

BODYBIO

SOP# 02-007.9	Standard Operating Procedure	Written/Revised By/Date: <i>DS</i> 01 06 22
Effective Date FEB 18 2022	General Manufacturing, Packaging, Laboratory and Warehouse Area Cleaning	Approved By: <i>Jan Kent</i> 01/07/22
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1.0 Purpose

- 1.1 To establish the required frequencies for the general manufacturing, packaging, laboratory and warehouse areas and to formalize the necessary cleaning procedures.

2.0 Scope

- 2.1 This procedure applies to all manufacturing, packaging, laboratory and warehouse locations at Bodybio facilities (Figures 2 and 3) located at 45 Reese Rd and 25 Driskill St.

3.0 Responsibility and Frequency

- 3.1 Sanitation associates or designees will perform and record the cleaning/sanitizing on the Area Cleaning Log (Attachment 1) which will be kept in binders that are designated to the areas that are being cleaned (Figure 1).
- 3.2 Cleaning personnel will perform and record cleaning/sanitizing on the Restroom cleaning log (Attachment 2) for Reese Rd and the Bathroom Cleaning Logbook for Driskill St, which is kept in the designated bathrooms as well as the Area Cleaning Log (Attachment 1), if necessary.
- 3.3 Frequency is illustrated in the Master Cleaning schedule (Attachments 3 and 4).
- 3.4 The Manufacturing Manager and Demand & Logistics Manager are responsible for overseeing that the Master Cleaning schedule is being followed by the sanitation associates at each facility.
- 3.5 Quality personnel will verify cleaning/sanitization on the Area cleaning log (Attachment 1) following the Master cleaning schedule (Attachment 3 and 4).

4.0 References

- 4.1 21 CFR 111
- 4.2 21 CFR 117

5.0 Procedure

- 5.1 Daily Cleaning

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5.1.1 At the end of each days production, the areas involved must be thoroughly cleaned to remove trash and residue from the days activities. This includes the outside of equipment, table tops, floors and sinks. Tha Daily cleaning shall be documented by completing the Area Cleaning Log (Attachment 1).

5.2 Weekly Cleaning

5.2.1 Bathrooms, changing rooms and sinks will be cleaned and disinfected using the approved products listed in SOP 02-004.

5.2.2 Must be documented on the Restroom cleaning log (Attachment 2) or the Bathroom Cleaning Logbook.

5.3 Monthly Cleaning

5.3.1 Manufacturing, Packaging, Laboratory and Warehouse must go through a more thorough Cleaning and Sanitizing.

5.3.1.1 Clean all areas of the location including floors, doors, walls, counter tops, under tables, sinks, air vents, exposed pipes, corners, under pallets/racks and the outside of equipment with an approved cleaner/disinfectant per SOP-02-004 for product non-contact surfaces.

5.3.1.2 Floor drains will be opened, cleaned and disinfected using the approved products listed in SOP 02-004.

5.3.1.2.1 A 1% bleach solution will be poured down the drain periodically to eliminate the chance of microbial resistance to the approved disinfectants.

5.3.1.2 Must be documented in the areas cleaning log.

5.4 Bi annually (twice a year)

5.4.1 During the fall (November) and Spring (April) the following Sporicidal agent will be used on the floors, walls, counter tops, under tables, sinks, air vents, exposed pipes and the outside of equipment.

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5.4.1.1 Spor-Klenz or bleach (1%)

5.4.3 Must be documented on the areas cleaning log.

5.5 Biennially (once every two years)

5.5.1 Production and Manufacturing areas will have ceilings, fans and ledges
Wiped down with approved products per SOP 02-004

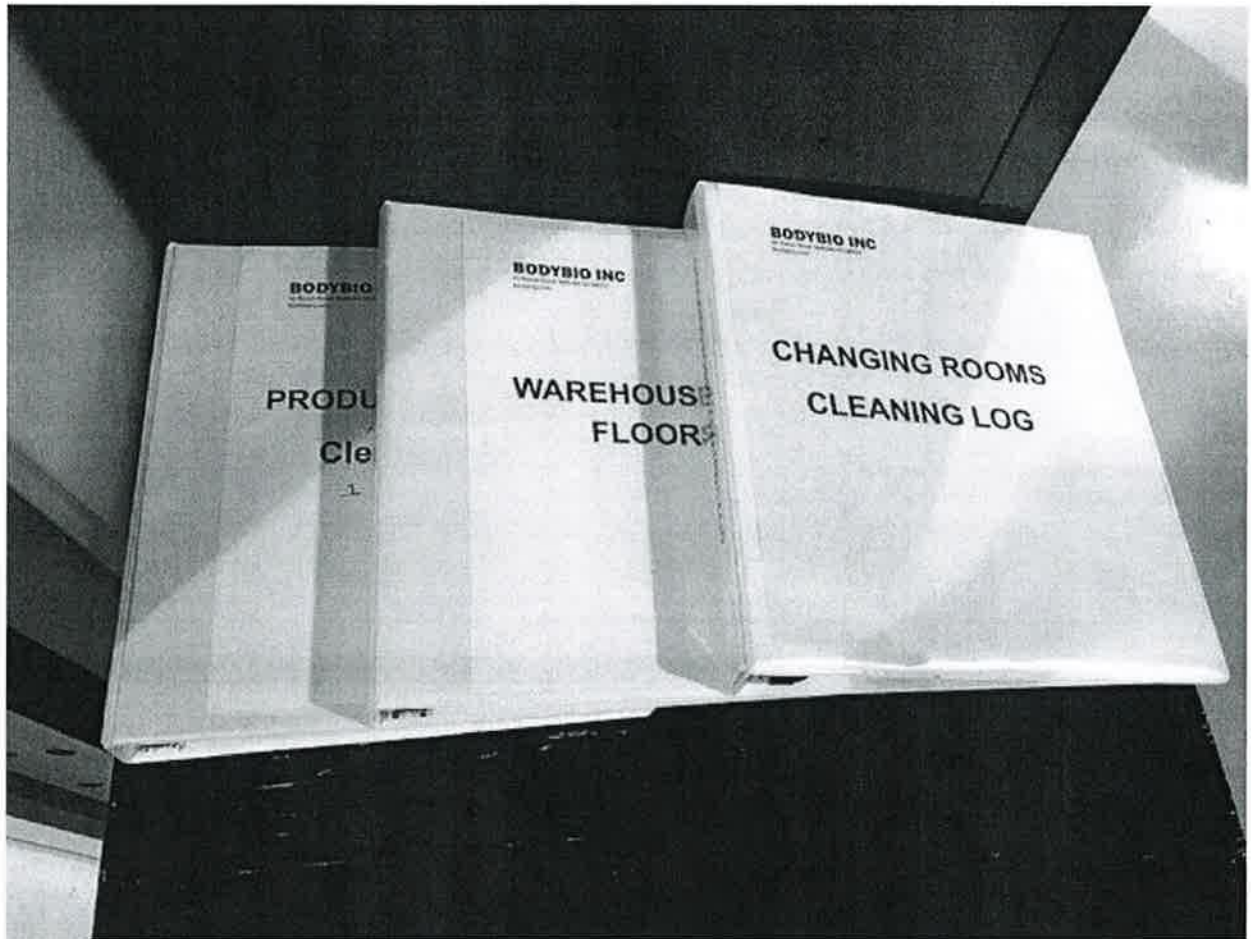
5.5.1.1 Must be documented in the areas cleaning log

5.5.1.2 If contract service is used, the vendor must provide a final report
that describes the cleaning performed and the approved chemicals
used.

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Figure 1: Cleaning Logs

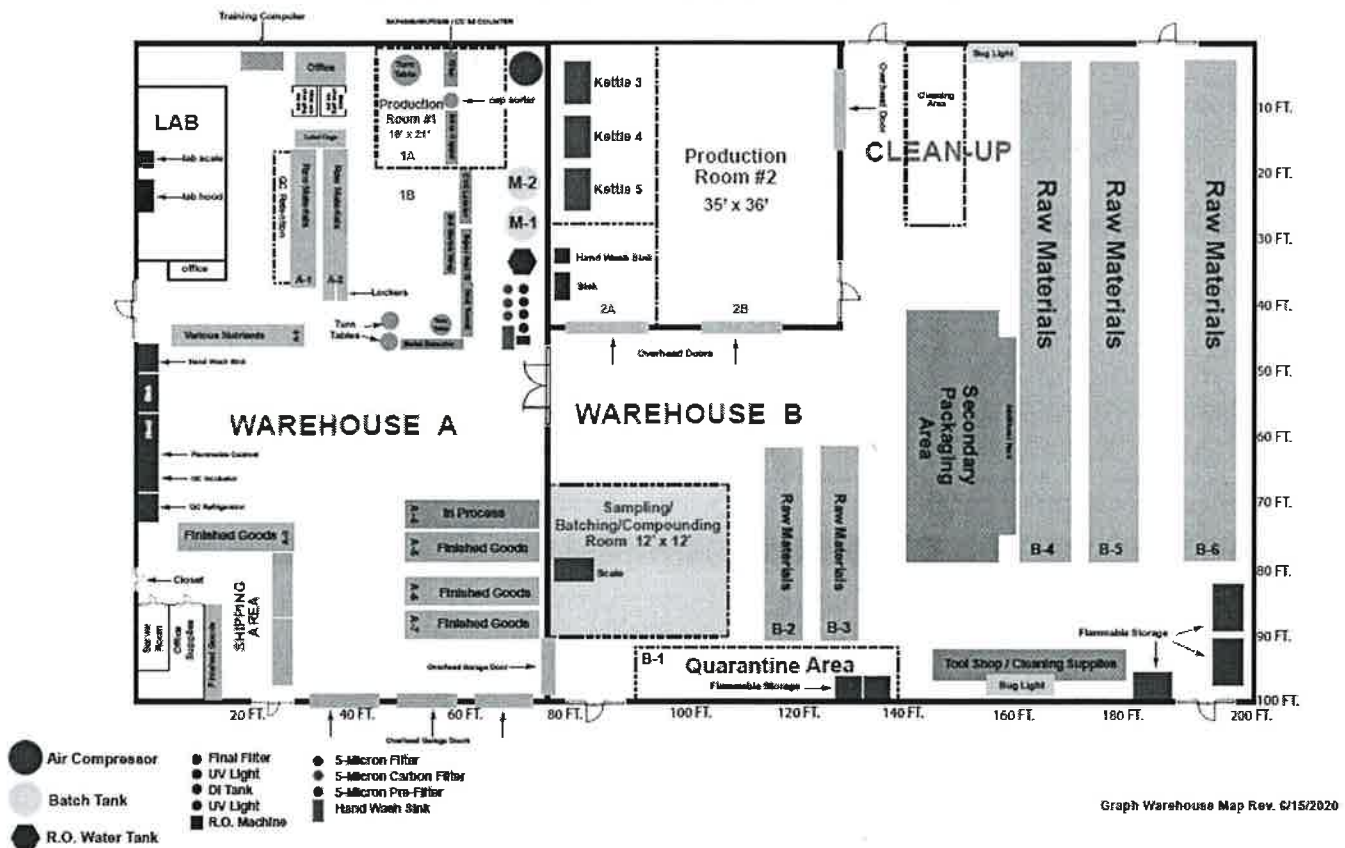


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Figure 2: 45 Reese Rd Warehouse Map

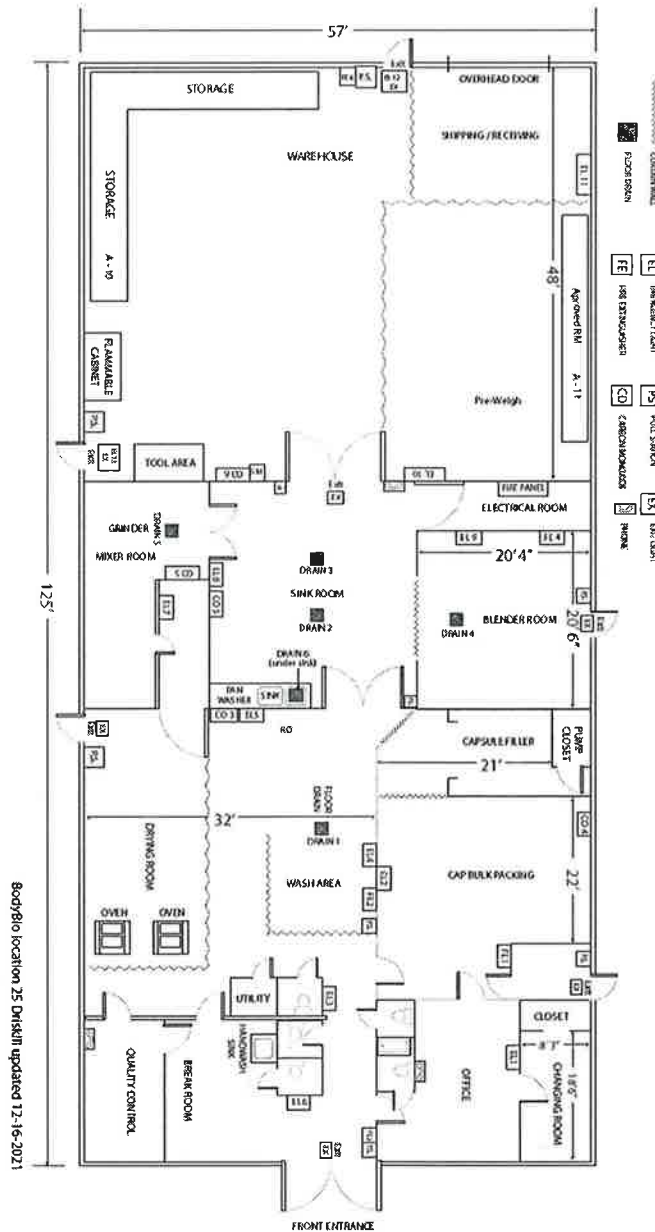
BODYBIO WAREHOUSES A & B



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Figure 3 25 Driskill St Map



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Revision History

Date	Revision	Comments
08/27/10	0	New
02/09/16	1	Removed Lysol and Process NPD. Added biennial cleaning. Floor drains and bathroom cleaning. Bathroom cleaning log (attachment 2)
03/15/17	2	Transferred drain cleaning from biannual to monthly
08/09/17	3	Deleted drain cleaning from biannual. Added master cleaning schedule.
08/06/18	4	Updated responsibility and frequency. Added attachment 4 and 5. Added changing rooms. Updated attachment 2 and 3. Added to floor drains procedure.
9-12-18	5	Updated format of SOP and attachments. Changed attachment 4 to Figure 1. Changed attachment 5 to Figure 2. Added cleaning of corners, under racks and pallets to the monthly cleaning.
11-05-18	6	Added rolling doors to Production 2 cleaning schedule on Attachment 3. Added doors to the monthly cleaning.
07-01-19	7	Updated Figure 2. Added Item cleaned column and Date to Attachment 1. Included cleaning personnel on the cleaning of the Labs counter tops, floors, walls and windows. Changed logo. Updated Titles.
09-30-20	8	Updated Warehouse map. Changed job title of Manufacturing Supervisor to Demand & Logistics Manager. Removed reference of 21 CFR 110 and replaced with 21 CFR 117.

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Date	Revision	Comments
FEB 18 2022	9	Added map of 25 Driskill St (figure 3). Updated attachments 1 and 2 to include location addresses. Added Attachment 4: Master Cleaning Schedule Driskill St.