Overview of Nonconforming Product

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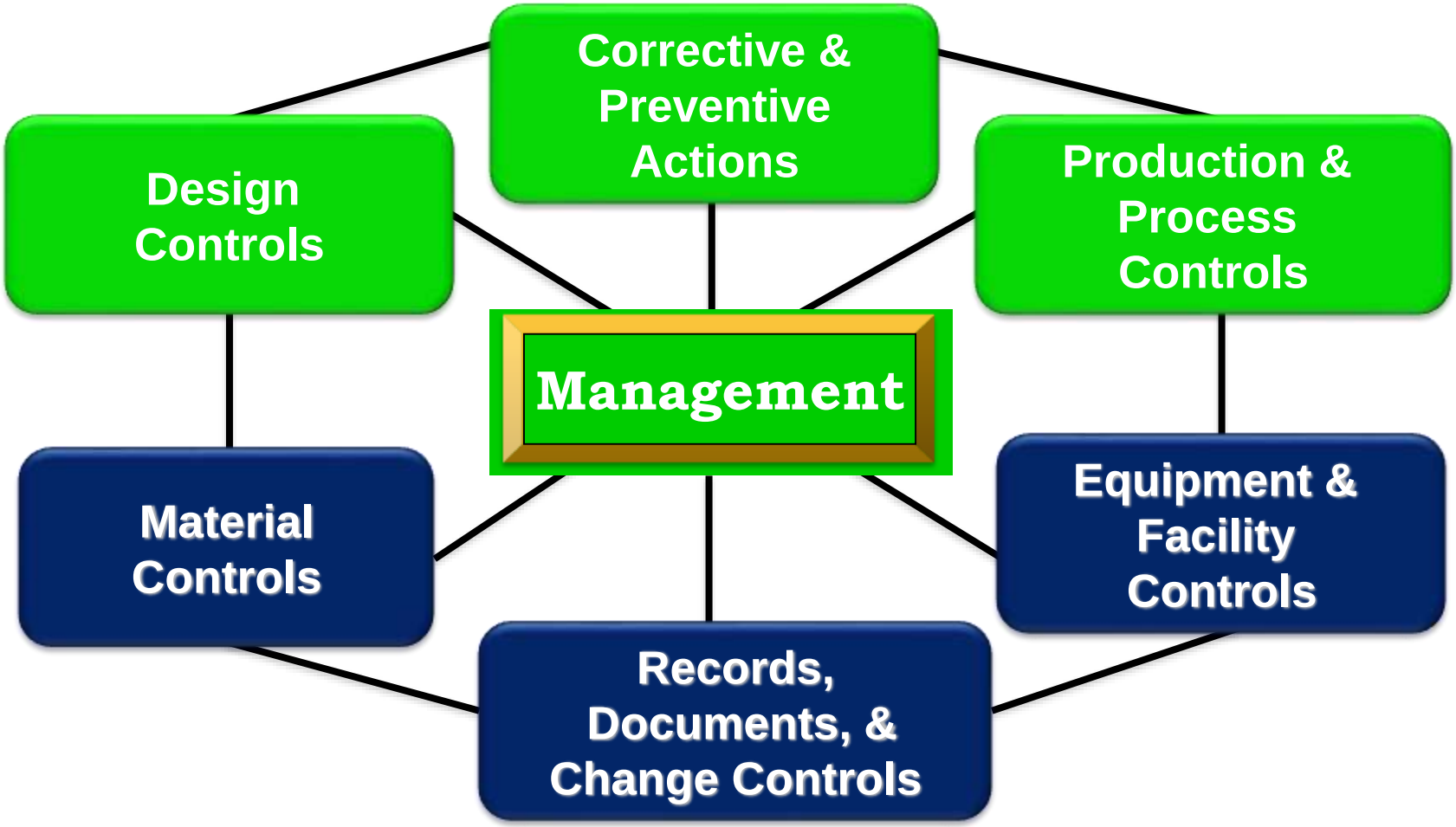
Learning Objectives

- **Define** nonconforming product
- **Understanding** the Process Flow
- Know the **Importance** of disposition with regards to nonconforming product

The 7 Subsystems of a Quality System

Guide to Inspections of QS: Quality System Inspection Technique

The 4 Major Subsystems

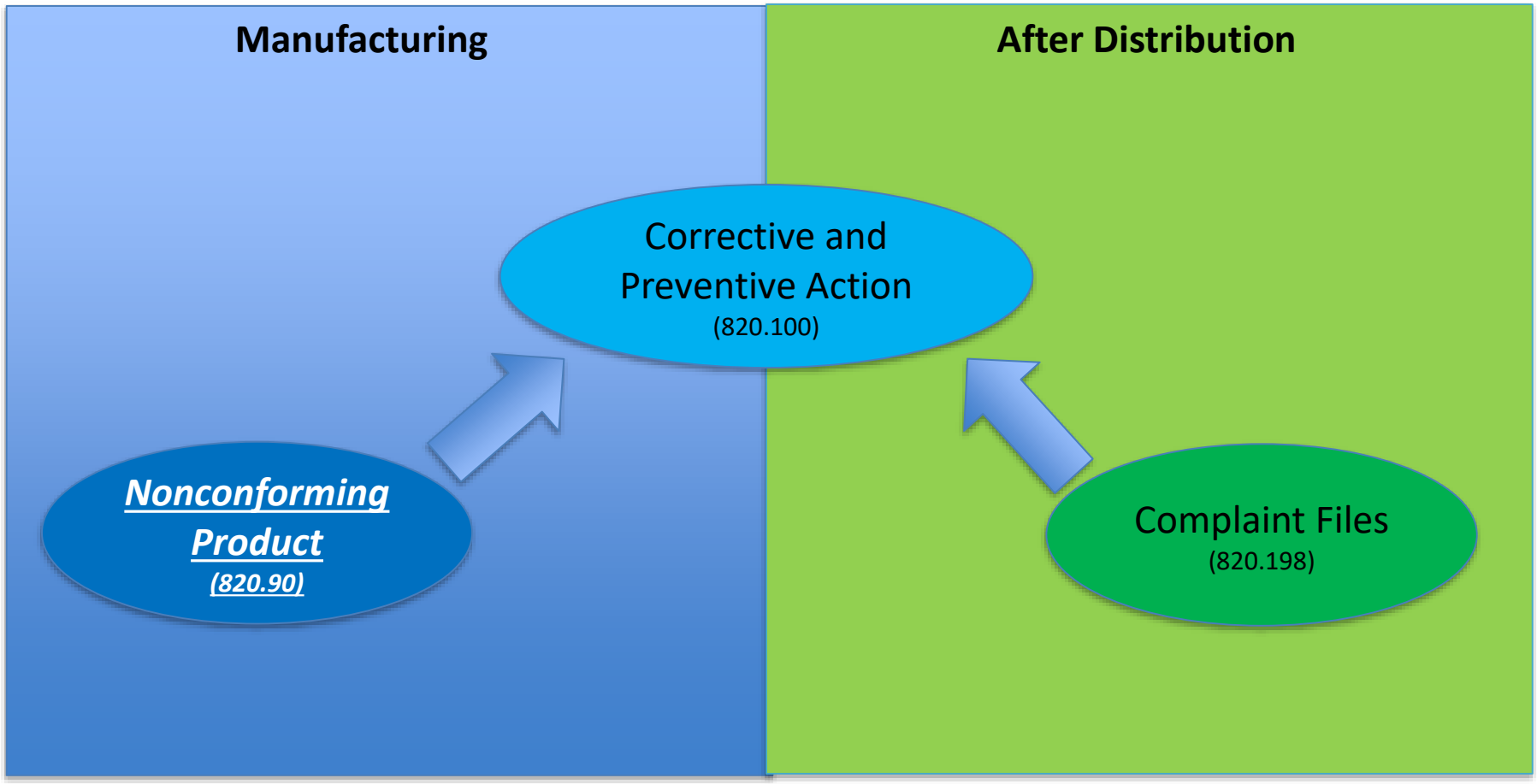


Guide to Inspections of QS: Quality System Inspection Technique

What is the CAPA Subsystem?

- One of the 4 major Quality System subystems
- Corrective and Preventive Action (CAPA) Subsystem
  - **Nonconforming product (21 CFR 820.90)**
  - Corrective And Preventive Action (21 CFR 820.100)
  - Complaint Files (21 CFR 820.198)

The CAPA Subsystem



Frequent CAPA Subsystem Citations

- **483 Observations**
  - 1,017 of 3,027 (34%)
  - Most frequent observation
  - ~17% of CAPA were Nonconforming Product
- **Warning Letters**
  - 189 of 594 (32%)
  - CAPA Subsystem second most common citation
  - ~25% of CAPA citation were Nonconforming Product

Source: "*2016 Annual FDA Medical Device Quality System Data: Inspections, FDA Form 483 Observations, and Warning Letter Citations*" (CDRH Office of Compliance, Division of Analysis and Program Operations, Registration & Risk Branch)

Control of Nonconforming Product 21 CFR 820.90(a)

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

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

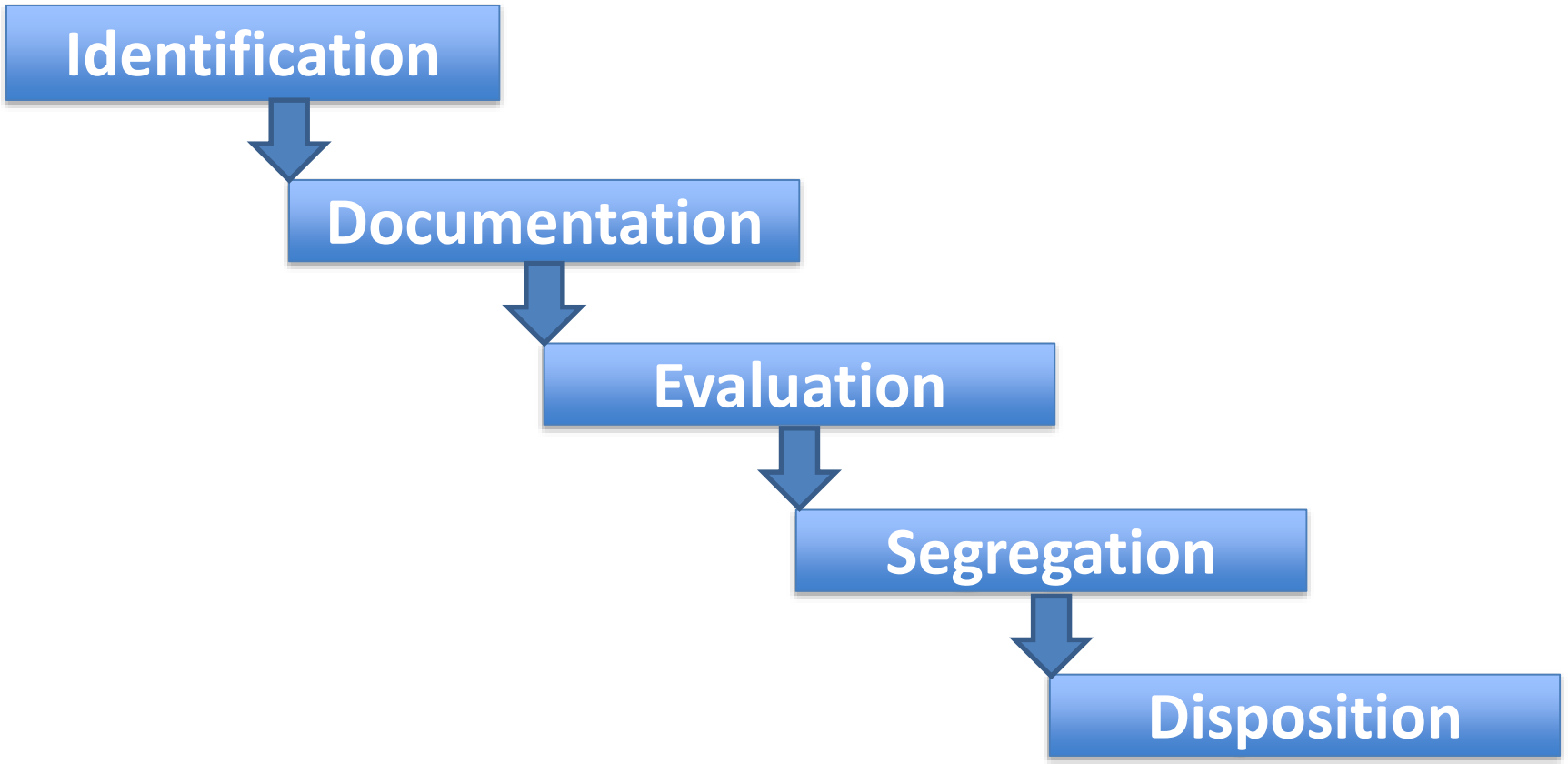
What is Nonconforming Product?

- **Specification** = any requirement with which a product, process, service, or other activity must conform **[21 CFR 820.3(y)]**
- **Nonconformity** = the nonfulfillment of a specified requirement. **[21CFR 820.3(q)]**
- **Product** = components, manufacturing materials, in-process devices, finished devices, and returned devices. **[21CFR 820.3(r)]**

What is Nonconforming Product?

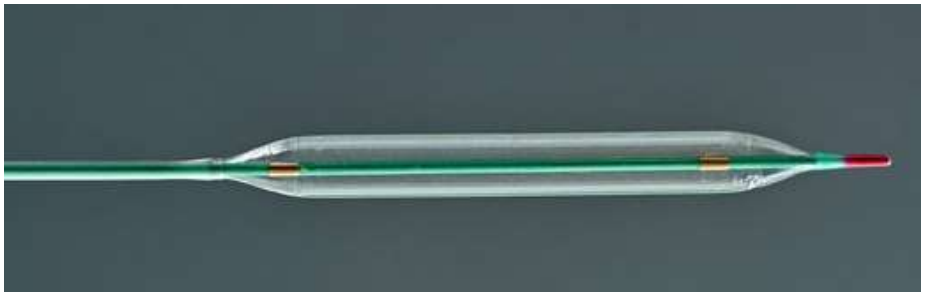
- Product that does not fulfill its specified requirements
- Nonconformance can occur in both product and process
- Nonconforming processes can lead to nonconforming product

Process Flow

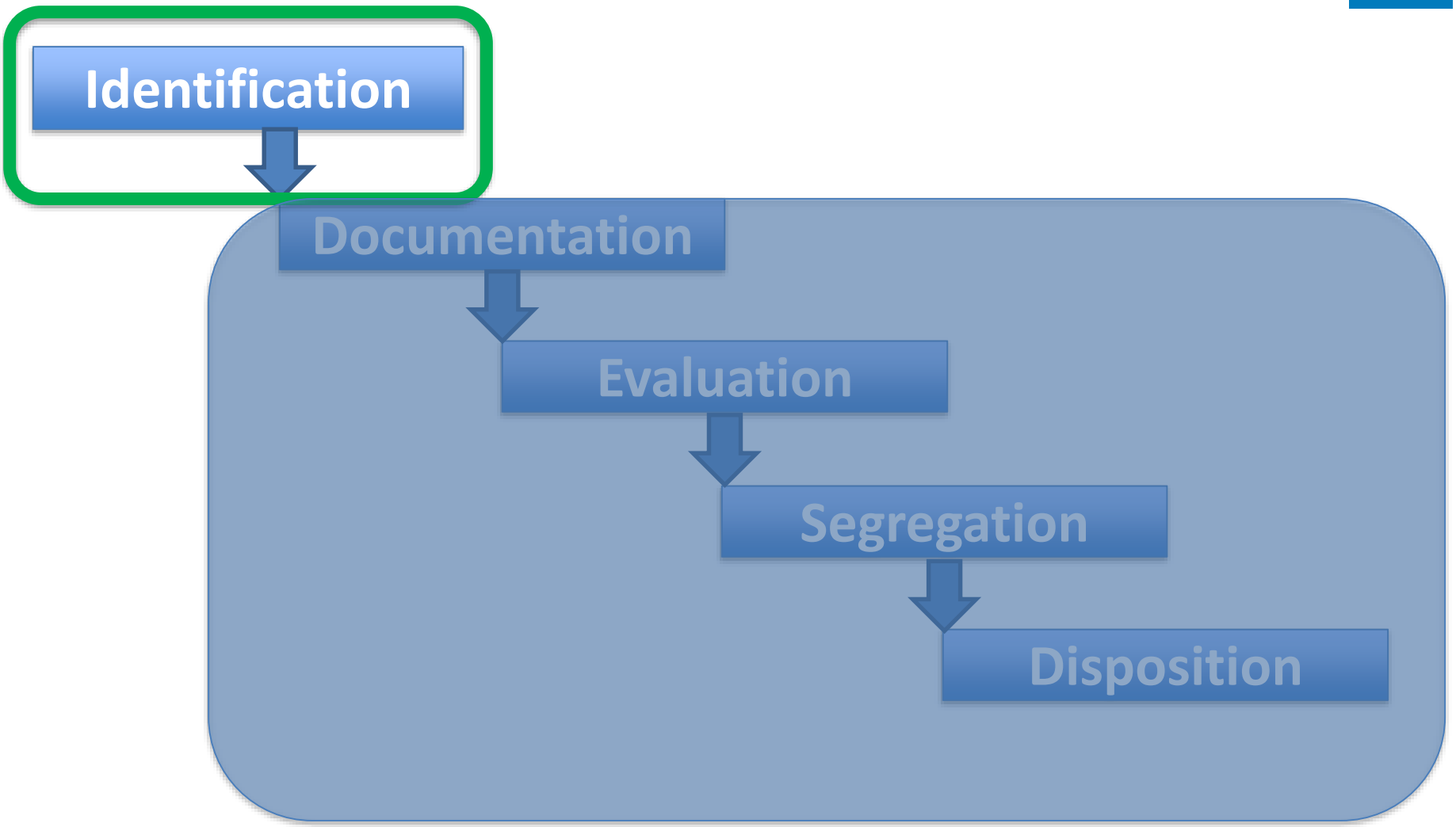


Case Study

Company A purchases all the extruded tubing for the catheter from Supplier B.



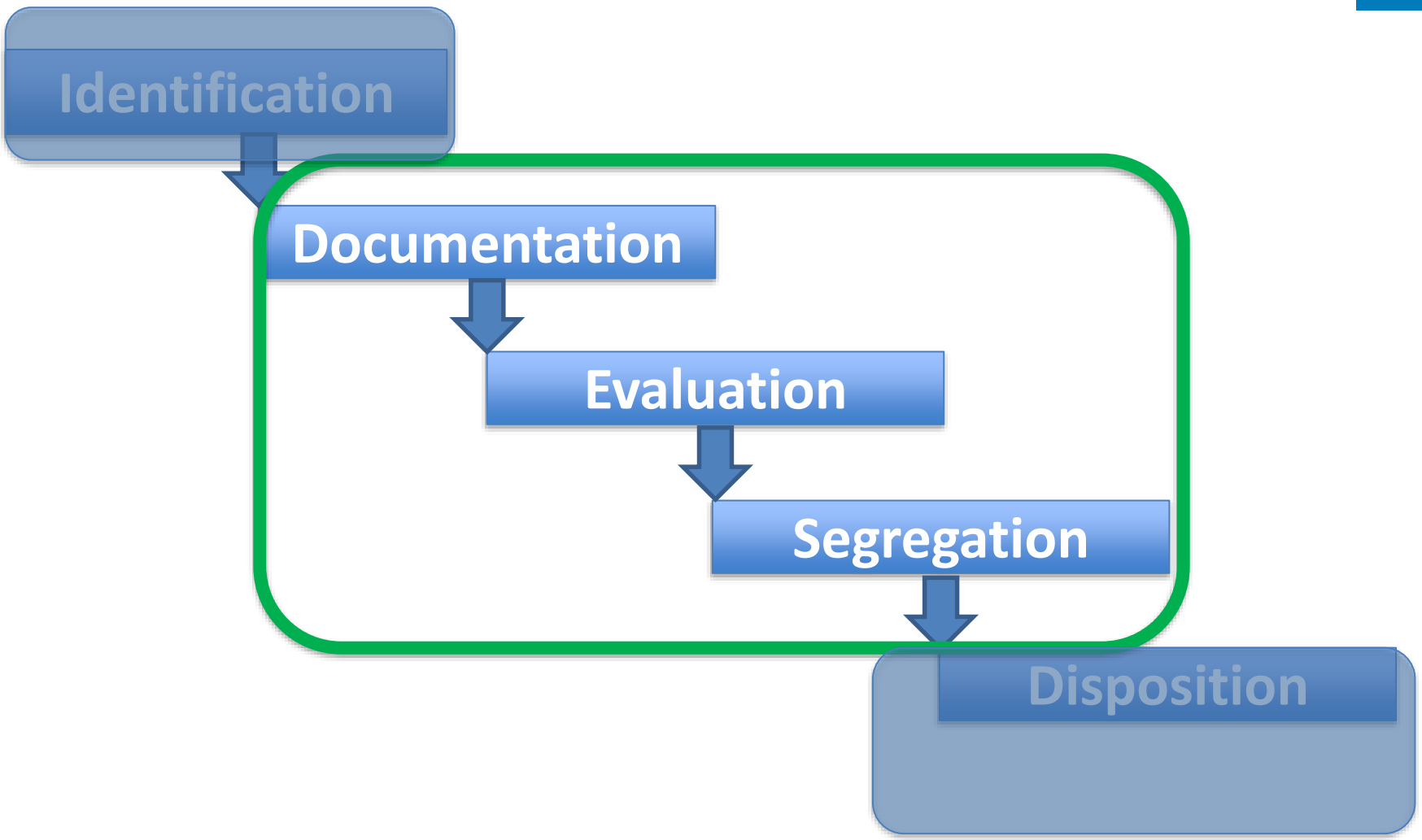
Process Flow



Sources of Nonconforming Product

- Received components/material that fail incoming inspection
- Products/components that fail inspection or test steps during manufacturing
- Product returned to manufacturer with defects through complaint handling and segregation

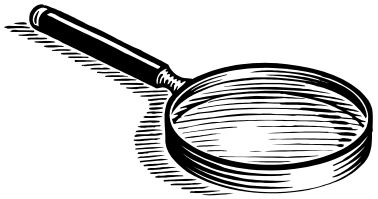
Process Flow



Control 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.

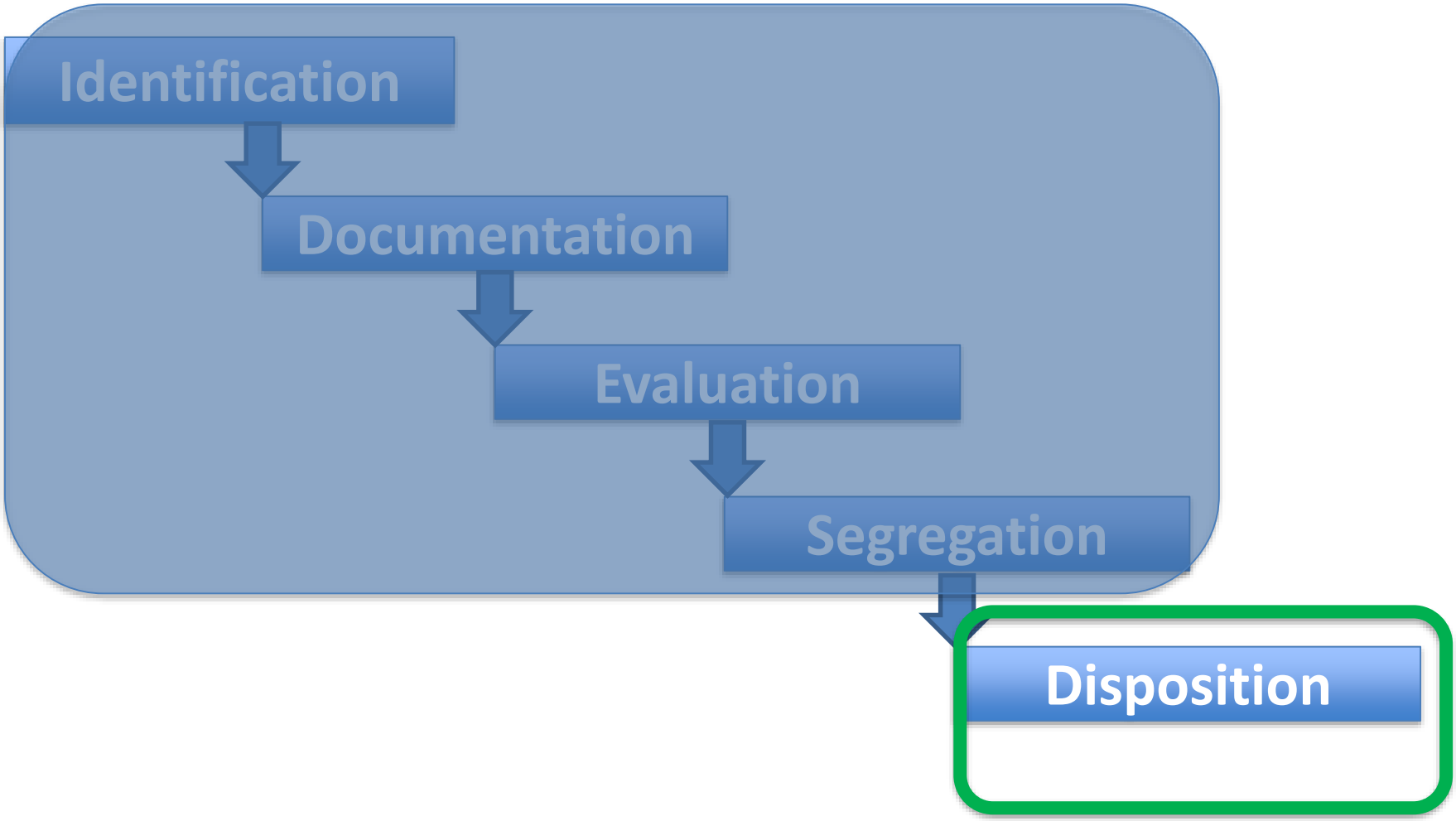
*Investigation is **Not Always** required*



Common Industry Practice

- Material Review Board/Material Review Committee (MRB/MRC),
  - Not ad hoc, but in an approved procedure
  - May need CAPA if you see the same non-conformity over and over again.
- Typically a form that identifies the material, the problem, evaluation, segregation, the investigation (if any), disposition and signatures

Process Flow



Disposition of Nonconforming Product 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.

Disposition of Nonconforming Product 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

- Scrap
- Return to Supplier
- Use As-Is
- Rework
- Downgrade

"... 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

Rework Procedures
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**.

Rework Procedures
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].

Thresholds

When should Non-Conformance be handled under 820.90 and when should they be referred to Corrective and Preventive Action?

Thresholds – 820.90

Handle corrections under 820.90 if:

- Easy/specific correction
- Isolated incident
- Minor issue
- Not design issue/does not impact design
- Not Manufacturing issue/does not impact Manufacturing

Thresholds – CAPA

Refer to CAPA and consider for continuous improvements if:

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

Thresholds – Balance is Key

- Too many Failures handled under 820.90 may fail to address systemic issues.
  - Generally simple, specific, contained issues
- Too many referrals to CAPA will overwhelm the system.
  - Generally more complex, ambiguous, systemic issues

Summary

- Identification and monitoring of nonconforming product often “triggers” CAPA activities.
- Nonconforming product investigations can also be leveraged during CAPA investigations.
- Not every nonconformance is a CAPA.

References

- **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
- **CDRH Learn Module on CAPA**
  fda.yorkcast.com/webcast/Play/c78cfebf72774163a59f8f6f197435451d
- **Inspection Guide - Complaint Handling System**
  www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114934.htm#Control
- **Quality System Inspection Technique (QSIT)**
  www.fda.gov/iceci/inspections/inspectionguides/ucm074883.htm
- **CY 2016 Annual FDA Medical Device Quality System Data**
  www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm554548.pdf
- **Global Harmonization Task Force (GHTF) document: Quality Management System-Medical Devices- Guidance on corrective action and preventive action and related QMS processes**

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D2S04

Call to Action

- Control your nonconformance
- Nonconformances are inputs for CAPA
- Information from the disposition of nonconforming product leads to continuous improvement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