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QUALITY MANAGEMENT DOCUMENTS

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ABSTRACT

The quality system is an integrated system that aims to carry out the activities that can directly or indirectly influence the quality of the products and services offered, in such a way as to give the necessary confidence to both the customers and the own management in order to obtain the specified quality.
The paper presents quality management documents used to define and implement the quality system in a company.

KEYWORDS: Quality system, Quality management documents, ISO 9000, Quality assurance.

1. INTRODUCTION

The quality system represents organizational structures, procedures, processes and resources necessary for the implementation of quality management.

The quality system does not automatically determine the realization of quality products or services, but creates the prerequisites for their realization. In other words, the quality system is a tool for achieving, maintaining and improving quality.

A quality system must be developed and implemented in accordance with the ISO 9000 series of standards.

The decision to implement a quality system can be determined by a whole series of factors, most of the time combined. Among the most common factors we mention:

•to give customers confidence;
•the requirement of the regulatory authority;
•the desire to penetrate new markets;
•the desire to surpass competing companies;
•simplifying and even reducing supervision audits;
•Management's intention to gain the necessary trust.

The quality system, being the way through which the supplier can assure his business partners that the product complies with the specified conditions, must have a documentation.

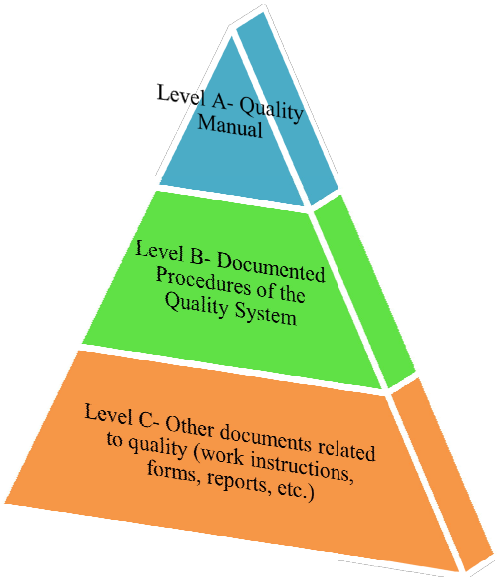

Fig.1 The typical hierarchy of quality system documents

The total quality management documents used to define and implement the quality system in an enterprise are:
-the quality manual;
-quality plans;
-quality system procedures;
-work instructions;
-quality records.

The typical hierarchy of quality system documents, stipulated in SR ISO 10013:2003, is presented in figure 1. The order of development of this hierarchy in a certain organization depends on the situation of this organization, but as a rule, it starts with the development of the quality policy and the organization's quality objectives.

2. THE QUALITY MANUAL

This document presents the quality policy and describes the quality system of an organization (SR ISO 8402:2001).

According to the above, the general quality policies, procedures and general practices of the enterprise in the field of quality are presented in the quality manual.

The quality manual is authorized for quality implementation and represents a point of reference in the organization's activity. Suggestions for the development of the quality manual are provided in SR ISO 10013:2003.

In the quality manual, references are made to:

• the company's quality policy;

• responsibilities and attributions;

• relationships between the people who lead, perform or check the activities that influence the quality;

• the procedures and instructions of the quality system;

• instructions for revising, updating and managing the company manual.

The quality manual contains the following sections:

a) general sections;

b) administrative sections;

c) technological sections.

The general sections include:

- the general director's statement containing a message on the meaning of the manual. The declaration includes the signatures that give it legitimacy;

- the object and use of the manual;

- contents of the manual;

- quality objectives and unit policy in the field of quality;

- organizational charts and tables of responsibilities for the quality function, as well as the organizational structure of the quality assurance sector;

- the list of those who receive copies of different sections of the manual;

- measures for periodic updating of the manual or periodic audits and scheduled analyses;

- additional data for using the manual (glossary of terms, a list of abbreviations with their meanings, a list of materials that appear in the references and the bibliography).

The administrative sections include:

- the company's relations with clients;

- quality planning for new products: phases or stages, product objectives (reliability, average time between failures, time for repairs, warranty), project review, building and testing models, developing and testing processes, specifications, qualification tests, procedures for making project changes;

- manufacturing: analysis of productivity, specification and purchase of equipment, control of manufacturing processes, organization of a pilot production;

- relations with the supplier;

- inspections and tests;

- test equipment: its design, purchase, calibration, maintenance;

- materials that do not comply with the established norms;

- actions after manufacturing: packaging, storage, delivery, transport;

- technical assistance;

- quality assurance;

- quality costs;

- the IT quality system;

- statistical methodology;

- quality improvement (for chronic quality problems);

- professional training of the staff.

The technological sections include:

-guidelines for the development of materials and components processing technologies;

-assembly instructions;

-control, verification and testing technologies;

- the organization of pilot productions and the adaptation of projects to the technological process based on the conclusions reached in the pilot production.

3. THE QUALITY PLAN

According to SR EN ISO 9000:2006, the quality plan is the document that specifies which procedures and associated resources must be applied, by whom and when for a specific project, product, process or contract.

For the preparation of the quality plan, the provisions of the SR ISO 10005:2007 standard are respected.

The main requirements that must be respected when creating the quality plan are:

• the quality plan is developed as a guide for the supplying organization;

• a quality plan is used to monitor and evaluate compliance with quality conditions;

• the quality plan is analyzed and officially approved by an authorized group that includes

representatives of all interested functions in the enterprise;

• the quality plan is made up of several parts: one plan for each distinct stage (design, supply, production, inspections and tests);

• the quality plan is revised whenever changes are made to the product, project or contract.

The quality plan must reflect the requirements of the quality system related to the product, services, projects or contracts. Thus, this document refers to management responsibility, procedures, instructions and other documents of the quality system.

The elements that must be defined by the quality plan are: a) the objectives to be achieved; b) the phases of the processes necessary to make the product; c) assigning responsibilities for all product development phases; d) procedures and work instructions; e) the test, examination and audit program; f) a written procedure regarding the changes made in the quality plan, g) a method that allows determining the degree of achievement of the objectives.

4. QUALITY SYSTEM PROCEDURES

SR ISO 9000:2006 defines the procedure as the specified way of carrying out an activity or a process.

All company departments involved in activities that can influence product quality perform tasks based on practices or tradition. The manner of carrying out each type of activity must be presented in a procedure or regulation of the compartment that describes the implementation of the quality policy objectives. Procedures are written and are called documented procedures.

The ISO 10013 guide can be used as a reference model for the development of quality system procedures.

Some basic rules to follow are:

•documents must be identified, controlled, kept up to date and available where they are needed;

•the documents must be approved;

•documented procedures must form the basis for the overall planning and administration of all activities that may affect the final product;

•the procedures must describe, at a level of detail that ensures the maintenance of adequate control, the following aspects:

a) the purposes and fields of application of an activity;

b) what must be done and who is responsible;

c) when, where and how the activity is performed;

d) what materials, equipment, documents will be used;

e) how to control and record the activity.

If the elements of the quality system concern several departments, one gets the responsibility of developing the procedure, while its preparation and revision is done jointly by the involved departments.

The content and structure of the procedures is established according to:

- unit size;
- the specific nature of the activity;
- the scope and structure required for the quality manual completed with the elaborated procedures.

5. WORK INSTRUCTIONS

Work instructions are information that is given to workers at their workplaces. These have the role of presenting the way in which the activities will be carried out at the workplace, as well as the required level of quality.

Work instructions must be written in simple terms, easy to understand by workers with a low level of knowledge, and can be consulted whenever needed.

These documents take the form of technological sheets or operation plans.

Instructions can be for:

• manufacturing operations;
• control operations;
• assembly operations;
• use of test equipment, etc.

For manufacturing operations, work instructions must include the following information:

-the name of the operation to be executed;
-the material or semi-finished product that will be used;
-the necessary equipment, tools, devices, testers;
-adjustment and calibration of machines, devices.
-the sequence of activities (phases) at the workplace;
-environmental conditions (temperature, humidity) that must be respected;
-the code of the operation or practice that must be carried out and the quality conditions that must be respected.

6. QUALITY RECORDS

These are materials that prove the degree of satisfaction of the quality conditions and can be quality records for the product and records regarding the operation of the quality system.

Analysis of quality records provides

important information for corrective actions and for quality improvement. The manufacturer must establish procedures for the identification, collection, indexing, completion, use, storage and archiving of quality records.

Product quality records include the following material categories:

- product specifications (drawings, calculation elements, etc.);
- equipment drawings;
- specifications for subassemblies and materials entered into the unit;
- reports on the control and receipt of materials;
- records of materials that do not comply with established norms and standards;
- records of product quality complaints and records of remedial actions undertaken.

Quality system performance records demonstrate the operational effectiveness of the quality system in an organization and include:

- quality audit reports;
- records of assessment and selection of suppliers and their performance levels;
- manufacturing control records;
- records regarding the calibration of measuring and control equipment and devices;
- records related to staff training and instruction;
- records regarding inspections and tests;
- quality cost reports.

Quality records can be made on paper, computer or other means.

Keeping quality records under control requires maintaining them for a specified period, so that they are easily accessible for analysis, in order to identify the trends of the results of the measures taken in the field of quality and the necessity or effectiveness of the corrective actions taken to eliminate the causes of non-conformities or defects.

7. CONCLUSIONS

A documented quality system defines responsibilities and authorities, ensures competition, reduces the tendency of wrong practices, provides reference for both internal and external audit, creates conditions for self-control, provides training material, transforms solved problems into recorded knowledge for later reference, optimizes the company's activity at a general level and ensures the possibility of participation of all management levels in achieving the desired quality.

All personnel involved in the implementation process of the quality system must go through a comprehensive training program in order to become familiar with the procedures and other relevant documents, and to be aware of the need for continuous quality improvements and to know how to use modern techniques and practices specific to the field of quality.

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