INVITATION TO BID

SUPPLY AND INSTALLATION OF AN ELECTRONIC QUALITY MANAGEMENT SYSTEM (EQMS) FOR THE NUCLEAR MEDICINE DEPARTMENT, ITHEMBA LABS, CAPE TOWN.

Bidder Name:	
Bid Number:	NRF ILABS WI53/05/2025-26-1
Closing Date	**05 December 2025**
Closing Time:	**11:00 am**
Bid Box Address	Tender Box, Main Security Gate, iThemba LABS, Old Faure Road, Faure Western Cape, 7131, South Africa GPS coordinates: 34.025°S 18.716°E Dimensions of tender box opening: 300 mm x 20 mm
Envelope Addressing	On the face of each envelope, the Bid Number and Bidder's Name, Postal Address, Contact Name, Telephone Number and email address mail. Electronic Submission will be accepted (scm2@tlabs.ac.za)

Bidding procedure enquiries are directed in writing to:		**Technical information queries are directed in writing to:**	
Section	Supply Chain Management	Section	Nuclear Medicine
Contact person	SCM Team	Contact person	Project Manager
E-mail address	scm2@tlabs.ac.za	E-mail address	scm2@tlabs.ac.za

Fraud alert! It is common for scammers to call bidders pretending to be NRF's employees and offering to swing tenders your way for a fee. DO NOT FALL FOR IT, IT IS A SCAM! The NRF would never offer payment or any other consideration in return for the favourable consideration of a bid. Please report any suspected acts of fraud or corruption to the following toll-free number - 0800 701 701 or SMS 39772.

TABLE OF CONTENTS

INTRODUCTION

INTRODUCTION TO THE NRF

The National Research Foundation ("NRF") is a juristic person established in terms of the National Research Foundation Act as amended, Act 19 of 2018 that will contract with the awarded bidder.

The NRF is the government's national agency responsible for promoting and supporting research and human capital development through funding researchers, provision of the National Research Platforms, and science outreach platforms/programs to the broader community. The NRF provides these services in all fields of science and technology, including natural science, engineering, social science, and humanities.

Please visit the NRF website (https:www.nrf.ac.za) for more information.

INTRODUCTION TO THE ITHEMBA LABS BUSINESS UNIT

iThemba LABS (Laboratory for Accelerator-Based Sciences) is a multi-disciplinary research laboratory based at two sites in the Western Cape and Gauteng respectively, these provide facilities for:

- Basic and Applied Nuclear Physics Research using Particle Beams
- Research Radiation Biophysics
- The supply of Accelerator-produced Radioactive Isotopes for Nuclear Medicine and Research

Please visit the iThemba LABS website (http://tlabs.ac.za) for more information.

CONTEXT OF THIS PROCUREMENT NEED

iThemba LABS is required by Good Manufacturing Practise (GMP)guidelines and regulatory authority to update our manual Quality Management System (QMS) to one that is electronic. This will establish the QMS as a modern element UpToDate with requirements of cGMP. The current manual system will be replaced with a system that has better control over data integrity and reduced opportunity for error and manipulation. The new EQMS will also allow for future expansion and integration with other electronic elements required by iThemba LABS.

PART A – CONTRACT

CONTRACT OBJECTIVE

iThemba LABS seeks to appoint a service provider to supply and install an Electronic Quality Management Systems (EQMS) for the Nuclear Medicine Department at iThemba LABS.

REQUIRED EQUIPMENT

1. **SUPPLY OF ONE ELECTRONIC QUALITY MANAGEMENT SYSTEM (EQMS)**
2. Server with peripherals and all necessary licenses

EQUIPMENT SPECIFICATIONS

Minimum server specifications:

Processor: 8 Core Intel Xeon or AMD

Memory: 32 GB ECC

Storage: SDD/ NVMe

- Redundancy and High Availability: RAID 5/6/10 configured for redundancy
- Include at least 2 hot spare disks

Operating System: Windows Server 2019 / 2022 – ensure compatibility with EQMS software

- Operating System should be configured on separate disk configured RAID 1

Database: Microsoft SQL - ensure sufficient resources to handle operations efficiently

Network: 10 Gbps Fibre with redundancy

- 2 x 10GB SFP+ NIC ports
- 2 x 5m Multimode fibre LC-LC cable

Redundant power supplies

Hot swappable hardware

Server hardware must be upgradable for future expansion (Memory. Storage, CPU)

Security: Hardware must support encryption and secure access controls

Server Rails for rack mounting

SERVICES SPECIFICATIONS

Electronic EQMS iThemba LABS NMD

1. OBJECTIVE

The User Requirement Specification (URS) is a key document to specify the functional and operation requirements that the electronic Quality Management System (EQMS) should comply with, to fulfill the needs of iThemba LABS. The URS shall provide the Vendor clarity on the technical, quality and documentation requirements of iThemba LABS. The URS is required to contain clear, concise and testable requirements to serve as a baseline for validation and qualification for the successful compilation and implementation of the Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) of the EQMS Software.

Accept: Yes/No		Comment:	

2. SCOPE

2.1. Governance

The URS will be applicable to govern and outline the requirements of the following EQMS software modules to comply with 21CFR Part 11 and cGMP requirements:

- Change Controls
- Deviations
- CAPA
- Customer Complaints
- Audit Management
- Documentation Management (SOPs, Batch books, Drawings, Protocols and Reports)

Accept: Yes/No		Comment:	

2.2. Implementation

This system must be implemented at the following iThemba LABS Site:

- iThemba LABS Faure Date Centre (DC) Old Faure Rd, Cape Town, South Africa

Accept: Yes/No		Comment:	

3. RESPONSIBILITIES

3.1. Quality Assurance (System Owner)

The System Owner for this EQMS software is the Quality Assurance department. The System Owner is responsible for assisting for the development of the URS and reviewing and approving the final URS to ensure that it accurately

reflects the requirements of the system intended, to users. Quality assurance verifies cGMP requirements, as well as applicable validation guidelines for qualification and provides feedback to subsequent qualification protocols. The System Owner is also the owner of the URS document.

3.2. Implementation Team

The Implementation Team Users will be responsible to conduct the User Acceptance Testing as per the site's requirements. All Users will receive training from the service provider or bidder as and when required.

4. OVERVIEW

4.1. Background

The EQMS software system must be an integrated Quality Assurance Management System which will provide iThemba LABS with a highly configurable, workflow driven process automation with 21CFR Part 11 and cGMP compliance.

Accept: Yes/No		Comment:	

4.2. Project Overview

4.2.1. Project Summary

The EQMS system must be developed and configured as part of iThemba LABS commitments. The EQMS must enable the Applicant, iThemba LABS, to process Change Controls, Deviations, CAPAs, Customer Complaints, Audits and documentation in an electronic validated environment.

Accept: Yes/No		Comment:	

4.2.2. Key Objectives

The key objective is to provide an electronic Quality Assurance Management System with the required functionality while simultaneously meeting the requirements of ISPE GAMP 5, cGMP, FDA's 21 CFR Part 11.

Accept: Yes/No		Comment:	

4.2.3. Anticipated Benefits

The EQMS must be able to integrate with other products, or future products, to further improve the overall compliance to the required regulatory requirements throughout iThemba LABS with products such as (electronic Batch Records Management System, LIMS (Laboratory Information Management System).

Accept: Yes/No		Comment:	

The EQMS system must be highly configurable, quick to implement, and can mimic the current formats and workflow, thereby reducing training needs and process changes.

Accept: Yes/No		Comment:	

The system must be a pre-validated central framework that will reduce validation efforts during and after its implementation.

Accept: Yes/No		Comment:	

To improve Regulatory Compliance

To implement a core Quality Management System within the iThemba LABS that will promote a high standard across all areas of the business.

To have a tool that consolidates all information and can provide an overview to the Quality Assurance of all QA activities across the iThemba LABS.

Accept: Yes/No		Comment:	

To increase the effectiveness, efficiency and turn-around time of the QA processes as manual systems are more time consuming with authenticated electronic signatures.

To identify trends within each QA process that will identify areas for improvement and promote continuous improvement.

Accept: Yes/No		Comment:	

To have real-time validated data you can trust and which you can access from any location through being connected to the internet.

To promote a consistent format of capturing data across all iThemba LABS sites.

Traceability if changes are made.

To generate consistent month end reports across all iThemba LABS sites and spend less time to consolidate data for reporting purposes.

Accept: Yes/No		Comment:	

To be able to export data from system in a report *.pdf format as well as raw data in MS Excel format

Accept: Yes/No		Comment:	

To automatically send initial and reminder notifications to users to perform activities on records.

Accept: Yes/No		Comment:	

To escalate records to the approving manager or senior management for records nearing due dates and those passing due dates.

Accept: Yes/No		Comment:	

Provide secure access to non-iThemba LABS affiliated contract manufacturers to upload and comment and approve customer complaints

Accept: Yes/No		Comment:	

4.3. Facility Overview

4.3.1. Existing Facilities and Equipment

The iThemba LABS Facilities as identified in section 2.2, are a combination of manufacturing, distribution, research and development and administration facilities. The introduction of the electronic Quality Management System will have no little to no impact on the existing physical facilities and/or equipment. The existing server room located within iThemba LABS will house the new equipment “Database Server” for the EQMS system.

4.3.2. New Facilities and Equipment

The introduction of the electronic Quality Management System does not require a new facility to house the new Database Server. All other facilities will have access to the new Database Server through existing connections within the iThemba LABS Network.

4.3.3. Modifications to Existing Facilities and Equipment

No major modifications of the existing facilities and/or equipment is required except to connect the new Database Server with the existing iThemba LABS Network.

4.4. Automated Overview

4.4.1. Existing Systems

The iThemba LABS Facilities as identified in section 2.2, are a combination of manufacturing, distribution, research and development and administration facilities. The introduction of the electronic Quality Management System will have no little to no impact on existing systems within the facilities identified as these facilities don’t have any existing

electronic EQMS to replace or migrate data from. The EQMS system is a stand-alone web-based software application and can operate on its own.

Accept: Yes/No		Comment:	

4.4.2. New Systems

The EQMS will require a new Database Server and will have to be connected to the existing iThemba LABS Network.

Accept: Yes/No		Comment:	

4.4.3. Modifications to Existing Systems

No major modifications of the existing systems are required except to connect the new Database Server with the existing iThemba LABS Network. As part of iThemba LABS's requirements, selected product and vendor information from The MRP system will be integrated into EQMS.

4.5. Main Functions and Interfaces

4.5.1. Functions

Management Change Controls

Accept: Yes/No		Comment:	

Management of Deviations

Accept: Yes/No		Comment:	

Management of CAPAs

Accept: Yes/No		Comment:	

Management of Customer Complaints

Accept: Yes/No		Comment:	

Management of Audits

Accept: Yes/No		Comment:	

Management of documentation

Accept: Yes/No		Comment:	

4.5.2. Interfaces

MRP System

Accept: Yes/No		Comment:	

4.6. Applicable GxP requirements

USFDA: 21CFR Part 11

Accept: Yes/No		Comment:	

SAHPRA: Guide to Good Manufacturing Practice for Medicines in South Africa (Jun 10 v5)

SAHPRA: Good Wholesaling Practice for Wholesalers, Distributors and Bonded Warehouses (March 12 v2)

ISPE GAMP 5

Accept: Yes/No		Comment:	

4.7. Other Applicable regulations

EudraLex: The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.

WHO: Quality Assurance of Pharmaceuticals, a compendium of guidelines and related materials, Volume 2, 2nd updated edition, Good Manufacturing Practices and inspection.

5. OPERATIONAL REQUIREMENTS

5.1. Functions

5.1.1. Management Change Controls

Refer to Annexure 1 for more details.

5.1.2. Management of Deviations

Refer to Annexure 2 for more details.

5.1.3. Management of CAPAs

Refer to Annexure 3 for more details.

5.1.4. Management of Customer Complaints

Refer to annexure 4 for more details

5.1.5. Management of Audits

Refer to annexure 5 for more details

5.1.6. Management of Documentation

Refer to annexure 6 for more details

5.1.7. Reporting Requirements per function

Refer to Reporting sub-sections within Annexures 1 – 6.

5.2. Modes of operations

The system should provide 2 operation modes:1. Testing/Simulation Environment and Production Live Environment

Accept: Yes/No		Comment:	

5.2.1. Testing / Simulation Environment

The system shall allow users to simulate each process function which includes:

Accept: Yes/No		Comment:	

The ability to work through a workflow, by selecting the appropriate users to review, testing the system to assign records automatically to the relevant approvers (as pre-defined).

Accept: Yes/No		Comment:	

The ability to test all possible scenarios within the system.

Accept: Yes/No		Comment:	

The ability to temporarily force input errors and return the process to a previous state where inputs can be corrected.

Accept: Yes/No		Comment:	

The ability to set and configure the frequency of notifications and escalations in accordance with the configured workflows for each module.

Accept: Yes/No		Comment:	

5.2.2. Production / Live Environment

During normal operation, the system shall enable the user to perform required operations based on privileges associated with the user's account.

Accept: Yes/No		Comment:	

5.3. Performance and timing requirements

5.3.1. EQMS Performance

The system should perform at adequate levels to provide an effective and responsive system. The following guidelines are intended to indicate performance expectations:

Activity/Event	Performance Expectation
Process Monitoring and Basic Controls	EQMS should be monitoring each record generated in any Module in accordance with the workflow to indicate the process status and overall progress.
Process Input Display	EQMS display should be immediate as typing and drop-down fields are selected. Where information is collected from an integrated system i.e. MRP, the information retrieval and input generated into the form fields should be reflected immediately without delay.
User Control Command	Evidence of EQMS response to user commands (e.g., submitting comments, approving activities/processes) and the status change where applicable of the record should be presented to the user within one (1) second (e.g., by changing from "pending Approval" to "QA Approved").
Display Navigation	Evidence of EQMS response to a user command to change displays between screens of the workflow should be presented to the user immediately without delay.
Workstation Synchronization	When a process attribute is changed from one workstation, the attribute change must be reflected on another workstation displays. Such attribute changes should be reflected on all workstations within three (3) seconds and or after the display is refreshed.

Accept: Yes/No		Comment:	

5.3.2. Date and Time

Data integrity is of utmost importance and the time an entry was made. The time of all actions need to be standardized and aligned across all users and take into consideration when users work on the system across different time zones.

Accept: Yes/No		Comment:	

Users should not be able to change the date and time of their operating system to influence the date and time of actions being recorded.

Accept: Yes/No		Comment:	

The EQMS shall be designed to minimize and, as necessary, compensate for differences in date and time values amongst different workstations used by different users.

Accept: Yes/No		Comment:	

Date/time compensation will be periodically reconciled to a known accurate date/time source. The date/time value should not normally deviate from the known accurate date/time source value by more than ten (10) seconds between periodic reconciliations.

Accept: Yes/No		Comment:	

All date/time reconciliations shall be recorded in the EQMS event log(s) in a way that allows determination of the pre-reconciliation date/time value offset.

Accept: Yes/No		Comment:	

5.3.3. Action required in case of failure

If a power failure takes place, the system should enable the user to carry on with work from the last saved point.

Accept: Yes/No		Comment:	

A manual documented procedure is required to be used in case of system down time. The manual forms will be designed as per the electronic system to capture all required information, which can then be captured into the system and the source information uploaded, when the system is operational again.

Accept: Yes/No		Comment:	

EQMS fault conditions (such as hardware anomalies; software failures and anomalies; communication failure and anomalies) that potentially impact data quality should be communicated by the system to the user and should be incorporated into the system's event log.

Accept: Yes/No		Comment:	

5.4. Safety

5.4.1. Desired Product / Process Safety Systems:

The System shall be protected with computer Anti-Virus software, Anti-Ransomware, Anti-Malware and adequate Firewalls to prevent data pilferage and misuse.

Accept: Yes/No		Comment:	

EQMS Database Server equipment should comply with site electrical and construction standards including appropriate grounding and fusing and an un-interrupted power supply.

Accept: Yes/No		Comment:	

5.4.2. Any other specific requirements:

None.

5.5. Security

5.5.1. Desired Product/ Process Safety Systems:

All EQMS modules shall be designed to protect against deliberate and/or accidental activities that could potentially compromise electronic records.

Accept: Yes/No		Comment:	

Logical controls should include user authentication for any process control or modification activity. Refer to the User Interfaces section (5.8) for additional descriptions related to logical controls.

Accept: Yes/No		Comment:	

The System shall be designed to allow the system administrator to control access of all users.

Accept: Yes/No		Comment:	

System access shall be restricted to authorized users only.

Accept: Yes/No		Comment:	

User permissions will be restricted in accordance with the level of authority assigned to a user. The User permissions are: “Initiator, Reviewer and Approver.

Accept: Yes/No		Comment:	

All the forms shall have the security statement that the forms are proprietary property of iThemba LABS and no part of the forms shall be reproduced in any form either electronic or manual mode.

Accept: Yes/No		Comment:	

5.5.2. Other specific requirements

The system should automatically identify the user access level based on the user's role and restrict a user to either site specific user view or an unrestricted view for a Quality Assurance user.

Accept: Yes/No		Comment:	

5.6. Data

5.6.1. Definition

Data will be referred to all text entries entered into form fields by means of manually typing, selecting entries from a pre-defined dropdown list, or the uploading of file attachments as supporting documentation into defined fields.

Accept: Yes/No		Comment:	

5.6.2. Capacity requirements

The hardware "Database Server" should allow for significant future expansion to extend to other vendor software packages with the purchase of additional hardware, if required. The following capacity constraints are recommended:

Feature	Capacity
Processing Power	No more than 50% of the processing capacity of the EQMS Database Server should be required to provide normal processing and display functionality with satisfactory performance.
Memory	No more than 50% of the installed physical memory in the EQMS Database Server should be required to provide normal processing and display functionality.
Local Electronic Storage	No more than 50% of the installed hard disk capacity in the EQMS Database Server should be consumed by installed software.
Historical and Archive Storage	Historical data storage capacity should allow for online retrieval of any historical data.

Accept: Yes/No		Comment:	

5.6.3. Access speed requirements

Real-time Data

Access to real-time data, via the user interface displays, is a primary function of the PCS. Refer to the "Functions - Performance and Timing" subsection for a description of performance expectations including input display and workstation synchronization features.

Historical Data

EQMS historical data includes all of the following:

- Process data records generated within of each of the 5 modules,
- File attachments,
- Alarm and event logs

Accept: Yes/No		Comment:	

The User interface to access historical data should include all of the following:

- Time-sequenced trending of values,
- Query-driven display of records,
- Pre-configured reports (which can also be exported into various file formats such as *.pdf, *.xlsx, *.tiff, *.docx)
- Access to historical data (i.e., not yet archived) should be optimized for efficient retrieval. However, no specific access speed specification is applicable due to the diverse nature of potential queries. Instead, the following interface guidelines are recommended:
  - For data retrieval that could take more than ten (10) seconds, an on-screen "in progress" indication should be provided.
  - For data retrieval that could take more than twenty (20) seconds, an ability to cancel the query should be provided.
  - For data retrieval that could take more than thirty (30) seconds, a rough progress indicator (e.g., percent complete bar graph) should be provided.

Accept:		Comment:	

Yes/No			

5.7. Archive requirements

EQMS historical data retention capabilities must conform to site and/or product data retention requirements. In general, all historical data should be accessible for at least ten (10) years. Any robust archiving technology is acceptable; however, existing site archiving facilities, technologies, and procedures should be exploited if possible. Archive system design should consider the potential for having to migrate the historical data so that access can be preserved beyond the point of de-commissioning.

Accept: Yes/No		Comment:	

EQMS system manuals must include detailed procedures for committing historical data to archive and for retrieving historical data from archive. Retrieved historical data must include any and all data that was, or may have been, considered for verifying manufacturing and/or product quality. Retrieved data context, format, and/or access must be identical to, or at least comparable to, original data context, formats, and/or access. The EQMS system must provide the ability to retrieve archived data without interrupting ongoing process operations.

Accept: Yes/No		Comment:	

Back-up and recovery mechanism shall be in place to prevent a loss of data in case of power failure and data shall be stored on database with backup media for backup and archival.

Accept: Yes/No		Comment:	

5.8. Data security and integrity with regards to the requirements of 21 CFR Part 11

The EQMS data security and integrity features must be consistent with controls required by 21 CFR Part 11 to protect electronic records. The following table identifies anticipated EQMS design features intended to satisfy these requirements:

Part 11 Control	EQMS Compliance Feature(s)
System Validation	EQMS development lifecycle and documentation must be adequate to support system validation. This should include a specifications traceability matrix and/or similar quality control mechanism.
Copying Records	EQMS manuals should include detailed procedures for generating accurate and complete copies of records in both human readable and electronic form.
Protection through Retention Period	Refer to the 5.7. "Data - Archive Requirements" subsection of this document.
Limiting System Access	Refer to 5.8 "Functions - Security" and 5.9 "User Interfaces - Security" subsections of this document.
Audit Trails	All EQMS historical records shall use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.
Operational System Checks	EQMS specification documentation shall clearly identify permitted sequencing of steps and events that must be enforced, if any. The EQMS must be designed to enforce this sequencing, as appropriate.
Authority Checks	Refer to the 5.6 "Functions - Security" and 5.9 "User Interfaces - Security" subsections of this document.
Device Checks	EQMS specification documentation shall clearly identify restrictions to valid sources of data input or operational instruction, if any. The EQMS must be designed to enforce these restrictions, as appropriate.
System Documentation Controls	System operation and maintenance documentation must be included with the EQMS. Distribution of, access to, and use of this documentation must be adequately controlled and subject to revision and change control procedures that maintain an audit trail that documents time-sequenced development and modification of systems documentation.
Open System Controls	Systems with any component(s) that are not installed in an environment in which system access is controlled by persons responsible for the content of electronic records that are on the system are considered "Open Systems". Open systems must include controls to ensure the authenticity and integrity of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include additional measures such as document encryption and use of appropriate digital signature standards.

Accept: Yes/No		Comment:	

5.9. User Interface

5.9.1. User Interface Design

User Interfaces are designed to facilitate both general process awareness and specific tasks. The EQMS software application is designed with a User Interface and is the backbone to login onto the software application, navigate between processes and tasks to capture data into the Database Server. The following table outlines the specific tasks accommodated by the EQMS user interface features:

Task	Description
Process Monitoring: Overview	Features designed to provide a rapid and accurate assessment of the status of a record within a specific process (Change Control, Deviation, CAPA, Customer Complaint and Audit Management). Overview displays the status of a record and this could be displayed graphically through a dashboard display. When a record is accessed the workflow view will be displayed to identify the state of the record.
Process Monitoring: Detail	Features designed to provide structured access to all important attributes. When a workflow is accessed to provide an overview of a record, the individual elements can be accessed to obtain further details on what actions are required to progress the records to next record state.
Process Monitoring: Analytical	Features designed to display historical and/or statistical information to users. These typically include a historical trend display of records.
Process Control	Features that provide for monitoring and control to initiate, review and approve records within each process module (Change Control, Deviation, CAPA, Customer Complaints and Audit Management). Process Control features typically include screens for workflow driven initiation of a record, review of records by various users and the ability for users to provide their comments, user prompts/responses, approvals by authorized personnel, rejection of records as a whole, or rejection of selected content by authorized personnel and reports.
Super Administrator Functions	Features, protected from normal user (initiator, reviewer and approver) access, designed to provide extraordinary process management controls. Super Administrator capabilities may include to re-open closed records when required, moving records to a previous state when additional information is required, etc. but doesn't include the capability to erase or change data without being logged in an audit trail.

Task	Description
Notification Management	Features designed to notify user of activities, records assigned to the user to be executed.
Reports	Features designed to select and display/print written summaries of historical production data.
Software Application Configuration	Features provided to allow for the customization and modification of the software application, i.e. identification of public holidays to calculate working day.

Accept: Yes/No		Comment:	

5.9.2. User Interface Hardware

User Interface hardware refer to the computer terminals/laptop, as the EQMS system is designed to be operated on a computer terminal/laptop.

Accept: Yes/No		Comment:	

5.9.3. Security

All EQMS user interfaces must be designed to control user access. Access controls must be consistent with 21 CFR Part 11 requirements for protection of computer systems that employ electronic records and electronic signatures. These include (but are not limited to) the following:

- User accounts shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
- User accounts not based on biometrics shall employ at least two distinct identification components such as a User ID and password. At least one of these components should be secret or otherwise guaranteed to be unique.
- Workstation logins should expire (e.g., by automatic logout) if no user activity occurs within a pre-determined, definable time period.
- Use of transaction safeguards to prevent unauthorized use of a user account, and to detect and report in an immediate and urgent manger any unauthorized access attempt to the system security unit, and, as appropriate, to organizational management.

Access level assigned to an individual will dictate which functions, interfaces, and displays a user has access to, and which operations the user can perform. Where feasible, user access administration should leverage existing site computer security policies and procedures (including security administration servers and existing user accounts).

Records of operator actions should include the operator's identity, as confirmed by user account login information. All access attempts and results must be recorded and accessible for review and/or reporting.

5.9.4. Workstation Display Navigation

Display navigation design should provide easy access to all user interface features. The following navigation characteristics should be provided:

	Navigation Attribute
☐	Display navigation should be limited, as appropriate, based on the user login and permission levels.
☐	A hierarchical menu system (e.g., in "site map" format and/or dropdown list) should be provided. Process Workflow displays should provide single keystroke/click navigation to this menu system.
☐	Process displays should provide single keystroke/click navigation to detail displays related to objects shown on the display (e.g., overview to detail).
☐	Process displays should provide single keystroke/click navigation to the previously viewed display(s) (e.g., a "Back" button).
☐	Process displays should provide single keystroke/click navigation to upstream and downstream process displays according to a comprehensive sequence, or sequences, of process displays within the workflow.

Accept: Yes/No		Comment:	

5.9.5. Reports

The user interface should provide the features needed to request, display, and print reports. A comprehensive process record report should be generated (per module / function i.e. Change Control, Deviation, CAPA, Customer Complaint and Audit Management) that includes all data entries made during the procedure (All required fields per workflow are stipulated within Annexure 1 - 5).

Additional required reports may include:

- Monthly and Quarterly Trend Analysis Reports per Process
- Efficiency Reports monitoring the time duration of records

Accept: Yes/No		Comment:	

5.9.6. Interfaces with other Systems

Communications to iThemba LABS's ERP system is required to access Product Names, Batch Numbers and

Vendor/Supplier Names. The intended communication mechanism will be through TCP/IP communication and will be communicated to EQMS on a daily basis to update the Database Server.

Accept: Yes/No		Comment:	

5.10. Environment

5.10.1. Location

The Database Server is located within iThemba LABS Data Centre

Accept: Yes/No		Comment:	

5.10.2. Physical conditions

- Electrical power supply should be 230 V AC, three phase and 50 Hz.
- UPS (Un-interrupted power supply) connectivity
- Temperature controlled conditions to a set-point of 16 °C
- Raised floors

Accept: Yes/No		Comment:	

6. CONSTRAINTS

6.1. Timescales and milestones

The implementation of the 6 modules within EQMS will take place in 2025.

Accept: Yes/No		Comment:	

6.2. Compatibility

- Server PC
- User Terminal PC
- LAN Components

- File Attachments compatibility to new and older versions of Adobe Acrobat pdf. Files; MS Office *.docx files; MS Excel *.xlsx files throughout product lifetime to access historical data.

Accept: Yes/No		Comment:	

6.3. Availability

6.3.1. Reliability requirements

The maximum allowable period for maintenance or other downtime will should not interrupt daily operations at the designated sites. To prevent any disruptions any scheduled maintenance should take place outside of South African Office hours to ensure all process activities can take place without interruption. Maintenance should not take longer than 12 hours at a time.

Accept: Yes/No		Comment:	

6.4. Procedural constraints

6.4.1. Regulatory and statutory obligations

Regulatory and statutory obligations should be adhered to as set out in section 4.6 (21 CFR Part 11, GMP, and ISPE GAMP 5)

6.4.2. Workflows

Ensuring that the EQMS workflows are closely configured to current working methods and workflows to minimize training requirements.

Accept: Yes/No		Comment:	

6.4.3. Training requirements

Training manual from Vendor

Accept: Yes/No		Comment:	

Roll-out to all 20 users

Accept: Yes/No		Comment:	

6.4.4. Skill

Computer literacy user skill levels

Accept: Yes/No		Comment:	

6.4.5. Licenses

Impact if reduced licenses are procured and how this will limit the workflow to key users. Workflows will require a minimum of 3 users to participate (initiator, reviewer and approver).

The total number of licenses required for the EQMS system is 20 to allow all users to work without any constraint,

Accept: Yes/No		Comment:	

Vendor agreed to grant iThemba LABS free additional licenses for first year during implementation after which the number of licenses to be finalised

Sites / Departments	Minimum Requirements for Functional Electronic EQMS	Required Licence Numbers: Validated
QUALITY	**# Users**	**# Users**
Production	3	3
Quality Control	3	3
Quality Assurance	3	3
Logistics	1	1
R&D	1	1
Procurement	1	1
Human Resources	1	1
Engineering	1	1
Radiation Safety	1	1
Admin	5	5
Total	**20**	**20**

Accept: Yes/No		Comment:	

6.5. Maintenance

Software updates and the ease thereof to update and enhance the software procured.

Expected lifetime and long-term support.

Accept: Yes/No		Comment:	

6.6. Vendor requirements

Documentation

Supply of user manuals

Supply of UAT DQ IQ OQ PQ protocols and execution thereof with the iThemba team

Accept: Yes/No		Comment:	

Services

Supply of Database server, software and hardware for installation at iThemba LABS

With the iThemba IT team setup and installation of the EQMS server

Accept: Yes/No		Comment:	

7. Life Cycle

7.1. Development

The Supplier shall provide a Quality and Project Plan as part of their proposal. The Supplier shall have a quality system in place. Internal quality procedures shall be available for the User's review. The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.

Accept: Yes/No		Comment:	

The project shall utilize the GAMP methodology when developing the system and documentation.

Accept: Yes/No		Comment:	

Testing

To describe the Supplier testing requirements e.g. via remote/VPN

Accept: Yes/No		Comment:	

The EQMS will be validated in accordance with a Validation Test Plan before the system will be commissioned.

Accept: Yes/No		Comment:	

In order to verify system performance, the Users will take part in the User Acceptance Test procedure to verify the system workflows, configurations and all features as specified in the URS.

Accept: Yes/No		Comment:	

7.2. Delivery

The EQMS system, with all options, shall be installed onto the User's Database Server and the documents listed below delivered to the User during the implementation phase and site visits.

Accept: Yes/No		Comment:	

7.3. Documentation

Installation, operation, and maintenance instruction documentation for the system shall be developed to a level that is comprehensible to a high school graduate.

Accept: Yes/No		Comment:	

The Supplier shall use the formats described in the GAMP Supplier Guide, Current Version, to produce the

documentation. The Supplier shall provide the documentation for preliminary review. The Supplier shall provide the final documentation in accordance with the agreed workflows and configurations made with final delivery.

Accept: Yes/No		Comment:	

All final documents shall be shipped with transmittals that identify them as contractually required documents.

Accept: Yes/No		Comment:	

All documents shall be in English and supplied with hard copies and electronic versions supplied in the format identified for each document:

Document	Format
Project Plan	Microsoft Projects Microsoft Word 2019(*.docx)
User Requirements Specification	Microsoft Word 2019(*.docx)
Impact/Risk Assessment	
GAP Analysis	
System Impact Assessment	
Validation Plan	
Qualification and Validation Protocols	Microsoft Word 2019 (*.docx)
Functional Specification/Requirements	Microsoft Word 2019 (*.docx)
Design Specifications	Microsoft Word 2019 (*.docx)
Hardware Installation Test	Microsoft Word 2019 (*.docx)
Operational Test	Microsoft Word 2019 (*.docx)
Operator, Maintenance and Service Manuals	Microsoft Word 2019 (*.docx)

Accept: Yes/No		Comment:	

7.4. Support

The following supporting activities will be required after acceptance:

7.4.1. Start-up Support

Training

Accept: Yes/No		Comment:	

Super User / Implementation team training on all modules within EQMS system

Accept: Yes/No		Comment:	

7.4.2. Post Start-up Support

Technical Support Telephone (Voice/modem/router/LAN connection/WIFI)

Accept: Yes/No		Comment:	

7.4.3. User Site Support

Preventative Maintenance (list maintenance contracts available)

Accept: Yes/No		Comment:	

Database Server Backups

Accept: Yes/No		Comment:	

System Improvements (supplier shall notify user of any improvements available on a regular basis)

Accept: Yes/No		Comment:	

8. RESOURCES AND PROJECT SUPPORT

8.1. Resources

The project will require a full-time Project Manager.

Accept: Yes/No		Comment:	

A resource from I.T. will be required to ensure proper installation and network configuration hardware.

Accept: Yes/No		Comment:	

During the implementation of EQMS the site's full-time support is required for the User Acceptance Testing, implementation and hand over.

Accept: Yes/No		Comment:	

The iThemba site will require an administrator to control the efficient running of the system.

Accept: Yes/No		Comment:	

Management of Change Controls

Change Control Form

Login/Initiator workflow and fields requirement

Reference number shall be configurable and may be different for individual sites and corporate office. Number shall be allocated by QA department. Numbering shall be as follows: Department code/Sequential number/Year. The numbering shall be automatic once workflow has been initiated.

Provision to enter Market/customer/country

Generation of CC number is based on the selection of department. CCR/XXX/001/2025. Where xxx is defined by PRO, QQA, QQC, ENG, TAR

Provision to enter Date of initiation.

Provision to enter Initiator name.

Provision to enter Department.

Provision to enter Title of the document.

Provision to enter Document reference number.

Provision to enter Details of change proposed:

Provision to enter the change related to: Master formula, BMR, BPR, Batch size, SOP, Specification, Test method, Facility, Utilities, Equipment, Artwork, Vendor, Product, Process and others (Multi selection).

In case of Printed Material code/ Art work change, Provision to enter Ref. Art work Revision Number.

Provision to enter details of Existing status (Option for file attachment)

Provision to enter details of Change proposed (Option for attachment)

Provision to enter details of Reason for change (Option for file attachment)

Provision to attach supporting information (Option for file attachment)

Initiator signature / date and time (electronically completed)

Provision for user to review historical data. Documents upload - Provision to select requirement of documents as supporting data (Yes/No). If yes provision of file attachment. Format of files for attachments should include pdf, jpeg and tiff. To send mail alert in advance (at least 3 working days) to document controller and QA Manager/ Designate and Factory Manager for non-completion of identified actions.

Continuous workflow requirement

Initiator to Dept. Manager to complete Review and Evaluation comments.

Form shall move Dept. Manager to QA/ EQMS Manager to complete Review, Evaluation and Assessment of the change.

Enter the classification of change like Critical, Major and Minor.

Enter the documents affected by change or new documents to be prepared as a result of change like Artwork, BMR, BPR, Specification, Test Method, Validation Docs, SOPs, Vendors list, BOM and others (Multi selection). Integrating to CAPA module.

Enter other departments whose approval and assessment is required (Multiple selection from a list).

Form shall move to all selected department managers simultaneously for their comments.

Form shall move to QA Manager/ Designate to enter the customer approval: Applicable/Not Applicable.

If customer approval is applicable, the change request (updated till this stage) shall go to customer through e-mail along with supporting data (Optional file attachment). The form stays at QA Manager/ Designate ID.

QA Manager/ Designate shall approve the change control behalf of the customer based on the supporting data/documents supplied. (Option for file attachment).

The filled form shall move to QA manager/ designate to write summary of change control, enter certification of implementation of change control.

In case of product related change final implementation date shall be entered.

To decide further requirements like Validation, Stability, additional testing and Training.

Identification of requirement of other actions triggered by the change controls e.g. other documents affected.

After completion of identified other activities, provision to review all the revised documents, activities done.

Provision to enter implemented activity details to give Implementation of change reviewed and verified comments. And closing of change control.

Form fields requirement for Initiator Department Manager

Provision to give detailed description of the Review and Evaluation (Option for file attachment).

Initiator Dept. Manager sign/date and time.

Form fields requirement for QA Manager/ Designate

Provision to give detailed description of the Review, Evaluation and Assessment

Provision to enter the documents affected by change or new documents to be prepared as a result of change like Artwork, BMR, BPR, Specification, Test Method, Validation Documents, SOPs, Vendors list, BOM and others (Multi-Selection).

Provision to identify different departments to be affected by the change for their comments (Multi-Selection)

Provision to select customer for their comments.

Provision to enter requirements for Validation, Stability, Training and others as separate fields with (Yes/No) option.

Provision to enter the certificate of implementation of change control: Proposed actions subsequent to change, Responsibility, Completed on, Ref.No. Reviewed by/date (Option for file attachment). Option to select more than one task and have each task owner notified via email

In case of Product related change, provision to enter final implementation date.

Verified by Sign. / Date

Provision to enter Validation/Qualification completed (If applicable)

Provision to enter Validation/Qualification Report No.

Verified by Sign. / Date

Training Completed (If Applicable)

Verified by Sign. / Date

Provision for Others to capture additional information.

Verified by Sign. / Date

Provision to enter Implementation of change reviewed and verified comments

Change control closing date

Manager sign/date and time with QA option

Form fields required to different Department Managers

Provision to enter comments

Department Manager sign/date and time

Form fields required to Customer (Provision shall be with QA Manager/ Designate)

Mail based task intimation is required with receiver's selection option

Provision to enter comments. (Option for file attachment)

Customer sign/date and time

References

SOP RPG-SOP-0006 Change Control Procedure

Reports

Reports generated by the system shall be configurable. (Overdue, by department, by category)

Management of Deviations

Deviation Form

Login /Initiator workflow and form fields Requirement

Initiator should have the provision to select planned deviation, unplanned deviation or Incident, based on the event.

Reference No. shall be configurable and may be different from sites to corporate office (Sequential number for Deviation and Incident e.g. DEV/001/08/2024, where DEV - deviation, 001- sequential number for deviation, 08- represents the month deviation initiated, 2024- represents the year deviation logged).

Allocation of the sequential number shall be automatically generated by the system.

Provision to enter Initiation Date from the calendar.

Provision to enter Initiator Department as drop-down menu.

Provision to enter event related to: e.g. Product /Material /Document/Equipment etc.

Provision to enter Batch No. /Lot No

Provision to enter Batch Size

Provision to enter Mfg. Date

Provision to enter Expiry Date

Provision to enter A.R. No.

Provision to enter other details (if any)

Deviation Details (Provision to give detailed description of the deviation)

Provision to attach any files/documents for reference (Option for file attachment)

Initiated by signature / date and time.

Continuous Workflow Requirement

Initiator to initiator Dept. Manager and subsequently to QA Manager. Justification/ Root Cause Investigation will be completed by Initiator and Initiator's Dept. Manager. (Option for file attachment)

Initiator dept. manager will propose the CAPA.

QA Manager / Manager shall complete assessment and approve the CAPA.

Then it shall be linked to CAPA tracking based on target completion date.

If the CAPA is proposed, for example training to be conducted then it shall be linked to the Training SOP (QA manager / Designate shall have the provision to select if it should be completed through CAPA or not).

Flow of this form to Site Responsible Pharmacist or Plant Manager for comments.

This form now moves to QA manager / Designate to directly approve or reject the deviation/incident.

If required he should have the provision to send to Regulatory /customer where applicable.

After evaluation, if customer approval is required this information shall go to the customer through mail and the supporting data shall be attached. (Option for file attachment). The e- form stays at QA Manager ID.

QA manager / Designate shall approve the deviation behalf of the customer on the basis of supporting data. (Option for file attachment)

If the CAPA is generated it is tracked through the CAPA system and an ID of the issue stays at QA Manager ID. If no CAPA is selected then the issue closes at this point.

Final closure: After implementation of the CAPA, QA manager / manager shall enter disposition comments and close the deviation.

If deviation is permanent, it shall be linked to change control management but the deviation will be closed where necessary.

Form fields requirement for Initiator dept. Manager

Field required to enter detailed description of the Justification/Root cause investigation (Option for file attachment).

Initiator Dept. Manager / Manager sign/date and time

Field required to enter detailed description of the Corrective actions proposed (Option for file attachment)

Field required to enter detailed description of the Preventive Actions Proposed (Option for file attachment)

Initiator Dept. Manager / Manager sign/date and time

Form fields requirement for QA dept. Manager / Manager

Field required to approve the Justification/Root cause investigation

QA Dept. Manager / Manager sign/date and time

Field required to enter comments and approval of the corrective actions proposed

Field required for entering comments and approval of the preventive actions proposed

QA Manager / Designate sign/date and time

Field required to enter comments (Approved/Rejected)

Field required to Approve or Reject the deviation/incident

QA Dept. Manager / Manager sign/date and time

Field required for selecting notification to: Regulatory/Customer/Contract giver/license holder (Yes/No).

Field required for entering customer Approved/Rejected comments. (Field require in the name of customer but the provision should have the QA manager / manager)

Field required to Approve / Reject the deviation/incident (on behalf of customer) (Option for file attachment).

QA Dept. manager / manager sign/date and time

Field required to enter disposition comments

Deviation/Incident closed signature/date/time

Form fields requirement for Plant Manager

Field required to enter comments on the proposed Deviation/Incident

Plant Manager sign/date and time

Form fields requirement for Customer

Field required to enter comments on the proposed Deviation/Incident

Customer sign/date and time

References

SOP DEV-010 Handling of Deviations

Reports

Reports generated by the system shall be configurable(Overdue, by department, by category)

Annexure Management of CAPA

CAPA Form

Login /Initiator work flow and form fields Requirement

Initiator should have the provision to select planned deviation, unplanned deviation or Incident, based on the event.

Reference No. shall be configurable (Sequential number for Deviation and Incident e.g. CAPA-DEPT-YYYY- XXX, where CAPA - CAPA, DEPT for drop down list YYYY - represents the year CAPA logged) XXX is the sequential number.

Allocation of the sequential number shall be automatically generated by the system.

Provision to enter Initiation Date from the calendar.

Provision to enter Initiator Department as drop-down menu.

Provision to enter event related to: e.g. Product /Material /Document/Equipment etc.

Provision to enter Batch No. /Lot No

Provision to enter Batch Size

Provision to enter Mfg. Date

Provision to enter Expiry Date

Provision to enter A.R. No.

Provision to enter other details (if any)

Deviation Details (Provision to give detailed description of the deviation)

Provision to attach any files/documents for reference (Option for file attachment)

Initiated by signature / date and time.

Continuous work flow requirement

Based on the significance respective Department Manager shall propose CAPA and target completion dates and assign responsible person.

Proposed CAPA shall move to QA Manager for approval.

QA Manager shall have the provision to evaluate and approve the CAPA.

Based on origin of CAPA, QA Manager/Designate shall have the provision to allocate the unique CAPA tracking number and this number shall be configurable.

CAPA/001/2024 where CAPA - Corrective and Preventive Action, 001=Sequential number, 2024 - shows the year CAPA initiated.

CAPA shall move to responsible person for implementation (Option for file attachment).

Implemented CAPA shall be reviewed by respective dept. Manager.

Form shall move to QA Manager for review and approval of implemented CAPA.

QA Manager shall identify the department/regulatory body/auditor to whom the communication of compliance to be sent and provision to send mail communication.

If CAPA is not completed in target completion dates, initiator dept. Manager shall request QA Manager for an extension for target completion along with justification.

QA Manager shall give comments and extend the target completion date

QA Manager sign/date.

Form field requirement for Initiator Department Manager

Provision to propose CAPA and target completion dates.

Initiator Dept. Manager sign/date

Provision to assign the work to responsible person.

Initiator Dept. Manager sign/date

Provision to review implemented CAPA.

Initiator Dept. Manager sign/date

Provision for mail alert to the department responsible person to comply with CAPA in advance to target completion date.

Provision to request to increase target completion duration.

Initiator Dept. Manager sign/date.

Form field requirement for Responsible person

Provision to complete the work in target completion dates (option for file attachment)

Responsible person sign/date

Form field requirement for QA Manager

Provision to approve the proposed CAPA

QA Manager sign/date

Provision to approve the implemented CAPA

QA Manager sign/date

Provision to approve the request/justification from initiator dept. manager to increase the duration for target completion (Option for file attachment)

QA Manager sign/date

Provision for CAPA closure

QA Manager sign/date

Provision to identify the department/regulatory body/auditor to whom the communication of compliance to be sent

Provision to send a mail communication and option for file attachment.

References

RPG SOP 0136 Corrective and Preventative Actions Procedure

Reports

Reports generated by the system shall be configurable(Overdue, by department, by category

Annexure 4 Management of Complaints

Login /Initiator workflow and form fields Requirement

Initiator should have the provision to select complaint, based on the event.

Reference No. shall be configurable and may be different from departments (Sequential number for Complaint e.g. COMP/001/08/2024, where COMP - complaint, 001- sequential number for complaint, 08- represents the month complaint received, 2024- represents the year complaint logged).

Allocation of the sequential number shall be automatically generated by the system.

Provision to enter Initiation Date from the calendar.

Provision to enter received by Function/Department as drop-down menu.

Provision to enter received from whom and how (mail, fax, call, letter)

Provision to enter sample received

Provision to enter event related to: e.g. Product /Material /Document/Equipment etc.

Provision to enter Batch No. /Lot No

Provision to enter Batch Size

Provision to enter Mfg. Date

Provision to enter Expiry Date

Provision to enter A.R. No.

Provision to enter other details (if any)

Provision for response and acknowledgement of complaint

Deviation Details (Provision to give detailed description of the complaint)

Provision to attach any files/documents for reference (Option for file attachment)

Initiated by signature / date and time.

Continuous Workflow Requirement

QA to allocate initiator Dept. Manager and subsequently to QA Manager. Justification/ Root Cause Investigation will be completed by allocated Dept. Manager. (Option for file attachment)

Allocated dept. manager will propose the CAPA.

QA Manager / Manager shall complete assessment and approve the complaint and the CAPA.

QA manager to allocate classification

Then it shall be linked to CAPA tracking based on target completion date.

References

SOP RPG-QA-012 Complaints and recalls

Reports

Reports generated shall be configurable Overdue, by department, by category

Annexure 5 Management of Audits

Login /Initiator workflow and form fields Requirement

Initiator should have the provision to select audit, based on the event.

Audits can be internal, service, vendor, regulatory type audits

Provision for Audit schedules to be uploaded.

Provision for completed audits to be uploaded.

Provision to enter Initiation Date from the calendar.

Provision to attach any files/documents for reference (Option for file attachment)

Initiated by signature / date and time.

Continuous Workflow Requirement

QA to allocate initiator Dept. Manager and subsequently to QA Manager for response and capa (Option for file attachment)

Allocated dept. manager will propose the CAPA.

QA Manager / Manager shall complete assessment and approve the audit response.

QA manager to allocate classification where applicable

Then it shall be linked to CAPA tracking based on target completion date.

References

SOP RPG-PRG 0822 Control of Internal Quality Audits

SOP RPG-SOP-0123 Vendor Inspection Audits

Reports

Reports generated shall be configurable

Annexure 6 Management of Documentation

Login /Initiator workflow and form fields Requirement

Initiator should have the provision to select document by title or number.

Provision for iThemba department numbering of documents

Documents to have a prepared by reviewed by and approved by provision

Document versions are controlled

Provision for document effective dates and expiry dates

New documents supersede previous versions with strict version control

Provision for tracking of distribution of printed copies

Withdrawal and printing of documents to have a withdrawn by and printed by and time stamp. Document to expire after 24hrs is also to be printed

Documents to be created in word and saved as pdf

Electronic signatures to be provided for document review and approval

Provision for monitoring and notification of document pending expiry date

Continuous Workflow Requirement

QA to allocate prepare, review and approve

QA Manager / Manager shall complete assessment and review.

References

RPG-SOP-0001 Control of Documentation

RPG-SOP-0003 Production Control Documents

Reports

Reports generated shall be configurable

MANDATORY QUALIFICATION TO EXECUTE THE CONTRACT

1. **Technical: The bidder provides the following as proof of being able to execute the contract to the contract terms:**
   - 1.1. Bidders must provide list (minimum three (3)) of contactable references where the bidder has successfully implemented similar systems.
   - 1.2. Bidders must provide a letter confirming that they are authorised to sell the Electronic Quality Management System on behalf of the Vendor.
   - 1.3. Bidders are required to complete the User Requirement Specifications (URS) as per specifications. If any response is NO then an alternative to meet the requirement must be stipulated by the bidder. Failure to completely respond to the URS elements will be seen negatively
   - 1.4. Presentation of the proposed systems elements from the bidders is required if 1.3 successful (met the URS).
   - 1.5. The successful bidder must agree to complete the URS again on the Quality Assurance template for validation purposes. The identical URS v 1.3 will be used

CONTRACT PERIOD

Five (5) years, with option to renew

SPECIAL CONDITIONS OF CONTRACT MANAGEMENT

Special conditions amending specific clauses of the general conditions of contract reference the specific clause in the title The General Conditions forming part of these special conditions and conditions of contract are those stated from page 53 to page 67

Project Management

The Nuclear Medicine department of iThemba LABS Cape Town is responsible for this Tender and subsequent contract. Contact details provided to the appointed service provider's Key Account Manager.

Implementation, hand over, and product management

The appointed bidder provides the delivery management as specified in the detailed specification on page 4 and on page 5 for installation and ongoing support. iThemba LABS will issue written purchase orders as a project control tool for each requirement under this contract.

Incidental Services and Spares to the subject matter of this contract (General Condition of Contract Clause No: 13 and 14)

In the event of requiring such incidental services and/or spares, it is only valid for payment when issued through the issue of a written purchase order that specifies, where applicable, quality, quantity, description, unit price, and delivery date.

Performance Verification (General Condition of Contract Clause No: 8)

The iThemba LABS appointed project manager verifies the performance of this contract with reference to the required requirements and any other element specified in this contract:

1. The appointed bidder delivers equipment including spares, upgrades meeting the specifications under this contract.
2. The appointed bidder provides services to the specification level set in this contract.
3. All performances are verified by the iThemba LABS appointed project manager.
4. Both parties signed off on performance on the verification documentation
5. Both parties agree on quantity, unit cost, and total value on the same signed document.

Contract Due Diligence during the contract period

iThemba LABS has the right to conduct supply chain due diligence. The iThemba LABS Project Team have the right to conduct site visits and inspections at any given time during the contract period.

Communication (General Condition of Contract Clause No: 31)

1. The appointed bidder communicates in writing through regular mail, physical delivery, or email.
2. The appointed bidder states the contract number and purchase order number on communication documentation.
3. The contract bidder does not act upon any communication without the contract number or must verify such communication with the iThemba LABS project manager prior to acting upon it.
4. NRF and the contracted bidder maintain all contract documentation, and communications and correspondence, etc. for record purposes.
5. Any notice, request, consent, approvals, or other communications made between the Parties pursuant to the Contract shall be forwarded to the addresses specified in the contract.
6. Any notice, request, consent, approvals or other communications made between the parties shall be given as set out hereunder and shall be deemed to have been received when:
    - 6.1. Hand delivered – on the day of delivery;
    - 6.2. Registered mail – five (5) working days after mailing;
    - 6.3. Email – one (1) working day after it has been sent

Performance Security (General Condition of Contract Clause No: 7)

1. Advance payment security:
    - 1.1. An acceptable financial performance bond is required where iThemba LABS pays an upfront deposit in excess of R 1 million to the same value as any such upfront deposit.
2. Performance security:
    - 2.1. No other performance security is required.

Packing (General Condition of Contract Clause No: 9)

Components (where applicable) must be packaged such that they prevent damage during transportation and storage.

Delivery and Documentation (General Condition of Contract Clause No: 10)

Refer to paragraph 6 of bid specification.

Payment (General Condition of Contract Clause No: 16)

Payment terms are within 30 days of receipt of an invoice issued following successful rendering of services and earlier where the invoices are accompanied by signed iThemba LABS delivery validation documents including proof of performance stating acceptance of quantity, acceptance to specification, and unit pricing in agreement with the contract and any purchase orders issued in terms of the contract.

The supplying party's invoices must meet the following minimum requirements:

1. Reference the purchase order number
2. Detailed line items as specified in purchase order
3. Include statement of account
4. Include detailed line items as specified in purchase order

It is in the interests of the appointed bidder to adhere to these to receive prompt payment.

Any losses incurred through exchange rate variations or interest charged on late payment will be charged to the appointed bidder where these costs arose from non-adherence to the above.

Warranty (General Condition of Contract Clause No: 15)

1. The warranty periods set out in GCC15.2 are 12 months.
2. The supplier shall within five business days of receipt of a warranty claim confirm the repair or replacement of the defective goods or parts has commenced.

PERFORMANCE LEVEL (General Condition of Contract Clause No: 22)

1. Service Management

1.1. The service performance levels are stated in Performance Levels Statement

1.2. The NRF measures the contracted bidder's performance against these in the execution of the contract.

1.3. The contracted parties recognize that its failure to meet the performance levels has material adverse impact on the operations of NRF and that the damage from the contracted bidder's failure to meet any performance level is not susceptible to precise determination.

2. If the contracted parties fail to meet any performance level

2.1. Both iThemba LABS and the appointed bidder shall jointly investigate and report on the root causes of the performance level failure;

2.2. Promptly correct the failure and begin meeting the set performance levels;

2.3. Advise iThemba LABS as to the extent requested by iThemba LABS of the status of remedial efforts being undertaken with respect to such performance level failure; and

2.4. Take preventive measures to prevent the recurrence of the performance level failure.

2.5. In the event of the non-performance as per the agreed contract, iThemba LABS will appoint an alternative provider at the cost of the appointed bidder. The defaulting appointed bidder is obliged to settle the damages/additional costs that iThemba LABS has incurred as result of the non-performance of the appointed bidder.

3. Termination for Default (General Condition of Contract Clause No: 23)

In the event of the non-performance as per the agreed contract, iThemba LABS will appoint an alternative provider at the cost of the appointed bidder. The defaulting appointed bidder is obliged to settle the damages/additional costs that iThemba LABS has incurred as result of the non-performance of the appointed bidder.

STATEMENT OF PERFORMANCE LEVELS

Performance being Measured	Measurement Methodology	Penalty and Trigger Level
Delivery of the specified system	Both iThemba LABS and bidder jointly check and confirm specifications are met	Penalty – GCC 22 in the general clause section Replacement of non-performing components at the bidder's own cost including transport
Timeous delivery as per delivery plan	One (1) week delay that is outside the delivery date agreed on the purchase order.	Penalty – GCC 22 in the general clause section
Timeous delivery of on-site support as per agreed date on purchase order		
Timeous delivery of spares, consumables as per agreed date on purchase order		
Response to logged call, either in-person and remote	Response to logged call, is within 10 minutes of logging the call	Penalty – GCC 22 in the general clause section

EVALUATION PROCESS

A multiple stage process, with sub-stages when required, is followed:

Administrative stage (One): (CSD registered/SBD's//Returnable document list/datasheet) Compliance with administrative and evaluation requirements as stated in Part A especially Mandatory Qualification To Execute The Contract on page 44. All bidders that fail to meet these requirements are disqualified

Technical stage (Two): Compliant bidders will be evaluated based on the technical compliance in Part A especially Mandatory Qualification To Execute The Contract on page 44.This stage may consist of multiple sub-stages as set out in Part A especially Mandatory Qualification To Execute The Contract on page 44.All bidders that fail to meet the technical minimum are disqualified from further evaluation.

Scoring stage (Three): Points are scored on the basis of Price as indicated on SBD 6.1 in accordance with the PPPFA 2000 and its 2022 Regulations.

RETURNABLE DOCUMENT CHECKLIST TO QUALIFY FOR EVALUATION

Returnable Documents	**Specification**			
(M – Mandatory); (O – Optional)	**SUBMITTED and MEETS REQUIREMENTS**		**Bid Section Reference**	**Reference to Bidder's document**
for				
Procurement Invitation (SBD 1), signed and completed.	**M**	❑ Yes ❑ No	Page 71, 84	
Bidder's Disclosure (SBD 4), signed and completed	**M**	❑ Yes ❑ No	Page 75	
Preference Points Claimed (SBD 6.1), signed and completed with B-BBEE certificate or sworn affidavit.	**O**	❑ Yes ❑ No	Page 78	
A resolution granting authority to sign documents on behalf of the company to the signatory on every document in the tender bid where required (If documents completed and signed by the Owner/Partner/Managing Director, Resolution not needed from the bidder)	**O**	❑ Yes ❑ No		
Bidder Support Due Diligence Eligibility				
Bidders must provide list (minimum three (3)) of contactable references where the bidder has successfully implemented similar systems.	**M**	❑ Yes ❑ No	Page 44	

RETURNABLE DOCUMENT CHECKLIST TO QUALIFY FOR EVALUATION

Returnable Documents	**Specification**			
(M – Mandatory); (O – Optional)	**SUBMITTED and MEETS REQUIREMENTS**		**Bid Section Reference**	**Reference to Bidder's document**
Bidders must provide a letter confirming that they are authorised to sell the Electronic Quality Management System on behalf of the Vendor.	**M**	❑ Yes ❑ No	Page 44	
Bidders are required to complete the User Requirement Specifications (URS) as per specifications. If any response is NO then an alternative to meet the requirement must be stipulated by the bidder. Failure to completely respond to the URS elements will be seen negatively	**M**	❑ Yes ❑ No	Page 44	
Presentation of the proposed systems elements from the bidders is required if 1.3 successful (met the URS).	**M**	❑ Yes ❑ No	Page 44	
The successful bidder must agree to complete the URS again on the Quality Assurance template for validation purposes. The identical URS v 1.3 will be used	**M**	❑ Yes ❑ No	Page 44	

Pricing Competition Documents

RETURNABLE DOCUMENTS CHECKLIST FOR PRICE COMPETITION

(M – Mandatory); (O – Optional)	**Submitted**		**Bid Section Reference**	**Reference to Bidder's document**
Pricing (SBD 3.2) in the format provided in this document (separate envelope)	**M**	❑ Yes ❑ No	Page 67 to 70	

BIDDER NEEDS TO KNOW

ACKNOWLEDGEMENT OF READING EACH PAGE

The bidder warrants by signature in this document that the bidder has read and accepts each page in this document including any annexures attached to this document.

CENTRAL SUPPLIER DATABASE REGISTRATION

The NRF requests bidders to register on the Central Supplier Database and to include in their bid their Master Registration Number (Supplier Number) in order to enable the NRF to verify the supplier's tax status on the Central Supplier Database.

CLARIFICATION

If the respondent wishes to clarify aspects of this request or the acquisition process, they write to the contact officials listed under the enquiries section above. The National Research Foundation distributes the response to a clarification request to all respondents that have communicated their intention to bid (i.e. briefing session attendance register) within 2 working days of receipt of the query. The National Research Foundation does not provide the origin of the request to any party.

RESPONSE PREPARATION COSTS

The NRF is not liable for any costs incurred by a bidder in the process of responding to this Bid Invitation, including on-site presentations.

COUNTER PROPOSALS

No counter proposals or variations are accepted

TWO ENVELOPE SYSTEM

The NRF, in the interests of transparent procurement, utilises the two-envelope system to minimise any form of price bias in the technical selection phase.

a) All responses must be submitted in two sealed envelopes/boxes; the first envelop/box shall have the technical, and the second envelop/box shall only have the financial response. Bidders must ensure that they do not indicate any financial information in the first envelop/box.

b) Bidders are required to package their response/Bid as follows:

- **Envelope 1-part A: Bid Forms and Compliance Response**
- **Envelope 1-part B: Technical Response (response to scope of work)**
- **Envelope 2 : Financial Proposal and Bid Submission Form**

COLLUSION, FRAUD AND CORRUPTION

Any effort by Bidder to influence evaluation, comparisons, or award decisions in any manner will result in the rejection and disqualification of the bidder concerned.

FRONTING

The NRF supports the spirit of broad based black economic empowerment and recognizes that achieving real empowerment is through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent, and legally compliant manner. Against this background, the NRF condemns any form of fronting. The NRF, in ensuring that bidders conduct themselves in an honest manner will, as part of the bid evaluation processes where applicable, conduct or initiate the necessary enquiries/investigations to determine the accuracy of the representation made in the bid documents. The onus is on the bidder to prove that fronting does not exist, should the National Research Foundation establish and notify the bidder of potential breaches. Failure to do so within a period of 7 days from date of notification will invalidate the bid/contract and may also result in the restriction of the bidder to conduct business with the public sector for a period not exceeding 10 years, in addition to any other remedies the NRF may have against the bidder concerned.

DISCLAIMERS

The NRF has produced this document in good faith. The NRF, its agents, and its employees and associates do not warrant its accuracy or completeness. The NRF makes no representation, warranty, assurance, guarantee or endorsements to any provider/bidder concerning the document, whether with regard to its accuracy, completeness or otherwise and the NRF shall have no liability towards the responding service providers or any other party in connection therewith.

GENERAL DEFINITIONS

"B-BBEE" means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);

"Bid" means a written offer in a prescribed or stipulated form in response to an invitation by the National Research

Foundation for the provision of goods or services, through price quotations, advertised competitive bidding processes or proposals;

"Contract" means the entire bid document inclusive of scope of work, specification, price conditions, price quote table, service delivery conditions, performance conditions with their key performance indicators, and general conditions when attached to the Standard Bidding Document 7.1 (SBD 7.1) which has been signed by the awarded bidder and the National Research Foundations;

"EME" means an Exempted Micro Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;

"Market Price" means tests to verify the offered prices are market related to the NRF in allowing the bidder to complete the work without risk of performance failure to the NRF and that the price provides the sustainability to the bidder.

"Proof of B-BBEE status level of contributor" means:

a. B-BBEE Status level certificate issued by an authorized body or person;
b. A sworn affidavit as prescribed by the B-BBEE Codes of Good Practice;
c. Any other requirement prescribed in terms of the B-BBEE Act.

"QSE" means a qualifying small business enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act.

Checking Tax Compliance

iThemba LABS verifies tax status as set out in the SBD 1 through the CSD and, for non-resident respondents, obtains the Confirmation of Tax Obligations letter from the South Africa Revenue Services after submitting their SBD 1 tax questionnaire to South Africa Revenue Services.

Award and Contract Signing

The NRF nominates the bidder with the highest combined score for the contract award subject to the bidder having supplied the relevant administrative documentation.

Cancellation of the Bid prior to Award

The NRF cancels the Bid Invitation prior to making an award where

a. Due to changed circumstances there is no need for the specified procurement in the document, or
b. No bids meet the minimum required specification, or
c. A material irregularity occurred in the bid process, or
d. Where the price is too low/high in comparison to the pre-bid defined market price range with no bidder prepared to negotiate the price into the determined market price range.

NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

GENERAL CONDITIONS OF CONTRACT

In this document words in the singular also mean in the plural and vice versa, words in the masculine mean in the feminine and neuter, words "department" means organs of state inclusive of public entities and vice versa, and the words "will/should" mean "must".

The National Research Foundation cannot amend the National Treasury's General Conditions of Contract (GCC). The National Research Foundation therefore appends Special Conditions of Contract (SCC) providing specific information relevant to a GCC clause that requires the addition of Special Conditions in the Special Condition of Contract Section in above in Part A.

GCC1	**Definitions - The following terms shall be interpreted as indicated:**
1.1	"**Closing time**" means the date and hour specified in the bidding documents for the receipt of bids.
1.2	"**Contract**" means the written agreement entered into between the purchaser and the supplier, as recorded in the contract form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
1.3	"**Contract price**" means the price payable to the supplier under the contract for the full and proper performance of his contractual obligations.
1.4	**"Corrupt practice"** means the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution.
1.5	**"Countervailing duties**" imposed in cases where an enterprise abroad is subsidized by its government and encouraged to market its products internationally.
1.6	"**Country of origin**" means the place where the goods were mined, grown, or produced, or from which the services are supplied. Goods produced when, through manufacturing, processing or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components..
1.7	"**Day**" means calendar day.
1.8	"**Delivery**" means delivery in compliance of the conditions of the contract or order.
1.9	"**Delivery ex stock**" means immediate delivery directly from stock actually on hand..
1.10	"**Delivery into consignees store or to his site**" means delivered and unloaded in the specified store or depot or on the specified site in compliance with the conditions of the contract or order, the supplier bearing all risks and charges involved until the supplies are so delivered and a valid receipt is obtained.
1.11	"**Dumping**" occurs when a private enterprise abroad market its goods on own initiative in the RSA at lower prices than that of the country of origin and which have the potential to harm the local industries in the RSA.
1.12	"**Force majeure**" means an event beyond the control of the supplier and not involving the supplier's fault or negligence and not foreseeable. Such events may include, but is not restricted to, acts of the purchaser in its sovereign capacity, wars, or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

GENERAL CONDITIONS OF CONTRACT	
1.13	"**Fraudulent practice**" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of any bidder, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the bidder of the benefits of free and open competition.
1.14	"**GCC**" mean the General Conditions of Contract.
1.15	"**Goods**" means all of the equipment, machinery, and/or other materials that the supplier is required to supply to the purchaser under the contract.
1.16	"Imported content" means that portion of the bidding price represented by the cost of components, parts or materials which have been or are still to be imported (whether by the supplier or his subcontractors) and which costs are inclusive of the costs abroad, plus freight and other direct importation costs such as landing costs, dock dues, import duty, sales duty or other similar tax or duty at the South African place of entry as well as transportation and handling charges to the factory in the Republic where the supplies covered by the bid will be manufactured.
1.17	"**Local content**" means that portion of the bidding price, which is not included in the imported content if local manufacture does take place.
1.18	"**Manufacture**" means the production of products in a factory using labour, materials, components, and machinery and includes other related value-adding activities.
1.19	**"Order**" means an official written order issued for the supply of goods or works or the rendering of a service.
1.20	"**Project site**", where applicable, means the place indicated in bidding documents.
1.21	"**Purchaser**" means the organization purchasing the goods.
1.22	"**Republic**" means the Republic of South Africa.
1.23	"**SCC**" means the Special Conditions of Contract.
1.24	"**Services**" means those functional services ancillary to the supply of the goods, such as transportation and any other incidental services, such as installation, commissioning, provision of technical assistance, training, catering, gardening, security, maintenance and other such obligations of the supplier covered under the contract.
1.25	"**Written**" or "**in writing**" means handwritten in ink or any form of electronic or mechanical writing.
GCC2	**Application**
2.1	These general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents.
2.2	Where applicable, special conditions of contract laid down to, cover specific supplies, services or works.
2.3	Where such special conditions of contract are in conflict with these general conditions, the special conditions shall apply**.**

GENERAL CONDITIONS OF CONTRACT	
GCC3	**General**
3.1	Unless otherwise indicated in the bidding documents, the purchaser shall not be liable for any expense incurred in the preparation and submission of a bid. Where applicable a non-refundable fee for documents may be charged.
3.2	With certain exceptions (National Treasury's eTender website), invitations to bid are only published in the Government Tender Bulletin. The Government Tender Bulletin may be obtained directly from the Government Printer, Private Bag X85, Pretoria 0001, or accessed electronically from www.treasury.gov.za
GCC4	**Standards**
4.1	The goods supplied shall conform to the standards mentioned in the bidding documents and specifications.
GCC5	**Use of contract documents and information**
5.1	The supplier shall not disclose, without the purchaser's prior written consent, the contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the supplier in the performance of the contract. Disclosure made to any such employed person is in confidence and shall extend only as far as may be necessary for purposes of such performance.
5.2	The supplier shall not make, without the purchaser's prior written consent, use of any document or information mentioned in GCC clause 5.1 except for purposes of performing the contract.
5.3	Any document, other than the contract itself mentioned in GCC clause 5.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the supplier's performance under the contract if so required by the purchaser.
5.4	The supplier shall permit the purchaser to inspect the supplier's records relating to the performance of the supplier and to have them audited by auditors appointed by the purchaser, if so required by the purchaser.
SCC5A	**Copyright and Intellectual Property** **Intellectual property** are creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, images used in commerce; and includes copyright (a legal term describing the rights that creators have over their literary and artistic works including books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings); trademark (a legal term describing a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises); and patents (a legal terms describing an exclusive right granted for an invention providing the patent owner with the right to decide how - or whether - the invention can be used by others). **Background intellectual property** is the intellectual property pertaining to this contract, created, and owned by any of the appointed parties to this contract prior to the effective date of this contract. **Contract intellectual property** is the intellectual property created by the parties to this contract for and

	in the execution of the contract. All background intellectual property (existing prior to this contract) invests in and remains the sole property of the appointed parties to this contract. Both parties disclose openly such intellectual property ownership to the parties in writing at the commencement of this contract. The supplier/ grants the purchaser a fully paid up, irrevocable, and non-exclusive licence to use its background intellectual property for the exploitation of this contract to enable the purchaser to obtain the full benefit of the appointed deliverables for this contract. The parties agree that all right, title, and interest in contract intellectual property created during the execution of this contract invests with the purchaser unless where agreed in writing to a different allocation of the ownership of the contract intellectual property as set out in the below special condition (SCC 5B). Both parties to this contract shall keep the intellectual property created during this contract confidential and shall fulfil its confidentiality obligations as set out in this document. The supplier agrees to assist the purchaser in obtaining statutory protection for the contract intellectual property at the expense of the purchaser wherever the purchaser may choose to obtain such statutory protection. The purchaser shall procure where necessary the signatures of its personnel for the assignment of its respective contract intellectual property to the National Research Foundation or as the National Research Foundation may direct, and to support the National Research Foundation or its nominee, in the prosecution and enforcement thereof in any country in the world. The purchaser irrevocably appoints the National Research Foundation to be its true and lawful agent in its own name, to do such acts, deeds, and things and to execute deeds, documents, and forms that the National Research Foundation in its discretion requires in order to give effect to the terms of this clause.
SCC5B	**Confidentiality** Each party shall be careful and diligent as not to cause any unauthorised disclosure or use of the confidential information, in particular, during the consistency of the Contract and after termination of the Contract. Without the prior consent of the other party, each party will keep confidential and will not : a. Disclose the confidential information, directly or indirectly, to any person or entity, b. Use, exploit or in any other manner whatsoever apply the confidential information for any other purpose whatsoever, other than for the execution of the contract and the delivery of the deliverables or c. Copy, reproduce, or otherwise publish confidentiality information except as strictly required for the execution of the contract. The parties shall ensure that any employees, agents, directors, contractors, service providers, and associates which may gain access to the confidential information abide by the undertakings in this clause both during the term of their associations with the recipient and after termination of their respective associations with the parties, not to a. Disclose the confidential information to any third party, or

	b. Use the confidential information otherwise than as may be strictly necessary for the execution of the contract, c. The parties shall take all such steps as may be reasonably necessary to prevent the confidential information from falling into the hands of any unauthorised third party. The undertakings set out in this clause shall not apply to confidential information, which the parties are able to prove: a. Was independently developed or in the possession of the recipient of the confidentiality information prior to its involvement with the other part; b. Is now or hereafter comes into the public domain other than by breach of this contract by any of the parties ; c. Was lawfully received by the recipient from a third party acting in good faith having a right of further disclosure and who do not derive the same directly or indirectly from the other party, or d. Required by law to be disclosed by the recipient, but only to the extent of such order and the recipient shall inform the other party of such requirement prior to any disclosure. Each party shall within one (1) month of receipt of a written request from the NRF to do so, return to the other party all material embodiments, whether in documentary or electronic form, of the confidential information including but not limited to: a. All written disclosures; b. All written transcripts of confidential information disclosed verbally; and c. All material embodiments of the contract intellectual property. The parties acknowledge that the confidential information was made available solely for the execution of the contract and for no other purpose whatsoever and that the confidential information would not have been made available, but for the obligations of confidentiality agreed to herein. Except as expressly herein provided, this contract shall not be construed as granting or confirming, either expressly or impliedly any rights, licences or relationships by furnishing of confidential information by either party pursuant to this contract. The recipient acknowledges that the unauthorised disclosure of confidential information may cause harm to the NRF. The recipient agrees that, in the event of a breach or threatened breach of confidentiality, the NRF is entitled to seek injunctive relief or specific performance, in order to obtain immediate remedies. Any such remedy shall be in addition to and not in lieu of any other remedies available at law, including monetary damages.
SCC5C	**Protection of Private Information** The supplier hereby gives the purchaser permission, in terms of the Protection of Personal Information Act 4 of 2013, to process, collect, receive, record, organise, collate, store, update, modify, retrieve, alter, consult, use, disseminate, distribute, merge, link, erase or destroy personal information received. By submitting a bid, the supplier gives its voluntary explicit consent to the terms of this special condition.
GCC6	**Patent rights**

GENERAL CONDITIONS OF CONTRACT	
6.1	The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.
GCC7	**Performance security**
7.1	Within thirty days (30) of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.
7.2	The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete his obligations under the contract.
7.3	The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms: 7.3.1 bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or 7.3.2 a cashier's or certified cheque.
7.4	The performance security will be discharged by the purchaser and returned to the supplier within thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.
SCC7	The additional terms for performance securities as detailed in Special Conditions Of Contract Management on page 44-47 are applicable.
GCC8	**Inspections, tests and analyses**
8.1	All pre-bidding testing will be for the account of the bidder.
8.2	If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the purchaser or an organization acting on behalf of the purchaser.
8.3	If there are no inspection requirements indicated in the bidding documents and contract makes no mention, but during the contract period, it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.
8.4	If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.
8.5	Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the supplier shall defray the cost in connection with these inspections, tests, or analyses.
8.6	Supplies and services referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.

GENERAL CONDITIONS OF CONTRACT	
8.7	Any contract supplies may on or after delivery be inspected, tested or analysed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies are held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies, which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.
8.8	The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract because of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.
SCC8	Additional inspection procedures as detailed in Special Conditions Of Contract Management on page 44 are applicable.
GCC9	**Packing**
9.1	The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.
9.2	The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.
SCC9	Additional packing requirements as detailed in Special Conditions Of Contract Management on page 44 are applicable.
GCC10	**Delivery and Documentation**
10.1	The supplier in accordance with the terms specified in the contract shall make delivery of the goods/services. The SCC specifies the details of shipping and/or other documents furnished by the supplier.
10.2	Documents submitted by the supplier specified in SCC.
SCC10	Additional delivery documentation requirements as detailed in Special Conditions Of Contract Management on page 44 are applicable.
GCC11	**Insurance**
11.1	The goods supplied under the contract are fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.
SCC11	Professional indemnity insurance cover in accordance with Special Conditions Of Contract Management on page 44-47 is required.

GENERAL CONDITIONS OF CONTRACT	
GCC12	**Transportation**
12.1	Should a price other than an all-inclusive delivered price be required, this shall be specified in the SCC.
GCC13	**Incidental services**
13.1	The supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC: 13.1.1 Performance or supervision of on-site assembly and/or commissioning of the supplied goods; 13.1.2 Furnishing of tools required for assembly and/or maintenance of the supplied goods; 13.1.3 Furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied goods; 13.1.4 Performance or supervision or maintenance and/or repair of the supplied goods, for a period of time agreed by the parties, provided that this service shall not relieve the supplier of any warranty obligations under this contract; and 13.1.5 Training of the purchaser's personnel, at the supplier's plant and/or on-site, conducted in assembly, start-up, operation, maintenance, and/or repair of the supplied goods.
13.2	Prices charged by the supplier for incidental services, if not included in the contract price for the goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the supplier for similar services.
GCC14	**Spare parts**
14.1	As specified in SCC, the supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the supplier: 14.1.1 Such spare parts as the purchaser may elect to purchase from the supplier, provided that this election shall not relieve the supplier of any warranty obligations under the contract; and 14.1.2 In the event of termination of production of the spare parts: 14.1.2.1 Advance notification to the purchaser of the pending termination, in sufficient time to permit the purchaser to procure needed requirements; and 14.1.2.1 Following such termination, furnishing at no cost to the purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.
GCC15	**Warranty**
15.1	The supplier warrants that the goods supplied under the contract are new, unused, of the most recent or current models and those they incorporate all recent improvements in design and materials unless provided otherwise in the contract. The supplier further warrants that all goods supplied under this contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the purchaser's specifications) or from any act or omission of the supplier, that may develop under normal use of the supplied goods in the conditions prevailing in the country of final destination.

15.2	This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.
15.3	The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.
15.4	Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.
15.5	If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take such remedial action as may be necessary, at the supplier's risk and expense and without prejudice to any other rights, which the purchaser may have against the supplier under the contract.
SCC15	The additional warranty requirements as detailed in Special Conditions Of Contract Management on page 44-47 are applicable.
GCC16	**Payment**
16.1	The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.
16.2	The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfilment of other obligations stipulated in the contract.
16.3	Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.
16.4	Payment will be made in Rand unless otherwise stipulated in SCC.
SCC16	Additional payment terms as detailed in Special Conditions Of Contract Management on page 44-47 are applicable.
GCC17	**Prices**
17.1	Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.
GCC18	**Contract amendment**
18.1	No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.
GCC19	**Assignment**
19.1	The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.
GCC20	**Subcontract**
20.1	The supplier shall notify the purchaser in writing of all subcontracts awarded under this contract if not

	already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract
SCC20	The requirements of sub-contractor management as detailed in Special Conditions Of Contract Management on page 44-47 are applicable.
GCC21	**Delays in supplier's performance**
21.1	Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.
21.2	If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.
21.3	No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.
21.4	The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.
21.5	Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.
21.6	Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without cancelling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.
GCC22	**Penalties**
22.1	Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.
GCC23	**Termination for default**

GENERAL CONDITIONS OF CONTRACT	
23.1	The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part: 23.1.1 If the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2; 23.1.2 If the Supplier fails to perform any other obligation(s) under the contract; or 23.1.3 If the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract. h
23.2	In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in suc manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.
23.3	Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.
23.4	If a purchaser intends imposing a restriction on a supplier or any person associated with the supplier, the supplier will be allowed a period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.
23.5	Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.
23.6	If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information: 23.6.1 The name and address of the supplier and / or person restricted by the purchaser; 23.6.2 The date of commencement of the restriction 23.6.3 The period of restriction; and 23.6.4 The reasons for the restriction. These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.
23.7	If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not

	less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.
SCC23	The additional terms of termination as detailed in Special Conditions Of Contract Management on page 44 are applicable.
GCC24	**Anti-dumping and countervailing duties and rights**
24.1	When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which may be due to him
GCC25	**Force Majeure**
25.1	Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.
25.2	If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event
GCC26	**Termination for insolvency**
26.1	The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.
GCC27	**Settlement of disputes**
27.1	If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.
27.2	If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.

27.3	Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.
27.4	Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.
27.5	Notwithstanding any reference to mediation and/or court proceedings herein, 27.5.1 The parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and 27.5.2 The purchaser shall pay the supplier any monies due the supplier.
GCC28	**Limitation of liability**
28.1	Except in cases of criminal negligence or wilful misconduct, and in the case of infringement pursuant to Clause 6; 28.1.1 The supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and 28.1.2 The aggregate liability of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.
GCC29	**Governing language**
29.1	The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.
GCC30	**Applicable law**
30.1	The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.
GCC31	**Notices**
31.1	Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice.
31.2	The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice
SCC31	Electronic communication, to the extent it meets the requirements of legal notices, is also permitted.
GCC32	**Taxes and duties**
32.1	A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.
32.2	A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery

	of the contracted goods to the purchaser.
32.3	No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid, the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services
SCC32A	The "tax certificate" in clause 32.3's second sentence refers to the documents specified in National Treasury Instruction Note 9 of 2017/18 applicable to public entities and departments.
GCC33	**National Industrial Participation Programme**
33.1	The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.
GCC34	**Prohibition of restrictive practices**
34.1	In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).
34.2	If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchaser, has/have engaged in the restrictive practice referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.
34.3	If a bidder(s) or contractor(s), has / have been found guilty by the Competition Commission of the restrictive practice referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

CONTRACT PART B - PRICING

PRICE SPECIAL CONDITIONS (GENERAL CONDITION OF CONTRACT CLAUSE NO: 17)

Prices

The price schedule for the bid under the contract shall not vary from the prices quoted by the service provider in their bid with iThemba LABS with the exception of any price adjustments authorized in this section.

1.	**Exceptions:** Exceptions to the clause are incidental services, changes in Value Added Tax as gazetted.	
2.	**Price Adjustment Rules:** Price adjustments and their corresponding rules for the managing of price risks on the basis of the iThemba LABS and the appointed bidder sharing the risk equally.	
3.	Additional Services – iThemba LABS may require, as determined by future operational requirements, additional services. iThemba LABS, in such event, will notify the appointed bidder of such requirements. The appointed bidder provides revised pricing detailing reasons for price variations substantiated by evidence such as manufactured country's inflation rates, technology refresh rate impacts, verifiable consumer price variations, and verified movement in exchange rates. iThemba LABS enters in negotiation on the submitted price quotation and variation reasons. iThemba LABS reserves the right to obtain three price quotes from the market to verify the submitted pricing are within such identified market price ranges.	
4.	Exchange rate prices – Where the supplied requirements are from overseas, the appointed bidder will state the portion and currency payable overseas separating local costs. iThemba LABS will only consider exchange rate variations on the identified foreign price component. The rate variation is the difference between the current exchange rate and the exchange rate ruling at the date of signing the SBD 7.1. Exchange rates are obtained from ABSA or for the www.xe.com website. iThemba LABS will verify the submitted exchange rate variation and enter into negotiation with the appointed bidder on the agreed variation.	
5.	**Ceiling Price Calculation for price competition:** iThemba LABS provides bidding estimates of quantities to allow for the calculation of a bidding price for the contract that allows an equal comparison basis equitable to all bidders for award selection.	
6.	**Commitment to Appointed Services Provider:** iThemba LABS, through the signed contract, guarantees its procurement of service from the appointed party only where the appointed party meets or exceeds the contractual performance levels.	

7.	**Contract Price Management in terms of the Contract:** iThemba LABS issues written purchase orders authorising the work as required in this contract as addendums to the contract. The purchase orders stipulate quantity, work description, delivery date, and the unit price in accordance with this contract. iThemba LABS, when issuing the written purchase order, guarantees that the funding is available for the value of that purchase order.		
8.	**Contract Price:** The cumulative value of all purchase orders issued and paid for is the total value of this signed contract at its expiry/completion date.		

Submit pricing in separate envelope (stand-alone) **SBD 3.2**	
9.	**Price Quotation Basis:** Unit prices are fully inclusive of all applicable taxes, less all unconditional discounts, and all costs to deliver the services and/or goods to the specified iThemba LABS price delivery point in terms of General Conditions of contract clauses 12, 32.1 and 32.2.
	Delivery Site iThemba LABS, Old Faure Road, Faure, Western Cape, South Africa, 7131
10.	**Calculating the Bid Price:** iThemba LABS provides bidding quantities below to bidders for calculating their bid price that allows for a fair and equal comparison equitable to all bidders for price competition and contract award selection.

PRICING SCHEDULE

No.	QTY	DESCRIPTION	UOM	UNIT PRICE	TOTAL (including VAT)
1.	1	EQMS Software licensing for 20 users	Each		
2.	1	Server hardware and peripherals	Each		
3.	1	Software licences (for operating system)	Each		
4.	1	Installation, training (Operational and Technical) and validation	Each		
5.	1	Support services Year 1	Each		
6.	1	Support services Year 2	Each		
7.	1	Support services Year 3	Each		
8.	1	Support services Year 4	Each		
9.	1	Support services Year 5	Each		
		All the five (5) year Support services should include software and hardware maintenance			
TOTAL BID PRICE INCLUSIVE OF VAT AND OTHER TAXES					

PRICES SUBJECT TO RATE OF EXCHANGE VARIATIONS

1. Please furnish full particulars of your financial institution, state the currencies used in the conversion of the prices of the items to South African currency, which portion of the price is subject to rate of exchange variations and the amounts remitted abroad.

PARTICULARS OF FINANCIAL INSTITUTION	ITEM NO	PRICE	CURRENCY	RATE	PORTION OF PRICE SUBJECT TO ROE	AMOUNT IN FOREIGN CURRENCY REMITTED ABROAD
				ZAR=		
				ZAR=		
				ZAR=		
				ZAR=		
				ZAR=		
				ZAR=		

2. Adjustments for rate of exchange variations during the contract period will be calculated by using the average monthly exchange rates as issued by your commercial bank for the periods indicated hereunder: (Proof from bank required)

AVERAGE MONTHLY EXCHANGE RATES FOR THE PERIOD:	DATE DOCUMENTATION MUST BE SUBMITTED TO THIS OFFICE	DATE FROM WHICH NEW CALCULATED PRICES WILL BECOME EFFECTIVE	DATE UNTIL WHICH NEW CALCULATED PRICE WILL BE EFFECTIVE

CONTRACT PART C - RETURNS

INVITATION TO BID (SBD 1)

Bid Number	NRF ILABS WI53/05/2025-26-1
Closing date and time	**05 December 2025: 11:00 am**

iThemba LABS recognises the date and time as recorded on its systems for closure purposes

HIGH LEVEL SUMMARY OF BID REQUIREMENTS

SUPPLY ELECTRONIC QUALITY MANAGEMENT SYSTEM (EQMS) FOR THE NUCLEAR MEDICINE DEPARTMENT AT ITHEMBA LABS, CAPE TOWN

THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7.1).

Bid response documents are deposited in the tender box situated physically at:

Physical address: iThemba LABS, Main Security Gate, Old Faure Road, Faure, 7131 **Tender box opening hours** 08:00 am till 16:30 pm **GPS Coordinates** Latitude: 34°1'56'' S Longitude: 18°43'64'' E **Dimensions of tender box opening** 300 mm x 20 mm	**Addressed as follows:** iThemba LABS Cape Town Main Security Gate Old Faure Road Faure Western Cape **7131**

Number of ORIGINAL bid documents for contract signing	**2**

Bidders must submit the above sets of original bid documents (including the bidder's response to the specification and the bidder's pricing) in hard copy format (paper document) to iThemba LABS. This serves as the original master set for the legal contract document between the bidder and iThemba LABS. The master set remains at iThemba LABS and has precedence over any other copies in the case of any discrepancies within the other sets of documents. The bidders attach the originals or certified copies of any certificates stipulated in this document to these original sets of bid documents. The signed legal contract constitutes the closure of the competitive bid/tender/request for quotation process and sets out each party's obligations for executing the contract.

Number of EVALUATION copies (Mark pages as "Evaluation Copy" and number all pages sequentially)**:**	1 electronic document as secured PDF
TWO ENVELOPE SYSTEM	**YES**

BID VALIDITY PERIOD FROM DATE OF CLOSURE		150 days	
Bidding procedure enquiries are directed in writing to:		**Technical information queries are directed in writing to:**	
Section	Supply Chain Management	Section	Nuclear Medicine
Contact person	SCM Team	Contact person	SCM Team
E-mail address	scm2@tlabs.ac.za	E-mail address	scm2@tlabs.ac.za

SUPPLIER INFORMATION					
Name Of Bidder					
Postal Address					
Street Address					
Telephone Number					
Code		Number			
Cell Phone Number					
Code		Number			
Facsimile Number					
Code		Number			
E-Mail Address					
VAT Registration Number					
Tax Compliance Status	Tax Compliance System PIN			Central Supplier Database No.	MAAA
Are you the accredited representative in South Africa for the goods /services/works offered?	❑ Yes ❑ No [If yes enclose proof]		**Are you a foreign-based supplier for the goods/services/ works offered?**	❑ Yes ❑ No [If yes, answer the questionnaire below]	

QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS	
Is the entity a resident of the Republic of South Africa (RSA)?	❑ Yes ❑ No
Does the entity have a branch in the RSA?	❑ Yes ❑ No

Does the entity have a permanent establishment in the RSA?	❑ Yes ❑ No
Does the entity have any source of income in the RSA?	❑ Yes ❑ No
Is the entity liable in the RSA for any form of taxation?	❑ Yes ❑ No

If the answer is "No" to all of the above, then it is not a requirement to register for a tax compliance status system pin code from the South African Revenue Service (SARS) and if not registered as per 2.3 below.

BID SUBMISSION

1.	Bids must be delivered by the stipulated time to the correct address. Late bid will not be accepted for consideration.
2.	All bids must be submitted on the officially provided forms or in the manner prescribed in the bid document and not retyped
3.	This bid is subject to the Preferential Procurement Policy Framework Act, 2000 and the Preferential Procurement Regulations, 2022, the General Conditions of Contract (GCC) with its special conditions of contract, and if applicable, any other legislative requirements.
4.	The successful bidder will be required to fill in and sign a written contract form (SBD 7.1).

TAX COMPLIANCE REQUIREMENTS

1.	Bidder must ensure compliance with their tax obligations.
2.	Bidders are required to submit their unique personal identification number (PIN) issued by SARS to enable the organ of the state to verify the taxpayer's profile and tax status.
3.	Application for tax compliance status (TCS) pin may be made via e-Filing through the SARS website www.sars.gov.za
4.	Bidders may also submit a printed TCS certificate together with the bid.
5.	In bids where consortia/ joint ventures/ sub-contractors are involved; each party must submit a separate TCS certificate/ PIN/CSD number.
6.	Where no TCS is available but the bidder is registered on the Central Supplier Database (CSD), a CSD number must be provided.
7.	No bids will be considered from persons employed by the state, companies with directors/close corporations connected with the bidder employed by the state.

STANDARD BIDDING DOCUMENT (SBD) 4

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest[1] in the enterprise, employed by the state?

YES/NO

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

[1] the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

2.2 Do you, or any person connected with the bidder, have a relationship with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:

……

……

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? **YES/NO**

2.3.1 If so, furnish particulars:

……

……

3 DECLARATION

I, the undersigned, (name)……. in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

3.1 I have read and I understand the contents of this disclosure;

3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;

3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium[2] will not be construed as collusive bidding.

3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the

[2] Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.

3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

…… ……

Signature Date

…… ……

Position Name of bidder

STANDARD BIDDING DOCUMENT (SBD) 6.1

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022

This preference form must form part of all tenders invited. It contains general information and serves as a claim form for preference points for specific goals.

NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

---

1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to invitations to tender:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 **To be completed by the organ of state**

a) The applicable preference point system for this tender is the 80/20 preference point system.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:

(a) Price; and

(b) Specific Goals.

1.4 **To be completed by the organ of state:**

The maximum points for this tender are allocated as follows:

	POINTS
PRICE	80
SPECIFIC GOALS	20
Total points for Price and SPECIFIC GOALS	**100**

1.5 Failure on the part of a tenderer to submit proof or documentation required in terms of this tender to claim points for specific goals with the tender, will be interpreted to mean that preference points for specific goals are not claimed.

1.6 The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the organ of state.

2. DEFINITIONS

(a) **"tender"** means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive tendering process or any other method envisaged in legislation;

(b) **"price"** means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;

(c) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

(d) **"tender for income-generating contracts"** means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and

(e) **"the Act"** means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

3.1. POINTS AWARDED FOR PRICE

3.1.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 - \frac{Pt - Pmin}{Pmin}\right) \quad \text{or} \quad Ps = 90\left(1 - \frac{Pt - P\,min}{P\,min}\right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. POINTS AWARDED FOR PRICE

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 + \frac{Pt - P\,max}{P\,max}\right) \text{ or } \quad Ps = 90\left(1 + \frac{Pt - P\,max}{Pmax}\right)$$

Where

Ps	=	Points scored for price of tender under consideration
Pt	=	Price of tender under consideration
Pmax	=	Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:

4.2. In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—

(a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or

1.

(b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system,

Then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.

Note to tenderers: The tenderer must indicate how they claim points for each preference point system and explain the relationship between the B-BBEE level and specific goals

The specific goals allocated points in terms of this tender (B-BBEE Status Level of Contributor)	Number of points allocated (90/10 system) (To be completed by the organ of state)	Number of points allocated (80/20 system) (To be completed by the organ of state)	Number of points claimed (90/10 system) (To be completed by the tenderer)	Number of points claimed (80/20 system) (To be completed by the tenderer)

1	10	20	
2	9	18	
3	6	14	
4	5	12	
5	4	8	
6	3	6	
7	2	4	
8	1	2	
Non-compliant contributor	0	0	

Broad Based Black Economic Empowerment (B-BBEE) certificate or sworn affidavit must be submitted to substantiate the points claimed on the above table

DECLARATION WITH REGARD TO COMPANY/FIRM

4.3. Name of company/firm……..

4.4. Company registration number: ……...

4.5. TYPE OF COMPANY/ FIRM

- □ Partnership/Joint Venture / Consortium
- □ One-person business/sole propriety
- □ Close corporation
- □ Public Company
- □ Personal Liability Company
- □ (Pty) Limited
- □ Non-Profit Company
- □ State Owned Company

[TICK APPLICABLE BOX]

4.6. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;

iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –

(a) disqualify the person from the tendering process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution, if deemed necessary.

…….
SIGNATURE(S) OF TENDERER(S)
SURNAME AND NAME: …….
DATE: ……
ADDRESS: ……
……
……
……

REFERENCE LETTER FORMAT FOR BIDDER

Referee Legal Name :			
Bidder's name:			
Bid Number:	NRF ILABS WI53/05/2025-26-1		
Describe the service/work, start date and completion date the above bidder provided to you below			
Criteria/Risks	**Below requirements**	**Meets requirements**	**Exceeds requirements**
Quality of rendered services as measured against your service level			
Response to support calls			
Satisfied with work done			
Overall Impression	Other comments		
Approximate value of contract			
Would you use the provider again?			❑ YES ❑ NO
Completed by:			
Signature:			
Company Name:			
Contact Telephone Number:			
Date:			

NB: The above reference letter format is optional. service provider/bidder may use their own template as long as the information

therein is in line with the one specified in the "**Due diligence of capacity and capability**" or "**Returnable documents**" tables from page 48.

BID SIGNATURE (SBD 1)

I hereby undertake to supply all or any of the goods, works, and services described in this procurement invitation to the NRF in accordance with the requirements and specifications stipulated in this Bid Invitation document at the price/s quoted. I confirm that I have satisfied myself as to the correctness and validity of my offer/bid in response to this Invitation, cover all my obligations and I accept that any mistakes regarding price(s) and rate(s) and calculations will be at my own risk. My offer remains binding upon me and open for acceptance by the NRF during the validity period indicated and calculated from the closing time of Bid Invitation. I accept full responsibility for the proper execution and fulfilment of all obligations and conditions devolving on me in terms of this Bid Invitation as the principal liable for the due fulfilment of the subsequent contract if awarded to me.

I declare that during the bidding period did not have access to any NRF proprietary information or any other matter that may have unfairly placed our bid in a preferential position in relation to any of the other bidder(s).

The following documents are deemed to form and be read and construed as part of this offer / bid even where integrated in this document:

a) Contract Part A
b) Contract Part B – Price Schedule
c) Contract Part C including annexures in support of the bid

I confirm that I am duly authorised to sign this offer/ bid response.

NAME (PRINT)	
CAPACITY	
SIGNATURE	
DATE	