

	Standard Operating Procedure	SOP Number D-305	Revision 3
	Reclassifying Raw Materials	Effective Date 11/18/22	Page Page 1 of 6
Written by/ Date KBurns 10/21/22	Reviewed by/ Date  10/21/22	Approved by/ Date  10/26/22	
Title: Quality Assurance Director	Title: Senior Financial Analyst	Title: Quality Control Director	

1.0 Purpose

This procedure defines guidelines for reclassify or transfer raw materials based on a strength metric or extraction ratio. This procedure also defines guidelines for transferring raw materials between raw materials IDs between vendors specific and/or classes of raw materials to include dietary supplements, companion animal, cosmetics and OTC.

2.0 Scope

This procedure applies to all raw materials for use in dietary, companion animal, cosmetic and OTC products at Ion Labs. This reclassification does not apply to expired raw materials that fail the CofA challenge for recertification.

3.0 Responsibility

- 3.1 It is the responsibility of the department whom is requesting the transfer to fill out form D-305-F1 Raw Material Identification Change Request, as well as to provide supplemental support documentation.
- 3.2 It is the responsibility of QC Chemists to test raw materials, confirm test results, and complete new laboratory testing records for the new RMID.
- 3.3 It is the responsibility of QC Laboratory Management and R&D to determine if a raw material qualifies to be used under a different raw material ID.
- 3.4 It is the responsibility of Purchasing to determine if the raw material to be transferred is available for use under the new RMID.
- 3.5 It is the responsibility of the Warehouse to relabel any raw material containers with the

transfer ID and transfer material in SAP.

- 3.6 It is the responsibility of Finance to reconcile cost in financials and approve the transfer of material to a different RMID.

4.0 Definitions

- 4.1 **QC** – Quality Control
- 4.2 **OOS** – Out of Specification
- 4.3 **R&D** – Research and Development
- 4.4 **ID** – Identification
- 4.5 **RMID** – Raw Material Identification
- 4.6 **RMP** – Raw Material Profile
- 4.7 **RMTS** – Raw Material Testing Summary
- 4.8 **OTC** – Over the Counter

5.0 References

- 5.1 D-305-F1, Form, Raw Material Identification Change Request
- 5.2 C-502, SOP, Record Storage, Retention, and Destruction

6.0 Procedure

- 6.1 Requesting transfer of a raw material to a different RMID:
- 6.1.1 The process is initiated when a department initiates a request using Form D-305-F1 Raw Material Identification Change Request

6.1.2 The following information will be documented on form D-305-F1 Raw Material Identification Change Request, along with required supplemental support documentation attached and routed for approval:

6.1.2.1 Requesting Department

6.1.2.2 Initiator - Name

6.1.2.3 Type of Change including Class Change

6.1.2.4 Vendor specific change

6.1.2.4.1 A generic RMID to a customer specific RMID requires documentation that the supplier is approved for use by the customer.

6.1.2.5 Class Change

6.1.2.5.1 The CofA for the specific R# to be transferred is required.

6.1.2.6 Raw Material # (R#)

6.1.2.6.1 CofAs must have R# documented.

6.1.2.7 Current RMID

6.1.2.8 Current Name - Designated by Ion Labs

6.1.2.9 Quantity Available

6.1.2.10 Proposed RMID

6.1.2.10.1 If a proposed RMID is of a higher class or Customer specific, RMID CofA will be required for approval.

6.1.2.11 RMID Material Name - Designated by Ion Labs

6.1.2.12 Quantity Needed

6.1.2.13 Signature and Date

6.1.3 Form D-305-F1 Raw Material Identification Change Request requires approval from:

6.1.3.1 Purchasing – to ensure that the material is available for transfer and is not promised to a different batch.

6.1.3.2 R&D – to determine if material has chemical properties to meet label claim requirements as well as the appropriate physical properties to meet production requirements of the formulas impacted.

6.1.3.3 QC Laboratory – to determine required testing for change, if applicable.

6.1.3.4 Finance – to confirm that the material is suitable for transfer from a cost perspective and to reconcile cost in financials

6.1.4 Once form D-305-F1 Raw Material Identification Change Request is fully approved, the request is delivered to the QC Laboratory for processing.

6.2 Requirements for Reclassifying a Raw Material without a class change:

6.2.1 A botanical raw material with a standardized strength metric or extract ratio can be reclassified to a different RMID when the strength requirements of the initial RMID are superior to the reclassified RMID.

6.2.1.1 A completed RMTS under the new RMID will be required to re-release the raw material.

6.2.1.2 If transferring into a Customer Specific RMID, the material must come from one of the customer's pre-approved vendors. Documentation of this approval is required to proceed with the transfer.

- 6.2.1.3 If all metrics were previously tested through CofA challenge process, then the data can be transposed from the original RMTS to the new RMTS for release.
- 6.2.1.4 Any metrics on the original RMTS that are reported from the CofA or tests on the new RMTS that have not been tested during the original raw material challenge must be challenged before re-releasing under a new RMID.
- 6.2.1.5 If the material passes the CofA specifications of the new RMID but unchallenged physical properties are different between the two RMIDs then the material cannot be transferred.

Examples: Encapsulation matrices differ

Different carriers

Chelates

Proprietary blend raw materials

- 6.2.1.6 If the tested strength can potentially lead to exceeding the safety thresholds for that analyte in a formula using the material under the transitioned RMID then the material cannot be reclassified for that RMID.
- 6.2.1.7 For mineral strength claims, the strength cannot exceed 25% of the raw material specification and must meet all safety limits.
- 6.2.1.8 For extract ratios, strength cannot exceed 2X strength claim of the transitioned RMID. Example: 8:1 → 4:1 (yes), 8:1 → 2:1 (no). This limitation does not apply when a higher extract raw material is reduced to a lower extract ratio using acceptable carrier and/or excipients in the adjustment.

- 6.2.2 A raw material that has undergone a CofA challenge and one or more strength metrics are below the minimum specifications for the RMID, the raw material

can be released under another RMID without an OOS investigation when each CofA test for the challenged raw material passes when compared against the specifications of the alternate RMID.

6.3 Requirements for Reclassifying a Raw Material with a class change:

6.3.1 All requirements under 6.2 must also be met for dietary and companion animal raw materials. Cosmetic and OTC cannot substitute alternate strength raw materials.

6.3.2 All released OTC raw materials can be transferred to another class RMID.

6.3.3 All dietary supplement raw materials can be transferred to companion animal and cosmetic RMIDs.

6.3.4 All other types of raw material class transfers require an evaluation of additional testing required before approval.

6.4 Documentation

6.4.1 For traceability, the RMID transition needs to be documented in the comments section of the new RMTS and the completed transfer form must be attached to the new RMTS. The transfer form and new RMTS packet will be filed as one packet and retained following SOP C-502 Document Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/14/16	New	16-0596	B. Johns
1	03/02/18	Added additional instructions to clarify process.	18-0077	L. Titolo
2	06/04/21	Triennial review. Updated to reflect current process.	CC-21-0215	J. Sassman
3	10/21/22	Updated procedure to include Financial approval of change. Revised throughout to reflect current processes.	CC-22-0416	K. Burris

**Raw Material Identification Change Request**

Form: D-305-F1

CCR No. CC-22-0416

Revision: 4

Current Material Information to be Transferred

R#		RM ID#	
Material Name			
Vendor/Manufacturer		Lot #	
Receipt Date		Expiration Date	
Current Classification:		Quantity Remaining (kg)	
Vendor Specific Material:	<input type="checkbox"/> Yes <input type="checkbox"/> No	<i>Generic to Customer specific (RMP needed)</i>	
CofA Attached	<input type="checkbox"/> Yes <input type="checkbox"/> No	<i>Further testing may not be required if transfer is: Dietary to Companion Animal or OTC to Dietary</i>	

Transfer to Change Request Information

New RMID#		Vendor approved for use with new RMID (provide documentation)	<input type="checkbox"/> Yes <input type="checkbox"/> No
New Classification:		Quantity to Transfer (kg)	
Requested Completion Date:		Requested By/Date	
Comments:			

Transfer Request Approvals

Purchasing Approved By:		Date:	
R&D Approved By:		Date:	
Finance Approved By:		Date:	

QC Lab:

Additional Testing Required	<input type="checkbox"/> Yes <input type="checkbox"/> No	Additional Testing Completed/Approved By/Date:	
QC Lab Approved By/Date:			

Material Disposition:

Containers Relabeled By/Date:	
Inventory Adjusted By/Date:	
QC Lab Records Updated By/Date:	