STANDARD OPERATING PROCEDURE

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DEVIATION MANAGEMENT FOR COLD STORAGE

Document No.: SOP-DEV-2023-014

Effective Date: January 15, 2024

Version: 2.1

Supersedes: Version 2.0 dated June 1, 2023

1. PURPOSE

This Standard Operating Procedure ("SOP") establishes the systemat

for identifying, documenting, investigating, and resolving deviations re

cold storage operations at Polar Dynamics Robotics, Inc. ("Company"

where BlueCore(TM) autonomous mobile robots are tested, maintaine

2. SCOPE

1 This SOP applies to all temperature-controlled environments where

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Testing facilities

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Quality control chambers

-

Client simulation environments

-

Production validation areas

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Maintenance bays with temperature control 2

2 This procedure covers deviations in:

-

Temperature specifications

-

Humidity levels

-

Operating parameters

-

Performance metrics

-

Safety protocols

-

Regulatory compliance requirements

3. DEFINITIONS

1 "Deviation" means any departure from established specifications, pr

2 "Critical Deviation" means any deviation that may impact:

-

Product quality or performance

-

Safety systems

-

Regulatory compliance

-

Client deliverables

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BlueCore(TM) technology integrity

3 "CAPA" means Corrective Action and Preventive Action.

4. RESPONSIBILITIES

1 Quality Assurance Manager:

- Overall responsibility for deviation management system
- Final approval of deviation investigations
- CAPA implementation oversight

2 Operations Personnel:

- Initial deviation identification and reporting
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Implementation of immediate corrective actions

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Documentation of deviation details

3 Technical Review Board:

-

Deviation impact assessment

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Investigation oversight

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CAPA recommendation approval

5. PROCEDURE

1 Deviation Identification

a) Personnel shall immediately report any observed deviation from es

parameters.

b) Initial assessment using Form DEV-101

c) Classification of deviation severity (Critical/Major/Minor)

2 Documentation Requirements

a) Complete Deviation Report Form (DEV-102) including:

-

Date and time of occurrence

-

Environmental conditions

-

Affected systems/components

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Initial impact assessment

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Immediate actions taken

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Supporting data/evidence

3 Investigation Process

a) Technical Review Board assembly within 24 hours for Critical Devia

b) Root cause analysis using approved methodologies

c) Impact assessment on:

-

Product quality

-

Regulatory compliance

-

Client obligations

-

Safety systems

4 CAPA Development

a) Corrective actions to address immediate issue

b) Preventive actions to prevent recurrence

c) Implementation timeline

d) Responsibility assignment

e) Effectiveness verification criteria

6. MONITORING AND CONTROL

1 Temperature Monitoring

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Continuous monitoring through validated systems

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Alert parameters: 2 C from setpoint

- Automated notification system

- Backup monitoring requirements

2 Documentation Control

- Electronic deviation management system

- Secure data storage

- Audit trail requirements

- Record retention (7 years minimum)

7. REPORTING REQUIREMENTS

1 Internal Reporting

- Monthly deviation trend analysis
- Quarterly review meetings
- Annual system effectiveness assessment

2 External Reporting

- Client notification protocols
- Regulatory authority communications
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Audit response procedures

8. TRAINING REQUIREMENTS

1 Personnel must complete:

- Initial deviation management training
- Annual refresher training
- System update training as needed
- Competency assessment

9. QUALITY METRICS

1 Key Performance Indicators:

Deviation resolution time

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Recurrence rate

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CAPA effectiveness

-

Training compliance

10. REVISION HISTORY

Version | Date | Description of Changes | Approved By

---|---|---|---

1 | 2024-01-15 | Updated temperature parameters | E. Frost

0 | 2023-06-01 | Major revision | M. Chen

0 | 2022-05-15 | Initial release | S. Nordstrom

11. APPROVALS

Position | Name | Signature | Date

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Chief Executive Officer | Dr. Elena Frost | _ |

Chief Technology Officer | Marcus Chen | _ |

Quality Assurance Manager | Robert Thompson | _ |

12. DISCLAIMER

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