1.0 PURPOSE

This SOP defines the minimum requirements for the disposition of raw materials, packaging materials, labels and/or finished products due to reasons such as expiry, nonconformance, discontinuance, returns and/or recalls.

2.0 SCOPE

This SOP applies to all raw materials, packaging materials, labels and/or finished products that have been determined to be eligible for destruction and/or return to the vendor and the related documentation.

3.0 RESPONSIBILITY:

3.1 All employees involved in the disposition of the rejected materials are responsible for following this SOP.
3.2 The QA/QC department is responsible for completing the paperwork required by this SOP.
3.3 Production Manager and the QA Manager are responsible for ensuring this SOP is followed.
3.4 The QA manager is responsible for maintaining the paperwork required by this SOP.

4.0 POLICY: N/A

5.0 DEFINITION (S): N/A

5.1 **Rejected Material** is a material failing to meet established specifications, identified as such, and quarantined.
5.2 **Destruction** is to render a material unusable/useless and safe for disposal.

6.0 REFERENCE:

6.1 SOP ADM – 007 Return Goods Procedure
6.2 SOP QA-008 – Out of Specification Results Handling
6.3 SOP QA-006 – Stability and Shelf Life
6.4 SOP ADM-008 – Product Recalls

7.0 EQUIPMENT / MATERIALS:

7.1 Shredder or milling machine

8.0 PROCEDURE

8.1 Rejected Materials

8.1.1 Materials rejected by QC and/or the Material Review Board (MRB) are identified with “Rejected” stickers placed on the material by the QC Department. Attach the Non-Conformity Report to the container(s).

8.1.2 Move the rejected materials to the designated rejected materials location.

8.1.3 QA/QC and/or the MRB are responsible for determining if the material/product is to be returned to the vendor or destroyed.

8.1.4 If the material/product is to be returned to the vendor, Purchasing is responsible for coordinating the pick-up, return, reimbursement, and/or replacement material/product. Refer to Section 8.3 below.

8.1.5 If it is necessary to destroy a material/product, the designated department initiates a Product Destruction notice.

8.1.6 The following information is recorded on the Material / Product Destruction notice:

- Material/product name and lot number
- Quantity by weight/volume and number of containers
- Current inventory location
- Package size (if bottled product)
- Reason for proposed destruction
- Requested by and date

8.1.7 The individual requesting the destruction forwards the form to his/her department management for department review and approval. After approval, the form is forwarded to other designated departments for review and approval.

8.1.8 QA is the final review and approval of the form. When completed, copies of the form are sent to inventory control, purchasing, QA, and other departments as needed.

8.1.9 The production manager is responsible for contacting the designated waste hauler if the quantity of materials/products to be destroyed and disposed of is too large to be accommodated by the facility’s dumpsters, or if the materials/products require a specific destruction method, such as incineration, landfill, etc.

8.1.10 The QA manager is responsible for contacting an appropriate hazardous waste hauler if the material/product is determined to be hazardous.

8.2 Destruction and Disposal

8.2.1 Before removing the material/product to be destroyed from the facility, the Plant Manager (or designee) transfers the material/product to the loading dock area. A Destruction List is prepared using copies of the completed Destruction Notices.

8.2.2 Acceptable methods for destruction include: shredding, milling, dilution, and using water as a solvent. NEVER DISCARD WHOLE, SEALED BOTTLES.

8.2.3 If the material/product can be sufficiently diluted and flushed down the drain, this can be performed in the presence of a QA/QC employee. Follow the instructions found on the material / product MSDS sheet.

8.2.4 Labeled bottles/containers must have all labels defaced.

8.2.5 Materials/products determined to be of a hazardous nature are maintained in appropriate containers and identified with the applicable hazardous material waste labels to await pickup by the required hazardous waste disposal services.

8.2.6 If the material/product requires special handling and disposal, such as incineration or landfill, a QA/QC employee accompanies the material/product to the destruction site and verifies the destruction. The QA/QC employee obtains a receipt from the landfill or incinerator facility for the material/product. This receipt is filed in the QA/QC department.

8.2.7 If the material/product requires hazardous waste disposal, a QA/QC employee maintains a copy of the manifesto listing the materials/products to be destroyed. A QA/QC employee obtains a receipt from the disposal service certifying appropriate destruction of the materials/products. This receipt is filed in the QA/QC department.

8.3 Materials Returned to the Vendor

8.3.1 Purchasing contacts the vendor, informs them of the rejection or disposition, and obtains authorization to return the material/ product.

8.3.2 Purchasing negotiates the method of return, including credit for and/or replacement of the material/product. This includes vendor responsibility for the freight costs in accordance with Hamida's standard purchasing terms & conditions. Purchasing notifies Accounting of any related financial transactions.

8.3.3 If the vendor can show cause for not authorizing the return of the material, Purchasing may go back to QC and/or the MRB for additional review and disposition.

8.3.4 Purchasing coordinates the material return with Shipping & Receiving as appropriate.

8.3.5 Appropriate details and supporting documentation for materials return are recorded on the "Disposition of Rejected Materials Record".

9.0 SAFETY / PRECAUTION (S) :

9.1 Follow all Hamida-required safety policies when destroying material on-site. Review material/product MSDS sheets as needed prior to destruction.

10.0 ATTACHMENT (S):

10.1 SOP Attachment – 10.10.2 Non-Conformity Report
10.2 SOP Attachment – 10.14.20 Return Label
10.3 SOP Attachment – 10.14.25 Rejected Label
10.4 SOP Attachment – 10.3.6 Shipping Log
10.5 Material / Product Destruction Notice
10.6 Disposition of Rejected Materials Record