Available online at www.sciencedirect.com

ScienceDirect

Procedia Engineering 80 (2014) 565 – 572

Procedia Engineering

www.elsevier.com/locate/procedia

3rd International Symposium on Aircraft Airworthiness, ISAA 2013

Analysis of relationship between quality management system and design assurance system

Zhao Zhang[a*], Tao Song[a], Jiashan Song[a],

[a]*Airworthiness Technology Research and Management Center, China Aero-Polytechnology Establishment, AVIC Jingshun Rd. 7, Chaoyang District, Beijing, 100028, China*

Abstract

To assure customer satisfaction, the aerospace design organization must establish its own quality management system to demonstrate that its capabilities to produce, and continually improve, safe, reliable products meet or exceed customer. At the same time, the design organization must establish the design assurance system for obtaining the design organization approval (DOA). Both of these documented systems should be prepared for new design organizations, such as Commercial Aircraft Corporation of China, Ltd. (COMAC). After presenting these two systems in detail, the relationship between them are analyzed and concluded. This article suggests that the new design organization could optimizer their own structure for making some saving costs during requesting the certifications of DOA and AS9100.

Selection and peer-review under responsibility of Airworthiness Technologies Research Center, Beihang University/NLAA.

Keywords: Quality management system; Design assurance system; Design organizaiton

Nomenclature

COMAC	Commercial Aircraft Corporation of China, Lt
DAS	Design Assure System
DOA	Design Organization Approval
QMS	Quality Management System

* Corresponding author, M.Sc. Tel.: +86-188-1105-1781; fax: +86- 6468-2871.
E-mail address: zhangzhao423@126.com.

Selection and peer-review under responsibility of Airworthiness Technologies Research Center, Beihang University/NLAA.
doi:10.1016/j.proeng.2014.09.112

1. Introduction

According to provisions of EASA Part 21 Subpart G and J, the competent authority verify on the basis of the exposition and by appropriate investigations that the design organization has established and can maintain their documented DAS. It is also known that AS9100 has been resulted as a cooperative effort of the International Aerospace Quality Group and AS9100 standard is the internationally recognized quality management system requirements specific to the aerospace industry. As the important aerospace industry organizations, such as Airbus, they already have obtained respectively the certification of DOA and AS9100.

In this paper, we discuss the design organizations which have not yet obtained the DOA and certification of QMS and which are prepared to request the DOA and AS9100 certification, such as COMAC. The design organization here is considered as an organization producing the data for aircraft and related products (aircraft engine or propellers), parts and appliances that needs airworthiness approval. This is not limited to the design office but includes other departments and partners/subcontractors.

It is all known that the procedures of certifications need a lot of resources and costs. The design organizations begin to consider if there is a possibility to simplifier these two systems with the help of EASA. In addition, the Industry seeks to optimize its own organizational structures and try to do a better coordination among the different functions for making some improvements.

Indeed, the theoretical relationship between the design assurance system and the quality management system is presented and analyzed at first. After studying the true case of other mature design organizations, this paper proposes to COMAC an optimized method for preparing its own quality management system and design assurance system.

2. Quality management system (QMS)

The quality system is an organizational structure with responsibilities, procedures, processes, and resources which implement a management function to determine and enforce quality principles. A quality system sets out the standards that you are working to, and how you are going to meet them. The system should define what people, actions and documents are going to be employed in order to carry out the work in a consistent manner, leaving evidence of what has happened.

A QMS enables an organization to achieve the goals and objectives set out in its policy and strategy. It provides consistency and satisfaction in terms of methods, materials, equipment, etc, and interacts with all activities of the organization, beginning with the identification of customer requirements and ending with their satisfaction, at every transaction interface. There are two types of 'management' - management of organizations and management of activities (delivery of research projects, of processes, etc).

The quality system should be documented in such a way that the documentation can be made easily available to personnel who need to use the material for performing their normal duties, in particular:

- Procedures, instructions, data to cover the issues of 21A.139 (b)(1) are available in a written form, distribution of relevant procedures to offices/persons is made in a controlled manner;
- Procedures which identify persons responsible for the prescribed actions are established;
- The updating process is clearly described.

2.1. QMS requirements – AS/EN 9100

To assure customer satisfaction, aviation, space and defense organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and

national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations. AS/EN9100 standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Indeed, AS9100 certification has already become the basic requirement demanded by all these companies to their suppliers.

The AS9100 standard includes extensive supplementation in design-and-development functions due to complexity of aerospace products and customers' expectations for reliable performance during a protracted period of time. The standards cover planning for design-and-development activities and ensuring interim control points during the design process. Design outputs are supplemented to provide identification of key characteristics, and the data essential for the product that will be identified, manufactured, inspected, used and maintained is detailed.

Implementing AS9100 will motivate staff by defining their key roles and responsibilities. Cost savings can be made through improved efficiency and productivity as product or service deficiencies will be highlighted. From this, improvements can be developed, resulting in less waste, inappropriate or rejected work and fewer complaints. Customers will notice that orders are met consistently, on time and to the correct specification. This can open up the market place to increased opportunities. An additional benefit due to the standardized processes and procedures is the reduction in multiple expectations due to the consistency in verification.

2.2. Elements of QMS

There are several elements to a quality system, and each organization is going to have a unique system. The most important elements of a quality system include participative management, quality system design, customers, purchasing, education and training, statistics, auditing, and technology. The elements that are identified as difficult to implement are: corrective and preventive actions, design control, management responsibility, statistical techniques, process control, document and data control and quality system.

A QMS must ensure that the products/services conform to customer needs and expectations, and the objectives of the organization. Issues to be considered when setting up a QMS includes its:

- Design
- Build
- Control
- Deployment
- Measurement
- Review
- Improvement

The tool of QMS is an independent assessment of a procedure called an audit. Audit is a sampling process looking for independent confirmation that standards have been met, so it provides a snap shot of the scene rather than continuous footage. The quality of the process or its outputs must not depend on audit.

2.3. Quality control

Quality control is a pivotal part of the QMS. The quality of the process depends directly on quality control. Quality control is undertaken by those performing, managing or supervising the process to ensure that the required standards have been met. Quality control comprises routine procedures by the personnel

1. to ensure that the design of the products, parts and appliances or the design change thereof, comply with the applicable type-certification basis and environmental protection requirements; and
2. to ensure that its responsibilities are properly discharged in accordance with:
   (i) the appropriate provisions of this Annex I (Part 21); and
   (ii) the terms of approval issued under point 21.A.251;
3. to independently monitor the compliance with, and adequacy of, the documented procedures of the system. This monitoring shall include a feed-back system to a person or a group of persons having the responsibility to ensure corrective actions.

(b) The design assurance system shall include an independent checking function of the showings of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency.

(c) The design organization shall specify the manner in which the design assurance system accounts for the acceptability of the parts or appliances designed or the tasks performed by partners or subcontractors according to methods which are the subject of written procedures.

3.2. Design function

The discharge of the responsibilities associated with the design function includes the accountabilities, delegations of powers, powers of attorney, delegation of authority. In accordance with Part 21, the head design office has the responsibility for all parts of the organisation producing the data for aircraft and related products, parts and appliances that needs airworthiness approval. Therefore in this position he acts on behalf of the company:

- To determine that the design of products; changes and repairs thereof comply with the applicable requirements and have no unsafe features;
- To submit to the Authorities statements and associated documentation to confirm the compliance with the applicable requirements;
- To establish and maintain the design organisation Manual that identifies the organisation, responsibilities, procedures and signatories in accordance with Part 21 DOA related requirements;
- To ensure that the design organisation manual is applied by all involved personnel whether reporting directly or indirectly to him.

3.3. Airworthiness function

An Office of Airworthiness, or equivalent function, has been established and staffed on a permanent basis to act as the focal point for co-ordinating airworthiness and environmental protection matters; it reports directly to the head of the Design organisation or is integrated into an independent quality assurance organisation reporting to the Head of the Design Organisation.

A basic common responsibility within all of the Office of Airworthiness teams is to develop and perform Airworthiness training courses for their respective working area. This group is responsible for ensuring that the international requirements for airworthiness and certification are treated consistently. The group leads the certification panel activities for new or amended type certification and changes to the type design. In addition, Airworthiness Standards has a leading contribution to the involvement in the international rulemaking activities.

3.4. Independent System Monitoring.

undertaking a process, or others, to check and ensure that the process meets defined requirements. These checking, inspection and surveillance activities form part of the QMS. Quality control may also involve external quality control systems and inter-laboratory testing to demonstrate that processes are providing comparable results between organizations.

Every QMS should have clearly-defined and appropriate quality control systems. The output from quality control activities should be reviewed to indicate the degree of adequacy of performance and also to monitor trends where there is improvement or deterioration. The operational techniques and activities undertaken within the quality system verify that the requirements for quality of the activities have been fulfilled. This includes overseeing the progress of an activity, and of ensuring that it is conducted, recorded, and reported in accordance with the standards defined.

2.4. Quality assurance

All those planned and systematic actions that are established to ensure that the activity is performed and the data are generated, documented (recorded), and reported in compliance with stated standard operating procedures. This includes a systematic and independent examination of activity related activities and documents to determine whether the evaluated related Activities were conducted, and the data were recorded, analyzed and accurately reported according to the standards defined.

Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the user. Thus, quality assurance is just one part of a quality system. A quality system provides the framework for developing quality assurance policy and management controls.

Quality assurance may use similar techniques to quality control but the fundamental difference is that quality assurance is independent of the activities that are being audited. Quality assurance is a management or oversight function; it deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making.

3. Design assurance system (DAS)

The DAS is the organizational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organization in accordance with the provisions laid down in the European Commission Regulation (EC) No748/2012 annex Part21 and its corresponding acceptable means of compliance and guide material. It is described in the design organization manual directly or by cross reference to relevant procedures. In addition, the DAS is based upon three distinct functions: design function, airworthiness function and independent monitoring function.

This DAS outlines the arrangements and procedures designed to provide and maintain the design efficiency essential to the organization's competitiveness and to achieve compliance with statutory airworthiness, safety, quality and reliability requirements.

3.1. Airworthiness requirements

Specific airworthiness requirements about DAS are given in EASA Part 21.A.239 as follows:

(a) The design organization shall demonstrate that it has established and is able to maintain a design assurance system for the control and supervision of the design, and of design changes, of products, parts and appliances covered by the application. This design assurance system shall be such as to enable the organisation:

1. to ensure that the design of the products, parts and appliances or the design change thereof, comply with the applicable type-certification basis and environmental protection requirements; and
2. to ensure that its responsibilities are properly discharged in accordance with:
   (i) the appropriate provisions of this Annex I (Part 21); and
   (ii) the terms of approval issued under point 21.A.251;
3. to independently monitor the compliance with, and adequacy of, the documented procedures of the system. This monitoring shall include a feed-back system to a person or a group of persons having the responsibility to ensure corrective actions.

(b) The design assurance system shall include an independent checking function of the showings of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency.

(c) The design organization shall specify the manner in which the design assurance system accounts for the acceptability of the parts or appliances designed or the tasks performed by partners or subcontractors according to methods which are the subject of written procedures.

3.2. Design function

The discharge of the responsibilities associated with the design function includes the accountabilities, delegations of powers, powers of attorney, delegation of authority. In accordance with Part 21, the head design office has the responsibility for all parts of the organisation producing the data for aircraft and related products, parts and appliances that needs airworthiness approval. Therefore in this position he acts on behalf of the company:

- To determine that the design of products; changes and repairs thereof comply with the applicable requirements and have no unsafe features;
- To submit to the Authorities statements and associated documentation to confirm the compliance with the applicable requirements;
- To establish and maintain the design organisation Manual that identifies the organisation, responsibilities, procedures and signatories in accordance with Part 21 DOA related requirements;
- To ensure that the design organisation manual is applied by all involved personnel whether reporting directly or indirectly to him.

3.3. Airworthiness function

An Office of Airworthiness, or equivalent function, has been established and staffed on a permanent basis to act as the focal point for co-ordinating airworthiness and environmental protection matters; it reports directly to the head of the Design organisation or is integrated into an independent quality assurance organisation reporting to the Head of the Design Organisation.

A basic common responsibility within all of the Office of Airworthiness teams is to develop and perform Airworthiness training courses for their respective working area. This group is responsible for ensuring that the international requirements for airworthiness and certification are treated consistently. The group leads the certification panel activities for new or amended type certification and changes to the type design. In addition, Airworthiness Standards has a leading contribution to the involvement in the international rulemaking activities.

3.4. Independent System Monitoring.

The system monitoring function may be undertaken by the existing quality assurance organisations when the design organisation is part of a larger organisation. The organisation should establish the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective. It can keep the continued effectiveness of the DAS.

The independent checking function of the showing of compliance should consist of the verification by a person not creating the compliance data. Such person may work in conjunction with the individuals who prepare compliance data. The verification should be shown by signing compliance documents, including test programmes and data.

The efficiency of the DAS shall be ensured by the independent monitoring function covering:

- Design assurance activities,
- Design management review,
- Design assurance reviews of third parties.
- Programmed audits.
- Day to day monitoring of routine tasks.
- Report DAS deficiencies and propose DOA solution to head of design Organisation.

4. Application at COMAC

COMAC is a Chinese state-owned aerospace manufacturer established on 11 May 2008 in Shanghai, China. It functions as the main vehicle in implementing large aircraft programs in China and it is also mandated with the overall planning of developing trunk liner and regional jet programs and realizing the industrialization of civil aircraft in China. The operations general directorate of COMAC is in charge of the design, manufacturing, procurement and quality. The company endeavors to manufacture large passenger aircraft that are safe, economical, comfortable and environmentally friendly.

With the globalization of the aerospace industry, COMAC is considering requesting the certification of DOA. COMAC needs establish a design assurance system with the purpose of ensuring that the design of its products complies with the applicable regulations. At the same time, the Certification AS9100 of QMS has become obligatory and COMAC is preparing establishing its own quality management system.

From the airworthiness point, there are no requirements for quality management system to design organization. But from the management aspect, it's necessary to have a QMS to assure the customers. These documented systems are related and the following section gives the relationship in details.

4.1. Establishment of DAS and QMS

The establishment of DAS and QMS could consider the following notes:

The design assurance system is fundamentally based on the quality System which consists of:

- Organisation manual for all departments
- Manuals describing design procedures and practices
- Design Review Procedure

The quality system requires performing the necessary design reviews to:

- Consider other design alternatives;
- Assure that the design meets the contractual requirements and the applicable regulations.
- Assure that the design can be manufactured, inspected, tested, installed, operated and maintained to the customer's satisfaction.

The quality system is described in the quality system manual and requires that periodic audits are conducted in order to assess the effectiveness of the system. It includes a corrective action procedure that assures that corrective actions are taken to correct the non conformances detected in the audits.

4.2. Audit

The programmed DOA audits are managed by the DOA manager "Surveillance" and executed through the Quality function. Execution of audits contained within the surveillance plan is allocated to the quality function when the audit is included in the "General Engineering Surveillance Plan" established by the quality function. Execution is allocated to the quality function of the relevant department when the audit is outside of engineering.

The DOA audit needs are identified by the DOA manager. The audit team leader distributes DOA audit reports to all involved parties, including the quality department. The programmed audits covering DOA requirements are performed by quality using the audit system.

4.3. Suppliers and Partners/Sub-contractors.

In meeting the requirement of Part 21A.139 (c), the applicant for a DOA may adopt the following policy in working/controlling their partners/sub-contractors.

i). The satisfactory integration of the partners/sub-contractors and applicant's design assurance systems should be demonstrated for the activities covered under the applicant"s terms of approval.

ii). In the event that a partners/sub-contractor holds a DOA, the applicant may take this into account in demonstrating the effectiveness of this integrated system.

iii). When partners/sub-contractors does not hold a DOA then the applicant will need to establish to its own satisfaction, the adequacy of that partner"s/sub-contractor"s design assurance system in accordance with design organization manual.

Design activities covered by Part 21.239 (c) include:

- Aircraft systems and equipments that are furnished by suppliers according a Purchaser Technical Specification.
- Industrial subcontracting and in particular: the full subcontracting where both production and design of an A/C part are subcontracted.
- Each of these activities has their own industrial constraints which lead to specific design assurance and quality procedures with some shared concepts of:
    1. Initial qualification of the supplier/part or task couple and continuous surveillance of this qualification under Quality department responsibility;
    2. Emission of technical specifications under design office responsibility;
    3. « product » verification including design reviews and qualification as applicable under design office responsibility;
    4. One technical focal point in the design organisation for each part or task.

4.4. Recommendations

COMAC will benefit from establishing an effective QMS. Certain mission and responsibilities of COMAC quality department are as follows:

- to respect and promote the deployment of COMAC QMS and all functional policies, guidelines, rules and regulations;
- to ensure the effectiveness of the Engineering Quality Management System.

The quality control department participates also at the hand-over transfers from POA to DOA and DOA to POA. All managers, not just the staff in the "quality department", need to be fully committed to operating an effective quality management system for all the people within COMAC. The system must be

planned to be effective and achieve its objectives in an uncomplicated way. It should also not be static, but be flexible, to enable constant seeking of improvements.

The Design Office should be established to:

- Maintain & develop core competences for all aircraft design domains;
- Deliver mature solutions that match product objectives and requirements;
- Pro-actively contribute to the Company business development objectives;
- Ensure sound exercise of its technical authority.

To lead and coordinate the certification and continued airworthiness processes, COMAC needs to set up a transnational office of airworthiness. The Chief Engineer carries out the design responsibilities primarily through ensuring the application of engineering standard of quality and engineering policies and the applicable product assurance procedures.

5. Conclusions

From this study, it can be concluded that during establishing the QMS and DAS, the design organization could optimizer its own structure, especially in the aspect of suppliers and subcontractors, audits etc. However, the suggestions in this article are just as references. In practice, the new design organizations should consider the actual situation and these recommendations only as a reference.

References

[1] Branislav TOMIĆ, Vesna SPASOJEVIĆ-BRKIĆ, Milivoj KLARIN. Quality management system for the aerospace industry. JEMC Vol.2, No.1, 2012,11-15

[2] EN9100 Quality Management Systems – Requirements for Aviation, Space and Defense Organizations

[3] European Commision Regulation (EU) No748/2012 Annex1 Part21