Non-conforming Product and Equipment Lesson

1. Policy
   - 1.1. Detection of non-conforming product are established and maintained procedures to control product that does not conform to specified requirements.
   - 1.2. There are established procedures to address the identification, documentation, evaluation, segregation, and disposition of non-conforming products.
   - 1.3. Documentation includes the justification for the nonconforming product use and the signature of the individual authorizing the use.
   - 1.4. Ensure there is a process of inspection during receiving storage, handling, and in delivery
   - 1.5. Ensure that the product meets its current approved specifications.

2. Procedure
   - 2.1. Definitions (21 CFR 820.3)
     - 2.1.1. Specification of any requirement with which a product, process, service, or other activity conformed [21 CFR 820.3(y)]
     - 2.1.2. Product components, manufacturing materials, in-process devices, finished devices, and returned devices [21 CFR 820.3(r)]
     - 2.1.3. Non-conformity the nonfulfillment of a specified requirement [21 CFR 820.3(q)]
   - 2.2. Detection of non-conforming product.
     - 2.2.1. Non-conforming Product is a product that does not fulfill its specified requirements.
     - 2.2.2. Non-conformances can occur in both product and process.
     - 2.2.3. Nonconforming processes can lead to nonconforming product
     - 2.2.4. Identification procedure
       - 2.2.4.1. Received components/material that fails incoming inspection.
       - 2.2.4.2. Products/components that fail inspection or test during manufacturing.
       - 2.2.4.3. Product returned to the manufacturer with defects.
       - 2.2.4.4. Non-conformances and Non-conforming reports (NCR) have to be evaluated.
   - 2.3. Evaluation of non-conformance
     - 2.3.1. The evaluation of non-conformance and any investigation are documented. Refer to *CAPA*
   - 2.4. Segregation of non-conforming product and equipment
     - 2.4.1. Marking the product and equipment with tags, signs, or stickers.
     - 2.4.2. Securing the product and equipment in a holding cage or designated cabinet specially marked for non-conforming products and equipment
     - 2.4.3. Putting the product and equipment in an appropriately identified bin, box, and bag.
     - 2.4.4. Remove it from the production or repair area
   - 2.5. Disposition of non-conforming products and equipment
     - 2.5.1. The following disposition of non-conforming products that is reviewed by the authority.
       - 2.5.1.1. Scrap
       - 2.5.1.2. Return to Supplier
       - 2.5.1.3. Downgrade
       - 2.5.1.4. Use as Is
   - 2.6. Rework of product and equipment
     - 2.6.1. Retesting and reevaluation of the nonconforming product and equipment to ensure that the product meets its current approved specifications.
     - 2.6.2. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product.

3. Responsibility
   3.1. Supervisors or department heads and team leaders are responsible to;
      3.1.1. Ensure (inspect) and verify this policy and procedure is adhered to and;
      3.1.2. Take corrective action to ensure compliance with this policy.
   3.2. All Personnel
      3.2.1. Shall adhere to this policy.
   3.3. Quality Control Personnel
      3.3.1. Validate training and adherence to policy and procedure.
      3.3.2. Monitor and document non-conformance observation also known as discrepancy, using Corrective Action Preventive Action-CAPA Report.
   3.4. Quality / Compliance Department
      3.4.1. Document control, records, and archive.
   3.5. Preventative Control Qualified Individual (PCQI)
      3.5.1. Visually inspect areas for compliance with this policy.
      3.5.2. Oversee (Verify) compliance of procedure.
      3.5.3. Monitor and take corrective action to ensure compliance with this policy.

4. Corrective action
   4.1. In the event found out a non-conforming product and equipment;
      4.1.1. Report to the Quality department and supervisor
      4.1.2. Hold the product and equipment
      4.1.3. All inspection and validation must be documented anytime when encountering non-conforming products and equipment.
      4.1.4. All products or equipment under quarantine must be on separated storage to prevent mixing with other products or equipment.

5. Review-Quality
   5.1. Review of the procedure for non-conforming product/equipment;
   5.2. Identification of non-conforming product and/or equipment and the action taken
   5.3. Records of product that has not met the specification
   5.4. Records of product disposition;
   5.5. Records of repair of non-conforming equipment.

6. History

Revision No.:	Revision Date:	Description of Change:	Originator / Author Name:	Title / Department:
0	20220908	Original	Arnel Ryan	PCQI / Compliance

Requirements:

(1) The trainee has read or received a verbal translation of all or part of the policy, procedure, method, and or SOP for which they are being trained.
(2) The trainee has demonstrated the task they are to perform or the procedure for which they are being trained as required.
(3) The trainee has demonstrated the ability to perform the task with acceptable proficiency and with minimal supervision as required.