

Research on the Implementation Method of Internal Monitoring and Auditing of Design Assurance System

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Abstract. For the independent supervision function of design assurance system, the implementation method of internal monitoring and auditing is given, and the module distribution of design assurance system inspection; This article introduces the method of establishing a failure mode list for the design assurance system, proposes optimization directions for internal monitoring and audit processes, and proposes evaluation models and calculation methods. It also provides application examples to provide solutions for internal monitoring and audit of the design assurance system.

Keywords-design assurance system; independent oversight function; internal monitoring; failure mode inventory; process optimization

1 Introduction

The concept of Design Assurance System (DAS) originated from the joint British-French design of the Concorde supersonic airliner project, and the first DAS certification came from Europe[1-2]. In 2002, the European Union decided to set up a "European Aviation Safety Agency (EASA)", which took over all the functions and activities of the JAA and at the same time carried out the certification work related to type conformity assessment. The airworthiness management of EASA pays special attention to the capability of enterprises, and it has developed a distinctive airworthiness management method of Organization Approval (OA). EASA requires aerospace manufacturers to demonstrate that they have the design and production capabilities to meet airworthiness requirements by obtaining a Design Organization Approval (DOA) and a Production Organization Approval (POA). EASA requires organizations to continually maintain organizational capabilities (internal independent monitoring functions) through system audits to ultimately ensure product safety[3].

Civil Aviation Administration of China (CAAC) and FAA do not have a corresponding regulatory basis for the organization of type certificate applicants to perform product conformity confirmation and approval at the TC stage. The Civil Aviation Administration of China (CAAC) and FAA for the type certificate applicant's organization, in the TC stage, there is no corresponding airworthiness regulations that can give the design organization the right to perform the product conformity confirmation and approval, all are directly by the Bureau of airworthiness review[4]. However, with the development of the times and in order to promote

the development of the national aviation industry, in order to alleviate the pressure of human resources of the FAA in the process of type certification, to make up for the limited resources of the FAA in the field of technical level in the field of design, and at the same time to satisfy the urgent demand of the industry for the efficiency of certification in the process of obtaining the certificate of the type of the aircraft, the concept of the airworthiness supervision of the CAAC is gradually shifting to the mode of the organization's authorization and approval.

The construction of domestic design assurance system is being gradually carried out by aviation manufacturing enterprises, and most of the design assurance systems have not yet been authorized by the Bureau of Airworthiness Approval (the authority to independently deal with minor design changes), and the corresponding internal monitoring and audit implementation method of the design assurance system is in the exploratory stage.

2 Designed to ensure an independent oversight function

The Design Assurance System (DAS) consists of three parts: the airworthiness function, the design function and the independent oversight function[5-7], which are implemented through the organization, responsibilities, procedures and resource arrangements of the DAS. The relationship between the three functions of the design assurance system is shown in Fig.1. The independent oversight function is to conduct continuous oversight and review of the operation of the design assurance system, to report on problems identified, and to ensure that the design assurance system continues to be effective, and its main role is to:

- Independently monitor compliance of the Design Assurance Manual, system documents, supporting documents, and their modifications to CCAR-21-R4;
- Independently monitor the compliance of the Design Assurance System system documents, supporting documents and their modifications to the Design Assurance Manual;
- Independently oversee the compliance, suitability and completeness of the design assurance system in performing its duties with respect to the design assurance manual and system documentation;
- Feedback the results of independent monitoring to the relevant responsible departments and report to the Bureau, and follow up the implementation of corrective actions.

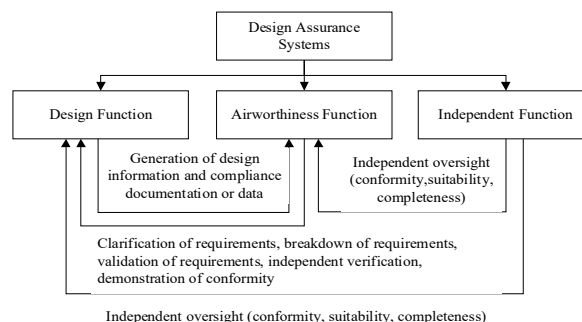


Figure 1. Relationship between the three functions of the design assurance system.

The independent supervision function of the design assurance system can draw on the way and method of carrying out the work related to the quality system audit of each unit, and formulate the corresponding independent supervision work procedures, clarifying the contents of daily monitoring, special investigation, handling of problems found, corrective and preventive measures, and reports on the independent supervision function.

3 Internal Control Audit Implementation

The independent oversight function of the design assurance system is carried out through internal monitoring activities covering the design assurance system applicant/licensee and its suppliers. In order to meet the Civil Aviation Product and Component Qualification Regulations (CCAR-21), the internal monitoring activities of the design assurance system include internal audits, monitoring and inspections conducted by the applicant/licensee of its design assurance system to ensure that the organization's design assurance system is capable of self-monitoring and continuous improvement. The independent oversight function of the design assurance system is responsible for ensuring the compliance, adequacy, effectiveness, and appropriateness of the design assurance manual and its related procedures, while extending to suppliers to ensure that the requirements of the Design Assurance System are effectively implemented and maintained.

3.1 Audit Methods

Internal monitoring of the design assurance system is divided into daily monitoring and centralized auditing.

Daily monitoring means that any person within the Design Assurance System (including suppliers) has the right to report to the Internal Monitoring Implementation Unit any organizational changes, identified problems, deficiencies, and needed improvements that may affect the proper operation of the Design Assurance System; and to communicate and coordinate with the Bureau to report changes to the Design Assurance System in a timely manner.

Centralized audit refers to the activity of monitoring and checking the topics and processes covered by the design assurance system several times within an audit cycle, and formulating corrective measures for the problems found during the checking process[8]. Each centralized audit may involve one or more topics and processes of the design assurance system, and these topics and processes need to be selected in accordance with the requirements of the design assurance system at different stages of product development or the key topics of the Bureau's attention. The centralized audit should be able to fully cover all topics and processes of the design assurance system in one audit cycle.

In addition, the applicant's design assurance system requirements need to be extended to the supplier, and in order to ensure the supplier's continued compliance with the applicant's design assurance system extension documents and applicable procedures (or equivalent documents), it is necessary to conduct internal monitoring and inspection of the supplier by means of centralized audits and to use the results of the internal monitoring and inspection as one of the important inputs for the supplier's performance evaluation.

3.2 Checklist module distribution

The bureau's laws and regulations, the bureau-approved design assurance manual and related system documents and supporting documents constitute the complete management requirements of the design assurance system, and are also the basis for the centralized audit of the internal monitoring of the design assurance system. Under the premise of meeting the airworthiness regulations and management requirements of the Bureau, the system is constructed to refine the company's management process and operation process, covering the requirements of planning, implementation, monitoring, correction and improvement activities in the whole process from determining customer requirements, design and development, test flight, assembly and manufacturing, product inspection, product delivery and customer service. However, in the specific implementation and internal monitoring process, it is necessary to carry out targeted inspections according to different business units in the operation process of the applicant's internal organization, which requires the use of checklists to refine the content of internal monitoring from a modular perspective.

According to the three functions and the main business content of the system on the design assurance system management requirements for classification, each category under the multiple modules, for different modules targeted preparation of checklists. The checklist is used for pre-audit preparation and on-site audit when the auditor comprehensive inspection, checklist module distribution as Table.1.

Table.1 Distribution of checklist modules

Form	Independent monitoring	Design Function	Airworthiness Functions	File System	Supplier Management	Personnel Qualifications
module	1) Internal Control Implementation 2) Non-conformity rectification 3) Approval of changes to the design assurance system 4) Internal Monitoring Program and Reporting	1) Configuration control 2) Design control 3) Design review 4) Manufacturing deviation engineering disposal 5) Continuing airworthiness documentation 6) Running class files 7) Repair programming (including over-the-manual repair programs) 8) Design Information Management	1) Model Forensics 2) Model Design Changes 3) Management of test flight activities 4) Operational and Continuing Airworthiness Documentation and Over Manual Repair Program Approval 5) Conformity verification	1) Design Assurance System Documentation Training 2) Document retention and archiving 3) Manual and document management for design assurance systems 4) System Documentation Inspection	1) Vendor management program 2) Supplier Selection 3) Supplier control a) Design process control b) Airworthiness process control c) Review of manuals and product deliverables 4) Vendor oversight	1) Design Assurance System Authorized Personnel Management 2) Design assurance system authorizes personnel to perform their duties

3.3 Failure mode inventory creation

For the problems found in internal monitoring (including daily monitoring and centralized auditing), in addition to tracking, rectification, verification and closure, in order to analyze the deficiencies of the system and subsequent iterative review of the system, it is necessary to refine and summarize the typical, multiple and universal problems that appear in the process of internal monitoring as the risk of failure of the system to categorize them and form a list of failure modes. Different failure modes are categorized and managed and coded.

The list of failure modes should be set up according to the module distribution of the checklist, with the purpose of harmonizing with the checklist and forming a closed control of the audit process. The list of failure modes can be used as input for the next round of planning process of system documents to avoid the defects in the process of system construction; it can also be used as input for internal monitoring to form the inspection focus for different business modules. The list of failure modes should be supplemented and improved and dynamically managed according to the problems found in previous internal monitoring.

In general, the failure mode checklist is constructed using a "three-tier structure". Checklist in the "design control" module, for example, in order to facilitate the management of failure mode, it is necessary to refine it into a two-tier module, including process specification design, process specification verification, process specification changes and other secondary modules. Each secondary module under the specific three-level failure mode content. Failure mode content with the system operation process problems and continuous improvement. Table.2 is a sample of failure mode list.

Table.2 Sample list of failure modes.

module	Second-level module code	Secondary detailed classification	Three-level module code	Failure mode content
Design control	RD06.1	Process specification design	RD06.1.1	The process and requirements for the preparation, countersigning, validation, review, release, and modification of process specifications were not clearly defined (such as the preparation plan and basis, evaluation and countersigning of process specification stakeholders, and approval before release).
			RD06.1.2	Failure to effectively identify the process specifications required by the organization (e.g. some processes lack specifications).
			RD06.1.3	When applicable, a list of process specifications has not been established and regularly maintained and released.
			RD06.1.4	The issue of process specification review was not tracked and implemented.
			RD06.1.5	Failure to maintain records of process specification validation, review, changes, etc. (including airworthiness approval records when applicable).

	RD06.2	Process specification validation	RD06.2.1	When applicable, the process specifications were not verified according to relevant requirements (such as test outline, conformity inspection of test piece manufacturing, test report).
	RD06.3	Process specification changes	RD06.3.1	Failure to effectively control changes to process specifications (such as initial change control, version control, revalidation after changes, including airworthiness approval when applicable).
			RD06.3.2	Failure to evaluate the impact of changes to process specifications (such as the impact and disposal of work in progress) or failure to implement changes to process specifications
	RD06.4	RD06.4.1

The list of failure modes mainly provides a basis for analyzing the effectiveness of the various modules of the design assurance system, such as the number of repetitive problems in the process, etc.; and also provides a basis for determining the appropriateness of the root causes of the problems identified by the quality audits, such as the risk elements involved in the problems. It also provides focus and areas of attention for the subsequent audit activities of design assurance system for the organization.

3.4 Audit process optimization

Design assurance system internal monitoring and auditing process is often random task allocation, the lack of corresponding task decomposition mechanism, the whole audit process auditor in the audit team to assume different roles when the work interface is not clearly delineated, the entire audit process lacks a unified linkage of the process control requirements and other issues.

Before the internal control audit, the audit process should be planned in an integrated way, considering the requirements of the relevant parties related to the quality audit business, analyzing and categorizing the demand capture of the relevant parties, studying the decomposition of the audit tasks, dividing the work interfaces at different stages of the whole audit process, and further determining the optimization dimensions of the quality audit workflow, with the specific steps as follows.

3.4.1 Preliminary determination of the optimization direction

Combined with the actual audit business activities, find the problems and deficiencies in the audit workflow, identify the key nodes that need to be optimized in the process, and focus on the direction of quality audit workflow optimization.

Integrate the list of necessary materials before the audit, sort out the requirements of the existing work nodes, organize the delivery and transfer time requirements, find out the key control points and deficiencies in the on-site audit process and the problem closure process, and initially determine the preliminary optimization direction of the materials to be used in the audit process, the audit process, and the requirements of the audit delivery and transfer. According to the preliminary process optimization direction, comprehensively assess the existing audit materials (including plans, checklists, various form templates, audit reports) control methods, refine the specific requirements.

3.4.2 Business stakeholder requirements capture

In addition to identifying problems and deficiencies in business processes as optimization directions, it is also necessary to analyze business stakeholders and capture their needs. Considering the requirements of stakeholders related to quality audit business, further determine the optimization dimensions of quality audit workflow. Stakeholders related to quality audit business mainly come from business regulators, management, auditees, and audit teams (as shown in Fig.2). Conduct research on the needs of relevant parties for the audit business, and develop a requirement capture checklist for relevant parties.

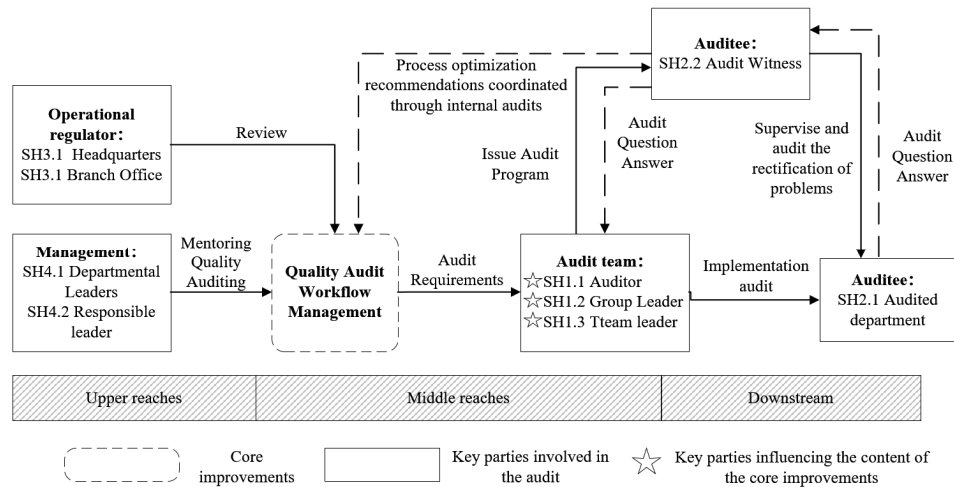


Figure 2. Relevant parties involved in the audit business.

3.4.3 Determine the process optimization architecture

After determining the direction of quality audit optimization, it is also necessary to carry out integrated planning, analyze and categorize the demand capture of the relevant parties, study the decomposition of audit tasks, and delineate the work interfaces at different stages of the whole audit process. Determine the final business optimization dimensions, mainly from the personnel responsibilities, audit material time limit requirements, pre-audit concerns about the definition of the content and the optimization of the existing process of process optimization in four dimensions. Give the specific optimization nodes of each optimization dimension and determine the process optimization structure.

3.4.4 Specific optimized content implementation

For the process optimization structure, the different nodes under each optimization dimension are refined, and each dimension is optimized as:

- Optimize the responsibilities of different people within the audit team;
- Refine the time frame for reviewing materials;
- Optimization of existing business process nodes;

d) Preparation of generic templates.

4 Evaluation model and calculation method

Based on the implementation strategy of the internal monitoring audit mentioned above, a supplier capability evaluation model is developed, and the evaluation model and calculation method are as follows:

Table. 3 Default score weight for first level dimension.

First level dimension(D _i)	Weight θ_i
Independent monitoring	15%
Design Function	25%
Airworthiness Functions	20%
File System	10%
Supplier Management	15%
Personnel Qualifications	15%

1) The default scoring weights for the six first level dimensions are shown in Table.3. The evaluation team can reset the scoring weights for each first level dimension based on specific project characteristics;

2) The evaluation team can develop evaluation checklist items applicable to the second level dimension based on the project situation, and form an evaluation checklist;

3) According to the scoring criteria and evaluation scores, obtain the final evaluation result according to Eq. (1), and the calculation steps and methods are as follows:

a) According to the scoring criteria in the checklist, provide the evaluation score for each evaluation check item (inspection element);

b) Add up the scores of each evaluation check item in the second level dimension and calculate the corresponding score in the second level dimension;

c) Add up the scores of the second level dimension to obtain the corresponding score of the first level dimension;

d) Divide each first level dimension by the total score of 6 first level dimensions and then multiply by 100 to obtain the percentile score for each first level dimension;

e) Multiply the corresponding weight coefficients in Table.3 by the percentile scores of each first level dimension and add them together to obtain the final evaluation result. b) The evaluation team can develop evaluation checklist items applicable to the second level dimension based on the project situation, and form an evaluation checklist.

1) According to the scoring criteria and evaluation scores, obtain the final evaluation result according to Eq. (1), and the calculation steps and methods are as follows:

a) According to the scoring criteria in the checklist, provide the evaluation score for each evaluation check item (inspection element);

b) Add up the scores of each evaluation check item in the second level dimension and calculate the corresponding score in the second level dimension;

- c) Add up the scores of the second level dimension to obtain the corresponding score of the first level dimension;
- d) Divide each first level dimension by the total score of 6 first level dimensions and then multiply by 100 to obtain the percentile score for each first level dimension;
- e) Multiply the corresponding weight coefficients in Table.3 by the percentile scores of each first level dimension and add them together to obtain the final evaluation result.

$$Sum = \sum_{i=1}^6 \left[\theta_i \left(\frac{\sum_{j=1}^{a_i} \sum_{n=1}^{b_j} D_{ijn}}{\sum_{j=1}^{a_i} 4b_j} \right) \times 100 \right] \quad (1)$$

In the Equation:

Sum—To evaluate the score of the results, expressed on a percentage system;

D_{ijn}—Is the evaluation score of each evaluation element, which is the score of the *n*th evaluation element under the *i*-th first level dimension and the *j*th second level dimension;

a_i—The number of secondary dimensions under the *i*-th primary dimension;

b_j—The number of evaluation elements in the *j*th secondary dimension;

θ_i—The weight corresponding to the *i*-th first level dimension.

5 Design Assurance System Capability Assessment Implementation Case

Based on the internal monitoring audit implementation strategy and supplier capability evaluation model studied in this article, a certain company is taken as an example to evaluate its design assurance system capability. Based on the inspection modules listed in Table 1 and the failure modes listed in Table 2, each evaluation inspection item under the secondary dimension is scored, and then the scores of the secondary dimension are summarized to obtain the scores of each primary dimension, as shown in Fig.3. According to Table.3 for weighted calculation, the total score of the company is 77.74.

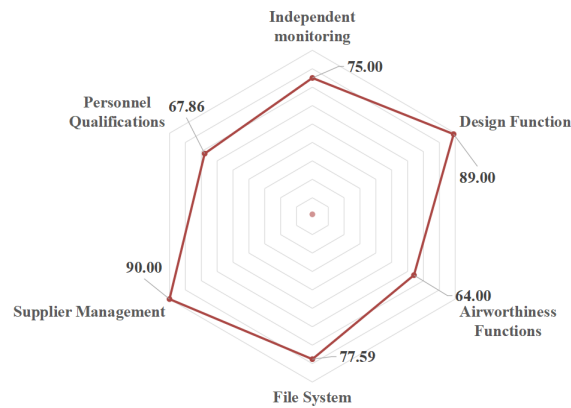


Figure 3. Scores after evaluating each level 1 dimension of a company.

6 Conclusion

The design assurance system is a reflection of the applicant's design capability. Internal monitoring is a requirement of the Bureau, but also an important means of internal control of the applicant, through which it can ensure that the applicant's design assurance system can be self-supervised and continuously improved, and be trusted by the Bureau. Relying on a variety of ways to carry out internal monitoring, can ensure the continuous and effective operation of the design assurance system. Through checklists, failure mode lists and process optimization, the content of audit can be refined, the focus of inspection can be highlighted, and the internal monitoring work can be carried out efficiently.

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