THE QUALITY SYSTEM REGULATIONS

SUBPART D – DOCUMENT CONTROLS
SUBPART M - RECORDS

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21 CFR 820.40
DOCUMENT CONTROLS

21 CFR 820.40
Document Controls

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

(a) Document approval and distribution.

- *Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part.*
- *The approval, including the date and signature of the individual(s) approving the document, shall be documented.*
- *Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.*

Doucment control impacts most aspects of the quality system for example (not a complete list): 820.25, 820.50, 820.60, 820.70, 820.72, 820.75, 820.80, 820.86, 820.90, 820.100, 820.198

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Document Controls

(b) Document changes.

- *Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise.*
- *Approved changes shall be communicated to the appropriate personnel in a timely manner.*
- *Each manufacturer shall maintain records of changes to documents.*
- *Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.*

Remember to take into account 820.25

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Document Controls

- Document control is the cornerstone and foundation of an effective quality system.
- All procedures and documents required by the QSR flow through the document control process.
- Document controls are inherently interconnected to compliance with all of the other QSR requirements.

21 CFR 820.40
Document Approvals

- The procedure should identify the individuals required to approve the release of new or modified documents that are controlled within your document control system. The following are suggestions:
  - By department/function or title
  - By organizational level
  - By document type
    - May need different functions involved in reviewing a test protocol than a component drawing.
- Approvals
  - Approval must be by signature, written or electronic (21 CFR 11).
  - Signatures must be dated.
  - New or modified documents are not distributed or used until all approvals are received and appropriately documented.

21 CFR.40
Document Controls

Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary,

21 CFR 820.40
Communication of Document Changes

- The change control process should consider the impact and implementation of the document changes:
  - Functional groups impacted
  - Impact on raw materials, work in progress, or finished goods
  - Training to new/modified procedure
    - Document Control System should link with the training system
  - Vendor notification (if change to purchased part)

21 CFR 820.40
Document Change Records

- Best Practices for description of the change:
  - Be specific and/or attach redlined documents.
  - Provide appropriate justification/ reason for the changes.
    - Reference associated or supporting documents.
  - Consider and document the impact of the changes. For example, are modification to other documents or processes (suggestions below) required as a result of and/or prior to implementation of the change?
    - Design Specifications
    - Design Verification / Validation
    - Biocompatibility
    - Process Validation
    - Risk Management File
    - Regulatory Submissions
    - Labeling
    - Vendor notification/verification/validation
    - Material dispositions

21 CFR 820.40
Document Change Records

- **Identification of the affected documents**
  - List all of the documents included in the change request:
    - Document number
    - Document title
    - Current revision
    - New revision
- **Signature of the approving individual(s) and approval date(s)**
- **Effectivity**
  - Effectivity / implementation requirements, e,g., training, inventory dispositions
  - Effective date = date the document is put into use <u>after</u> all of the implementation activities have been completed.

21 CFR 820.180
GENERAL REQUIREMENTS

21 CFR 820.180 Records – General Requirements

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections.

- *Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s).*
- *Such records shall be legible and*
- *Shall be stored to minimize deterioration and to prevent loss.*
- *Those records stored in automated data processing systems shall be backed up.*

- *(a) Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.*

21 CFR 820.180
Records – General Requirements (cont)

- *(b) Record retention period. All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.*

Every section of the QSR that require records are impacted by this section.

21 CFR 820.180
Records – General Requirements (cont)

- *(c) Exceptions*. *This section does not apply to the reports required by 820.20(c) Management review, 820.22 Quality audits, and supplier audit reports used to meet the requirements of 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.*

CFR 820.180
Records – General Requirements

- Define the record retention periods for each quality record type.
- Define location of current and archived records.
  - Number of years maintained on-site
  - Use of off-site record management companies (approved supplier)

21 CFR 820.186
QUALITY SYSTEM RECORDS

21 CFR 820.186
Quality System Record

Each manufacturer shall maintain a quality system record.

- *The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by 820.20 (Management Responsibility).*
- *Each manufacturer shall ensure that the QSR is prepared and approved in accordance with 820.40 (Document Control).*

21 CFR 820.186
Quality System Record

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- *Each manufacturer shall ensure that the QSR is prepared and approved in accordance with 820.40 (Document Control).*

Poll:

FDA routinely looks at Internal Audits and Management Reviews

A) True

B) False

QUESTIONS?