This procedure provides general rules for controlling different categories of documents, and documents in different media.

The procedures is based on the assumption that the IMSXpress system is used for controlling most of the documents, but that there also are some paper documents (legacy drawings, customer documents, etc.).

IMSXpress Document Control system is suitable for controlling any category and type of documents, including engineering drawings, specifications, reports, etc.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for the establishment, review, authorization, issue, distribution, and revision of controlled documents.

II APPLICATION

This procedure applies to the following categories of documents:

Make sure to coordinate this list with Quality Manual Section 4.2 where these documents are also listed and defined. Edit the list to be appropriate for your company, for example, if you don't install or service your devices, delete any references to installation and servicing.

- Quality manual;
- Operational procedures;
- Work instructions;
- Forms;
- Device, labeling and packaging specifications;
- Manufacturing, installation and servicing specifications;
- Quality assurance procedures and specifications; and
- Standards and codes.

III PROCEDURE

1 IMSXpress electronic document control system

1.1 Whenever possible and practical, documents are controlled and distributed through the IMSXpress electronic document management system. The system consists of two modules: Document Library and Document Control.

1.2 The Document Library module is for distributing company's documents. From this module users can display and print documents, but cannot change them. When available, users can also view and/or download attachments associated with the document. Only the current (Active) approved and released document revisions are available in the Document Library. Users can view only those document folders (categories) for which they have explicit viewing permission.

1.3 The Document Control module is for managing documents, to include:

- Creating new documents and document revisions
- Organizing documents in a folder tree
- Administrating Document training
- Approving and releasing documents
- Controlling document viewing and editing permissions

2 Paper document control systems

2.1 Paper documents are controlled using manual document control system based on hand signed approvals, master lists, physical distribution, and identification/segregation of obsolete documents. This specifically applies to:

- Legacy paper engineering design documents, specifications and drawings;
- Various confidential documents regarding legal, financing, personnel, contracts and other such confidential documents and records.

Edit this list of excluded the types of documents as applicable in your company.

3 Categories of controlled documents

3.1 **Quality System Records (QSR):** Documents defining the quality management system, in particular the quality manual, operational procedures, and work instructions that are not specific to any particular device or its manufacturing process, are referred to as Quality System Record (QSR). QSR documents are established and controlled following the same rules that generally apply to all controlled documents, e.g., as defined in this document control procedure.

Documents in this category include:

- **Quality System Manual (QM):** This top-level document defines the company's quality policies and quality objectives; defines the scope of the quality system, including details and justification for any exclusions (refer to ***QM Section 1.4***); describes the overall quality system, its processes, and their sequence and interaction; and references applicable operational procedures.
- **Quality System Operational Procedures (QOP):** These are second-level documents defining specific quality system processes. Operational procedures explain the what, when, who and how for a process, and define what records must be established to document the results. Operational procedures are code numbered QOP-SS-xx. QOP stands for Quality Operational Procedure, SS is the section in the quality manual to which the procedure pertains, and xx is the consecutive number of a procedure pertaining to the same section. For example, QOP-75-03 is the third operational procedure pertaining to QM Section 7.5.
- **Quality Procedure Forms (QOP**F):** These are usually one-page manual forms providing a blank template for establishing a record. Forms are code numbered QOP-SS-xx-Fx. SS-xx is the code-number of the procedure to which the form pertains, and F is the designation for Form, followed by a consecutive number of a form pertaining

to the same procedure (to distinguish between different forms associated with the same procedure). For example QOP-82-01-F2 is the second form associated with procedure QOP-82-01.

Forms are established as separate documents, but are associated with specific procedures through the numbering system.

3.2 **Device Master Records (DMR)**: Documents that define the device, manufacturing process, and quality assurance specifications are organized into a file and/or are referenced in an index called a Device Master Record (DMR). Operational Procedure QOP-42-03, Device Master Record, defines how DMRs are established and maintained. DMR documents are established and controlled following the same rules that generally apply to all controlled documents, e.g., as defined in this document control procedure.

Device Master Record (DMR) is a term used in CFR 820.181. In ISO 13485 the file containing the same set of documents is referred to as Medical Device File. Requirements for this file are in ISO 13485 Clause 4.2.3. We use the DMR designation because it seems to be more popular, especially in the US.

Documents in this category include:

- **Product specifications:** These documents include component, subassembly, assembly, packaging and labeling drawings and specifications; bills of materials (or lists of ingredients); compositions; formulations; wiring and piping diagrams; software specifications; user manual, packaging artwork, and other such documents defining the product and its packaging. For some contracts these documents may be of external origin, i.e., supplied by customers.

  Refer to these documents as is customary in your industry and company. For example, in your industry, specifications may be called data sheets, and there may be no drawings but diagrams. If labeling or packaging specifications are not applicable, delete these references accordingly. Whatever the format and names, this clause refers to documents defining your product. If you never receive such documents from your customers, delete the last sentence.

- **Manufacturing specifications:** Documents under this category include process flow charts; diagrams of process/assembly lines; specifications for equipment, tools, and molds; setup procedures; operator instructions; machine maintenance procedures; blank work orders (job travelers), nonconforming product/process forms, and other reporting forms; and other such documents defining the manufacturing processes and the manner of production.

  As written now this clause mentions too many things. This is intentional to give you examples of what types of documents to include. You must edit this clause to include only the types of documents that exist and are actually used in your company. For example, don't mention molds if you don't use molds, and don't include setup procedures if they are not relevant.

- **Quality control procedures and specifications**: Documents in this category include process control specifications/charts; control plans, instructions and acceptance criteria for incoming, in-process, and finished product inspection and testing; procedures and acceptance criteria for the verification of packaging, labeling, installation, and servicing activities; blank forms for inspection/testing reports and other quality records; release document review list; and other such documents defining how products and

manufacturing processes are controlled and verified.

Delete items that are not applicable. For example, if you don't use SPC, delete references to process control; if you don't do labeling, installation or servicing delete references to these activities; if you don't use control plans don't reference them, etc.

- **Work Instructions (WI):** The purpose of work instructions is to guide personnel in performing specific tasks, such as carrying out and controlling a production processes (process operator instructions), handling products, calibrating measuring equipment, conducting tests or inspections, etc.

  Give examples that are relevant in your company.

- **Standards and codes:** These are international, national and local regulations, standards, and codes that define operational, quality and product requirements.

  If you don't use any standards and codes you can delete this whole clause (remember to coordinate with Part II Application and with Clause 4.2.1.1 in the Quality Manual). If you are using only one or two, you could reference them here directly. If there are many different standards, you can just leave this clause as is and list the actual standards to be controlled in the document control master list.

4 Document Identification

4.1 In the IMSXpress control system documents are identified by:

- Document ID
- Title
- Revision level
- Issuing authority
- Effective date
- Review/Approval authority

4.2 IMSXpress system automatically generates a header with document control information (ref. to 4.1 above) and merges the header with the document. This information is also displayed in the Release notes and Changes in the IMSXpress document viewer window.

4.3 Paper documents are, at a minimum, identified by:

These are generic requirements that apply to all types of controlled documents. For specific types of documents, such as engineering drawings, for example, your internal identification requirements may be much more comprehensive. It is usually better to cover such special requirements in separate procedures or work instructions, rather than complicating this general document control procedure.

- Unique title and/or code/number,
- Effective date and/or revision level, and
- Identification of the issuing/approving authority.

The identification is usually displayed in the document header, but this may vary depending on the type of document (drawing, procedure, report, etc).

4.4 At a minimum, all controlled documents are identified with respect to their revision level by

the effective date. In addition, alphanumerical identification of revision level is applied for some types of documents to facilitate their management.

The purpose of this clause is to establish the principle that when there is no numerical or alphanumerical revision level identified on a document, the date is considered to be the revision level. Edit this clause to accurately define how revision level of engineering drawings and specifications is identified.

5 Initiating new documents and revisions

5.1 Personnel on all levels are encouraged to identify the need for, and propose development of new procedures, work instructions, workmanship standards, and additional product-related documents. Personnel are also encouraged to critically evaluate the documents they use and request revisions to correct errors and inconsistencies.

5.2 Anyone in the company may request the issue of a new document, or a revision of an existing document. The person wishing to initiate a document or a revision submits a new document request or document change request in the IMSXpress Change Control module (also accessible from the Document Library module). The processes for submitting requests, evaluation requests, and implementing document changes are defined in operational procedure QOP-42-02 Control of Document Changes.

6 Initial issue

6.1 Prior to issue and release, documents are reviewed for adequacy, correctness, and conformity with company policies.

6.2 Approved and released documents are identified with the name of the person or organizational unit that issued the document, and where appropriate, with the document approval signatures; and the effective date. In the IMSXpress system, this information is entered into the Revision Record, and can be seen in the document header and/or in the Release Notes & Changes tab in the document viewer window.

6.3 In paper (hard copy) documents, hand-written or "wet" approval signatures on documents are not required, although they may be used for particular types of documents (usually for external communication).

Edit if you disagree with this statement, but remember that requirement for "wet" or even for "electronic" signatures makes it more difficult to control and distribute documents electronically. You should not require signatures when there are no real security considerations that warrant it.

7 Revisions

7.1 Changes to documents are reviewed and approved by the same function that approved the initial document, unless specifically designated otherwise. The issuing of revisions follows the same procedure that applies to the issuing of initial documents.

7.2 Revised documents are formally issued when the issuing/approving authority and the new effective date are identified in the document (as well as the new alphanumerical revision

level, where applicable).

This defines how draft documents are distinguished from approved and released documents. Edit to accurately reflect how this is done in your company.

7.3 In IMSXpress system changes are listed and summarized in the Release Notes & Changes record (part of the Revision Control). This Information is then available in the Release Notes & Changes tab in the document viewer window.

7.4 When paper (hard copy) documents are changed by handwritten corrections without the document being re-issued on a higher revision level, the changes are signed and dated. When multiple controlled copies of a document are distributed to different locations, all copies are changed. Paper printouts of documents that are distributed electronically (e.g., are available on the network) may not be changed by handwritten corrections.

This pertains to the so-called redline corrections. If such corrections are not allowed in your company (a good idea), change this clause to simply state that correcting and altering documents by hand is not permitted. Otherwise, edit to accurately describe how handwritten redline corrections are controlled in your company.

8 Distribution of initial issues and revisions

When distributing revised documents, the recipient must be informed what has been changed and what is new in the document. In IMSXpress document viewer there is a special tab, Release Notes and Changes where this information is displayed.

In a paper document there can be a note on the margin, highlighted text, or a cover sheet/transmittal letter summarizing changes. You could also have a "Change History" matrix permanently included in the title page of the document with summaries of changes for each new revision..

8.1 Documents are distributed to personnel and locations where they are needed to correctly carry out, manage, and verify the pertinent processes, activities and jobs.

8.2 Electronic documents are available for viewing and printing in IMSXpress Document Library module. When a document is revised, the old edition is taken down and is replaced with the revised document. This is done automatically in the IMSXpress system so that only the latest (Active) approved and released documents are available in the Document Library. Users can view only documents for which they have explicit viewing permission.

8.3 In the Document Library module, documents are displayed in a document viewer window with three tabs:

- **Document:** displays the main document
- **Attachments:** displays attached documents and files
- **Release Notes and Changes:** displays:
  - Document control information (ID, title, revision, effective date and issuing authority)
  - List of document approvals with electronic signatures
  - Release notes
  - Summary of changes from previous revision of the document

8.3 Paper (hard copy) documents are distributed to specific recipients and/or document stations.

Revisions of paper documents are distributed to the same personnel and locations as the original issues. Upon receiving a new, revised copy of a document, the recipient is required to remove and destroy the old, superseded version of the document. Maintaining unauthorized files with superseded revisions of controlled documents is prohibited.

Some auditors will want to see something more than just such a policy statement that recipients must destroy paper copies of obsolete revisions, and that maintaining unauthorized files with obsolete documents is prohibited. Ideally, there should be a system that ensures the removal of obsolete documents without relying on the recipient remembering to do it. Often the recipient is not interested in giving up the old document because he made some hand-written notes on it (which should be prohibited anyway) or he is simply a pack rat. For example, it could be a system where someone will physically deliver the revised document in "exchange" for the old one; or where old documents must be brought or sent back to the document control function who tracks the return status for each recipient. In a small company with only one location the most practical system would probably be having someone actually go out there and retrieve the old documents.

9 Master list

9.1 In the IMSXpress system, master list of active documents can be displayed and/or printed out in the Document Control module.

9.2 For paper (hard copy) documents there is a master list of controlled documents maintained in an Excel spreadsheet. The list identifies each issued document by its ID/code number, title, approval/issuing authority, effective date, and revision level, as applicable. For paper documents, distribution records are also maintained.

Document Master List is no longer required in the newer editions of the standards. However, especially for paper documents, there must be some way to document what is the latest version of a give document, and what is the distribution list for the document. In electronic document control systems there is no need for such list. Revision and distribution control are fully automated.

10 Customer engineering documents and changes

This is mostly relevant only for subcontractors. If you don't receive and/or use technical documents from customers or other external sources, you can delete this section.

10.1 Engineering documents (standards, specifications, drawings, samples, etc.) and changes received from customers are logged in the Customer Engineering Documents (CED) Log.

You can also log these documents in special customer or contract-related logs or project books, etc. Whatever you do you must have an easily accessible record of engineering documents received from customers and their current status (revision level, approval status and the date on which they were implemented in production).

Whatever the scope of this log, it would be most practical to have it on a computer (an Excel spreadsheet or a database).

10.2 After the documents are logged, they are forwarded for review and approval. The scope of the review includes checking for correctness of the document and its revision level, identification of all changes (for revisions), and verification that the document has been approved by the customer's issuing authority. If any ambiguities or errors are detected, the

customer is contacted. Approval of external documents is indicated by the approval date, the name or initials of the person approving the document, and a note stating that the document is approved for production.

10.3 Only documents approved internally by an authorized function may be used in production or inspection activities.

If you regularly receive customer documents, you probably already have a system for logging, reviewing and maintaining these documents. Edit and further develop this section to define your system as it is implemented. Jus make sure that it includes the review and approval activities.

11 Uncontrolled copies

11.1 Printouts of electronic documents (IMSXpress system and network files) are not controlled and must be destroyed after one-time use.

11.2 Documents issued to personnel and outside parties who are not affected by the document, but need a copy for information only, are stamped UNCONTROLLED across the title page. Such documents are not followed up with revisions. Uncontrolled copies of documents may not be used by personnel or outside parties who manage, perform, or verify work that is directly affected by the document.

12 Retention of obsolete documents

12.1 At least one copy of obsolete controlled documents is retained. This is to ensure that documents used in the manufacture of medical devices are available after the devices have been commercially distributed.

12.2 Obsolete documents are retained for at least the lifetime of the device, but not less than the retention period of any resulting records (refer to Operational Procedure QOP-42-04, Control of Records). In any case the retention period may not be less than two years from the date the device was released for commercial distribution, or as specified by relevant regulatory requirements.

The two years minimum retention period is required by 21 CFR Part 820.180. If you are only implementing ISO 13485 you can delete this sentence.

12.3 For electronic documents, e.g., files in the IMSXpress system or on network drives, obsolete documents are:

- Maintained in the IMSXpress system (they will be automatically designated as Archive and quarantined by the system)
- Downloaded from the IMSXpress system or removed from the network, and are stored in permanent electronic archiving media (removable disks, tapes, etc.)
- Printed out, stamped ARCHIVE and are kept in special files as paper (hard-copy) archive

12.4 For paper (hard copy) documents, retained copies of obsolete documents are stamped OBSOLETE and are kept in special files separate from active documents.

IV REFERENCED DOCUMENTS

- Operational Procedure QOP-42-02 Control of Document Changes
- Operational Procedure QOP-42-03, Control of Records
- Operational Procedure QOP-42-04 Device Master Record