9100:2016-Series Clarifications

According to IAQG Procedure 210, clarifications provided by the International Document Representative/Sponsor with agreement of SMC Sector Focals are summarized below. Please contact the applicable Sector Document Representative/Liaison if you have any questions. Sector Document Representative/Liaison names and contact information can be found on the IAQG website.

These clarifications are binding where the 9100-series standard leadership believes a published response is necessary since it has a profound impact or understanding upon the use of the standard or when a significant dispute exists. The applicability of each clarification to the 9100, 9110, and 9120 standards are indicated in the table.

ISO/TC 176/SC2 has a listing of formally approved interpretations, Frequently Asked Questions (FAQs), and Auditing Practices Group to help interested parties understand the ISO 9001:2015 changes. IAQG has developed support materials and FAQs to help interested parties understand the 9100:2016 changes.

See **bold** text for revisions to this 9100:2016-Series Clarification since the last update.

Clause	Clarification Request	Clarification	Applicability		
			9100	9110	9120
4. Context of the Organization					
Intended Application	**What does the term "*their own products and services*" mean in the 9100 intended application paragraph?**	**The "*own products and services*" means products and services that were originally manufactured or service provided by the organization. (added 10/2023)**	**X**	**X**	**X**
Intended Application	**What does the term "*substantially different from their production operations*" mean in the 9100 intended application paragraph?**	**The "*substantially different from their production operations*" means MRO operations on products and articles for which they are not the manufacturer or OEM (added 10/2023)**	**X**	**X**	**X**
1.0	**If the customer or applicable statutory or regulatory requirement is less stringent than 9100, does that become the requirement? Clause 1.0 states, "*If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.*"**	**9100 requirements form the minimum expectation for organizations. If customer, statutory, or regulatory requirements are less, then 9100 requirements at a minimum are required. Typically, customer, statutory, or regulatory requirements will provide more detailed requirements that do not conflict with 9100 requirements. (added 10/2023)**	**X**	**X**	**X**
4.2	Shall the organization determine EVERY relevant interesting party and its requirements? Shall third-party auditor issue the NCR if NOT ALL relevant interesting parties relevant to the quality management	The requirement is: to determine the "relevant" interested parties and their requirements. The wording "relevant" is key, and it is the responsibility of the organization to determine those which are relevant. An explanation is provided in the Annex A3 of the 9100-series standards, "There is no requirement in this International Standard for	**X**	**X**	**X**

	system and its requirements are determined by organization? Clause 4.2, Understanding the Needs and Expectations of Interested Parties "... the organization shall determine: a. the interested parties that are relevant to the quality management system. b. the requirements of these interested parties that are relevant to the quality management system.	the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system." An accepted practice is to use categories. For example, there is no need to list every customer or every employee. The category of customers and employees are adequate. The organization needs to identify and understand their relevant interested party requirements and feedback as part of their Quality Management System.			
4.3	Is it allowable for an organization to claim non-applicability with any sub-clause or sub-paragraph of 9100-series?	Yes. Organizations can claim non-applicability down to a shall statement or portions of a shall statement. It is required that any non-applicability with a clause or "shall" statement be justified with documented information.	**X**	**X**	**X**
4.3	Is it required that any non-applicability with a requirement be documented in the scope section of the Quality Manual?	No. It is required that any non-applicability with a clause or "shall" statement be justified with documented information but does not have to be documented in the scope section of a Quality Manual.	**X**	**X**	**X**
4.3	Is it required that an organization document non-applicability justification for a requirement that starts with "shall consider" or "take into consideration"?	Yes. It is required that any non-applicability with a clause or "shall" statement be justified with documented information.	**X**	**X**	**X**
4.3	Is an Aerospace manufacturer or assembler that builds and delivers parts to customer engineering requirements (Build-to-Print organization) able to justifiably have clause 8.3 as not applicable if they contract, design, make, and sell the tooling to the customer? Tooling could consist of tooling to verify parts or fixtures to assist in production of flight hardware.	No, the tooling in the clarification request is considered a product that is contracted, designed, material procured, and manufactured for a customer. If the tooling is not contracted or sold to the customer, then the development of tooling is an enabler to product build and <u>not</u> be confused with the actual product being delivered to the customer. The development and making of tooling in this instance are covered under clause 8.5.1d and 8.5.1.1.	**X**	**N/A**	**N/A**
4.3	Can the 9100-series clause 8.1.X requirements be non-applicable?	The IAQG 9100-series Teams expectation is that some level of operational risk management, configuration management,	**X**	**X**	**X**

		product safety, and preventing counterfeit parts would occur in every aviation, space, and defense organization in the 9100-series standards. It would be rare but possible to take a permissible non-applicability to clauses 8.1.X as long as the requirements in clause 4.3 have been satisfied and justified. In the 9110 and 9120 standards, implementation would be expected to incorporate clause 8.1.5 Prevention of Suspected Unapproved Parts and 9110 clause 8.1.6 Installation of Approved Parts.			
4.3	**Our organization does not perform "Special Processes"; however, we purchase materials and supplies that may have been originally manufactured using Special Processes. In addition, any "Special Processes" needed will be outsourced. In these cases, appropriate certifications are flowed down to the customer as needed. Is this an acceptable exclusion that we may claim in our operations?**	**No. It appears that Special Processes clause 8.5.1.2 is still applicable to your QMS. Your organization outsources those process to your supplier. Therefore, excluding this clause would not be permissible and controls would need to be placed on the supplier. (added 10/2023)**	**X**	**X**	**X**
4.4.1	Lately, I have witnessed suppliers being awarded 9100 certification and the scope reads the supplier is a distributor. Historically, the distinguishing difference between the 9120 and the 9100 was clearly distributor vs manufacture/ assembly. In questioning the distributor previously assigned 9120, how is it that you now are assigned 9100, I am being advised that the distributor now provides "value-added" services. Where is this term "Value-added" defined? How was this new term communicated to the ASD industry?	The term "value-added distributor" has been around for a long time, and it has caused confusion. The 9120 Writing Team deliberately did not mention it in the 9120 standard. Some distributors actually advertise on their websites that they do "value-added" work, and then add a list of the various services they provide. There was a standard AS7202 "National Aerospace and Defense Contractors Accreditation Program (NADCAP) Requirements for Accreditation of Value-Added Distributors" – it had a definition of value-added distributor that was along the lines of distributors can perform services as long as the services do not affect specification performance. This definition aligns with 9120 – distributors can "add value" to their customers, as long as they do not affect product characteristics/conformity.	**X**	**X**	**X**

		Therefore, some consider activity that doesn't affect product characteristics/conformity as being "non-value-added" work. No matter what term is used – value-added or non-value-added - ANY work performed by a 9120 distributor must not impact product characteristics/conformity, or it must be completely under the authority and control of a customer or regulatory body (customer-controlled services). If the distributor is performing services that impact product characteristics/conformity, it is outside of the scope of 9120 and into the scope of 9100.			
4.4.1b	Is using the process diagram in Figure 2 from clause 0.3.2, in your quality manual for interaction between the processes sufficient?	No. 9100-series standards are a process-based standard with requirements to identify the organization's QMS processes and their interaction. The diagram on page 8 of 9100-series includes the relationships of the 9100-series sections 4 through 10. This diagram is not intended to define an organization's processes and their interaction. Additional information is available from the ISO 9001 Auditing Practices Group website and IAQG 9100 Key Changes Presentation on the topic Process Management/Approach. In addition, Annex A.1 of the standard provides this statement: "The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives, and processes."	**X**	**X**	**X**
4.4.1c	Is it required that the control of nonconforming outputs (Clause 8.7) process be measured and included in a Process Effectiveness Assessment Report (PEAR)?	It depends. It is required that the control of nonconforming outputs (clause 8.7) be monitored. It is up to the organization to determine if it is a top-level process to be measured and included on the PEAR. Regardless of clause location, the organization determines its core processes, the sequence, and the interaction of QMS processes. The standard requires monitoring, measurement where applicable, and analysis of these QMS processes.	**X**	**X**	**X**
4.4	Does clause 4.4 apply to all QMS processes? Does clause 4.4 require all support processes to have measures?	Yes. All QMS processes. No. Clause 4.4.1.c requires the organization "to determine and apply criteria and methods (including monitoring,	**X**	**X**	**X**

		measurements, and related performance indicators) to ensure the effective operation and control of the processes defined by the organization as needed for the QMS." This includes operational processes, management processes, support process, and any other process required by the QMS.			
4.4.1c, g	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.	No. 9100-series standards require the organization to determine if the identified processes are effective and achieving planned results (see clause 4.4.1c). Each process measure should evaluate the effectiveness of that process and be value-added. This is the measure that would be included in Process Effectiveness Assessment Report (PEAR) as the key performance indicator for that process. The 9100-series standards 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. The organization can have additional working level measures that may not flow up to top management or management review.	**X**	**X**	**X**
		5. Leadership			
5.1.1	**What is the definition of Top Management?**	**Top management is defined by the organization and should include the appropriate level(s) and function(s) of management, including program/ project leadership, that are responsible for clause 5.1.1 including a) establishing the quality policy and objectives, and b) integrating those policies/objectives into the organization's business processes and c) ensuring quality management system effectiveness.** **Per ISO 9002 (Quality management systems – Guidelines for the application of ISO 9001:2015), top management has the power to delegate authority and provide resources within the organization. (added 10/2023)**	**X**	**X**	**X**
5.1.1	**Is it appropriate for auditors to issue a clause 5.1.1**	**No. A nonconformance is to be issued against Clause 5.1.1 when a violation of the**	**X**	**X**	**X**

	leadership nonconformance as a result of NCRs being raised against other clauses during the audit? Afterall, organizational leaders are accountable for performance of the QMS and should receive an NCR when the QMS is not meeting requirements.	**requirement in that clause has been identified. Any valid NCR must contain objective evidence that specifically demonstrates a violation of the audit criteria (see definition of Nonconformity Report from section 3.5 of 9101). If the auditor believes that leadership is the root cause and attempts to issue an NCR without specific evidence of a nonconformity to an element of 5.1.1, then the auditor is violating the auditor independence requirements. Root cause determination is an organization responsibility, not an auditor responsibility. (added 10/2023)**			
5.2.1	**Clause 5.2.1 requires the quality policy…c. includes a commitment to satisfy applicable requirements and d. includes a commitment to continual improvement. Does the 9100-series standard require the word "requirements" or "improvement" to be included in a company's policy? Does a certified organization have the flexibility to create a policy using words that are meaningful to the organization and its stakeholders that captures the intent of the standard without parroting the specific words?**	**The Introduction to the 9100-series standard states "It is not the intent of this International Standard to imply the need for: ...the use of the specific terminology of this International Standard within the organization." It is acceptable for the organization to use words meaningful to the organization as long as the intent of the requirement is met. The organization is required to articulate/describe how they meet the requirement and there is no need to use specific verbiage to match the standard. The QMS isn't about the words…it is about meeting the requirement and showing objective evidence. (added 10/2023)**	**X**	**X**	**X**
5.3	Does 9100 require that the QMS Management Representative report to top management?	No. The management representative is required to be a specific member of the organization's management that can perform management representative activities outlined in clause 5.3 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 report to 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.	**X**	**X**	**X**

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5.3	Is the intent to have the Management Representative monitor all individual processes within the QMS, see 5.3 b requirements (some of which they will not own)?	The requirement states that the Management Representative will have oversight of the requirement that would include ensuring the processes are delivering their intended output. At a minimum, this would include the top-level process measures that are presented in management review.	**X**	**X**	**X**
6. Planning					
6.3	When the organization determined the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). What are the expectations? What level of change requires planning?	The change requirement references clause 4.4 so the standard is including these top level QMS process type changes.	**X**	**X**	**X**
7. Support					
7.1.5	Does the standard require an organization using customer supplied gages be current for calibration if they received a customer waiver stating the gages do not need to be calibrated?	It depends. If the gages are common metrology devices (e.g., calipers, micrometers, depth gage, etc.), it is expected that an organization that claims to be 9100-series certified needs to comply with all applicable 9100-series requirements regardless of a customer waived requirement. If the customer-supplied gages are unique customer tooling and the customer provides you a waiver that the gages do not require calibration, then it is encouraged to utilize other methods as appropriate to ensure product repeatability and accuracy of measurements. The customer waiver stating that the gages do not need calibration should be included in or referenced on the paperwork returned to the customer. This is subject to regulatory constraints and the organization may need to ensure calibration regardless of the source.	**X**	**X**	**X**
7.1.5	Does clause 7.1.5 require the national measurement standard traceable information (e.g., NIST Number) to be listed on the calibration certification?	No. There is no 9100-series requirement that national measurement standard traceability information is recorded on the calibration certificates. It is expected that your organization selects calibration sources that meet requirements and that these sources are monitored according to 9100-series, clause 8.4 requirements.	**X**	**X**	**X**

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		The organization may have regulatory requirements to have standards traceable to NAA.			
7.1.5.2	**Is it acceptable to have a statement in our procedures that measurement equipment not identified is reference only instead of marking each piece of equipment? Only items with a calibrated control sticker may be considered calibrated and used for acceptance.**	**No. Clause 7.1.5.2b states "measuring equipment shall be identified in order to determine their status." Visual identification is required to determine if the equipment is suitable for use. The reference in procedures does not satisfy this requirement.** **ISO/TS 9002:2016 states: The status of calibration/verification be identified (e.g., whether the measuring equipment has been calibrated/verified, and if so, to what extent and until when it can be used). This identification might be on the measuring equipment itself, on its container or by other administrative means such as the use of a unique identifier for the equipment that can be matched to a database. (added 10/2023)**	**X**	**X**	**X**
7.1.5.2	The 9100:2009-series verbiage require a calibration register and the definition of processes for calibration / verification (including equipment type, ID, frequency, methods and acceptance criteria), but didn't seem to require them to be one in the same. The 9100:2016 standard appears to mandate these definitions be incorporated into the register itself, as opposed to just being defined. Is this required to be taken literally that the register is required to have this information is absolute?	The 9100-series clause 7.1.5.2 was not intended to force organizations to have the register specifically include the "equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria." The organization is required to have this information for equipment listed on the calibration register but not specifically in the register.	**X**	**X**	**X**
7.5.3.1	**Can an organization decide which documented information <u>IS</u> controlled and which documented information <u>IS NOT</u> controlled?**	**No, if the documented information supports the Quality Management System.** **1. ISO 9000:2015 - 3.8.6 defines <u>Documented Information</u> as "information required to be controlled and maintained by an organization and the medium on which it is contained."**	**X**	**X**	**X**

		2. ISO 9001:2015 – 7.5.3.1 states "Documented information required by the quality management system and by this International Standard shall be controlled." 3. ISO/TS 9002:2016 states "7.5.1 General – The intent of this subclause is to ensure that the organization controls the documented information needed for conformity to ISO 9001, as well as the documented information that it has determined is needed for the effectiveness of its quality management system." (added 10/2023)			
7.5.3	**Is it acceptable to use pencil on documentation that will become records? An organization has a contractual agreement with the Defense Department to follow maintenance data collection systems to document maintenance actions. These contractual documents allow use of pencil or pen when completing aircraft records and does not require initialing or dating aircraft records when a value or text is changed. Which of the following positions are correct?** **1. The 9100:2016 introduction states if there is a conflict between the standard and applicable customer requirements, the latter shall take precedence. Therefore, the organization can use pencil and not initial or date changes.** **2. 9100:2016 does not specifically mention the use of pencil or identifying/dating changed records. 9100:2016 requires documented information control,**	**No. When an organization is compliant and certified to 9100:2016, they must meet all 9100:2016 requirements over and above customer, statutory, and regulatory requirements. Therefore, position 1 is not valid.** **9100:2016 requirements include wording regarding adequate protection which pencil would violate because of lead smudging or ability to easily erase records. The ability to change records without a record of who authorized the change, violates the requirements for the records to be adequately protected and to show the person authorizing the change. 9100:2016 supporting clauses include:** • **Clause 7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:** **b. it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).** • **Clause 7.5.3.2 Documented information retained as evidence of conformity shall be protected from unintended alterations.** • **Clause 8.5.6 The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.** **The use of pencil on quality documentation is not acceptable. (added 10/2023)**	**X**	**X**	**X**

	protection, and integrity that is contrary to using pencil and not initial or date changes.				
		8. Operations			
8.1.4 (see 8.7)	Can destroyed counterfeit parts be returned to the supplier for credit?	It depends. Counterfeit parts are typically retained for investigations. The concept is that the aviation, space, and defense industry does not want these parts within the supply chain or to risk re-assembly of these parts. If they are rendered unusable and the supplier was not knowingly the source of the counterfeit, and there are no legal implications, returns are not prohibited, but also not encouraged as they are to be destroyed and disposed of at the point of discovery once investigations are complete. Those organizations that have contracts with the Department of Defense are prohibited from returning counterfeit electronic parts and in some cases they may want those parts held in their current "as received" state to be used for investigation and potential prosecution of the person or persons dealing in counterfeit parts.	**X**	**X**	**X**
8.2.1 8.2.2	Where is the requirement 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? What are the grandfathering rules pertaining to obsolete specifications / material per 9100?	The customer requirements are determined in clause 8.2.1 and clause 8.2.2 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 9100-series to deviate from customer requirements.	**X**	**X**	**X**

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8.3	The organization must develop and validate a complex process to achieve the results (i.e., special processes, control software, automated measuring equipment). Are they required to use design and development processes?	No. 9100-series requirements are for design and development of products and services, not of processes. An organization can use clause 8.3 for process development but it is not a requirement. 9110 process development would be considered technical data developed by the design authority.	**X**	**N/A**	**X**
8.3	**Would Reverse Engineering of customer sample guided by a drawing with boundary dimensions and material specifications be considered engineering or design? We currently measure samples provided by the customer to determine component dimensions.**	**Yes. When an organization performs reverse engineering, they are performing engineering or design. Some level of clause 8.3 would be applicable to the product.** **(added 10/2023)**	**X**	**N/A**	**N/A**
8.3.3	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 9100 standard. How can I justify this situation?	9100-series, Clause 1 states that the statutory or regulatory requirements take precedence from the standard in case of conflict.	**X**	**X**	**X**
8.3.6	In accordance with clause 8.3.6 “The organization shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements”. Could you please explain what criteria are considered? What is it - criteria for notifying customers? Maybe you can provide 2-3 examples.	The organization is required to develop a process and include what is done if the design change affects customer requirements. Criteria would include such things as who to notify regarding changes affecting customer requirements, type of the change, impact of the change, timeliness of notification, contractual considerations, etc. The requirement is to notify the customer when changes affect customer requirements.	**X**	**X**	**X**
8.4	Does 9120 allow for a distributor to contract/ outsource the manufacturing of product to an external provider?	When a distributor takes on selection of a manufacturing source or outsources the manufacturing themselves, they have taken on control of the manufacturing process, and as such, are inherently affecting product characteristics/conformity – this is outside of	**N/A**	**N/A**	**X**

		the scope of 9120. Distributors may coordinate regulatory controlled processes (e.g., repair/overhaul from regulatory-approved repair stations) or may coordinate customer-designated processes from approved sources (e.g., special processes) – this is within the scope of 9120.			
8.4	What constitutes externally provided processes, products, and services? Do we have to treat our sister sites as external entities? Does this apply to all commodities?	Externally provided processes, products, and services combines the requirements from 9100:2009-series Purchasing and Outsourcing. If processes, products, and services are coming from outside your defined QMS and affect process, product, or service conformity; they are required to be controlled in accordance with clause 8.4. This would include external resources performing work on your premises. Annex A.8 provides some good guidance on this topic.	**X**	**X**	**X**
8.4.1	Clause 8.4.1: The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer. Does this include or exclude GFE? The source is defined and parts procured by the customer. We cannot be responsible for the conformity as we do not see the requirements?	The intent of this requirement is that certified organizations manage all external providers, even customer-directed sources. Government or Customer Furnished Equipment provides unique challenges since the organization does not always control the scheduling or quality verification of these products. These parts can impact the final product on-time delivery and quality. It is expected, at a minimum, that the organization verifies the condition upon receipt (visual for damage and identification), tracks these on-time delivery and quality impacts, and communicates any concerns back to the government or customer.	**X**	**X**	**X**
8.4.1	The standard requires periodic assessment of external provider performance. Does these controls apply to service suppliers, like tooling and calibration service suppliers, or just airplane part suppliers?	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. 9100-series, clause 8.4.1 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 or service has on subsequent product realization or the final product.	**X**	**X**	**X**
8.4.1	Is a calibration supplier required to be accredited?	It depends. There is no requirement in 9100:2016-series for a calibration supplier to be ISO 17025, Z540.1, 9100, or even ISO 9001	**X**	**X**	**X**

		certified, however it is a good practice. Organizations are required to evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements (see clause 8.4.1). The organization is required to 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.			
8.4.1	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)?	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.	**X**	**X**	**X**
8.4.1.1	What is meant by "its external providers" in clause 8.4.1.1.b? Does this mean that an organization must maintain a register of all its external providers or is a register of a limited subset sufficient? Based on clause 8.4.2 that begins with, "The type and extent of control …", our organization maintains a register of Class 1 Products/ Services suppliers.	The 9100-series requirements in clause 8.4 are applied to the organization's external providers that affect process, product, or service conformity. Type and extent of control is 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.	**X**	**X**	**X**
8.4.1.1	**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… is that acceptable?** **Can you confirm which is the correct interpretation?** **1. Every supplier that effects process, product or service conformity must**	**Clause 8.4.1.1c requires a periodic review of external provider performance, including conformity and on-time delivery. So, it is required that every supplier that affects product, process, and service conformity have a periodic review of this information. The organization can review this information at various frequencies depending upon risk, but the information is still required to be reviewed. So, #1 is correct.** **Without a periodic review of quality and OTD how would an organization apply a risk management approach? (added 10/2023)**	**X**	**X**	**X**

	have their performance for conformity and OTD periodically reviewed. **2. Since an organization can determine the type and extent of control applied to a supplier, dependent upon the effect of the purchased product or service, they can decide that some suppliers do not require the periodic review of quality and OTD. For example, only reviewing performance for top 25 suppliers or only for certain commodities.**				
8.4.1	Are <u>all</u> external providers required to have a formalized risk assessment by the organization?	No. The organization is required to develop a process for assessing and managing supplier risks in accordance with clause 8.1.1 in 9100 and 9110. It does not require every supplier to be assessed for risk. For example, the organization may want to define its process where supplier risk is based upon process, commodity/ product, or performance. The context of supplier is slightly different for 9120 insomuch as where a distributor's suppliers are OEM manufacturers and the distributor is authorized or franchised to the OEM, hence the "supplier" is not really a supplier in common terms, and the supplier risk may be lower. Where a distributor buys from another distributor or on the open market, then the risk might be very high and needs to be assessed.	**X**	**X**	**X**
8.4.2	Some international customers insist on signatures on Certificates of Conformity (CoC). Is this a 9100 requirement?	The standard does not specify that CoCs are required to be signed. However, to be a "Certificate" it must have some sort of authorization to be a valid record of product conformity with manufacturer approval for the product conformity. If a signature block is included on a CoC form, it is required to be signed as a valid record. The CoC indicates some type of authorization, typically if not a signature, then a traceable stamp for the CoC attestation.	**X**	**X**	**X**
8.4.2	Would you agree that we could be compliant to the	It depends. If your organization uses external provider test reports to verify product, then	**X**	**X**	**X**

	standard without receiving or reviewing test reports for non-critical raw material?	your organization is required to have a process to evaluate the data in these reports.			
8.4.2	When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports. Question: What does this look like in practice. Do we have to be there when they are performing the test to validate the accuracy OR perform the same test internally?	The organization is required to understand the significant operational risks for the product such that mitigating actions can be implemented. When the raw material provides a significant operational risk, the accuracy of the test report is required to be validated by either an external source or internally within the organization. The appropriate process (frequency, method) for the validations are to be determined by the organization.	**X**	**N/A**	**X**
8.4.2	**What level of verification is required when external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements?** **1. Would ensuring that the material test report was received and matched the material be sufficient?** **2. In addition to #1, would ensuring the results meet the requirements for the raw material composition be compliant?** **3. In addition to #1 and #2, would periodic testing be required to verify the material test report accuracy?**	**It depends on the process the organization has put in place to verify the product meets requirements. As long as the process evaluates the test report data and it is confirmed to meet the requirements, which is basically #1, then it should suffice. Depending on the product and requirements it might be necessary to do #2 or #3 to confirm it meets requirements, but that would lead you back to review what is the process the organization put in place and is it sufficient to confirm the test report data meets the requirements.** **(added 10/2023)**	**X**	**N/A**	**X**
8.4.3	Do companies have to flow down all requirements listed in section 8.4.3? There are many different approaches which auditors are taking in	ISO 9001:2015 has removed the "where appropriate" wording from ISO 9001:2008, clause 7.4.2. ISO 9001:2015 clause 4.3 allows organizations to apply requirements only when applicable. Organizations can determine what portions of the clause 8.4.3	**X**	**X**	**X**

	this area and requiring flow down of requirements.	listing are applicable or not applicable to **a certain PO** or their organization. Not applicable requirements are required to be justified with documented information.			
8.4.3	The standard 9100:2009, clause 7.4.2 requires that purchasing information shall identify purchased product including revision status of technical data. The standard 9100, clause 8.4.3 does not include this requirement. This information is no more required?	The clause 8.4.3a requirement... identification of relevant technical data...would include the revision status if applicable or required to fully define the product or service or configuration required.	**X**	**X**	**X**
8.4.3	Please provide clarity of the requirement in clause 8.4.3e…" The organization shall communicate to external providers its requirements for: e. control and monitoring of the external providers' performance to be applied by the organization;"	Clause 8.4.3e is an ISO 9001:2015 requirement and the ISO/TS 9002 provides some good narrative on this topic: The performance of external providers needs to be monitored. The type and frequency of the monitoring that the organization will use should be included in the information. This could specify the level of performance that the external provider must meet or provide information relating to how the results of the organization's performance evaluations will be communicated. So, in the information for external providers the organization needs to communicate includes the supplier performance expectation and how performance will be evaluated.	**X**	**X**	**X**
8.4.3	Does 9100 require flow down of 9100 into supplier and subtler supplier contracts?	No. It is only a requirement to flow down 9100-series if there is a customer contractual or organizational QMS requirement. Regardless, the organization can also decide to flow down QMS requirements to its supplier, see clause 8.4.3k.	**X**	**X**	**X**
8.4.3	Notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval; Is this for any Suppliers subtler supplier even if it is not a company directed	This requirement starts with "The organization shall communicate to external providers its requirements for... the need to...". So, it is up to the organization to determine its requirements and needs for external provider coordination including their external providers.	**X**	**X**	**X**

	source? Suppliers change their subitems all the time and unless they are a company source directed supplier, they do not have to notify our organization and we don't have to give them approval.				
8.5.1	Is a Build-to-Print organization required to define key characteristics if no key characteristics are established by the customer?	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 8.3.5, 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.	**X**	**N/A**	**N/A**
8.5.1	Please confirm if 9100-series requires organizations to document evidence that production processes produce parts and assemblies that meet all specification requirements and, if so, please state where this requirement exists in 9100-series?	Yes, the evidence of conformity to product definition, manufacturing, or inspection including shop traveler is typically denoted as an electronic or manual stamp or initials to show satisfactory completion (see 9100 clause 8.5.1c, I, m, and n).	**X**	**X**	**X**
8.5.1	Is it required that an organization have evidence that every operation and inspection step be complete?	Yes. Clause 8.5.1.n requires evidence that all production and inspection/verification operation steps have been completed as planned or otherwise documented and authorized. Examples of evidence can include stamps, electronic signatures, initials, or names.	**X**	**X**	**X**
8.5.1.1	What kind of equipment is included in the term 'equipment', as it relates to the referenced clause? For example, would a forklift be considered production equipment and therefore require validation?	Clause 8.5.1.1 terminology of production equipment pertains to equipment that adds value to the product or service in achieving customer requirements thus needing validation. A forklift moves or transports parts and requires maintenance under infrastructure in 7.1.3.b and c, but packaging equipment could be included for a distributor under 8.5.1.1 as it is part of their service process.	**X**	**X**	**X**

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8.5.1.2	If an organization outsources special processes, is it expected they verify conformity to clause 8.5.1.2 for that external provider?	Yes. The organization is responsible for the conformity of all externally provided processes, products, and services (see 8.4.1). The organization is required to make clause 8.5.1.2 applicable since it is being performed on the product. Therefore, the organization is required to ensure compliance with clause 8.5.1.2 requirements at the external provider. Some methods to ensure compliance would include on-site supplier audit, Nadcap certification, or other certified special process approval.	**X**	**X**	**N/A**
8.5.1.3	Does 9100 require production process verification of all assemblies?	It depends. The organization defines its production process verification process to cover parts and assemblies. Assembly can include subassemblies, component assemblies, and even final product.	**X**	**N/A**	**N/A**
8.5.1.3	Is an organization required to have production process verification records for all parts including supplier parts?	It depends. Yes, the organization claiming 9100 conformity has the responsibility to have production process verification records for their manufactured parts and assemblies unless a valid exclusion exists. The organization claiming 9100 conformity has the responsibility to comply with 9100 that includes provisions for control of externally provided processes, products, and services in clause 8.4. There are no 9100 clause 8.4 contractor requirements to flow 9100 down to suppliers. If 9100 is not flowed down to the supplier or a contract requirement does not exist, then clause 8.5.1.3 for Production Process Verification is not expected for these commodities from the supplier and the organization does not have a requirement to perform this verification.	**X**	**N/A**	**N/A**
8.5.1.3	Does 9100 mandate that a Production Process Verification 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?	Yes. 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 that would invalidate the previous PPV.	**X**	**N/A**	**N/A**
8.5.1.3	What was the intent of the writing team by adding two separate standalone	The first clause 8.5.1.3 requirement was introduced so all organizations, including those with small production quantities (such	**X**	**N/A**	**N/A**

	requirements within this clause? The previous version of 9100:2009 did not include two requirements (Ref: 7.5.1.1 Production Process Verification). The standard now states in Clause 8.5.1.3: ***The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.*** and ***The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements.*** Some may interpret this to mean that a retained FAI report can satisfy both of the above requirements, however there are two requirements for a reason and requires clear retained documented information for both requirements.	as in Space industry), could apply the Production Process Validation (PPV) instead of identifying it as not applicable (exclusion). The Team wanted to open the door for other "process" methods to perform PPV that may be implemented to provide an alternative methodology to the previously written PPV requirement. The team decided to keep the second requirement for all the organizations as a FAI can be done according to internal rules (or according to the 9102 when required by contract). The first paragraph was added since only performing a FAI does not provide the warranty that the whole "production" process will be able to product parts that meet requirements. Actually, it only provides the warranty that the "manufacturing" process is able to "manufacture" a product compliant with the requirements relating to the "product." The other requirements regarding the "production" process (in terms of quantities to produce, lead-time, cost constraints, ...) cannot be verified with only a FAI. It was not the team's intent to require PPAP or process capability for each production process. Regarding the "records" we require the organization to retain documented information on how they ensure production process verification is implemented.			
8.5.2	Does the 9100 standard require the traceability to individual who actually did work and/or inspection?	Clause 8.5.2 requires traceability of the product, not specifically to the operator or inspector. Clause 8.5.1n 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, if applicable.	**X**	**X**	**X**
8.5.5	If a company does not provide service to products after the	Clause 8.5.5, Post-Delivery Activities, is applicable when servicing of your product is	**X**	**X**	**X**

	part is delivered to a customer, can they claim clause 8.5.5 as not applicable?	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 activities (such as warranty work), clause 8.5.5 cannot be excluded in its entirety. At a minimum, the portion "***When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting***." 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 8.5.5 is applicable. The organization may utilize the Control of Nonconformity Outputs process and Corrective Action process as the method for implementing this requirement; however, Clause 8.5.5 would not be excluded in its entirety.			
8.7	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 of material in a marked bin adequate or does each piece require marking?	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 8.7 is for <u>product that does not conform to product requirements</u>. Therefore, if the materials are conforming and there is material excess from die cutting, water jet cutting or routing operations (or other splitting operations for distributors); your excess material does not fall within the scope of scrap control in this clause. If your product is nonconforming to product requirements that is when the scrap provisions of clause 8.7 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.	**X**	**X**	**X**
8.7	Please explain what conspicuously and permanently marked includes.	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,	**X**	**X**	**X**

		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.			
8.7	Please explain positively controlled?	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.	**X**	**X**	**X**
8.7	Can you provide some examples of physically rendering product unusable?	Physically rendering product unusable (product mutilation) be accomplished in such a manner that the parts become unusable for their original intended use. Mutilated parts are not 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).	**X**	**X**	**X**

		- 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.			
8.7	What is the difference between non-conforming product and counterfeit parts?	Non-conforming product is a broader term to indicate that the product does not meet requirements and could potentially become conforming under certain conditions. Counterfeit parts are a subset of non-conforming product that were produced and/or distributed and can deceive users to believe that parts are from a genuine source. Counterfeit parts can never be conforming	**X**	**X**	**X**
8.7	Can destroyed counterfeit parts be returned to the supplier for credit?	It depends. Counterfeit parts are typically retained for investigations. The concept is that the aviation, space and defense industry does not want these parts within the supply chain or risk re-assembly of these parts. If they are rendered unusable and the supplier was not knowingly the source of the counterfeit, and there are no legal implications, returns are not prohibited, but are also not encouraged as they be destroyed and disposed of at the point of discovery once investigations are complete.	**X**	**X**	**X**
9. Performance Evaluation					
9.1.1	In accordance with clause 9.1.1 General, "The organization shall retain appropriate documented information as evidence of the results." (final phrase). Please clarify what type of documented information is mentioned? As a result of ALL Monitoring, Measurement, Analysis, and Evaluation activities. Or only as a result of evaluating the performance and the effectiveness of the quality management system?	The 9.1.1 (Monitoring, Measurement, Analysis, and Evaluation) states that "The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results." Yes, the results expected to answer to this clause are "only" those related to the performance and effectiveness of the QMS. But several requirements related to the monitoring and measurement activities for products and services are mentioned in 8.5.1 c).	**X**	**X**	**X**
9.2.2	Does the standard require the performance of internal audits on an annual schedule?	No. Clause 9.2.2 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	**X**	**X**	**X**

		audits are conducted at some minimum frequency. Audit planning includes: 1. The organization considered the status and importance of the processes and areas to be audited. The audit frequency demonstrates 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 be conducted to that clause. A very dynamic QMS/organization has 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 Certification Body. It is intended that internal audits are conducted more frequently and at a greater depth than Certification Body audits. Areas that are not internally audited at the right frequency would place the organization at increased risk of a major nonconformity from their Certification Body.			
9.2.2c	Does the standard allow the Quality Assurance manager to be the lead auditor in an Internal Audit and audit QA specific questions?	It depends. The requirement in 9100-series is "select auditors and conduct audits to ensure objectivity and the impartiality of the audit process." This ISO 9001 text is in place to ensure an effective internal audit by having an objective and impartial auditor. Where this practice is not optimal, if there are adequate controls, documentation of a thorough audit, and the audit is generating nonconformities; then it is acceptable for the QA Manager to be the lead auditor.	**X**	**X**	**X**
9.2.2	Is it required for an internal auditor to receive training on 9100-series requirements?	There is not a specific 9100-series training requirement for internal auditors. Internal auditors will need to be competent given the requirements of clause 7.2 including the organization defined internal auditor competence requirements **including 9100 understanding, 9101 awareness, SCMH, and ISO 19011**. If the internal audits are conducted in a professional manner given good internal audit techniques and the internal audits are identifying issues including	**X**	**X**	**X**

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		9100-series specific requirements, a noncompliance cannot be justified.			
9.2.2	Clause 9.2.2 (d) states that the 'organization' shall…d. ensure results of audits are fed back to the relevant manager, and section 9.2.2 (e) the 'organization' shall take appropriate correction and corrective action without undue delay. However, there is no indication of 'who' should perform 9.2.2 (e). With 9100:2009 (section 8.2.2 b), it was clear that this was the responsibility of 'the management responsible for the area being audited' - however, no such similar statement is made in the 2016 revision. My concern is that this may lead to confusion/arguments regarding who is responsible for correction and corrective actions.	The responsibility may depend upon the type of finding and person responsible. Here are some examples: 1. The finding pertains to a process issue so the finding is best answered by the process owner and may include a procedure change. 2. The finding pertains to a supporting organization, like equipment on the floor had incorrect calibration label or has wrong calibration date, which would be issued to Calibration Department. Or Engineering Change Order paperwork contained error or was not being processed timely which would be issued to Engineering. 3. The audited area could have leads but no management, so the finding could be issued to the lead. What is important is the internal auditor is not the one making the correction and corrective action since this would impact their objectivity.	**X**	**X**	**X**
9.3	Is it required that Management Review is conducted in a single meeting?	No. Management Review can be reviewed in a variety of manners as long as it satisfies the 9100-series requirements, engaged top management, and is conducted in a planned manner. Organizations remember that the intent of management review is to review the suitability, adequacy, effectiveness, and alignment with strategic direction of the organization. It is expected that a minimum frequency be an annual review. A summary report to consolidate results is a good practice when multiple methods are used for management review.	**X**	**X**	**X**
9.3.2	Provide clarity on management review input requirements as to what should be addressed by the organization based for #5-monitoring and measuring results.	Monitoring and measuring results link back to clause 9.1.1 with this linkage shown in ISO/TS 9002:2016. The content for discussion would include what is the organization monitoring and measuring to evaluate the performance and effectiveness of the quality management system.	**X**	**X**	**X**

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10. Improvement					
10.2.1.b.2	**Is it acceptable to just list "human factor" as the cause as stated in this requirement?**	**No. The intent of adding "those related to human factors" is to consider human factors in the causal analysis and not stop at "human factor" or workmanship. (added 10/2023)**	**X**	**X**	**X**
10.2.1.b.2	Does the Standard mandate Human Factors Training?	No. Not mandated for 9100 and 9120 standards. ISO 9001:2015 text requires consideration of human factors for work environment (clause 7.1.4) and mistake proofing (clause 8.5.1). 9100-series:2016 requires consideration of human factor during the causal aspects of performing corrective action (clause 10.2.1). The organization needs to determine the appropriate method of implementing for their business, which could involve training. For 9110, Human Factors training is a requirement for certificated MRO organizations in most jurisdictions.	**X**	**X**	**X**
10.2.1.e	Clause 10.2.1.e requires organizations to "update risks and opportunities determine during planning, if necessary." Does this need to be performed for every corrective action?	The organization determines when to update risk and opportunities based upon corrective actions. This is the risk feedback loop where a possible escape from the risk process has occurred, and the organization determines if inclusion to risk and opportunity planning is required.	**X**	**X**	**X**