



Pure Nutra Labs
65 Crest Ridge Drive,
Suwanee, GA, 30024

Title: Control of Non-Conforming Product & Equipment, Rejects, and Returns		Approved By: Quality Director	
Policy #: SOP-0032	Issue Date: 09/06/2025	Revision: 2	Page 1 of 9

Purpose:

To set forth the methods and responsibilities for detection and control of non-conforming product, raw material, ingredients, work-in-progress, product or equipment during receipt, storage, processing, handling, or delivery. These procedures will assure that product or equipment on QC Hold is not inadvertently used or shipped.

Scope:

It is essential to the production of safe and wholesome products that product, materials, and equipment that do not meet company, customer, or regulatory requirements be held in a manner to prevent the inadvertent use or shipping of the product or equipment.

Definition:

Non-Conforming Product or Equipment – Any product or equipment that has become adulterated, expired, does not meet specifications, or otherwise is not fit for consumption or use.

Procedures:

I. Identification and Storage

- A. Materials (packaging components, raw materials/bulk solution, and returned/finished product) which are suspected of not meeting specifications will be placed on Quality Hold, remain quarantined, and identified with a Quarantine label. The materials will remain on Quality Hold and in the Quarantine Area, pending final disposition from Quality. The material status must be clearly identified with a Quarantine Tag.
- B. Quarantined, non-conforming, and rejected materials must be stored and appropriately identified. Only approved materials may be utilized in manufacturing and packaging.



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1. Customer-supplied material holding on disposition from a customer can be staged in the quarantine area. This includes, but is not limited to, Raw Materials, Bulk Solution, Components, and Finished Goods. All items must maintain traceability with an Item #, Lot #, and identified with a RED or ORANGE Quarantine label.

2. All non-conforming materials identified for return or disposition need to be moved within the electronic system to the warehouse location “Returns” (for returns) or “Reject” (for rejections) at the time they are physically moved to the Returns/Rejections racks. Upon physical return-to-vendor or disposition, a stock transaction for non-conforming materials needs to be entered in the system to remove that inventory from Pure Nutra Labs’s books. The RMR form should be scanned, the file attached to the non-conforming material’s product/lot records, and only then shall the RMR form be disposed.

a) **NOTE:** Non-Conforming Materials are not to be removed from the designated area without Quality approval.

3. Inventory management systems for non-conforming product shall be challenged at least twice annually. This is done during the internal audits.

C. Disposition

1. Disposition of non-conforming materials will be handled through a Purchasing Department designee, the supplier for the item, and Quality Management.

2. A trained member of the Quality Department will notify the Purchasing Department of the suspected non-conformance. A Purchasing Department designee will contact the supplier for item disposition. Pure Nutra Labs Customer Service will be notified if the item is customer-supplied.



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3. Acceptable – Material is found to be acceptable for use and not non-conforming.

a) For example, a Production employee may place a material in the Non-Conforming Material Area, and upon inspection or investigation, the material may be acceptable and usable.

b) If materials are Acceptable, remove from Quality Hold and apply a BLUE Approved label.

4. Confirmed Non-Conforming – Material is deemed unsuitable for use, or expired. A trained member of the Quality Department will assign a Rejected Material number (RMR #) to track the destruction and/or disposal of the material.

a) The material must be identified with a Non-Conforming Tag, complete with the following information:

(1) Item Number, Item Name, Receiving Control Number, Description of Non-Conformance, By/Date.

b) Packaging materials are to be moved to the designated Non-Conforming Material Storage Area by specific production shift that placed the Non-Conforming Material Tag on the material. Non-Conforming raw materials and bulk solutions are to be stored in a designated Quarantine Area in the warehouse with proper identification until further investigation is complete, and final return/disposal.

5. On a regular basis, a reconciliation (verification of accuracy of inventory) and evaluation of all product on hold will occur.

D. Assignment of RMR #



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1. When items are placed in the designated Non-Conforming areas, Quality Management is to be alerted. A trained member of the Quality Department will log the Non-Conforming Material on the Non-Conforming/Rejected Material Log.

2. Each item will be assigned an RMR # for tracking as follows:

- a) The code is preceded by RMR.
- b) The first two digits indicate the last two digits of the current year. (e.g. 08 = 2008, 18 = 2018, etc.)
- c) A letter indicates the month of the non-conformance. (e.g. A = January, B = February, etc.)
- d) The third and fourth digits indicate the consecutive order of the non-conformance for the month.

3. The Non-Conforming/Rejected Material (RMR) Log contains the following information:

- a) Initiated By (The personnel that assigned the RMR)
- b) Date Initiated
- c) RMR # (Next consecutive in RMR Log)
- d) Item # / Finished Product #
- e) Lot #
- f) Supplier / Manufacturer
- g) Item Name
- h) Quantity Received / Produced
- i) Quantity Rejected
- j) Reason for Non-Conformance
- k) Date Purchasing / Customer Service Notified
- l) Date Destroyed / Disposed
- m) Comments (If Applicable)

E. Rejection of Non-Conforming Materials



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1. The Rejected Material Report (RMR) is used for all non-conforming materials that are rejected. The following information is recorded on the RMR:

- a) The assigned (next consecutive number in the RMR Log) RMR #
- b) Initiated By and Date
- c) CAPA # (If Applicable)
- d) Item Name
- e) Item # / Finished Product #
- f) Lot #
- g) Reason for Non-Conformance
- h) Quantity Received or Produced
- i) Quantity Rejected

(1) If Quantity Received / Produced does not equal Quantity Rejected, record amount discrepancy and the justification.

- j) Does supplier have additional quantity of lot in current inventory?
- k) Is material customer-supplied?
- l) Label each container/pallet of rejected material with a RED Rejected label.
- m) Quality associate rejecting the material shall sign and date.
- n) Trained personnel updating material status shall sign and date.
- o) Rejected material must be moved to the Rejected Material Area. Trained personnel who moves the material shall sign and date.
- p) Quality will give direction on how to dispose of rejected material.
- q) Financing and Purchasing associates who review the rejected material disposal shall sign and date.



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r) A trained member of Customer Service and Quality must review, sign, and date the completed RMR form.

F. Returned Material Authorization

1. Products cannot be authorized for return unless a Returned Materials Authorization (RMA) number is issued by trained Pure Nutra Labs personnel.

a) An RMA number may be issued for customer product and material return or management requested product returns.

2. The next consecutive RMA number is assigned using the RMA log.

3. Requestors returning product will be instructed to indicate the RMA number legibly on the box/pallet and how to properly package the return for shipping.

4. The following information shall be recorded in the RMA log:

- a) Date of issuance
- b) Name of requestor or shipping party
- c) Tracking number
- d) RMA number issued
- e) Product type for return and supporting details
- f) Reason for return

5. When the product return arrives, the product will be staged in a designated receiving area.



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6. Returned goods shall be inspected for product content, condition, and conformity according to the receiving SOP. The return shall be documented in the RMA log and, if acceptable, entered into the system.

G. During the Raw Material Trace Exercise, follow the procedure for Mock Recalls.

1. Limiting the damage and restoring customer confidence after a recall:

a) The Quality Director is responsible for conducting the product recall.

(1) To ensure all suspect product from the Product Recall Team brief is removed from the marketplace.

(2) To issue instructions how this should be carried out. In the case of a recall, product should be brought back, quarantined for a proper disposal and completion of an effectiveness check.

(3) To ensure a similar product, i.e. from the same job number, is held separate from production stock in a quarantine area, checked and only sold when the Product Recall Team has given a decision.

(4) Re-starting Production - No production of the product-at-risk should be made until authority is given by the Product Recall Team.

(5) After any recall, an investigation of like or similar issues are completed to see if any similar issues have occurred.

2. Deliberate or Malicious Contamination



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a) The product at risk may have been caused by deliberate contamination. This information may come from the initial communication, e.g. Outside telephone call, letter. A special course of action may be necessary as the problem will become a police matter and the Crisis Management Procedure should be followed.

b) In the event of a member of staff receiving communication of the above, this information must be passed to the Plant Manager immediately. Do not discuss the matter with colleagues. Should the Plant Manager be absent, then the CEO should be contacted.

H. Records

1. Records shall be maintained for one (1) year beyond the shelf life of the product, or two (2) years beyond the date of distribution of last nonconforming batch, whichever is greater; records of the handling; corrective action; and disposition of nonconforming product or equipment.

Document History

Revision #	Review Date	Description of Change	Reviewer Name
1	03/21/2025	New procedure.	Chad Hinson, Quality Director
2	09/06/2025	Updated company name.	Chad Hinson, Quality Director



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Approvals:

Chad Hinson

Chad Hinson (Sep 7, 2025 17:24:22 EDT)

Title: CTO

Sam Holguin

Sam Holguin (Sep 7, 2025 12:52:18 EDT)

Title: CEO

J

Josh Blankenship (Sep 7, 2025 20:00:50 EDT)

Title: COO



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Rejected Material Report (RMR)

RMR #:		Initiated By:	
CAPA #: (If Applicable)		Initiation Date:	
Item Name:		Item #/Finished Product #:	
Lot #:		Additional Identifying Information:	
Reason for Non-Conformance:			
QTY Received / Produced:		QTY Rejected:	
Discrepancy in QTY?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, justification:		
If entire lot is contaminated or does not meet requirements, does supplier still have any of lot in current inventory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Customer Supplied?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, customer notified on date:		
<u>Label EACH container / pallet of rejected item with a RED Rejected Label</u>			
Rejected By (Quality):		Date:	
Updated Status in Datacor By:		Date:	
Physically Moved Material to Rejected Material Area By:		Date:	



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DISPOSAL OF REJECTED MATERIAL

Return to Supplier Destroy Hold Waste Disposal

Method of Destruction: Internal External N/A

Standard Cost of Material: _____

Signature (Purchasing):		Date:	
Signature (Finance):		Date:	

Reviewed By:

Customer Service

Date

Quality

Date











SOP-0032r2 Recall Control of Nonconforming Product


Final Audit Report

2025-09-08

Created:	2025-09-06
By:	Kayla Faust (kayla@ajhhconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA4qBP95_FBz_H8rIPQ8ypdylyg2cU_WEn

"SOP-0032r2 Recall Control of Nonconforming Product" History

-  Document created by Kayla Faust (kayla@ajhhconsulting.com)
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-  Document emailed to chad@purenutrallabs.co for signature
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-  Document emailed to josh@purenutrallabs.co for signature
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-  Email viewed by sam@purenutrallabs.co
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-  Signer sam@purenutrallabs.co entered name at signing as Sam Holguin
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-  Email viewed by chad@purenutrallabs.co
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-  Signer chad@purenutrallabs.co entered name at signing as Chad Hinson
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 Signer josh@purenutrallabs.co entered name at signing as Josh Blankenship

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 Document e-signed by Josh Blankenship (josh@purenutrallabs.co)

Signature Date: 2025-09-08 - 0:00:50 AM GMT - Time Source: server

 Agreement completed.

2025-09-08 - 0:00:50 AM GMT