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Information Management Solutions

Document Control

White Paper
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Abstract

The primary purpose of document control is to ensure that only current documents and not documents that have been superseded are used to perform work and that obsolete versions are removed. Document control also ensures that current documents are approved by the competent and responsible for the specific job persons and are distributed to the places where they are used. In regulated industries, this function is mandatory.

This white paper describes document control procedures, the role of document control in regulated industries and for ISO 9001, and document control system implementation.

ISO 9001 and Document Control

ISO 9001 specifies requirements for a Quality Management System (QMS) where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements. An organization is required to establish, document, implement, and maintain a quality management system and continually improve its effectiveness.

A cornerstone of the QMS is document control. Therefore, in order for an organization to meet ISO 9001 requirements, it must have a document control system in place. Auditors pay particular attention to document control.

Document control is an essential preventive measure ensuring that only approved, current documents are used throughout the organization. Inadvertent use of out-of-date documents or not approved documents can have significant negative consequences on quality, costs, and customer satisfaction.

What is Controlled Document?

Controlled document is any document that is used to perform work and not for reference. A typical example would be a technical specification, which can be used as a base for design and development of a new product. Furthermore, ISO 9001 states that documents required by the QMS should be controlled.

The QMS includes the following documents: statements of quality policy and quality objectives, quality manual, procedures, and records determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes.

The format and structure of the quality policy, quality objectives, and quality manual is a decision for each organization, and will depend on the organization's size, culture and complexity.

A small organization may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by the standard. Large, multi-national organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

ISO 9001 specifically requires the organization to have documented procedures for the following six activities:

1. Control of documents
2. Control of records
3. Internal audit
4. Control of nonconforming product
5. Corrective action
6. Preventive action

Some organizations may find it convenient to combine the procedure for several activities into a single documented procedure (for example, corrective action and preventive action). Others may choose to document a given activity by using more than one documented procedure (for example, internal audits). Both are acceptable.

In order to demonstrate compliance with ISO 9001, the organization has to be able to provide objective evidence that its QMS has been effectively implemented.

The typical controlled document types include:

- policies - the company's position or intention for its operation;
- procedures - responsibilities and processes for how the company operates to comply with its policies;
- work and/or test instructions - step-by-step instructions for a specific job or task;
- forms and records - recorded information demonstrating compliance with documented requirements;
- drawings - those that are issued for work;
- process maps, process flow charts, and/or process descriptions;
- specifications;
- internal communication;
- production schedules;
- approved supplier lists;
- test and inspection plans;
- quality plans.

The type and extent of the documentation will depend on the nature of the organization's products and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.

Document Control Procedure

ISO 9001 states that the procedure for document control should be established which should include the following:

1. To approve documents for adequacy prior to issue.

Document approvals are mandatory and must be kept as a record as well. When determining who should approve a particular document, limit approvals to those with direct knowledge or responsibility for the document.

Approval signatures must be recorded prior to the release and use of the document. Approvals may be in the form of a written signature or a password-protected electronic approval record. The date of all approvals must precede the document's release date.

While not explicitly stated, this requirement also applies to temporary memos or postings that are used to communicate QMS or product-related requirements. Any temporary documents must be clearly identified, signed and dated. It is advisable to include an expiration date on temporary documents to ensure they are removed from use when intended.

2. To review and update as necessary and re-approve documents.

All documents must be reviewed periodically and updated and re-approved if needed. This review can be tied to a company's internal audit process, management review or scheduled on some periodic (annual) basis. A record of such reviews must be kept.

3. To ensure that changes and the current revision status of documents are identified.

When a document is updated, a record must be kept of the change, including the reasons for and nature of the change. In addition, current revision status must be maintained. This includes the current development stage (draft, review, approval, etc.) and the date or revision level (number or letter) identifying the current version of the document.

4. To ensure that relevant versions of applicable documents are available at points of use.

The storage and access of documents must easily allow individuals to find the appropriate version of a document to use where needed. Older versions of a document that are still needed (e.g. specifications for an older product) may remain active if necessary, but the revision level must be made clear.

You should consider where designated controlled locations of your documents will be established and whether short-term reference copies of controlled documents will be permitted. Typically, the easier it is for employees to access controlled copies when needed, the fewer times they will feel the need to use an uncontrolled copy of a document. Ensuring timely and convenient access to documents is frequently the source of high costs and repeated discrepancies.

5. To ensure that documents remain legible and readily identifiable.

The format and storage of documents must protect a document from being rendered unreadable due to wear or damage and that every document can be clearly identified through a title, document number or other suitable identification.

6. To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled.

Documents that do not originate within the organization, but are necessary for ensuring quality and meeting customer requirements must also be controlled. These can include customer, supplier or industry documents. However, the extent of control is limited to clear identification and controlled distribution. A log or other record would suffice to track external documents.

7. To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Out-of-date documents or older versions of revised documents must be protected from unintentional use. This usually requires segregation or disposal of obsolete documents. Any obsolete documents that are kept for reference or other purposes must be clearly identified through markings, separate storage areas, or other means.

Controlled documents need to be clearly identified. Hard copy documents need to be stamped. Electronic documents need to be watermarked so that when they are printed, they could be identified that they are controlled documents and a user needs to verify an electronic version prior to use of this document.

Main Objectives

These are some of the main objectives of an organization's documentation system:

1. Communication of Information - documentation is viewed as a tool for information transmission and communication.
2. Evidence of conformity - documentation is viewed as provision of evidence that what was planned, has actually been done.
3. Knowledge sharing - documentation is used to disseminate and preserve the organization's experiences.

Measuring Success

How can you measure the performance of your document control process? Here are some suggested metrics:

- **User satisfaction** – Periodically survey your employees regarding the usability of your documentation. Use the results to improve the format of your documents and training of your authors.
- **Document errors** – Track the number of document revisions due to information mistakes in your documentation. Results will often reveal weaknesses in your review and proofreading processes.
- **Up-to-date** – Count the number of document revisions or audit discrepancies stemming from a document that is out-of-date. This will tell you whether your periodic document reviews or obsolete document provisions are effective.
- **Cycle time** – Measure the time it takes a document to be developed or revised from initial draft to release. Work to improve the efficiency of your document control process as you would any other business process.
- **Cost** – Consider tracking the costs associated with your documentation including developing, revising, storing, retrieving, distributing, filing, auditing, reviewing, approving, etc. Of these potential costs, document retrieval is often an expensive hidden cost generated when individuals must search endlessly for a document because of inadequate indexing, organization, storage or training.

Results of the performance measures of your document control process can help you determine how to drive continual improvements into your entire QMS.

GxP/GMP and Document Control

ISO 9001 is one example of the regulated environment. It is usually used in engineering types of companies. In food, drugs, medical devices, and cosmetics industries, GxP/GMP regulations are used. Documentation is a critical tool for ensuring GxP/GMP compliance.

This is what GMP states about document control:

Each manufacturer shall establish and maintain procedures to control all documents that are required. The procedures shall provide for the following:

1. Document approval and distribution. Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents shall be available at all locations for

which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.

2. Document changes. Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the review and approval of original documents, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

The role of QA, in regards to the document system, is one of management and overview. QA ensures that all documents are maintained in a controlled fashion and that all procedures are being used within a company are approved by the appropriate subject matter experts, are consistent with other documents, and are the most current version. One way that QA ensures this is by being the last signature on all approved documents. All documents; current, obsolete, superseded, as well as all the history on the creation and revision of the document are kept in Quality Assurance.

These are the steps of the document control procedure:

Creation

Any knowledgeable employee should be able to write or revise documents as needed.

Revising

When revising a document the redline changes along with detailed justification of the changes should be routed.

Routing

The document control function of QA is responsible for routing documents for review and approval. It is suggested that a pre-route be done to ensure that all affected parties are in agreement with the document before it is submitted to QA. There should be a documented process detailing how documents are submitted for review and approval.

A controlled form listing all the changes made to the document, justification for the changes, and a list of personnel who need to review the document needs to be routed along with the document. At a minimum the author's manager, all affected department heads, and QA need to review the document. Other Subject Matter Experts can be included.

Approval

Once all affected parties have agreed to the changes, document control will prepare the document for approval. All changes will be incorporated into the document. For new documents the version # will be 00. For each revision of a document the version number will increase (01, 02, 03, etc.) A master document will be routed for approval signatures.

Typically the approval signatures are the Author, the Department Head, and QA. QA must be the last signature on all documents. Usually the approval signatures only appear on the first page of the document. Once the master document has been signed, and effective date is stamped onto each page of the document. The effective date must be far enough in advance to allow for the document to be trained on before it becomes effective (typically this is 5 days).

Distributing

On the effective day copies of the signed master document are routed to the affected departments. The departments will remove the old version and replace it the new version (for revised documents). If the document is new, there will be no replacement document to remove.

The old versions must be returned to document control. On a periodic basis document control personnel should audit the binders to determine if they contain the correct versions. Each document binder should

contain a table of contents and only those documents that the department is responsible for. A full set of all approved documents should be in the QA department as well as in a central company location.

Archiving

Old revisions of documents will be stamped as superseded. No document revisions will be discarded or altered. A file will be maintained within QA that contains all the superseded documents and the signature approvals of personnel who agreed to the revisions.

Obsolete

If a document will no longer be used by any department in the company it can become obsolete. The document must be stamped as Obsolete and all copies removed from all document binders. It is a good idea to place a notice in the document stating that the document has been Obsolete.

Good manufacturing practice (GMP) regulations require that all documentation be issued, managed and controlled using a document management system.

Document Control System Implementation

Follow these steps for a successful document control system implementation.

Select a System

Select an electronic system in which you are going to control your documents. If you already have a content management system in place, it could serve document control purpose as well. If you don't have a content management system, select a system specifically designed for document control. Most widely used and popular systems specifically designed for document control are Agile, Arena, and Omnify. If in future you decide to implement a content management system, you would be able to integrate it with your document control system.

Define Controlled Documents

Controlled document is any document that is used to perform work. Reference document is any document that is used for reference only and NOT to perform work. These documents must NOT be used to perform work.

Identify all your document types, for example specifications, drawings, schedules, meeting minutes, etc. Among these documents, identify which documents are going to be controlled documents and which are going to be reference documents.

Be careful about designating documents as controlled. Controlled documents must be approved by authorized approvers in order for them to be valid and to be able to use them. The author or modifier of a controlled document must get this document approved before it can be used to perform work. Each controlled document would need to have a number. All controlled documents must be accounted for, their distribution is strictly controlled. For this reason, choose your controlled document types with great care.

So, if a document so not need to be approved or their distribution is strictly controlled, make it a reference document. For example, if a document is going to be used for work and this work needs to be controlled as far as its quality and safety, then this document should be controlled.

Define Document Approvers

Define who in your staff is going to approve documents when they are going to be created or changed. Define the procedure for documents approval.

ECO Process

When a new document is created or a document is going through a change, Engineering Change Order (ECO) is used to document and approve the document creation or changes. It can also be called Engineering Change Notice (ECN) or Document Change Notice (DCN). ECO outlines the proposed change, lists the product or

part(s) that would be affected and requests review and approval from the individuals who would be impacted or charged with implementing the change. ECOs are used to make modifications to components, assemblies, associated documentation and other types of documents.

The change process starts when someone identifies an issue that may need to be addressed with a change to the product. It ends when the agreed-upon change is implemented. ECOs are used in between to summarize the modifications, finalize the details, and obtain all necessary approvals. Every time a document is created or changed, ECO would need to be created and used to get this document approved.

You would need to assign a number to each ECO and if you are not using an electronic system for generating ECO or lists which could be used as ECO list, you would have to scan and upload ECO into your system.

Taxonomy

Every information system should include two access points to information: search function and browse function. Users use search function when they know exactly what they are looking for. Users use browse function when they do not know what they are looking for. Taxonomy needs to be created to accommodate the browse function in the system.

Users do not always know what they are looking for. In fact, in most cases, users do not know what they are looking for or they know it but are not able to find it using search. Users are going to look for ways to find documents. It is easy to find uncategorized documents when there are just few of them in the system. When there are many items in the system, it is going to be very difficult to find them.

Create taxonomy for your documents. Taxonomy should be validated in the user study and user side testing when necessary and adjusted as needed.

Metadata, Naming Conventions, Controlled Vocabulary

Metadata

Metadata values for documents need to be defined to accommodate the search function of documents in the system. Each document type should have metadata assigned to it. Metadata values would be the criteria that users need to use to search for documents.

The general system search will accommodate the full text search of content. This search would be sufficient when there are just few documents in the system. When there are many documents in the system, the general system search will retrieve a long list of irrelevant items. Users are not going to browse through long lists of items. To make the search precise, the presence of metadata is necessary. If metadata is present, the search can be performed using metadata rather than full text search.

Metadata should be validated in the user study and user side testing when necessary and adjusted as needed.

Naming Conventions

The role of naming conventions is very important in order for users to identify documents in the list without opening each one of them. Naming conventions should be created for each document type. Naming conventions should be validated in the user study and user side testing when necessary and adjusted as needed.

Controlled Vocabulary

Controlled vocabulary is the list of controlled terms that should be used for some of the metadata fields. These controlled terms should be standard terms used in standard publications, documents, majority of users, etc. Controlled vocabulary would help to ensure that metadata values are consistent. Consistent metadata will ensure high precision search.

Assure Documents Distribution

During this step, you need to make sure that everyone who needs the document gets a copy.

Distribution may be physical (paper documents) or electronic. When posting the document on intranet or other electronic systems, ensure that everybody who needs to have the new document knows about the posting (e.g. through an email or workflow notifications). When distribution is physical (paper documents), documents need to be stamped to identify that this is a controlled document and that a user of this document needs to verify that this is the most current version before starting work.

Controlled documents need to be watermarked so that if they are printed, users know that they need to verify their version before using them.

An inventory of controlled documents should be created with the exact location of each controlled document.

Remove Obsolete Documents

This is easy if you use an electronic documentation management system but is more complicated with hard copy documents. Each hard copy document must be replaced when it has been changed.

You may request the receiver of new documents to send back obsolete ones. If for some reason you need to retain obsolete versions of documents, they need to be marked to avoid unintended use. Many organizations use a stamp: "obsolete document".

Final Recommendations

In the regulated environment, the document control is the cornerstone of the quality system. It is so important that if an external audit identifies deficiencies in the document control system, the entire organization can be shut down.

Establishing and following document control procedures therefore is extremely important for compliance.

About Galaxy Consulting

GALAXYCONSULTING
Information Management Solutions

Galaxy Consulting provides services in business analysis and usability, content and knowledge management, records management, information architecture, enterprise search, taxonomy development and management, document control, and information governance.

Galaxy Consulting was founded with the mission and vision of helping organizations to manage their valuable information assets. Many of our clients, both large and small, have dramatically improved efficiency and reduced unnecessary labor hours through efficient methods, processes, and solutions we created.

Galaxy Consulting believes in partnerships with our clients. We are committed to working with you and to helping you transform your business. We will increase efficiency and productivity, maintain regulatory and legal compliance, improve collaboration, enhance innovation, and reduce costs through effective information management!

Call us TODAY to schedule a free, no obligation consultation!

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