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|  | Standard Operating Procedure | | SOP Number F-506 | Revision 6 |
| | Facility Maintenance and Sanitation | | Effective Date 01/26/23 | Page Page 1 of 7 |
| Written by/ Date Wayne Chubb 01-16-23 | | Reviewed by/ Date [Signature] 01-17-23 | | Approved by/ Date [Signature] 01/17/23 |
| Title: Facility Manager | | Title: Warehouse Manager | | Title: Quality Assurance Director |

1.0 Purpose

This procedure describes the sanitation requirements for non-production areas of the Belcher and 114th Avenue facilities.

2.0 Scope

This procedure applies to all non-production areas of Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of the Facility Manager or designee to implement this procedure and to ensure that the procedure is being followed.
- 3.2 It is the responsibility of Warehouse and Facility personnel to follow this procedure and to ensure that the facility is in good sanitary condition at all times.

4.0 Definitions

- 4.1 **Office** – areas used by office support staff that include: offices, cubicles, meeting rooms, QC Laboratory, restrooms, and breakrooms.
- 4.2 **Production** – all areas to include: manufacturing rooms, product storage, shipping, and receiving.
- 4.3 **Manufacturing** – all areas to include: rooms that are used to manufacture or process product.
- 4.4 **Warehouse** – area used to store raw materials, finished product, production supplies, receiving, and shipping areas.

4.4.1 W1 warehouse is defined as storage racks, shipping area, and receiving area located at 8031 114th Avenue.

4.4.2 W2 warehouse area is defined as the storage area, shipping area, and receiving area located at 10950 S. Belcher Road.

4.5 **Perimeter** – outside area of building to include: parking lots, receiving/loading dock, compactor or dumpster storage, and landscaped areas.

4.6 **PQV** – Process Quality Verification

5.0 References

5.1 F-506-F1, Form, Office Area and Restroom Cleaning Log

5.2 F-506-F2, Form, Warehouse and Facility Floor Cleaning Log

5.3 F-506-F3, Form, Cleaning of Upper Areas in Production/Warehouse/Grounds Log

5.4 A-106, SOP, Documentation Guidelines for cGMP Records

5.5 C-502, SOP, Record Storage, Retention, and Destruction

5.6 Master Cleaning Schedule

5.7 21 CFR parts 111, 114, 117, 210 and 211

6.0 Procedure

6.1 General Requirements

6.1.1 Areas that need cleaning will be listed on the Master Cleaning Schedule.

6.1.2 The Master Cleaning Schedule will be kept in the Sanitation Manual.

6.1.3 The Master Cleaning Schedule will be maintained by the Facility Manager or designee.

6.2 Ground Requirements

6.2.1 Properly store equipment, remove litter and waste, and cut weeds or grass and trim any bushes or trees within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding. All vegetation must be cut back from the exterior perimeter of the facility to prevent pest harborage or debris accumulation.

6.2.2 Maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, finished product, or contact surfaces are exposed.

6.2.3 Have adequately operating waste treatment and disposal systems so that they do not constitute a source of contamination in areas where components, finished product, or contact surfaces are exposed.

6.2.4 The exterior grounds maintenance shall be inspected and maintained monthly or as needed. Facility or Operations employees that are designated to cleaning and maintaining the Grounds area shall record their cleaning on F-506-F3 Cleaning of Upper Areas in Product/Warehouse/Grounds.

6.3 Facility Requirements

6.3.1 The facility must be in sufficient condition to prevent components, finished product, or contact surfaces from becoming contaminated.

6.3.2 Cleaning compounds and sanitizing agents must be free from microorganisms of public health significance, and must be safe and adequate under the conditions of use.

6.3.3 Toxic materials cannot be used or held in a facility in which components or finished product are manufactured, unless those materials are necessary as follows:

- 6.3.3.1 Those required to maintain clean and sanitary conditions
- 6.3.3.2 Those necessary for use in laboratory testing procedures
- 6.3.3.3 Those necessary for use in the plant's operation
- 6.3.3.4 Those necessary for plant and equipment maintenance and operations
- 6.3.4 Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of components and finished product.
- 6.3.5 The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Water intended for use or associated with the manufacture and production (or may become a component of a dietary supplement) will comply with all Federal, State, and Local requirements. Water for manufacturing is supplied by an in-house, purified DI water system.
- 6.3.6 Any water that contacts components, finished product, or contact surfaces shall be safe and of adequate sanitary quality.
- 6.3.7 Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the cleaning of equipment, utensils, or for employee sanitary facilities.
- 6.3.8 Hand washing stations shall be adequate and convenient with hot running water, hand soap, and paper towels. Hand washing stations shall be furnished in the manufacturing area.
- 6.3.9 Readily understandable signs directing employees to wash and sanitize their hands before they start work, after each absence from post of duty, and when a restroom is used.

6.3.10 Trash cans in all areas are to be properly maintained so that trash cans are clean with no visible buildup and excessive trash does not overflow from the can. Trash cans are to be marked or labeled as such and covers should be in place for trash receptacles in commonly shared areas.

6.4 Office Area Cleaning

6.4.1 Facility employees that are designated to clean the office areas shall record their cleaning on F-506-F1 Office Area and Restroom Cleaning Log. This should be done daily.

6.4.2 Office area cleaning may be performed by an external janitorial cleaning service. The contracted cleaning service has the option to provide external cleaning documentation, with the stipulation that it covers the scope of work for office cleaning listed on form F-506-F1 Office Area and Restroom Cleaning Log.

6.4.3 Carpet floors should be vacuumed a minimum of two times per week, or as needed.

6.4.4 Office cubicles should be dusted a minimum of 1 time per week, or as needed.

6.4.5 Restrooms are to be cleaned and inspected for proper sanitation daily or as needed.

6.4.6 Walls are inspected for damage and/or cleaning (e.g. cobwebs) daily or as needed.

6.4.7 Employees with a private office may request cleaning from Facilities as needed.

6.4.8 Breakroom refrigerators should be cleaned a minimum of one time per week.

6.4.9 Breakroom sinks, tables, floors, and microwaves should be cleaned daily or as needed.

6.5 Floor scrubbing and mopping for Production and Warehouse areas

6.5.1 Facility employees that are designated to scrub or mop Production Floors shall record their cleaning on F-506-F2 Warehouse and Facility Floor Cleaning Log. This should be done daily.

6.5.2 Floors in Production areas (not inside Manufacturing Rooms) need to be scrubbed with an electric floor scrubber or wet mopped a minimum of 1 time a day.

6.5.3 The warehouse area (to include shipping, receiving, and storage locations) will have the floors scrubbed as follows:

6.5.3.1 For high traffic areas – floors are to be scrubbed or wet mopped weekly.

6.5.3.2 Inactive areas – floors are to be scrubbed monthly or as deemed necessary by Management walkthroughs.

6.6 Cleaning of upper level areas in Production

6.6.1 Facility or Operations employees that are designated to upper levels shall record their cleaning on F-506-F3 Cleaning Log of Upper Areas in Product/Warehouse/Grounds.

6.6.2 The ceilings, duct work, and piping above Manufacturing Rooms (e.g. Packaging, Blending, and Tableting) must be swept or vacuumed monthly to remove dust buildup.

6.6.3 The pallet racks located in the Shipping Warehouse and Production areas near Blending and in front of the Liquid rooms will be wiped down or vacuumed on a quarterly basis.

6.6.4 The rafters used to support the ceiling will be swept or vacuumed on a bi-annual basis.

6.6.5 All cleaning will be verified by the Facility Manager or Senior Operational Management.

6.7 Monthly GMP and Sanitation Audit

6.7.1 A monthly audit will be conducted by the Food Safety and Regulatory Supervisor or designee to ensure GMP and sanitation standards are in compliance. A copy of the GMP and Sanitation Audit Checklist will be kept in the Sanitation Manual. Audits will be maintained by the QA department.

6.8 Documentation Requirements

6.8.1 A PQV check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

6.8.2 Documents will be maintained following SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

| Revision | Date | Description of Changes | CCR # | By |
|----------|----------|---|------------|-------------|
| 0 | 04/04/14 | New | 14-0295 | V. Iltcheva |
| 1 | 07/18/14 | Added Section 6.2.5 | 14-0574 | S. Millar |
| 2 | 03/11/16 | Revised to update source of water used in manufacturing and to update job titles. | 16-0233 | D. Popp |
| 3 | 06/03/16 | Removed hand sanitizing stations from 6.2.8 | 16-0568 | V. Zelaya |
| 4 | 11/20/17 | Complete rewrite to reflect current practices. | 17-1474 | K. Tyrell |
| 5 | 08/24/21 | Scheduled review: Updated titles and responsibilities. | CC-21-0336 | W. Asbell |
| 6 | 01/16/23 | Revise to include both warehouses. Add external janitorial service. Revise forms to split facilities. Update formatting and logo. Change wording throughout for clarification. Added documentation requirements and SOP references. | CC-23-0019 | W. Asbell |



Office Area and Restroom Cleaning Log

Form: F-506-F1

CCR No. CC-23-0019

Revision: 3

Location: 8031 114th Ave 10950 Belcher Road

Directions:

All areas are to be cleaned or checked daily, unless otherwise noted. Place your initials after you have performed cleaning or checked/refilled supplies for each section. Place N/A if the work was not performed. Place W/O if a Work Order was placed for repairs.

- * Floors vacuumed 2 times per week
** Cubicles dusted 1 time per week
*** Refrigerator cleaned 1 time per week

Table with 4 columns: DATE, OFFICE AREA, RESTROOMS, and BREAKROOMS. It contains 5 identical rows for data entry, each with sub-sections for Sinks, Toilets, Supplies, and Trash, and checkboxes for various cleaning tasks.



Warehouse and Facility Floor Cleaning Log

Form: F-506-F2

CCR No.

CC-23-0019

Revision: 3


Location (check one):

 8031 114th Ave 10950 Belcher Rd.**Directions:**

- Scrubbing or mopping of floors outside manufacturing rooms will be done a minimum of 1 time per day.
- Only use Tennant Degreaser or other Floor Scrubber approved cleaning chemicals in the electric floor scrubber.
- Only use Damp Mop Floor Clearer or Germicidal Bleach in mop buckets.
- Place your initials when you have completed the floor scrubbing or mopping.
- Place N/A if the floors were not scrubbed or mopped during that shift.
- Spot cleaning or cleaning of spills do not require your initials.
- High traffic areas to be scrubbed weekly.
- Inactive areas to be scrubbed monthly or as deemed necessary by Management walkthroughs.

| DATE | Gowning Hallway | Behind Liquid Rooms | Front of Packaging | Behind Packaging | Outside Tableting | Outside Encapsulation | Behind Blending | Front of Blending | *Warehouse |
|------|--|--|--|--|--|--|--|--|--|
| | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ |
| DATE | Gowning Hallway | Behind Liquid Rooms | Front of Packaging | Behind Packaging | Outside Tableting | Outside Encapsulation | Behind Blending | Front of Blending | *Warehouse |
| | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ |
| DATE | Gowning Hallway | Behind Liquid Rooms | Front of Packaging | Behind Packaging | Outside Tableting | Outside Encapsulation | Behind Blending | Front of Blending | *Warehouse |
| | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ |
| DATE | Gowning Hallway | Behind Liquid Rooms | Front of Packaging | Behind Packaging | Outside Tableting | Outside Encapsulation | Behind Blending | Front of Blending | *Warehouse |
| | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ |
| DATE | Gowning Hallway | Behind Liquid Rooms | Front of Packaging | Behind Packaging | Outside Tableting | Outside Encapsulation | Behind Blending | Front of Blending | *Warehouse |
| | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ | 1 st shift: _____ 2 nd shift: _____ |

* This includes Shipping, Receiving, and Storage locations

| | | | | | | |
|---|--|----------|---------|------------|-----------|---|
|  | Cleaning of Upper Areas in Production/Warehouse/Grounds Log | | | | | |
| | Form: | F-506-F3 | CCR No. | CC-23-0019 | Revision: | 2 |

CLEANING OF ROOM CEILINGS (must be done monthly)

| Room(s) | Above Ceiling | | Duct Work | | Pipes | |
|---------------|---------------|---------|-----------|---------|-------|---------|
| | Date | Done by | Date | Done by | Date | Done by |
| Liquid | | | | | | |
| Coating | | | | | | |
| Tableting | | | | | | |
| Encapsulation | | | | | | |
| Blending | | | | | | |
| Gummy | NA | NA | NA | NA | NA | NA |
| Packaging | | | | | | |
| Flex | NA | NA | | | | |

EXTERIOR GROUNDS

| | | |
|--|-------|----------|
| Exterior Ground Maintenance (must be done monthly/as needed) | Date: | Done by: |
|--|-------|----------|

CLEANING OF WAREHOUSE RACKS (must be done quarterly)

| Rack Area Cleaned | Date | Done by |
|---------------------------------------|------|---------|
| Rack 1 in front of Encapsulation Area | | |
| Rack 2 in front of Blending Area | | |
| Rack 3 in front of Liquid Area | | |
| Aisle 1 rack in Shipping Area | | |
| Aisle 2 rack in Shipping Area | | |
| Aisle 3 rack in Shipping Area | | |
| Aisle 4 rack in Shipping Area | | |
| Aisle 5 rack in Shipping Area | | |
| Aisle 6 rack in Shipping Area | | |

CLEANING OF CEILING SUPPORT RAFTERS (must be completed bi-annually)

| List areas cleaned | Date | Done by | List areas cleaned | Date | Done by |
|--------------------|------|---------|--------------------|------|---------|
| | | | | | |
| | | | | | |

Work has been verified by: _____ (print name) _____ (signature) _____ (date)