DEVELOPEMENT OF A PRODUCTION ORGANIZATION EXPOSITION SCHEME TAKING INTO ACCOUNT EN9100 REQUIREMENTS

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Abstract

This comparison paper includes a new approach to adopt structure of Production Organization Exposition [POE] *required under European Aviation Safety Agency (EASA) Part 21-G requirements taking into account implications of EN9100 standard. The aim is to develop a new model of POE in line with EN9100 in order to reduce the work load of those companies which have EN9100 certification and are looking for a production organization approval in accordance with Subpart G of EASA Part 21. It covers evaluation of organization, facilities, personnel and product. The last but not the least the paper presents the situation of Industry face to authority requirements. This defines for each important topic covering the regulation, differences and similarities and then a harmonization which ends up with the proposal of common structure of procedures of POE including specific requirements of EASA Part 21-G.*

1 General Introduction

There are two systems for recognition of production organization. Industry system based on EN9100 requirements and authority system based on EASA Part 21-G requirements. These two systems have large parts of common requirements and some items specific to each system which would be discussed in section 4.

2 Authority system for production organization approval

ICAO is an international organization related to aviation safety created in 1944 after the Second World War. Its aim was setting up international standards for air safety to solve sovereignty problems over the airspace above each country, regulate network air routes for international flights and ensure an acceptable level of safety. These standards are published by ICAO under 18 annexes. According to annex 8 which includes requirements for airworthiness of aircraft, each State should impose aircraft production surveillance in accordance with government-approved method.

In Europe the certification procedures for aircraft and associated products like engine and propeller and parts were in JAR 21 which by creation of EASA, in Sep 2003 was replaced by Part 21.

According to this regulation there are two options for Production organization approval described in Subpart F and G of Part 21.

2.1. Production authorization

This method which is regulated by Subpart-F is applicable to companies with an inspection system but no quality system (small companies) when there is no flow production and a simple technology is involved or a transition to subpart G approval is requested.

In this case conformity documents for aircraft or components and spares are signed by the authority. [1]

2.2. Production Organization Approval

This method which is regulated by Subpart-G is based on recognition of quality systems and is a tool for the authority to accept from the approved organization “statements” that products, parts and appliances are in “conformity” with “approved design”.

It is also an acknowledgement of the capacity of company to manufacture products and their components, in accordance with a reference definition, approved in the case of delivery to operation and to maintain new products and their components. The company has the following privileges:

Performing production activities under subpart-G

Obtaining the aircraft individual certificate of airworthiness from the authority in view of the conformity certificate signed by the organization

Issuing EASA Form 1 for components and spares

Approving for return to service following work on a new aircraft or components.[1]

3 Industry system for production organization

IAQG is an organization who establishes and maintains a dynamic cooperation based on trust between international aerospace companies on initiatives to make significant improvement in quality and reductions in cost throughout the value streams .Its processes are established in a set of agreed, documented, operational procedures .Its objectives are:

Establishing commonality of quality standards & requirements

- Common aerospace basic quality systems
- Best practices in aerospace industry
- Performance metrics
- Establishing process of continuous improvement at suppliers
- Establishing methods to share results:
- Audits
- Inspections
- Supplier performance

Coordinate initiatives and activities with regulatory and government agencies and other industry stakeholders interests.

3.1. International aerospace quality standard (IAQS 9100)

This standard lays down ISO 9001:2000 quality management system requirements and specifies additional requirements for the aerospace industry. Quality management system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements. It is a worldwide reference in the quality systems compared to Part 21-G applicable only in Europe. It includes the eight quality management principles defined in ISO 9000:2000 which is described as Customer focus, Provide leadership, Staff involvement, Process approach, System approach, Continual improvement, Factual approach to decision taking, Cooperation with suppliers.[2]

4 Result of comparison

Results are divided into 2 sections: common and non-common items.

4.1. Common items [2]

4.1.1. General

Needs to demonstrate company ability to consistently provide product that meets customer and applicable regulatory requirements

Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements

Requirements are generic and are intended to be applicable to all organizations, regardless of type, size and product provided

In the case of exclusions , claims of conformity to requirements are not acceptable unless these exclusions are limited in the way that they can not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements

4.1.2. Quality system

Establish, document, implement and maintain a quality system / quality management system and continually improve its effectiveness

4.1.3. Documentation

Documented procedure for required activity

Records

Quality system documentations

Accessibility of personnel, customer and regulatory authority representative to documentation system

Documents can be in any form

Establishing documented procedure to define the controls needed

- To approve documents for adequacy prior to issue,
- To review and update as necessary and re-approve documents,
- To ensure that changes and the current revision status of documents are identified,
- To ensure that relevant versions of applicable documents are available at points of use,
- To ensure that documents remain legible and readily identifiable,
- To ensure that documents of external origin are identified and their distribution controlled, and

Coordination of document changes with customers and/or regulatory authorities

Control of records

Availability of records to customer and regulatory authority

4.1.4. Management responsibility

Top management commitment to the development and implementation of the quality system and continually improving its effectiveness by establishing the quality policy and ensuring availability of resources.

Top management shall ensure quality policy is appropriate to the purpose of the organization and comply with requirements and continual effective improvement of the quality system.

Top management shall ensure that responsibilities and authorities are defined and communicated inside organization

Top management responsibility shall ensure processes needed for the quality system are established, implemented and maintained and ensure organization freedom to resolve matters pertaining to quality, is in receipt of quality system performance and any required improvement and is in liaison with external parties on the matter relating to the quality system.

Top management shall review customer feedback, follow-up actions from previous reviews, changes affecting quality system and recommendations for improvement.

4.1.5. Resource management

Provision of resources

Human resources

- Determine the necessary competence for personnel performing work affecting product quality
- Provide training or take other actions to satisfy these needs
- Evaluate the effectiveness of the actions taken
- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- Maintain appropriate records of education, training, skills and experience

Infrastructure

- Buildings, workspace and associated utilities

- Process equipment (both hardware and software)
- Supporting services (such as transport or communication)

Work environment

4.1.6. Product realization

Planning

- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
- Records needed to provide evidence that the realization processes and resulting product meet requirements

Determination of requirements related to the product

Purchasing

- Verification of purchased product through
- Inspection and audits at the suppliers permits
- Review of required documents
- Inspection of product upon receipt
- Delegation of verification to the suppliers
- Obtaining objective evidence of quality of product like certificate of conformity, test reports, statistical records
- Responsibility of organization against purchased product
- Evaluation and re-evaluation of suppliers
- Record results of evaluation
- Maintain a register of approved suppliers
- Define necessary actions for non conformity of suppliers
- Ensure using of customer approved special processes
- Ensure functions for disapproving use of supplier quality system in the case of non conformity
- Purchasing Information shall describe the product to be purchased

Production and service provision

- Establishment of process controls and developments of control plans where key characteristics have been identified
- Availability of information that describes the characteristics of the product
- Use of suitable equipment
- Availability and use of monitoring and measuring devices
- The implementation of release and delivery
- Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized
- Drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards) and inspection documents

And identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements

Control of production equipment, tools and numerical control (N.C.) machine

Programs

Control of work transferred, on a temporary basis, outside the organization's

facilities

A method of collecting and analyzing in-service data

Actions to be taken where problems are identified after delivery, including

investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements

The controls required for off-site work (e.g., organization's work undertaken at

the customer's facilities)

- The organization shall establish arrangements for special processes including as applicable:
- Defined criteria for review and approval of the processes, qualification and approval of special processes prior to use
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures to control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto

- Requirements for records
- Revalidation
- Identification and traceability
- Where appropriate, the organization shall identify the product by suitable means throughout product realization

- The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration

- The organization shall identify the product status with respect to monitoring and measurement requirements

- Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4)

- Identification should be maintained throughout the product life

- Preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage, control of monitoring and measuring devices

- Where necessary to ensure valid results, measuring equipment shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards

4.1.7. Measurements, analysis and improvement

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- To demonstrate conformity of the product

- To continually improve the effectiveness of the quality management system

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process

Auditors shall not audit their own work

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes

Internal audits shall meet contract and/or regulatory requirements

Record of measurement results

First article inspection

Control of non conforming product

- Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained

- When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity

- In addition to any contract or regulatory authority reporting requirements, the organization’s system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

- Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities

Analysis of data

- The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources

- The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall

be appropriate to the effects of the nonconformities encountered and should be documented.

4.2. Non common items [1] ,[2]

There are 2 categories of non common items, one which is specific to requirements of Part 21-G, another are items specific to EN9100 which are useful in support of Part 21-G.

4.2.1. Definition

Differences in the terms of definitions between both requirements are:

Part 21-G

Product- Aircraft, Engine, Propellers
Part/appliances-
Quality concept
Supplier and sub-contractor
Applicable design
Technical customer
Certifying Staff
Key Characteristics

EN9100

Product- Production of company and its service
Part/appliances What is not defined as product and kept under same name of product
Quality management system
Processes
Commercial customer

4.2.2. Application

Part 21-G

Company should have eligibility of applying for Production Organization Approval.

EN9100

All requirements of this international standard are applicable to all organizations regardless of type, size and product provided.

4.2.3. Quality system

Part 21-G

Quality system is based on the previous ISO which is asking a plain level of activities all documented procedures.

EN9100

Quality management system based on new ISO by modern concept of management is identifying organization activities into processes and sub-processes and where is needed some documented procedures to describe activities of those processes. Then organization shall

- Determine interaction of processes.
- Check the operation-ability and monitor-ability of processes.
- Ensure availability of resources to support those processes.
- Measure effectiveness of processes in order to implement continual improvement.

4.2.4. Documentation

Part 21-G

Control procedures of quality system required by 21A.139

Documented procedures of POE required by 21A.143 and amendment procedures for it.(28 procedures)

A distribution list for control of procedure should be established

Definition of archiving periods depends on essentiality of data for continuous airworthiness or data for the conformity of product

No limitation for the accessibility of records

EN9100

Documented state of quality policy and objective

Quality Manual

Internal documents needed by organization to ensure effective planning, operation and control of its processes (7 documented procedures)

Same archiving period for data concerning continuous airworthiness and data supporting conformity of product

Access to records in accordance with contract / regulatory requirements

Documented procedures control preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.5. Management responsibility

Part 21-G

Management commitment for implementation of POE by designation of an accountable manager responsible to the authority

Acceptance of managers by the authority and showing their competency through EASA Form Four

Showing associated chain of responsibility of managers by organizational chart

Designation of quality manager and its special responsibilities under request of Part21 Subpart-G

EN9100

Customer focus with aim of enhancing costumer satisfaction

Commitment of top management against quality policy ,quality objectives and quality management system planning

Management review to ensure suitability, adequacy and effectiveness of quality management system and its inputs and outputs

4.2.6. Resource management

Part 21-G

A general description of man power resources is needed

Certifying staff

Documented procedures for competence, awareness and training, certifying staff and infrastructure are needed.

EN9100

Necessary competence for all personnel performing work affecting product quality

Provide resources needed to enhance costumer satisfaction

4.2.7. Product realization

Part 21-G

Production flight test as a means of verification and validation

Keep up to date data for all necessary airworthiness, noise and fuel…and make them available to all personnel

Establish link between design and production

Establish an arrangement for full access of authority to organization ,its partner and supplier or subcontractor for determination of compliance and continued compliance in purchasing information

Documented procedures for all POE and quality system requirements

Work carried out after completion of product

EN9100

Planning of product realization as a process which is consistent with the requirements of the other processes of the quality management system

to define quality objectives and requirements for the product

to establish process , document provide resources specific to the product and to support operation and maintenance of product

Customer related process (determination of requirements related to product, review of requirements and customer communication)

Processes and necessary documented procedures for product realization such as

monitoring and measuring devices

preservation and protection

service provision and its control

identification and traceability

changes affecting processes

4.2.8. Measurement, analysis and improvement

Part 21-G

Check adequacy of documented procedures

Release of product under specific EASA forms

Findings by authority

Time limitation for corrective actions depends on the level of findings

EN9100

To ensure conformity of quality management system

Using statistical techniques to support

design verification

process control

selection and inspection of key characteristics

inspection

process capability measurements

design of experiment

statistical process control

Customer satisfaction

Detailed tools and techniques to support audit requirements and their acceptability

Dealing with non conformity and its relative corrective action through processes

Control and monitoring of key characteristics

Positive-recall procedures

Inspection documentation

Continual improvement

Preventive action

Non conformity

found by organization

included return product from customer

eliminate detective non conformity

release or acceptance under concession

Precluding its original intended use / application

4.2.9. Terms or scope of approval

Part 21-G

The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise its given privileges

4.2.10. Changes to the production approval

Part 21-G

Significant changes which should be approved by the competent authority include:

- Significant changes to production capacity or methods.

- Changes in the organisation structure especially those parts of the organisation in charge of quality.

- A change of the accountable manager or of any other nominated manager.

- Changes in the production or quality systems that may have an important impact on the conformity/airworthiness of each product, part or appliance.

- Changes in the placement or control of significant sub-contracted work or supplied parts.

- Changes of location of manufacturing facilities

- Changes of the terms of approval

- Change in ownership

The organization shall demonstrate to the Competent Authority before implementation of the change that it will continue to comply with Subpart G of Part 21. No such precise requirements exist in EN9100.

4.2.11. Duration and continued validity

Part 21-G

A production organization shall make arrangements that allow the Competent Authority to make any investigations necessary to determine compliance and continued compliance with the applicable requirements of Subpart G of Part 21. The organization shall provide all needed assistance to the competent authority in the investigation process.

Duration /Continued validity

- A production organization approval issues for an unlimited duration .It shall remain valid unless it is surrounded, suspended or revoked under special conditions. Upon surrender or revocation, the certificate shall be returned to the Competent Authority. No such precise requirements exist in EN9100.

5 New common structure procedure of POE

A color code is used to facilitate understanding for readers. Common items are specified in blue, added items specific to Part 21-G are underlined in red format and the rest in black are items specific or items more precise in EN9100 which are in support of Part 21-G.

For all the items directly required in POE, the reference of Part 21-G items is added (POE, Ref XXX):

1.Introductions

2.Description part

3.General organization of company

4.Quality management system

4.1 General requirements

4.2 Documentation requirements

4.2.1. General

4.2.2. Quality manual (POE, Ref 21A.143 (a) (11)

4.2.3. Control of documents (POE, Ref 21A.139 (b) (1) (i)), (POE, Ref 143(a) (10))

4.2.4. Control of records (POE, Ref 21A.139 (b) (1) (x))

4.3 Configuration management

5.Management responsibility

5.1 Management commitment (POE, Ref 21A.143 (a) (1))

5.2 Customer focus

5.3 Quality policy (POE, Ref 21A.143 (a) (1))

5-.4 Planning

5.4.1 Quality objectives

5.4.2 Quality management system planning

5.5 Responsibility, authority and communication (POE, Ref 21A.143 (a) (2), (a) (3), (a) (4))

5.5.1 Responsibility and authority

5.5.2 Management representative

5.5.3 Internal communication

5.6 Management review

5.6.1 General

5.6.2 Review input

5.6.3 Review output

6.Resource management

6.1 Provision of resources

6.2 Human resources

6.2.1 General (POE, Ref 21A.143 (a) (6))

6.2.2 Competence, awareness and training (POE, Ref 21A.139 (b) (1) (xi))

6.2.3 Certifying staff (POE, Ref 21A.139 (b) (1) (xi)) & (21A.143 (a) (5))

6.2.3.1 Responsibilities

6.2.3.2 Qualification/Training

6.2.3.3 List of certifying staff

6.2.3.4 Records

6.2.3.5 Authorization document

6.3 Infrastructure (POE, Ref 21A.143 (a) (7))

6.4 Work environment

7.Product realization

7.1 Planning of product realization (POE, Ref 21A.139 (b) (1) (vi))

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

7.2.2 Review of requirements related to the product

7.2.3 Customer communication

7.2.4 Link between design and production (POE, Ref 21A.139 (b) (1) (ix))

7.3 Design and development (reserved)

7.4 Purchasing (POE, Ref 21A.139 (b) (1) (ii), (iii))

7.4.1 Purchasing process (POE, Ref 21A.143 (a) (12))

7.4.2 Purchasing information

7.4.3 Verification of purchased product

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.1.1 Production documentation

7.5.1.2 Control of production process changes

7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs

7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities (POE, Ref 21A.139 (b) (1) (xv))

7.5.1.5 Control of service operations (POE, Ref 21A.139 (b) (1) (xv))

7.5.1.6 Work carried out after product completion (POE, Ref 21A.139 (b) (1) (xvi)

7.5.2 Validation of processes for production and service provision (POE, Ref 21A.139 (b) (1) (v))

7.5.3 Identification and traceability (POE, Ref 21A.139 (b) (1) (iv))

7.5.4 Customer property (optional)

7.5.5 Preservation of product (POE, Ref 21A.139 (b) (1) (xiii))

7.6 Control of monitoring and measuring devices (POE, Ref 21A.139 (b) (1) (vii))

8.Measurement, analysis and improvement

8.1 General

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

8.2.2 Internal audit (POE, Ref 21A.139 (b) (1) (xiv))

8.2.3 Monitoring and measurement of processes

8.2.4 Monitoring and measurement of product (POE, Ref 21A.139 (b) (1) (vi))

8.2.4.1 Inspection documentation

8.2.4.2 First article inspection

8.2.4.3 Release of product (POE, Ref 21A.139 (b) (1) (xii))

8.3 Control of nonconforming product (POE, Ref 21A.139 (b) (1) (viii))

8.4 Analysis of data

8.5 Improvement

8.5.1 Continual improvement (optional)

8.5.2 Corrective action (POE, Ref 21A.139 (b) (1) (xiv))

8.5.3 Preventive action (optional)

9.Part 21-G production approval

9.1 Terms of approval/ scope (POE, Ref 21A.143 (a) (8))

9.2 Changes to the production approval (POE, Ref 21A.143 (a) (9))

6 Conclusion

1. This study started by the idea of identifying requirements requested in EASA Part 21-G which does not exist in EN9100 because it was initially thought that EASA Part 21-G was more powerful and detailed than the standard. By progressing in the job and going deeply in EN9100, it appeared that the standard was much more detailed on a number of topics, while EASA Part 21-G was very light or even dumb on some major items. Then the aim of study changed to create a modified version of the standard based on EN9100 structure but in harmony with EASA Part 21-G requirements, containing a combination of powerful and compulsory points of both requirements.

2. ISO approach in 2000 changed to quality management system which relies on the description of the organization's activities by processes limiting the number of written procedures to be developed. EASA Part 21-G is written on the basis of quality system of ISO 9002-1994 and still requires a number of procedures (forming the POE).

3. Compared to ISO standards, EN9100 includes some requirements which are in EASA Part 21-G such as:

- Mandatory occurrence reporting system
- Control of work occasionally performed
- Procedures for traceability

Thus, making industry and Authority requirements closer.

4. There are still more precise requirements in EASA Part 21-G on the following subjects:

- Management of airworthiness of product
- Release of product
- All items linked to the approvals
  - Scope
  - Privileges
  - Management of changes
  - Continued compliance
  - Conditions for suspension /revocation

5. Beyond this theoretical comparison of both requirements, two main questions will have to be studied:

- How will the two certification systems work together in the future?
- Will the authority rely on the industry system, if yes, in which conditions?

References

[1] EASA Part 21 – Subpart G., 2003

[2] 9100 - Quality System for Aerospace Manufacturers.