
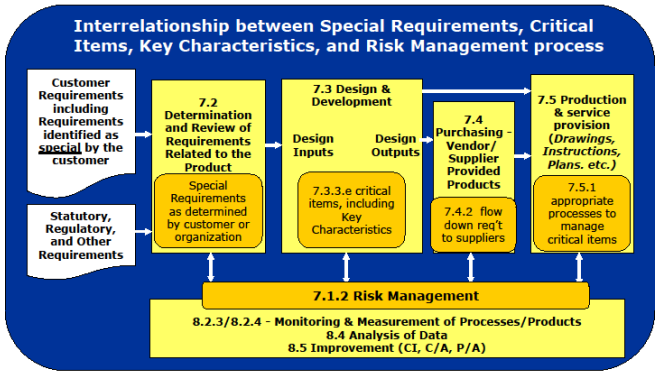


IAQG 9100:2009 Clarifications (Based on ISO 9001:2008 Standard)

According to IAQG Procedure 103, clarifications are provided by the IAQG and Sector Document Representatives are summarized below. Please contact the applicable Sector Document Representative if you have any questions. Sector Document Representative names and contact information can be found on the IAQG website at: http://www.iaqg.sae.org/iaqg/publications/SDRs_listing.pdf.

ISO 9001 posted interpretations can be found at <http://www.tc176.org/Interpre.asp>.

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9100 Clause	Clarification Request IAQG 9100 Standard Requirements	Clarification
3. Quality Management System		
3.2 & 3.3	<p>What is the relationship between Special Requirements, Critical Items, and Key Characteristics</p> <p>Clause 3.2 Special Requirements definition</p> <p>Clause 3.3 Critical Items definition</p>	<p>These three IAQG 9100 terms can be interrelated, but it is not required. The common feature of these terms is the inclusion in the risk management process. The special requirements and critical items concepts can be applied independently. An organization can have special requirements determined which do not directly result in identification of critical items. Likewise, an organization may have critical items identified and not determined to have special requirements. The concept of critical items and key characteristics are interrelated since key characteristics are a subset of critical items when variability needs to be controlled.</p> <div style="text-align: right; margin-top: 20px;">  </div> <div style="text-align: center; margin-top: 20px;"> <p>9100:2009 Key Changes</p> <p>Interrelationship between Special Requirements, Critical Items, Key Characteristics, and Risk Management process</p>  </div>

3.4	<p>Since Interchangeable/Replaceable components affect product fit, are they automatically key characteristics?</p> <p>Clause 3.4 Key Characteristic: An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.</p>	<p>No. Key characteristics are only applicable when variation has <u>significant</u> effect on the product fit, form, function, performance, service life or producibility. This variability requires appropriate controls like the use IAQG 9103. Interchangeable/Replaceable items would fit the 9100:2009 definition of a critical item. It is not necessary for the organization to change the terminology to critical item but the 9100 standard critical item requirements would apply to those components.</p>
4. Quality Management System		
4.1b & 4.2.2c	<p>Is using the process diagram in IAQG 9100, page 6 in your quality manual for interaction between the processes sufficient?</p> <p>Clause 4.1 b: The organization shall ...</p> <p>b) determine the sequence and interaction of these processes</p> <p>Clause 4.2.2c: The organization shall establish and maintain a quality manual that includes... c) a description of the interaction between the processes of the quality management system</p>	<p>No. IAQG 9100 is a process-based standard with requirements to identify the organization's QMS processes and their interaction. The diagram on page 6 of IAQG 9100 includes the relationships of the IAQG 9100 sections 4 through 8. This diagram is <u>not</u> intended to define an organization processes and their interaction. Additional information is available from the ISO 9001 Auditing Practices Group website on the topic Understanding the Process Approach.</p>
4.2.3	<p>Does clause 4.2.3 include the requirement to maintain and have available red-line versions of the changed document?</p> <p>Clause 4.2.3c requires "...to ensure that changes and the current revision status of documents are identified"</p>	<p>It depends. The IAQG 9100 standard requires that the organization develop controls on how changes and current revision status is identified. The organization determines how this identification occurs. All changed documents would need to comply with requirements of clause 4.2.3 regarding approval, legibility, identifiable, etc.</p>
4.2.3	<p>Is a maintenance manual supplied with equipment required to be controlled as a document of external origin?</p> <p>Clause 4.2.3 requires "Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p> <p>A documented procedure shall be established to define the controls needed...</p> <p>f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled."</p>	<p>It depends. The IAQG 9100 clause 4.2.3 states that "documents of external origin determined by the organization...are identified and their distribution controlled." The organization understands its business and should understand the risk concerning which external documents are relevant and need to be controlled (kept current). An auditor can challenge this definition if the organization obviously did not adequately consider all risks associated with not maintaining these documents.</p>
4.2.4	<p>How do you differentiate clause 4.2.4 records from all records? The standard is not very specific in what type records to control. We have many that consider every record, including ice box In/Out logs and others think we should control the bare minimum.</p> <p>As an example, some feel the completed planning is the manufacturing record. Others feel we must not only have the planning but all other documents supporting the planning as controlled records.</p> <p>Clause 4.2.4 requires "Records shall be established and maintained to provide evidence of conformity to requirements and of the effective</p>	<p>ISO 9001:2000 removed the term "quality" from the old 4.16 Quality Record clause. Many businesses spend time trying to decide if a record is a business or quality record instead of just controlling the record. The IAQG 9100 standard includes 4.2.4 references to establish minimum record requirements.</p> <p>The organization decides what records it needs to prove conformity of the product, demonstrate compliance to the process, and evaluate performance trends. The completed planning in your example is the primary record of manufacturing task completion.</p> <p>The organization gets to decide how long they maintain the records in accordance with legal, regulatory, and</p>

	operation of the quality management system. Records shall remain legible, readily identifiable and retrievable.” and disposition of records.	contractual requirements and what is appropriate given the size and complexity of the QMS. A "simple" rule of thumb when determining whether to keep a record would be “do I have adequate evidence of task completion if I discard this record.” ISO 15489 is an ISO Standard on Records Management which may be helpful. In Europe, EN9130 provides guidance on applicable records and retention times.
4.2.4	The records requirement in the standard are denoted with “(see 4.2.4).” In the bold type in IAQG 9100, records are mentioned without references to 4.2.4, for example 7.3.6.2 b and 7.4.1 b. Are these separate required records?	No. IAQG 9100 requires that records “provide evidence of conformity to requirements and of the effective operation of the quality management system.” The IAQG 9100 standard references of (see 4.2.4) only establish minimum records requirements and are not considered a full listing of all records required to meet clause 4.2.4 requirements.
	Clause 4.2.4 requires “Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.”	In the two examples you have provided (clause 7.3.6.2b and 7.4.1b), there are record requirement callouts in the ISO 9001 text prior to the additional IAQG 9100 requirements. As to them being "separate," that is a matter for the organization to decide how records are maintained with their system.
5. Management Responsibility		
5.5.2	Is it required for the QMS Management Representative to be a member or report to top management?	No. The level of the management representative in the organization is not important as long as they can perform management representative activities outlined in clause 5.5.2 of the standard. For example, a nonconformity would exist if the Management Representative did not have the organizational freedom to resolve matters pertaining to quality even if they are a member of the organization’s top management. Likewise, the Management Representative requires unrestricted access to top management even if he/she does not directly report to top management.
	Clause 5.5.2 requires “Top management shall appoint a member of the organization’s management who, irrespective of other responsibilities, shall have responsibility and authority that includes... d) the organizational freedom and unrestricted access to top management to resolve quality management issues.”	
6. Resource Management		
6.2.2	Does the organization have to train employees on their own procedures and keep training records? These procedures do affect product quality.	The organizations employees are required to be competent to perform their job which includes awareness of the applicable procedures to their job and be able to execute to those procedures. IAQG 9100, clause 4.2.1, requires that personnel “are aware of relevant procedures.” It is up to the organization to choose how to impart this competence and evaluate effectiveness. Training with valid training records is certainly an option to provide this demonstrated ability to apply knowledge and skills (competence).
	Clause 6.2.2 requires “The organization shall a) determine the necessary competence for personnel performing work affecting product quality”	

7. Product Realization		
7.1.1, 7.1.2, 7.1.3, 7.1.4	Since these new 9100 clause requirements are contained in Section 7, can they be excluded? Clause 1.2 requires "Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements."	Yes, it is possible to take a permissible exclusion as long as the requirements in clause 1.2 have been satisfied since these requirements reside in Section 7. The IAQG 9100 Team expectation is that some level of project planning, risk management, configuration management, and controlling work transfers would occur in every aviation, space and defense organization.
7.1.1	Is the new Project Management requirement concerned with how I conduct improvement or maintenance projects? Clause 7.1.1 - Project Management requires: "As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints."	No. Clause 7.1.1 is not about managing improvement or maintenance projects. It pertains to how a company plans and manages their <u>product realization</u> activities. These activities are frequently called "program management" which is not an ISO defined term...so the IAQG team used the ISO "accepted" project management terminology. As the clause 7.1.1 text indicates, it how the organization plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.
7.1.2	Is it required that I apply Risk Management to the entire QMS? Clause 7.1.2 - Risk Management requires: "The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product"	No. Risk Management was deliberately placed in clause 7.1.2 to be an iterative part of product realization planning as it pertains to product risks across section 7 product life cycle processes. Risk Management also has interrelationships with special requirements and critical items. (See 3.2 and 3.3)
7.1.2	Is there a guidance document or an ISO standard that I can obtain that defines a process for Risk Management? Clause 7.1.2 requires "The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product"	Yes. There are several good resources for Risk Management which are listed below: <ul style="list-style-type: none"> ➤ IAQG Supply Chain Management Handbook has Chapter 11.2 on Risk Management which can be accessed at http://www.sae.org/iaqg/handbook/scmtermsfuse.htm ➤ IAQG 9134 Supply Chain Risk Management ➤ ISO Guide 73 Risk Management Vocabulary ➤ ISO 17666 Space Systems - Risk Management ➤ ISO 16085 Systems-Software Engineering - Risk Management ➤ ISO 31000 Risk Management ➤ Project Management Institute ➤ Risk Management Guide for DoD Acquisition <p>There are numerous risk management resources and IAQG 9100 is not prescriptive in providing the "how" risk management is to be performed, only that certain aspects be established, implemented, and maintained as appropriate.</p>
7.1.2 7.1.3	Are the new 7.1 clauses (i.e. risk management and configuration management) required to be listed in my interaction of processes (clause 4.1) and discussed in management review (clause 5.6c)? Clause 4.1 requires "The organization shall a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of	It depends, the organization determines its sequence and interaction of processes and how these processes are evaluated during management review.

	these processes”	
7.1.3	<p>Where can users get additional information for the new sub clause listing under clause 7.1.3?</p> <p>Clause 7.1.3 requires “The organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product a) configuration management planning, b) configuration identification, c) change control, d) configuration status accounting, and e) configuration audit.”</p>	<p>Additional information on the new AS9100 Clause 7.1.3 bullet items can be found in ISO 10007, an internationally accepted standard on configuration management which provides additional insights and information. The IAQG Supply Chain Management Handbook (SCMH) has Configuration Management “how-to’s” and best practices in Chapter 11.3 which can be accessed at http://www.sae.org/iaqg/handbook/scmhtermsfuse.htm.</p>
7.1.4	<p>Please provide clarification of what is meant by clause 7.1.4 - Control of Work Transfer.</p> <p>Clause 7.1.4 Control of Work Transfers requires “The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.”</p>	<p>The concept of work transfer is very similar to clause 4.1 outsourcing requirement. Work transfers/ outsourcing activities are often controlled by the purchasing process. Adequate planning is required when work is transferred from one organizational facility to another. If these facilities are within the same QMS, this transfer activity presents minimal risk. If the transfer is to a sister company on some inter-work transfer, then the activity would require some additional planning. This could also include work performed at a company facility at a customer location.</p>
7.2.1 7.2.2	<p>Where is the requirement within 9100 for superseded / obsolete specs / material? Here are the questions I have in regard:</p> <ol style="list-style-type: none"> 1) If a customer with an old drawing references obsolete specifications or material would the manufacturer have to comply with old documentation, or could it comply with the superseded or adopted industry specification? 2) If a customer’s drawing specifies a revision on a standard, do you have to use that specific revision, or could you use a superseded revision? 3) What are the grandfathering rules pertaining to obsolete specifications / material per 9100? <p>Clause 7.2.1 requires “The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities” Clause 7.2.2 requires “The organization shall review the requirements related to the product. This review shall be conducted prior to the organization’s commitment to supply a product to the customer and shall ensure that a) product requirements are defined”</p>	<p>The customer requirements are determined in clause 7.2.1 and clause 7.2.2 processes review that the requirements will be met. If a customer specifies a superseded / obsolete specification, then these differences need to be resolved with the customer prior to the organizational commitment to supply the product. There is no allowance in IAQG 9100 to deviate from customer requirements.</p>
7.3.3	<p>The definitions for verification and validation activities applied in my organization follow the regulation (such as DO 254 for certification) and are exactly at the opposite from the definition of the IAQG 9100 standard. How can I justify this situation?</p> <p>Clause 1.1 states “It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory</p>	<p>IAQG 9100, Clause 1.1 states that the statutory or regulatory requirements take precedence from the standard in case of conflict.</p>

	requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.”	
7.4.1	The standard requires periodic assessment of supplier performance. Would these controls apply to tooling suppliers and calibration service suppliers or just airplane part suppliers? Clause 7.4.1 requires “The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.”	An organization is expected to monitor supplier performance (i.e. quality and delivery) to determine how its suppliers are performing and whether the organization wishes to do business with them in the future. IAQG 9100, clause 7.4.1 requires that the type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
7.4.1	If a nonconformance were written on an IAQG 9100 audit because a calibration supplier was not accredited, would that be a justifiable nonconformance? Clause 7.4.1 requires “The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).”	It depends. There is no requirement in IAQG 9100 for a calibration supplier to be ISO 17025, IAQG 9100, or even ISO 9001 certified. Organizations are required to evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements (see clause 7.4.1). The organization should have supplier selection criteria for a calibration vendor to be included on the approved supplier listing. For a calibration supplier, standards traceability back to recognized National Standards would be an expected requirement.
7.4.1	If “evaluate” refers to an initial evaluation, can that initial evaluation occur after the supplier has been selected and placed on the register (such as the case of a supplier who is evaluated based on an evaluation of initial parts after receipt)? Clause 7.4.1 requires “The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements.”	The supplier is required to meet company established supplier criteria prior to engaging in business with that supplier. If the supplier meets these “initial” requirements and the organization wishes to not approve the supplier until receiving acceptable parts or have some period of sustained performance, it is an acceptable practice that the supplier could be identified as conditionally approved until the full requirements were realized.
7.4.1a	What is meant by “its suppliers” in clause 7.4.1a? Does this mean that an organization must maintain a register of all its suppliers, or is a register of a limited subset sufficient? Based on the second sentence of paragraph 7.4.1 which begins with, “The type and extent of control ...”, our organization maintains a register of Class 1 Products/Services suppliers. Clause 7.4.1a requires “The organization shall a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),”	The requirements in IAQG 9100 clause 7.4 are applied to the organizations suppliers based upon the scope of certification and supplier impact on product realization. If the organization wishes to apply a risk management approach to suppliers indicating varying levels of rigor for evaluation, approval, and re-evaluation dependent upon the effect on product conformity...that is acceptable.
7.4.2g	If customer requirements do not include QMS subtier flow down requirements, is it required to flow down 9100 into subtier contracts? Clause 7.4.2 requires “Purchasing information shall describe the product to be purchased, including, where appropriate...”	No. It is only a requirement to flow down 9100 if there is a customer contractual QMS requirement.

	g) requirements regarding the need for the supplier to... - flow down to the supply chain the applicable requirements including customer requirements,"	
7.4.2i	Is it a requirement to include right of access for regulatory agencies on all purchase orders? Our organization does not have any oversight by regulatory agencies that would need authority through our purchase orders to do their job. Clause 7.4.2 requires "Purchasing information shall describe the product to be purchased, including where appropriate... i) right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records"	It depends. The intent of this clause to ensure the supplier understands that the organization, their customers, and regulatory authorities have access to their facilities and records, as appropriate. Regulatory authorities are defined as governmental agencies that regulate business in the public interest. The term "as appropriate" means if it is appropriate you shall comply. If your organization does not have any regulatory authority oversight and your customer does not require this requirement flow down, it is not required to list right of access on their purchase orders.
7.5.1.1	Does 9100:2009 now require the organization to perform production process verification - a.k.a. first article inspection (FAI)? The last version of 9100 only required a process for FAI. Does the customer still need to contractually require FAI be performed? If a customer requires the supplier perform in accordance with 9102, is it correct that they need to specifically require 9102?	It depends. Clause 7.5.1.1 requires all organizations to perform production process verification unless the organization has a valid exclusion for this section 7 process. A company may take an exclusion if they make prototypes or single parts instead of a product run. Organizations that provide services or software as their products would also likely be able to justify an exclusion.
	IAQG 9100, clause 1.2 states: Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.	If a customer wants to ensure production process verification is performed in accordance with 9102, they can include a contractual requirement. The organization and their customer may agree on another approach to production process verification which is acceptable.
7.5.1.3	If the tooling fixtures in the factory have been disassembled and moved to another location within the same facility, does IAQG 9100 mandate that a First Article must be performed or that the fixture must be verified to the First Article? Clause 7.5.1.3 requires " Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.	It depends. It is expected that the organization would have some tool verification activity, commensurate with the amount of tool disassembly, to ensure the fixture is still capable of building conforming hardware. It is thought that disassembly and reassembly of a fixture would be specified as one of the requirements which would invalidate the previous FAI.
7.5.1.3	What kind of equipment is included in the term 'production equipment', as it relates to the referenced clause? For example, would a fork lift be considered production equipment and therefore require validation? Clause 7.5.1.3 requires " Production equipment, tools and software programs used to automate and control/monitor product	Clause 7.5.1.3 terminology of production equipment pertains to equipment that adds value to the product in achieving customer requirements thus needing validation. A forklift moves or transports parts and requires maintenance under infrastructure in 6.3 c, "supporting services (such as transportation or communication)."

	realization processes, shall be validated prior to release for production and shall be maintained.	
7.5.1.4	<p>If a company does not provide service to products after the part is delivered to a customer, can they take exclusion to clause 7.5.1.4?</p> <p>Clause 7.5.1.4 requirements</p>	<p>It depends. IAQG 9100, Clause 7.5.1.4, Post-Delivery Support, is applicable when servicing of your product is performed after initial delivery. The location of the service is irrelevant no matter whether the servicing is taking place at your facility or in the field. If a warranty is applicable to the product, then the servicing clause 7.5.1.4 is applicable.</p> <p>Since Clause 7.5.1.4 is contained in section 7, it is possible to take a justified exclusion for portions of this clause that may not be applicable.</p>
7.5.2	<p>1) What is the intent of revalidation and at what type of frequency?</p> <p>2) Is revalidation a complete repetition of the initial validation characteristics, documents, and details?</p> <p>3) How is "as applicable" applied in this requirement? It appears that all the elements "a" through "e" are always applicable. When would they not be applicable?</p> <p>Clause 7.5.2 requires "The organization shall establish arrangements for these processes including, as applicable</p> <p>a) defined criteria for review and approval of the processes, - qualification and approval of special processes prior to use, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, - control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto, d) requirements for records (see 4.2.4), e) revalidation."</p>	<p>1) The intent of revalidation is to ensure the process continues in a controlled state. The organization gets to choose the frequency of the revalidation based upon risk and process stability. For example, if the organization validates the process annually or after every 100th unit and notices the processes remain stable and in control over the past several revalidations, the revalidation period can be extended. The use of "as applicable" applied to revalidation indicates that it is incumbent upon the organization to choose which processes must be revalidated and which may not as well as frequency and method for those processes which do require revalidation.</p> <p>2) It is up to the organization to assess the risk associated with the process and determine if the revalidation includes a complete repetition or lesser activity.</p> <p>3) ISO has several "as applicable" statements to stay appropriate for their stakeholders. An example is that b) would not be fully applicable if the process was fully mechanized and did not include personnel.</p>
7.5.3	<p>What is the level of traceability required on a non-flight critical component?</p> <p>Clause 7.5.3 requires "Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4)."</p>	<p>Each IAQG 9100 traceability requirement starts with "Where traceability is a requirement." The organization should understand the traceability requirements in contracts or regulatory sources for their products and be able to articulate when traceability is required. It is up to the organization to develop the process for material traceability.</p>
7.5.3	<p>Does the 9100 standard require the traceability to individual who actually did work and/or inspection?</p> <p>Clause 7.5.3 requires "Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4)."</p>	<p>IAQG 9100, Clause 7.5.3 requires traceability of the product, not specifically to the operator or inspector. Clause 7.5.1h requires evidence that all production and inspection/verification operations have been completed as planned, which typically includes identification of the operator performing the work and the inspector that buys-off the work.</p>
7.6	<p>An organization is using customer supplied gages which are past due for calibration. The organization has received a waiver from their customer so gauges do not need to be calibrated. Is this compliant?</p> <p>Clause 7.6 requires "The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring</p>	<p>No. An organization that claims to be IAQG 9100 certified needs to comply with all applicable IAQG 9100 requirements regardless if a customer waived requirements. IAQG 9100 sets the minimum requirements for certification to the IAQG 9100 standard. In your example, an organization would be expected to have current calibration of customer supplied gauges to ensure repeatability and accuracy of</p>

	devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).”	measurements.
8. Measurement, Analysis and Improvement		
8.2.2	Does the IAQG 9100 standard mandate the performance of internal audits on an annual schedule? Clause 8.2.2 requires “The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.”	No. Clause 8.2.2 does not include a minimum timeframe in which internal audits are to be conducted. The customer contractual, regulatory authority or Registrar may have requirements in their procedures or terms & conditions with their clients requiring that internal audits are conducted at some minimum frequency. Paraphrasing from the standard, internal audits are to be conducted at planned intervals to determine whether the QMS conforms to the planned arrangements and is effectively implemented and maintained. Furthermore, an audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. Audit planning should consider: 1. The organization considered the status and importance of the processes and areas to be audited. The audit frequency should demonstrate an understanding of the QMS as conditions change. For example: The more important a particular clause is to the QMS/organization, the more frequent audits should be conducted to that clause. A very dynamic QMS/organization should have more frequent audits. 2. The organization utilized prior audit results to assess risk and audit frequency. 3. The organization conducts internal audits at a frequency greater than the Registrar. It is intended that internal audits are conducted more frequently and at a greater depth than Registrar audits. Areas that are not internally audited at the right frequency would place the organization at increased risk of a major nonconformity from their Registrar.
8.2.2	Can the Quality Assurance manager be the lead auditor in an Internal Audit and audit QA specific questions? Clause 8.2.2 requires “The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.”	No. The requirement in IAQG 9100 is "The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work." This ISO 9001 text is in place to ensure an effective internal audit by having an objective and impartial auditor. It also states that auditors shall not audit their own work to ensure an independent set of eyes are being used to conduct the audit.
8.2.2	Is it required for an internal auditor to receive training on IAQG 9100 requirements? Clause 6.2.1 requires “Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.”	There is not a specific IAQG 9100 training requirement for internal auditors. Internal auditors will need to be competent given the requirements of clause 6.2.1 including the organization defined internal auditor competence requirements. If the internal audits are conducted in a professional manner given good internal audit techniques and the internal audits are identifying issues including IAQG 9100 specific requirements, a noncompliance cannot be justified.
8.3	Please explain what conspicuously and permanently marked includes. Clause 8.3 requires “ Product dispositioned for	The scrap product shall be marked to be clearly visible that it is scrap material. The marking shall be permanent given the product storage environment (e.g.

	scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable."	parts stored outside, subject to rain and sunshine, should be marked with water resistant, non-fade markings) such that it will not be rubbed off inadvertently or become removed during handling. Remember that this is a temporary step in the process until the part is rendered unusable. The intent of this requirement is to differentiate scrap parts from good parts to avoid parts being used unintentionally.
8.3	Please explain positively controlled? Clause 8.3 requires "Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable."	Positively controlled means unauthorized personnel do not have direct access to product or controls are in place, like a bar coding system where parts are scanned prior to installation so unauthorized parts cannot inadvertently be placed in work. The intent of this requirement is to keep the part from re-entering the value stream. It is not to be processed, used or sold as a good part.
8.3	Can you provide some examples of physically rendering product unusable? Clause 8.3 requires "Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable."	Physically rendering product unusable (product mutilation) should be accomplished in such a manner that the parts become unusable for their original intended use. Mutilated parts should not be able to be reworked or camouflaged to provide the appearance of being serviceable such as, re-plating, shortening and re-threading long bolts, welding, straightening, machining, cleaning, polishing, or repainting. The intent of this requirement is for it to be impossible for the part to be used for its originally intended purpose. Mutilation may be accomplished by one or a combination of the following procedures, but is not limited to: <ul style="list-style-type: none"> - Grinding. - Burning. - Removal of a major integral feature. - Permanent distortion of parts. - Cutting a significant size hole with a cutting torch or saw. - Melting. - Sawing into many small pieces. - Removing manufacturer's identification, part, lot, batch, and serial numbers. The following procedures are examples of mutilation that are often <u>less</u> successful because they may <u>not</u> be consistently effective: <ul style="list-style-type: none"> - Stamping (such as a stamped "R" on a part). - Spraying with paint. - Hammer marks. - Identification by tag or markings. - Drilling small holes. - Removal of a lug or other integral feature. - Sawing in two pieces. (Reference: FAA Order 8120.11 and FAA Best Practice - Scrap or Salvageable Aircraft Parts and Materials)
8.5.3	Regarding preventive action...Can the documented procedure state that "reviewing effectiveness of the preventive action taken" is not required? Or does the documented procedure have to state that "reviewing effectiveness of the preventive action taken" must be done and explain how to fulfill the	It is required that the preventive action documented procedure include how organization will review effectiveness of the preventive action taken.

	requirement?	
	Clause 8.3 requires “A documented procedure shall be established to define requirements for e) reviewing the effectiveness of the preventive action taken.”	
8.5.3	Are the examples given in the preventive action clause required to be implemented? Clause 8.5.3 states “ NOTE Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources. ”	No. The examples provided were to illustrate different types of preventive actions since some users were confused that preventing recurrence when taking corrective action qualified for preventive action.