



Quality Procedure ISO 9001: 2008 – Control of Documents

1 Purpose

FablesSemi Inc¹ controls all documents that are required by our Quality Management System (QMS).

The purpose of this procedure is to define the process and responsibilities to ensure that internal documents, external and customer-supplied documents (standards, specifications, procedures, etc.), and data within FablesSemi Inc are controlled.

2 Scope

The requirements of this procedure apply to all drawings, procedures, work instructions, forms, etc. used within the QMS that affect the quality of products or services at FablesSemi Inc.

3 Revision History

3.1.1 Approval

This Quality Procedure has been approved for use throughout FablesSemi Inc:

Date of Initial Version: February 2nd, 2009
Name and Title of Approver: Any Name (Director)
Date of Approval: April 21st, 2009

This Quality Procedure was written and published by **Any Name** of FablesSemi Inc. Please contact any.name@fablessemi.com with questions, comments and improvement ideas.

3.1.2 Revision History

The following revisions have been made to this procedure since its initial publication:

Revision Date	List of Changes	Author	Approval
02/02/09	First draft	PW	
10/03/09	Incorporated review comments from the QA team and up-issued	PW	
21/04/09	Issued as an example document and published to the Extranet Library at www.cognidox.com	PW	PW

4 Related Documents

All references to ISO 9001 in this procedure refer to the requirements of ISO 9001:2008.

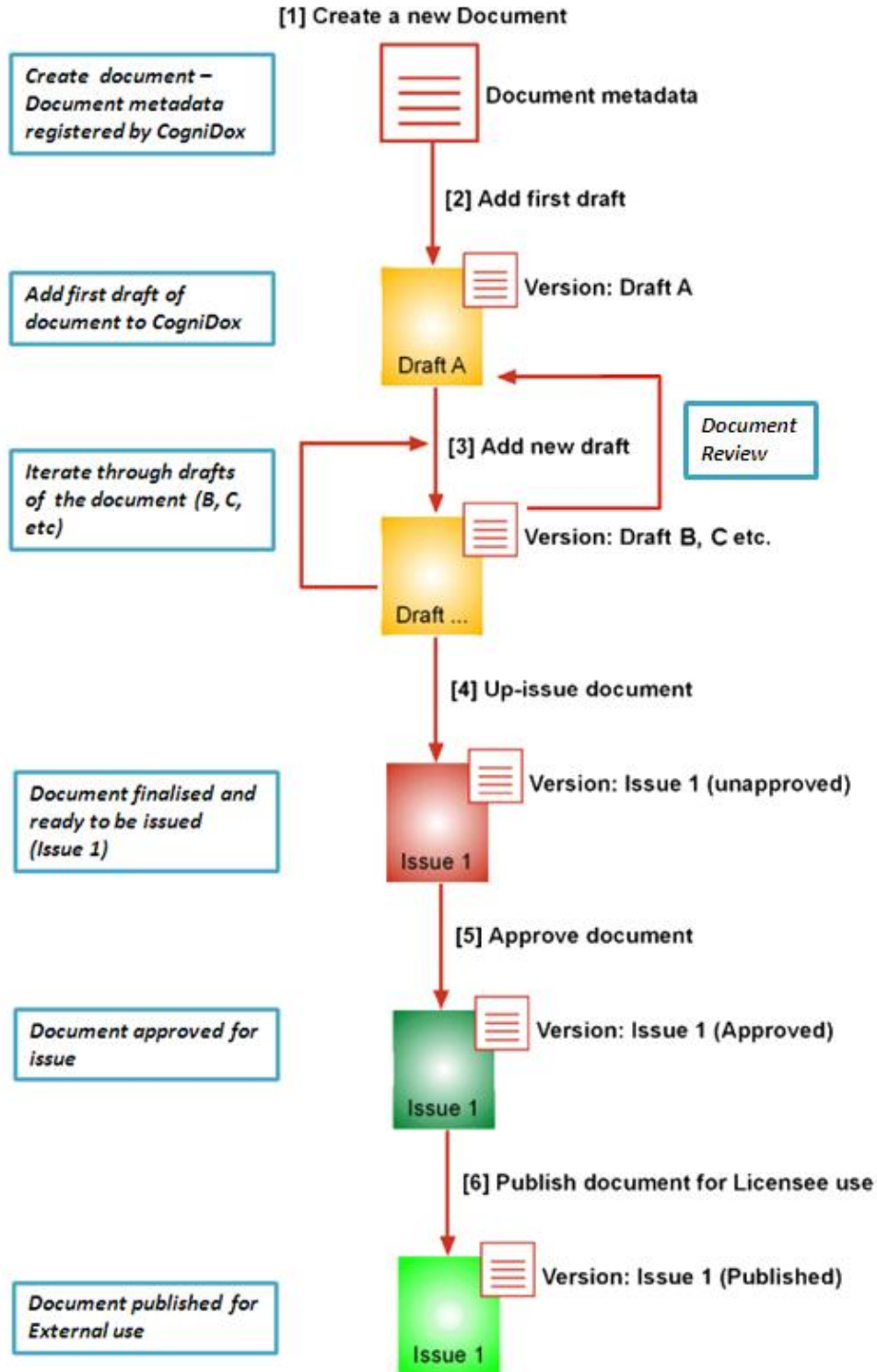
¹ FablesSemi Inc is a fictional company. The domain www.fablessemi.com is registered and controlled by Cognidox Limited (www.cognidox.com) as a demonstration of its document control software.

This procedure is referenced in our Quality Manual as follows:

- Quality Procedure for Control of Documents (referenced in Chapter 4.2.3)

This document is itself established, documented, implemented and maintained using the procedure described herein.

5 Process Flow Chart



6 Procedure

6.1 QMS Documents

This procedure applies throughout FablessSemi Inc to the following documents, data, or other information sources that comprise the QMS:

- Quality Manual and QMS Procedures & Forms that describe the QMS and specific QMS processes applicable across all departments / areas
- Local work instructions, forms, or other process specific documentation applicable only to a specific department / area process

QMS documents are stored electronically within the CogniDox management system. Using a standard format, the following requirements will be met for QMS document control:

- all documents shall be approved for adequacy prior to use
- review and update as necessary and re-approve documents
- ensure that changes and current revision status of documents are identified
- ensure that relevant versions of applicable quality documents are available at points of use
- prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

The standard format for QMS procedures shall include, as appropriate:

- header and footer on each page containing: document name, document number, revision level, latest revision date, latest printed date, page number
- scope and objectives
- applicability
- related documents
- procedure flow chart
- procedure
- responsibilities
- record retention
- document control
- document revision history
- approval and date

6.2 Product Realization Documents

FablessSemi Inc implements and maintains documents for use in the product realization process. These documents, by way of example, include marketing requirements, engineering specifications, software and customer training materials.

Product realization documents are stored electronically within the CogniDox management system. All product realization documents meet the following requirements for document control:

- documents shall be approved for adequacy prior to use
- review and update as necessary and re-approve documents

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- ensure that changes and current revision status of documents are identified
 - ensure that relevant versions of applicable documents are available at points of use

6.3 Document Repository

All QMS and product realization documents are stored electronically within the CogniDox management system. This provides a set of category and sub-category headings that enable users to drill down into the different levels of the documentation category tree.

QMS documents are created and maintained within a top level category entitled "ISO 9001 Quality Management System (QMS)". Documents in this category follow a 4-tier approach:

- Quality Manual - company scope and process interactions within the QMS
- Quality Procedures – responsibilities, controls and activities within the QMS that effect customer service
- Records - objective evidence to demonstrate our goal in achieving customer satisfaction
- Forms & Reports to support the QMS processes

Product realization documents are stored in categories corresponding to Products, Projects and Departments. Each document is unique, but can be accessed from multiple categories.

Documents created within the FablessSemi Inc CogniDox system are assigned a unique identifier using the format "PO-NNNNNN-XX"; where the "PO" prefix identifies them as FablessSemi Inc documents, the "NNNNNN" is an automatically generated and uniquely assigned numerical ID, and the "XX" suffix indicates the document type.

All FablessSemi Inc personnel are responsible for creating document part numbers and uploading documents to an appropriate category. Selected users with additional system privileges are responsible for creating and maintaining document categories.

6.4 Document Review

Documents required for the QMS and product realization are required to be reviewed. The document owner is responsible for choosing a set of reviewers from a selection list and informing reviewers of e.g. review due date.

Reviewers are contacted automatically by email and are responsible for entering their review comments in the review section of the document part in CogniDox.

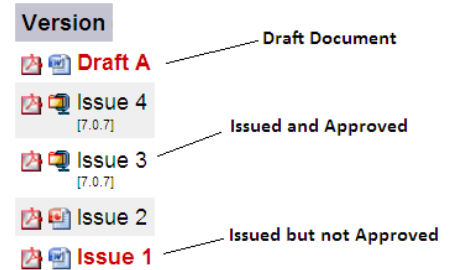
The document owner is responsible for integrating the review comments and uploading a modified version of the document in accordance with those review comments.

6.5 Document History

Each document part created in CogniDox enables the user to access the full version history of the document.

The document process flow chart is depicted in Section 5.

Draft documents are displayed in red, bold font. Documents that are issued but not approved are also highlighted in red, bold font. Documents that are issued and approved are displayed in black, regular font. The latest, approved version of each document is shown at the top level for each document part.



From the document details page for each document part the previous version history and approvals history is available.

6.6 Document Approval

Documents required for the QMS and product realization are required to be approved. For each document, CogniDox will present a list of FablesSemi Inc personnel names that are authorized approvers for that document or category of documents.

Only issued documents can be approved.

The CogniDox user selects an approver or approvers; the approver is notified by email, and the subsequent approval is recorded as part of the document metadata.

Only approved documents can be published externally.

6.7 Change Identification

Each time that a new draft or issue of a document is uploaded to CogniDox, a new version identifier is automatically recorded by the system.

The convention is letters for drafts (Draft A, Draft B, etc) and number for issues (Issue 1, Issue 2, etc). When an issue is being amended prior to being up-issued, the convention is to record it as Issue 1A, Issue 1B, etc. Promoting e.g. Draft E to Issue 1 is a one-click operation.

6.8 Document Availability

Documents in the CogniDox repository are available to FablesSemi Inc personnel following authentication with their company username and password.

This is subject to document access control and security restrictions that may have been placed on a document, but generally-available documents (such as the Quality Manual) will not be restricted.

The system is web-browser based and does not required special client-side software, so it can be accessed from any computer.

This includes remote access over a virtual private network (VPN).



6.9 Document Publication

Documents required for product realization may optionally be published, that is, made available to external users such as customers and suppliers.

Only documents that have been issued and approved are permitted to be published. This is a system restriction imposed by CogniDox. The publication process itself is automated. External users must be authenticated to access these published documents.

An audit history of usage by external users (e.g. date and time of document download) will be maintained by the system.

6.10 Control of External Documents

Documents of external origin such as quality standards, industry standards, customer specifications, customer marks, etc. may be used as part of the product realization process.

External documents are stored electronically within the CogniDox management system in a clearly-designated folder; verified as current and when necessary have their distribution controlled.

It is the responsibility of Management and each Process Owner to review, implement, and maintain these documents and verify that they remain current at appropriate frequencies.

6.11 Obsolete Documents

A document can be marked as obsolete within CogniDox. An obsolete document is subsequently displayed with a line through the document title. This display gives a visual indication to all users that the document is obsolete and should not be used.

An obsolete document is not available for external publication; even it is issued and approved.

7 Responsibility

Quality Manager

Effective implementation of the document control system for QMS documentation, and maintain the system for the positive recall of documents and master list of documents.

Category Owners

Effective implementation of the document control system for product realization documentation, and maintain the system for document review, approval, publication and retirement.

System Administrator

Protect the integrity of the electronically stored documents and data by performance of system backups and ensuring restoration capabilities.

8 Records

Documentation will be maintained in accordance with procedure VI-401466-PS-B