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Methodology for implementing Document Management Systems to support ISO 9001:2008 Quality Management Systems

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Abstract

A Methodology for implementing Document Management Systems to support ISO 9001:2008 Quality Management Systems requirements is proposed in this paper. This methodology consists of six steps that executed in a cycle allows to obtain the optimal Document System. The proposal begins with the definition of ISO 9001:2008 document requirements; followed by the evaluation of the existing Document Management System in the organization; the identification of document strategies; the design of the Document Management System; its implementation, and finally the definition of the continuous improvement plan to guarantee the fulfillment of the initially detected requirements.

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1. Introduction

Although there are different methodologies to implement Quality Management Systems, and they all agree on the importance of the proper document treatment to ensure its success, none of them explains in detail how to design and implement the suitable Document Management System to handle this documentation, nor defines its associated document processes.

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This article is focused on filling this gap by developing a methodology that serves as a reference and tool to support those organizations aiming to implement a Document Management System that meets the requirements of ISO 9000.

2. Methodology

Based on the analysis of the document requirements stated on "ISO 9001:2008 Quality management systems" and in the study of "ISO 30301:2011 Information and documentation -- Management systems for records", document processes associated with Quality Management Systems have been identified, and taking advantage of the current existing tools in any organization, the necessary steps to implement proper ISO-supporting Document Management Systems has been proposed.

The proposed methodology consists of six steps, which customize the steps outlined in ISO 30300: Information and Documentation for the documentation associated with the QMS.

- Step 1. Definition of document requirements
- Step 2. Evaluation of existing systems
- Step 3. Identification of document management strategies in the organization
- Step 4. Design the Document Management System
- Step 5. Implementation of the Document Management System
- Step 6. Maintenance and continuous improvement of the Document Management System

Each of these steps are described below

2.1. Step 1. Definition of document requirements

The main objective of this first step is to determine, through a careful analysis of the organization and its environment, the types of documents and the processes for their generation and treatment, which must exist in the ISO system to ensure that business processes are carried out under controlled conditions.

In short, documents and document processes required to establish the optimal model of the activities carried out in the organization should be fixed: a model defining how the organization should work.

This requires the study of:

- The main objectives and strategies to achieve this objectives
- The general functions supporting the objectives and strategies
- Specific sector regulations
- The activities carried out for the fulfillment of the functions
- Groups of transactions or processes that contribute to the execution of each activity
- The results generated in each of these transactions

In general, although ISO gives the possibility to decide the extent of the documentation required for the quality management system (in accordance with the characteristics of the organization in terms of size, type of activity performed, complexity of processes and their interactions, and competence of the staff), organizations must have at least†:

- Quality Manual
- Procedures Manual
- General and specific procedures
- Records
- Quality Plans

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† V. Nava, A.R. Jiménez. ISO 9000:2000: estrategias para implantar la norma de calidad para la mejora continua. Editorial Limusa, 2005
Specifications

Although following the analysis we will have a comprehensive view of which the required documents are. Once identified these documents it will be necessary to analyze in which process they should be generated, and how they should be handled, studying the procedures and responsibilities associated with their management. That is, document processes must be defined.

In this respect ISO needs defining how documents will be created, and how they will be approved before being issued, and explaining how further review will be carried out to ensure their updating. These three elements are the key document processes: creation, approval and review.

In addition, the Standard states that a written procedure must be defined to establish:

- Documents identification. Documents must incorporate some type of control to allow its clear identification.
- Storage. The organization must define a plan to file/store all the relevant generated documents.
- Security. Documents, depending on their format and way of storage, must require the implementation of protection methods. For instance, the generation of back-up copies.
- Retrieval. Documents are created to be used, or potentially used, in the future. When retrieval of documents is complex, specific retrieval methods must be implemented.
- Retention period. Documents contain information on past facts that can be meaningless and useless in the future. The organization must define how long documents must be preserved.
- Disposition. The term refers to the order arrangement and distribution. This requirement is closely related to the storage. The organization shall define in writing those management and distribution methods that are needed to easily locate documents.

Once established these terms, we will know the requirements (documents and document processes) that must be considered for the optimal Document Management System implementation and will be able to advance to the next step of the methodology.

2.2. Step 2. Evaluation of existing systems.

The purpose of step 2 is to analyse information and document management systems in the organization and to evaluate if they concretize document processes defined above, or if they have the appropriate functionalities to do.

To do this, we will start from the document requirements identified in the previous step and we will analyse the gap between the requirements of the organization (in terms of document management) and the functionalities of its existing systems. Also we will identify incidents, such as duplication of information, systems that could be replaced by a new document management system, as well as the document management strengths that can be used to promote the proper management of documents.

To complete step 2 is necessary to carry out the following tasks.

Task 1.- Identify existing information systems in our organization
We must identify information management systems within our organization:

- For paper documents
- For electronic documents
- For simultaneously paper and electronic documents

For this identification it is recommended starting with the analysis of the activities and transactions of the organization, so that we can identify the existing systems in the context of the business processes.

Task 2.- Analyze existing systems
This involves identifying how these systems meet the requirements of the organization.

**Task 3.** Prepare a report as a result of the identification and analysis of existing information management systems in our organization

All the points detected in the above two points should be reflected in a comprehensive report before designing or redesigning the existing systems.

This report should include:

- A brief summary of the analysis
- A list of the strengths and weaknesses of the systems
- Detailed information about the features the system must provide to meet each of the document management requirements

### 2.3. Step 3. Identification of document management strategies in the organization.

The goal of this step is to determine the most appropriate policies, practices, standards, tools and other tactics the organization should take to remedy the weaknesses identified in the previous step and ensure they meet the document requirements identified in Step 1.

The choice of these strategies must take into account the nature of the organization, the type of activities carried out, its human resources, tools and technology, the company culture and any kind of external socio-political constraints.

It is vital involving users so that, not only document management requirements are covered, but also users requirements are taken into consideration. It is essential to ask the users about those elements that affect them, and incorporate progressive changes in design until both document management and users requirements are satisfied. It is, in short, to determine the best way to incorporate the necessary changes to improve document management throughout the organization.

To complete this step, we must:

- Explore the different document management strategies to be applied
- Identify the most appropriate strategies for our document management requirements
- Assess the factors that can support or discourage the adoption of these strategies
- Adopt the most appropriate strategy

Among the possible strategies to be implemented four are the most usual:

- Establishment of principles that set the procedures on document management within the organization: corporate policies, instructions, directives or other instruments
- Development of mandatory standards
- Using market IT solutions
- Implementation of specific ad-hoc solutions. Whether intrusive (where employees consciously take care of document management tasks) or invisible (where document management is carried out as part of a business process routine).

The nature of this step may vary considerably depending on the selected strategies. And consequently different measures can be taken. For example:

- Review document management policies and procedures in the organization
- Assign document management roles and responsibilities
- (Re) design business processes
- Design electronic or mixed systems for document creation, capture and control
• Develop document management guidelines and procedures
• Conduct regular reviews of document management in the organization
• Develop initial training plans
• Prepare an implementation plan for the designed document management system

![Diagram of document management strategies](image)

Fig. 1. Identification of document management strategies in the organization

2.4. Step 4. Design the Document Management System.

This step aims to transform the strategies and techniques selected in the previous step in a plan for the design of the document management system that meets the defined requirements and remedies any document management weaknesses detected in the evaluation of the existing systems.

The term “system” should be understood in a global way and not tied exclusively to IT applications, but considering people, processes, tools and technology. Its development therefore involve:

• The design of changes in the current systems, processes and practices
• Adaptation or integration of technological solutions
• The definition of the best way to incorporate these changes to improve document management in our organization

Throughout this step we must compare design elements to management requirements, asking users about the elements that affect them and making appropriate design changes until these needs are met.

Logically, the steps to follow in the design of the system will depend on the strategy or approach we have selected in the previous step. Thus, we can decide:

1. Review policies and procedures related to document management in our organization.
2. Improve the functionality of the information management systems in the organization and increase training of those responsible for document management.
3. Develop and implement a new management system for high-risk areas within our organization.
4. Develop and implement a new management system for the entire organization.

Regardless of the strategy, the outcome of this step will be reflected, mainly, in the draft of a system specification document and a plan with deadlines, tasks and responsibilities to implement the system.

2.5. Step 5. Implementation of the Document Management System.

The main purpose of this step is the implementation of the plan developed in the previous step. And it may arise as a single project, or as a "portfolio" of interrelated projects to enhance document management in the organization. This is a complex task to undertake, with high responsibility and economic investment. However, any risk is solved if we apply a careful planning of the implementation process.

To complete this step is necessary:

- Select the most appropriate execution techniques
- Plan the implementation process of these techniques (implementation plan)
- Manage the implementation of the system
- Develop and maintain the plan

After completing this step we will achieve the implementation of document management in the organization with minimal disruption to their activities.

2.6. Step 6. Maintenance and continuous improvement of the Document Management System.

Once implemented the system and after a reasonable trial period, we must measure its effectiveness, identifying any weaknesses with the purpose of correcting them. This is the purpose of step 6: measuring the effectiveness of document management systems and practices, focusing on the solutions implemented, based on the detected document management requirements and organizational constraints defined in the previous steps.

This step also allows to evaluate the effectiveness and suitability of the development process, and recommend and implement any corrective actions to correct its deficiencies.

To complete this step is necessary:

- Define an evaluation plan, including evaluation criteria
- Collect and analyze performance data
- Report on the findings to management
- Take corrective measures

To do this, different techniques can be used: interviews with managers, staff and / or other stakeholders, surveys, analysis of documents generated during the early stages of the project, and the observation and random control of document activities.

As new processes or activities that imply new document management needs in the organization, not satisfied with what was initially proposed and designed, may arise, this ‘check’ will be made on a regular basis.

For this reason, to evaluate the system and its viability in the future, it is not only sufficient to detect these changes, it is necessary also to periodically carry out all the steps defined above, so that the method becomes a continuous improvement Deming cycle.

3. Conclusions

This methodology not only provides the means to meet the document requirements of ISO 9001:2008, but also a method to ensure that activities within a quality system are embodied in accessible, relevant and reliable
documents, and a method to define the control processes and the evaluation framework that foster the maintenance and continuous improvement of the system. This methodology is also applicable (with the exception of the first step, which must be particularized for each family of ISO standards) to other ISO Management Systems (14001, 27001, 50001, 26000). In all these standards an essential part of their approach is the creation of documents that "rule" the system - both for planning (policy, goals, plans) and for its operational implementation (procedures) - and require a system that supports the generation of these documents.

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