AUTOMATED SYSTEM VALIDATION MASTER PLAN

Polar Dynamics Robotics, Inc.

Document No.: VAL-2024-001

Effective Date: January 15, 2024

Version: 1.0

1. PURPOSE AND SCOPE

1. This Automated System Validation Master Plan ("Validation Plan") establishes the framework and requirements for validating automated systems, including autonomous mobile robots (AMRs), control systems, and associated software developed by Polar Dynamics Robotics, Inc. ("Company").

2. This Validation Plan applies to all automated systems intended for deployment in temperature-controlled environments, including but not limited to:

- IceNav(TM) Navigation Platform
- Cold-resistant actuator systems
- Thermal management systems
- Mission-critical logistics control software
- Environmental monitoring systems

2. REGULATORY COMPLIANCE

1. This Validation Plan ensures compliance with:

- ISO/IEC 25051:2014 (Software engineering requirements)
- ANSI/RIA R15.06-2012 (Industrial Robot Safety)
- 21 CFR Part 11 (Electronic Records/Signatures)
- GAMP 5 Guidelines
- ISO 9001:2015 Quality Management Systems

3. VALIDATION METHODOLOGY

1. Risk Assessment

- System classification based on GMP risk levels
- Impact analysis on product quality and safety

- Identification of critical control points
- Risk mitigation strategies

2. Validation Approach

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Process Performance Qualification (PPQ)

3. Test Environment Requirements

- Temperature range: -40 C to +25 C
- Humidity control: 20% to 95% RH
- Network connectivity specifications
- Safety system integration
- Environmental monitoring systems

4. DOCUMENTATION REQUIREMENTS

1. Required Documentation

- Validation Protocol
- Requirements Specification
- Design Specification
- Risk Analysis
- Test Scripts
- Test Results
- Deviation Reports
- Change Control Records
- Validation Summary Report

2. Document Control

- Version control procedures
- Change management process

- Electronic signature requirements
- Document retention policies
- Access control protocols

5. ROLES AND RESPONSIBILITIES

1. Validation Team

- Validation Manager
- Quality Assurance Representative
- System Owner
- Technical Subject Matter Experts
- End User Representatives

2. Review and Approval Authority

- Chief Technology Officer
- Quality Assurance Director
- Regulatory Compliance Officer
- Chief Robotics Officer

6. VALIDATION LIFECYCLE

1. Planning Phase

- Project scope definition
- Resource allocation
- Timeline development
- Risk assessment
- Protocol development

2. Execution Phase

- Test execution
- Data collection
- Deviation management
- Change control
- Results documentation

3. Maintenance Phase

- Periodic review requirements
- Revalidation criteria
- Change impact assessment
- Continuous monitoring
- Performance trending

7. ACCEPTANCE CRITERIA

1. System Performance

- Navigation accuracy: 5mm
- Temperature operation range compliance
- Battery performance metrics
- Safety system response times
- System uptime requirements

2. Data Integrity

- Audit trail completeness
- Data backup verification
- Electronic signature compliance
- Error handling verification
- System security requirements

8. CHANGE CONTROL

1. All changes to validated systems shall follow the Company's Change Control Procedure (SOP-CC-001) and require:

- Impact assessment
- Risk evaluation
- Validation requirements determination
- Implementation plan
- Post-implementation review

9. DEVIATIONS AND EXCEPTIONS

1. Management of deviations shall include:

- Documentation requirements
- Risk assessment
- Corrective action plans
- Approval requirements
- Implementation tracking

10. APPROVAL AND AUTHORIZATION

This Validation Master Plan is approved and authorized by:

Dr. Elena Frost

Chief Executive Officer

Date:

Marcus Chen

Chief Technology Officer

Date:

Dr. James Barrett

Chief Robotics Officer

Date:

11. REVISION HISTORY

Version | Date | Description | Approved By

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

0 | 2024-01-15 | Initial Release | E. Frost

9 | 2023-12-20 | Final Draft | M. Chen

8 | 2023-12-01 | Initial Draft | J. Barrett