Documents, Change Control and Records

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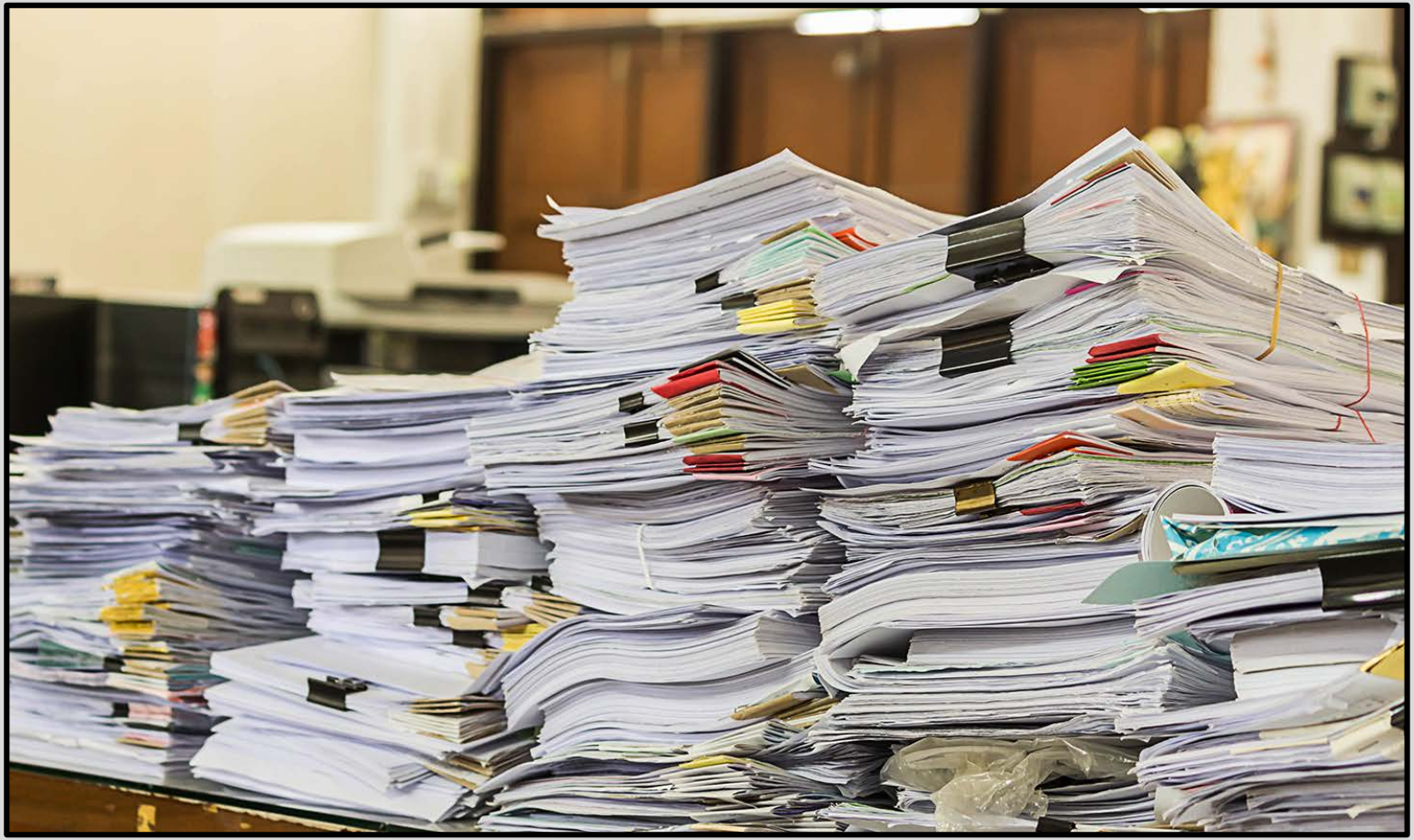


Learning Objectives

1. Identify key definitions related to documents and records

2. Describe key categories and how they inter-relate

3. Describe requirements and intent for Document Controls, General Records, Device Master Records, Device History Records, and Quality System Records

Definitions

Definitions (21 CFR 820.3)

- **Establish**

  define, document (in writing or electronically), and implement

  [21 CFR 820.3(k)]

- **Design history file (DHF)**

  compilation of records which describes design history of a finished device

  [21 CFR 820.3(e)]

CFR = Code of Federal Regulations

Definitions (21 CFR 820.3)

- **Device master record (DMR)**

  compilation of records containing procedures and specifications for a finished device

  [21 CFR 820.3(j)]

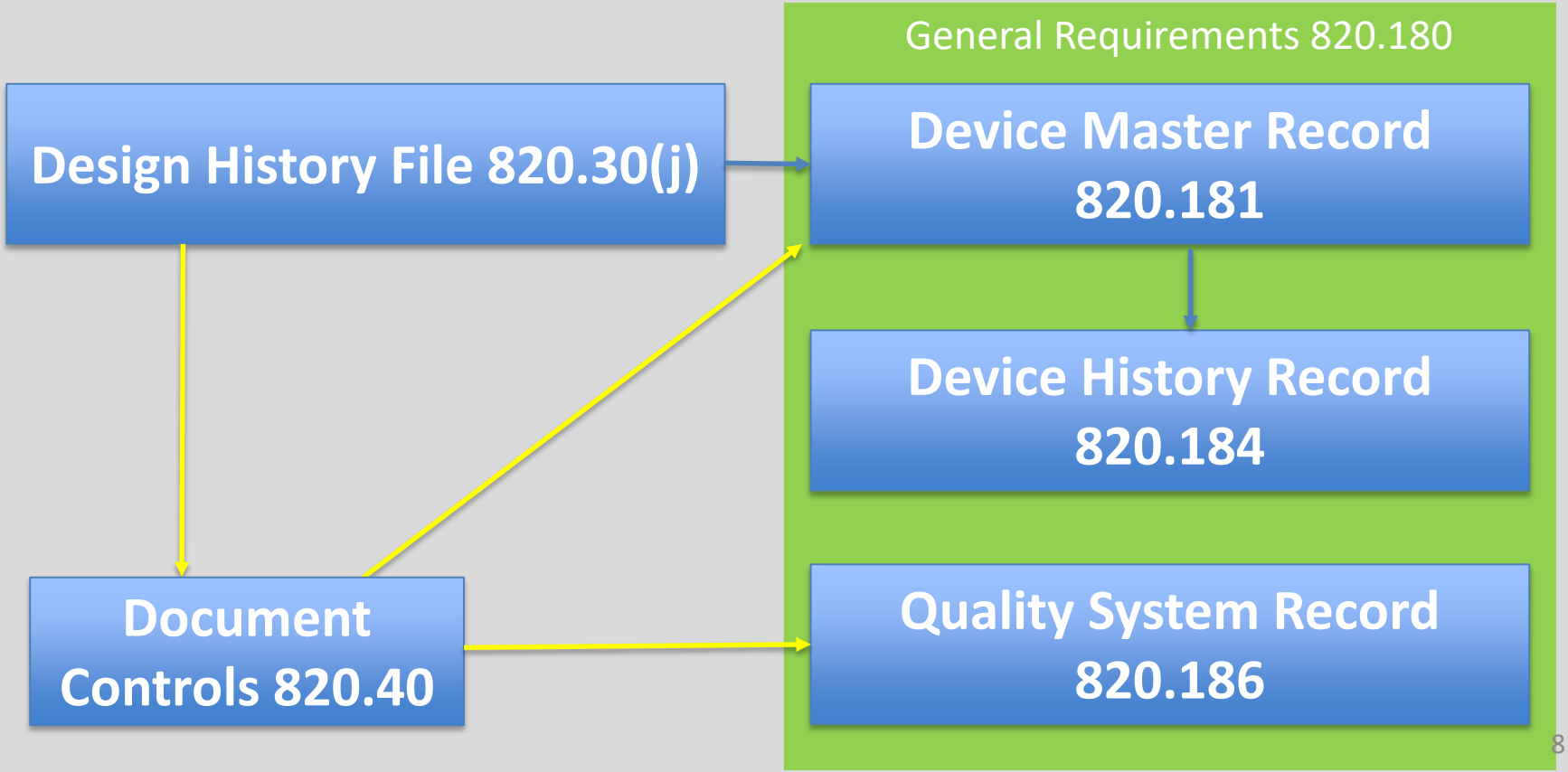
- **Device history record (DHR)**

  compilation of records containing production history of a finished device

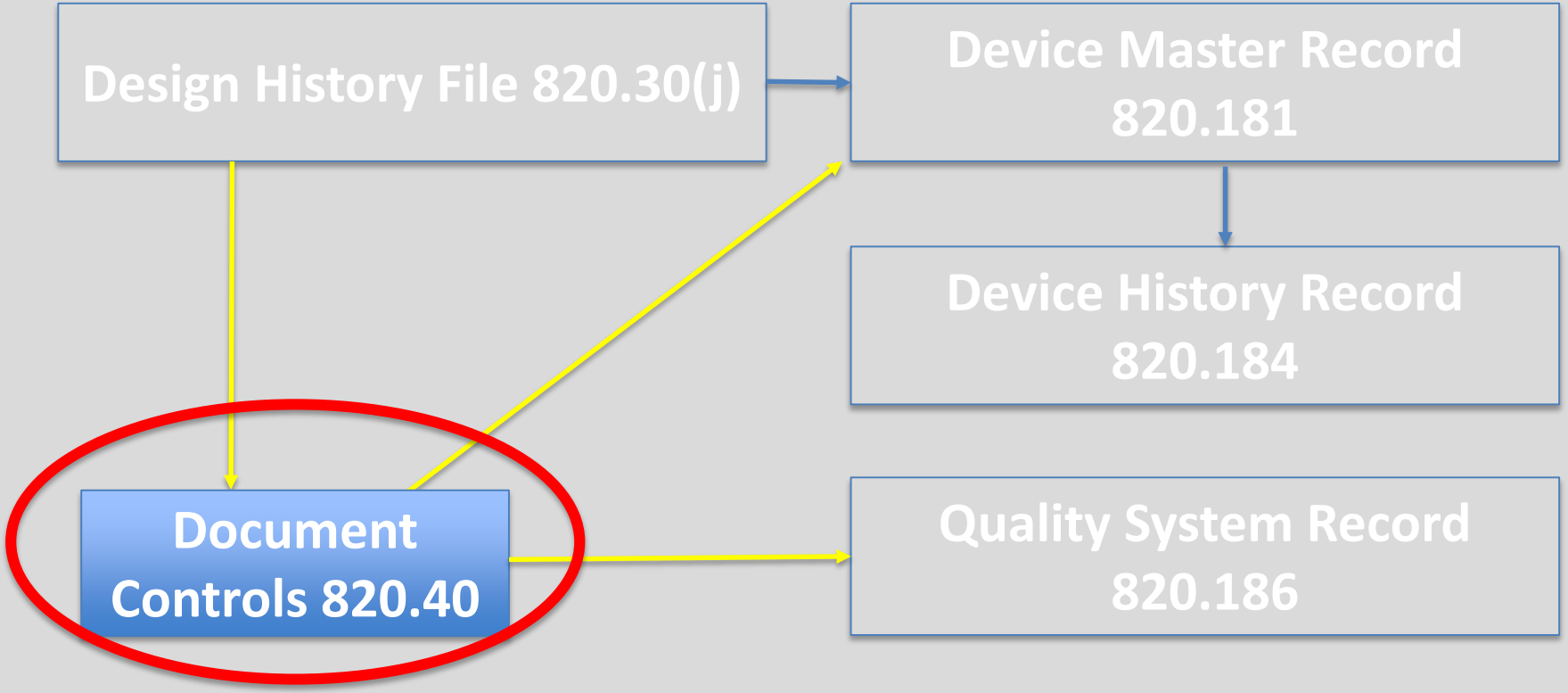
  [21 CFR 820.3(i)]

Overview of Documents and Records

Document and Record: Overview



General Requirements 820.180



Document Controls

- Establish and maintain procedures to control all documents required by 21 CFR Part 820
- Procedures shall provide for:
  1. Document Approval
  2. Document Distribution
  3. Document Changes

1. Document Approval

- Designate individual(s) to:
  - review documents for adequacy
  - approve documents prior to issuance
- Document approval must include:
  - date and signature of approving individual(s)

2. Document Distribution

- Required documents shall be available
  - at all locations where designated, used, or otherwise necessary
- Obsolete documents:
  - remove promptly or
  - prevent unintended use

3. Document Changes

- Changes to documents
  - require review/approval
  - by individual(s) from same function or organization that performed original approval
  - unless specifically noted otherwise
- Changes must be communicated
  - to appropriate personnel in a timely manner

Preamble: Review of Changes

Intent

- Ensure that original document approver has opportunity to review any changes
- Document approvers typically have best insight on impact of changes

Preamble: Review of Changes

Flexibility

- Permits manufacturer to designate others (not original document approver) to review and approve changes

Preamble: Communicating Changes to Personnel

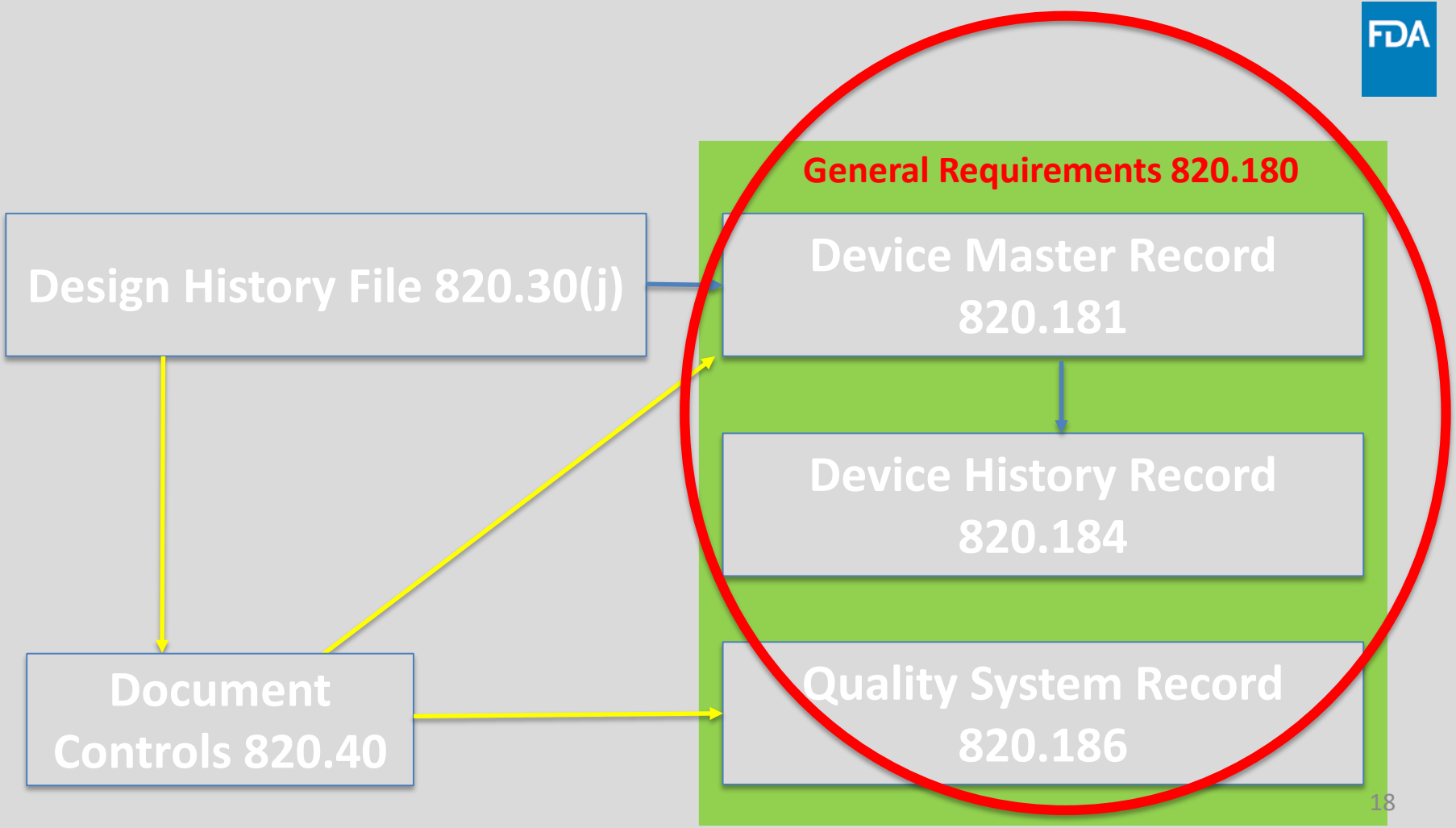
"FDA has had many experiences where manufacturers made corrections to documents, but the changes were not communicated in a timely manner to the personnel utilizing the documents. The result of these untimely communications was the production of defective devices."

Preamble, Comment 96

3. Document Changes

Include in change records:

1. Description of change
2. Identification of affected documents
3. Signature of approving individual(s)
4. Approval date
5. Date change becomes effective


General Requirements 820.180
Design History File 820.30(j)
Device Master Record
820.181
Device History Record
820.184
Document
Controls 820.40
Quality System Record
820.186

Records – General Requirements

- Maintain all records required by Part 820:
  - at manufacturing site or
  - at location reasonably accessible to manufacturer and FDA

- Make required records **readily available** for review and copy

Preamble: “readily available” records

“FDA expects that such records will be made available during the course of an inspection. If the foreign manufacturer maintains records at remote locations, such records would be expected to be produced by the next working day or two, at the latest...”

Preamble, Comment 180

Records – General Requirements

- Shall be legible
- Stored in a way that minimizes deterioration and prevents loss
- Records stored in an automated data processing system shall be backed up

Records - Confidentiality

- During an inspection manufacturers may mark records as “confidential”
  - to assist FDA in determining whether information may be disclosed under Freedom of Information Act

Records: Exceptions

Manufacturers are not required to make these record types available for review and copy by FDA:

- management review reports and results
- quality audit reports
- evaluations of suppliers, contractors and consultants

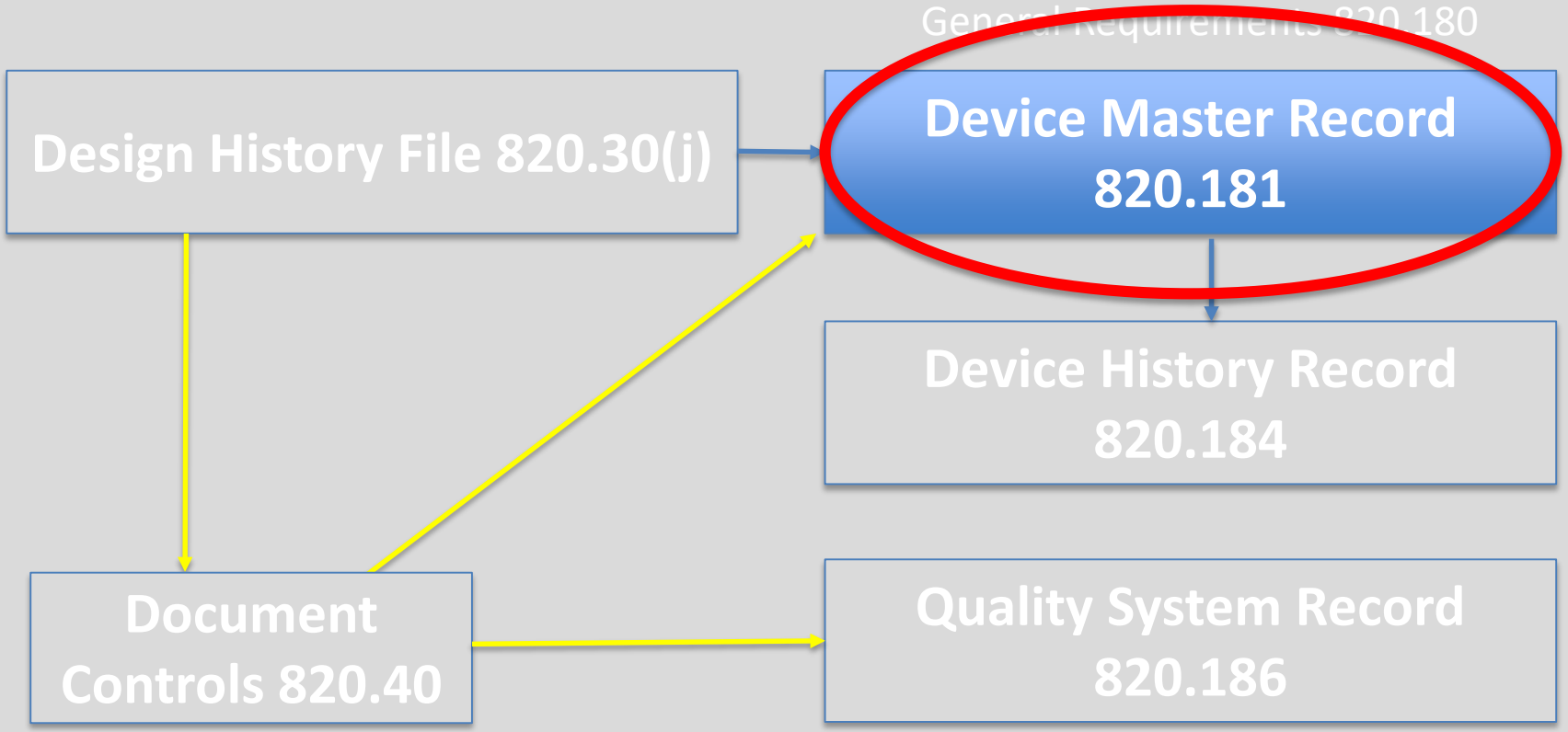
Records: Exceptions

- However, during FDA inspections manufacturers must make ***procedures*** available for review for:
  - management reviews
  - quality audits
  - evaluating suppliers, contractors and consultants

Record Retention Period

Retain all records required by Part 820 for:

- expected life of device, or
- at least 2 years from date of release for commercial distribution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Device Master Record

- Maintain a Device Master Record (DMR)
- Prepare and approve DMR in accordance with 21 CFR 820.40, “Document Controls”

DMR: What's Included

1. Device specifications
2. Production and process specifications
3. Quality assurance procedures and specifications
4. Packaging and labeling specifications
5. Installation, maintenance and servicing procedures

1. Device Specifications

- Bill of Materials
- Drawings and schematics
- List of Ingredients
- Component Specifications
- Material Composition
- Formulations
- Assemblies
- Software specifications

2. Production and Process Specifications

- Production environment specifications
- Cleaning procedures
- Equipment specifications
- Calibration procedures
- Process flow charts
- Set-up procedures
- Production methods
- Production procedures

3. Quality Assurance

- Acceptance criteria
- Testing and measurement equipment
- Inspection/test procedures
- Inspection/test forms
- Instrument charts
- Reporting forms
- Process control charts

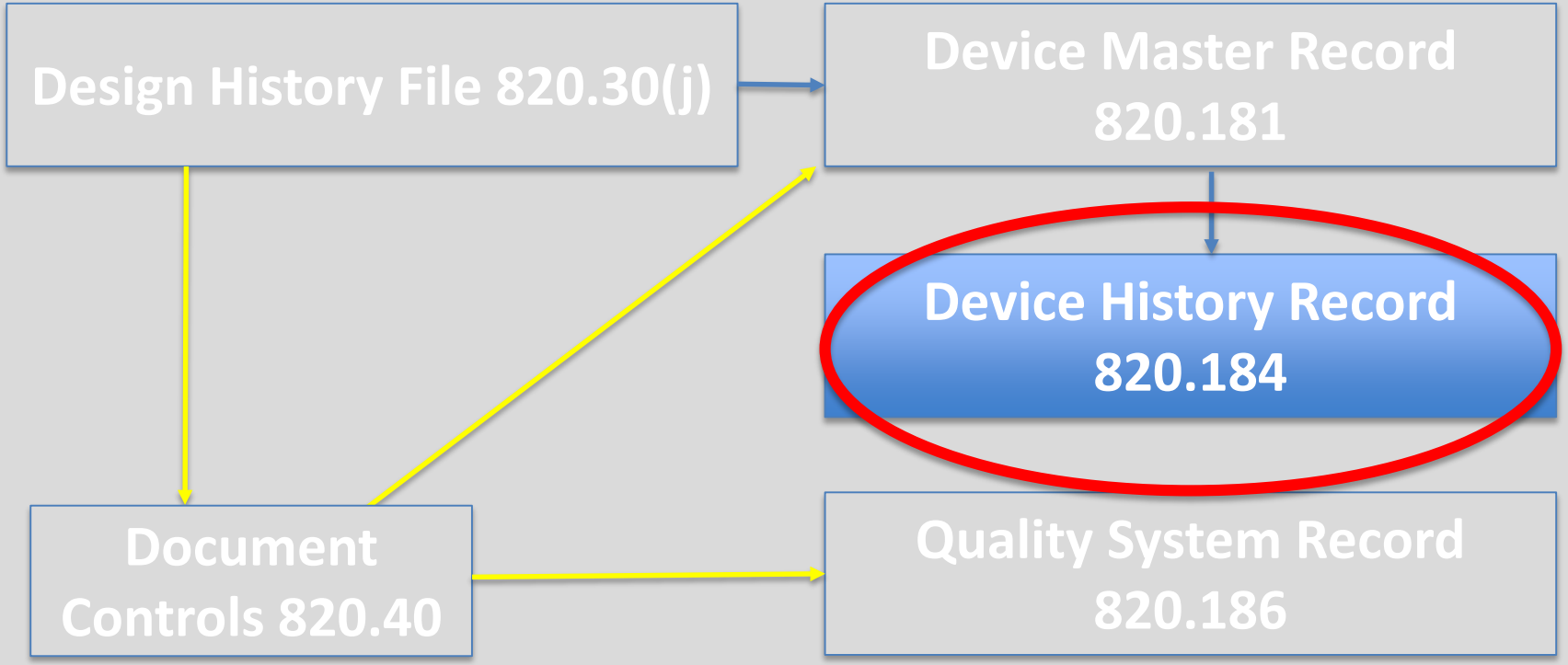
4. Packaging and Labeling

- Packaging and labeling specifications
- Package/Label drawings
- Instructions for Use
- Service manuals
- Packaging/labeling review and control
- Packing procedures
- Shipping procedures
- Customer feedback forms

5. Installation, Maintenance, and Servicing

- Installation procedures
- Service procedures
- Tools, testers and instruments
  - for installation and servicing
- Forms for installation and servicing
  - including regulatory forms as necessary

General Requirements 820.180



Device History Record

- Maintain device history record (DHR)
  - to demonstrate that device is manufactured in accordance with the Device Master Record and Part 820
- Establish and maintain procedures for DHR

Device History Record

Shall include:

1. Dates of manufacture
2. Quantity manufactured
3. Quantity released for distribution
4. Acceptance records that demonstrate device is manufactured in accordance with Device Master Record

Device Labeling and the DHR

Document in the DHR:

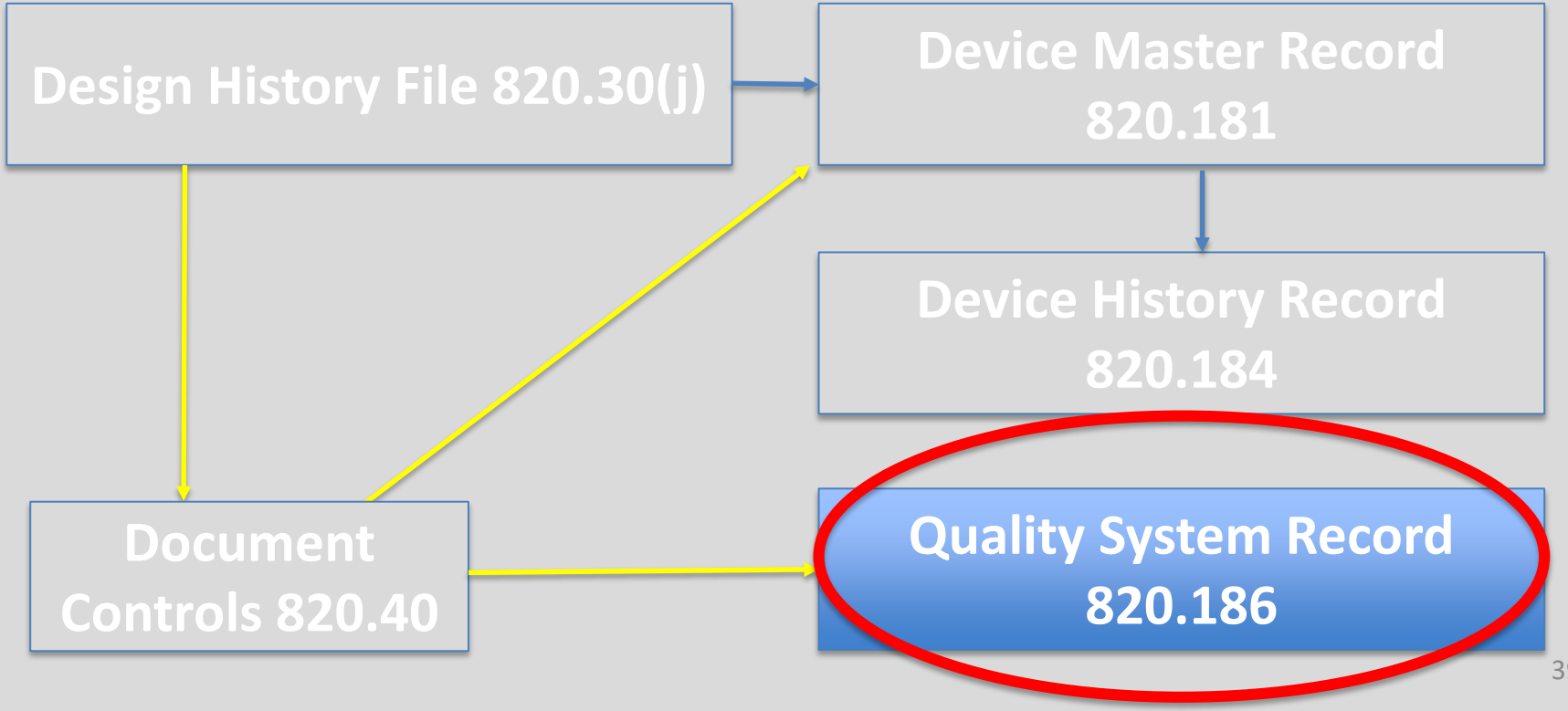
- Release of labels and date/signature of person examining the labeling
- Label/labeling used for each production unit, lot or batch

Preamble: Automated Readers for Labeling Inspections

"several recalls on labeling have been attributed to automated readers not catching errors. The requirement does not preclude manufacturers from using automated readers where that process is followed by human oversight. A "designated individual" must examine, at a minimum, a representative sampling of all labels that have been checked by the automated readers."

Preamble, Comments 169

General Requirements 820.180



Quality System Record

- Maintain Quality System Records (QSR)
- Prepare and approve per 21 CFR 820.40
- Include/refer to location of:
  - Procedures and documentation of activities required by Part 820 that are not specific to a particular type of device
  - Records required by 21 CFR 820 Subpart B

Quality System Record: Examples

- Training Procedures and Qualification Records
- Internal Audit Procedures and Records
- Management Review Procedures and Records

Your Call to Action

1. Meet your document and record requirements.
2. Take time to learn about documents, document controls and how to write good documents.
3. Write useful and effective documents that provide direction and evidence of compliance and quality.

QS Regulation and Guidance

- **Quality System Regulation and Preamble**

  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm

- **Inspection Guide – Pages 8, 15, 21, 22 and 23**

  https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074899.htm

- **Guide to Inspections of Quality Systems [Quality System Inspection Technique (QSIT)]**

  www.fda.gov/iceci/inspections/inspectionguides/ucm074883.htm

Industry Education: Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice: Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE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