

	Standard Operating Procedure	SOP Number F-507	Revision 10
	Warehouse Maintenance and Sanitation	Effective Date 05/10/24	Page Page 1 of 5
Written by/ Date K. Bunn 03/25/24	Reviewed by/ Date [Signature] 03-25-24	Approved by/ Date [Signature] 03-25-24	
Title: Director of Quality Assurance	Title: Warehouse Manager	Title: VP of Quality & Regulatory Affairs	

1.0 Purpose

The purpose of this procedure is to outline the steps that need to be taken to ensure that the warehouse areas meet all requirements for cleanliness and product containment.

2.0 Scope

This procedure applies to any Ion Nutritional Labs warehouse that is used to store raw materials, components, WIP, and finished products.

3.0 Responsibility

- 3.1 It is the responsibility of Warehouse and Facility Personnel to follow this procedure and to ensure that the warehouse is in adequate condition at all times. Warehouse and Facility Personnel are also responsible for completing Form F-507-F1 Warehouse Sanitation and Inspection Log, and also for reporting any negative findings to Warehouse Management, Production Management, and Quality Management.
- 3.2 It is the responsibility of the Warehouse Manager and Facility Manager to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of the Warehouse Manager to keep this procedure aligned with current practices.

4.0 Definitions

- 4.1 **RH** – Relative Humidity
- 4.2 **DC** – Document Control

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4.3 **WIP** – Work In Progress

4.4 **PQV** – Process Quality Verification

5.0 References

5.1 F-505, SOP, Environmental Monitoring Program

5.2 E-401, SOP, Refrigerator Unit Requirements

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

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

5.5 F-507-F1, Form, Warehouse Sanitation and Inspection Log

6.0 Procedure

6.1 Warehouse Refrigerator Requirements

Note: Refrigerator inventory contents can be identified by running a location report in the inventory management system.

6.1.1.1 The refrigerator temperature must be within the range of 2°C (36°F) and 8°C (46°F) per SOP E-401 Refrigerator Unit Requirements.

6.1.1.2 Any temperature or humidity nonconformance will be addressed in accordance with SOP F-505 Environmental Monitoring Program.

6.1.1.3 The refrigerator units will be cleaned weekly and logged onto form F-507-F1 Warehouse Sanitation and Inspection Log.

6.2 Pests (to be performed daily)

6.2.1 Walk through the warehouse area and look for signs of insects/vermin.

- 6.2.2 For materials that are prone to attract insects/vermin, use a pallet jack to pull out the pallet and inspect every side of the pallet and surrounding area.
- 6.2.3 Document any findings on Form F-507-F1 Warehouse Sanitation and Inspection Log.
- 6.3 Damaged Product/Raw Materials (to be performed daily)
 - 6.3.1 Walk through the warehouse area and look for signs of damage to any of the material stored in the warehouse. These contents are maintained through our cycle count program.
 - 6.3.2 For materials that are more prone to possible damage, such as bags of raw material, inspect the pallets for signs of damage such as spillage or tears.
 - 6.3.3 Document any findings on Form F-507-F1 Warehouse Sanitation and Inspection Log.
- 6.4 Warehouse Sanitation and Inspection Log
 - 6.4.1 Form F-507-F1 is to be completed as specified and will contain the following information:
 - 6.4.1.1 Date
 - 6.4.1.2 Pest Sightings
 - 6.4.1.3 Damaged Product
 - 6.4.1.4 Floor swept
 - 6.4.1.5 Garbage removed
 - 6.4.1.6 Shipping/Receiving docks cleaned
 - 6.4.1.7 Forklifts cleaned

6.4.1.8 Company trailer swept and cleaned

6.4.1.9 Damaged pallets

6.4.1.10 12" perimeter checked weekly and cleaned as needed

6.4.1.11 Refrigerator units cleaned

6.4.1.12 Name of Employee Performing the Walkthrough

6.4.2 Form F-507-F1 Warehouse Sanitation and Inspection Log will be maintained by warehouse personnel while in use and will be submitted to DC once an assigned logbook has been completed. Forms will then be maintained by DC following SOP C-502 Record Storage, Retention, and Destruction.

6.5 Warehouse Sanitation

6.5.1 All areas of the warehouse must be properly swept daily and be free of debris (i.e. shrink wrap, plastic straps, broken pallets, etc.) within the warehouse and shipping/receiving docks.

6.5.2 Empty garbage from the designated containers throughout the warehouse daily.

6.5.3 All material/pallets are to be staged no less than 12 inches from the perimeter wall of the warehouse to ensure adequate space to perform all operations, to include inspection and cleaning. Cleaning in this designated space shall be included as part of the normal warehouse and facility sanitation program.

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	08/01/14	New	14-0605	K. Burris
1	09/08/14	Added requirements for warehouse sanitation. Added Form F-507-F2. Changed SOP title.	14-0693	K. Burris
2	02/10/15	Added requirements for new warehouse. Added Form F-507-F3.	15-0150	K. Burris
3	05/12/15	Added new hygrometer location for WIP Area. Changed Form F-507-F3 to Forklift inspection form.	15-0413	D. Popp
4	06/17/15	Added warehouse refrigerator requirements.	15-0528	K. Burris
5	03/10/16	Added reference to cutting instruments and knives.	16-0217	S. Millar
6	06/21/16	Added forklift cleaning; Added company truck to daily cleaning	16-0612	V. Zelaya
7	12/02/19	Scheduled review: Removed information in sections 6.2.2, 6.2.3, and 6.6.6. Updated titles.	19-0911	J. Murphy
8	03/02/21	Removed warehouse inspection log and combined with sanitation log. Removed temperature and humidity requirements. Removed forklift inspection requirements.	CC-21-0010	J. Murphy
9	01/06/23	Remove shelf cleaning and floor scrubbing. Change from company truck to company trailer. Revise weekly cleaning of 12" perimeter. Split out buildings on form. Update logo and format. Clarify procedure throughout. Add additional references.	CC-22-0006	J. Murphy
10	03/25/24	Updated logbook requirements. Expanded responsibilities. Updated format and logo.	CC-24-0111	K. Burris