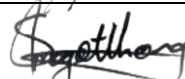
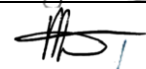


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ACTION	NAME & EXPERTISE	SIGNATURE	DATE
Originated By:	P Sinxo <i>Engineering</i>		2026/06/11
Checked By:	M van Vuuren <i>Process Engineering</i>		2026/06/11
Checked By:	T More <i>HVAC Engineering review</i>		2026/06/17
Checked By:	L Mogotlhong <i>Project Management Review</i>		2026/06/19
Checked By:	M Sekgodi <i>Operations Review</i>		2026/06/19
Checked By:	T Ntuli <i>Maintenance Management Review</i>		2026/06/19
Checked By:	KP Gota <i>IT Enterprise Management</i>		2026/06/22
QA Approved By:	L Moremi <i>Quality Assurance Review</i>		2026/06/30
Approved By:	V Legoabe <i>Engineering Review</i>		2026/06/30
Approved By:	J Selome <i>Project Sponsor Review</i>		2026/07/22
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1 PURPOSE

The purpose of this document is to define the user requirements for the Building Management System (BMS) to be installed in the Activation Iodine-131 API Manufacturing Facility located in Building P1900 on the Necsa site [Located at R104, Pelindaba, Brits Magisterial District]. It outlines the functional, technical, and performance expectations to ensure the system meets operational needs and regulatory compliance.

2 SCOPE

This User Requirement Specification (URS) covers the design, manufacture, installation, commissioning, qualification and documentation of the BMS. The BMS is required to continuously monitor, log and alarm equipment, services and systems parameters including room differential and absolute pressures, temperatures, relative humidity.

3 REFERENCES

This document complies with the requirements of:

NTP-PRG-0300: Control of Documented Information and Forms

The following documents are referenced in this document:

NTP-SOP-7006	: Good Documentation Practices & Data Integrity
NTP-PRG-0300	: Control of Documented Information and forms
NTP-PRG-0400	: Control of Records
NTP-PRG-0732	: Procedure for change control
NTP-SOP-7077	: Qualification Procedure of Equipment, Utilities and Facilities
SAHPGL-INSP-02_v10	: SAHPRA Guideline on Good Manufacturing Practice for Medicines, Version 10, April 2026
ASHRAE 135 / ISO 16484-5	: BACnet Data Communication Protocol for Building Automation
IEC 62443	: Industrial Automation and Control Systems Security
ISO 41001	: Facility Management - Management Systems - Requirements with Guidance
SANS 10400	: National Building Regulations
SANS 204	: Energy Efficiency in Buildings
ISO 50001:2018	: Energy Management Systems
OHS Act	: Occupational Health and Safety Act (No. 85 of 1993)
SANS 10142-1	: The Wiring of Premises, Part 1: Low-Voltage Installations
ISPE GAMP 5	: A Risk-Based Approach to Compliant GxP Computerized Systems
PIC/S PE 009 Annex 11	: Computerised Systems
FDA 21 CFR Part 11	: Electronic Records; Electronic Signatures
PIC/S PI 041-1	: Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments

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WHO TRS 1033 Annex 4 : Guideline on Data Integrity
 WHO TRS 1019 Annex 3 : Validation

4 ABBREVIATIONS AND DEFINITIONS

4.1. The following abbreviations are used in this document:

ACPH	: Air Changes Per Hour
AI	: Analog Input
ALCOA+	: Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available
AO	: Analog Output
API	: Application Programming Interface
ASHRAE	: American Society of Heating, Refrigerating and Air-Conditioning Engineers
BACnet	: Building Automation and Control Network
BMS	: Building Management System
CFR	: Code of Federal Regulations
CPU	: Central Processing Unit
DDC	: Direct Digital Controller
DI	: Digital Input
DO	: Digital Output
DP	: Differential Pressure
DQ	: Design Qualification
FAT	: Factory Acceptance Testing
FDA	: Food and Drug Administration (United States)
FDS	: Functional Design Specification
GAMP	: Good Automated Manufacturing Practice
GMP	: Good Manufacturing Practice
GUI	: Graphical User Interface
GxP	: Good Practice (collective term for GMP, GLP, GCP, etc.)
HMI	: Human-Machine Interface
HTTP	: Hypertext Transfer Protocol
HTTPS	: Hypertext Transfer Protocol Secure
HVAC	: Heating, Ventilation and Air Conditioning
IEC	: International Electrotechnical Commission
IP	: Internet Protocol
IQ	: Installation Qualification
ISA	: International Society of Automation
ISO	: International Organization for Standardization
IT	: Information Technology
LA	: Low Activity
LAN	: Local Area Network
NIST	: National Institute of Standards and Technology

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OQ	: Operational Qualification
OHS Act	: Occupational Health and Safety Act (No. 85 of 1993)
OT	: Operational Technology
PIC/S	: Pharmaceutical Inspection Co-operation Scheme
PLC	: Programmable Logic Controller
PQ	: Performance Qualification
SAHPRA	: South African Health Products Regulatory Authority
SANS	: South African National Standard
SAT	: Site Acceptance Testing
SCADA	: Supervisory Control and Data Acquisition
SNMP	: Simple Network Management Protocol
SOP	: Standard Operating Procedure
TCP	: Transmission Control Protocol
TCP/IP	: Transmission Control Protocol / Internet Protocol
TLS	: Transport Layer Security
UPS	: Uninterruptible Power Supply
URS	: User Requirements Specification
USB	: Universal Serial Bus
VLAN	: Virtual Local Area Network
WAN	: Wide Area Network
WHO	: World Health Organization

4.2. The following definitions are provided to ensure a uniform understanding of this document.

Autonomous Operation	:	The ability of BMS controllers to independently execute pre-programmed control logic, maintain setpoints, and respond to alarms without requiring active input or connectivity from a supervisory system.
Building Management System (BMS)	:	An integrated computerised system used to monitor, control, and manage a building's mechanical, electrical, and environmental systems, including HVAC, critical equipment, and utilities.
Heating, Ventilation and Air Conditioning (HVAC)	:	The technology and systems used to provide environmental comfort and air quality control within a facility, including temperature regulation, humidity management, pressurisation, and ventilation.
Interlock	:	A safety or operational condition that shall be satisfied before a particular action or equipment operation is permitted.
Manual Override	:	The deliberate suppression or bypassing of automatic control to allow direct manual control of a system or component by authorised personnel.
Setpoint	:	A defined target value for a controlled parameter (e.g., temperature, humidity) against which the control system regulates equipment operation.

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Shall	:	Indicates a mandatory requirement. The supplier or system shall comply with this requirement without exception.
Supervisory System	:	A higher-level software platform (e.g., SCADA or centralised BMS workstation) responsible for coordinating, monitoring, and where authorised, overriding individual controllers across the facility network.
Validation	:	The documented process of establishing evidence that a system consistently performs to its specified requirements, in accordance with applicable regulatory and quality standards.

5 GENERAL

5.1. Project Background

NTP Radioisotopes SOC Ltd. (NTP), a subsidiary of the South African Nuclear Energy Corporation SOC Ltd. (NECSA), is a leading global producer and supplier of nuclear medicine and radiation-based products and services. NTP would like to establish a manufacturing facility to produce activation I-131 API in Building P1900 located on the Necsa site [R104, Pelindaba, Brits Magisterial District].

The Activation I-131 Manufacturing Facility will house the activation I-131 production process together with its support functions and infrastructure to enable continuous and sustainable manufacturing of the activation I-131 API product.

The Activation I-131 Manufacturing Facility BMS will provide centralized monitoring and control of critical building, services and systems parameters/conditions, supporting improved operational performance, environmental monitoring, and facility safety. The system shall ensure continuous operation, data integrity, and regulatory compliance in accordance with applicable GMP requirements and relevant industry best practices.

5.2. Objectives of the BMS

The primary objective of the BMS is to ensure compliance with defined performance targets and regulatory standards. Key objectives include:

- a) Centralized monitoring and control of critical building, services and systems parameters/conditions, such as Heating, Ventilation and Air Conditioning (HVAC) systems, gas systems, back-up power systems, effluent management systems etc.
- b) Maintenance of consistent environmental conditions across critical areas.
- c) Improved energy management through automated systems.
- d) Integration with existing facility infrastructure to enable reliable operation.

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5.3. BMS Project Lifecycle

The project lifecycle of the BMS entails:

- a) The design and manufacture of the BMS.
- b) Supplier qualification and compliance assessment.
- c) Factory acceptance testing (FAT).
- d) Installation.
- e) Site acceptance testing (SAT).
- f) Installation qualification (IQ).
- g) Commissioning.
- h) Operational qualification (OQ); (note: the commissioning report shall serve as an input to the OQ protocol but does not substitute for the OQ.)
- i) Performance qualification (PQ).
- j) Ongoing maintenance and support of the installed system.

6 RESPONSIBILITIES

6.1. It is the responsibility of NTP to:

- a) Ensure the BMS is applicable for its intended purpose as defined in this URS.
- b) Provide the necessary resources to support installation, commissioning and qualification (as required).
- c) Observe, assist, and witness the installation, commissioning and qualification activities in accordance with NTP-SOP-7077.

6.2. It is the responsibility of the Service Provider to:

- a) Design and implement a BMS that is fit for purpose, ensuring reliable monitoring, alarming, trending, and recording of critical environmental, equipment, service, and system parameters required for operation of the GMP facility.
- b) Adhere to the requirements set out in this URS as the technical basis for all contractual obligations.
- c) Perform appropriate pre-shipment testing of assembled equipment, panels, instruments, software configurations, and integrated system components prior to shipment, as applicable.
- d) Notify NTP of any defects discovered after product release.
- e) Provide design documentation and support qualification activities, including Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), as applicable. Supplier responsibilities shall include provision of protocols, test documentation, commissioning records, traceability information, and technical support required to facilitate qualification activities.
- f) Ensure that all supplier-generated documentation, data, and records conform to ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent,

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Enduring, Available) in compliance with SAHPRA GMP requirements and NTP's quality management system.

7 PROCESS

7.1. Overall System Requirements

7.1.1. High-Level Requirements

The BMS shall:

- a) enable automated alarms for system faults (e.g. system trip, low levels or pressure etc.) and environmental deviations (i.e. room pressure, temperature and RH).
- b) provide user-friendly dashboards for real-time data visualization.
- c) be scalable to accommodate future expansion of the facility.

7.1.2. System Architecture and Control Hierarchy

- a) The BMS shall implement a hierarchical architecture consisting of field devices, distributed automation controllers, and supervisory systems.
- b) Automation controllers shall perform direct monitoring and control of connected equipment and sensors, while supervisory systems shall provide centralized monitoring, visualization, and supervisory control functions.
- c) The architecture shall support reliable, scalable, and maintainable system operation.

7.1.3. Control Philosophy Overview

- a) The BMS shall provide automatic control of environmental and mechanical systems to maintain defined operational conditions.
- b) The system shall utilize configurable control strategies to regulate equipment operation, maintain environmental parameters within defined limits, and ensure safe, stable, and efficient operation under all defined operating conditions.

7.1.4. Controller Autonomy and Supervisory System Independence

- a) Automation controllers shall be capable of autonomous operation and shall continue to perform control functions independently of supervisory system availability.
- b) Loss of communication with supervisory systems shall not result in loss of control functionality, unsafe equipment operation, or interruption of critical environmental control functions with systems that have independent control capabilities, e.g., the HVAC system.

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7.2. Functional Requirements

7.2.1. Environmental Monitoring and Control

- a) The BMS shall support comprehensive environmental monitoring and control to maintain defined operational conditions within the facility. The list of key areas to be included is detailed in the sub-sections below, viz.:

7.2.1.1. HVAC Systems

- a) The BMS shall integrate with HVAC systems to enable precise temperature, room pressures, humidity, and airflow control (differential pressures) in critical areas such as cleanrooms and laboratories.

7.2.1.2. Pressure Cascade Control

- a) The BMS shall support monitoring and control of differential pressure relationships between classified areas to maintain the required pressure cascade defined by the facility design.
- b) Loss of pressure cascade conditions shall generate alarms and initiate appropriate control actions to restore compliant operating conditions.

7.2.1.3. Temperature and Humidity Control

- a) The system shall maintain consistent temperature and humidity levels, adhering to predefined setpoints, with real-time monitoring and adjustments.

7.2.1.4. Ventilation and Air Quality

- a) The BMS shall monitor and control HVAC system parameters, including supply and return air volumes and air changes per hour (ACPH), to support the maintenance of required environmental conditions. Ventilation control accuracy shall be as specified in the HVAC design documentation.

7.2.1.5. Energy Management

- a) The BMS shall include features to monitor, analyse, and optimize energy consumption. It shall provide insights into energy usage patterns and support automated controls to minimize waste.

7.2.1.6. Alarm Management

- a) The system shall generate real-time alarms for deviations from setpoints, equipment faults, or system failures. Alarms shall be prioritized and displayed on the user interface with detailed diagnostics.

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7.2.1.7. Scheduling and Automation

- a) The BMS shall enable scheduling of system operations, such as HVAC cycles, based on time-of-day or occupancy levels. Automation rules shall be configurable to reduce manual intervention.

7.2.1.8. Integration with Other Systems

The BMS shall integrate with the following building and utility systems to ensure coordinated monitoring, control, and alarm management across the facility:

- a) HVAC system (including chilled water system).
- b) Differential pressure monitoring system.
- c) Compressed air system.
- d) Nitrogen gas system.
- e) UPS and generator systems.
- f) Low Activity (LA) effluent system.
- g) Chemical/industrial effluent system.

7.2.1.9. Equipment Sequencing and Interlocking

- a) The system shall provide automatic sequencing and interlocking of equipment to ensure proper operational order, prevent equipment damage, and maintain system efficiency. Equipment shall operate only when required operational conditions and permissive interlocks are satisfied. Specific equipment sequences shall be defined in the Functional Design Specification (FDS).

7.2.1.10. Operating Modes and State Management

- a) The system shall support monitoring and control of HVAC operating modes, including emergency exhaust operation where applicable. Emergency operating sequences, permissives, and interlocks shall be defined in the Functional Design Specification (FDS) and implemented in accordance with the approved facility control philosophy.
- b) The system shall transition between operating modes based on defined operational conditions, schedules, operator commands, or safety requirements.

7.2.1.11. Fault Handling and Failover Logic

- a) The system shall detect equipment faults, communication failures, and abnormal operating conditions. Upon detection of such conditions, the system shall generate appropriate alarms and execute predefined control actions to maintain safe system operation and minimize operational disruption.

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7.2.2. Manual Override

7.2.2.1. Manual Override Authority and Operational Constraints

- a) The system shall allow authorized personnel to manually override automatic control functions when required for operational, maintenance, or emergency purposes.
- b) Manual override actions shall not compromise system safety, equipment protection, or critical environmental control functions.

7.2.3. Security and Safety Considerations

7.2.3.1. Access Control and Override Security

- a) Manual override functionality shall be secured to prevent unauthorized access.
- b) Access to override functions shall be restricted to authorised personnel based on user roles and responsibilities.
- c) Override actions shall be logged for accountability and traceability, capturing sufficient detail to identify the user, the system affected, and the duration of the override.
- d) The system shall notify relevant personnel whenever a manual override is activated.

7.2.3.2. Automatic Resumption of Control

- a) The system shall define the criteria, timing, and required manual confirmation for resuming automatic control after a manual override ends. Resumption of automatic control shall be conditional upon confirmation that manual override conditions have been resolved, and normal operating conditions have been restored.

7.2.3.3. Safety Override and Emergency Control

- a) The system shall respond appropriately to safety and emergency conditions, including signals from external safety systems. Upon detection of emergency conditions, the system shall execute predefined safety control actions to ensure safe operation and protection of personnel, equipment, and the facility.

7.3. **Technical and Operational Requirements**

7.3.1. General Requirements

- a) The BMS shall provide reliable monitoring, control, alarming, trending, and recording functionality for facility environmental conditions, utilities, and associated systems required for GMP operation.
- b) The BMS shall be scalable and support future facility expansion and integration requirements.
- c) The BMS shall support centralized supervision and distributed control architecture appropriate for the facility operational requirements.

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7.3.2. Technical Requirements

7.3.2.1. General Hardware Requirements

- a) The system shall be built around controllers that offer flexible, powerful, and scalable solutions for integrating HVAC and other building systems.
- b) The BMS shall utilise reliable hardware components to ensure system functionality and scalability.
- c) Controllers shall:
 - i. Support multiple communication protocols (e.g. BACnet, Ethernet, Modbus, LonWorks).
 - ii. Provide sufficient processing capacity.
 - iii. Feature modular expandability to meet future requirements.

7.3.2.2. Communication and Networking Requirements

- a) The BMS shall support industry-standard communication protocols, including BACnet/IP (primary) and other protocols as required for integration with specific equipment.
- b) Protocol requirements for individual equipment interfaces shall be defined in the Functional Design Specification (FDS).
- c) The BMS shall support integration with the systems identified in Section 7.2.1.8.
- d) The network infrastructure shall support reliable communication between all BMS components and associated systems.
- e) All BMS servers, controllers, operator workstations, and historical data systems shall maintain synchronized system time using the facility IT network time synchronization services to ensure consistent timestamping of alarms, events, trends, audit trails, and system records. The system shall generate an alarm upon loss of time synchronization or excessive time deviation beyond a defined threshold.

7.3.3. Performance Requirements

- a) The BMS shall provide monitoring and control of environmental parameters within defined operational accuracy limits.
- b) The BMS shall display airflow values as measured by field instrumentation. Airflow control accuracy shall be as specified in the HVAC design documentation.
- c) The selected BMS controllers shall monitor and report the following parameters within defined accuracy limits:
 - i. Temperature and humidity control accuracy within $\pm 0.5^{\circ}\text{C}$ and $\pm 2\%$ RH respectively.
 - ii. Accurate energy usage monitoring and reporting to facilitate optimization initiatives.
 - iii. Stable and reliable control performance under normal facility operating conditions.
 - iv. Room differential pressure monitoring accuracy as specified in the facility design documentation.
 - v. Supply and return airflow rate monitoring as specified in the HVAC design documentation.
 - vi. Air changes per hour (ACPH) monitoring for classified areas.

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7.3.4. Data Management and Storage Requirements

- a) The BMS shall provide secure storage and retrieval of historical operational data, alarms, events, and trends. Retention periods shall align with NTP document retention requirements and applicable GMP record retention requirements.
- b) The system shall support configurable trend logging intervals and retention periods appropriate for GMP and operational requirements.
- c) The system shall support export of historical data and reports for engineering, maintenance, and compliance purposes.

7.3.5. Alarm Management Requirements

- a) The BMS shall generate alarms for environmental deviations, equipment faults, communication failures, and critical system events.
- b) Alarm priorities, acknowledgement requirements, and alarm handling procedures shall be configurable in accordance with the facility alarm philosophy.
- c) The system shall maintain historical alarm records for audit and troubleshooting purposes.

7.3.6. Energy Management Requirements

- a) The BMS shall support monitoring of energy usage associated with HVAC systems and other integrated utilities where applicable.
- b) The system shall support identification of abnormal energy consumption trends and facilitate optimisation initiatives.

7.3.7. Compliance and Regulatory Requirements

7.3.7.1. Industry Standards

- a) The BMS shall comply with relevant industry standards to ensure reliability and interoperability.
- b) Communication protocol compliance shall align with the integration requirements defined in Section 7.2.1.8 (Integration with Other Systems).
- c) Applicable standards include:
 - i. ASHRAE Standard 135 for building automation.
 - ii. ISO 16484 standards for BMS design and implementation.

7.3.7.2. Local Regulations

- a) The BMS installation shall comply with applicable electrical installation requirements in accordance with SANS 10142, as applicable to the facility.
- b) The BMS shall monitor environmental parameters that support compliance with the Occupational Health and Safety Act (Act No. 85 of 1993), as applicable to the facility.
- c) The system shall adhere to applicable local and regional environmental regulations.

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7.3.7.3. Environmental and Safety Requirements

- a) The BMS shall monitor and alarm environmental parameters that support facility safety and regulatory compliance.
- b) Requirements include:
 - i. Monitoring and alarming of HVAC system parameters that support compliance with environmental and occupational health requirements.
 - ii. Receiving and displaying status signals from external safety systems (e.g. fire detection) where required for operational awareness. The BMS shall not perform direct fire safety control functions.
 - iii. BMS hardware components shall comply with applicable environmental regulations.

7.3.8. System Security Requirements

- a) The BMS shall implement appropriate cybersecurity and access control measures to protect system integrity and operational continuity.
- b) The system shall support role-based access control (RBAC) aligned with operational responsibilities.
- c) The system shall maintain audit trails for critical operator actions, alarms, overrides, and configuration changes. GMP critical monitored parameters and equipment shall be identified through formal risk assessment and subject to appropriate validation and access control requirements.

7.3.9. Cybersecurity Compliance

- a) The system shall comply with recognized cybersecurity standards and practices to protect against unauthorized access and data breaches.
- b) Requirements include:
 - i. Following NIST Cybersecurity Framework guidelines.
 - ii. Implementing secure communication protocols such as HTTPS and TLS where applicable.
 - iii. Performing periodic vulnerability assessments and applying appropriate security updates.

7.3.10. Operational Requirements

7.3.10.1. User Roles and Responsibilities

- a) The BMS shall support various user roles with specific permissions and responsibilities.
- b) Examples include:
 - i. Administrators responsible for system configuration and management.
 - ii. Operators responsible for daily monitoring and control activities.
 - iii. Maintenance personnel responsible for troubleshooting and updates.

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7.3.10.2. Training Requirements

- a) Comprehensive training shall be provided to ensure users can effectively operate and maintain the system.
- b) Training materials shall include:
 - i. User manuals and quick-reference guides.
 - ii. On-site training sessions for operators and administrators.
 - iii. Maintenance training covering troubleshooting, preventive maintenance procedures, and fault diagnosis.

7.3.10.3. Maintenance and Support

- a) The BMS shall support scheduled maintenance and troubleshooting activities with minimal disruption to facility operations.
- b) The vendor shall provide technical support documentation and recommended maintenance procedures.
- c) The vendor shall provide technical support during the defects liability / warranty period, including fault diagnosis, corrective support, and software support services as defined in the project contract documentation.

7.3.11. Documentation Requirements

7.3.11.1. Manuals and Guides

The vendor shall provide detailed documentation, including:

- a) User operation manuals.
- b) Installation and configuration guides.
- c) Maintenance and troubleshooting procedures.

7.3.11.2. As-Built Documentation

The system shall include up-to-date as-built documentation reflecting the installed configuration. Documentation shall include:

- a) Wiring schematics.
- b) Network topology diagrams.
- c) Equipment layouts.
- d) Equipment lists.
- e) I/O lists.
- f) For upgrade (brownfield) projects, existing documentation shall be updated to reflect the as-installed configuration. For new (greenfield) installations, documentation shall be progressively developed and issued as the design advances.

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7.3.11.3. System Configuration Documentation

- a) Comprehensive documentation of the system configuration shall be provided.
- b) Documentation shall include:
 - i. Parameter settings for controllers and devices.
 - ii. Network configuration details.
 - iii. Software backup and recovery procedures.
 - iv. User access configuration details.
 - v. The vendor shall provide system backup files, controller configurations, graphics configurations, parameter databases, administrative credentials, and all relevant engineering documentation required for operation, maintenance, backup, and future modification of the BMS. Provision of proprietary engineering software shall be subject to applicable vendor licensing and training requirements.

7.4. Project Implementation Requirements

7.4.1. Project Timeline

- a) Project timeline requirements, including milestones, dependencies, risk mitigation strategies, and stakeholder review checkpoints, shall be defined in the tender documentation and are not within the scope of this URS.

7.4.2. Commissioning and Validation Plan

- a) The commissioning and validation plan shall ensure systematic installation, configuration, testing, qualification, and handover of the BMS with minimal disruption to facility operations.
- b) Key elements shall include:
 - i. Validation activities aligned with the project lifecycle defined in Section 5.3 (BMS Project Lifecycle), including IQ, OQ, and PQ.
 - ii. Validation documentation, including protocols, summary reports, and traceability to URS requirements.
 - iii. Detailed commissioning schedules, installation procedures, and pre-commissioning checklists.
 - iv. Phased commissioning to maintain continuity of facility operations.
 - v. Coordination with other teams where applicable.
 - vi. The BMS shall be designed and documented to support GMP validation activities in accordance with applicable regulatory and GAMP 5 requirements. Supplier documentation shall provide sufficient detail and traceability to support NTP validation activities, including IQ, OQ, and PQ.

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7.4.3. Change Management

- a) All changes to the BMS design, configuration, or documentation during the project shall be managed in accordance with NTP-PRG-0732.
- b) Change requests shall be documented, reviewed, approved, and communicated to relevant stakeholders prior to implementation.
- c) A change log shall be maintained and included within the final project documentation package.

7.5. **Supervisory System / SCADA Overview**

- a) The BMS supervisory system shall provide centralized visualization, monitoring, alarm management, historical data review, and supervisory control functionality for all integrated facility systems.
- b) The supervisory system shall interface with distributed automation controllers and field devices through approved communication protocols.
- c) The supervisory system architecture shall support virtualization, centralized administration, and future system scalability.

7.6. **Graphical User Interface (GUI) Requirements**

- a) The BMS shall provide graphical user interfaces accessible to authorised users through approved operator workstations and engineering stations.
- b) Graphical displays shall provide clear indication of equipment status, alarms, process values, trends, and operating modes.
- c) Navigation between graphics shall be logical, consistent, and designed to support rapid operator response.

7.7. **Graphics and Mimic Standards**

- a) BMS graphics shall utilise standardized symbols, colour conventions, and display philosophies throughout the system.
- b) Dynamic animations shall accurately represent equipment status and operating conditions.
- c) Alarm conditions shall be visually distinguishable from normal operating conditions.

7.8. **Operator Workstations and Client Access**

- a) The system shall support operator workstations, engineering workstations, and approved client access interfaces.
- b) Remote access functionality shall be controlled through approved cybersecurity and IT access management procedures.
- c) Access from mobile or portable devices shall be subject to approval by NTP and applicable cybersecurity requirements.

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7.9. Electronic Records and Data Integrity

- a) Electronic records generated by the BMS shall comply with ALCOA+ principles and applicable GMP data integrity requirements. The system shall support compliant electronic signatures where approval workflows require them.
- b) System records shall be protected against unauthorized modification, deletion, or corruption.
- c) Historical operational data, alarms, events, trends, and audit trails shall be securely retained for approved retention periods.

7.10. Audit Trail Requirements

- a) The system shall maintain secure and computer-generated audit trails for critical operator actions, configuration changes, alarm acknowledgements, overrides, and system modifications.
- b) Audit trail records shall include user identification, timestamps, affected parameters, previous values, and updated values where applicable.
- c) Audit trail records shall not be modifiable by standard system users.

7.11. Alarm Annunciation and Management

- a) The supervisory system shall provide centralized alarm annunciation, alarm acknowledgement, alarm prioritization, and alarm history functionality.
- b) Alarm priorities and alarm handling requirements shall align with the approved facility alarm philosophy.
- c) The system shall maintain historical alarm records for troubleshooting, operational review, and GMP compliance purposes.

7.12. Historical Data and Trend Management

- a) The system shall provide historical data collection, storage, retrieval, and trend visualization functionality.
- b) Trend data collection intervals and retention periods shall be configurable in accordance with operational and GMP requirements.
- c) Historical trend data shall support engineering analysis, troubleshooting, and compliance investigations.

7.13. Reporting Requirements

- a) The system shall support generation of operational, alarm, environmental monitoring, and audit-related reports.
- b) Reports shall support export to approved electronic formats including PDF and CSV where applicable.
- c) Automated report scheduling functionality shall be supported where required by operational or GMP requirements.

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7.14. User Account Management

- a) The system shall support controlled user account management in accordance with NTP IT and cybersecurity requirements.
- b) Password policies, account lockout rules, session timeout periods, and administrator controls shall comply with approved NTP policies.
- c) User accounts shall be uniquely assigned to individual users and shall not be shared.

7.15. Role-Based Access Control (RBAC)

- a) Access to BMS functions shall be restricted according to approved user roles and responsibilities.
- b) Role-based permissions shall restrict access to configuration changes, overrides, alarm management, and engineering functions.
- c) User role definitions shall be documented and approved as part of the system configuration documentation.

7.16. Backup and Disaster Recovery

- a) The system shall support automated backup of configuration data, historical data, application software, and system databases. Backup restoration procedures shall be periodically tested and documented to verify recoverability and data integrity.
- b) Backup procedures and recovery procedures shall be documented and periodically verified.
- c) Recovery of the BMS following system failure shall support restoration of validated system functionality and historical records. Recovery of the BMS shall restore validated operation within approved business continuity requirements.

7.17. Server and Virtualization Requirements

- a) BMS servers may be implemented within a virtualized server environment approved by NTP IT.
- b) Virtual machine configurations, server resources, and redundancy requirements shall be defined during detailed design.
- c) Integration with the facility IT domain and cybersecurity infrastructure shall comply with approved IT requirements.

7.18. Network Architecture Requirements

- a) The BMS network architecture shall support secure and reliable communication between controllers, servers, workstations, and integrated systems.
- b) Network segmentation, firewall requirements, and secure communication protocols shall comply with approved IT and cybersecurity requirements.
- c) Remote connectivity shall be restricted to approved and secured access methods.

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7.19. Computerized System Lifecycle Requirements

- a) The BMS shall be developed, implemented, tested, and maintained in accordance with applicable GAMP 5 and GMP computerized system lifecycle principles.
- b) System lifecycle documentation shall include URS, FDS, design documentation, FAT records, SAT records, and validation support documentation.
- c) Requirements traceability between URS requirements and system implementation documentation shall be maintained.

7.20. Configuration and Change Management

- a) System configuration changes shall be controlled through approved change management procedures.
- b) Configuration baselines, software versions, and revision histories shall be maintained throughout the system lifecycle.
- c) Changes affecting validated system functionality shall be assessed for GMP impact prior to implementation.

7.21. Redundancy and High Availability

- a) The system architecture shall support high availability and reliable operation appropriate for critical facility monitoring functions.
- b) Redundancy requirements for servers, communication networks, and historical data systems shall be defined during detailed design.
- c) System recovery following communication or infrastructure failures shall minimize operational disruption and loss of historical records.

7.22. Third-Party System Integration

- a) The BMS shall support integration with approved third-party systems and equipment through standard communication interfaces.
- b) Responsibilities for interface configuration, testing, and data exchange validation shall be defined during detailed design and implementation.

8 RECORDS

Record	Retention Period	By Whom
None	N/A	N/A

9 TASK HAZARD ASSESSMENT

N/A

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10 LIST OF FORMS

Form Title	Form Number	Exhibit Number
N/A	N/A	N/A

11 REVISION HISTORY

Rev.	Date Approved	Nature of Revision	Originated by
1	See Title page	First issue	P Sinxo