1. **Purpose**

This document defines the policies and procedures for managing nonconforming product. These policies and procedures include control of nonconforming product, product review and disposition, and nonconforming product rework.

1. **Scope**

This procedure applies to all product nonconformities within the company facilities or control. Any nonconforming product identified at a contract manufacturer shall be managed under their quality systems. Nonconforming product identified by a customer shall be managed under Customer Complaints.

1. **General** 
   1. **Definitions** 
      * **Material Review Board (MRB)** – The party responsible for evaluating, identifying corrections, and determining the disposition of nonconforming product.
      * **NCR** – Non-Conformance Report
      * **Nonconformity** – Non-fulfillment of a specified requirement
   2. **Responsibilities**

**Engineering** – Engineering is responsible for assisting in the investigation and disposition as necessary.

**Operations** – Operations is responsible for reporting all non-conformances to the Quality Department.

**Quality** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – Engineering, Operations, and Quality personnel shall be trained to the procedures specified in this document.
  4. **Record Management** – All NCR’s are managed and maintained by the Quality Department.
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

**QP-0012** – Corrective and Preventive Action (CAPA) Process

**QP-0013** – Management Review and Data Analysis Process

**QF-0008-1** – Non-Conformance Report (NCR) Form

1. **Nonconforming Product Procedure**

Nonconforming products are documented on nonconformance reports (NCR’s). Nonconforming products are generally identified as the results of formal verification, inspection, or test activities; however, may be identified at any point. The following procedures are utilized to ensure the appropriate handling of nonconforming product. Nonconforming product trending and analysis is accomplished through Management Review and Data Analysis Process (QP-0013).

* 1. **Control of Nonconforming Product**

Nonconforming product should be appropriately identified and quarantined to prevent the inadvertent use or distribution of the product. The specific method of identification is dependent on the product and may consist of appropriately labeled bins, tags, sticker, etc. All nonconforming product shall be segregated from product acceptable for distribution.

* 1. **Product Review and Disposition**

Nonconforming product shall be reviewed and dispositioned appropriately by the Material Review Board (MRB). The MRB shall consist of functional expertise from each department impacted by the nonconformance. The Quality Department is responsible for ensuring the necessary parties are represented. Team members typically include Operations, Engineering, Marketing, and Quality. Authority to review and disposition nonconforming product may be delegated to an individual for previously identified and reviewed failure modes. All reasonable efforts shall be made to document and disposition NCR’s in a timely manner.

* + 1. **Review**

The MRB shall review each nonconforming product and document this review on the NCR Form. If the nonconformance is determined to be systematic, the MRB may escalate the NCR to a CAPA (QP-0012). The MRB shall determine and implement any necessary corrections. Review shall include potential impacts to other products and whether notification is necessary to any external party responsible for the nonconformity.

* + 1. **Disposition**

The disposition of the nonconforming product shall be determined and approved through the MRB. The disposition of the product shall be documented on the NCR form. The following are examples of acceptable dispositions:

* No impact to product, acceptable for distribution
* Rework
* Return to Supplier
* Scrap
* Acceptance under Concession

Any product accepted under concession is required to meet all regulatory requirements and the identity of the authorizing person(s) shall be documented.

* 1. **Rework of Nonconforming Product**

Nonconforming product that has been dispositioned for rework shall be processed under documented procedures that have undergone the same authorization as the original production process procedures. Any adverse effect of rework upon the product shall be evaluated and documented on the NCR Form.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0008 |  |  | Initial implementation of the Nonconforming Product Process |