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QOP-42-01	Control of Documents		
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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 ISOXpress system is used for controlling most of the documents, but that there also are other local departmental document control systems that are separate from ISOXpress, for example, for controlling engineering specifications and drawings

If you don't generate much engineering or other product-related documentation, it should be possible for you to control all your documents through the ISOXpress system. In this case delete any references to the 'other control systems'.

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   ISOXpress document control system

1.1   Whenever possible and practical, documents are controlled and distributed through the ISOXpress document management system, consisting of two modules: Document Menu and Document Control.

1.2   The Doc Menu 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 download a (master) file associated with the document. Only approved and released documents are available in this menu. Users can view only those document folders

(categories) for which they have explicit viewing permission (set up from the Doc Control module)

1.3   Documents have automatically generated headers and footers with information about their revision level, effective date, issuing authority and approval status. This information is picked up directly from the document control record (maintained in the Document Control module), ensuring that it is always accurate and up to date.

1.4   The Document Control module is for creating and managing documents, to include:

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

2   Other document control systems

2.1   Some categories of documents are controlled locally by the departments that establish and/or use the documents, and are not entered in the ISOXpress system. This specifically applies to:

- Engineering design documents, specifications and drawings;

    If you decide to exclude engineering documents form ISOXpress (which would be appropriate in some cases), the engineering department must then have their own document management system that complies with ISO 13485 and general requirements of this procedure. They would also need to have a separate procedure or work instruction defining their system.

- 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-NN. QOP stands for Quality Operational Procedure, SS is the section in the quality manual to which the procedure pertains, and NN 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 Forms (QF):** These are usually one-page manual forms providing a blank template for establishing a record. Forms are code numbered QF-SS-NN-M. QF stands for Quality Form, SS-NN is the code-number of the procedure to which the form pertains, and M is the consecutive number of a form pertaining to the same procedure (to distinguish between different forms associated with the same procedure). For example QF-82-01-2 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-42-02, 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.

Although the concepts of DMR and QSR are defined in CFR 820.181 and 820.186, ISO 13485 also requires the same types of documents. The difference is in how the documents need to be organized rather than what controlled documents are actually required.

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 ISOXpress control system documents are identified by:

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

4.2   ISOXpress system automatically generates a header with document control information (ref. to 4.1 above) and merges the header with the document.

4.3   In other document control systems 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 specific format and method for applying the identification depend on the type of document and whether the document is in paper or electronic medium.

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 draft of the proposed document to the manager or supervisor responsible for issuing this type of documents (or, if revision, to the author of the original document). The manager responsible for approving and issuing the document may revise or reject the draft. Regardless of who initiates a document, the responsibility to review, approve, and issue the document always rests with the manager authorized to issue the particular type of documents.

> *If you already have an established process for initiating documents and requesting revisions, rewrite this clause to accurately describe your process. Larger companies often have special forms for requesting new documents and changes, but this is not necessary in a small company.*

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 (or initials) of the issuing, and where appropriate, approving authority; and the effective date. In the ISOXpress system, this information is entered into the Document Control Record, and can be seen in the document header.

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　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

Your company may have a much more elaborate system for distribution of paper (hard copy) documents. For example, you may have a system of transmittal letters (or cover sheets) that the recipients sign and return upon receiving new or revised documents; and you may require that obsolete copies of superseded documents be formally returned. Such formal systems are not explicitly required, but if you are already doing these kinds of things, document them here in this procedure.

When distributing revised documents, the recipient should be informed what has been changed and what is new in the document. In a paper document tt 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 (this would also be suitable in an electronic document uploaded to ISOXpress). None of these methods are documented in this procedure because the ISO 13485 standard does not explicitly require you to have such a system for communicating changes. However, it was required in the previous, 1996 edition of the standard, and many auditors still expect some type of change briefs.

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. Electronic documents are accessed from computers and/or terminals, or printouts of electronic documents are distributed for one-time use. Paper (hard copy) documents are distributed to specific recipients and/or document stations.

8.2　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 the superseded versions of revised documents, 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.

Taking the minimalist approach this procedure does not define any specific system for ensuring the removal of obsolete documents and relies instead on people following the stated policy. If this is questioned by an auditor, especially if there are actually identified instances of obsolete documents being found where they should not be, you can then respond with developing and implementing a more robust system. In any event, this potential problem is only relevant to paper-controlled documents. With more and more documents being controlled electronically there is a good chance that, especially in a small company, this issue will not come up at all.

8.3   Electronic documents are uploaded to the ISOXpress server or are posted on the network and are available for viewing and printing from ISOXpress Doc Viewer or relevant computers and terminals. When a document is revised, the old edition is taken down from ISOXpress or the network and is substituted with the revised document.

9   Master list

9.1   Any document control system maintains a master list of controlled documents. The list identifies each issued document by its code/number, title, approval/issuing authority, effective date, and revision level, as applicable. For paper documents a distribution record is also maintained.

9.2   In the ISOXpress system, such a master list is maintained in the Doc Control module.

If you produce a large number of engineering documents (drawings, specifications, etc.), you would probably want to have a separate and independent control system for these documents, and thus also a separate control list. You could define a separate system for controlling engineering documents by adding a special section to this procedure, or by establishing a new additional procedure or work instruction.

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, as in 8.2.

11   Uncontrolled copies

11.1   Printouts of electronic documents (ISOXpress server 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-42-03, 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 paper (hard copy) documents, retained copies of obsolete documents are stamped OBSOLETE and are kept in special files separate from active documents.

12.4   For electronic documents, e.g., files on network drives and ISOXpress server, obsolete

documents are either:

- Printed out, stamped ARCHIVE and are kept in special files as paper (hard-copy) archive, while the electronic files are deleted; or
- The documents files are downloaded from the ISOXpress server or are removed from the network, and are stored in permanent electronic archiving media (removable disks, tapes, etc.).

IV   REFERENCED DOCUMENTS

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

V   ASSOCIATED RECORDS

In addition to the records listed below, many companies also have a form for requesting the establishment of a new documents or revision of existing documents. This form would usually be called "Document Initiation/Change Request Form." I did not include this form because you can get by without it, and in a small company it would unnecessarily bureaucratize the system. But if you like the idea, make up such a form and include it in your system.

- **Lists of controlled documents and document control records**: Lists of issued controlled documents and records with their control information. Documented in the ISOXpress system > Document Control.
- **Records of received customer engineering documents**: Customer Engineering Documents (CED) Log for recording the receipt of customer engineering documents and changes.

  A template for this log is not included in this documentation. It would only be relevant if you are a subcontractor and regularly receive drawings from your customers. Refer to comments under Section 10 of this procedure.