



MARLOW OFFSHORE GERMANY GMBH & Co. KG

ISO 9001:2015

Control of Documented Information

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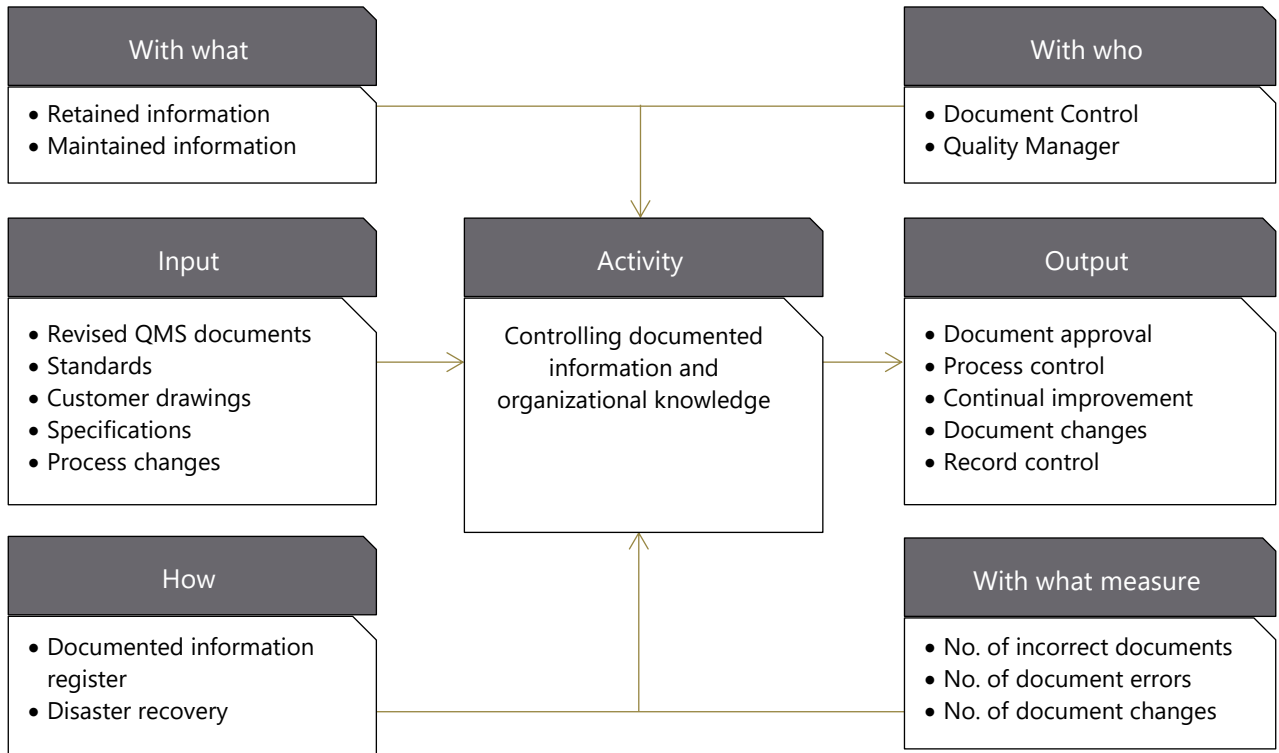
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1 Control of Documented Information

1.1 Introduction & Purpose

The purpose of this procedure is to ensure that all relevant documented information and organizational knowledge which forms an integral part of our quality management system is managed under controlled conditions and that all documented information is reviewed and approved by authorized personnel prior to issue.

1.1.1 Process Activity Map



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Documented Information	Information (3.8.2) Required to be Controlled and Maintained
Record	Document (3.8.5) Stating Results Achieved or Providing Evidence
Quality Manual	Specification (3.8.7) for the Quality Management System
Specification	Document (3.8.5) Stating Requirements
Objective Evidence	Data (3.8.1) Supporting The Existence or Verity of Something

1.2 Application & Scope

Documented information is retained to provide evidence of conformity to the requirements specified by ISO standards, customer requirements and of the effective operation of our management system. Marlow Offshore Germany GmbH & Co. KG uses standard forms and templates accessed via a local area network computer system. This documented procedure defines the controls for:

1. Approving documents for adequacy prior to issue;
2. Reviewing and revising as necessary and re-approving documents;
3. Ensuring that changes and current revision status of documents are identified;
4. Ensuring that relevant versions of applicable documents are available at points of use;
5. Ensuring that documents remain legible and readily identifiable;
6. Ensuring that documents of external origin are identified and their distribution controlled;
7. Preventing the unintended use of obsolete documents;
8. Ensuring that documents of external origin are identified and their distribution controlled.

This procedure applies to all quality management system documentation and is to be followed by all personnel where appropriate.

1.3 Requirements

Top management ensures that when we create documented information it is appropriately identified and described (e.g. title, date, author, reference number) and is available in an appropriate format (e.g. language, software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy.

An electronic document management system, which is backed up and updated as required, is used to retain documented information ensuring only the current versions are available to users. Records from process outputs are generated and maintained by the departments responsible for their creation. For electronic records, back up procedures are established, employees are responsible for backing up their data.

1.4 Creating, Updating & Controlling Documented Information

Marlow Offshore Germany GmbH & Co. KG applies the following criteria to all types of 'documented information' in order to assess whether the information is necessary for demonstrating the effectiveness of our QMS, and whether it should be formally controlled.

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.

1.4.1 General

All documents and data are reviewed and approved by authorized personnel prior to issue. Each department issues and maintains its own documents. Current revisions of appropriate documents are available at locations where they are used. Documents controlled by this procedure include but are not limited to the following:

1. Specifications and drawings;
2. Quality management manual;
3. Operational procedures, reports and forms;
4. Management review and design review minutes;
5. External documents.

1.4.2 Document & Data Identification, Approval and Use

All documents are identified with a title, revision level and where applicable, a code or part number. Certain work instructions have a revision level. Only original forms, which are stored on file, are identified with the issuing authority. All documents are reviewed and approved (signed and dated) prior to issue.

1. Prior to issue and release, documents are reviewed for correctness and compliance to quality requirements.
2. Documents that require more than one approval signature indicate how many and which signatures are required for approval and issue.
3. The Quality Manager is responsible for ensuring that the quality manual is reviewed, approved and distributed as required. Copies of the manual will be serialized and issued on a controlled distribution basis.
4. Uncontrolled copies will be marked 'UNCONTROLLED' and will be provided for use outside of the company, although a controlled copy can be issued to customers upon customer request.
5. Customer documents (e.g. standards, specifications & drawings) and external documents (e.g. changes received from customers) are reviewed by the Quality Manager.
6. If any ambiguities or errors are detected, the customer is notified.
7. Only documents approved may be used for production and service operations.
8. Each department issues and maintains its own documents and produces a master document index of all documents and their current revision.
9. Current revisions of appropriate documents are available at locations where they are used.
10. When documented information is transmitted external parties; the initiating person identifies its distribution to the Document Control Department who will generate a document issue sheet.

1.4.3 Revising a Controlled Document

Controlled documents may be temporarily amended by authorised personnel through a red-lining process and includes hand-written amendments which are initialled and dated by the authorised person. Current revisions of appropriate documents are available at locations where they are used by staff.

1.4.4 External Documents

The Quality Manager periodically verifies the current revision of external documents (e.g. international standards, customer specifications, etc.) and amends the documents and master document index accordingly when new revisions are available. Notification of revision changes is given to those departments shown in the distribution list.

1.4.5 Uncontrolled Documents

Copies of documents issued to personnel and outside parties for information only (are not affected by the documents) are stamped '**UNCONTROLLED**' across the front page. Such documents are not under revision

control. Uncontrolled copies of documents may not be issued to personnel or outside parties who manage, perform, or verify work that is directly affected by the document.

1.4.6 Document Change Requests

Changes to a document are requested using the document change request form if a document is found to be deficient. Any employee can request a change to a document but the review and approval must be performed by the same functions that performed the original review and approval.

1.4.7 International Standards & Specifications

The Quality Manager maintains a controlled and up to date set of relevant International Standards and Specifications, relevant to our operations, for the purpose of reference and to assist compliance to company and client requirements. Controlled copies of such standards maybe distributed as required and/or placed on the company website.

1.4.8 Obsolete Documents

Obsolete documents are removed from points of use and may be retained for reference or for legal obligations are marked '**OBSOLETE**' and kept separate from active documents. Obsolete document documents are stored and retained in accordance this procedure.

Filing cabinets containing obsolete documents are segregated and labelled 'OBSOLETE'. Obsolete electronic documents are removed from the network and are stored in media that is accessible upon request. Any obsolete documents that need to be reactivated must be reviewed, approved and released in the same manner as newly established documents.

1.5 Management System Records

Records are retained to attest to the proper implementation of various aspects of the integrated management system. Records are stored as secured computer files or in designated filing cabinets to prevent deterioration and damage. Such records are easily accessible for use and are made available for review upon request.

Master forms are be signed by the initiator and date indicated to evidence their authority. Forms are controlled via their document number and revision status. Standard forms, e.g. pre-printed material are listed in the appropriate procedure or work instruction.

Archival records and data retained for legal or knowledge preservation purposes or both are suitably identified. All records must contain sufficient data to attest to satisfactory completion of the recorded activity and at minimum, must be signed and dated by the individual responsible for completing the record. The following documents are acceptable records:

1.5.1 Protection, Storage and Retrieval of Documented Information

Documented information may exist in either hard copy or electronic formats. Hard copies are stored where they are protected from physical deterioration, loss and damage due to environmental conditions. Electronic back up data are located on main server and NAS (Network Attached Server). Contract documents are stored in a lockable cabinet/ room.

Documented information is labelled and indexed for ease of retrieval and for proper referencing. All filing cabinets, containers, and devices are clearly marked and labelled to identify their contents. Retained

documented information is indexed and grouped for expedient retrieval. Retained documented information must not be stored on personal storage drives or files.

1.5.2 Retention Period for Records

Document	Retention Period
Management Reviews	2 Years
Audit Reports	5 Years
Process Monitoring Records	5 Years
Legal & Compliance Records	10 Years
Risk & Opportunity Assessments	10 Years
Business Plans	5 Years
Corrective Action Reports	5 Years
Complaint Records	2 Years
Inspection and Test Reports	5 Years
Non-conformance Reports	5 Years
Training Records	10 Years
Calibration Records	5 Years

1.5.3 Disposal of Records

Upon expiration of the retention period, Quality Manager will dispose of such records in an appropriate manner. Confidential records are shredded.

1.5.4 Register of Documented Information

Marlow Offshore Germany GmbH & Co. KG **maintains** the following Documented Information:

ISO 9001:2015	Description
4.3	The scope of the quality management system
4.4	Information necessary to support the operation of QMS processes
5.2	The quality policy
6.2	The quality objectives

Marlow Offshore Germany GmbH & Co. KG **retains** the following Documented Information:

ISO 9001:2015	Description
4.4	Information necessary to support the operation of QMS processes
7.1.5.1	Evidence of fitness for purpose of monitoring and measuring resources
7.1.5.2	Evidence of the basis used for calibration of the monitoring and measurement resources
7.2	Evidence of competence of people doing work under the control of the organization that affects the performance and effectiveness of the QMS
7.5.1b	Documented information required by the QMS
8.2.3	Results of the review and requirements for the products and services
8.3.2	Records to demonstrate compliance with design and development requirements

ISO 9001:2015	Description
8.3.3	Records of design and development inputs
8.3.4	Records of the activities of design and development controls
8.3.5	Records of design and development outputs
8.3.6	Design and development changes, including the results of the review and the authorization of the changes and necessary actions
8.4.1	Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any actions arising
8.5.2	Evidence of the unique identification of outputs when traceability is a requirement
8.5.3	Records of property of the customer or external provider that is lost, damaged or non-conforming and of its communication to the owner
8.5.6	Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken
8.6	Records of authorized release of products for delivery to the customer including acceptance criteria and traceability to the authorizing person(s)
8.7	Records of non-conformities, actions taken, concessions and the identity of the authority deciding the action in respect of the nonconformity
9.1.1	Results of the evaluation of the performance and the effectiveness of the QMS
9.2.2	Evidence of the implementation of the audit programme and the audit results
9.3.3	Evidence of the results of management reviews
10.2.2	Evidence of the nature of the nonconformities and any subsequent actions taken
10.2.2	Results of any corrective actions

1.6 Organizational Knowledge

1.6.1 General

Marlow Offshore Germany GmbH & Co. KG recognizes that organizational knowledge is a valuable resource that supports our quality management activities and ensures continual product and service conformity. There is a strong link between organizational knowledge and the competence of our people, the latter being peoples' ability to apply knowledge to their work.

1.6.2 Sources of Organization Knowledge

Sources of internal knowledge often include the organization's intellectual property; knowledge gained from experience; lessons learned from failures and successes; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services.

Sources of external knowledge often include other ISO standards; research papers; conferences; or knowledge gathered from customers or external parties. Your organization considers internal and external sources, such as:

- Lesson learnt from non-conformities and corrective actions, near miss situations and successes;
- Gathering knowledge from customers, suppliers and partners;
- Capturing knowledge that exists within the organization, e.g. through mentoring, succession planning;
- Benchmarking against competitors;
- Sharing organizational knowledge with relevant interested parties to ensure sustainability of the organization;

- Updating the necessary organizational knowledge based on the results of improvement;
- Knowledge from conferences, attending trade fairs, networking seminars, or other external events.

1.7 Forms & Records

Master forms are signed by the initiator and date indicated to evidence their authority. Forms are controlled via their number and revision status. Standard forms, e.g. pre-printed material are listed in the appropriate procedure or work instruction.

Title & Description
Master Document & Record Index
Document Change Request