THE QUALITY SYSTEM REGULATIONS

SUBPART I - NONCONFORMING PRODUCT

21 CFR 820.90
Nonconforming Product

Definition:

- ***Nonconformity*** *[820.3(q)]:* "…the nonfulfillment of a specified requirement…"
- ***Specification*** *[820.3(y)]: '…any requirement with which a product…must conform…"*

- GHTF (Guidance on corrective action and preventive action and related QMS processes; GHTF/SG3/N18:2010):
  - *Section 2.6 Nonconformity: Non fulfillment of a requirement.*
  - *Section 3.0: It is important to understand that requirements may relate to product, process or the QMS.*

21 CFR 820.90(a)
Nonconforming Product

(a) *<u>Control of Nonconforming product</u>. Each manufacturer procedures shall establish and maintain procedures to control product that does not conform to specified requirements…"*

ISO13485:2016 section 8.3:

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.

21 CFR 820.90(a)
Nonconforming Product

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

ISO 13485:2016 section 8.3: The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

21 CFR 820.90(b)(1) *Nonconformity review and disposition*

(b) Nonconformity review and disposition.

- *(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 shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.*

ISO 13485:2016 section 8.3: Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained.

21 CFR 820.90 (b)

General triggers for investigation:

The nonconformance is unanticipated, or otherwise not well understood, such as:

- New failure mode
- Range of an existing failure mode exceeds acceptance tolerances
- Rate of an existing failure mode rises beyond specified tolerances
- Prior investigation(s) of the same failure mode are no longer valid

21 CFR 820.90
Identification, documentation, segregation

Use properly established 820.80 (Receiving, in-process, and finished device acceptance) and 820.86 (Acceptance records) subsystems to assure proper identification and segregation, and to avoid redundant documentation

21 CFR 820.90(b)
Review & Disposition

Typical Types of disposition:

- Scrap
- Accept “as-is” (i.e., by “concession”)
- Return to source/vendor
- Repurpose for other use (if appropriate)
- Rework

ISO 13485:2016, section 8.3.2:
The organization shall deal with nonconforming product by one or more of the following ways:
a) taking action to eliminate the detected nonconformity;
b) taking action to preclude its original intended use or application;
c) authorizing its use, release or acceptance under concession.

21 CFR 820.90(b)(2)
Requirements for rework

Special requirements for rework:

- *Definition in 820.3(x)*
  - *'…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 and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR…"*

21 CFR 820.90(b)(2) *Nonconformity review and disposition*

(b) Nonconformity review and disposition.

- *(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 and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.*

Correction vs. Corrective Action

Correction: action to eliminate a detected nonconformity

- A correction can be made in advance of, in conjunction with or after a corrective action.
- A correction can be for example, rework or regrade

Corrective Action: action to eliminate the cause of a nonconformity and prevent recurrence

- there can be more than one cause for a nonconformity
- corrective action is taken to prevent recurrence where as preventive action is taken to prevent occurrence.

ISO 9000 - Quality Management System - Fundamentals and Vocabulary

21 CFR 820.90

Kim Trautman (formerly FDA's Medical Device Quality Systems Expert):

> *'…Need a mechanism such that what is expected is understood, so that when something unexpected happens, then it can be escalated to the CAPA system…"*
>
> ***BUT***
>
> *'…Every nonconforming issue is not a CAPA…"*

21 CFR 820.90

The non-conformance system impacts many other areas and provides information on how various systems are performing such as:

- Design Controls 820.30
- Purchasing Controls 820.50
- Production and Process Controls 820.70-.75

Non-conformances feed into the Corrective Action and Preventive Action system (820.100) and Management Reviews (820.20(c).

21 CFR 820.90
Warning Letter Example

Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example:

A) Your firm's nonconformance records (NRC) were inadequate in that the (b)(4) out of the (b)(4) reviewed records did not include an investigation determination as required in the firm’s document Control of Nonconforming Products, Revision D & E – Procedure QP-XXX.

B) NCRs related to detected nonconformances in final testing were not found during the inspection. Your quality technician confirmed that he had communicated the nonconformances during the (b)(4) test to your Production Manager. However, these NCRs were missing during the inspection.

21 CFR 820.90
Warning Letter Example

Failure to establish procedures to control product that does not conform to specified requirements, pursuant to 21 CFR 820.90(a).

For example, “Non-Conforming Material Procedure”, SOP XXX, Rev 2, defines “Use-As-Is” as (b)(4).” Your firm decided to “use-as-is” Controls with an initial average value assignment that would result in a range with a lower limit below the testing range for the Product XXX after your firm changed the Product XXX Lead Control Level 1 average value assignment for Lot # XXX (Nonconforming Product Record NCP ID # XXX opened 9/24/2015) and Lot # XXX (Nonconforming Product Record NCP ID # XXX opened 12/29/2015) without documenting that the Controls were verified to be acceptable for use. The lots identified in these nonconforming product records were later the subject of 71 Customer Complaints regarding customers unable to use their analyzers, due to the Controls being out-of-range.

Poll:

What is a correction:

A) Action to prevents the recurrence of the nonconformance
B) Action to prevents the occurrence of the nonconformance
C) Action to eliminate a detected nonconformity

QUESTIONS?