9100:2016 Series of Standards
Frequently Asked Questions (FAQs)

In developing this list of Frequently Asked Questions (FAQ's) for the 9100:2016 Series revisions, input has been obtained from experts and users of the standard from around the world. The list is 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

1.1 Why has it been decided to issue a new version of ISO 9001 baseline text?

Business needs and expectations have changed significantly since the last major revision of ISO 9001 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.

1.2 Does the 9100:2016 Series still apply to all organizations - big, small, different sectors and different items – products, services?

The concept of the standard has not changed; it's applicable to any type of organization, regardless of the size, type or its core business.

1.3 How has the structure of the standard changed?

The structure has been changed to align with the common 10 clauses high-level structure developed by ISO to ensure greater harmonization among its many different management system standards.

The new 10 clauses high-level structure will apply to all ISO management system standards, which is built around the PDCA (Plan-Do-Check-Act) sequence. This will make it easier for organizations to address the requirements of more than one ISO Management System Standard within a single, integrated system.

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

- 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

- Improved applicability for services
- A requirement to define the boundaries of the QMS
- Increased emphasis on organizational context
- Increased leadership requirements
- Greater emphasis on achieving desired process results to improve customer satisfaction

1.5 How has documentation requirements changed?

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. The extent of the documentation that is needed will depend on the business context.

1.6 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. 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. The 9100:2016 standard added requirements in clause 4.4.2 that included the previous quality manual requirements in addition to including additional information. Your organization must comply if you have statutory, regulatory, or customer requirements to maintain a quality manual.

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

The sequence of the new version of 9100:2016 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.

1.8 The title of management representative has been removed from ISO 9001:2016 and then added in 9100:2016.

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. Some organizations might find it convenient to maintain their current structure, with a single person carrying out this role. Others might take advantage of the additional flexibility to consider other structures depending on their organizational context.

1.9 Why has product been changed to product and service?

9100:2009 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.

1.10 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 that have the biggest impact on the quality of the 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 **ISO TC176 website** at http://isotc.iso.org/livelink/livelink/open/tc176SC2public and Annex A.

Risk based thinking has merged very well with the 9100:2009 addition of risk management, which was product focused and limited to the Product Realization clause, now Operations. See Annex A.4 for additional information on the differences

1.11 What has been changed in terms of planning?

9100:2016 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.

1.12 Are organizations still allowed to exclude requirements of ISO 9001?

9100:2016 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.

1.13 What is the process approach and is it still applicable to 9100:2016?

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 9100:2016 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*.

1.14 What are the benefits of the new version of 9100:2016?

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
- Opportunity for an integrated management system that addresses other elements such as environment, health and safety, business continuity, etc.

1.15 What are the differences between performance, effectiveness and efficiency of the QMS and its processes?

- Performance: the capability of a process to produce its deliverables; this can be evaluated with "performance indicators" (different from "management indicators" used to manage the day to day activities).
- Effectiveness: when the objectives defined are reached
- Efficiency: when resources affected to carry out the activities are optimized

1.16 What are the diferences between prEn versus EN?

In the European sector, ASD-STAN is publishing the IAQG9100 documents as ASD-STAN prEN9100 and related documents, to make the standard as the same time available as it is published in the American and Asian-Pacific sectors. ASD-STAN **prEN** means ASD-STAN **projected EN** and ***ASD-STAN prENs are technically equal (with exactly the same content) to the later EN publications by the CEN members.***

The ASD-STAN prEN is an early publication of the CEN EN. The **CEN EN is a later re-distribution of the ASD-STAN publication** with a CEN coversheet. **ASD-STAN prEN publications can be used for any training and certification activity. More information can be found at https://www.asd-stan.org/frequently-asked-questions/**

1.17 Why is there such a short transition period?

IAQG decided to match the ISO 9001:2015 transition period of September 2018 so organizations could avoid two separate transition efforts and audits.

Questions relating to specific clauses in the standard

2.1 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).

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

- The organization will need to determine the 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.

2.3 What are expectations relating to Human Factors?

- In clause 7.1.4, the ISO text requires that the organization implements a suitable environment taking into consideration human factors and the note mentions examples of social fields (e.g., non-discriminatory, calm, non-confrontational) and psychological fields (e.g., stress-reducing, burnout prevention, emotionally protective). So, appropriate working conditions are expected for people working within the organization in order to mitigate the risks of human factors effects on the employees and performance of the organization.
- In clause 8.5.1g, the focus is on preventing human error through mistake-proofing or Poke-A-Yoke techniques in how work is conducted.
- In clause 10.2.1.b.2, human factors may be at the origin of the nonconformities:
  a. The tool, the internal procedure relating to problem solving, the templates or checklists, the training material can be used by the organization to support the determination of the causes of the nonconformities that should include the consideration of human factors.
  b. The people involved in this process should be aware of the aspects of human factors on work performed.

2.4 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 and share the knowledge with others.

Implementation considerations include activities to benefit from lessons learned, e.g., database, communications, incorporation of lessons learned in processes and procedures; identification of experts able to transfer knowledge; on job training; tutorial sessions; documented information on how to perform tasks; competency matrices; and succession planning activities.

2.5 What is expected for Awareness (7.3)?

Individuals should be able to explain their role (i.e. sales, engineering, procurement, operator, repair technician) and how they contribute to quality; quality basics such as following instructions, reporting events, maintaining records; and know the use of the products and potential impact of failures.

2.6 Documents and records have been replaced by documented information. What does this mean? (7.5)

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.

2.7 What is the expectation for implementing and auditing escape prevention? (8.1)

This requirement was re-enforced in the standard since the industry continues to see a high level of escapes to the customer. The organization is required to show effective controls to prevent the delivery of nonconforming products and services to the customer and robust corrective actions when escapes are encountered.

2.8 Is there a guidance document or an ISO standard that I can obtain that defines a process for Risk Management (8.1.1)?

Yes. There are several good resources for Risk Management which are listed below:

- ISO 31000 Risk Management
- 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
- 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
- Project Management Institute

- Risk Management Guide for DoD Acquisition

There are numerous risk management resources and 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. Risk Management for operational processes is a subset of Risk-based Thinking (6.1) which transcends the entire QMS. See 9100:2016 Annex A.4 for additional information.

2.9 Is the requirement relating to product safety applicable for all the organizations; such as raw material providers, small organizations, lower tier, build to print, machine shops, as for complex organizations, equipment manufacturers? (8.1.3)

The requirement relating to product safety is directly linked to the final use of the product. All the organizations should know the final use of the product that they deliver. They may get this information internally or from their customers (or from the customer of their customers).

According to the use of their product and the potential consequence of their failure, they should be able to determine "critical items" as per 9100 definition, and implement appropriate actions to manage them.

Note: Some organizations (e.g. those providing COTS or raw materials) may have a lower level of knowledge of the final use of their products than those producing by customer specification.

Reminder:

a) The organization must understand the definitions:
   - Safety = aviation, space and/or defense safety
   - Safety of people onboard, around the aircraft or product, overflown
   - Related to the product operation (the use in service of the product)

   Different from:

   - People safety at work (HSE)
   - Security including fighting malicious actions (terrorism, sabotage, vandalism…)

b) The organization should be aware of the followings:
   - Achieving the product safety objective requires to implement safety dedicated provisions during the complete life cycle of the product (development, production, operations, maintenance, disposition (scrapping or reuse of dismantled parts)
   - Develop proactivity (risk management) in addition to reactive methods (e.g. processing of occurrences)
   - Identify risks potentially impacting the safety of the products and address them before they generate adverse effects
   - Building the product according to the engineering without deviations
   - Everybody has a role to play

c) The 9100 standard does not require the implementation of a safety management system (SMS), which is a more encompassing concept. But 9100 compliance requirements will contribute to build a SMS within the organization. A SMS includes:

- Safety risk management (system and product analysis and hazard identification for critical items, safety risk assessment and mitigation, non-conformities collection, analysis, reporting of occurrences)
- Safety assurance (safety performance monitoring and measurement, management of change of product and organization, continuous improvement)
- Safety promotion (training and education and communication)

2.10 What are some methods to implement counterfeit part prevention (8.1.4)?

- Training in the awareness and prevention of counterfeit parts
  - Procurement personnel in trusted source selection and requirements
  - Inspection personnel for prevention of counterfeit items (visual, test)
  - Design personnel in obsolescence management
- Obsolescence monitoring of design decisions and parts selections to be appropriate for service life of product
- Controls for acquiring parts from original manufacturers, authorized distributors, or other approved sources
- Assuring traceability of parts and components to their original manufacturers:
  - Original Equipment Manufacturer (OEM) or
  - Authorized manufacturer (e.g., in case of PMA, direct delivery authorizations)
- Verification and test methodologies to detect counterfeit parts:
  - Parts identification or marking
  - Tests or chemical analysis
- Counterfeit parts reporting
  - Monitoring reporting from external sources (access to databases, information letters from OEMs)
  - Quarantine and reporting of internal incidences in appropriate government and industry reporting systems (determine the responsibilities in the escalation process, the process to follow to report to authorities and customers)
- Requirement regarding non conformance control:
  - Segregate and control suspected or known counterfeit products
  - Ensure these products are not re-introduced into the supply chain

2.11 How are the design and development (8.3) requirements applicable to services? (Examples for Training organization, Design service provider, Testing laboratories)

The activities of organizations providing services need to be developed before being proposed to customers, especially to study the various ways to answer to customer requirements. The

new version of the clause 8.3 relating to design and development (D&D) allows adapting the requirements to each type of service.

For example, a Training provider D&D activity can be to study several ways to propose trainings (classroom, e-learning,). For a Design service provider or a Testing laboratory, a D&D activity can be to study various methodologies to perform their activity.

2.12 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.

2.13 Explain in detail the intent of section 8.4.3 m (a flow down requiring awareness of supplier personnel).

The intent of this requirement is to ensure external provider personnel understand the role they play in conformity, product safety, and ethical behavior as part of final product meeting requirements. The intent of the flow down to external providers of the awareness requirement is to ensure that the whole supply chain have the same awareness on the topics listed

The organizations can answer with:
- a general requirement to all their external providers or to key external providers (reminding that they are working for types of aerospace products)
- specific requirements (in POs or in Contracts) to relevant external providers reminding that they are supplying products having safety impacts on the final products.

2.14 What has happened to validation of processes or what used to be called special processes? (8.5)

ISO 9001:2015 chose to remove the standalone sub-clause on special processes, this requirement continues, and has been incorporated into the sub-clause f on control of production and service provision (Ref. 8.5.1). This was not specific or detailed enough for Aviation, Space, and Defense so 9100:2016 added it as clause 8.5.1.2, Validation and Control of Special Processes.

2.15 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. This could include, for example, technical support, routine maintenance, or in some cases recall.

2.16 What are examples of documentation required for Release of Product? (8.6)

Organizations are required to retain documented information of plan and 9100 8.5.1 Notes includes examples documents for verification of products and services. As for release of product, organization is required to retain those verification documented information includes the evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release.

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

9100:2016 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. 9100:2016 therefore uses the more general term improvement, of which continual improvement is one but not the only component.