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Non-Conforming Product Process

1. **PURPOSE**

To describe a system for the control and documentation of non-conforming or discrepant materials.

2. **SCOPE**

This procedure applies to all incoming materials, in-process materials, finished products, and field returns determined to be non-conforming.

3. **REFERENCES**

- 3.1 QM-01-00001: Quality Manual
- 3.2 SOP-01-00021: Incoming Inspection Procedure
- 3.3 SOP-01-00002: Document Change Orders
- 3.4 SOP-01-00010: Corrective and Preventive Action
- 3.5 SOP-03-00002: Supplier Control
- 3.6 US FDA 21 CFR PART 820 Quality System Regulation

4. **DEFINITIONS AND ACRONYMS**

Non-Conforming/Discrepant Materials (NCM): Any item or material that is found to deviate from an applicable standard; a rejected item.

Material Review Board (MRB): A group of two or more qualified persons designated to review and determine the disposition of non-conforming materials. One member will be from the quality assurance function.

DCO: Document Change Order

NCMR: Non-conforming Material Report

5. **RESPONSIBILITIES**

5.1 Regulatory/Quality

- Responsible for reviewing, approving, and following this procedure.
- Responsible for oversight and control of this procedure.
- Responsible for determining if any CAPA is necessary related to NCM
- Responsible for participating and approving all NCM as a member of the MRB

5.2 Customer Service

- 5.2.1 Responsible for reviewing, approving, and following this procedure.
- 5.2.2 Responsible for participating and approving all NCM as a member of the MRB
- 5.2.3 Responsible for physically and electronically executing the disposition decisions agreed upon by the MRB.

- 5.3 All Personnel performing activities described in this procedure
 - Responsible for understanding and complying with this procedure.

6. **PROCEDURE**

- 6.1 Non-Conforming Materials
 - 6.1.1 All items requiring inspection shall be documented at receiving and immediately quarantined per SOP-01-:00021 "Incoming Inspection Procedure".
 - 6.1.2 The inspector will perform the appropriate inspections on each incoming item.
 - 6.1.3 For single use items returned after use, no NCM will be required. These items can simply be discarded.
 - 6.1.4 For reusable items considered to be consumable such as bone pins, drills, etc. that will deteriorate with time, an NCM is required unless the item has a defined lifespan. For example, if a bone pin is defined to have a life span of 2-3 uses and returns bent, it could be scrapped without an NCM.
 - 6.1.5 The inspector will apply a label to any item(s) found to be discrepant and move the item(s) to the "Quarantine" area. (The NCM report (FR-01-00025) should be initiated and the NCM number written on the label or container).
 - 6.1.6 The materials will be electronically moved from "inspection" to "on hold".
 - 6.1.7 For inventory parts, the inspector will notify operations that there is an NCM awaiting review and disposition.
 - 6.1.8 All NCM items must be properly identified with a Nonconforming label, and must be safely segregated to prevent their unauthorized use.
 - 6.1.9 A Non-Conforming Material Report (FR-01-00024) will be created for discrepant materials. Multiple discrepant materials may be grouped on a single NCM report.
 - 6.1.10 All inspection reports will be referenced in the NCMR and other supporting information should be referenced or attached to the NCMR.
 - 6.1.11 The purchase order and applicable purchasing requirements should also

be reviewed and changes recommended as may be appropriate.

6.1.12 Note: In the event that non-conforming product is detected after delivery or during use, the Company will take action appropriate to the effects, or potential effects, of the non-conformity. The appropriate actions will be determined by the MRB and documented through the guidelines provided in this procedure.

6.2 Material Review Board

6.2.1 All NCM's should be referred to the MRB.

6.2.2 The Company will schedule periodic audits of NCMR files and supplier files in order to detect any trends that may emerge. MRB may be used to evaluate any trends.

6.2.3 A Regulatory/Quality or Customer Service Representative may call a meeting as necessary to review an NCMR. Note: These meetings may be convened immediately when a problem has arisen that must be addressed without delay.

6.3 Material Review Board Membership and Responsibilities

6.3.1 The MRB membership consists of an appropriate person or group of persons having the experience and knowledge to review NCMRs and to make decisions that are in the best long-term interests of the customer or patient and the company.

6.3.2 *Note: The effect of any decision on the safety and efficacy of the finished product must always be the primary focus of the MRB.*

6.3.3 The MRB may consist of qualified person(s) from the quality /RA, Customer Service, and other functions as may be appropriate for the NCM. A person from the quality function will be part of each MRB.

6.3.3.1 MRB will minimally be as follows:

- Regulatory/Quality and Customer Service will be members of all MRB's.
- Finance will not be a member of the MRB but will be notified if the disposition is: Return to Supplier, Rework/Reprocess, or Scrap.

6.3.4 Regulatory/Quality will be consulted whenever interpretation of specifications, standards, and/or regulations may be necessary. Note: MRB activities will be fully documented.

6.3.5 The MRB should proceed with the following items as appropriate for each NCMR:

6.3.5.1 The MRB assigns an authorized individual to evaluate the non-conforming product, investigate (if required), and conclude how it is to be dispositioned.

6.3.5.2 Initiate and complete the Investigation/Root Cause section of the Non-conforming Material Report. This section is to include the following.

63521 Authorized individual's name

63522 Investigation/Root Cause detail information and results (as applicable). The investigation information should include personnel interviewed, records reviewed, analysis methods, etc.

6.3.5.3 Initiate and complete the Corrective/Preventive Action Required section of the Non-conforming Material Report if applicable.

63531 An authorized Quality individual will determine based on the investigation and root cause information, if immediate correction or preventive action is required

63532 If not required, select "No" for CAPA

63533 If required, select "Yes" and enter the CAPA number assigned. Proceed with corrective/preventive actions in accordance with the CAPA process (SOP-01-00010).

63534 If the MRB determines that root cause may be a systemic issue originating at a supplier, a supplier corrective action request will be initiated.

6.3.5.4 Evaluate the NCMR, test and inspection reports, specifications and any other available information to facilitate competent decision-making.

6.3.5.5 Review any materials, samples or products pertinent to the problem under consideration.

6.3.5.6 Request additional information, more samples, technical expertise or further testing or inspection as needed.

6.3.5.7 Summarize the discussions and findings relevant to the NCM, documenting this information.

6.3.5.8 Indicate the disposition of the NCM:

- Return to Vendor: (vendor to replace or modify so as to meet original purchase specifications). If applicable, the Return Material Authorization (RMA) number should be recorded on the NCMR.
- Use As Is: (use without further modification or adjustment, problem is minor and will not affect the safety, efficacy, quality, identity, etc. of the finished product). Any Use As Is disposition should be evaluated to determine if a change to the specification or procedure is appropriate in order to prevent the same condition from being considered a discrepancy in the

future. The DCO number documenting this change should be entered into the appropriate area of the MRB section of the NCM report. If the specifications and/or procedures are not being updated, a justification will be provided

- Rework or Reprocess: If the MRB determines that local rework is appropriate for the rejected product, they will provide a detailed set of rework instructions for the manufacturing assembler as well as clarification of the acceptance criteria for re-inspection of the product to continue the process. This could include but is not limited to: replacement of damaged shrink wrap, removal of burs, removal of writing/stickers on boxes, etc. The MRB will also determine and document all potential adverse effects of this rework process for the product, if any exist. This is to be used for items being reworked in-house.
- Scrap (dispose of or render unfit for use with any product). This disposition may include notes to give to Marketing for use in demos or labs only if the defect does not affect function, and transact out of electronic stock. On the NCM form, specify if the scrap item is to be destroyed, given to Training, given to Marketing, or given to R&D.

6.3.5.9 Note: The NCM will be properly labeled, and quarantined if appropriate, immediately after disposition is determined, affixing labeling such as "Accepted", "Rework required", "Return to Vendor", etc.

6.3.5.10 Provide specific information describing how to implement the disposition decision, such as giving rework instructions, supplier corrective activities, how to scrap, etc. The person or department responsible for the action, and the date for completion, will also be assigned by the MRB.

6.3.5.11 If appropriate, outline the corrective action required to prevent or minimize the recurrence of the same problem in the future.


6.3.5.12 In the event that the disposition is to return to UOC Taiwan, the NCM may be closed out once the material is physically and electronically moved to the quarantine area/warehouse(s) for items awaiting return to Taiwan. Physical return may occur at a later time due to customs restrictions.

6.4 Records

6.4.1 Regulatory/Quality will assure the proper maintenance of all NCM/MRB records, MRB activities and subsequent corrective actions.

6.4.2 The records maintained should accurately reflect the sequence of all authorized changes using the DCO system.

6.4.3 Regulatory, if requested, will provide copies of these records to the FDA

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or other authorized regulatory agency in accordance with company policy.

6.4.3.1 Once the NCMR has been dispositioned, and any required supplier follow- up has been completed, the record will be routed for approval signatures.

6.4.3.2 After approval, proceed with the actual disposition of the parts and the closure of the NCMR record.

END OF PROCEDURE