9120:2016 Series of Standards Frequently Asked Questions (FAQs)

In developing this list of Frequently Asked Questions (FAQ's) for the 9120:2016 Series revisions, input has been obtained from experts and users of the standard from around the world. The list will be reviewed and updated on a regular basis to maintain its accuracy, and to include new questions where appropriate. It is intended that this list will also provide a good source of information for new users of the standards.

Questions about the change (9120:2016)

1. Why has it been decided to issue a new version of ISO9001 and 9120?

Business needs and expectations have changed significantly since the last major revision of ISO9001 in the year 2000. Examples of these changes are ever more demanding customers, the emergence of new technologies, increasingly more complex supply chains and a much greater awareness of the need for sustainable development initiatives. ISO9001 was revised and published in September 2015. Since 9120 uses ISO9001 as its baseline text (adding requirements in bold italic text for IAQG specific requirements), it was necessary to incorporate the new ISO text.

2. Who provided input to the 9120 revision?

The 9120 team requested input from stakeholders (interested parties) which included IAQG and its sector member companies, IAQG Strategy Streams and Teams, suppliers, civil airworthiness authorities, certification/registration bodies, defense industry and authorities, space industry companies, regulatory authorities and trade group associations.

3. What process was used to determine the changes to 9120?

The 9120 team used a project management approach to solicit input and manage the revision as follows:

Project Management Inputs - Design Specification; IAQG Strategy; 9120 objectives; Stakeholder inputs; and Web survey inputs
Data Mining and Consolidation - MCRT (Master Comments Review Template) which was used to collect comments and proposals
Review Process - Review of proposals by the IAQG 9120 team based on the Design Specification
Draft coordination and voting - 1st coordination draft issue July 2015, 9120 team review October 2015, stakeholders comments review October 2015; formal ballot issue November 2015, vote December 2015; release April 2016.

4. Does the 9120:2016 Series still apply to all distribution organizations – large or small, different sectors and different items - products, services?

The concept of the standard has not changed; it's applicable to any type of distribution organization, regardless of the size or type (OEM or aftermarket) of business. All of the standard is applicable as stated in clause 4.3, whereas it's up to the organization to justify what's not applicable. With this change in ISO 9001, it is now the organization's responsibility to determine applicability of clauses such as 8.3 "Design and Development of Products and Services" are not within their scope. Also see question 15 below.

5. How has the structure of the standard changed?

The structure has been changed to align with the common 10 clause high level structure developed by ISO to ensure greater harmonization among its many different management system standards.
The new structure is built around the PDCA (Plan-Do-Check-Act) sequence. All ISO management system standards are now required to adopt this structure. This will make it easier for organizations to address the requirements of more than one ISO Management System Standard within a single, integrated system.
The 10 sections are: 1.0 – Scope, 2.0 – Normative references, 3.0 – Terms and definitions, 4.0 – Context of the organization, 5.0 – Leadership, 6.0 – Planning, 7.0 – Support, 8.0 Operation, 9.0 – Performance evaluation, and 10.0 – Improvement

6. If our company's documentation is based on the 8 clause structure, do we need to update the numbering to the new structure?

Annex A.1 in 9120 provides guidance on the subject and states the following:

- There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.
- 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.

7. What are the main differences in content between the old and new version?

Differences in ISO9001 Text

- The adoption of the high level structure as set out in Annex SL of ISO Directives Part 1
- An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach
- Fewer prescriptive requirements
- More flexibility regarding documentation and some new terminology
- Improved applicability for services
- A requirement to define the boundaries of the QMS and alignment of the QMS policy and objectives with the strategy of the organization
- Increased emphasis on organizational context
- Increased leadership requirements including ensuring integration of the QMS into business processes
- Greater emphasis on performance evaluation and achieving desired process results to improve customer satisfaction
- Emphasis on change management
- Introduction of knowledge management

Changes in Terminology

- Products -> products and services
- Exclusions -> Scope of QMS defined
- Documentation, records, documented Procedures -> Documented information, maintained or retained
- Purchase products -> Externally provided products and services
- Supplier -> External provider

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider").

Differences in 9120 Additional Requirements

- **Product Safety** added in carefully selected areas and consistent with 9110
- **Human Factors** added as a consideration in Nonconformity / Corrective Action
- **Risk** merged current 9100 requirements with the new ISO requirements and emphasis on risks into 9120 in appropriate
- **Preventive Action** current clause requirements absorbed into Risk & Opportunities and Nonconformance & corrective action clauses, 9120 additions reinforce prevention
- **Counterfeit Part** added in carefully select areas and expanded on new requirements
- **Configuration Management** clarified and improved considerably to address stakeholder needs
- **Product Realization & Planning** clarified and enhanced planning throughout the standard

- **Post Delivery Support** merged current 9100 requirements with the new ISO requirements
- **Project Management & Work Transfer** combined with Operation Planning clause and worded in the context of a Distributor
- **Design and Development of Products and Services** The ISO 9001:2015 text is included, it cannot be "excluded" but must be justified as "not applicable" per clause 4.3 of the standard if it is not part of the distributor's QMS processes
- **Supplier Management** ISO text from the previous standard has been added back in a few places to meet the IAQG needs
- **Quality Manual** note added pointing to the requirements that make up a Quality Manual or the equivalent
- **Management Representative** requirement added back in for QMS oversight
- Added validation process of tests report accuracy for raw materials used in critical items

8. How have documentation requirements changed?

Documentation, documents and records are now collectively referred to as documented information. Where that documented information might be subject to change (as in the case of procedures, work instructions, etc.), organizations are required to MAINTAIN the information up-to-date; where the information is not normally subject to change (for example records) the organization is required to RETAIN that information. Specific documented "procedures" are no longer mentioned; it is the responsibility of the organization to maintain documented information to support the operation of its processes and retain the documented information necessary to have confidence that the processes are being carried out as planned.
While the full extent of the documentation that is needed will depend on the business context, there are several instances of requirements for maintained documented information as follows;

- Section 4.3 – The scope of the quality management system
- Section 4.4.2 - maintain documented information to support the operation of processes
- Section 4.4.2 - The organization shall establish and maintain documented information that includes:
  - a general description of relevant interested parties ;
  - the scope of the quality management system, including boundaries and applicability;
  - a description of the processes needed for the quality management system and their application;
  - the sequence and interaction of these processes;
  - assignment of the responsibilities and authorities for these processes;
  - the documented information established for the quality management system, or reference to it.

  NOTE - This documented information can be referred to as a quality manual.
- Section 5.2.2 – The Quality Policy
- Section 6.2.1 – The Quality Objectives
- Section 8.1.e. - determining and keeping documented information to the extent necessary:
  - to have confidence that the processes have been carried out as planned;
  - to demonstrate the conformity of products and services to their requirements;
- Section 8.7.1 – Non-conformance control process

9. The standard does not mention a quality manual, is it still required?

A quality manual is no longer specifically required. The new standard requires the organization to maintain documented information necessary for the effectiveness of the quality management system (QMS). There are many ways to do this and a quality manual is just one. 9120 (4.4.2) text adds a note to clarify that this documented information can be referred to as a quality manual. If it is convenient and appropriate for an organization to continue to describe its quality management system in a quality manual then that is perfectly acceptable.

10. Why has management review been moved to performance evaluation? (9.3)

The sequence of the new version of 9120:2016 is based on the Plan, Do, Check, Act cycle and so, in order to evaluate quality management system performance, it makes sense for management review to follow the measurement of the system performance.

11. The title of management representative has been removed. How is the performance of the system reported to top management?

Although the title of a management representative has been deleted from the ISO 9001 baseline text, it has been added back in as 9120:2016 text. The ISO intent was that it is up to top management to ensure that the roles and responsibilities are assigned for reporting on the performance of the QMS. The IAQG has added back the requirement for top management to appoint a specific member of the organization's management who shall have the responsibility and authority for oversight of QMS and the organizational freedom and unrestricted access to top management to resolve quality management issues.

12. Why has product been changed to product and service?

9120:2009 already made it clear that the term product in the previous version of the standard also includes service, so there is no impact in practical terms. The term product and service is now used throughout the standard to reflect the far greater use of the standard outside of the manufacturing sector, and to emphasize its applicability in the service industries. See Annex A.2 and A.5 for more info. Since distribution can be considered a "service" the applicability is unchanged in this regard.

13. What is risk-based thinking and why has it been introduced into the standard?

The phrase risk-based thinking is used to describe the way in which the ISO 9001:2015 baseline text addresses the question of risk. The concept of risk has always been implicit in the ISO 9001 text, by requiring the organization to plan its processes and manage its business to avoid undesirable results. Organizations have typically done this by putting greater emphasis on planning and controlling processes having the biggest impact on the quality of products and services they provide. The way in which organizations manage risk varies depending on their business context (e.g. the criticality of the products and services being provided, complexity of the processes, and the potential consequences of failure). Use of the phrase risk-based thinking is intended to make it clear that while an awareness of risk is important, formal risk-management methodologies and risk assessment are not necessarily appropriate for all business situations and organizations. For further information about risk-based thinking, see Annex A.

14. What has been changed in terms of planning?

9120:2016 requires the organization to address risks and opportunities, quality objectives and planning of changes throughout the organization. As new products, technologies, markets and business opportunities arise, it is to be expected that organizations will want to take full advantage of these opportunities. This has to be done in a controlled manner, and be balanced against the potential risks involved, which could lead to undesirable side-effects.

15. Are organizations still allowed to exclude requirements of ISO 9001?

9120:2016 no longer refers to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can determine the applicability of requirements. All requirements in the new standard are intended to apply. The organization can only decide that a requirement is not applicable if its decision will not affect its ability or responsibility to ensure the conformity of products and services and the enhancement of customer satisfaction. The scope of the QMS, as determined by the organization, shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable.

16. What are the benefits of the new version of 9120:2016?

- Less prescriptive, but with greater focus on achieving conforming products and services
- More user friendly for service and knowledge-based organizations
- Greater leadership engagement
- More structured planning for setting objectives
- Management review is aligned to organizational results
- The opportunity for more flexible documented information

- Addresses organizational risks and opportunities in a structured manner
- Addresses supply chain management more effectively
- Focus on the complete supply chain and stakeholders
- Opportunity for an integrated management system that addresses other elements such as environment, health & safety, business continuity, etc.

17. What is the process approach and is it still applicable to 9120:2016?

The process approach is a way of obtaining a desired result, by managing activities and related resources as a process. Although the clause structure of 9120:2016 follows the Plan- Do-Check-Act sequence, the process approach is still the underlying concept for the QMS. For further guidance, please refer to the Support Package module: *Guidance on the Concept and Use of the Process Approach for management systems.*

Questions relating to specific clauses in the standard

18. What does "customer or regulatory controlled process" mean in the "intended application" section of the standard?

9120 AQMS standard serves both the production and aftermarket sectors of the AS&D community. In the production application, there is allowance for the customer of a distributor to direct work to be performed on a product the distributor buys and subsequently sells to the customer. However, the selection, approval and oversight of the source belong with the customer. The work performed and ultimate acceptance of that work belongs with the customer.
For example, the customer of a distributor of raw material wants the raw material heat treated and nondestructively tested before shipment from the Distributor to the customer. The customer can specify in the PO the use of a Nadcap or customer approved and controlled source and the distributor can facilitate the logistics and provide the results with the product documentation upon delivery to the customer. This would not violate the distributor's 9120 certificate.
In the aftermarket use of AQMS 9120, distributors (brokers) of parts for AS&D end users often buy "cores" or salvageable items from used product and have them "repaired or maintained" in accordance with applicable approved design data and regulatory requirements. When the work of the repair or maintenance is performed wholly under the authority and direction of an approved maintenance facility (that is separate from the distributor) that has the authorization and ability to determine product airworthiness, then this is acceptable under the 9120 certification, provided that the Distributor is maintaining traceability and airworthiness records, but is NOT creating airworthiness determinations.

19. 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 adding value – this is outside of 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.

20. What constitutes 'splitting' within the context of 9120:2016? (3.7)

9120:2016 defines splitting as "***The division of product either physically or by batch quantity, without affecting the product characteristics or conformity***." The issue that comes up often is the word "physically" which draws some question about what limits of work may be performed on a product which is why the qualifier was added that product conformity or characteristics were not to be affected during any splitting operations. The terms of doing "kitting" or the process of taking large batches of products and breaking them down into smaller shipping quantities is the traditional role of a Distributor.
In practical terms there is an example of a raw material provider that may have large lengths or bar or sheet or tube of materials from a mill; or a provider of liquids or adhesives that are delivered in large containers; or of wire where the manufacturer provides large spools of product. Customers may desire smaller quantities than what is on hand, so the Distributor may 'cut, saw or other method (but not a special

process)' to divide the product into smaller units which will not affect the material's conformity or product characteristics.

21. What is meant by the context of the organization? (4)

This is the combination of those internal and external factors that affect an organization's approach to the way in which it provides products and services that are delivered to its customer.
External factors can include, for example, cultural, social, political, legal, regulatory, financial, technological, economic, and competitive environment, at the international, national, regional or local level.
Internal factors typically include the organization's corporate culture, governance, organizational structure, technologies, information systems, and decision-making processes (both formal and informal).

22. What are the needs and expectations associated with interested parties? (4.2)

The organization will need to determine the General interested parties that are relevant to the quality management system and the requirements of those interested parties, as outlined in clause 4.2. This does not extend past the quality management system requirements and the scope of this International Standard.
As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

23. Is QMS risk included in the 9120 standard? (6.1)

9120 promotes risk based thinking; clause 6.1 addresses identifying risks and opportunities when planning for the quality management system of the organization. In addition to clause 6, risk is discussed throughout the standard in clauses 1, 4, 5, 8, 9, 10 and Annex A.4.

24. What is meant by organizational knowledge? (7.1.6)

Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives. Requirements regarding organizational knowledge were introduced for the purpose of safeguarding the organization from loss of knowledge and encouraging the organization to acquire new knowledge as its business context changes.

25. What does product safety mean in the 9120 standard (3.6)?

Product safety is defined in 9120 section 3 as: "Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property."
Product safety is included in the following clauses: *7.3 (awareness), 8.1 (operational planning and control), 8.4.3 (information for external providers).* Each of these clauses speaks to the organizational responsibility to ensure employee awareness of maintaining the product in a condition so as not to affect adverse harm to persons using the product and any potential harm that could occur during the product's use. (e.g. ESD, FOD, shelf-life controls, storage and handling conditions).

26. Is Design and Development "applicable" to Distributors in 9120:2016? (8.3)

ISO 9001:2015 has changed so that it would be inclusive of service oriented organizations. Since Distributors could be a "service provider" beyond just the providing of products to customers, it may be appropriate for an organization to include this clause (see question 15 above). Distributors may have services that they "design and develop" for customers, hence the expectation would be evidence of compliance from the aspect of the distributor's delivery of that service. This can be dependent on the size and type of services a distributor provides. The applicability of 8.3 is dependent on the complexity of the services a distributor provides to the customer. Refer to ISO 9001: 2015 Annex A.5.

27. Why has Purchasing changed to 'Control of externally provided processes, products and services'? (8.4)

This change reflects the fact that not all products, services or processes that an organization acquires are necessarily purchased in the traditional sense. Some may be acquired from other parts of a corporate entity, for example, as part of a shared pool of resources, products donated by benefactors or services

provided by volunteers.

28. What is meant by post-delivery activities and what is the extent of an organization's responsibility? (8.5.5)

This means that based on customer agreements or other requirements, the organization may be responsible for providing support for their product or service after delivery (e.g. queries or warranties).

29. What is the difference in the standard between improvement and continual improvement? (10)

9120:2009 used the term continual improvement to emphasize the fact that this is an ongoing activity. However, it is important to recognize that there are a number of ways in which an organization may improve. Small step continual improvement is only one of these. Others may include breakthrough improvements, re-engineering initiatives or innovation. 9120:2016 therefore uses the more general term improvement, of which continual improvement is one but not the only component.

30. What is meant by the “consequences of obsolescence” (8.5.1)?

For the purpose of this of the Standard, "consequences of obsolescence” requires the distributor to consider the obsolescence of their inventory (e.g. shelf-life expired product, one-way interchangeable part numbers, product revision/configuration levels, beyond cure-date limits for packaging materials) and the consequences these scenarios could have if unintended use or sale occurs. For example, a means of demonstrating control of obsolescence includes; maintaining batch/lot control, labeling protocols, shelf-life control processes, inventory cycle-audit processes.

General Questions

31. What is the purpose of the 9120 standard?

The 9120 standard on quality management system requirements is intended to be used by distribution organizations that support both product manufacturers and the AS&D aftermarket. Its use can result in improved quality, schedule and cost performance. This standard is primarily developed for the aviation, space and defense industry, but can also be used in other industries.
This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

32. Where can I find more information about the 9120 standard (including deployment information) and other IAQG published standards?

The IAQG website is located at http://www.sae.org/iaqg/organization/requirements.htm

33. Who is responsible for updating the 9120 standard?

The International Aerospace Quality Group (IAQG) is responsible for the development and maintenance of the 9120 standard. For further details contact 9120 team via the IAQG website.

34. How can you tell the difference between the ISO 9001 text and the 9120 text?

The bold, italic text represents the aviation, space and defense specific additions.

Registration

35. How long will we have to transition to 9120:2016?

Organizations having dual certifications to ISO9001 and 9120 will have 18 months from September 2015 (publication date of ISO9001) to transition to the new 9120:2016 standard. Companies will be encouraged to upgrade during their scheduled audit cycle.

36. Will auditor and registrar training be available?

Yes, the sanctioned aerospace auditor transition training (AATT) will be conducted and will consist of 9100, 9120 and 9101 training.

37. Where can copies of new 9100, 9110, 9120 and 9101 standards be obtained?

There are numerous national and regional standards bodies. Each has their own publication schedule requirements. The sector standard bodies are as follows:

- SAE (Americas): http://.aerospace.sae.org/
- ASD (Europe): http://www.asd-stan.org/
- SJAC (Asia/Pacific): http://www.sjac.or.jp/en_index.html

38. Our company is currently registered to 9120, but based on the new Scope statement we should be registered to 9100 or 9110. Does this mean we will have to change our registration?

If an organization does not meet the “intended application” statement in 9120:2016 then the use of 9100 or 9110 (Maintenance) should be considered and the additional registration requirements should be determined by customer and regulatory requirements. More than one standard registration may be necessary if the products of the company meet several of the standards´ scopes (i.e. a company that manufactures products and also sells maintenance services). Clause 1.2 Introduction outlines the new applicability statements for 9100, 9110 and 9120.

39. Where do I find definitions of some of the terms used in 9120?

IAQG Dictionary has a wide range of definitions and includes definitions from ISO 9000:2005. The 9120:2016 uses both of these sources in lieu of adding definitions to the standard.

40. What are the benefits of implementing IAQG quality standards?

- IAQG members agree to use standards internally and with suppliers - One voice, minimize variation, shared resources, reduced duplication and waste
- Focus on the complete supply chain and stakeholders
- True global Aerospace cooperation and harmonization
- Higher quality products at reduced cost
- Fewer, customer-unique documents
- System for Third Party approval
- Shared supplier approval database
- Recognition by Regulatory Authorities
- Open sharing of “Best Practices”
- Networking with Quality Directors / VPs in Primes and Suppliers
- Rapid consensus & deployment