Vladimír Němec, Andrej Novák, Petr Hutla
Department of Air Transport, Czech Technical University in Prague
Faculty of Operation and Economics of Transport and Communications University of Zilina

UNIFICATION OF QUALITY SYSTEMS ISO 9000 AND REGULATION 2042

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Summary: The scientific paper deals with the quality system requirements given by the standard ČSN EN ISO 9001:2010 and Commission Regulation (EC) No 2042/2003. Quality control is one of the most important processes in the organization, as it includes a number of sub-activities such as quality policy, customer focus, human resources, etc. By identifying the demands this work includes design of the structure of the quality manual and a possible form of manuals for the organization dealing with the training of maintenance personnel.

Keywords: Quality Manual, Quality Management System, standard, process, document, record, quality policy, product, customer, resource management, measurement, monitoring

1. INTRODUCTION

With the development of the market, whether the market for trade, provision of services or market production, has organizations that wanted to keep on top come up with something that would ensure the smooth running of the business, high quality services or products manufactured and what they would simply provide a competitive advantage. That "something" was the implementation of the quality system to management.

Quality management can be thought of as an organizational structure with well-defined and divided responsibilities, with defined processes documented procedures and secured resource that is in coordination with the leadership of the organization to identify and promote the principles of quality.

At first glance it may seems that quality management cannot be beneficial for the organization and it's only a "hole for the money." If the quality system is unprofessional and does not undergo appropriate checks, it may so happen. On the other hand, if the quality system is running well, organization can gain only benefit.

Benefits, which established and implemented a quality system affords enterprises can be divided into two main categories: Internal and External.

Internal advantages lie in a nutshell in control processes which are done within the organization and ensuring that these processes are carried out in accordance with the
concept of the Organization. Properly functioning processes, related processes and linking processes with other elements of the organizational structure of the company can save both money and time. Among other advantages we can mention ensuring that the products sold or services provided will meet a quality.

External benefits are reflected in the strengthening of the company's image in the eyes of customers and partners. Especially in the business world, where the market is saturated with low quality products to customers beginning to reorient and instead looking for quality products. Also enterprise that has own business card, such as for example web pages, with information on the quality system is perceived by potential and existing customers / partners as a reliable company.

To implement the quality management system the international standard EN ISO 9001:2010 is used. This standard provides its interpretation of the requirements for quality management and determines the structure of the quality manual.

In a case of the specialistic areas, such as civil aviation, international standard may be supplemented with specific requirements of the regulations and orders by an aviation organization. This work specifically addresses the requirements that the EASA (European Aviation Safety) has imposed on the quality system in Commission Regulation (EC) 2042/2003

2. TECHNICAL STANDARDS, TYPES AND ORIGINS

Standards can be defined in many ways. The simplest and at the same time concise definition of standards is: Technical standards are documented agreements providing with rules, regulations, guidelines or characteristics for activities or their results. Their goal is to ensure the conformity of materials, products, processes or services with the purpose and requirements.

2.1. TYPES OF STANDARDS

Just as there are multiple definitions there are distinctions between many types of the standards. In terms of the content, which is crucial for purposes of their use, the standards are divided into:

- Terminology,
- Basic,
- Test,
- Product standard,
- Safety regulations,
- Standard procedures/services,
- Quality Management,
- Interfaces.

By the place of issue and validity of the standards they are divided into:

- Czech standards – ČSN,
- European standards – EN,
- International standards – ISO,
- and more.

2.2. ORIGIN

In the Czech Republic the Bureau of Standards, Metrology and Testing (ÚNMZ) is given a charge over the job with the standards, i.e. their creation, modification, and extinction.

Production of standards is ensured in four ways:
- Creation of separate Czech standards (accounting for only 10% of total production);
- Translation (about 60% of the total volume of loan standards). Text of the standard is in the Czech language;
- By taking the original. Text of the standard is in Czech and English (and possibly other) language;
- Endorsement. The use of European standards is published in the Journal of ÚNMZ, and if the standard customer requires that he receives the original English text embedded in an envelope with the name and designation standards in the Czech language.

3. THE ISO STANDARDS

The abbreviation ISO contains a name of the International Organization for Standardization. ISO is a worldwide federation of national standards bodies (ISO member bodies). The International Standards are carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has the right to work on, can be represented in that committee. It can also take part in the governmental and non-governmental international organizations, parallel with ISO working relationship. ISO also collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. International Standards are drafted in accordance with the rules set out in Part 2 of ISO / IEC. The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of voting members. For the quality management system the standards ISO 9000 and ISO 9001 are essential.

3.1. THE ISO 9000 STANDARD

ISO 9000 standard was developed on account of helping organizations of any type to implement and operate effective quality system. This standard describes the basic
principles of quality management systems and specifies the terminology for quality management systems.

3.2. THE ISO 9001 STANDARD

ISO 9001 standard specifies requirements for the quality management system where an organization needs to demonstrate its ability to provide products that meet with customer and applicable regulatory requirements and aims to enhance customer satisfaction.

The quality system requirements of the ISO 9001 standard are divided into the following categories:
- The quality system requirements,
- Management responsibility,
- Resources management,
- Product realization,
- Measurement, analysis and improvement.

In the foregoing chapters the standard also mentions the requirements for activities necessary for efficient operation of the quality system.

3.3. THE QUALITY SYSTEM REQUIREMENTS

The above standard defines the quality management system. Features and principles of implementing and maintaining the quality system. It includes requirements for documentation and its management. There are maps presented here of the processes of an organization from which connectedness and continuity can be seen.

3.4. MANAGEMENT RESPONSIBILITY

Management responsibility for the proper and efficient operation of the quality system is one of the most important requirements of the above standard. This chapter specifies the quality management mission and there are given the evidence and the methods of its involvement and activity. Quality Management is responsible for establishing the quality policy as well as setting of the key rules and principles which are binding for all employees, and to be inspected and required. The quality policy must be presented to staff in internal communication and, on the other hand, it can also be used for external presentation of the company to customers and partners.

Other responsibilities of quality management are planning of quality goals. These objectives are generally planned for a specific time period (quarter, semester, year, etc.) and must be measurable, i.e. those that permit the control in order to achieve these objectives. The standard points out the necessity of introducing management representative and quality manager. It is possible that both functions can be performed by one person, who is given charge over:
- enforcement of obligations in politics,
- ensuring compliance with ČSN EN ISO 9001:2010,
- checks,
- evaluating the effectiveness of the quality management system,
- maintaining the quality management system processes,
- providing training to employees in the field of quality management system,
- many more.

Management responsibility lies in ensuring seamless internal communication. There are many communication tools and options for the organization and it is up to management to determine the right means of communication, so that they can be seamlessly implemented processes. The last important duty of the quality management implementation is the management review to ensure its suitability, accuracy and efficiency. For this purpose it is necessary to ensure appropriate input for the review. From its own inspection activity then it produces outputs representative of the quality management.

### 3.5. MANAGEMENT RESOURCES

Under the term resource management more than just providing funds for the operation of the quality system is hidden. The resources are divided into:
- Work – employees;
- Material - raw materials, energy;
- Capacity - machinery, equipment, production capacity;
- Financial - loans, capital, profit;
- Others - information, time.

The above resources need to be controlled so as to avoid shortage or the surplus of unwanted elements.

### 3.6. PRODUCT REALIZATION

Part of the implementation of the product states that the organization implements section meeting the requirements of the product. The actual implementation of the product must be planned so that there is conformity with the standards and expectations of the organization and the realization was in accordance with the requirements of other processes. It also must take into account the customers’ requirements, also those that customers did not say. Product realization process extends also into the shopping area. It must be ensured that all purchased inputs needed for product realization, meet the specified requirements. Subsequent provision of products is the main process, and therefore must take place under controlled conditions.
3.7. MEASUREMENT, ANALYSIS AND IMPROVEMENT

Measurement and subsequent analysis is used to demonstrate compliance with the specified requirements. The measurement and analysis can be deduced reasons for the discrepancies that cause the product or service is not liable to the requirements of organization or customer. That could lead to a lasting improvement in the processes and the links between them. It is first necessary to identify the causes of nonconformities. Therefore, the measured and examined are:

- customer satisfaction,
- quality management system,
- processes,
- products.

The actual review of the quality management system, processes and products is ensured through internal audits. If a process or a product is found that exhibits non-compliance with requirements then this subject goes to the further proceedings. In such cases it is necessary to proceed and find a solution that will ensure that in the future such mistakes will not be repeated. One of the most important goals is to make quality management system also steadily improved. Therefore, the measures are used such as quality policy, quality objectives, audit results, corrective and preventive actions and management reviews.

4. EASA AND QUALITY MANAGEMENT

The obvious mission of the European Union in the field of civil aviation is to continuously improve the level of safety. In fulfillment of this vision there is a key role for the European Aviation Safety Agency (EASA) that with its pronouncements and regulations tries to increase this level and is the centerpiece of the European strategy. In the area of standards and quality the EASA made a significant step in 2010 when the Executive Director, Mr. Patrick Goudou, decided to implement an integrated management system (IMS) that gave to the agency an opportunity to deploy new effective procedures to improve the Agency's services and achieve the requirements of ISO 9001: 2008. This step by EASA gave to its partners indication of the direction in which it is possible to proceed and increased its prestige. Agency introduced an integrated management system IMS that is designed and used so as to effectively support the achievement of objectives (e.g. in the area of quality and safety), and generally improves the agency. Internal control standards (ICS) are developed by the Commission, specifying the requirements and expectations for measures that are necessary to build an effective system of internal controls to provide reasonable assurance of sound financial management and achieving business goals. To avoid duplication of standards, the Agency has developed its own management standards adopted by the Administrative Council with regard to both ISO 9001:2008 standards developed by the Commission and ICS.
Commission Regulation (EC) 2042/2003 (the Regulation) describes the requirements of the European Aviation Safety Agency (EASA) to organizations working in the field of civil aviation. It sets out common technical requirements and administrative procedures to ensure the continuing airworthiness of aircraft, including any component for installation thereto, which are registered in a Member State or registered in a third country and used by an operator for which a Member State ensures oversight of operation. The Regulation and the related requirements are divided, according to the scope, into four parts:
- Part M - Requirements for continued airworthiness,
- Part 145 - Approval of maintenance organizations,
- Part 66 - Maintenance certifying staff,
- Part 147 - Requirements for organizations providing training for maintenance personnel.

Detailed interpretation of the Regulation provides document acceptable means of compliance (AMC) and Guidance Material (GM). The quality system requirements are not all the same for all parts of the Regulation, on the other hand. Each part has its own specificity of AMC and GM. The Commission Regulation 2042/2003 sets out the requirements for the quality system of each part in the following chapters:
- Part M - Chapter: M.A.712,
- Part 145 - Chapter 145.A.65,
- Part 147 - Chapter 147.A.130.

The Regulation and EASA does not take quality system lightly. On the other hand, the system is classified as a pivotal and allows organization or the authority to have supervision over the course of processes within the organization. Among the main points of the quality system requirements contained in the Regulation the following can be mentioned:
- the feedback system,
- accountable manager,
- ensuring and conducting independent audits and inspections.

5.1. THE FEEDBACK SYSTEM

The feedback system is generally a key element for control and process improvement. Any organization, small or large, can only benefit from such system and thus improves, controls and develops its activities. On the other hand, advanced organization can hardly be imaginable without the functional feedback system. Therefore, the Regulation places on this process due consideration. The basic function of the feedback system for aviation organization is to ensure that all findings resulting from the independent audits of the quality of the organization are properly and timely investigated and remedied to the accountable manager to allow proper awareness of safety issues and the extent of compliance with the Part. Roughly it can be said that through the feedback the organization
gains the management objective perception of reality, and has an idea of whether or not the disagreement with the planned state exists. If a situation arises where there is no agreement, then the leadership accepts the audit conclusions and sets out actions to correct.

5.2. ACCOUNTABLE MANAGER

The Accountable Manager is selected by senior management to ensure the effective operation of the quality checks, processing of reports, etc. Accountable manager organizes regular meetings with staff to check the status of corrective action, except that in large organizations such meetings may be from day to day transferred to the Quality Manager. But these are subject to the accountable manager meetings, at least twice a year, however, take place with senior staff and include an examination of the volume of output and at least once every six months the adoption of an overall report on the findings of non-compliance.

5.3. ENSURING AND CONDUCTING INDEPENDENT AUDITS AND INSPECTIONS

Ensuring the independence of the audit is a critical issue if it is to comply with the objectivity of inspections carried out. An independent audit is the process of routine sample checks of all aspects of the organization's ability to carry out training for all at the required level. It presents an overview of the overall training system and does not replace the need for instructors to ensure that the training is carried out according to the required standard. Independent audit can be achieved in two ways. First option is to ensure that auditors do not control the processes in which they are interested or in any way affect them. The second option is to use an external audit of the audit firm. It can be advantageously used in larger controls or auditing department functions. The advantage is a high degree of objectivity and quality of the audit, the disadvantage is then financial demands of such audit. An independent audit should ensure that all elements of compliance with their parts are inspected every 12 months, and can be implemented as a complete single exercise or subdivided into a period of 12 months in accordance with the established scheduled plan. The system of management control and monitoring should not be contractually bound up with persons outside the organization. The main task is to ensure that all final audit findings are enable timely removal and that the accountable manager was ever properly informed about the state of compliance.

6. POSSIBILITY OF UNIFORM REGULATIONS

One of the goals of this work is to consider the possibility to originate a single document that would specify the requirements of both documents, a standard ČSN EN ISO 9001:2010 and the Commission Regulation (EC) 2042/2003. Uniform documentation
could be benefits for organizations moving in civil aviation the moment they decided to establish a quality system in its organizational structure. The purpose of the uniform documentation is that an organization that establishes quality system can implement requirements from both sources at a same time. So, in one process of implementing a quality system the organization might eventually request a review of its quality management from the auditing firm engaged in both the awarding certifications ISO 9001 and the checks that the organization meets the requirements of the Regulation. It is therefore a certain simplification, which ensures reduction of costs incurred by the source. However, for the possible emergence of a single document, one must first get both documents at the same structural level. The ISO 9001:2010 is divided into categories and subcategories, the Regulations work with articles in which the requirements are listed. Due to the versatility of ISO 9001:2010 this standard was chosen as the main structure. Therefore, requirements of the Regulation must have been classified into appropriate categories allowing subsequent merger. Categories of the quality system by EASA are as follows:

- terminology,
- the amendments,
- document control,
- organization and distribution of quality,
- monitoring subcontractors,
- feedback and reporting,
- management evaluation,
- audits,
- checks,
- quality system training.

Requirements of the Regulation is therefore necessary to assign by content into categories and then we can proceed to the actual synthesis of the documents. During the synthesis, the structure and requirements of the Regulation are added into the structure and requirements of ISO 9001:2010. It is necessary to closely monitor the individual requirements in order to avoid their duplication.

7. DESIGN OF THE STRUCTURE OF THE QUALITY MANUAL

The structure of the quality manual is designed with the versatility for all types of organizations approved under Part M, 145 or 147. Proposed structure of the manual introduces a new type of numbering chapters and subchapters. This increases clarity of the manual for the user, so that it was immediately clear in which document specific category or subcategory is subject to the requirements. Proposed structure is accompanied by a short concise summary of the purpose of that particular category or subcategory.
7.1. THE NUMBERING STRUCTURE OF THE QUALITY MANUAL

The numbering structure of the quality manual is based on the principle of numbering the U.S. standard 100 ATA (Air Transport Association), which provides a methodology for numbering technical data manuals. The advantage of such numbers is due to the frequent use of technical papers in the field of aviation and quick orientation by the organization approved under Part M, 145 or 147. The numbering comprises three parts according to the following scheme:

5 - 1 - source requirement,

where the first symbol identifies the chapter, the subchapter is the second and third part states which of the documents a requirement is set for. For instance, designation 5-1 - ISO/147 states that the requirement is that of the ISO and of the Part 147 and is therefore valid for organizations dealing with maintenance training.

7.2. STRUCTURE OF THE QUALITY MANUAL

The resulting structure of the quality manual meets the requirements of both documents and by the numbering is properly arranged. According to this structure the possible appearance of quality manual for organizations dealing with maintenance training is also outlined at this work. The structure of the unified requirements includes the following:

- Introduction and general provisions,
- Related regulations and governing documents,
- Definitions and Abbreviations,
- Information about the organization,
- Quality Management System,
- General requirements,
- Documentation Requirements,
- Management responsibility,
- Personal involvement and activity management,
- Customer Focus,
- Quality Policy,
- Planning,
- Responsibility, authority and communication,
- Management review,
- Management of resource,
- Provision of resources,
- Human resources,
- Infrastructure,
- Work Environment,
- Product realization,
- Planning of product realization,
- Processes related to customer,
- Design and development,
- Shopping,
- Production and service provision,
- Control of monitoring and measuring devices,
- Monitoring subcontractors,
- Measurement, Analysis, Improvement,
- Monitoring and measurement,
- Audits,
- Checks,
- Feedback and reporting,
- Control of nonconforming product,
- Analysis of the data,
- Improving.

The categories are further divided into sub-subcategories. The last section outlines the possible form of manuals for the organization working in the training of maintenance personnel, based on the above categories.

8. CONCLUSION

The aim of the study was assessment option of uniform quality system documentation. Based on the analysis of both documents, this option was found to be feasible. The final structure form of the quality manual conforms to the requirements, which are set both in the standard ČSN EN ISO 9001:2010 and the Commission Regulation 2042/2003. This has completed the requirement of the paper thesis. As regards the possibility of using this structure in practice, it would be necessary to adapt the quality manual to organization conditions, but the authors believe that after some optimization it can be used as the manual.

References


POŁACZENIE SYSTEMÓW JAKOŚCI ISO 9000 ORAZ ROZPORZĄDZENIA WE 2042


Słowa kluczowe: księga jakości, system zarządzania jakością, norma, proces, dokument, zapis, polityka jakości, produkt, klient, zarządzanie zasobami, zarządzanie, monitorowanie