National Research Foundation | iThemba LABS Laboratory for Accelerator Based Sciences

INVITATION TO BID

PROCUREMENT FOR A PROFESSIONAL SERVICE PROVIDER TO SUPPLY, DELIVER, INSTALL, AND COMMISSION AN ENVIRONMENTAL MONITORING SYSTEM FOR NUCLEAR MEDICINE DEPARTMENT AT ITHEMBA LABS.

Bidder Name:	
Bid Number:	NRF/ILABS WI53/41/2023/24
Closing Date	**15 JULY 2024**
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 **Electronic Submissions are accepted (Email to scm3@tlabs.ac.za)**
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.

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	Mr O Mxenge / Ms L Gordon	Contact person	Project Manager: Ms. Charisse Perrang
E-mail address	scm3@tlabs.ac.za	E-mail address	scm3@tlabs.ac.za

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INTRODUCTION

INTRODUCTION TO THE NRF

The National Research Foundation ("NRF") is a juristic person established in terms of the National Research Foundation Act, Act 23 of 1998, and a Schedule 3A Public Entity in terms of the Public Finance Management Act. The National Research Foundation ("NRF") as the juristic legal entity 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

The iThemba Laboratory for Accelerator-Based Sciences (iThemba LABS) is business unit of the National Research Foundation (NRF) based in Faure, Western Cape. The Nuclear Medicine Department at iThemba LABS produces sterile radiopharmaceuticals. It seeks to appoint a service provider for supply, delivery, installation, and commissioning of an environmental monitoring system to iThemba LABS in Faure, Western Cape, and support services for a period of five (5) years.

The purpose of this document is to specify the user requirements for Environmental Monitoring System for iThemba LABS in line with current legislation, iThemba LABS standards and industry best practice.

Sections 3 and 4 of this URS contain requirements which relate to current Good Manufacturing Practice (GMP) and hence will be qualified according to the regulatory requirements of Section 2.

SA Health and Safety Legislation, Good Engineering Practice (GEP) and the Purchaser's General Engineering Standards which also apply and will become contractual requirements which must be demonstrated and documented.

PART A – CONTRACT

DETAILED SPECIFICATIONS

1.1. Purpose of the URS

This User Requirement Specification (URS) covers the design, manufacture, installation, testing and documentation of an Environmental Monitoring System (EMS).

This URS will provide a basis for:

- Design, manufacture and installation of the Environmental Monitoring System.
- Definition of performance testing requirements to be undertaken by the Supplier.
- Technical basis of contractual arrangements between the Supplier and the Purchaser.

1.2. Definitions

The definitions employed in this document are as follows:

Term	Definition
Purchaser	Organisation procuring and paying for the purchase in this case iThemba LABS
Project Manager	Person responsible from supplier for the project implementation
Designer	Person responsible from supplier for the project design
Supplier	Organisation supplying the system purchased that complies with the URS
Will / Must	The words “will/ must” denotes that the requirement is mandatory.
Should	The word “should” denote that the requirement is good practice/highly recommended, but is not mandatory. Where the Supplier does not meet this requirement, it must be agreed with the Purchaser in advance.
May	“May” is used where information is provided to assist the Supplier and no requirement is implied.
Future	A future provision on the EMS for a piece of process equipment. The points to be provided and tested for the equipment are specified and are to be included as a physical installation (cabling, wall plate, labelling, terminations etc.), on the software identifying equipment and as a protocol test. The instrument is not to be provided.

Term	Definition
Spare	A future provision on the EMS for a non-specified equipment item. The point(s) is to be provided and tested for the type of instrument. The point(s) is to be included as a physical installation (cabling, wall plate, labelling, terminations etc.), on the software identifying the instrument and as a protocol test. The instrument is not to be provided.
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate.
Suite	A number of rooms grouped together to provide one single operational unit (processing rooms and accompanying PALs/MALs and hatches).

The Supplier of the EMS must adhere to the content of this document; any deviations proposed must be clearly identified and justified by the Supplier. Compliance with the agreed contents must be a contractual requirement of the purchase order and any costs associated with meeting the agreed requirements must be included in the purchase price.

Notwithstanding anything to the contrary in this specification, the Supplier must be responsible for ensuring that the EMS is "fit for purpose" and in particular for achieving the performance set forth in this specification for a manufacturing GMP facility.

1.3. Purpose and Scope of the EMS

An Environmental Monitoring System (EMS) is required to continuously monitor, log and alarm (where applicable) facility and equipment parameters including:

- Room differential and absolute pressures, temperatures, humidity and particle counts (as relevant)
- Equipment pressures, temperatures, humidity and particle counts
- Incubator temperature,
- Cold storage equipment temperatures
- Critical equipment general fault signals and status signals.

The EMS must satisfy the requirements of the following documents which will be issued to the successful bidder:

- Drawings etc

Additionally, the EMS must record all alarm conditions which may affect product quality and be able to print these for batch records. In particular, the Environmental Monitoring System is required to provide validated records of production room and equipment environments which may be recorded in Batch Manufacturing Records.

It must be notated that the rooms and equipment may be decontaminated using vaporised hydrogen peroxide (VPHP), alcohols, and chlorine-based products. The rooms and Biological Safety Cabinets (BSC) will be decontaminated on a non-routine basis, using VPHP which will be generated by mobile generators.

The system must be equipped with calibrated sensors which are separate from those used by the Building Management System (BMS) and/or the controls systems of individual process equipment where applicable.

The system must be adequately protected against loss of data due to computer system or data signal malfunction.

2. Regulatory Requirements

2.1. Design

2.1.1. EMS will be used to document a GMP environment, so design, construction and installation must comply with current Good Manufacturing Practice.

2.1.2. The EMS must be designed, supplied, installed, commissioned, tested and documented in accordance with a documented quality assurance process (provided by the Supplier) and must comply with GAMP Guidelines.

2.2. Qualification Requirements

2.2.1. The qualification process will follow the principles set out in document the FEQP, which is based on the guidance given in EudraLex Volume 4, Part 1: EU GMP Guidelines for Medicinal Products for Human and Veterinary Use: Annex 15: Qualification & Validation, and ISPE Baseline Guide Vol. 5, Commissioning and Qualification

2.2.2. With relation to software the principles of ISPE Guidance GAMP 5, A Risk Based Approach to Compliant GxP Computerized Systems and EudraLex Vol 4 Part 1, Annex 11. Note: Compliance to Eudralex Vol 4 Part 1, Annex 11 is assumed is FDA 21 CFR Part 11 can be met.

2.2.3. The EMS has been assessed as a GMP Direct Impact system and will be qualified in the following stages, against this URS

Functional Design Specification (FDS), including Software Design Specification (SDS) and Hardware Design Specification (HDS)

Design Qualification (DQ). The Validation Traceability Matrix (VTM) may be required to assist the Supplier with testable attributes

Software Factory Acceptance Test, Hardware Factory Acceptance Test (FAT)

Commissioning (Comms)

Installation Qualification (IQ)

Operational Qualification (OQ)

Performance Qualification (PQ)

Software Configuration Specification (if applicable)

Software Configuration and Functional Testing.

2.2.4. To support qualification the Supplier may provide a cross reference matrix (Validation Traceability Matrix (VTM)) between this URS document, the design specification and specific tests to be carried out during DQ, IQ and OQ. The VTM must make reference to and be compiled from the points contained in the EMS Points Schedule. Supplier may use a different matrix but it must contain all qualification elements.

2.2.5. All testing, carried out by the Supplier, of critical items will be carried out following pre-approved protocols and test sheets and witnessed by the Purchaser.

2.2.6. The Supplier is responsible for providing all necessary documentation, labour, test equipment and consumables to execute the pre-approved test protocols, including commissioning (commissioning procedure). Where test sheets need to be completed, the Supplier must follow pre-approved documentation procedures, as defined in the VMP (to be issued).

2.2.7. The Supplier must, at the DQ/VTM stage, compile a matrix in the following way:

Where “Required” is entered in the DQ row, the Supplier must replace this with a statement which confirms design compliance or not with the URS and gives a documentary reference to the Suppliers Functional Design Specification which relates to the subject.

Where “Required” is entered in the IQ row, the Supplier must replace this with a test reference from their IQ protocol.

Where “Required” is entered in the OQ row, the Supplier must replace this with a test reference from their OQ protocol.

Where n.a. is entered in any row, this may be completed with the statement “No Qualification Test Required”.

The use of “n.a.” does not mean that all commissioning tests undertaken as good engineering practice do not need to be completed.

2.2.8. Completion of test sheets / validation protocols must be completed following principles of Good Documentation Practice. The integrity of the data generated must be assured and to do so the supplier

must ensure all operators involved in execution of test procedures take responsibility for assuring they maintain the principles of ALCOA whilst completing the documentation.

2.2.9. The following table summarises the responsibilities for qualification services.

Whilst the responsibility for qualification rests with the Purchaser, the Purchaser may appoint a GMP Compliance Manager (GMPCM)/ QA Manager(QAM) to manage the processes and the documentation, but the Supplier is required to execute the documents. However, the Purchaser will witness the tests and have responsibility for final sign-off of all reports, following the advice of the GMPCM.

Responsibilities for Qualification						
	Write Protocol	**Review Protocol**	**Approve Protocol**	**Execute Protocol**	**Write Report**	**Approve Report**
Impact Assessment	GMPCM	Purchaser	Purchaser	GMPCM	GMPCM	Purchaser
FDS, HDS and SDS	Supplier	n.a.	Purchaser review only	n.a.	n.a.	n.a.
DQ (inc. VTM)	Supplier	GMPCM	Purchaser	Supplier, witness by Purchaser, Main Contractor and/or GMPCM	Supplier	GMPCM & Purchaser
FAT	Supplier	GMPCM	Purchaser	Supplier, witness by Purchaser, Main Contractor and/or GMPCM	Supplier	GMPCM & Purchaser
Comms. (i)	Supplier	GMPCM	Supplier	Supplier, witness by Purchaser and/or Main Contractor	Supplier, review by GMPCM if leveraged	GMPCM & Purchaser
IQ	Supplier	GMPCM	Purchaser	Supplier, witness by Purchaser, Main Contractor	Supplier	GMPCM & Purchaser

				and/or GMPCM		
OQ (iii)	Supplier	GMPCM	Purchaser	Supplier, witness by Purchaser, Main Contractor and/or GMPCM	Supplier	GMPCM & Purchaser
PQ	Supplier	GMPCM	Purchaser	Supplier, witness by Purchaser, Main Contractor and/or GMPCM	Purchaser	Purchaser

(i) Correctly documented Commissioning results may be leveraged into IQ and OQ by agreement. Commissioning must be undertaken to pre-approved Commissioning Procedures. The results may only be used if there is sufficient assurance provided to the Purchaser of the integrity of the data reported during commissioning. To achieve this, suppliers must ensure principles of ALCOA are applied to the documenting and reporting of any commissioning data and reports are reviewed and approved.

(ii) Performance of the EMS OQ requires all EMS instrumentation to be as a minimum commissioned with the process equipment in its final position.

3. Specific Requirements

The attributes listed below are mandatory requirements which impact on GMP and must be qualified, line by line.

3.1. Measurement Parameters

Ref.	Attribute	Required
3.1.1.	The EMS must measure room pressures to a reference point as detailed in Appendix 1 Reference Documents. The reference point must be the same for all rooms being measured. The measuring instruments, electrical and pneumatic connections, mounting plates, labelling, documentation, testing, calibration, installation and qualification are part of the EMS supply.	DQ / IQ / OQ

3.1.2.	The EMS must monitor the differential pressure between rooms as detailed in Appendix 1 Reference Documents. The values for the differential pressure between rooms may be calculated as detailed in Appendix 1 Reference Documents. Any additional measuring instrument(s) and its installation is part of the EMS supply.	DQ / IQ / OQ
3.1.3.	The EMS must monitor temperature in the rooms listed in Appendix 1 Reference Documents. These measuring instruments and their installation are part of the EMS supply.	DQ / IQ / OQ
3.1.4.	The EMS must monitor humidity in the rooms listed in Appendix 1 Reference Documents. These measuring instruments and their installation are part of the EMS supply.	DQ / IQ / OQ
3.1.5.	The EMS must monitor temperatures, in the incubators listed Appendix 1 Reference Documents. Secure connection to instruments in the incubators is part of the EMS supply.	DQ / IQ / OQ
3.1.6.	The EMS must monitor temperatures in the refrigerated storage equipment listed in Appendix 1 Reference Documents. Connection to instruments in the storage equipment is part of the EMS supply. The location of specific refrigerators may be subject to change until the end of detailed design phase.	DQ / IQ / OQ
3.1.7.	The EMS must record differential pressure in each of the pieces of process equipment compared to the room it is located within as listed in Appendix 1 Reference Documents. These measuring instruments and their connections outside the process equipment must be part of the EMS supply.	DQ / IQ / OQ
3.1.8.	The EMS must record “continuous” 0.5 µm and 5 µm particle counts (at ‘point of use’) within the process equipment when they are in ‘production’ or ‘validation’ modes, from the time of completion of a pre-production VPHP sterilisation to the completion of the batch (production or media) as listed in Appendix 1 Reference Documents. Future viable (total) particle counting must be considered.	DQ / IQ / OQ
3.1.9.	The EMS must record “continuous” 0.5 µm and 5 µm particle counts within the rooms as listed in Appendix 1 Reference Documents. When the rooms are being	DQ / IQ / OQ

	VPHP sterilised the particle counters must be switched off and protected against VPHP ingress.	
3.1.10.	The EMS needs to record air velocities under unidirectional airflow contained within process equipment. These measuring instruments and their connections outside the process equipment must be part of the EMS supply.	DQ
3.1.11.	The EMS normally logs alarms associated with process equipment. Certain process equipment can operate in three states: “in production” or “not in production” or “fault”. The EMS will receive a signal from each item of process equipment indicating its status e.g. from a volt-free contact or a software datablock. When the item of process equipment is “not in production” all associated signals will be set to skip and equipment parameters will not be checked for alarms and no values will be displayed. If the process equipment has associated particle monitoring the particle counter must be switched off upon receipt of a signal from the process equipment in the event of VPHP gassing. The schedule of equipment with this requirement is contained within Appendix 1 Reference Documents.	DQ / IQ / OQ
3.1.12.	The EMS must keep a continuous record of the time using a timer that maintains accuracy and automatically updates. This could be e.g. via an atomic clock module, communication with an external GPS clock or other method. The EMS must communicate with a clock network, maintaining synchronised time displays throughout the facility. If provided, the networked clocks will provide a digital display of time and date and will be suitable for installation as flush-mounted units in the clean room wall panel system. The clocks and their connections must be part of the EMS supply. NB: Digital GPS Based Clean Room Synchronized Clocks may be proposed as an alternative. e.g. The clocks must be installed in the rooms as detailed in Appendix 13. Room Clock Schedule.	DQ / IQ / OQ
3.1.13.	The required range and accuracy of the instrumentation and of the recorded data is given in the table below.	DQ / IQ / OQ

	*Note: The highest room to atmospheric differential pressure is expected to be +35 Pa, the lowest being -80Pa				
	Instrument	**Range**	**Accuracy**	**Precision**	
	Room Pressure	-100 to + 60 Pa	± 2 Pa	1 Pa	
	Room Temperature	0 to 50 °C	± 0.5 °C	0.1 °C	
	Room Humidity	0 to 100 %RH			
	Room and/or Incubator/Cabinet Humidity	0 to 100 %RH	± 5 %RH	1 % RH	
	Refrigerator / Freezer Temperature	-100 to +50 °C	± 0.5 °C	0.1 °C	
	Incubator Temperature**	0 to 50 °C	± 0.5 °C	0.1 °C	
	Particle Count	0 to 5000 /m^3	± 2 /m^3	1 /m^3	
	Air Velocity	0.3m/s to 5.6m/s	0.01m/s	0.005m/s	
3.1.14.	The suggested frequency of data recording is given in the table below. The frequency of recording data shall be a configurable parameter changeable by the User at the correct access level. The configurable parameter will apply to all points globally.				DQ / IQ / OQ
	Parameter	**Minimum Frequency of Date Recording**			
	Room Pressure	Every 30 seconds			
	Room Temperature	Every 30 seconds			
	Refrigerator / Freezer Temperature	Every 30 seconds			
	Incubator Temperature	Every 30 seconds			
	"Continuous" Particle Count	Depends on sample size and rate to comply with clean room standards			
	Incubator parameters	Every 30 seconds			
	Air Velocity	Every 30 seconds			
3.1.15.	Alarm levels (warning/action) must be programmable but should be set initially				DQ/IQ/OQ

<table>
<tr><td></td><td>as follows: These specifications are for initial guidance only & may be subject to alteration by the end user. All warning & action alarm limits must be reviewed and approved by the end user for inclusion in the ‘sensor table’
<table>
<tr><th>Parameter</th><th>Warning Alarm (from setpoint)</th><th>Action alarm (from setpoi</th></tr>
<tr><td>Room Pressure Differentials</td><td>± 5 Pa</td><td>± 10 Pa</td></tr>
<tr><td>Transfer Hatch Pressure Differentials (variable only active when opened)</td><td>± 7.5 Pa</td><td>± 10 Pa</td></tr>
<tr><td>Room Temperature</td><td>± 3 °C</td><td>± 5 °C</td></tr>
<tr><td>Room Humidity</td><td>± 5 %RH</td><td>± 10 %RH</td></tr>
<tr><td>Refrigerator / Freezer Temperature</td><td>± 3 °C</td><td>± 5 °C</td></tr>
<tr><td>Incubator temperature</td><td>± 1 °C</td><td>± 2 °C</td></tr>
<tr><td>Particle Count (non-viable)</td><td colspan="2">Action levels > 3,200 /m^3 for 0.5µm & >16 for 5µm</td></tr>
<tr><td>Velocity sensors</td><td>± 0.05 m/s</td><td>± 0.08 m/s</td></tr>
</table></td><td></td></tr>
<tr><td>3.1.16.</td><td>The Supplier must produce a sensor table which lists the instruments and signals connected to the EMS.
The Sensor Table must clearly indicate the specification & all alarm limits for for each instrument listed in the EMS Sensor Schedule. The Sensor Table must provide the following as a minimum:-
Instrument Tag (unique identifier)
Set point
Warning Alarm Limits
Action Alarm Limits
Equipment Tag
Room Number and Title
Location</td><td>DQ / IQ / OQ</td></tr>
</table>

	The Sensor table brings together all of the instruments and signals required as part of the EMS. For information the data is contained in the following documents:- Room and Equipment Pressures; Room Temperatures Temperature Controlled Storage; Equipment List Fault or Status Signals EMS Sensor Schedule	

3.2. System Operation

Ref	Attribute	Required
3.2.1	Isokinetic sample nozzles and Bev-a-line tubing will be installed in the process equipment and/or room(s) by the Supplier (including blanking caps for clean down using hand sprayed cleaning agents). Tubing length not to exceed 1m. The EMS Supplier must provide and install all room sampling equipment and components. Particle counting sensors in the BSC must be installed below the operating surface. In the event of VPHP gassing of either rooms and or process equipment the Supplier must recommend which option will be selected as follows: A) The EMS must include valves, which if in the particle flow path between the sampling head and particle counter, must be designed to strictly minimise particle interference, and control logic to isolate the particle counters from the process equipment and/or room(s) when they are in VPHP sterilisation mode or B) Alternatively, "VPHP resistant" particle counters may be included if these are reliable and cost effective.	DQ / IQ
3.2.2	The system must be capable of being user programmed to allow identification of equipment status: • "Enabled" – critical equipment in use • "Disabled" – critical equipment not in use • "Inactive" – no equipment attached/equipment switched off/not being monitored.	DQ / IQ / OQ

	Logging must occur for equipment identified as “Enabled” and the associated alarms should be activated when equipment has reached the specified alarm level(s). Logging must still occur even when equipment is identified as “Disabled” however; no alarms will be activated when this equipment has reached the specified alarm level(s). Logging will not be required if the particular signal/equipment is identified as “Inactive” and no alarms will be activated whether or not there is or isn’t a signal.	
3.2.3	The EMS must reveal alarm conditions occurring in all the parameters it is monitoring. These alarms must be logged and displayed at the EMS user station.	DQ / IQ / OQ
3.2.4	Alarm limits (both “warning” and “action” levels) must be programmable by the user. Alarm annunciation must differentiate between “warnings” and “actions”.	DQ / IQ / OQ
3.2.5	All alarms must be latched, i.e. Alarms can only be cleared by manual intervention at the HMI once the excursion has been corrected. Muting the annunciator must not clear the alarm.	DQ / IQ / OQ
3.2.6	Alarms relating to room and process equipment must be annunciated in the associated room by both audible and visual means. All annunciators must be provided with a ‘mute’ button.	DQ / IQ / OQ
3.2.7	Alarms relating to storage equipment must be annunciated at the HMI by both audible and visual means and be capable of relay via the Internet or telecommunications to selected members of staff.	DQ / IQ / OQ
3.2.8	The EMS must be capable of notifying at least five telephone numbers of out-of-hours alarms (does not need to specify the alarm). Telephone numbers used must be user programmable. If alarms remain unacknowledged after a configurable time period, the alarm will be annunciated at the central PC and dial the nominated mobile phones with a SMS text/automated voice message.	DQ / IQ / OQ
3.2.9	EMS audible and visual alarms must not be confusable with building fire alarms. An alarm stack must be supplied in each of the 5 cleanrooms.	DQ / OQ
3.2.10	The EMS must incorporate automatic error checking, signal out of range and transmitter failure checks.	DQ / IQ / OQ
3.2.11	The User must have the ability to programme delays before alarms are annunciated to prevent continuous instantaneous alarms on the system.	DQ / OQ

3.3. Environmental Monitoring System Components

Ref	Attribute	Required
3.3.1.	All instruments connected to the EMS and the EMS itself must be calibrated on-site in accordance with agreed national and international standards. Supplier must provide a calibration protocol for review by the Purchaser prior to commencement of calibration on site.	DQ / IQ / OQ
3.3.2	Instruments connected to the EMS must be separate from those already installed for HVAC control and indication purposes.	DQ / IQ
3.3.3	Sensing devices must be easily accessible and removable for calibration and maintenance purposes.	DQ / IQ
3.3.4	All pressure impulse and vacuum lines must be installed so that they are protected from mechanical damage, especially accidental disconnection or squashing.	DQ / IQ
3.3.5	The EMS must include vacuum pump(s) and interconnecting tubing to be used to withdraw air samples from the isolators and rooms and pass them through the particle counters at a fixed and reproducible flow rate. Air sample tubing must be specifically designed and installed so as to prevent, as far as possible, particle drop out.	DQ / IQ / OQ
3.3.6	EMS data cabling must be run in containment separate from power cable.	DQ / IQ
3.3.7	Connections to equipment must be made via plugs and sockets, so that equipment can be moved for cleaning and maintenance. Sockets to be integrated into the design of the clean room fabric and construction.	DQ / IQ
3.3.8	EMS cable marshalling panels and outstations must be located in readily accessible positions, but well away from potential sources of heat, moisture, dust or vibration. The EMS cable marshalling panels and outstations must be of a modular design so that the system may be extended in the future. Marshalling panels and outstations must not be located in clean rooms.	DQ / IQ
3.3.9	The EMS must be supplied with a dedicated UPS with capacity for 30 minutes operation. UPS to be alarmed for failure or low battery. If there are multiple locations for control cabinets with separate data acquisition modules these must be provided with control cabinet specific UPS(s).	DQ / IQ / OQ

	Standalone UPS's must be provided for the following: 1. PC Server and workstation 2. Data Acquisition Modules.	
3.3.10	All instruments and hardware components must be clearly labelled in English with their function.	DQ / IQ
3.3.11	The EMS must be a standalone system and must not be connected to any computer network in the building. (Staff remote log in must be possible to view events & alarms. At least 10 licences must be available)	DQ / IQ / OQ
3.3.12	The Supplier must provide wall plates and sockets (free issue to the specialist sub-contractor) as required for the quick disconnect of EMS equipment associated with process equipment. This will be required for cleaning, maintenance etc.	DQ / IQ
3.3.13	The components which are mounted within the cleanroom, extract air from the cleanrooms or within the isolators will be exposed to cleaning agents and vaporised hydrogen peroxide and must be suitable for regular exposure to these chemicals. This includes air samplers and particle counters which must be resistant to accidental exposure to cleaning agents and VPHP. The clean will be performed using Prochlor and Hydropure (chlorine and peroxide) disinfectant followed by IPA 70% or approved equivalent. Note that cleaning materials may change, but will be of substantially similar chemical composition.	DQ / IQ / OQ
3.3.14	The majority of EMS monitoring instruments will be located in clean rooms, therefore they must be designed and installed to minimise un-cleanable crevices and ledges. It will be preferable to have flush surface mounted transmitters in the walls, with a short cable from the sensor to a plug connection on the transmitter faceplate. If this is not possible, consideration must be given to mounting the transmitter on the back or side of the machine being monitored.	DQ / IQ
3.3.15	Instruments installed within equipment must be able to withstand the conditions during all modes of operation. This includes exposure to radiation. Where instrumentation is being offered which does not meet this requirement the Supplier must state it as a specific deviation from this URS.	DQ / IQ / OQ
3.3.16	It must be possible to calibrate the temperature probes within cold storage equipment in situ.	DQ / IQ / OQ

	This could be achieved by the provision of aluminium thermal blocks with two probe holes. One hole to be used for the EMS system temperature probe and the second probe hole to have a silicon bung inserted. This enables the calibration temperature probe to be inserted into the unused probe hole when required. The second probe hole bung would be prevented from "icing up" and would therefore facilitate calibration. The aluminium block would also provide good thermal inertia and avoids warning and alarms being raised when the door is briefly opened.	
3.3.17	The EMS supplier must liaise with equipment suppliers/purchaser to provide a secure and cleanroom compatible method of fixing sensor boxes to equipment. Flush mounting is essential. Requirements for the EMS to be specified to ensure compatibility.	DQ / IQ
3.3.18	In order to ensure complete flexibility of equipment location, each user point must be user addressable, so that every item of equipment is monitored no matter where it is physically plugged in.	DQ / IQ / OQ

3.4. HMI and Reporting Requirements

Ref	Attribute	Required
3.4.1	The central Human Machine Interface (HMI) for the EMS will be located in the Plantrooms as part of the detailed design by the Supplier, external to the clean rooms. Read Only EMS screens (Alarm Display Panels) will be repeated from the Central Unit to each of the manufacturing suites as listed in Appendix 1 Reference Documents.	DQ / IQ / OQ
3.4.2	Audible and visual alarms will be provided as listed in Appendix 1 Reference Documents or 3.1.15. The audible and visual alarms will be generated via the EMS work station/Alarm Display panel as appropriate.	DQ / IQ / OQ
3.4.3	The Central HMI for the EMS must comprise a Server-PC incorporating a RAID type hard disc drive array, DVD data writer, a minimum 30" plasma screen monitor, and a colour A4 size laser printer.	DQ / IQ
3.4.4	Alarm Display Panels in the clean rooms must be capable of being sprayed with pharmaceutical grade alcohol-based cleaners on a daily basis without degradation of the screen or electrical components.	DQ / IQ

3.4.5	Manufacturing suites may be decontaminated using Vaporised Hydrogen Peroxide. All instruments and components including display panels located within clean rooms and/or equipment must be capable of withstanding the VPHP process.	DQ / IQ
3.4.6	Access to the HMI and any other data access points must be under password control, with at least three levels. 1. Level 1 to view data, printout reports and acknowledge alarms 2. Level 2 to design reports, change alarm levels, change logging frequency and change equipment status 3. Level 3 for system maintenance and validation, including user name and password assignment and change telephone call out parameters. All changes and attempted (unauthorised and unsuccessful) changes under password authorisation must be logged.	DQ / IQ / OQ
3.4.7	The EMS server must store at least five year's data in a RAID configured disc drive.	DQ / IQ
3.4.8	All EMS encrypted data must be downloadable to DVD disc or other hard format such as a secure USB drive. The download, or back up of the data is a manual activity which will be covered by Purchaser Standard Operating Procedures.	DQ / IQ / OQ
3.4.9	All EMS data stored on DVDs/USB drives must be readable (for viewing or printing) on the system, without interrupting or overwriting any current data. However, DVD/USB data must be restorable in case of a disaster recovery.	DQ / OQ
3.4.10	All EMS data written to DVDs/USB drives must be encrypted so that it can only be read on the EMS workstation(s).	DQ / OQ
3.4.11	The EMS must be capable of analysing data into reports. Reports must be configurable as follows: • All data in a defined time period • Selected data points in a defined time period • Data Excursion reports (i.e. data outside alarm limits) for all data in a defined time period • Batch Excursion reports (i.e. data outside alarm limits) for selected data points in a defined time period, typically for a "batch" • Trend reports (selected data point over an extended period) • Comparative reports (selected data point(s) "side-by side" over a period).	DQ / OQ

3.4.12	The data recorded and stored by the EMS must not be alterable by any operator action. The EMS must maintain an audit trail of all operator, supervisor and maintenance interventions.	DQ / OQ
3.4.13	The information system components, hardware, installation and testing must comply with national and internationally recognised standards to be provided by the Supplier and agreed. Confirmation of compliance with Purchaser standards will be required as part of the Design Qualification. Supplier to provide listing of all relevant standards.	DQ / IQ / OQ
3.4.14	It must be possible to view real-time data values local to EMS probes to facilitate routine monitoring of equipment and/or set-up of probes.	DQ / OQ
3.4.15	The system must be adequately protected against loss of data due to computer system or data signal malfunction.	DQ / OQ
3.4.16	It is desirable to be able to view the HMI display screen on a portable device such as a tablet for commissioning and qualification activities.	DQ / OQ
3.4.17	All electronic signatures, data and records must be compliant with Good Documentation Practices and GxP Data Integrity guidances required for GMP manufacture.	DQ / OQ
3.4.18	Access Control - The system must have the capability to enforce access control using individual and unique, secure, user name and password combinations. The system must be configured to ensure access is controlled in this way.	DQ / OQ
3.4.19	Password length must be a minimum of 8 characters long.	DQ / OQ
3.4.20	Timeout - timeout after 15 mins of inactivity, after which the user will be required to re-enter their password to gain access to the system.	DQ / OQ
3.4.21	Password update prompts - Enforce that users change their passwords after a maximum of 90 days validity period. The system must be configured to ensure that password validity is set to 90 days.	DQ / OQ
3.4.22	Previous Passwords - The system must be configured to ensure that the previous 5 user passwords are not used when passwords are changed.	DQ / OQ
3.4.23	Obscure Passwords during entry - The system must be configured such that password entry is obscured.	DQ / OQ
3.4.24	Audit Trails - Users. The system audit trail(s) must capture the name of the User who performed the action, the date and time that the action was performed, a description of the action that was performed, the previous and new values and (where applicable) a	DQ / OQ

	reason for the change.	
3.4.25	Audit Trails – The system must be able to generate electronic audit trail(s) which independently record all operator actions that create, modify and delete electronic records. Audit trail(s) to be enabled and cannot be disabled by the operator. It must not be possible to modify audit trails.	DQ / OQ
3.4.26	Physical Access restriction – The system must have the ability to restrict access to authorised individuals using physical security measures e.g. suitable environment for server location, access restriction to room where system is located etc.	DQ / OQ
3.4.27	Input devices - If the system has inputs from electronic devices, the system must recognise those devices which are used for data input.	DQ / OQ
3.4.28	Printer - The system must allow accurate and complete paper copies (true copies) of electronic records (including audit trail(s)) to be generated.	DQ / OQ
3.4.29	Electronic record reference - The system must provide the ability to link signed paper copies of electronic records with their respective electronic records.	DQ / OQ
3.4.30	Access of Electronic Records - The system must allow electronic records (including audit trail(s)) to be accessed in human readable format.	DQ / OQ
3.4.31	Electronic Records on Portable Media - The system must allow password protected, encrypted, read only, accurate and complete electronic copies of electronic records to be generated on portable media e.g. USB port, DVD writer.	DQ / OQ
3.4.32	Electronic Backup – The system must have the ability to allow electronic records to be backed up, restored, archived, and retrieved. Supply to include all necessary items for remote access (cable, software, modem etc.).	DQ / OQ

3.5. Visual Indication of Differential Pressure, temperature, and humidity

Ref	Attribute	Required
3.5.1	Visual indication of room differential pressure, temperature and humidity is required for the Users to check the status before entering rooms. Digital readouts are required to indicate room to room differential pressure and must be located in the wall partition system flush mounted, external to the cleanroom i.e. in the Production Corridor (see Appendix 1. HMI Screen and Alarm Display Panel Schedule).	DQ / IQ/ OQ
3.5.2	The digital room to room differential pressure readouts/gauges are listed in Appendix 1.	DQ / IQ

	Visual Indication of Differential Pressure.	
3.5.3	The visual indicators for differential pressure are for indication only and do not require visual or audible alarm status. Alarm logged differential pressures are listed in Appendix 1. Room Differential Monitoring.	DQ / IQ
3.5.4	The signals for digital readouts of room to room differential pressure can be calculated from the instrumentation contained in Appendix 1. Room Absolute Pressure Monitoring. No additional instrumentation needs to be provided to fulfil this requirement.	DQ / IQ / OQ

3.6. Construction and Testing of Future Points

Ref	Attribute	Required
3.6.1	For all EMS points marked as "future" the instruments will not be supplied.	DQ / IQ
3.6.2	For all EMS points marked as "future" the infrastructure (containment, cabling, wall plates with appropriate plug in sockets, communications modules, software etc.) to use future points must be provided by the Supplier.	DQ / IQ
3.6.3	Future points will be configured, shown on mimics and will be software tested (including alarm limits) at Software FAT. Where future points are used these can be hidden for clarity until they are configured with the instrument at some time in the future.	DQ / IQ / OQ
3.6.4	The infrastructure for each "future" point will be tested at IQ to pre-approved IQ Protocols. An SOP for adding future infrastructure will be provided by the supplier detailing the mechanism on how to add additional infrastructure in the future, including naming conventions etc.	DQ / IQ
3.6.5	The intention is that the system is supplied as a "plug in and play" for future points so that the validation can be limited to the new instrument and its software configuration with alarm limits.	DQ / IQ
3.6.7	Notwithstanding specification for future requirements, the system must be supplied with 20% spare capacity in the I/O boards and software capability to allow for future unforeseen requirements. Spare capacity to be stated.	DQ / IQ

3.7. Data Integrity

Ref.	Attribute	Required

3.7.1	The EMS system generates data which is used by the purchaser to provide assurance of compliance with GMP procedures. The system should be included as part of any DIRA (Data Integrity Risk Assessment) as a future proofing conducted for the facility and based on the assessment the following principles of ALCOA should be assured if deemed appropriate.	DQ / IQ
3.7.2	The data held by the access control system must be attributable: The identity of the person completing a record should be unambiguous. The use of aliases or abridged names should only be permitted where this is consistently used, and attributable to an individual. The same alias or IT system log-in which cannot differentiate between different individuals should not be used.	DQ / IQ / OQ
3.7.3	The data held by the access control system must be legible: It should not be possible to modify or recreate data without an audit trail which preserves the original record. It is important not to forget paper records in this context. Blank forms for manual recording of data should also be controlled in a manner which prevents unauthorised re-creation.	DQ / IQ / OQ
3.7.4	The data held by the access control system must be contemporaneous: Demonstrate that the data logged and stored is obtained as the event happens.	DQ / IQ / OQ
3.7.5	The data held by the access control system must be original: Original records must preserve data accuracy, completeness, content and meaning. Metadata (data about data) is vital in this aim by enabling reconstruction of an activity – who did what, where and when.	DQ / IQ /OQ
3.7.6	The data held by the access control system must be accurate: It must ensure any data generated is accurate in terms of what happened, when, by whom and why.	DQ / IQ / OQ

4. Documentation Requirements

4.1. Documentation General

Ref	Attribute	Required
4.1.1	All documentation, including software printouts, must be in English.	DQ / IQ
4.1.2	Documentation must meet, as a minimum, the following requirements:	DQ / IQ

	• Providing all the details necessary so that the system and the design can be qualified • Providing 'as built' records and drawings. • Providing information so that standard operating and maintenance procedures can be prepared.	
4.1.3	Plant items are to be uniquely identified on cable routing diagrams.	DQ / IQ
4.1.4	The final issue by the Supplier of any piece of documentation is to be marked and certified as the 'As-built' or 'As installed' versions. The "As-built" and "As-installed" document is defined as the document which accurately represents the system at Handover, having passed through FAT, DQ, Commissioning, IQ and OQ with all documentation discrepancies cleared and final data verified.	DQ / IQ / OQ
4.1.5	The supplier must provide Operation and Maintenance Manuals and copies of all other documentation relevant to the specific EMS as required (NB: copies of a generic manual covering numerous models is not permitted).	DQ / IQ / OQ
4.1.6	The supplier must provide one paper copy and one digital copy of the Operation and Maintenance Manual relevant to all parts of the EMS including but not limited to all hardware components, software programmes, instrumentation and consumables. (NB: copies of a generic manual covering numerous models are not permitted). Digital copies must be delivered electronically or on a CDROM, DVD or read-only USB Flash-Drive and must be re-coded in industry standard software packages such as Microsoft Office, Adobe PDF and AutoCAD for drawings. For system architecture, P&ID's, layouts etc. all electronic files must be editable so that Purchaser can modify documents in the future if so required. PDF's may be used for manuals so long as the native file is also supplied of the base documents.	DQ / IQ

4.2. Supplier Documentation Package – Pre-Commissioning

Ref	Attribute	Required
4.2.1	Functional Design Specification (FDS), Software Design Specification, Hardware Design Specification, equipment and controls.	DQ / IQ
4.2.2	Design drawings and specifications for approval.	DQ / IQ
4.2.3	General arrangement and cable routing drawings.	DQ / IQ

4.2.4	Instrumentation list.	DQ / IQ
4.2.5	DQ Report, as noted in Section 2.	DQ / IQ
4.2.6	Operating and Maintenance manuals.	DQ / IQ
4.2.7	Parts list and component specifications.	DQ / IQ
4.2.8	Panel layouts and wiring diagrams.	DQ / IQ
4.2.9	For software systems: • Validation Traceability matrix (against the Functional Design Specification, this User Requirement and the system change control log) • Specification installed hardware system • Specification of installed software system • Software design logic schematic • Disaster recovery procedure (note: this procedure must be tested as part of the Site Acceptance Testing). Note that the Source Code of the installed version of software, annotated in English to be interpretable, must be available for inspection by the Purchaser if required.	DQ / IQ

4.3. Supplier Documentation Package – Post-Commissioning

Ref	Attribute	Required
4.3.1	Commissioning records.	DQ / IQ
4.3.2	Calibration certificates for installed instruments.	DQ / IQ
4.3.3	Calibration certificates for all test equipment used at any stage.	DQ / IQ
4.3.4	For software systems, software test results and report.	DQ / IQ
4.3.5	Preventative maintenance schedule and details of all required maintenance	DQ / IQ
4.3.6	Any documentation which was issued as “preliminary” or “draft” or any documentation which requires revision as a result of commissioning and testing must be certified “As Installed” and re-issued.	DQ / IQ
4.3.7	Qualification protocols for approval and executed qualification protocols and qualification reports for approval, as noted in Section 2.	DQ / IQ

5. Regulatory Focus and Glossary

5.1. GMP Requirements

The focus for this facility is for the GMP manufacture of radiopharmaceutical and radionuclides. The quality of the material, manufacturing/QC methods, documentation and facility needs to stand up to scrutiny by regulators and commercial companies in EU and US.

As defined in the URS this facility is required to comply with both EU and SA standards for the manufacturing of radiopharmaceuticals . It is anticipated that through adherence to these standards, the facility will comply with most other relevant countries e.g. Japan via the international harmonisation scheme PIC/s (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme).

The manufacture of advanced therapy medicinal products (ATMPs) must be in compliance with the principles of Good Manufacturing Practices as set out in the European Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

The following regulations are applicable:

- EU Directive 2001/83/EC, November 6 2001
- EU Regulation (EC) 1394/2007, November 13 2007
- EU Regulation (EC) 726/2004, March 31 2004
- EU Directive 2009/120/EC, September 14 2009
- EudraLex Volume 4: EU GMP Guidelines for Medicinal Products for Human and Veterinary Use: Part 1, Annex 1, Annex 2, Annex 11, Annex 13, Annex 15
- EMEA, Committee for Medicinal Product for Human Use (CHMP), London May 2008
- EU Directive 2003/94/EC, October 8 2003.
- Code of Federal Regulations Title 21 Chapter 1 Subchapter C Parts 211: cGMP for Finished Pharmaceuticals and 210 cGMP in manufacturing, processing, packing or holding of drugs, general
- FDA Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – cGMP.

5.2. Other Relevant International Standards and Guidelines

The following standards and guidelines are applicable:

- ISO 14644 “Cleanrooms and associated controlled environments”.

- ISPE Baseline Guide Vol.5, Commissioning and Qualification.
- ISPE GAMP Guides.
- MHRA Guidance GxP Data Integrity.

5.3. Quality Assurance and Qualification Documents

The qualification of the EMS should be as described by The Purchaser.

5.4. Health & Safety – Chemical and Biological

Relevant UK health and safety regulations need to be applied in relation to containment of Dangerous Pathogens (DP), Genetically Modified Organisms (GMO) and chemicals. This facility should be designed at Containment Level 2 for both DPs and GMOs.

	Source	Document Title	Type
1	Health & Safety Executive (HSE)	The Control of Substances Hazardous to Health Regulations 2002 Schedule 3. Approved Code of Practice and guidance	HSE Guidance
2		The Genetically Modified Organisms (Contained Use) Regulations 2014	HSE Guidance

5.5. Health & Safety and Environmental – Design and Construction

The design, construction and operation of the facility must comply with all current, at the time of start-up, UK health, safety and environmental statutory regulations and legislation as well as any specific requirements imposed by The Purchaser.

The following items are specified because they impact on safety, environment and/or Good Engineering Practice.

5.5.1 Mechanical and Electrical Design

5.5.1.1	The EMS components must be ergonomically designed to allow ease of use, cleaning and maintenance.
5.5.1.2	The EMS components must be easily accessible and removable for calibration and maintenance purposes.
5.5.1.3	The EMS Components must have adequate temporary protection suitable for transporting to

	site and for on-site storage and protection once installed up to and including the commissioning stage.
5.5.1.4	Major electromechanical components of the EMS must be permanently CE Marked to confirm compliance with all relevant EU Directives, and a suitable conformance certificate must be provided.
5.5.1.5	All electrical equipment, documentation and installation must comply with all UK regulations (the current edition of BS7671, IEE Wiring Regulations) and EN60204 Safety of Machinery, latest editions.
5.5.1.6	All electrical components must be contained in protective enclosures, having an Ingress Protection suitable for the installation environment. Note that components will need to withstand regular cleaning by disinfectant wipes and alcohol sprays and occasional fumigation using hydrogen peroxide vapour.
5.5.1.7	Access to electrical enclosures must only be permitted by use of a key or tools. Panel doors must be interlocked to disconnect power from exposed equipment when the door is opened. It is permissible to allow low voltage (24V) circuits to remain powered when the door is open if mains voltage equipment is strictly segregated and effectively protected from accidental contact.
5.5.1.8	All electrical circuits must be equipped with an isolation switch that completely isolates these circuits from the mains electricity supply.
5.5.1.9	Adequate short circuit protection must be installed to guard against failure of individual electrical circuits.
5.5.1.10	Clear labelling must be fitted to each fixed component and termination, labelling must correspond to that used on wiring diagrams and parts lists.
5.5.1.11	An Electrical Safety Test must be carried out and documented to confirm safe installation.

5.5.2 Site Safety

5.5.2.1	Where any site work (offloading, unpacking, moving into position, re-assembly, installation, connection to services, cleaning, commissioning, testing, calibrating etc.) is to be carried out by the Supplier or his Sub-Contractors, this will be under the direct control of the Main Contractor, although the DQC may inspect or witness the work. The Site Rules of the Main Contractor must be followed and Risk Assessments and Method Statements for the work must be submitted and

	approved before starting work. All staff working on site will be required to undergo Site Induction by the Main Contractor.

5.6. Glossary

ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
AHU	Air Handling Unit
BMS	Building Management System
DIRA	Data Integrity Risk Assessment
DQ	Design Qualification
EMS	Environmental Monitoring System
FAT	Factory Acceptance Test
FDS	Functional Design Specification
FEQP	Facility & Equipment Qualification Plan
GMP	Good Manufacturing Practices
GAMP	Good Automated Manufacturing Practice (guidance published by ISPE)
GMPCM	GMP Compliance Manager
HDS	Hardware Design Specification
HEPA	High Efficiency Particulate Air (filter)
HMI	Human Machine Interface
HVAC	Heating, Ventilation and Air Conditioning
IT	Information Technology
IQ	Installation Qualification
MAL	Materials Airlock
BSC	Biological Safety Cabinet
OQ	Operation Qualification
PAL	Personnel Airlock
PQ	Performance Qualification
QC	Quality Control
n.a.	Not Applicable
R	Required
RAID	Redundant Array of Independent Discs: allows for storing of data redundantly, increasing fault tolerance and data integrity

SDS	Software Design Specification
TBA	To Be Advised or To Be Agreed
UPS	Uninterruptible Power Supply
URS	User Requirement Specification
VPHP	Vapour Phase Hydrogen Peroxide
VTM	Validation Traceability Matrix

APPENDIX 1. Referenced Documents

The following documents are reference documents to be read in conjunction with this URS document.

Document No	Document Title	Source
URS-1001-01	EMS Schedule	iThemba LABS
URS-1001-02	Additional instruments	iThemba LABS
URS-1001-03	Schematics	iThemba LABS
URS-1001-04	Specifications as per RPG-SPE-0017	iThemba LABS
URS-1001-05	HMI and Alarm Panels	iThemba LABS
URS-1001-06	DP Temp and RH displays	iThemba LABS

Appendix 1: Referenced Documents

URS 1001 – 01 EMS schedule

Items	Description	Number	Site
OPC	CliMET, Hiac, Metone	3	BSC CR 1
		2	Background CR1
		3	BSC CR 2
		2	Background CR2
		2	CR2 Prep
		1	BSC CR 3
		2	Background CR3
		1	Micro ISO 5

DP Pass Through	DP for Passthrough hatches	8	1,2,3,4,5 – clean rms
DP for rooms	+30Pa	5	CR 1,2,3,M, R&D “B”
DP for rooms	-40Pa	3	Gen area
DP for rooms	+35Pa	5	CR 1,2,3,M, R&D “B”
DP for rooms	-80Pa	3	D11, hot cell, Na lab
DP for rooms	+20Pa	5	CR 1,2,3,M, R&D “C”
HMI	Touch panel	3	CR 1, 2, 3
T&H sensors	Temp and Humidity	35	CR1, 2, 3 and passages
DP T RH Dispalys	Digital displays	17	As per Appendix 1
Time clocks	Digital time display	4	CR 1, 2, 3 N15
Electrical cabinet	In technical room	1	Control Room
Scada PC	In control room	1	Control Room

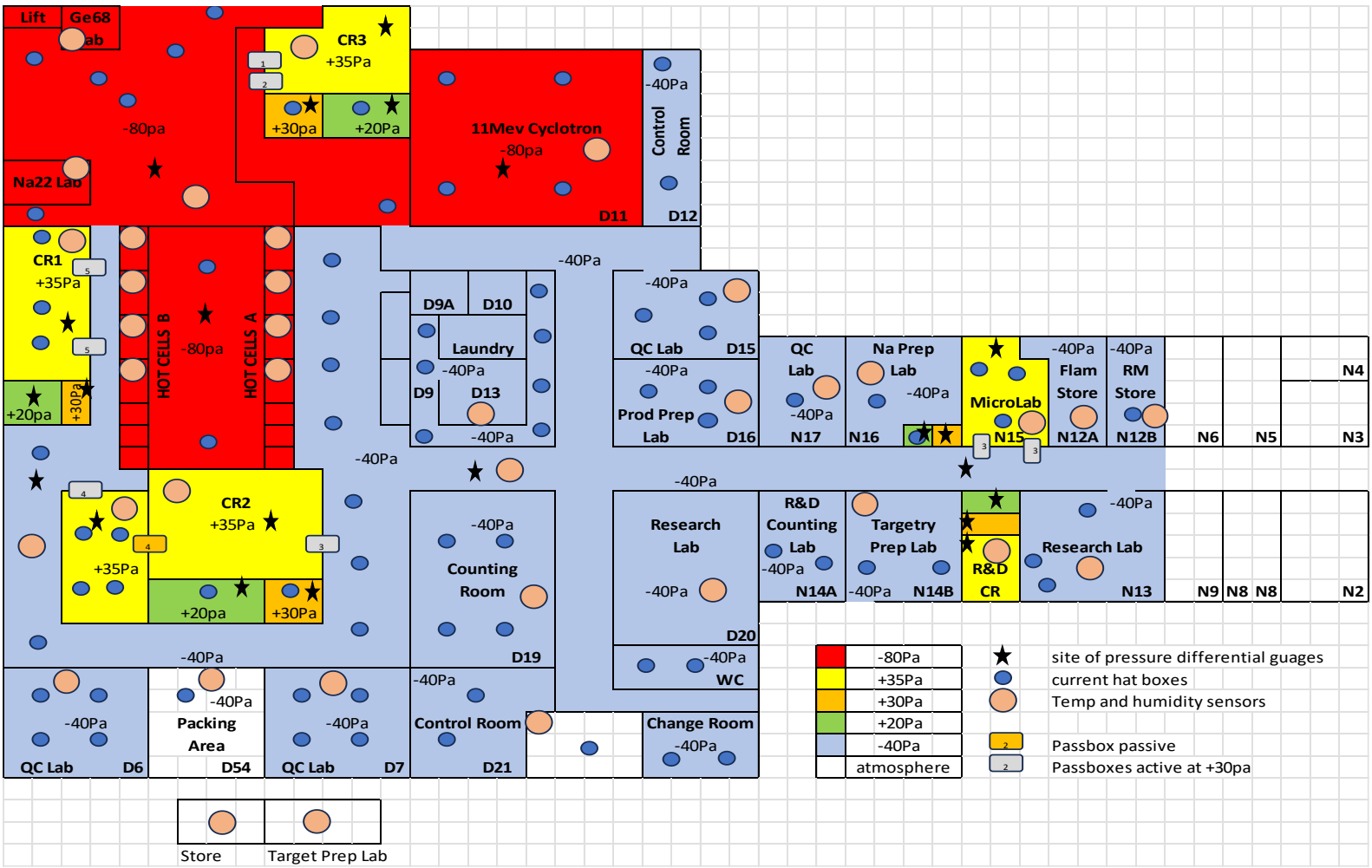
Appendix 1: Referenced documents

URS 1001 – 02 Additional Equipment

Equipment	**Device**	**Output**	**Location**
Autoclave	Temperature	1	D9
	Pressure	1	
Autoclave	Temperature	1	CR2 Prep
	Pressure	1	
Purified Water	TOC	1	CR2 Prep
	Conductivity	1	CR2 Prep
Oven forced convection Esco isotherm 100 - 180^{o}C	Temperature	1	CR2
Hot Air Oven Memmert U25 100 - 180^{o}C	Temperature	1	N16
Hot Air Oven Memmert U26 100 - 180^{o}C	Temperature	1	D6
Vacuum Oven Memmert VO400 100-180 ^{o}C,	Temperature	1	CR2
Vac -20mbar	Vacuum	1	
Vacuum Oven MRC 1430DIG 100-180 ^{o}C,	Temperature	1	N14
Vac -20mbar	Vacuum	1	

Furnace Carbolite CWF 200 – 850°C	Temperature	1	D27
Furnace Labcon RM4 200-850°C	Temperature	1	D20
Incubator 22.5 +- 2.5°C	Temperature	1	N15
Incubator 32.5 +- 2.5 °C	Temperature	1	N15
Incubator Attest 118 60-65°C	Temperature	1	N15
Fridge 5 +- 3°C	Temperature	1	N15
Freezer -20+-5°C Defy	Temperature	1	CR3
Freezer -20 +- 5°C Bosch	Temperature	1	N15
Freeze Drier Edwards Modulyo 2501 -20 to -50°C	Temperature	1	N14
Vac 6x10^{-2} mbar	Vacuum	1	

Appendix 1: Referenced Documents URS 1001 – 03 Schematics (not to scale)



Appendix 1: Referenced Documents URS 1001 – 04

Parameter	Range
Air change Rates	30ACPH
Pressure differential Grade B to B*	0-5pa
Pressure differential Grade B to C*	10-15pa
Pressure differential Grade C to D*	55-65pa
Temperature	19-23^{o}C
Humidity	45-60%
White Blue and Red areas**	
* refer to schematic URS 1001-03	
** refer to schematic URS 1001-03	

Appendix 1: Referenced Documents URS 1001 – 05 HMI and Alarm Panels

HMI and Alarm Panels	Location
HMI	Cleanroom 1
HMI	Cleanroom 2
HMI	Cleanroom 3
HMI	Cleanroom Micro
HMI	Cleanroom R&D

Appendix 1: Referenced Documents URS 1001 – 06 Digital displays

Digital displays for DP, Hum, Temp	Location
Cleanroom 1 to passage	Outside Grade C gowning of CR1
Cleanroom 1 B gowning to passage	Outside Grade C gowning of CR1
Cleanroom 1 C gowning to passage	Outside Grade C gowning of CR1
Cleanroom 2 to passage	Outside Grade C gowning of CR2
Cleanroom 2 B gowning to passage	Outside Grade C gowning of CR2
Cleanroom 2 C gowning to passage	Outside Grade C gowning of CR2
Cleanroom 2 prep to passage	Outside Grade C gowning of CR2
Cleanroom 3 to passage	Outside Grade C gowning of CR3
Cleanroom 3 B gowning to passage	Outside Grade C gowning of CR3
Cleanroom 3 C gowning to passage	Outside Grade C gowning of CR3
Microlab Cleanroom	Outside Grade C gowning of Micro
Microlab B gowning to passage	Outside Grade C gowning of Micro
Microlab C gowning to passage	Outside Grade C gowning of Micro
R&D Cleanroom	Outside Grade C gowning of R&D
R&D B gowning to passage	Outside Grade C gowning of R&D
R&D C gowning to passage	Outside Grade C gowning of R&D
Production Block to atmosphere	Outside entrance to Production

BIDDER'S DUE DILIGENCE OF ITS CAPACITY AND CAPABILITY

1. **The bidder provides as a minimum the following documents for conducting due diligence on the bidder, its capability to execute the contract to the contract terms:**
   1.1. Provide Functional Specification for the proposal that meets the specified requirements.
   1.2. Provide Design Specification for the proposal that meets the specified requirements

CONTRACT PERIOD

Installation date will be confirmed to the appointed Service Provider and must happen during shutdown period which will be 22 July 2024 till 23 August 2024.

The appointed Service Provider will be responsible for the maintenance, servicing (**but not limited to**) of EMS for the period of five (5) years.

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 **Error! Bookmark not defined.** to page 57

Project Management

The Nuclear Medicine department of iThemba LABS Cape Town is responsible for this Tender and subsequent contract.

Implementation, hand over, and product management

The appointed bidder provides the delivery management as specified in the detailed specification. iThemba LABS will issue purchase orders as a project control tool and will monitor the execution of the schedule until the purchase order requirements are received on site.

Incidental Services (General Condition of Contract Clause No: 13)

In the event of requiring incidental services, it is only valid if confirmed 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 manages all project activities and processes in accordance with accepted industry practice.
2. The appointed bidder will deliver to the site any deliverable required under this contract.
3. Both parties agree on quantity, unit cost, and total value on the same signed document.

Inspections, tests, and analyses (General Condition of Contract Clause No: 8)

The contractor shall carry out all the comprehensive tests, inspections, and checks required for the issuance of the Certificate of Analysis upon delivery of the items.

Contract Due Diligence during the contract period

iThemba LABS has the right to conduct supply chain due diligence. The iThemba LABS Project manager 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)

The appointed bidder communicates in writing through regular mail, physical delivery, or email. The appointed bidder states the contract number and purchase order number on communication documentation. 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.

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

An acceptable financial performance bond is required where iThemba LABS pays an upfront deposit over an amount of R 1 million to the same value as any such upfront deposit. 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.

Payment (General Condition of Contract Clause No: 16)

Payment terms are within 30 working days of receipt of an invoice issued following successful delivery 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.

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.

Prices (General Condition of Contract Clause No: 17)

The price schedule for the under the contract shall not vary from the prices quoted by the supplier in his/her 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, exchange rates and spare parts.
	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.
		Replacement components –iThemba LABS may consider price variations at the anniversary of the contract. The contract bidder provides detail reasons for price variations substantiated by evidence such as manufacturer's increase letters, verifiable consumer price variations. iThemba LABS enters in negotiation on the submitted price variations. iThemba LABS reserves the right to obtain three price quotes from the market to verify the submitted price variations are within such identified market price ranges.
		Additional Parts and Components – iThemba LABS may require, as determined by future operational requirements, additional parts and components. 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.
		Exchange 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. The supplier is not responsible for custom duties or import taxes associated with any component imported into South Africa.
	3.	**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.
	4.	**Commitment to Appointed Services Provider:** iThemba LABS, through the signed contract, guarantees its procurement of the equipment and service from the appointed party only where the appointed party meets or exceeds the contractual performance levels.
	5.	**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.
	7.	**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.

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.

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

If the appointed bidder fails to meet any performance level:

a) Both iThemba LABS and the appointed bidder shall jointly investigate and report on the root causes of the performance level failure;
b) Promptly correct the failure and begin meeting the set performance levels;
c) 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
d) Take preventive measures to prevent the recurrence of the performance level failure.
e) 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 services	Both iThemba LABS and bidder jointly check and confirm specifications are met	Penalty – Replacement of incorrect items and transport cost paid by bidder
Timeous delivery	Project completion delay exceeding 2 weeks from the contractual period agreed upon between both parties.	Penalty – GCC 22 in the general clause section
Technical Specifications and adherence to full tender documents	Compliance with the technical specifications and quality requirements of service to those stipulated in the tender documents.	Penalty – No payment will be made as stipulated on GCC16.2. iThemba LABS may also consider termination of the contract as stipulated on GCC23.1.

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. All bidders that fail to meet these requirements are disqualified from further evaluation.

Technical stage (Two): Compliant bidders will be evaluated based on the technical compliance in Part A. This stage may consist of multiple sub-stages as set out in Part A. 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**		**Bid Section Reference**	**Reference to Bidder's document**
Bidder Legislative Due Diligence Eligibility				
Procurement Invitation (SBD 1), signed and completed.	**M**	❑ Yes ❑ No	Pages 60 to 64, and 71	
Bidder's Disclosure (SBD 4), signed and completed	**M**	❑ Yes ❑ No	Pages 64 to 67	
Preference Points Claimed (SBD 6.1), signed and completed with B-BBEE certificate or sworn affidavit.	**O**	❑ Yes ❑ No	Page 67	
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)	**M**	❑ Yes ❑ No	Page 71	

RETURNABLE DOCUMENT CHECKLIST TO QUALIFY FOR EVALUATION

Returnable Documents	**Specification**			
(M – Mandatory); (O – Optional)	**Submitted**		**Bid Section Reference**	**Reference to Bidder's document**
Bidder Capability due diligence				
Portfolio of previous projects (more than 5 million) within the last five years	**M**	❑ Yes ❑ No		
Minimum of three written reference letters (signed and dated) from previous clients	**M**	❑ Yes ❑ No		
Provide Functional Specification for the proposal that meets the specified requirements.	**M**	❑ Yes ❑ No	Page 35	
Provide Design Specification for the proposal that meets the specified requirements	**M**	❑ Yes ❑ No	Page 35	
Qualifications of installing personnel	**M**	❑ Yes ❑ No		

Pricing Competition Documents				
(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 57 to 60	

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 are accepted as this is a request for quotation of supplies.

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**

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;

"B-BBEE status level of contributor" means the B-BBEE status of an entity 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;

"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;

"Broad-Based Black Economic Empowerment Act" means the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);

"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.

"Functionality" means the ability of a bidder to provide goods or services in accordance with specifications including quality that deliver the set levels of performance functionality as set out in the bid documents.

"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.
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.**
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 appointed supplier/party 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 appointed supplier/party 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 appointed supplier shall procure where necessary the signatures of its personnel for the assignment of its respective contract intellectual property to the Purchaser or as the Purchaser may direct, and to support the Purchaser or its nominee, in the prosecution and enforcement thereof in any country in the world. The appointed supplier/party irrevocably appoints the Purchaser 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 Purchaser 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 both during the term of their associations with the parties 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 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 other party to do so, return to the 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 Personal 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**
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**

GENERAL CONDITIONS OF CONTRACT	
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.
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.
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.

GENERAL CONDITIONS OF CONTRACT	
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.
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 35 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.
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 to the value of R7 million shall be required.
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.
15.3	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.
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.

GENERAL CONDITIONS OF CONTRACT	
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 35 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
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**
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 such 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.
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.
SCC27	The appointment of a mediator and the procedure shall be agreed between the parties. Regardless of the outcome of a mediation the parties shall bear their own costs concerning the mediation and equally share the costs of the mediator and related expenses.
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**

GENERAL CONDITIONS OF CONTRACT	
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 the second sentence of clause 32.2 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.

PART B - PRICING

Submit pricing in separate envelope (stand-alone) **SBD 3.2**	
1.	**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.
	Price *Delivery* Points are: iThemba LABS, Old Faure Road, Faure, Western Cape, South Africa, 7131
2.	**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.
3.	**Price Adjustment Rules:** The rules for allowable price adjustments as stipulated in section SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 35-38 are applicable.
4.	**Pricing:** Any reference to manufacturers' names, trade names, brand names, information and/or catalogue numbers / part numbers listed in a specification or BOM are for information and not intended to limit competition. If tenders are based on equivalent products, please indicate on the tender form the manufacturer's name and part number. Tenderers must submit with proposals datasheets with clear description and/or complete specifications of the equivalent product. iThemba LABS reserves the right to determine acceptance of item(s) as an approved equivalent.
5.	**Application of Preference Points:** Pricing is subject to the addition of Preference Points as stipulated below - Standard Bidding Document 6.1 Preference claim form.

PRICING SCHEDULE

Items	Description	Total	Quantity	Site	UNIT PRICE	TOTAL (including VAT)
1. OPC	CliMET, Hiac, Metone		3	BSC CR 1		
			2	Background CR1		
			3	BSC CR 2		
			2	Background CR2		
			2	CR2 Prep		
			1	BSC CR 3		

			2	Background CR3		
			1	Micro ISO 5		
			1	Micro Background		
			1	R&D iso 5		
		19	1	R&D background		
2. DP Pass Through	DP for Passthrough hatches		8	1,2,3,4,5 – clean rms		
3. DP for rooms	+30Pa		5	CR 1,2,3,M, R&D “B”		
4. DP for rooms	-40Pa		3	Gen area		
5. DP for rooms	+35Pa		5	CR 1,2,3,M, R&D “B”		
6. DP for rooms	-80Pa		3	D11, hot cell, Na lab		
7. DP for rooms	+20Pa	29	5	CR 1,2,3,M, R&D “C”		
8. HMI	Touch panel	3	3	CR 1, 2, 3, M, R&D		
9. T&H sensors	Temp and Humidity	37	37	CR1, 2, 3 and passages		
10. DP T RH Displays	Digital displays	17	17	As per Appendix 1		
11. Time clocks	Digital time display	5	5	CR 1, 2, 3 N15, R&D		
12. Electrical cabinet	In technical room	1	1	Control Room		
13. Scada PC	In control room	1	1	Control Room		
14. Alarm Stacks	OPC alarm stacks	11	11	CR 1,2,3, m, r&d, and background areas		
15. Annual service and qualifications (all units from number 1 to 14 of the pricing schedule)			5 Years			
16. Software updates for EMS			5 Years			

17. Repairs and spare parts (Provisional sum)				15% of the Total Bid Price **		

TOTAL BID PRICE INCLUSIVE OF VAT AND OTHER TAXES (EXCLUDING 25% PROVISIONAL SUM)	R
TOTAL BID PRICE INCLUSIVE OF VAT AND OTHER TAXES (INCLUDING 25% PROVISIONAL SUM)	R

Bidders are required to provide a list of critical spares as well callout fee, hourly rate and travelling fees (if applicable).

****On line 17 of the pricing schedule, the bidder must include 15% of bid price as provisional sum.**

Formula: ***[sum of item 1 to item 16] multiplied by 15%.***

PART C - RETURNS

INVITATION TO BID (SBD 1)

Bid Number	NRF/ILABS WI53/41/2023/24
Closing date and time	**15 JULY 2023**

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

HIGH LEVEL SUMMARY OF BID REQUIREMENTS

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	**1**

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.

Optional Briefing session

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	
BRIEFING SESSION OR SITE VISIT DETAILS			
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	Mr O Mxenge / Ms L Gordon	Contact person	Project Manager: Ms. Charisse Perrang
E-mail address	scm3@tlabs.ac.za	E-mail address	scm3@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

B-BBEE Status Level Verification Certificate	Tick Applicable Box. ❑ Yes ❑ No	**B-BBEE Status Level Sworn Affidavit**	Tick Applicable Box. ❑ Yes ❑ No

[A B-BBEE status level verification certificate/ sworn affidavit (for EMEs & QSEs) must be submitted in order to qualify for preference points for B-BBEE – also refer to the SBD 6.1]

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]

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

[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.

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**

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

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**

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

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.*)**

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: ……

……

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) Part A
b) Part B – Price Schedule
c) 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	