1.0 PURPOSE:

This procedure describes the process for handling non-conforming materials at Salient Medical Solutions. The purpose of this procedure is to assure control and proper disposition of product that does not conform to requirements.

2.0 SCOPE:

This procedure describes the methods/processes that will be used for the control of non-conforming product/materials.

3.0 DEFINITIONS:

Supplier: Can refer to a third party supplier or Contract Manufacturer.

4.0 RESPONSIBILITIES:

The President, Quality Management Representative (QMR) or designee is responsible for maintaining this procedure and adhering to the requirements as established. This would include any employee assigned by management to assist in non-conforming product activities.

All employees have authority and responsibility to notify their immediate supervisor of any problems perceived to be associated with non-conforming products.

Employees in conjunction with management will determine and document what action must be taken per this procedure.

5.0 PROCEDURE:

This procedure addresses the identification, segregation, documentation, evaluation, disposition and reporting of non-conforming product. Suspected non-conforming product may occur as a result of (but not limited to) these actions:

- Incoming receiving and inspection
- Material controls
- Customer complaints
- Returns

The non-conforming product process consists of:

- Identification
- Containment - Evaluation
- Root Cause Investigation
- Disposition
- CAPA Escalation

4.1. Identification

A non-conforming report will be initiated when an apparent non-conformance has occurred. Identification of the non-conformance may include:

- Initiator's name and date (date of discovery)
- Affected department/function
- Occurrence date
- Device part or code number
- Device lot number (if applicable)
- Device description (if applicable)
- Quantity (if applicable)
- Description of non-conformance. The description should be concise and complete. It must contain all the data and facts and written so that the problem can be easily understood and include (as appropriate):
- How the non-conformance was discovered
- Evidence as appropriate: attach supporting data and/or documentation (photocopies, photographs, etc.)
- Reference of the requirement(s) that relate to the non-conformance (e.g., SOPs, drawings, etc.)

4.2. Containment - Evaluation

Containment of Affected Product: Segregate and identify non-conforming product. All non-conforming items/product must be moved to a designated non-conforming hold area or scrap area as soon as possible and identified as such with either a tag (Sample Attached) traceable to the NCMR or an actual copy of the NCMR.

Description of immediate/remedial containment (if applicable): Describe activities at the time of discovering the non-conformance.

If it becomes evident that non-conforming product has been shipped to the customer an evaluation will take place immediately to assess the potential effects of the non-conformity on the product. If deemed appropriate, the quality department will notify the customer and issue an advisory notice as per SOP 8.2.3 Recall.

Each non-conformance will be evaluated to determine the extent of the non-conformance to other batches/lots of product.

- Determine if other lots/batches are affected. For finished goods, determine if other products may be affected.
- If other product is or may be affected, contain and identify all identified product.
- Update documentation or create a new non-conformance to include different components or product affected, as appropriate.

Each non-conformance will be compared with respect to previous non-conformances to assess the effectiveness of corrective/preventive actions taken and to evaluate the necessity for potential CAPA remediation of recurring trends.

Each non-conformance will be evaluated further within the Root Cause Investigation section and where applicable the notification of any external party responsible for the non-conformity.

4.3. Root Cause Investigation

Non-conformance root cause investigations consist of:

- Utilizing problem solving techniques (Pareto, Fishbone, 5 Why's, etc.) when applicable, perform any actions necessary to determine the root cause of the non-conformance, which may include testing, inspections, etc. Investigative documentation is to be included in the non-conformance file.

- When a root cause is identified, take action to remove and/or correct the situation utilizing the CAPA process.

Investigations are conducted to identify the underlying cause(s) of detected non-conformities, where possible. However, investigations will be commensurate with the risk of the non-conformity.

4.4. Disposition

Disposition of non-conforming product will be one of the following and documented on the NCMR as such.

Use As Is

When Salient Medical Solutions believes a non-conforming condition will not affect function of safety of the product but the product does not meet the customers established requirements, it shall be required that the customer be contacted and asked for a concession "Use As Is" for the non-conforming condition.

When "Use As Is", is the disposition decision, a thorough justification of acceptable use of the product with respect to its function and safety as well as any applicable regulatory requirements must be detailed in the Root Cause Investigation section.

Rework
In some situations rework may require a minor label change to bring the device into compliance. Devices to be reworked will be documented along with the NCMR form.

Scrap
Records of destruction must be documented.

Documented evidence of destruction will include, at a minimum:
- Catalog/part number(s)
- Lot number(s)
- Quantity of product destroyed
- Signature/date of individual performing destruction
- Signature/date of individual witnessing destruction

Return to Supplier/Contract Manufacturer
The supplier is contacted to obtain Return Goods Authorization.

Depending on specific site requirements, a Supplier Corrective Action Request may be initiated. The Supplier Corrective Action Request documentation must reference the non-conformance. SCAR uses the company's CAPA procedure (SOP 8.5).
- Note: the Supplier Corrective Action Request is optional.

If internal investigation is not required, proceed to section 6.0.

CAPA Escalation
Following the investigation, determine if the non-conformance should be escalated to CAPA status using the following risk-based criteria. If the non-conformance meets one or more of the three following criteria, a CAPA should be initiated as per SOP 8.5 – Corrective and Preventive Action.

1. Is there potential that the non-conformance would lead to a user or patient safety issue?
2. Is product labeling (e.g. finished product printed materials, including directions for use) involved?
3. Has the frequency of occurrence for this non-conformance changed to be at a higher rate than expected? (Use of non-conforming monitoring trending data should be utilized.)

The site may supplement with additional risk assessments in addition to determine if the non-conformance is to be escalated to a CAPA.

If there is a CAPA currently open for the same root cause, the CAPA must be identified in the non-conformance documentation.

1. No new CAPA is opened
2. The associated CAPA will be amended to reference the additional non-conformance.
3. The non-conformance may be closed and no effectiveness monitoring is required, as this will be addressed with the associated CAPA.

When an official CAPA is not generated and CAPA activities are conducted within the non-conformance, an effectiveness verification of the CAPA activities should be performed to document the resolution of the non-conformance. The results of these effectiveness verification activities should either be included within the NCMR or as a memo to the NCMR file.

As part of the CAPA activities and based upon the issue identified and the associated root cause(s), information related to any quality problems or non-conforming product will be disseminated to those directly responsible for assuring the quality of such product or the prevention of problems.

4.5 Closing Non-conformances

Non-conformances are closed when:

- The disposition is properly completed, and
- The applicable activities related to the root cause investigation are completed (with the exception of return to vendor/supplier disposition).

President or QMR will approve closure of non-conformance reports.

4.6 Annual Metrics – Management

Management Review Meetings will monitor the overall Non-conforming Product process at Salient Medical Solutions on an annual basis and determine the effectiveness of the various elements of the Non-conforming Product program.

Trending and monitoring of non-conformances is to be included in the annual site Management Review meetings, as per SOP 5.6 – Management Responsibility.

6.0 REFERENCES:

Not applicable

7.0 ATTACHMENTS:

F83-1 Non-conformance form
SAMPLE – Non-conforming Product Tag

8.0 APPROVALS

President _____ Date_____
Author
J. Herman

CEO _____ Date_____
M. Pizzorno

9.0 REVISION HISTORY

Revision 0 - Author – J. Herman, Effective date: Feb 28, 2019. Initial Release of Document
Revision 1 - Author – J. Herman, Effective date: Sept. 15, 2020. Minor edits and clarifications. Removal of M. Ciceran from Signatory, removal of position RA/QA Director.