

DESIGN AND DEVELOPMENT

CLAUSE 8.3

AUDITING AND APPLICABILITY

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A Tale of the Engineers and the Auditors

First Some Definitions

IAQG Dictionary

Design

- preparation of a set of [information](#) that defines the [characteristics](#) of a [product](#). (adapted from EN 13701:2001)
NOTE 1: The [information](#) is structured in the [design data file](#).

Design and Development

- set of [processes](#) that transform [requirements](#) into specified [characteristics](#) or into the specification of a [product](#), [process](#) or system.
NOTE 1: The terms “design” and “development” are sometimes used synonymously and sometimes used to define different stages of the overall design and development [process](#)
NOTE 2: A qualifier can be applied to indicate the nature of what is being designed and developed (e.g., [product](#) design and development or [process](#) design and development).
(ISO 9000:2005) [IAQG-history]



First Some Definitions

IAQG Dictionary

Design Activities

- The supplier design activity or subcontractor that owns the design and provides a deliverable to the customer.

Design Organization

- [organization](#) designing [products](#) or [changes](#) to [products](#).
NOTE 1: In civil aviation: an [organization](#) responsible for the design of [articles](#) or for [changes](#) thereto that is the holder of a Design [approval](#) granted by a [regulatory authority](#) i.e. [Type Certificate](#), Supplemental Type Certificate, Parts Manufacturer [approval](#) , or Technical Standard Order (TSO)/Joint TSO/European TSO, [European Part Approval](#) (EPA) or equivalent. [IAQG-history]



First Some Definitions

IAQG Dictionary

Design Authority

- An organization with formal authority for the design, validation, and service support of a product.

NOTE: In civil aviation, this is the organization responsible for the design of articles or for changes thereto that is the holder of a design approval granted by a regulatory authority [i.e., Type Certificate (TC), Supplemental Type Certificate (STC), Parts Manufacturer Approval (PMA), Technical Standard Order (TSO)/Joint TSO/European TSO, European Part Approval (EPA) or equivalent]. [9116]

Design Organization Approval

- approval of an organization by an applicable National Aviation Authority, that is responsible for the design of aeronautical products.



First Some Definitions

IAQG Dictionary

Design Characteristics

- Those **dimensional, visual, functional, mechanical, and material features or properties**, which describe and constitute the design of the article, as specified by drawing or Digital Product Definition (DPD) requirements. These characteristics can be measured, inspected, tested, or verified to determine conformance to the design requirements. Dimensional features include in-process locating features (e.g., target-machined or forged/cast dimensions on forgings and castings, weld/braze joint preparation necessary for acceptance of finished joint). Material features or properties may include processing variables and sequences, which are specified by the drawing or DPD (e.g., heat treat temperature, fluorescent penetrant class, ultrasonic scans, sequence of welding and heat treat). These provide assurance of intended characteristics that could not be otherwise defined (reference 9102 standard). [9145]



First Some Definitions

IAQG Dictionary

Design Data File

- structured set of [documents](#) constituting the response of the [product](#) designer to the technical requirements of the [customer](#).

NOTE 1: All the verifiable [product characteristics](#) (including the [acceptance criteria](#)) could be expressed in this [document](#) and the prescribed processes to produce it are indicated.

This file allows [identification](#) of the [product](#), in order to prepare its manufacturing and inspection file and its operating documentation.

NOTE 2: [certification](#) requirements have to be taken into account. (adapted from EN 9200:2005)

Design Risk Analysis

- Analytical techniques used by the design responsible organization to identify, to the extent possible, potential failure modes related to product performance (i.e., fit, form and function), durability, manufacturability, and cost. [9145]



First Some Definitions

IAQG Dictionary

Design Records

- The records of the **engineering definition/specification, which fully define the product** (system, part, component or assembly), including physical or electronic/digital drawings, electronic/digital models, software or other associated information. This includes records of authorized engineering changes not yet incorporated into the released engineering definition/specification. [9145]

Article

- Material, part, component, assembly, or appliance which is listed by the design organization as eligible for installation in/on the product or included in the design data approved by the authority. (9110) (9120) (not inclusive of standard parts).



IAF Audit Practices Group (APG)

ISO 9001:2015

- ISO 9001 clause 8.3 refers only to design and development of products and services. In some organizations it can be beneficial, but not required, to apply the same methodology to design and development of processes.
- In order for to determine if the organization is in fact involved in design and development, auditors need to establish who is responsible for defining the characteristics of the product or service, together with how and when this is carried out. This may apply to original design or ongoing design changes.



IAF Audit Practices Group (APG)

ISO 9001:2015 for Service

- For determining [their] applicability, an [service] organization will have to ensure that the requirements on design and development do not affect its ability or responsibility to ensure the conformity of its services and the enhancement of customer satisfaction. When an organization makes a claim for non-applicability of this requirement, auditors need to see documented objective evidence that the following two conditions are both fulfilled
 1. the requirement cannot be applied
 2. by not applying the requirement there is no effect on the organization's ability or responsibility to ensure the conformity of its services and the enhancement of customer satisfaction.

Only if these can be proven, should an auditor accept the non-applicability.



Applicability of Design and Development in the AS Standards (9100, 9110 and 9120)

- AS9100 – Design and development of all articles covered by the QMS of the organization. Limited to NEW articles for civil aviation applications
- AS9110 – Design and development of MRO services including “approved” repairs and maintenance services, but excluding NEW articles
- AS9120 – Design and development of “Services” offered to customers exclusive of the products



Audit Essentials

What are you Looking for?

- 8.3.2 – Design Planning
 - Program / Project management
 - Customer inclusion
 - Complete definition of the process to be used for a specific design
 - Including stages, approvals, testing, resources, RISKS, etc.
- 8.3.3. – Design Inputs
 - Requirements of the product (environment, application, safety, etc.)
 - Obsolescence



Audit Essentials

What are you Looking for?

- 8.3.4 – Design Controls
 - Design Verification – was the article built right? (insp / test)
 - Design Validation – was the right article built? (qualification)
 - Configuration Management (iterative process of design)
 - Test / Acceptance conditions
 - Design Reviews



IEC 61160 Design Review

The objectives of a design review include:

- **assessing whether the proposed solution meets the design input requirements that include, but are not limited to: specified general performance requirements, dependability, lifecycle costs, safety, endurance, environment, electromagnetic compatibility, human factors;**
- **assessing whether the proposed solution is the most robust, efficient and effective solution to achieve the product requirements;**
- **providing recommendations as required for achieving the design input requirements;**
- **assessing the status of the design in terms of the completeness of the drawings and specifications;**
- **assessing the evidence to support the verification of the design performance;**
- **proposing improvements.**

Design review facilitates assessment of the status of the design against the input requirements, identification of opportunities for improvement and guides the design manager towards appropriate action. It accelerates maturing of the product by reducing the time needed to stabilize design details, and allows product realization to proceed without frequent interruptions. Design review can also stimulate early product improvement.



Audit Essentials

What are you Looking for?

- 8.3.5 – Design Outputs
 - Configuration Information - Complete and approved
 - Drawings, specifications, acceptance testing
 - Information needed to manufacture
 - Maintenance requirements (as applicable)
 - ALL configuration information (reports, qualification, analysis, etc.)
- 8.3.6 – Design Changes
 - ANY change to configuration information
 - Customer notification and approval according to design Authority



Have you been listening?

FuelCo is a manufacturer of Fuel control valves for various industries.

They sell both special and catalogue fuel control valves

They have designed a special fuel valve for biomass aviation fuel (BMAF) and are now offering that valve for sale.



Fuelco has had interest from several AS&D organizations and hence became AS9100 certificated by Global Certification Body (GBC)

They have contracts with the following AS&D organizations and applications;

- Eurocontrols – for application in a new fuel control to be used in a new Volvo Engine yet to be certificated for commercial aircraft use
- DefCopter – for use in an existing military helicopter with converted fuel
- Fuel Supply – A Distributor to aviation manufacturers



Have you been listening?

Question 1

Who is the Design Authority for each of the following customers?



- Eurocontrols – for application in a new fuel control to be used in a new Volvo Engine yet to be certificated for commercial aircraft use
- DefCopter – for use in an existing military helicopter with converted fuel
- Fuel Supply – A Distributor to civil and defense aviation manufacturers



Have you been listening?

Question 2

FuelCo has completed all required testing for the valve per the Requirements FuelCo established for the valve. Is this valve fully approved and qualified?



- Eurocontrols – for application in a new fuel control to be used in a new Volvo Engine yet to be certificated for commercial aircraft use
- DefCopter – for use in an existing military helicopter with converted fuel
- Fuel Supply – A Distributor to civil and defense aviation manufacturers



Have you been listening?

Question 3

According to Design Requirements and CM rules FuelCo has identified the BMAF valve as part number FC4376BM-A for all Sales

Is this acceptable?

- Eurocontrols – for application in a new fuel control to be used in a new Volvo Engine yet to be certificated for commercial aircraft use
- DefCopter – for use in an existing military helicopter with converted fuel
- Fuel Supply – A Distributor to civil and defense aviation manufacturers



Have you been listening?

Question 4

FuelCo decides to license the BMAF fuel valve design and manufacture to HighTech Mfg (HTM) because the market volume is too low for Fuelco's market strategy.



HTM is required to be AS9100 certificated and has a limited engineering staff to support the manufacturing and maintain the drawings for Fuelco who still sells the item in it's catalogue but HTM has direct sales to the other customers.

HTM states in it's QMS documentation that Design and Development is not applicable. They justify this because they are not the design authority and no changes can be made even though they maintain the design information

Can this be acceptable?



Have you been listening?

Question 5

FuelCo decides to license the BMAF fuel valve design and manufacture to HighTech Mfg (HTM) because the market volume is too low for Fuelco's market strategy.



HTM is required to be AS9100 certificated and has a limited engineering staff to support the manufacturing and maintain the drawings for Fuelco who still sells the item in it's catalogue but HTM has direct sales to the other customers.

HTM does not have the same equipment or manufacturing methods as FuelCo for the housing or valve components so they create a complete set of process drawings for the machining and manufacture of component parts.

Is Clause 8.3 applicable because of these drawings?



Have you been listening?

Question 6

HTM decides to go into the repair business for fuel control valves and obtains an FAA Part 145 repair station approval and also obtains AS9110 certification for their MRO activities. As part of the repair of BMAF valves they have a repair method for the replacement of broken lead wires when they perform maintenance on returned valves.



Is clause 8.3 applicable to HTM under AS9110?



Have you been listening?

Question 7

Fuel Supply the distributor for the BMAF valves to the AS&D industry has entered into a contract to manage the FuelCo finished goods inventory for all of FuelCo valves. They will accept and process orders for FuelCo and ship directly to FuelCo customers for a percentage of the sales. They also have propriety software they are using to manage the inventory and estimate the demand to control the production schedules for HTM. Fuel Supply is AS9120 certificated.



Is clause 8.3 applicable to Fuel Supply under AS9120?



Clause 8.3 Summary

- AQMS Design and Development is not “simple”
 - The critically the application vs the process for development
 - The responsibility for design approval and changes
 - The relationship between design approval holders and product manufacturers
 - Commercial parts vs. designed application parts
 - Configuration management
 - Design in the lifecycle of the product (aftermarket)



Abundantly Clear? Questions?





TRANSITION TOGETHER

