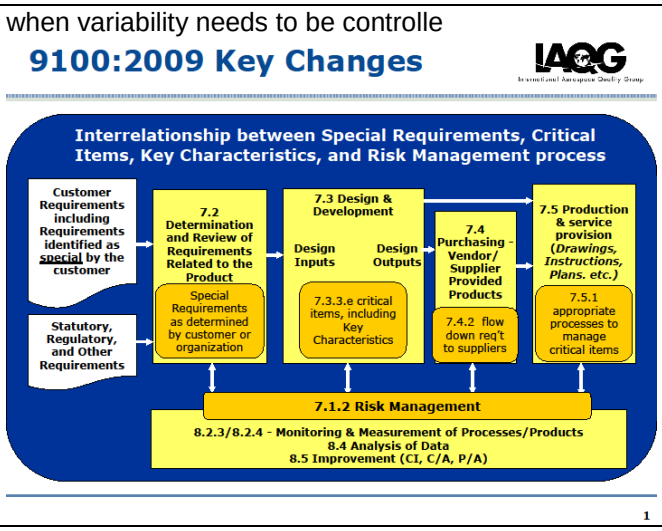
IAQG 9100:2009 Clarifications
(Based on ISO 9001:2008 Standard)

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 guidance and listing of formally approved interpretations**:**

- Guidance on some of the frequently used words found in the ISO 9000 family of standards - Download pdf
- Guidance on the concept and use of the process approach for management systems - Download pdf
- Implementation guidance for ISO 9001:2008 - Download pdf
- Guidance on ISO 9001:2008 - Sub-clause 1.2 Application' - Download pdf
- Guidance on the documentation requirements of ISO 9001:2008 - Download pdf
- Guidance on 'Outsourced processes' - Download pdf
- Guidance from ISO 9001 Auditing Practices Group - Download

9100 Clause	Clarification Request IAQG 9100 Standard Requirements	Clarification
1. Scope		
1.2	Is a Build-to-Print Aerospace manufacturer or assembler that builds and delivers parts to customer engineering requirements able to justifiably exclude clause 7.3 if they make tooling? Tooling could consist of production/shop aids to manufacture parts, tooling to verify parts, or fixtures to assist in production of flight hardware. The customer does not pay for these tools and they are not sent to the customer as product. Clause 1.2 states "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, this is a justifiable exclusion. The development of tooling is an enabler to product build and should not be confused with the actual product being delivered to the customer. The development and making of tooling is covered under clause 7.5.1c and 7.5.1.3. In case of that the customer purchases these tools and the tools are sent to the customer as product, then clause 7.3 for tool design is applicable since tooling would be considered a product.
3. Quality Management System		
3.2 & 3.3	What is the relationship between Special Requirements, Critical Items, and Key Characteristics ***Clause 3.2 Special Requirements definition*** ***Clause 3.3 Critical Items definition***	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 controlle 
3.4	Since Interchangeable/Replaceable components affect product fit, are they automatically key characteristics? ***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.***	No. Key characteristics are 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 of 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.
4. Quality Management System		
4.1b & 4.2.2c	Is using the process diagram in IAQG 9100, page 6 in your quality manual for interaction between the processes sufficient? Clause 4.1 b: The organization shall … b) determine the sequence and interaction of these processes 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	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's processes and their interaction. Additional information is available from the ISO 9001 Auditing Practices Group website on the topic Understanding the Process Approach.
4.1a, b & e	Is it required that the control of monitoring and measuring equipment (Clause 7.6) process be measured? Clause 4.1 requires: "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 these processes,… e) monitor, measure where applicable, and analyse these processes"	No. It is required that the control of monitoring and measuring equipment (clause 7.6) be monitored. It is up to the organisation to determine its processes and which are measured. The control of monitoring and measuring equipment is a support activity that assists production in achieving its goals i.e. testing of material and ensuring that measuring equipment is available. Regardless of clause location, the <u>organization</u> determines the sequence and interaction of QMS processes. The standard requires monitoring, measurement <u>where applicable</u>, and analysis of these QMS processes.

4.1e	Is it the intent of the standard that an organization can have just a top level requirement(s) that is used to evaluate the effectiveness of the QMS and several individual processes without those processes having specific metrics? For example, OTD of product to the customer of 98% is the top level metric and the metric used to evaluate the effectiveness of the purchasing process, contract review process, and the manufacturing process with no additional metrics. So if they have met the OTD of 98%, then all processes are deemed as effective. Clause 4.1 requires: e) monitor, measure where applicable, and analyse these processes	No. 9100 requires the organization to determine if the identified processes are effective and achieving planned results (see clause 4.1 c, e, f and 8.2.3). So for example, an organization measures quality and on-time delivery to its customers. For the purchasing process, the organization should be measuring supplier performance regarding quality and on-time delivery so appropriate actions can be taken with the purchasing process and understand how supplier performance is affecting company performance. The 9100 standard does not mandate a certain number of process measures. Small organizations typically have fewer measures than larger organizations. These small organizations have increased visibility regarding process health due to their size. Regardless, this does not alleviate the need for determining if processes are effective and achieving planned results.
4.1	Our organization manages process metrics at the enterprise and program level. There are common metrics used by all programs/functions that aggregate at the enterprise level. There are other metrics that are only at the enterprise level. Does clause 4.1 require that all QMS process measures be flowed down to all locations and tracked at a site level for processes performed? Clause 4.1 requires the organization to: • determine the QMS processes needed and their application throughout the organization, • determine the sequence and interaction of these processes, • determine criteria and methods needed to ensure that both the operation and control of these processes are effective, • monitor, measure where applicable, and analyse these processes, and • implement actions necessary to achieve planned results and continual improvement of these processes.	It depends. QMS processes are to be measured at the organization (enterprise) level and if applicable at each site. These QMS process measures may be structured by other criteria (e.g. sites or programs) instead of a site level. These measures should be available and utilized according to the set structure (e.g. site or program). The expectation is that QMS processes include flowdown as applicable as defined by the organization at a minimum whether it is based upon site or program.
4.2.3	Does clause 4.2.3 include the requirement to maintain and have available red-line versions of the changed document? Clause 4.2.3c requires "…to ensure that changes and the current revision status of documents are identified"	It depends. The IAQG 9100 standard requires that the organization develop controls on how changes and current revision status are 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.
4.2.3	Is a maintenance manual supplied with equipment required to be controlled as a document of external origin?	It depends. The IAQG 9100 clause 4.2.3 states that "documents of external origin determined by the organization…are identified and their distribution

	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. A documented procedure shall be established to define the controls needed… 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.”	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.
4.2.4	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. 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. 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. Records shall remain legible, readily identifiable and retrievable.” and disposition of records.	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. The organization decides what records it needs to prove conformity of the product, demonstrate compliance to the process, and evaluate performance trends to meet customer requirements. The completed planning in your example is the primary record of manufacturing task completion. The organization gets to decide how long they maintain the records in accordance with legal, regulatory, and customer 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? 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.”	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. 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	Does IAQG 9100 require that the QMS Management Representative be a member of 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

	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."***	in clause 5.5.2 of the standard. For example, a nonconformity would exist if the Management Representative did **not** have the organizational freedom, nor authority 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.
6. Resource Management		
6.2.2	Does IAQG 9100 require the organization to train employees on their own procedures and keep training records? These procedures do affect product quality. Clause 6.2.2 requires "The organization shall a) determine the necessary competence for personnel performing work affecting product quality"	It depends. 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).
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's 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***	Yes. There are several good resources for Risk Management which are listed below: ➢ IAQG Supply Chain Management Handbook has Chapter 11.2 on Risk Management which can be accessed at http://www.sae.org/iaqg/handbook/scmhtermsofuse.htm

	for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product"	➢ 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 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.
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 these processes"	It depends, the organization determines its sequence and interaction of processes and how these processes are evaluated during management review.
7.1.3	Where can users get additional information for the new sub clause listing under clause 7.1.3? 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."***	Additional information on the new IAQG 9100 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/scmhtermsofuse.htm.
7.1.4	Please provide clarification of what is meant by clause 7.1.4 - Control of Work Transfer. 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."***	The concept of work transfer is very similar to the 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 or at a customer location.

7.2.1 7.2.2	Where is the requirement within 9100 for superseded / obsolete specs / material? Here are the questions I have in regard: 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? 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"	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.
7.3.3	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? 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 requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence."***	IAQG 9100, Clause 1.1 states that the statutory or regulatory requirements take precedence from the standard in case of conflict.
7.4.1	The IAQG 9100 standard requires periodic assessment of supplier performance. Does 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."	Yes. 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	Is a calibration supplier required to be accredited? 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 a recognized standard is a requirement where necessary to ensure valid results.
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 conformity. 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.
7.4.2	We have a specific interpretation question regarding clause 7.4.2.g - notification of changes. We purchase Commercial Off-the-Shelf (COTS) parts from manufactures and distributors and continually run into issues with acceptance of this flow down requirement. Do the words in 7.4.2, "where appropriate", and "where required, obtain organization approval" allow us to selectively reduce or eliminate this requirement to our suppliers? If so, what considerations are necessary?	As you state, the requirements in subclause 7.4.2.g are "where appropriate." Therefore, where it is appropriate it shall be included. With COTS parts, it may not be necessary to apply all requirements within clause 7.4.2 and would therefore be acceptable to exclude certain purchasing information requirements.
	Clause 7.4.2 requires "Purchasing information shall describe the product ot be purchased, including, where appropriate… g) requirements regarding the need for the supplier to - ***notify the organization of nonconforming product…***	
7.4.2g	Does IAQG 9100 require flow down of IAQG 9100 into supplier and subtier supplier contracts if	No. It is only a requirement to flow down 9100 if there is a customer contractual QMS requirement. Regardless,

	customer requirements do <u>not</u> include QMS subtier flow down requirements? Clause 7.4.2 requires "Purchasing information shall describe the product to be purchased, including, where appropriate… ***g) requirements regarding the need for the supplier to…*** ***- flow down to the supply chain the applicable requirements including customer requirements,"***	the organization can also decide to flow down QMS requirements to its supplier.
7.4.2i	Does IAQG 9100 require 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	Does IAQG 9100 require the process of verification of raw material used in production of machined parts be documented during Production Planning (7.5.1)? Clause 7.5.1 requires "Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, ***NOTE This information can include drawings, parts lists, materials and process specifications.***	It depends, it is expected that parts are procured, manufactured, and delivered to the requirements outlined in the purchasing information (e.g. purchase order, accompanying materials, or referenced requirements) provided by the customer. If that purchasing information includes material to be used, it should be verified to ensure the organization is meeting requirements set by the customer. The requirement for validating test reports for raw material in IAQG 9100 clause 7.4.3 has been removed in IAQG 9100:2009. It is expected that if the part is categorized as a critical item then raw material verification would be expected as part of your risk management plan. Periodic validation of raw material could also be a contractual requirement from the customer.
7.5.1	Is a Build-to-Print organization required to define key characteristics if no key characteristics are established by the customer? Clause 7.5.1 requires "…***establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,"***	No, it is not required for Build-to-Print organizations to develop key characteristics if the customer has not identified or required them contractually. A Build-to-Print organization without design responsibility may not understand how parts will be used and thus requiring variability control. Key characteristics are established as part of the design effort (see clause 7.3.3, Design & Development Outputs). If the Build-to-Print supplier wishes to add focus/controls to a particular part attribute or feature due to increased nonconformities for example, they can identify it as a key characteristic or critical item internally.
7.5.1	Please confirm if 9100 requires organizations to document evidence that production processes produce parts and assemblies that meet all specification requirements and,	Agree, the evidence of conformity to product definition, manufacturing, and inspection including shop traveler is typically denoted as an electronic or manual stamp or initials to show satisfactory

	if so, please state where this requirement exists in 9100?	completion.(see clause 7.5.1 and 8.2.4)
	9100 requires organizations to: • evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized (see clause 7.5.1) • monitor and measure the characteristics of the product to verify that product requirements have been met at appropriate stages to ensure evidence of conformity with the acceptance criteria (see clause 8.2.4)	9100 requires organizations to: • provide appropriate information for purchasing, production, and service provision and contain or reference product acceptance criteria (see clause 7.3.3) • evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized (see clause 7.5.1) • monitor and measure the characteristics of the product to verify that product requirements have been met at appropriate stages to ensure evidence of conformity with the acceptance criteria (see clause 8.2.4)
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 product runs. Organizations that provide services or software as their products would also likely be able to justify an exclusion. If a customer wants to ensure production process verification is performed in accordance with 9102, they can include this as a contractual requirement. The organization and their customer(s) may agree on different acceptable approaches to production process verification.
	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.	
7.5.1.3	Does IAQG 9100 mandate that a First Article Inspection be performed and the fixture verified to the first article if the tooling fixtures in the factory have been disassembled and moved to another location within the same facility?	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.
	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.***	
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 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)."
	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.	
7.5.1.4	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? Clause 7.5.1.4 requirements	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 an organization provides any post-delivery support activities (such as warranty work), clause 7.5.1.4 cannot be excluded in its entirety. At a minimum, 7.5.1.4b would be applicable. Product that is found to be nonconforming after delivery to the customer require actions to be taken, including investigation and reporting; therefore 7.5.1.4b is applicable. The organization may utilize the Clause 8.3d and e, Control of Nonconformity Product process and Clause 8.5.2, Corrective Action process as the method for implementing Clause 7.5.1.4b; however Clause 7.5.1.4b would not be excluded.
7.5.2	1) What is the intent of revalidation and at what type of frequency? 2) Is revalidation a complete repetition of the initial validation characteristics, documents, and details? 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? Clause 7.5.2 requires "The organization shall establish arrangements for these processes including, as applicable 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."	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. 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. 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.
7.5.3	What is the level of traceability required in IAQG 9100 for a non-flight critical component? 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)."	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.
7.5.3	Does the 9100 standard require the traceability to individual who actually did work and/or inspection? Clause 7.5.3 requires "Where traceability is a	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

	requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4)."	as planned, which typically includes identification of the operator performing the work and the inspector that buys-off the work.
7.6	Does clause 7.6 require the national measurement standard traceable information (e.g. NIST Number) to be listed on the calibration certification? Clause 7.6 requires "Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);"	No. There is not an IAQG 9100 requirement requiring that national measurement standard traceable information is recorded on the calibration certificates. It is expected that your organization selects certification suppliers that meet requirements and that these suppliers are monitored according to IAQG 9100, clause 7.4.1 requirements.
8. Measurement, Analysis and Improvement		
8.2.2	Does the IAQG 9100 standard require 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 organization may have requirements in their procedures or terms & conditions 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	Does the IAQG 9100 standard allow 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	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

	audit their own work."	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.
8.2.2	Our organization has a well defined internal audit process that includes Findings, Minor Findings, Risk Observations, Opportunities for Improvement, and Positive Observations. Minor Findings are discussed in both an upper tier level command media document, as well as an audit specific practice. Regarding 8.2.2 and 8.5.2---is the intent here to assert that a finding, including a "single instance" item that is trended and treated collectively, be treated with a documented root cause, corrective/preventive actions and audit follow-up specific to the nonconformance? For example, we audited a receiving, inspection, stockroom and dock---four large areas. Of the many, many eye wash stations, one inspection was found not to be up to date. The auditee was asked to fix it right away. It was written as a "minor finding". We enter it in a database and collectively track it, trend it monthly. We did not require written response including root cause, corrective and preventive action and follow-up. Clause 8.2.2 requires "The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformity and their causes.	Clause 8.2.2 requires the management responsible for the area audited to ensure any necessary corrections and corrective actions are taken... 9100 clause 8.5.2 requires corrective actions be appropriate to the effects of the nonconformities encountered and evaluating the need for action to ensure that nonconformities do not recur. Records of the results of action taken are required as per clause 8.5.2 e). It is up to the organization to determine when correction versus corrective action is implemented. There is no 9100 requirement regarding how to treat a single, isolated instance unless defined otherwise by your procedures.
8.2.3	Is it required that organization have metrics or measures for all processes? Clause 8.2.3 requires "The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes."	No, regardless of clause location in the standard, IAQG 9100 requires the organization to determine the sequence and interaction of QMS processes. IAQG 9100 requires monitoring, measurement where applicable, and analysis of these QMS processes. It is expected that organizations will measure its key processes.
8.3	Our organization makes parts from foam, plastics and fiberglass and as such it is impossible to permanently mark the scrap (scrap is normally the excess material from die cutting, water jet cutting or routing). We had special bins made that had "Scrap/Trash" on the sides. These bins are emptied into a trash compactor as they fill up. Is putting this type material in a marked bin adequate or does each piece require marking? Clause 8.3 requires "The organization shall ensure that product which does not conform to	The intent of this requirement is to ensure no defective product re-enters the value stream which is the purpose of having the requirement to physically render nonconforming product unusable. It is important to remember that clause 8.3 is for product that does not conform to product requirements. Therefore, if the materials are conforming and there is material excess from die cutting, water jet cutting or routing operations; your excess material does not fall within the scope of scrap

	product requirements is identified and controlled to prevent its unintended use or delivery."	control in this clause. If your product is nonconforming to product requirements that is when the scrap provisions of clause 8.3 would be applicable. Once that material is dispositioned as scrap, it would need to be marked or positively controlled until it could be rendered unusable.
8.3e	How is clause 8.3e different from clause 8.5.2i and how is "to contain the effect of" defined? Clause 8.3e requires "by taking actions necessary to contain the effect of the nonconformity on other processes or products" Clause 8.5.2i requires "determine if additional nonconforming product exists based on the causes of the nonconformities and taking action when required"	The term "to contain the effect of" has not been further defined by IAQG or ISO. See below where this term has been defined and where the differences between these two requirements are discussed. Whereas these concepts are very similar, they occur at different points of the process in handling nonconforming product. 8.3 e) This requirement ensures that the effects of the nonconformity is contained so other processes and products are not affected. (This clause has to do with how a nonconformance for a particular product may affect other processes or products.) 8.5.2 i) This requirement is to determine if other nonconforming product exists resulting from the causes and corrective action process and taking further action as required. (This clause has to do with locating products that exhibits a particular nonconformance based upon the corrective action cause.)
8.3	Provide clarification of use-as-is dispositions being approved by an authorized representative. Is it required to receive authorized representative approval if my customer (not the design authority) is giving my organization approval? Clause 8.3 requires "***Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design."***	The intent of this requirement is to ensure approval of use-as-is or repair dispositions by a competent entity that has responsibility for the design. That entity has the best understanding on whether use-as-is or repair affects the performance in the deliverable item. Dispositions of use-as-is or repair shall be conducted in accordance with customer contractual and applicable statutory and regulatory quality management system requirements. Yes, it is required to have objective evidence from the design authority for approved repair/use-as-is disposition.
8.3	Please explain what conspicuously and permanently marked includes. Clause 8.3 requires ***"Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable."***	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. 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	Physically rendering product unusable (product

	rendering product unusable? Clause 8.3 requires ***"Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable."***	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: - 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: - 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 requirement? Clause 8.3 requires "A documented procedure shall be established to define requirements for e) reviewing the effectiveness of the preventive action taken."	It is required that the preventive action documented procedure include how organization will review 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.