
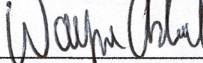
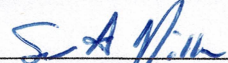
	Standard Operating Procedure		SOP Number E-401	Revision ①-56
	Refrigerator Unit Requirements		Effective Date 06/08/22	Page Page 1 of 3
Written by/ Date  04/22/22		Reviewed by/ Date  05-04-22		Approved by/ Date  05-04/22
Title: Warehouse Manager		Title: Facility Manager		Title: QA Manager

1.0 Purpose

The purpose of this procedure is to describe the operation of the raw materials warehouse refrigerator units and walk-in cooler.

2.0 Scope

This procedure applies to the raw materials warehouse refrigerator units and walk-in cooler at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all warehouse staff to follow this procedure.
- 3.2 It is the responsibility of production management or designee to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of QC Laboratory management or designee to implement the environmental monitoring.

4.0 Definitions

- 4.1 **CofA** – Certificate of Analysis
- 4.2 **Cold** – Any temperature not exceeding 8°C (46°F)
- 4.3 **Refrigerator** – A cold place in which the temperature is maintained thermostatically between 2°C and 8°C (36°F and 46°F). **Note:** the walk-in cooler is considered a refrigerator and falls under the scope of this procedure.

CONFIDENTIAL: For ION Labs use only

① Entry error KB 05/04/22

5.0 References

- 5.1 F-505, SOP, Environmental Monitoring Program
- 5.2 C-201, SOP, Deviation and Investigation Procedure

6.0 Procedure

- 6.1 Initial Operation of refrigerator unit
 - 6.1.1 Ensure that the doors can close completely.
 - 6.1.2 Plug the refrigerator unit's cord into a 115 volt outlet for power. The unit should come on with a humming sound.
 - 6.1.3 Allow temperature to equilibrate for approximately one hour.
 - 6.1.4 After one hour, verify the temperature on the thermometer. Assure that is it less than 8°C (46°F).
 - 6.1.5 Adjustments to the unit's temperature can be made from the front command panel. Hold the SET key for more than 2 seconds to change the set point value. The value of the set point will be displayed and the LED starts blinking. To change the set value, push the UP or DOWN key within 10s. To set new point value, push the Set key again or wait 10s.
 - 6.1.6 Contact Facility management if, after the adjustment, the temperature readings cannot be maintained within 24 hours.

Note: These steps do not apply to the walk-in cooler.

- 6.2 Temperature Monitoring
 - 6.2.1 Quality Management or designee routinely utilizes an environmental monitoring device and follows SOP F-505 Environmental Monitoring Program.

6.3 Storage Use

- 6.3.1 All incoming materials received will have the outside labeling reviewed by the warehouse department to ensure proper storage conditions.
- 6.3.2 If there is any question on the correct storage requirements of a material, the warehouse staff will contact quality for additional assistance to determine storage conditions.
- 6.3.3 Items requiring “cold” storage will be moved to the refrigerator or walk-in cooler.
- 6.3.4 Ensure that the loaded containers do not block the overhead cooler fans or the thermometer for the unit.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	09/01/10	New	-	-
1	02/20/13	New format. Updated SOP operation.	13-080	B. Mosall
2	09/03/14	Added section for temperature excursions. Updated SOP format.	14-0606	D. Popp
3	07/24/17	Biennial review: Revised sections 6.1.5 and 6.1.6	17-0826	I. Ilchev
4	10/01/20	Yearly Review. Updated Logistics and Facility Manager title to Facility Manager	CC-20-0700	J. Murphy
5	03/02/21	Add walk-in cooler requirements. Revise to reflect current environmental monitoring process.	CC-21-0011	J. Murphy
6	01/06/22	Revised to include the walk-in cooler.	CC-22-0005	J. Murphy