheets (SQA-05) as a tool to record evidence that may be used by the auditors.*

*5.9.6 Identifying and recording Audit Findings: The audit team shall complete the QMS Matrix to demonstrate which processes and 9100 standard clauses have been audited, including a summary of the evidence related to each 9100 requirement (Clauses 4, 5, 6 and 8). The PEAR is used to record evidence for clause 7.*

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*Note 1: If a PEAR is used by the auditor for clauses 4, 5, 6 and/or 8; there is no need to record the evidence in the QMS matrix. Reference to the applicable PEAR(s) should be stated in the QMS Matrix.*

*Note 2: Form 2 has several applications:*

- *Pre-populated, and modified/revised during each audit*
- *Used after the Stage 1 for preparation of the audit plan for Stage 2*
- *Used after the certification/recertification audit to prepare the audit plan for the certification cycle.*
- *Used to visibly cross-reference the standard and the client's processes.*

*The NCR form (4) shall be used to record non-conformities. Each NCR shall contain only one nonconformity. Nonconformities shall be classified as Major or Minor.*

The definition of Major and minor nonconformities are defined as follows:

Major Nonconformity - A non-fulfillment of a requirement which is likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products/services; it can be one or more of the following situations:

- a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
- the absence of or total breakdown of a system to meet a 91XX-series standard requirement, an organization procedure, or customer quality management system requirement;
- any nonconformity that would result in the probable shipment of nonconforming product; and/or
- a condition that could result in the failure or reduce the usability of the product or service and its intended purpose.

Minor Nonconformity - A non-fulfillment of a requirement which is not likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products/services; it can be either one of the following situations:

- a single system failure or lapse in conformance with a 91XX-series standard or customer quality management system requirement; or
- a single system failure or lapse in conformance with a procedure associated to the organization's quality management system.

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NOTE 1: A number of minor nonconformities against one requirement (e.g., similar nonconformities associated to different sites or different departments/ functions/ processes within a single site) can represent a total breakdown of the system and thus be considered a major nonconformity.

NOTE 2: For surveillance and special audits, the audit team leader will advise the organization whether recorded nonconformities jeopardize an existing certificate. In the event that certification is suspended, an appropriate course of action will be agreed between the organization and the SQA. Where there is a failure to agree on a course of action, the appropriate appeals procedure of SQA will be invoked.

NOTE 3: When auditors identify what they believe to be inaccurate, incomplete or unapproved changes to information represented as verbal or written objective evidence during the course of any type of 9100 certification audit (e.g. initial, surveillance, recertification or special audit) the Audit Team Leader shall classify the associated nonconformance in accordance with the 9101 definitions of Major or Minor. If the nonconformity is categorized as Major the audit team leader shall advise the certified organization that its certification status is in jeopardy as a consequence of this nonconformity and SQA shall initiate their certificate suspension or withdrawal process to determine whether the documented nonconformity warrants suspension or withdrawal of the certified organization's 9100 certificate.

*The need to identify containment shall be determined by the lead auditor and documented on the NCR form.*

*If there is a repeat of a non-conformity found on consecutive audits at a particular site or location, a major non-conformance shall be written against the organization's corrective action process (8.5.2).*

***No Soft Grading is permitted.***

*5.9.7 Process Results: the audit team shall record measurables, targets and values of KPIs to each audited product realization process taking into account confidential information.*

*Note: Upon agreement between SQA and our client, other processes can be recorded on PEARs.*

*Nonconformities determined for the evaluation of the process results shall be categorized as major and minor.*

*5.9.8 Process Realization: Record a summary of the audit trails and audit evidence to each audited product realization process on the PEAR.*

*Nonconformities determined from the evaluation of process realization shall also be classified as major and minor.*

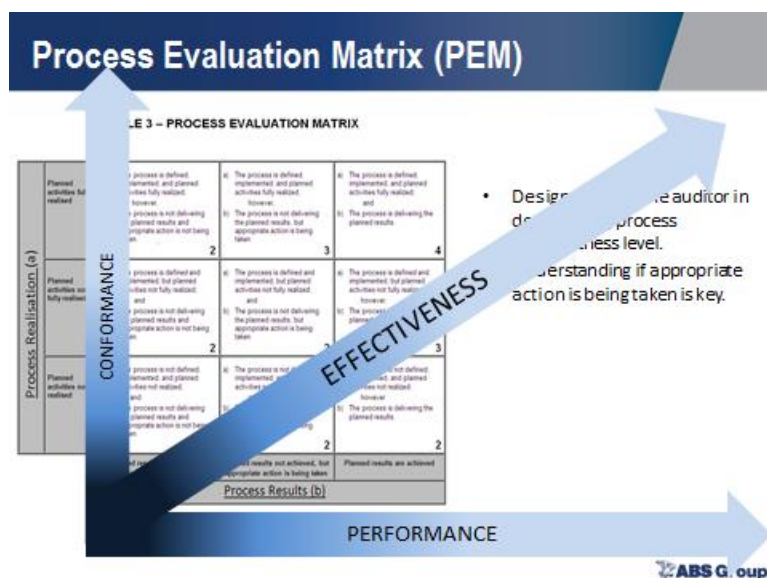
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**5.9.10 Process Effectiveness:** The audit team shall evaluate the effectiveness of each audited product realization process considering the following:

- process realization: the extent to which planned activities are realized
- process results: the extent to which planned results are achieved.

Determine the effectiveness level of the process audited arising from the PEAR and select the corresponding value from the PEM. The process effectiveness levels shall be recorded in the PEAR and documented on the QMS matrix.

See below as guidance in determining effectiveness rating:



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**TABLE 3 – PROCESS EVALUATION MATRIX**

Process Realisation (a)	Planned activities fully realised	a) The process is defined, implemented, and planned activities fully realized, however. b) The process is not delivering the planned results and appropriate action is not being taken.	2	a) The process is defined, implemented, and planned activities fully realized, however. b) The process is not delivering the planned results, but appropriate action is being taken.	3	a) The process is defined, implemented, and planned activities fully realized, and b) The process is delivering the planned results.	4
	Planned activities not fully realised	a) The process is defined and implemented, but planned activities not fully realized, and b) The process is not delivering the planned results and appropriate action is not being taken.	2	a) The process is defined and implemented, but planned activities not fully realized, and b) The process is not delivering the planned results, but appropriate action is being taken.	2	a) The process is defined and implemented, but planned activities not fully realized, however, b) The process is delivering the planned results.	3
	Planned activities not realised	a) The process is not defined, implemented, and planned activities not realized, and b) The process is not delivering the planned results and appropriate action is not being taken.	1	a) The process is not defined, implemented, and planned activities not realized, and b) The process is not delivering the planned results, but appropriate action is being taken.	2	a) The process is not defined, implemented, and planned activities not realized, however, b) The process is delivering the planned results.	2
		Planned results not achieved and appropriate action is not taken		Planned results not achieved, but appropriate action is being taken		Planned results are achieved	
		Process Results (b)					

The audit team shall issue a major nonconformances against 4.1c and/or 4.1f when the process effectiveness level is a 1.

If a nonconformance is written against the process, then the process effectiveness rating can never be a 4.

Note: NCRs issued against 9100 4.1c or 4.1f resulting from multiple PEARs can be combined into 1 NCR.

5.9.11 Conducting the closing meeting: The audit team leader shall provide the client, at a minimum, NCRs, PEARs and recommendation.

5.9.12 Audit Report: See Certification Structure Reporting Table above. The audit report (Form 1 and Form 5) and the QMS matrix shall identify any justified exclusions (section 7).

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*The content of the report , including the findings, shall give a true independent view of the status and determination of effectiveness in order to provide confidence to customers and potential customers enabling them to draw appropriate conclusions in regards to supplier selection.*

*Currently, SQA does not offer intergrated AQMS audits.*

*5.10 Non-conformity Management: after issuance of a nonconformity the team leader shall:*

- a) require the organaztion to anlayze the root cause and report the specific correction and corrective action taken, or planned to be taken to eliminate the detected nonconformities (must include toor cause analysis tool)*
- b) agree with the organization on correction, corrective action(s) and corrective action. When the nature of the nonconformity needs immediate containment action, the team leader shall required the organization to:*
  - describe the immediate actions (fix now) taken to contain the nonconforming situation and to control any nonconforming product. Correction is always required!*
  - Report within 7 calendar days, after the closing meeting, the specific containment actions, including correction and agreement on those actions with the audit team leader within the next 14 calendar days.*

*The NCR shall be used to document the verification of the corrective action. Evaluation and closong the corrective action plan and associated corrective actions relating to the nonconformity shall no tbe performed during the audit that the nonconformance was issued.*

*Verification activities shall be carried out, determined by the team leader (off-site). If the verification cannot be completed by reviewing evidences submitted, the activity must be completed on-site. If a major non-confromance is issued, the team leader shall conduct verification on-site unless specifically waived by SQA management.*

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Standard	N/C Type	Reply Timing*	Implemented and Effective*	Resulting Actions*	Maximum Suspension
AS91XX	Minor	T1 + 7 calendar days for containment next 14 days (initial C/A plan accepted lead auditor) T1+30 Days (C/A plans)	T1 + 60 Days	If late for implementation then Suspension and Withdrawal effective on 120 <sup>th</sup> day	120 days from T1
	Major	T1 +7 Days (containment) next 14 days (initial C/A plan accepted lead auditor) T1+ 30 days (C/A plans)	T1 + 60 Days	A decision is made within 14 calendar days of the identified major to determine if suspension warranted at that time. For late implementation, Suspension at T1/Withdrawal at 120 <sup>th</sup> day	120 Days from T1

5.10.1 Failure to meet the 7 day requirement will result in escalation of the severity of the NCR (minor will become major and major will become a suspension) and a fee of \$250 assessed may be assessed to the organization due to this failure.

5.10.2 Failure to meet the 14 day requirement may result in a fee of \$250 assessed to the auditor due to this failure.

*5.11 Audit Phase Specific Requirements: Organizations can deny auditors access to proprietary or classified information, and/or areas due to sensitive or national security regulations invoked in customer contracts. SQA shall require the organization to provide information to these activities/areas that are not accessible because of issues identified in this paragraph.*

*Any information considered confidential by the organization's customers and/or authorities, of the organization itself shall not be reported unless approved by the client.*

*SQA may "black out" using an appropriate method any references to individuals or information that is deemed confidential, restricted or controlled on any documents that are uploaded to OASIS in order to comply with regional, national, or international provisions or regulations that relate to privacy, confidentiality, security or export control (See IAQG resolution #128).*

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*5.12 Pre-audit activities: All activities to be included in the scope of certification shall be relevant to the scope of the applicable 9100 series of standards.*

*The scope shall not include processes that were not audited to sufficient depth to verify conformity or outsourced. They may be included if the processes can be proven to similar to processes that were assessed and the same QMS procedures and control. In the audit report, exclusions for these programs, customers, and/or activities shall be stated and justified.*

*5.13 Application: The CB shall require the organization to provide in addition to usual application:*

- a) % revenue for aviation, space and defense business, as a proportion of the organization's revenue.*
- b) Number of employees associated with aviation, space and defense business including the type (e.g. full-time, part-time) and % of total workforce*
- c) Identification of the major aviation, space and defense customers.*

### *Determining Certification Structure*

- SQA will determine certification structure through a conversation with the client and auditor (see Certification Structure Process Flow) along with a review of the organization's value streams (as defined on the CRW and/or RFQ). Audit day calculations will be included in this review.*
- Certification Structure recommendation will be documented on SQA-123 Certification Structure Worksheet, and includes common eligibility information (details on Certification Structures see CQAM-016.5).*
- SQA and client agreement on the certification structure will be maintained.*

#### *5.13.1 Requirements for SQA prior to scheduling Stage 1*

- a) Appoint an AEA as the team leader that also has the technical competence by IAF (see CQAM009) or add a technical expert as appropriate*
- b) Any additional requirements/requests from the organization and/or its customers.*
- c) Ensure that the audit time is per AS9104/1.*

*Note: Any of these items can have an influence on audit duration during the certification cycle,*

#### *5.13.2 Audit team leader requirements: Before scheduling the Stage 1, the team leader shall*

- a) Determine if the information received during pre-audit phase is sufficient to proceed to Stage 1*

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b) Verify the audit duration for Stage 1 and Stage 2.

**5.14 STAGE 1 Audit:** *Before Stage 1, the audit team leader shall confirmed and possible audit team members shall be identified. After the Stage 1, the team composition for the Stage 2 shall be reviewed based on information received and observed, then appoint final team.*

The Stage 1 shall:

- be performed by the audit team leader appointed for the initial audit with audit team assistance if needed; and
- include an on-site visit.  
**NOTE:** For 9120, the Stage 1 audit can be conducted off-site, based on organization considerations (e.g., size, location, risk, previous audit team knowledge). Justification shall be documented on the STAGE 1 report
- For organizations with more than one site that have a single quality management system, the Stage 1 audit shall also include an evaluation of the identified central function with the authority for administration, control, audit, review, and maintenance of the quality management system. Additionally, a relevant number of representative sites, including all sites with different technologies and dissimilar activities, shall be included.
- include a tour of the site facilities.
- Have the audit team collect sufficient information to:
  - confirm the audit program;
  - review the need for additional technical experts and/or auditors to compose a competent audit team;
  - determine any additional audit activities, as needed, for the fulfilment of the requirements for initial certification; and schedule the Stage 2 audit activities.
  - The audit team leader shall require the organization to provide the necessary information and documentation for review, including the following:
- quality manual;
  - description of processes showing their sequence and interactions, including the identification of any outsourced processes;
  - performance measures and trends for the previous 12 months;

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- 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);
- interactions with support functions on-site or at remote locations/sites;
- evidence of internal audits of processes/procedures, including internal and external quality management system requirements;
- the latest management review results;
- list of all major (e.g., top five) aviation, space, and/or defense and any other customers requiring 9100-series standard compliance, including an indication of how much business each customer represents and their customer specific quality management system requirements, if applicable; and
- evidence of customer satisfaction and complaint summaries, including verification of customer reports, scorecards, and special status or equivalent.

*Note: Customer specifics can include FAI (9102), record retention, flowdown requirements, design change responsibility, etc.*

**During the Stage 1 audit the following items shall be addressed, as applicable:**

- *% revenue of aviation, space and defense and a proportion to total revenue.*
- number of employees (i.e., full time, part time, contract, temporary) dedicated to aviation, space, and defense;
- number of shifts and shift patterns specific to production and/or maintenance;
- evaluation of *certification struction (e.g. single site, multiple site)* eligibility for determination of audit time and sampling;
- identification of high risk associated with processes and products;
- risk management and associated tools [e.g., Failure Mode and Effect Analysis (FMEA)];
- identification of special processes performed or subcontracted;
- regulatory requirements and authority approvals/recognitions;
- additional requirements on configuration management;

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- project/program management;
- continual improvement activities;
- OTD and quality performance measures;
- identification of special requirements/critical items, including key characteristics;
- production process verification
- prevention programs (FOD)
- special work environments [e.g., ESDS or clean room];
- customer presence at organization [e.g., resident representatives];
- customer satisfaction and complaints status, including customer reports and scorecards;
- any customer specific organization approval statuses, e.g., limited approval, probation, suspension, withdrawal;
- customer restricted areas or proprietary information/confidentiality;
- exclusions (exclusions must be limited to clause 7) and supporting justification; specifically product design
- export limitations/controls [e.g., ITAR and/or EAR];
- customer delegated verifications and MRB authority; and
- customer authorized direct ship/direct delivery.

**NOTE:** The audit team can begin recording objective evidence related to the quality manual, quality management system process documentation, and the applicable process and procedural conformity results.

**Stage 1 Conclusions**

The audit team leader shall use the results and any additional information obtained from the site tour to:

- determine the quality management system implementation status;

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- determine the organization's readiness for the Stage 2 audit;
- identify any areas of concern that would be classified as a nonconformity, if not resolved before the Stage 2 audit;
- develop a plan for the Stage 2 audit, that includes any additional quality management system requirements from the organization's aviation, space, and defense customers;
- verify the proposed scope of certification and, where necessary, communicate to the organization why the proposed scope should be modified;
- verify the information used for and recommend/revise, as needed, the audit day calculation;
- review the audit time for the Stage 2 audit and update the audit plan accordingly;
- adjust the composition of the audit team for the Stage 2 audit, including the addition of any technical experts or translators that are needed; and
- identify any changes required to the contract and communicate those revisions to the organization and SQA.
- The audit findings shall be recorded in the Stage 1 Audit Report (see Appendix F of 9101D). A copy of the audit report shall be given to the organization after completion of the Stage 1 audit.
- The CB (auditor) shall review the status of the areas of concerns to determine preparedness for the Stage 2 audit. This will be documented in 'Audit Team Leader Recommendations' in the 9101 Stage 1 report.

### 5.15 Stage 2 Audit

- Stage 1 and Stage 2 audits shall **not** be performed on the same day or on consecutive days (back to back).
- During the opening meeting, the audit team leader shall reconfirm with the organization the issues identified during the Stage 1 audit (see clause 4.3.2).
- After the opening meeting, the audit team leader shall:
- decide on conducting a facility tour to review substantial changes in scope or facilities, since the last visit; and

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- revise planning, as needed, due to organization changes since the Stage 1 audit (e.g., personnel changes, department/business unit reorganization, new customer complaint) or any objections from the organization that impact the audit.
- If the client is product design responsible, records of effective implementation must include one of the following: Current design (showing implementation of all design stages), or Historical design (showing implementation of all design stages) or Mock design (showing implementation of all design stages).
- All nonconformities shall be closed and verified by the audit team before a recommendation for certification can be made.

**NOTE:** Requirements for closure of nonconformities are contained in 9104.

**5.16 Surveillance**

- All applicable quality management system standard and the organization's processes shall be audited during the surveillance audits within one certification cycle.
- All sites (addresses) included in a campus certification structure shall be audited at least annually. This includes any sites such as a sales office.
- For surveillance audits, the audit team leader shall advise within the audit report whether the recorded nonconformities should be reason for suspension of the certificate. Failure by the organization to demonstrate effective corrective action to deal with repeat nonconformities, the lack of actual performance data, or lack of operational control shall warrant suspension of the certification.
- If the client is product design responsible, records of effective implementation must include one of the following: Current design (showing implementation of all design stages), or Historical design (showing implementation of all design stages) or Mock design (showing implementation of all design stages).

*Note: If there is more than 1 surveillance audit during the year, some activities may be spread over these audits.*

The requirement to conduct regular and scheduled surveillance shall be conveyed to the client in the SQA "Description of, and Agreement for, Services" (CGI-02) which forms the contract between the client and SQA.

Surveillance assessments shall be scheduled from the last day of the initial stage 2 audit or the last day of a recertification assessment in accordance with the table below:

Surveillance Interval	6 months	12 months
Number of assessments	5	2

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per 3 year cycle		
Allowable timing	-1 month/ + 1 month	-3 months/ +1 month

**5.17 Recertification**

- The recertification audit should be planned a minimum of three months before the expiry date of the current certificate.
- The SQA supplemental pages are required to be completed prior to scheduling re-certification to determine if additional audit time is required.
- If the client is product design responsible, records of effective implementation must include one of the following: Current design (showing implementation of all design stages), or Historical design (showing implementation of all design stages) or Mock design (showing implementation of all design stages).
- The organization's quality manual and quality management system process documentation shall be reviewed for changes.

**NOTE 2:** An full or partial Stage 1 audit, including an on-site visit by the audit team may be warranted based on organizational changes, etc.

The requirement to conduct a complete management system reassessment prior to renewing a certificate shall be conveyed to the client in the SQA "Description of, and Agreement for, Services" which forms the contract between the client and SQA.

**5.18 Special Audits**

- Special audits can be performed anytime during the certification cycle in response to one of the following situations:
  - in response to a customer or other interested party request, when a serious issue has been identified;
- NOTE:** In this case, the requester shall be notified in advance of the audit dates and made aware of the audit results.
- in response to an organization's request to change their scope of certification or revise the listing of certified sites; or
  - when receiveing a transferred certificate ( See SQA-73 form).
  - These audits shall be coordinated with the organization prior to the visit. The organization shall be given information about the specific reason and subject of the visit.

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- An audit plan shall be completed and submitted to the organization prior to arrival. The results for special audits shall be documented on the applicable *Forms (3, 4 and 5)*.

**5.19 Executive certification panel authority:** The Executive Certification Panel (ECP) member granting, not granting, suspending or withdrawing certificates shall have documented competency in Aerospace as defined in AS9104. Refer to CQAM-019 and CQAM-106. All decisions affecting certification shall be executed in an impartial manner.

**5.19.1** There are no certification extensions past 3 years. There shall be no special recognition of short term certificates.

**5.19.2** To qualify for auditing to AS91XX an auditor candidate must first meet the requirements for Lead Auditor as detailed in CQAM-009 and the requirements defined in AS9104/1 and AS9104/3.

**5.20 Maintenance of auditor qualifications/competency:** Auditors shall retain their level of competence by adhering to the requirements of CQAM-009

**5.20.1 AS91XX internal witness auditing:** All auditors on the SQA roster, regardless of their status as a contract auditor or employee auditor must be witnessed in accordance with the following:

5.20.1.1 An annual witness assessment schedule shall be established and maintained.

5.20.1.2 All AS auditors shall be witnessed at a minimum of once in 6 years.

5.20.1.3 Witnessing auditors may consist of other qualified AS91XX auditors and ISO/AS ECP members and must be independent of the audit team.

5.20.1.4 Witnessed audits may include Stage-2, surveillance and recertification assessments with the following caveats:

- Stage-2 witness assessments will be no less than 2 audit-days.
- Surveillance and recertification assessments will be no less than 1 audit-day.

5.20.1.5 All AS91XX auditors determined to be "incompetent" as a result of a witness assessment must be re-witnessed and judged competent within 3 months or they may not continue as an AS91XX auditor. See CQAM-009 for additional information regarding this determination.

5.20.1.6 Each auditor shall meet the minimum number of audits as defined in AS9104 to maintain certification.

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5.20.1.7 Each auditor will be responsible to complete the required number of continuing professional development credits.

### **5.21 Audit Teams**

**5.21.1** The audit team leader shall be an AEA. An audit team leader shall be present and participate in the entire certification cycle including Stage 1, Stage 2, surveillance, recertification, and special audits. The lead auditor role may change during the certification cycle. An AEA will be on-site and actively involved at each site during the entire audit. In addition, the audit team leader shall be on-site at one or more sites during all audit activity.

**5.21.2** The same audit team leader shall be limited to a maximum of two consecutive certification cycles at the client (organization). Rotation of supporting AEAs and auditors after each certification cycle is recommended.

**5.21.3** SQA will not change/substitute auditors per client request without the appropriate substantiated evidence of improper activity or contract violation.

**Transfer Process: To be conducted in accordance with Procedure CQAM 16.**

**5.22** Records to be uploaded into OASIS after each audit are defined in OASIS handbook, and AS9104/1 Appendix C.

5.22.1 Timing requirement for uploading information into OASIS are as follows:

- For audits involving a certification decision, the CB shall be responsible for the input of the required data into the OASIS database within 30 days after the certificate issue date. For all other audits, the CB shall submit the required data into the OASIS database within 90 days after the on-site visit date.
- OASIS database will be updated when an organization's AQMS standard certificates are suspended or withdrawn. This shall be performed by within 14 calendar days to reflect any change in an organization's certification status.

**5.23** When IAQG sends updates on changes to ICOP scheme resolutions and/or Supplemental Rulings, the documents will be printed from OASIS; a review will be conducted and resolutions implemented as appropriate. The date of the review and initials of the reviewer will be documented on the resolution log. Reviews will be completed within 2 weeks of publishing.

**5.24** Aerospace Computer Assisted Auditing Techniques- see additional requirements under CQAM-xxx "CAAT" (per ICOP Resolution #113 dated 2/27/14)

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**5.24.1** During the application of CAAT, as defined in IAF MD 4, to a Campus Certification structure the following shall apply:

- On-site audit time is not reduced; instead a portion of the time can be allocated to the remote audit activities using appropriate CAAT in accordance with 9104-001 clause 8.10.b).
- All sites must be physically visited during initial certification and recertification audits. Note: CAAT remote auditing may be used to eliminate an onsite audit at a campus site during surveillance.
- Each site within the campus structure shall be visited at least once during the 2 year surveillance cycle.
- No more than 30% of the calculated on site audit duration shall be met using an AB approved CAAT process.
- The 9101 audit report shall clearly indicate the use of CAAT and the amount of audit duration that was supported by the CAAT process.
- All sites within the Campus structure must be audited at least annually using CAAT remote auditing or onsite auditing.
- ANAB approval must be obtained prior to use of the CAAT process.

**6.0 REFERENCE:** AS9101E, CGI-02, CQAM-009, -016, -019, -102, -103, -106, Form SQA -45, -74, -78

**END OF DOCUMENT**