Nonconforming Product

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Nonconformances: Why Are They Important?

Opportunity for Continuous improvement

- Learn from Mistakes
- Product longevity
- Increased market share
- Better, safer, more effective product

Learning Objectives

1. Understand context of nonconformances within:
   - Overall Quality System and
   - Corrective and Preventive Action (CAPA) subsystem
2. Define nonconforming product
3. Explain the process flow
4. Learn how nonconforming product disposition contributes to quality and safety

What is the CAPA Subsystem?

- One of the seven Quality System subsystems
- Corrective and Preventive Action (CAPA) Subsystem

Parts of CAPA Subsystem	Regulation Number (21 CFR)	General Applicability
Nonconforming Product	**820.90**	**Manufacturing**
Corrective and Preventive Action	829.100	Manufacturing and After Distribution
Complaint Files	820.198	After Distribution

Definitions (21 CFR 820.3)

- **Specification**

  any requirement with which a product, process, service, or other activity must conform [21 CFR 820.3(y)]

- **Product**

  components, manufacturing materials, in-process devices, finished devices, and returned devices [21 CFR 820.3(r)]

- **Nonconformity**

  the nonfulfillment of a specified requirement [21 CFR 820.3(q)]

Nonconformances

- Nonconforming Product is product that does not fulfill its specified requirements
- Nonconformances can occur in both product and process
- Nonconforming **processes** can lead to nonconforming **product**.

Nonconforming Product - Regulation

21 CFR 820.90(a)

"Each manufacturer shall establish and maintain procedures to **control product that does not conform to specified requirements**...."

Nonconforming Product - Regulation

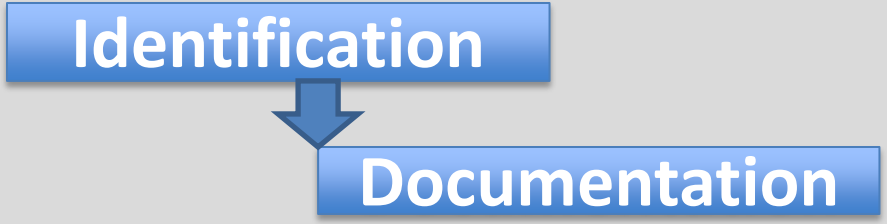
21 CFR 820.90(a)

"….The procedures **shall address the identification, documentation, evaluation, segregation, and disposition** of nonconforming product."

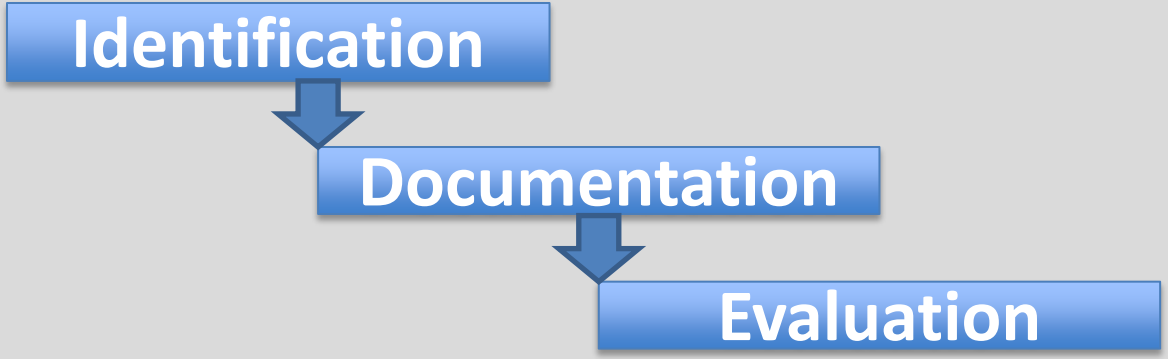
Process Flow

Identification

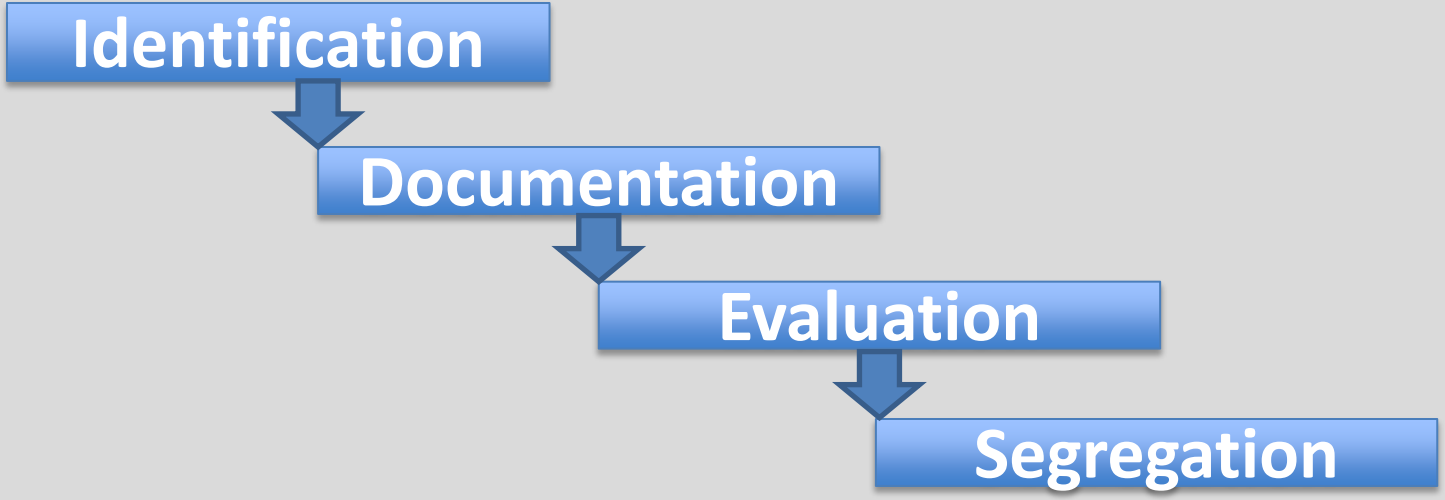
Process Flow



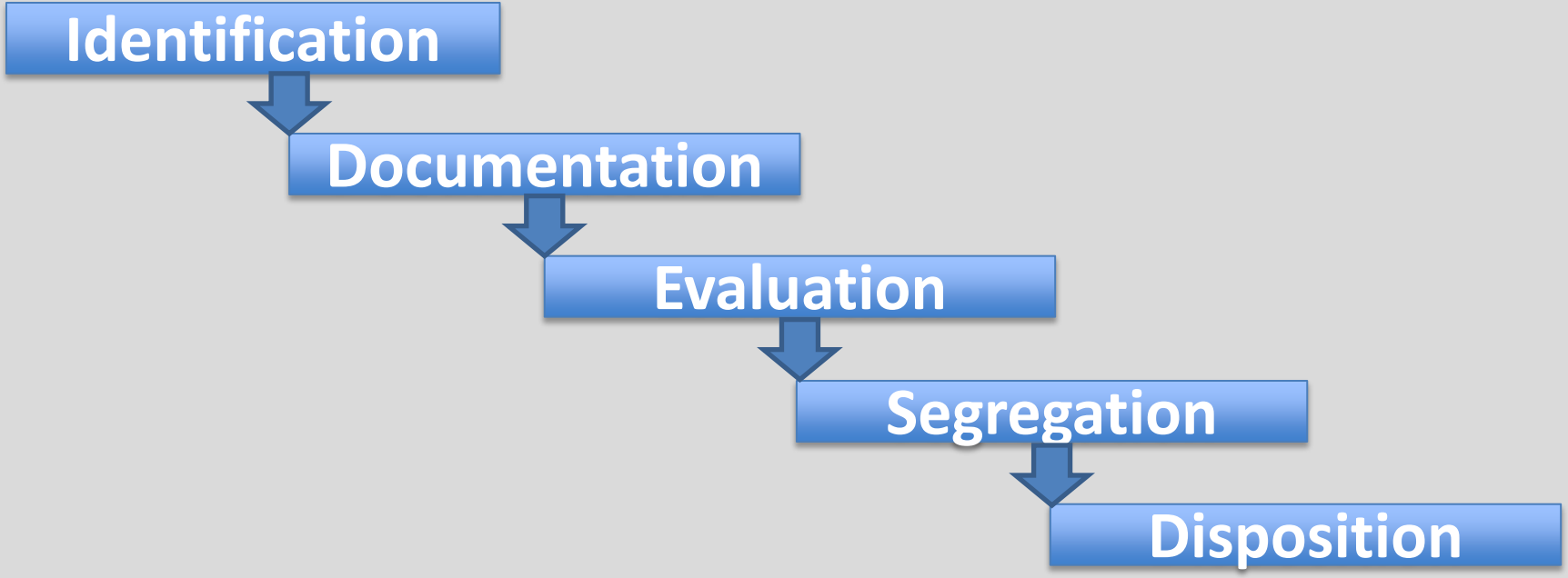
Process Flow



Process Flow



Process Flow



Process Flow

Identification

Sources of Nonconforming Product

- Received components/material that fail incoming inspection
- Example
  - Specification: 6 +/- 1 inch
  - Inspection result: 8 inch
  - This is nonconforming **product**

Sources of Nonconforming Product

- Products/components that fail inspection or test during manufacturing
- Example
  - Temperature range: 300 ± 10° F
  - Temperature set on bonding machine: 280° F
  - This is nonconforming **process**:
    - You need to evaluate the **product** to determine if it's within specification.

Sources of Nonconforming Product

- Product returned to manufacturer with defects
- Example
  - If a catheter is supposed to fit inside a 6 French guide and during procedure it does not fit.
  - Handled within the complaint system*

*not within the scope of this talk

Industry Practice: Example

- Nonconformances and Nonconforming reports (NCR) have to be evaluated.
- One practice is through
  - Material Review Board (MRB) or
  - Material Review Committee (MRC)
- Not ad hoc, but in an approved procedure

Process Flow

Documentation

Documentation - Industry Practice Example

- Form that identifies the material, the problem, evaluation, segregation, the investigation (if any), disposition and signatures
- Standard operating procedure (SOP)
- Work Instruction (WI)

Process Flow

Evaluation

Evaluation of Nonconforming Product

21 CFR 820.90(a)

... The evaluation of nonconformance shall include a **determination of the need for an investigation and notification of the persons or organizations responsible** for the nonconformance. The evaluation and any investigation shall be documented.

Evaluation of Nonconforming Product

21 CFR 820.90(a)

Investigations are **Not Always** required

– when an investigation has **already** been performed on a similar issue*

*Similar issue may not require investigation, but may require CAPA due to **recurrence**.

Process Flow

Segregation

Segregation of Nonconforming Product

- You must segregate non-conforming product to ensure it is not released.
- Examples
  - Locked Cages
  - Digital Controls
  - Separate Area

Process Flow

Disposition

Disposition

21 CFR 820.90(b)(1)

Each manufacturer shall establish and maintain procedures that **define the responsibility for review and the authority for the disposition of nonconforming product**. The procedures shall set forth the review and disposition process.

Typical Nonconforming Product Dispositions

- Scrap
  - where you decide not to use the product
  - destroy

Typical Nonconforming Product Dispositions

- Return to Supplier
  - When the reason for the nonconformance is the supplier

Typical Nonconforming Product Dispositions

- Downgrade
  - Reverting back to a safe and effective older version when there is a problem with an upgrade

Typical Nonconforming Product Dispositions

- Use as Is
  - Use the Nonconformance as is when it does not affect the safety and effectiveness of the final product
  - Example: Cosmetic defects that does not affect the performance of the product

Disposition

21 CFR 820.90(b)(1)

Disposition of nonconforming product shall be documented. **Documentation shall include the justification for use of nonconforming product** and the signature of the individual authorizing the use.

Typical Nonconforming Product Dispositions

"... FDA believes that the **justification** should be based on **scientific evidence**, which a manufacturer should be prepared to provide upon request. **Concessions** should be closely **monitored** and not become accepted practice"

Per preamble comment #156

Typical Nonconforming Product Dispositions

- Use as Is
  - Example
    - Cosmetic defect: refer recurring defect to CAPA.

Typical Nonconforming Product Dispositions

- Rework
  - Example
    - Product with unsealed pouches at final acceptance testing
      - Open NCR
        - Correction is Re-sterilize
          - Retest

Rework

21 CFR 820.90(b)(2)

Each manufacturer shall **establish and maintain procedures for rework**, to include retesting and reevaluation of the nonconforming product after rework, **to ensure that the product meets its current approved specifications**.

Typical Nonconforming Product Dispositions

- Rework
  - Example
  - Balloon burst strength of re-sterilized product needs to meet the original specification

Rework

21 CFR 820.90(b)(2)

Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be **documented in the DHR** [Device History Record].

When to Handle and When to Refer

When should a Nonconformance be:

1. handled under 21 CFR 820.90? or

2. referred to the CAPA System under 21 CFR 820.100?

Examples of Nonconformances Handled under 820.90

- Easy/specific correction
- Isolated
- Minor
- Not a Design issue
- Not a Manufacturing issue

Examples of Nonconformances Handled under CAPA

- No easy/specific correction
- Recurring (based on valid analytical method)
- Severe
- Design issue
- Manufacturing issue

Balance is Key

- Too many nonconformances handled under 21 CFR 820.90 may **fail** to address **systemic** issues.
  - Generally simple, specific, contained issues

- Too many nonconformances referred to CAPA will **overwhelm** the system.
  - Generally more complex, ambiguous, systemic issues

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 – Nonconforming Product**

  https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114934.htm

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

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

Call to Action

1. Use your nonconformance system to “Learn from mistakes”. They can impact:
    - Quality
    - Design
    - Manufacturing
2. Nonconformances are a gateway mechanism for CAPA and Postmarket activities
3. A robust nonconformance system can improve Quality and Safety

Industry Education: Three 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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