	<b>Standard Operating Procedure</b>		<b>SOP Number</b> B-108	<b>Revision</b> 7
	<b>Reprocessing Procedure</b>		<b>Effective Date</b> 01/28/22	<b>Page</b> Page 1 of 5
<b>Written by/ Date</b> K. Bunnings 12/14/21		<b>Reviewed by/ Date</b> Pam Run 12/27/21		<b>Approved by/ Date</b> S. A. Miller 01/04/22
<b>Title: Quality Systems Manager</b>		<b>Title: Production Director</b>		<b>Title: QA Manager</b>

## 1.0 Purpose

This procedure details the steps to be followed when reprocessing of an in-process batch or finished product is required.

## 2.0 Scope

This procedure applies to all products manufactured at Ion Labs, Inc. that require reprocessing to make compliant to predetermined specifications. This procedure does not apply to in-process line rework that occurs during normal manufacturing and packaging operations due to equipment adjustments (i.e. crooked labels from labeler drift, induction seal defects due to heat tunnel adjustment), as long as this rework is completed prior to the batch finishing normal production activities on the line that the defect occurred.

## 3.0 Responsibility

3.1 Production is responsible for:

- 3.1.1 Determining if reprocessing is required to produce a finished good that meets its predetermined specifications.
- 3.1.2 Initiating a deviation when predetermined specifications are not met and documenting the investigation on the deviation/investigation form.
- 3.1.3 Ensuring adequate training is documented and submitted to Quality prior to reprocessing.
- 3.1.4 Generating and reviewing reprocessing protocols and final reports.
- 3.1.5 Performing reprocessing manufacturing activities and executing approved protocols.

3.2 Quality is responsible for:

- 3.2.1 Determining if reprocessing can be applied and documenting the investigation and determination on the deviation/investigation form.

Standard Operating Procedure <b>Reprocessing Procedure</b>	<b>SOP No B-108</b>	<b>Rev 7</b>	<b>Page 2 of 5</b>
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3.2.2 Generating, reviewing, and approving reprocessing protocols and final reports.

3.2.3 Ensuring adequate training is verified prior to reprocessing (as needed).

3.3 Document Control is responsible for:

3.3.1 Issuing and maintaining official copies of protocols and final reports.

3.4 Research and Development is responsible for:

3.4.1 Determining if reprocessing can be applied and documenting the investigation and determination on the deviation/investigation form.

3.4.2 Generating and reviewing reprocessing protocols and final reports.

#### **4.0 Definitions**

4.1 **BPR** – Batch Production Record

4.2 **Reprocessing** – Using in the manufacture of a product, clean, uncontaminated components or products that have previously been removed from manufacturing and that have been made suitable for use in the manufacture of a product

4.3 **QC** – Quality Control

4.4 **DC** – Document Control

#### **5.0 References**

5.1 C-201, SOP, Deviation and Investigation Procedure

5.2 C-105, SOP, Protocol and Report Document Requirements

5.3 E-802, SOP, Quarantine of Materials/Products

#### **6.0 Procedure**

6.1 When a batch/material does not meet its predetermined specifications, the production operator will inform the department supervisor or designee that a deviation needs to be initiated in accordance with SOP C-201 Deviation and Investigation Procedure. A Hold Pending Disposition tag will be placed on the batch/material by a QC inspector until disposition is decided. The deviation will include an investigation to determine if reprocessing can be applied to rectify the situation and will clearly indicate the decision.

<b>Standard Operating Procedure Reprocessing Procedure</b>	<b>SOP No B-108</b>	<b>Rev 7</b>	<b>Page 3 of 5</b>
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- 6.2 When the results of the deviation indicate that reprocessing will be used to rectify the situation, the responsible person will request a protocol number, as specified in SOP C-105 Protocol and Report Document Requirements, and obtain an electronic copy of the protocol template.
- 6.3 All sections of the protocol will be written in accordance with the currently effective electronic template obtained from DC. The sections and details included in the protocol should include, but not be limited to, the following:
- 6.3.1 Introduction: The introduction will include information about why the protocol is being initiated. This will include, but not be limited to, the deviation number or event that triggered the need for reprocessing.
  - 6.3.2 Scope: The scope defines the specific products, batches, or materials to be reprocessed. Time frames or other limitations of the protocol are also explained.
  - 6.3.3 Purpose: The purpose of the protocol will state the reason why reprocessing is necessary, specific to the situation, and that additional action is needed to bring the material into compliance. It will state the specification limits and the initially observed results.
  - 6.3.4 Rationale: The rationale presents the scientific reasoning behind the approach of bringing the product, batches, or materials, back within specifications. It will also include a description of the step-by-step process which will be used to bring the material within specification.
  - 6.3.5 Procedure: The procedure details the step-by-step process to be followed in order to execute the protocol. The batch records or additional information needed to complete the manufacturing process is described and/or created within this section or as an attachment to the protocol. In-process inspection frequency may be increased during protocol execution. Quality will determine adequate inspection levels based on size of material/product batch.
  - 6.3.6 Acceptance Criteria: The acceptance criteria states what conditions must be kept in order to release the product.
  - 6.3.7 List of Attachments: The list of attachments will include a list of any attachment that is created as part of the protocol (e.g. forms where the reprocessing/rework steps are to be documented).
  - 6.3.8 Protocol Conclusion: The protocol conclusion will describe if a final report will be generated once the protocol has been executed and any deviations and their

<b>Standard Operating Procedure Reprocessing Procedure</b>	<b>SOP No B-108</b>	<b>Rev 7</b>	<b>Page 4 of 5</b>
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investigations have been completed. This section will also detail how the executed protocol/final report will be routed for approval.

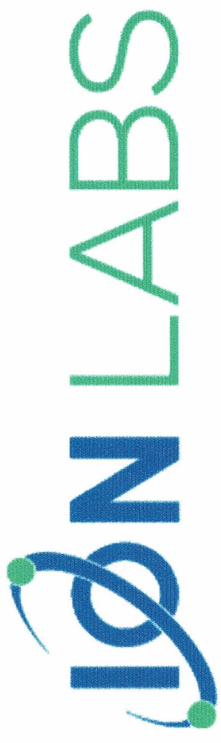
- 6.4 The reprocessing protocol will be submitted to quality for review/approval.
- 6.5 Once approved, the original signed copy of the reprocessing protocol will be submitted to DC to be maintained as per SOP C-105 Protocol and Report Document Requirements.
- 6.6 DC will provide an official copy of the protocol to production for execution that will be maintained with the executed BPR.
- 6.7 When the approved protocol is provided, production will execute the protocol by performing the steps in the procedure section of the protocol. All required information will be documented as indicated on the copy of the protocol provided for execution.
- 6.8 When the protocol execution is complete, the BPR and executed copy of the protocol will be provided to the initiator for report generation if required.
- 6.9 The initiator will generate a final report summarizing the results as described in the conclusion section of the protocol. The executed copy of the reprocessing protocol and/or the final report will be submitted to Quality for review and approval.
- 6.10 Once the protocol and/or final report have been approved, the deviation will be finalized with the results, the original protocol will be retrieved from DC, and all protocol documents will be filed with the associated BPR.

## **7.0 Reprocessed Pallet Identification**

- 7.1 Prior to batch/material being reprocessed, an identification of disposition must be clearly marked on the pallet/case/material/batch, by placing a Reprocessing In-Process tag on the pallet/case/material/batch.
- 7.2 QC will ensure that all products that are to be reprocessed are properly segregated and will place the Rework In-Process tag on each pallet.
- 7.3 The product to be reprocessed will be held in the designated quarantine area until ready for reprocessing.
- 7.4 Follow the reprocessing protocol and deviation put in place for the batch/material being reprocessed.

## 8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/21/10	New	-	-
1	11/07/12	Combined SOP B-108 & B-907 to be in compliance with Regulatory expectations and to provide clarity, changed SOP title and format	-	-
2	02/27/13	Removed "NOE" for all sections, added "deviation"	-	-
3	05/24/13	Removed section 4.1.3, 4.3.1 & 5.2, removed the form B-108-F1	13-403	V. Iltcheva
4	09/09/15	Biennial review: updated SOP format.	15-0568	V. Iltcheva
5	03/01/17	Add documentation and verification of training prior to work	17-0215	D. Popp
6	03/12/18	Add requirements for proper pallet identification.	18-0088	K. Burris
7	12/14/21	Scheduled review: Update SOP title, scope, and definitions. Remove/replace the word rework throughout. Update number and title of protocol procedure. Corrected reprocessing signage.	CC-21-0463	K. Burris

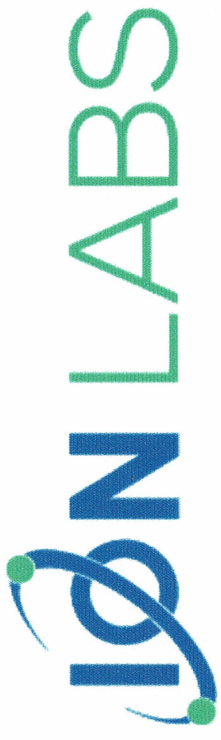


# HOLD PENDING DISPOSITION

**BATCH:** \_\_\_\_\_

**PALLET:** \_\_\_\_\_ **OF** \_\_\_\_\_

**QC BY:** \_\_\_\_\_ **DATE:** \_\_\_\_\_



# REPROCESSING IN-PROCESS

**BATCH:** \_\_\_\_\_

**PALLET:** \_\_\_\_\_ **OF** \_\_\_\_\_

**INITIALS:** \_\_\_\_\_ **DATE:** \_\_\_\_\_