

	Standard Operating Procedure		SOP Number B-103	Revision 8
	Small Parts Cleaning and General Sanitation		Effective Date 11/29/21	Page Page 1 of 5
Written by/ Date Wayne Ashall 10-29-21		Reviewed by/ Date [Signature] 10/29/2021		Approved by/ Date [Signature] 10/29/21
Title: Facilities Manager		Title: Facilities & Maintenance Director		Title: QA Manager

1.0 Purpose

The purpose of this procedure is to define the processes for general cleaning and sanitation of manufacturing equipment.

2.0 Scope

This procedure applies to all small equipment parts, buckets, drums and ancillary equipment used at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all production and facility personnel assigned to cleaning parts and equipment to follow this procedure and to fill out associated log books when and where required.
- 3.2 It is the responsibility of the Facility Manager to train applicable employees on this procedure. The Facility Manager will also implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of QC inspectors to ensure that small parts associated with a Major clean are properly cleaned and documented as required.

4.0 Definitions

- 4.1 **Approved Chemical List** – a list that has been approved by Quality Management containing current approved cleaning and sanitizing chemicals established for cleaning the facility
- 4.2 **Detergent** – Chemical used to remove residual buildup from surfaces
- 4.3 **Degreaser** – Chemical used to remove protein buildup from surfaces.
- 4.4 **Sanitizer** – Chemical used as a final kill step for bacteria or viruses on surfaces.
- 4.5 **Potable Water** – Clean water that is free of chemicals and food safe.

- 4.6 **PPE** – Personal Protection Equipment.
- 4.7 **SDS** – Safety Data Sheets
- 4.8 **UOM** – unit of measure
- 4.9 **Non-Product Contact** – equipment or parts that do not contact product
- 4.10 **Product Contact** – equipment or parts that contact product

5.0 References

- 5.1.1 Ion Labs Approved Chemicals List

6.0 Procedure for Small Parts Cleaning

6.1 General Practices

- 6.1.1 SDS books for all cleaning chemicals are located outside of production. SDS books are maintained by Operations Department.
- 6.1.2 Always follow manufacturer’s label instructions for handling, storage, and mixing of chemicals.
- 6.1.3 Always wear designated PPE when handling or using chemicals.

6.2 Cleaning of Small Parts from Production

- 6.2.1 Fill sinks with 10 gallons clean potable water, making sure to flush all lines for 30 seconds before closing off sinks.
- 6.2.2 Add the approved amount of cleaning chemical to the sink for cleaning per the “Approved Chemical List.”
- 6.2.3 Rinse excess residue from parts.
- 6.2.4 Submerge parts into soapy water for cleaning. Scrub parts using a nylon bristle brush or cleaning rag.
- 6.2.5 Let parts soak if needed to break down heavy residue.
- 6.2.6 After cleaning, rinse parts with clean potable water to remove any soap and residue.
- 6.2.7 Place cleaned part on a clean equipment cart.

- 6.2.8 When all parts have been cleaned, use compressed air to remove excess water or use a clean rag to dry surfaces.
 - 6.2.9 Apply sanitizer to all surfaces and allow to air dry or wipe with a lint-free rag before reassembly.
 - 6.2.10 Check sink for any small parts before returning equipment.
 - 6.2.11 Empty and drain sinks after each use.
 - 6.2.12 Rinse and wipe down sinks so they are clean and ready for use by the next operator.
 - 6.2.13 Small parts should be immediately returned to the product room for inspection.
 - 6.2.14 Any parts that are not immediately returned to their production room must be covered to prevent contamination.
 - 6.2.15 Any parts or equipment that needs to be stored will be brought to equipment storage area. The equipment must be covered to allow moisture to escape but prevent outside contamination.
 - 6.2.16 Make note of cleaning in the equipment cleaning log.
- 6.3 Cleaning Procedure for Buckets and Drums
- 6.3.1 Remove and discard liners prior to cleaning.
 - 6.3.2 Scrub inside and outside of drums and buckets with the approved cleaning agent per the “Approved Chemicals List”. Use a nylon bristle brush or a green scrubbing pad (for buckets/drums) to remove any residue or buildup if needed.
 - 6.3.3 Rinse all surfaces thoroughly with clean potable water. Allow drums and buckets to air dry or use compressed air to remove excess water.
 - 6.3.4 Stack drums and buckets so that they are not nested and can dry completely.
 - 6.3.5 When dry, drums and buckets will be stacked and stored on a clean plastic pallet. The cleaned drums or buckets will be wrapped, tagged with the cleaned-on date and stored away from or above product or raw materials.
- 6.4 Cleaning of Plastic Pallets
- 6.4.1 Clean plastic pallets in the mop sink area. Clean one pallet at a time.

- 6.4.2 Stand pallet up on one side.
- 6.4.3 Use pump sprayer filled with the approved cleaning agent from the “Approved Chemicals List” to soak all visible surfaces of the pallet and turn pallet as needed to ensure all surfaces are cleaned.
- 6.4.4 Let cleaner stand as needed to allow detergent to breakdown residue and then scrub pallet surfaces as required using nylon brush or scrub pad to remove dirt and debris. Note: A pressure washer may be used to remove stubborn stains.
- 6.4.5 Rinse all surfaces of pallet with clean potable water, turning pallet as needed to ensure all areas are rinsed of excess soap and residue.
- 6.4.6 Move cleaned pallet to clean equipment drying area. Spray surface with sanitizer and allow to air dry.
- 6.5 Cleaning of linens (Note: Linens used for cleaning only, not for sanitizing.)
 - 6.5.1 Keep soiled linens separate from clean linens. Soiled linens should be stored in containers marked “DIRTY”.
 - 6.5.2 Transport soiled linens to be cleaned on sight to the Sanitation Cleaning Area.
 - 6.5.3 Follow manufacturer’s instructions for proper use of washing machine.
 - 6.5.3.1 Place soiled linens in the washing machine and add a fragrance/dye free laundry detergent from the “Approved Chemicals List” to the load using the detergent manufacturer’s recommended amount—see label on container.
 - 6.5.3.2 Turn washing machine setting to “Normal” cycle. Turn water temperature to “Hot” and start the washing cycle.
 - 6.5.3.3 Dry all linens completely using electric dryer.
 - 6.5.3.4 Remove linens and store in a clean container marked “CLEAN”.
 - 6.5.3.5 After each cycle, wipe down outside of washer and dryer with sanitizer.
 - 6.5.3.6 Empty lint catcher after each use of the dryer.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/15/10	New	-	-
1	08/22/13	Updated SOP format.	13-283	M. Wienke
2	02/14/14	Added specific mixing instructions for cleaning agents. Updated entire SOP. Changed SOP title.	14-0131	M. Wienke
3	09/10/14	Added notes for chemical labeling and storage/use of chemicals. Added reference to approved chemical list.	14-0734	D. Popp
4	12/11/14	Added note to run water outlet for thirty seconds prior to use.	14-1003	S. Kovalik
5	12/01/15	Revised to reflect current process.	15-1075	D. Popp
6	06/01/16	Added new information in the Notes section of 6.0. Removed blending from section 6.4. Added sanitation supervisor responsibilities.	16-0554	V. Zelaya
7	11/20/17	Complete rewrite. Split procedure (new SOP B-105).	17-1245	K. Tyrell
8	10/28/21	Scheduled review: update to reflect current cleaning chemicals and associated cleaning procedures. Add the use of Enzyfoam and the portable foaming unit. Update the chemical mixing chart and added new cleaning solution mixing logs. Changed responsible parties.	CC-21-0400	W. Asbell