
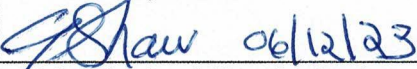

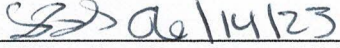


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|  | Standard Operating Procedure Floor Drain Cleaning and Sanitizing Procedure | SOP Number B-104 | Revision 2 |
| | | Effective Date 08/03/23 | Page 1 of 7 |
| Written by/ Date  06/12/23 Title: Senior Microbiologist | Reviewed by/ Date  06/14/23 Title: Sanitation Manager | Approved by/ Date  06/14/23 Title: Quality Control Director | |

1.0 Purpose

The purpose of this procedure is to define the process for cleaning and sanitizing floor drains throughout the facility. This process is designed to reduce contamination from floor drains.

2.0 Scope

This procedure applies to drains in non-production areas, warehouse areas, and production rooms.

3.0 Responsibility

- 3.1 It is the responsibility of Sanitation personnel or designees to clean and sanitize drains in the warehouse and non-production areas.
- 3.2 It is the responsibility of Production personnel to clean and sanitize drains in the production rooms as part of a major clean and sanitization.
- 3.3 It is the responsibility of QC and/or Operational personnel to verify drain cleaning and sanitizing has been completed as part of a major clean.
- 3.4 It is the responsibility of the Sanitation Manager or designee to maintain this procedure and to ensure that it is kept current.

4.0 Definitions

- 4.1 **Sporicidal Disinfectant** – Germicidal Bleach or SporKlenz RTU
- 4.2 **Foaming Degreaser** – Foaming Simple Green, Inspector's Choice or Alconox

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- 4.3 **Enzymatic Foaming Detergent** – Enzyfoam
- 4.4 **Portable Foaming Unit** – 20 gal Foam-it unit
- 4.5 **Foaming Attachment for drains** – 7-inch round, flat brush designed for foaming drains
- 4.6 **QC** – Quality Control
- 4.7 **PQV** – Process Quality Verification

5.0 References

- 5.1 B-104-F1, Form, Floor Drain Cleaning and Sanitizing Log
- 5.2 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment
- 5.3 D-115, SOP, Environmental Monitoring of Air and Surfaces
- 5.4 QS-114, SOP, Quality Risk Management
- 5.5 C-502, SOP, Record Storage, Retention, and Destruction
- 5.6 A-106, SOP, Documentation Guidelines for cGMP Records

6.0 Procedure

- 6.1 Floor drain cleaning can be conducted by using the Enzyfoam and Sporicidal Disinfectant/Bleach. Follow both floor drain cleaning procedure detailed below.
- 6.2 Enzyfoam
 - 6.2.1 Use the Portable Foaming Unit and drain foaming attachments with Enzymatic Foaming Detergent (Enzyfoam).

- 6.2.2 Make sure to wear goggles, disposable gloves, and disposable apron.
- 6.2.3 Pull floor drain cover off drain and Trap Seal and place upside down on the floor next to the floor drain. Inspect the drain for any blockage and remove as needed with a gloved hand. Immediately dispose of the blockage in a trash can, remove gloves, wash hands, and put on a fresh pair of disposable gloves.
- 6.2.4 Spray the underside of the drain cover with Enzymatic Foaming Detergent (Enzyfoam) using the Portable Foaming Unit and Drain cleaning attachment.
- 6.2.5 Spray the inside of the floor drain with Enzymatic Foaming Detergent (Enzyfoam), ensuring the drain is filled with foam until all surfaces are covered.
- 6.2.6 Place the floor drain cover back on the floor drain and spray Enzymatic Foaming Detergent (Enzyfoam) on the top surface of the cover and a one inch perimeter around the drain.
- 6.2.7 Let stand for a minimum of 15 to 30 minutes for in-depth action.

Note: For this application, this product is designed to be used without the need for a final warm water rinse.

- 6.2.8 Remove and discard disposable gloves prior to leaving the room or area and wash hands immediately.

6.3 Sporocidal Disinfectant/Bleach

- 6.3.1 Use a Sporocidal Disinfectant/Bleach without the use of the Portable Foaming Unit.
- 6.3.2 Make sure to wear goggles, disposable gloves, and disposable apron.
- 6.3.3 Pull floor drain cover off drain and Trap Seal and place upside down on the floor next to the floor drain. Inspect the drain for any blockage and remove as

needed with a gloved hand. Immediately dispose of the blockage in a trash can, remove gloves, wash hands, and put on a fresh pair of disposable gloves.

6.3.4 Spray the underside of the drain cover with foaming degreaser.

6.3.5 Spray the inside of the floor drain with foaming degreaser, ensuring all surfaces are covered.

6.3.6 Place the floor drain cover back on the floor drain and spray foaming degreaser on the top surface of the cover and a one inch perimeter around the drain.

6.3.7 Let stand for a minimum of five minutes or until foam dissipates.

6.3.8 Using one cup (eight fluid ounces) of non-diluted germicidal bleach (or SprorKlenz) pour evenly around the perimeter of the floor drain and let stand for five minutes.

6.3.9 Pour one gallon of warm water evenly around the perimeter of the floor drain. Do not splash water onto the floor drain.

6.3.10 Remove and discard disposable gloves prior to leaving the room or area and wash hands immediately.

6.4 Frequency of Cleaning/Sanitizing for each designated area of the facility

6.4.1 The cleaning frequencies defined in this procedure may be increased if a drain is observed to be dirty or if a drain swab as collected during environmental monitoring is approaching alert or action limits.

6.4.2 If a drain swab presents values that are over alert or action limits and/or presents positive for pathogen growth, then the drain requires immediate sanitization.

6.4.2.1 An alert/action notification will be sent to operational management as needed.

6.4.2.2 A risk assessment should be performed if pathogenic growth is recovered.

6.4.3 Production Rooms

6.4.3.1 As part of a regular schedule, production rooms that have drain(s) must be cleaned weekly with Enzyfoam and biweekly with Sporicidal Disinfectant/Bleach and documented on form B-104-F1 Floor Drain Cleaning and Sanitizing Procedure.

6.4.3.2 Follow the floor drain cleaning and sanitizing process as outlined in Section 6.2 or 6.3 of this procedure.

6.4.4 Non-Production Areas

6.4.4.1 Clean and sanitize the floor drain in the mop sink once weekly and log on form B-104-F1 Floor Drain Cleaning and Sanitizing Procedure.

6.4.4.2 Cleaning and sanitizing will be done by designated sanitation or facility personnel only.

6.4.4.3 Follow the floor drain cleaning and sanitizing process as outlined in Section 6.2 or 6.3 of this procedure.

6.4.5 Equipment/Sanitation Cleaning Area

6.4.5.1 Clean and sanitize all floor drains and surrounding drains once weekly and log onto form B-104-F1 Floor Drain Cleaning and Sanitizing Procedure.

6.4.5.2 Cleaning and sanitizing will be done by designated personnel only.

6.4.5.3 Follow the floor drain cleaning and sanitizing process as outlined in Section 6.2 or 6.3 of this procedure.

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6.4.6 Production Areas as part of Major Clean

6.4.6.1 Drains connected to sinks have an air gap to reduce the risk of backflow inside clean and sanitized sinks.

6.4.6.2 Floor drains are of adequate size and a p-trap piping installed to reduce the risk of sewer gas. All sewer lines are connected to the city sewer lines and are maintained by the city.

6.4.6.3 Floor drains must be cleaned and sanitized as the last step of a major clean and documented on form B-104-F1 Floor Drain Cleaning and Sanitizing Procedure.

6.4.6.4 Follow the floor drain cleaning and sanitizing process as outlined in Section 6.2 or 6.3 of this procedure.

6.5 Handling of an Overflow in a Floor Drain

6.5.1 Immediately contain the overflow with portable spill barriers.

6.5.2 Remove product and materials from the affected rooms and limit personnel in the rooms to essential personnel only.

6.5.3 Notify Facility and Sanitation Management immediately.

6.5.4 Contact the Municipal Water Authority to ensure that the issue is localized.

6.5.5 Once the overflow has subsided, a Major Clean for all affected rooms must be performed.

6.5.6 Follow the major cleaning process as outlined in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment and document on form B-104-F1 Floor Drain Cleaning and Sanitizing Procedure.

6.6 Documentation Requirements

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

6.6.2 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 | 03/15/18 | New | 18-0091 | K. Tyrell |
| 1 | 08/31/21 | Scheduled review: update procedure for foam gun and Enzyfoam usage. | CC-21-0340 | W. Asbell |
| 2 | 06/06/23 | Better defined cleaning process and frequency. Related SOP to EM. Updated format. Clarified procedure throughout. Add additional references and definitions. Added documentation requirements. | CC-22-0388 | J. Sassman |



Floor Drain Cleaning and Sanitizing Log

Form: B-104-F1

CCR No. CC-22-0388

Revision: 3

Drain Cleaning Log Procedure

- This log and procedure are to be used for floor drain cleaning only. Initial which floor drain cleaning procedure you used.
- Always wear proper PPE when handling chemicals.
- Draining cleaning should be done:
 - Once weekly with Enzyfoam and biweekly with Sporidical Disinfectant/ Bleach for Production Rooms
 - Last step of a Major clean
 - Once weekly for Mop Sinks
 - Once weekly for Equipment Cleaning/Sanitization and surrounding areas

| Room or Area to Clean | Reason for Cleaning | No. of Drains Cleaned | Date of Cleaning | Time of Cleaning | Enzyfoam with Foam Machine | Sporidical Disinfectant/Bleach |
|---|---|-----------------------|------------------|------------------|----------------------------|--------------------------------|
| <input type="checkbox"/> Room # _____ <input type="checkbox"/> Sanitation Area <input type="checkbox"/> Other _____ | <input type="checkbox"/> As part of Major <input type="checkbox"/> Regular Service <input type="checkbox"/> Other _____ | | ___ / ___ / ___ | | Employee Initials | Employee Initials |
| <input type="checkbox"/> Room # _____ <input type="checkbox"/> Sanitation Area <input type="checkbox"/> Other _____ | <input type="checkbox"/> As part of Major <input type="checkbox"/> Regular Service <input type="checkbox"/> Other _____ | | ___ / ___ / ___ | | Employee Initials | Employee Initials |
| <input type="checkbox"/> Room # _____ <input type="checkbox"/> Sanitation Area <input type="checkbox"/> Other _____ | <input type="checkbox"/> As part of Major <input type="checkbox"/> Regular Service <input type="checkbox"/> Other _____ | | ___ / ___ / ___ | | Employee Initials | Employee Initials |
| <input type="checkbox"/> Room # _____ <input type="checkbox"/> Sanitation Area <input type="checkbox"/> Other _____ | <input type="checkbox"/> As part of Major <input type="checkbox"/> Regular Service <input type="checkbox"/> Other _____ | | ___ / ___ / ___ | | Employee Initials | Employee Initials |
| <input type="checkbox"/> Room # _____ <input type="checkbox"/> Sanitation Area <input type="checkbox"/> Other _____ | <input type="checkbox"/> As part of Major <input type="checkbox"/> Regular Service <input type="checkbox"/> Other _____ | | ___ / ___ / ___ | | Employee Initials | Employee Initials |
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