

Production and Process Controls, Part 2: Acceptance Activities, Handling, Storage, Distribution, and Installation

Vidya Gopal

Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Production and Process Controls

Vidya Gopal

Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration



CDRH Learn: Production and Process Controls (Postmarket Activities)

fda.yorkcast.com/webcast/Play/c996037bfec443e4904ff2080833603a1d

Learning Objectives

1. Review the purpose of the production and process controls subsystem
2. Describe the aspects of acceptance activities, handling, storage, distribution, and installation

Production and Process Controls: Purpose

- Manufacture products that meet pre-determined specifications
 - Develop, conduct, control and monitor production processes
 - Validate or fully verify processes
 - Ensure that a device conforms to its specifications
 - Control the product and environment throughout handling, storage, distribution, and installation

Regulatory Requirements

| Subpart | Title | Regulation Number (21 CFR) |
|--|---|----------------------------|
| Subpart H - Acceptance Activities | Receiving, in-process, and finished device acceptance | 820.80 |
| | Acceptance Status | 820.86 |
| Subpart L – Handling, Storage, Distribution, and Installation | Handling | 820.140 |
| | Storage | 820.150 |
| | Distribution | 820.160 |
| | Installation | 820.170 |

Acceptance Activities

- Receiving, in-process, and finished device acceptance
 - Establish and maintain procedures for acceptance activities including inspections, tests, or other verification activities

[21 CFR 820.80\(a\)](#)

Acceptance Activities

- Receiving acceptance activities
 - Establish and maintain procedures for acceptance of incoming product
 - Inspect, test or otherwise verify that incoming product conforms to specified requirements
 - Document acceptance or rejection

[21 CFR 820.80\(b\)](#)

Acceptance Activities

- In-process acceptance activities
 - Establish and maintain acceptance procedures, where appropriate, to ensure that in-process product:
 - Meets specified requirements
 - Is controlled:
 - until required inspections, tests or other verification activities have been completed;
 - until necessary approvals are received and documented

[21 CFR 820. 80\(c\)](#)

Acceptance Activities

- Final acceptance activities
 - Establish and maintain procedures for finished device acceptance to ensure that each production run, lot or batch meets acceptance criteria
 - Hold finished devices in quarantine or control them until released

[21 CFR 820. 80\(d\)](#)

Acceptance Activities

- Final acceptance activities
 - Conduct the following activities before releasing finished devices for distribution:
 - Complete all activities required in the Device Master Record (DMR)
 - Review associated data and documentation
 - Authorize release by signature and date of designated individual

[21 CFR 820.80\(d\)](#)

Implementation

- Use of risk based approach for acceptance activities
 - Frequency of testing may be different based on risk
 - Low risk components may require less testing than a high risk component

Implementation

- Types of systems used for implementation
 - Kanban systems
 - Electronic
 - Bar-coded systems that can tell you status of each item – accepted, rejected, in process testing

Acceptance Activities: Example

- Receiving inspection
 - Tubing strength testing
 - Balloon tubing versus packaging tubing
- In Process Inspection
 - Bond strength testing
- Final Acceptance testing
 - Leak testing of catheter

Acceptance Activities

- Acceptance records
 - Documentation of required acceptance activities include:
 - Acceptance activities performed
 - Dates performed
 - Results obtained
 - Signature of individual(s) conducting activities
 - Equipment used (where appropriate)
 - These records shall be part of the Device History Record (DHR)

[21 CFR 820.80\(e\)](#)

Preamble On Acceptance Records

.....Where product fails to pass acceptance activities, the procedures for control of nonconforming product must be implemented to include investigations where defined. If the acceptance records are not clear about how the product failed, then the manufacturer may end up duplicating the acceptance activities in order to perform appropriate investigations.

Preamble Comment # 147, 2nd paragraph

Acceptance Activities

- Acceptance Status
 - Identify acceptance status with acceptance criteria:
 - conformance, or
 - nonconformance
 - Maintain acceptance status identification:
 - throughout manufacturing, packaging, labeling, installation, and servicing
 - to ensure only product which has passed required acceptance activities is distributed, used, or installed

[21 CFR 820.86](#)

Regulatory Requirements

| Subpart | Title | Regulation Number (21 CFR) |
|--|---|----------------------------|
| Subpart H - Acceptance Activities | Receiving, In-Process, and Finished device Acceptance | 820.80 |
| | Acceptance Status | 820.86 |
| Subpart L – Handling, Storage, Distribution, and Installation | Handling | 820.140 |
| | Storage | 820.150 |
| | Distribution | 820.160 |
| | Installation | 820.170 |

Handling

- Handling
 - Establish and maintain handling procedures to prevent:
 - Mix-ups
 - Damage
 - Deterioration
 - Contamination
 - Other adverse effects to product

[21 CFR 820.140](#)

Handling: Example

- Use of :
 - Anti-static measures
 - Gloves
 - Holding fixtures
 - Piping
 - Conveyors

Handling: Example

- To prevent mix ups -
 - Use of bins/carts/trays to move product
- To prevent deterioration especially for electrostatic discharge (ESD) sensitive products
 - Use of ESD protective containers/packages
 - ESD hoods

Reminder

- Use of “acceptance status” of parts is clearly notated when moving from:
 - station to station
 - start to finish

Storage

- Storage
 - Establish and maintain procedures for control of storage areas and stockrooms to prevent product:
 - Mix-ups
 - Damage
 - Deterioration
 - Contamination
 - Other adverse effects

[21 CFR 820.150 \(a\)](#)

Storage

- Storage
 - Establish and maintain procedures to ensure that no product is used or distributed if:
 - Obsolete,
 - Rejected, or
 - Deteriorated
 - Store product to facilitate stock rotation if quality of product deteriorates over time

21 CFR 820.150(a)

Storage

- Storage
 - Establish and maintain procedures describing methods for authorizing receipt from and dispatch to storage areas and stock rooms

21 CFR 820.150(b)

Implementation

- Storage area is contained
- Product is accounted for
- Acceptance status is notated
- Who can add or remove is designated and controlled

Implementation

- Controls for storage areas that may be considered for implementation include:
 - Security controls: limited access
 - Environmental controls: temperature, humidity, UV light
 - Contamination controls: dust free conditions
 - Personnel controls: cleanliness conditions
 - Packaging and handling controls: fragile products

Storage: Example

- Use of:
 - Cages
 - Red tag/green tag designation
 - Electronic system
 - Segregation/clearly labeled process

Distribution

- Distribution
 - Establish and maintain procedures to ensure:
 - Only devices approved for release are distributed
 - Purchase orders are reviewed; ambiguities and errors are resolved before release for distribution
 - Expired or deteriorated devices are not distributed

[21 CFR 820.160\(a\)](#)

Distribution

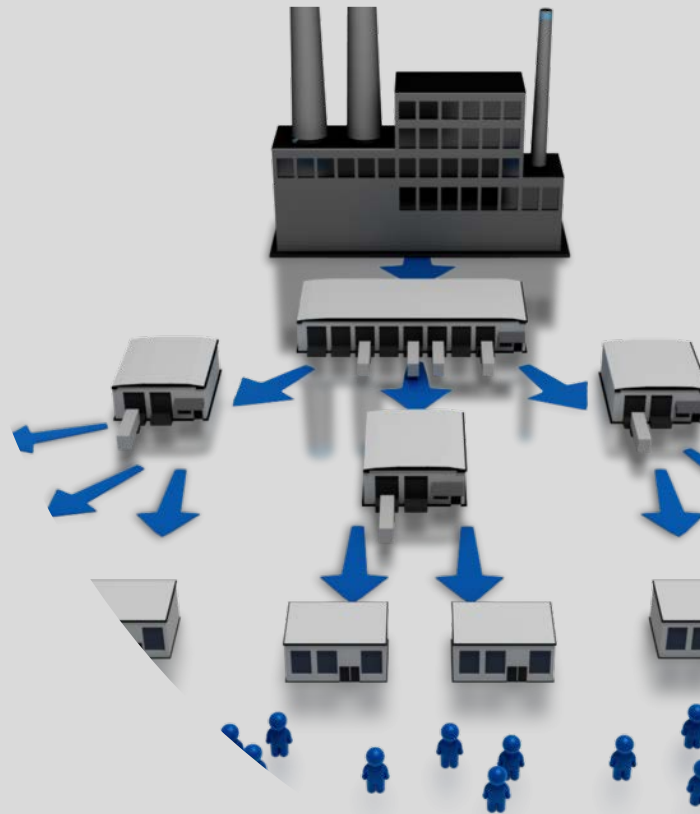
- Distribution
 - Maintain distribution records which include or refer to the location of:
 - Name and address of the initial consignee
 - Identification and quantity of devices shipped
 - Date shipped
 - Any control number(s) used

[21 CFR 820.160\(b\)](#)

A Common DICE Question

When is a device considered to be “in distribution”?

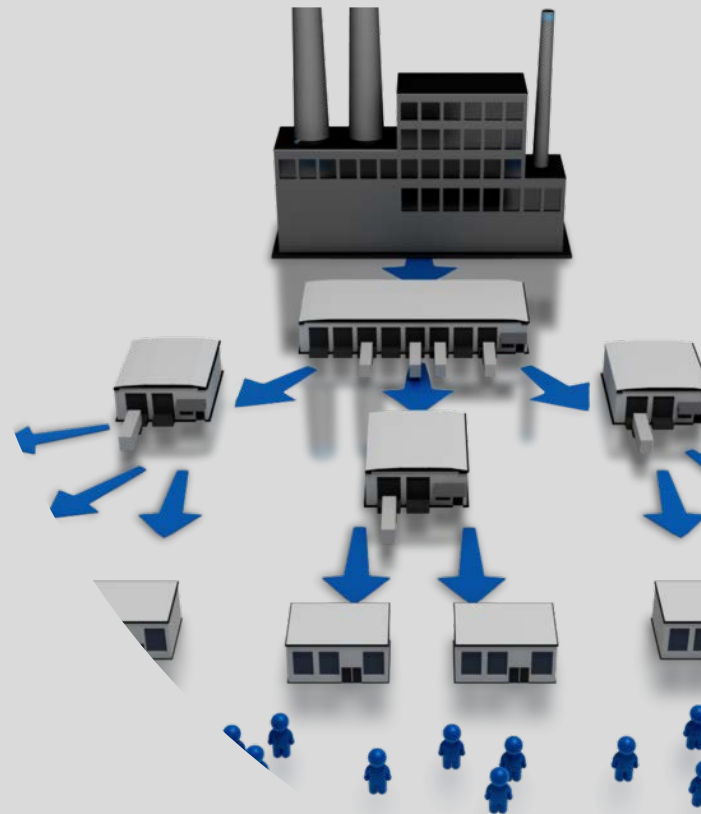
- All the forms are signed
- Leaves the building
- In a distribution warehouse



A Common DICE Question

When is a device considered to be “in distribution”?

- All the forms are signed
- **Leaves the building**
- In a distribution warehouse



Installation

- Installation
 - Ensure proper installation, by establishing and maintaining adequate:
 - Installation instructions;
 - Inspection instructions; and
 - Test procedures (where appropriate)
 - Ensure instructions and procedures are available to person(s) installing device

[21 CFR 820.170\(a\)](#)

Installation

- Installation
 - The person installing the device shall:
 - Ensure installation, inspection, and any required testing are performed in accordance with the instructions and procedures
 - Document inspection and any test results
 - Demonstrate proper installation

21 CFR 820.170(b)

Installation: Example

- If installation is included as part of the design:
 - installation instructions need to be provided
 - training is performed by qualified individuals

QS Regulation and Guidance

- **Quality System Regulation and Preamble**
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=820&showFR=1

www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation
- **Compliance Program Guidance Manual: INSPECTION OF MEDICAL DEVICE MANUFACTURERS**
www.fda.gov/media/80195/download
- **Guide to Inspections of Quality Systems [Quality System Inspection Technique (QSIT)]**
www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/quality-systems

Summary

- The production and process controls subsystem ensures that manufactured products meet specifications
- This subsystem includes acceptance activities, handling, storage, distribution, and installation

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

Your Call to Action

1. Make sure you document acceptance activities and the status of product
2. Ensure that product is controlled throughout handling, storage, distribution, and installation

