Procedure: Control of Non-Conforming Product

|  |  |  |  |
| --- | --- | --- | --- |
| Document information, authorship and approvals | | | |
| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

Table of Contents

[1. Purpose 3](#_Toc406575941)

[2. Scope 3](#_Toc406575942)

[3. Responsibilities 3](#_Toc406575943)

[4. Procedure 3](#_Toc406575944)

[4.1. Identification and documentation 3](#_Toc406575945)

[4.2. Non-conformance review and disposition 4](#_Toc406575946)

[4.3. Acceptance of non-conforming product 4](#_Toc406575947)

[4.4. Control of rework operations 4](#_Toc406575948)

[4.5. Closing out the Non-Conformance Report 5](#_Toc406575949)

[4.6. Advisory notices 5](#_Toc406575950)

This procedure is sufficient for a range of situations. If electronic records or automated in-line inspections are performed, this procedure will require modifying to reflect this technology.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for identification, documentation, evaluation and assigning disposition of non-conforming products.

# Scope

The scope of this procedure includes all purchased and in-house manufactured materials, components, subassemblies and finished products at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| All personnel |  |
| Quality Control (QC) Inspectors |  |
| Quality Manager |  |
| Production Manager |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## Identification and documentation

QC inspectors and production personnel are responsible for identifying non-conforming products as part of routine inspection and process monitoring. Additionally, all personnel, regardless of their responsibilities, are encouraged to watch for and flag any non-conformances.

When a non-conformance is identified it is documented by the QC inspector or by QA in a Non-Conformance Report (NCR). Refer to Form *FM805-1: Product Non-Conformity Report*.

When the non-conformity is documented, the NCR number is marked on the REJECTED label and the NCR forwarded to QA for review and disposition.

Alternatively, instead of a REJECTED label, a copy of the NCR can be attached to the non-conforming product.

## Non-conformance review and disposition

It is important to assign the NCR to the appropriate person or department so that an effective decision is made. The assignment of responsibility may require modification to suit the company.

Non-conforming products may be:

* reworked to meet the specifications
* accepted as-is (this will require justification)
* scrapped

The disposition of product may be made on two levels, depending on the nature of the non-conformance and available actions:

* QC inspectors and production supervisors are authorised to allocate a disposition when product is obviously deficient and must be scrapped or when it is easily reworked using existing authorised rework instructions.
* The QA Manager and/or Production Manager are authorised to make an ‘Accept as-is’ or a ‘Rework’ decision where there are no approved rework instructions. However, it must first be established that the rework processes can be implemented.

The disposition decision is documented and authorised in the NCR.

## Acceptance of non-conforming product

Only the QA Manager and/or Production Manager may authorise acceptance of non-conforming products. (Products not meeting regulatory requirements may not be accepted under any circumstances.)

The QA or Production Manager must document a justification for use of non-conforming product. The NCR should be signed and dated, identifying the position and name of the manager signing off.

## Control of rework operations

All rework operations are documented in written instructions. The instructions explain rework processes and determine how the reworked products will be inspected or tested to verify that they meet requirements.

Rework instructions are formally reviewed and approved in the same manner as other quality or production documents. Prior to authorisation and approval, the rework process is evaluated to determine any adverse effects. Results of the evaluation are documented in the Device History Record (DHR).

Reworked products are inspected thoroughly to verify they conform to specifications. The manner and scope of inspection are described or referenced in the rework instructions.

Rework activities and results of re-inspections and tests are recorded in the work order (and attachments) and are documented in the DHR.

Section 4.4 is a requirement of CFR 820.90(b)(2). It may be necessary to describe how reworks are documented, especially if part of a batch is reworked.

## Closing out the Non-Conformance Report

When the disposition decision is to accept as-is or to scrap the product, the NCR is closed out and filed.

Subcontractors may have to submit to the customer for a decision. If so, modify the NCR to reflect this and describe it here.

Rework re-evaluation results should be recorded in or attached to the NCR.

Before closing out an NCR, the QA Manager should evaluate whether a corrective or preventive action is appropriate. If a corrective or preventive action is initiated, the CAR (*Form FM810-1: Corrective Action Request*) number is noted on the NCR.

This satisfies CFR 820.90(a) and the more general requirement of ISO13485:2016. The ISO 13485 standard was updated to keep up with changes in the industry and to address changes in the underlying ISO 9001 standard. While the old ISO 13485 2003 standard was based on the old ISO 9001:2000 standard, the new one is based on ISO 9001: 2008. Since 2003, many jurisdictions had either revised or introduced new regulations for medical devices and these have been integrated with the new ISO 13485 standards.

for feedback of quality problems into the corrective action system.

## Advisory notices

When non-conforming product is detected after delivery, distributers and users are notified, as appropriate, to instruct them on how to mitigate or avoid the effects, or potential effects, of the non-conformity (refer to Procedure *QP808: Device Recall and Advisory Notices*).

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
|  |  |
|  |  |
|  |  |
|  |  |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP808 | Device Recall and Advisory Notices |
| FM805-1 | Product Non-Conformity Report |
| FM809-1 | Corrective Action Request |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END