Procedure # 01-002

Creating and Revising Documentation

Revision: U

Effective Date: September 28, 2015

Document Approvals

R&D, Quality Assurance, Marketing, Support

Document Revision History (see previous versions for earlier history)

| **Revision** | **Date** | **Name** | **Changes With Reasons** |
| --- | --- | --- | --- |
| V | August 25, 2015 | Alex Vereschagin | 1.4 – Added paragraph to describe process of creating/revising a document.  1.8 – Clarified annual review process and defined a location where records of the document reviews are to be stored. |

# Overview and General Requirements

## Document Types

This procedure specifies the process for creating and editing local documents of the Software and Informatics Business. This procedure is designed to comply with the requirements of the LSCA Document Controls process. This includes the following document types:

* **Procedure Documents** – these are local documents that describe how to carry out activities or processes. Generally, Procedure Documents are not specific to individual projects or products.
* **Project Documents** – these are documents for specific new product development projects (for example, specifications, plans, test cases).
* **Product Manufacturing Documents** – these are documents that describe activities or processes for manufacture of specific products.
* **Customer Documents** – these are documents that are intended for use by customers with products or as products themselves. These documents are not governed as part of this procedure.
* **Records** – these are documents that contain objective evidence that policy, procedure, technical, or other requirements are satisfied. For example, a procedure document may require a form be completed or a database updated. The completed form or database entry is considered a record. This procedure defines general requirements for the control of records but the requirements for specific records are defined in the procedures that specify them.

## ECM Document Control System

The Agilent OpenLAB Enterprise Content Management (ECM) system is used for document management. All employees will need access to the LSCA account in the ECM system at <http://scsecm.scs.agilent.com/> .

## Document Contents

All documentation must contain the following information:

* A unique document identifier\* and current revision
* Names or titles of the document owner, author (if not also the owner) and approver(s). These may be provided by the document management system. Where titles only are provided in the document itself, the document management system or document index must provide the actual names.
* The date approved and date effective (if different). Date format is either dd-Mon-yy or dd-Mon-yyyy where day and year are numeric and month is signified by a three-letter English abbreviation (either capitals or lower case), e.g. 06 JAN 09 or 06-Jan-2009; or ISO format, yyyy-mm-dd, e.g. 2009-01-06.
* A document revision log containing an overview of changes to the document since its last release. This may be maintained in the document management system. References to supporting documentation are made where appropriate.
* References to the parent document(s) that establish its higher level requirements as well as to any documents directly referenced within the document itself
* The current page number and the total number of pages within the document (example: Page 3 of 5)\*

Items with an asterisk (\*) can be included as part of the header or footer of the document so that they are displayed on each page of a multi-page document.

## Document Templates

When creating new documents, the documents must be created using the correct document template for the document type. These templates are located under *<SID General\Other Documents\Document Templates>* in ECM except for project documents where templates are located in the LSG Product Lifecycle site: <http://lsca.germany.agilent.com/lifecycle>.

New or revised documents shall be saved their respective In Process Folder in ECM until approved. Once the new or revised documents have been approved with all required signatures, the document shall be moved to the respective Current and Approved Folder in ECM.

## Retention Policy

Documents are retained in compliance with the Agilent record retention policy defined in Finance*Net*: Records and Information Management (RIM): <http://legal.agilent.com/rim/index.shtm> .

## Document Control

Documents are considered uncontrolled when they are printed or copied. Only controlled, online copies of documents are to be utilized when performing work.

## Customer Information

Customer information must be kept confidential to comply with confidential disclosure agreements (CDA) and other agreements. To the extent practical, customer names, contacts and other information should not to be included in any documents that may be subject to review by other customers during audits. In some cases, such as custom software projects, this is not practical.

## Document Review Cycle

All Software & Informatics Procedures and Product Manufacturing Documents must be reviewed by the document owner for suitability, adequacy, and effectiveness annually. Documents requiring revision shall be updated and re-approved.

When any updates are made to a document, the author is responsible for ensuring that any related documents are updated as required.

Upon completion of the annual document review, the document owner shall update the SID documents review records and inform the QMS Lead/Quality Manager of the update. If no update is made, an entry of “No update required” shall be entered. Records of this review shall be maintained under *<SID General\Records\Quality Assurance\Document Review>* in ECM.

## Obsolete Documents

When documents become obsolete for any reason, they must be moved from the Current and Approved drawer or folder of ECM to an Obsolete folder. When a document becomes obsolete, the author is responsible for ensuring that any related documents are updated as required.

# Procedure Documents

## General Requirements

For General and Department-specific Procedure Documents, there must be a procedure number assigned. Procedure numbers must be the format XX-YYY where XX indicates the procedure category as follows:

01 – General Procedures

02 – Engineering Procedures

03 – Quality Procedures

04 – Marketing Procedures

05 – Order Fulfillment Procedures

06 – Services and Support Procedures

07 – Other Procedures

YYY is a sequential number for procedures in each category. New procedures may be assigned the next sequential number. Previously used document numbers may not be reused even if a procedure has been made obsolete.

The procedure described in the document must present a clear statement of intent, a description of the process flow, and a clear reference where any generated records are stored.

Procedure Documents must have an Effective Date indicating the date that the new revision will become effective. This is not required for Project Documents.

## General Procedure Documents

General Procedure documents are those that contain general information and rules that apply to all departments of the company. This procedure is an example of such a document. General Procedure documents must include approvals from each of the department managers reporting to the General Manager.

General Procedure Documents are created using the “General Procedure.dot” template. The current and approved document must be saved to the *<SID General\Procedure Documents\Current and Approved\01 General>* folder in ECM.

It is the author’s responsibility to make sure new procedure documents are approved by the required approvers.

## Department-specific Procedure Documents

Department-specific procedure documents are those that contain information and rules that apply to only one department in the company (for example R&D). Department-specific procedure documents must include sign-offs from their respective departments. For example, an R&D procedure must be signed off by R&D, and Marketing procedure must be signed off by Marketing.

NOTE: for documents such as these that only require a single approval, the author may not be the one who approves the document. In this case, the author’s supervisor must sign. When the author’s supervisor is not from the same department, the author’s supervisor will still sign in the space for the department. In the case where department manager authors a procedure, the manager from another department may approve.

Department-specific procedure documents are created using the general procedure template “Procedure Document.dot” and then removing the boxes for signatures that are not required. The current and approved document must be saved to the appropriate folder under *<SID General\Procedure Documents\Current and Approved>* in ECM.

It is the author’s responsibility to make sure that their new Procedure Document is signed by the appropriate persons, as listed above.

# Project Documents and Electronic Project Notebook (ePN)

## General

Project documents are saved into the appropriate ECM cabinet, drawer, and folder under *<\SID Projects - Active>*. The LSCA Project Lifecycle templates and individual department procedures specify the requirements for these documents.

These documents do not require individual approvals as they are approved as a group at project checkpoints as specified by the LSCA Project Lifecycle.

Project documents are stored in an ECM drawer that is the electronic equivalent of a project notebook known as an Electronic Project Notebook (ePN). When creating a new ePN, the required folder structure must be created by using the Clone feature of ECM on the project notebook template found in ECM under <*\SID General\Other Documents*>.

# Product Manufacturing Documents

New Product Manufacturing Documents are created and saved into the appropriate ECM folder under *<SID General\Product Manufacturing Documents >*. These documents are created using the “Product Manufacturing Document.dot” template and must be approved by Order Fulfillment and Quality.

# Records

The control of records is generally specified in the document where the requirement for the creation of the record is specified. When practical, non-project records should be stored in ECM under <*\SID General\Records*>.

# References

Listed below are:

* Parent documents, higher level, that direct this document (P);
* Business documents, outside the LSCA quality system but within the Agilent organization, that supplement this document (B);
* Sibling documents, same level, that supplement this document (S);
* Child documents that are driven by this document (C);
* External documents, outside Agilent, that guide this document (E).

|  |  |  |
| --- | --- | --- |
| Document # | Title | P/B/S/C/E |
| LSCA-QA001 | LSCA Quality Manual | P |
| LSCA-QA100 | LSCA Document Controls | P |

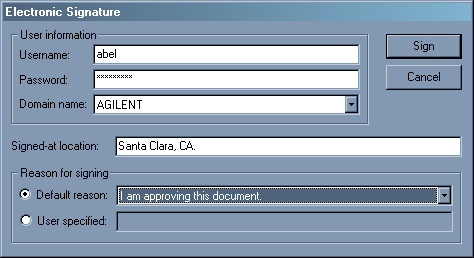
# Appendix

## Instructions for Performing ECM Approvals

For documents that must be individually approved, such as Procedure or Product Manufacturing documents, this procedure is used. The documents are in the OpenLAB ECM system, “LSCA” account, under the SID locations.

1. The author identifies the need for a new document or revision.
2. The author creates the new document or document version.   
     
   For revisions of existing documents, it is the responsibility of the author to ensure that the starting document is exactly the same as the last approved revision that is published in ECM. For convenience, source files may be stored in the appropriate *Source Files* folder of ECM but the author still must verify that the latest source file matches the current and approved document. If a source file cannot be found, the author must re-create it before making the desired changes.  
     
   All changes made to existing documents must be recorded in the revision history. New revision letters are only required from one approved version to another approved version. It is acceptable to issue additional revision letters during the review process as changes occur to facilitate communication but this is not required.
3. The author must then add the file to the appropriate *In Process* folder of ECM. The file name must be the same as the document title.
4. The author will then send an e-mail to request approval of the document to those who need to sign.
5. The approvers must either sign or inform the author the reason they cannot sign. To sign a document, follow the instructions in the ECM help for non-embedded ECM signature.

In the ECM signature dialog box, the reviewer must enter his or her username, password, geographic location, and reason that “I am approving this document”.



NOTE: The reviewer may delegate document approval authority to another employee. At the time of document approval, the delegate will enter their username, password, and geographic location as described above, and the reason that “I am approving this document on behalf of <name>”.

NOTE: There will be no title displayed since Windows domain users are used, and Windows domains do not contain/supply a title for users

1. If approvals are not obtained in time, the author must revise the Effective Date and ask for approvals again.
2. The author must conduct any necessary training on the document revision prior to the Effective Date.
3. On the Effective Date, the author must request someone with Documentation Administrator rights to move the document to the appropriate Current and Approved folder. This is done by moving the document from the *In-Process* ECM folder to the appropriate *Current and Approved* folder.
4. Finally, the author must notify all potential users of the document by e-mail that a new revision has been checked in and is effective.   
     
   Potential users are identified by the type of document. For example, Everyone must be notified of changes to General processes or procedures. All Manufacturing personnel must be notified of changes to Manufacturing documents, all Engineering personnel must be notified of changes to Engineering documents, etc.