

STANDARD OPERATING PROCEDURE

STANDARD OPERATING PROCEDURE

COLD STORAGE TEMPERATURE MONITORING

Document No: SOP-OPS-2024-113

Revision: 2.4

Effective Date: January 15, 2024

1. PURPOSE

1 This Standard Operating Procedure (SOP) establishes the requirements

2. SCOPE

1 This SOP applies to all Company facilities and customer installation

-

Ultra-low temperature freezers (-40 C to -20 C)

-

Standard freezers (-20 C to -0 C)

-

Refrigerated areas (0 C to 8 C)

-

Temperature transition zones

3. DEFINITIONS

1 "AMR" means autonomous mobile robot units manufactured by the

2 "BlueCore(TM)" means the Company's proprietary cold-environment

3 "Critical Temperature Range" means the specified temperature range

4 "Temperature Excursion" means any deviation outside the Critical T

4. RESPONSIBILITIES

1 Facility Operations Manager shall:

-

Ensure implementation of this SOP

-

Review temperature monitoring reports weekly

-

Authorize corrective actions when needed

-

Maintain compliance documentation

2 AMR Technical Supervisor shall:

-

Monitor real-time temperature data

-

Conduct daily system checks

-

Document any temperature excursions

-

Calibrate monitoring equipment quarterly

5. EQUIPMENT AND MATERIALS

1 Required monitoring equipment:

-

BlueCore(TM) integrated temperature sensors

-

Backup digital thermometers (calibrated)

-

Network connectivity devices

-

Data logging system

-

Emergency notification system

6. PROCEDURE

1 Temperature Monitoring

1.1 Automated Monitoring

-

BlueCore(TM) sensors shall record temperatures at 5-minute intervals

-

Data shall be transmitted to central monitoring system

-

System shall maintain 12-month rolling temperature history

-

Automated alerts trigger when temperatures deviate by 2 C

1.2 Manual Verification

-

Physical temperature checks twice per shift

-

Record readings in electronic log

-

Compare against automated readings

- - 6 -

Document any discrepancies

2 Documentation Requirements

2.1 Required Records

-

Continuous temperature logs

-

Equipment calibration records

-

Deviation reports

-

Corrective action documentation

-

Maintenance records

2.2 Record Retention

-

Electronic records: 5 years minimum

-

Calibration certificates: Duration of equipment life plus 1 year

-

Deviation reports: 3 years minimum

7. TEMPERATURE EXCURSION RESPONSE

1 Upon temperature excursion:

-

Initiate immediate investigation

-

Document extent and duration

-

Assess impact on AMR operations

-

Implement corrective actions

-

Prepare deviation report

2 Notification Requirements

-

Alert Facility Operations Manager within 30 minutes

-

Notify Technical Support if AMR performance affected

-

Document all communications

- - 9 -

Update customer if applicable

8. QUALITY CONTROL

1 System Verification

-

Monthly accuracy checks of all sensors

-

Quarterly calibration verification

-

Annual third-party validation

-

Documentation of all verification activities

2 Data Review

- - 10 -

Daily review of temperature logs

-

Weekly trend analysis

-

Monthly compliance review

-

Quarterly system performance evaluation

9. TRAINING REQUIREMENTS

1 Personnel must complete:

-

Initial SOP training

-

Annual refresher training

-

Temperature monitoring system operation training

-

Emergency response procedures training

10. REFERENCES

1 Related Documents

-

Equipment Operating Manual Rev 3.2

-

Quality Management System Manual

-

Emergency Response Plan

11. REVISION HISTORY

Version	Date	Description	Approved By
---------	------	-------------	-------------

-----	-----	-----	-----
-------	-------	-------	-------

2.4	2024-01-15	Updated temperature ranges and monitoring intervals	
		Wells, CFO	

2.3	2023-08-10	Added BlueCore(TM) specific procedures	M. Chen
-----	------------	--	---------

2.2	2023-03-22	Revised notification requirements	S. Nordstrom
-----	------------	-----------------------------------	--------------

12. APPROVALS

Document Owner: Operations Department

Approved By: Dr. Elena Frost, CEO

Approved Date: January 15, 2024

This document contains confidential and proprietary information belonging to

