

	<b>Standard Operating Procedure</b>		<b>SOP Number</b> B-313	<b>Revision</b> 2
	<b>IMB Ribbon Blenders</b>		<b>Effective Date</b> 06-23-20	<b>Page</b> Page 1 of 4
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## 1.0 Purpose

This procedure defines the process for setup, operation, and cleaning of the IMB Ribbon Blenders.

## 2.0 Scope

This procedure applies to the IMB Ribbon Blenders in operation at ION Labs.

## 3.0 Responsibility

- 3.1 It is the responsibility of a production (blending) personnel to follow this procedure.
- 3.2 It is the responsibility of the department supervisor/manager to implement this procedure and to ensure that this procedure is being followed.
- 3.3 It is the responsibility of all operators to immediately report any equipment which is malfunctioning or not working to the department supervisor.
- 3.4 It is the responsibility of all department Supervisors to immediately report any equipment malfunctioning, not working, or any safety concern to the EHS Manager, Maintenance and the Facilities Manager for an operational disposition.
- 3.5 It is the responsibility of the supervisor to create a work order which will clearly and specifically document the level of priority for the repair. The supervisor will ensure a system generated Work Order has been successfully entered by obtaining a copy of the work order with a computer generated number..
- 3.6 It is the responsibility of the Maintenance Manager and/or the Facility Manager to ensure all work orders are processed quickly and accurately.
- 3.7 It is the responsibility of the Maintenance Manager and/or the Facility Manager to immediately and completely repair and render safe all reported equipment malfunctions.
- 3.8 The Maintenance Manager and/or Facility Manager must communicate the status of all high priority repairs to all affected department Heads.

## 4.0 Definitions

- 4.1 QC = Quality Control

## 5.0 References

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- 5.1 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment.
- 5.2 SOP G-104 Lockout Tag out Procedure.
- 5.3 SOP G-105 Lockout Tag out Devices
- 5.4 SOP G-107 Confined Space Entry Program

## 6.0 Procedure

- 6.1 Start up
  - 6.1.1 Verify the Ribbon Blender operation by running the blender for 30sec, listening for sounds that are outside the normal functions.
  - 6.1.2 Check the switches in the electrical panel.
  - 6.1.3 Check the latches on the Ribbon Blender.
  - 6.1.4 Verify that the de-duster is powered on and working properly.
  - 6.1.5 Verify that the proper clean has been performed and signed off in the cleaning log.
  - 6.1.6 Check the accuracy of the floor scale and record information in batch record.
  - 6.1.7 Verify that the appropriate amount of materials has been weighed and pre-staged to blend the current batch.
- 6.2 Loading the Ribbon Blender
  - 6.2.1 Verify that the main lid is closed. If the lid to the Ribbon Blender is open call maintenance in order to close the lid.
  - 6.2.2 Load the blender following steps listed in the batch record.
  - 6.2.3 Place the pallet with raw materials to the loading platform using the elevator.
  - 6.2.4 In the event the elevator is inoperable for **any** reason, this must be reported immediately and DO NOT use the elevator until it has been fully repaired..
    - 6.2.4.1 A forklift may be used to lift the raw materials to the platform level for loading into the blender. Level the raw materials on the pallet as to not hit the ceiling.
  - Note:** All members of the blending department and QC personnel will be required to wear a safety harness during cleaning and verifying blender cleanliness.
  - 6.2.5 Carefully climb the stairs to reach the loading platform.

**Note:** All employees who are on the loading platform must be trained how to correctly attach the safety harness and how to properly attach safety harness to the “D” Rings.

6.2.6 Open the loading hatch.

6.2.7 Load material according to the batch record.

6.2.8 If another pallet is needed to load raw material repeat steps 6.2.1- 6.2.3. until Ribbon Blender is completely loaded.

6.3 Discharge of the blend

6.3.1 Place prepared drums or super sacks underneath the chute for material drop.

6.3.2 Three operators are needed to drop material from the Ribbon Blender.

6.3.3 One operator is responsible for the switch that operates the chute’s open and close switch.

6.3.4 Two operators are responsible for moving drums or super sacks into and out of position in order to start the process of dropping materials.

**Note:** Under **NO** circumstance should the operators need to reach into the chute or use anything to reach into the Ribbon Blender’s chute. Reaching into the chute can lead to serious personal injury.

6.3.5 Repeat filling the drums or super sacks until blender is emptied.

6.3.6 Weigh material according to the batch record requirements.

6.3.7 Return all unused product to the warehouse.

6.3.8 Once all drums are weighed and properly tagged, begin the appropriate clean.

## 7.0 Cleaning

7.1 Remove all product and paperwork from the previous batch.

7.2 Verify that the blender’s power supply has been locked out at the disconnect per SOP G104 and G-105.

7.3 Attach safety harness. All members of the blending department and QC personnel will be required to wear a safety harness when cleaning/verifying the cleaning of Ribbon Blender.

7.4 Blending rooms identified to have a confined space hazards will be designated and follow all of the guidelines prescribed in SOP G-107 Confined Space Entry Program.

- 7.4.1 All entrants working in Confined Space Entry “permit required” conditions must be trained and certified.
- 7.5 Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning procedure applicable to this type of equipment.
- 7.6 When cleaning the ground floor of the elevators the Supervisor only must take these steps to render the elevator safe:
  - 7.6.1 The Supervisor must raise the elevator to the top floor and engage the E-stop button rendering it locked in place.
  - 7.6.2 The Supervisor must isolate and render the disconnect inoperable by dropping the handle to off and Lockout the disconnect.
  - 7.6.3 The Supervisor must then manually release the door magnet allowing door to open and the ground floor to be cleaned.
  - 7.6.4 When the cleaning complete and quality has signed off, the Supervisor must ensure the elevator is completely clear, close the door engaging the magnet, activate the Start button, remove the lock from the power source, and raise the handle re-energizing the equipment.
- 7.7 Only after all of these steps are taken by the Supervisor, may operators continue to use the elevators in any room.
- 7.8 Document cleaning in the cleaning logbook.
- 7.9 Contact a QC inspector to verify equipment cleanliness and to check the cleaning logbook.

## 8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/13/16	New	16-0928	P. Perry
1	01/28/19	Remove reference to 200R. Revise section 7.0. Remove unneeded references.	19-0101	K. Burris
2	05/19/20	Safety guidelines added for inoperable elevator. LOTO Policy added	CC-20-0360	K. Patton