INVITATION TO BID

SUPPLY, DELIVERY, INSTALLATION AND COMMISSIONING OF RADIOPHARMACEUTICAL STERILITY TESTING AND RADIOPHARMACEUTICAL DISPENSING ISOLATORS INCLUDING MAINTENANCE TO ITHEMBA LABS IN FAURE, WESTERN CAPE, FOR A PERIOD OF FIVE (5) YEARS

Bidder Name:	
Bid Number:	NRF/ILABS 70IS/67/2022/23
Closing Date	**26 April 2023**
Closing Time:	11:00 am
Briefing session	**14 April 2023 at 11h00am** (See section **BRIEFING SESSION OR SITE VISIT DETAILS** on page 58)
Bid Box Address	Tender Box, Main Security Gate, iThemba LABS, Old Faure Road, Faure Western Cape, 7131, South Africa GPS coordinates: 34.025°S 18.716°E Dimensions of tender box opening: 300 mm x 20 mm
Envelope Addressing	On the face of each envelope, the Bid Number and Bidder's Name, Postal Address, Contact Name, Telephone Number and email address mail.

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 an arm of the National Research Foundation (NRF) which specializes in atomic particle acceleration based in Faure, Western Cape.

iThemba LABS intends to install a cGMP compliant Sterility and dispensing Isolators for the aseptic sterility testing of sterile radiopharmaceuticals.

The dispensing isolators will be installed in a grade B cleanroom, with all the required utilities to service the equipment. The isolators will operate at a negative pressure to avoid radioactive contamination of environment and operator. The equipment will be loaded with all the necessary tools, consumables and vials thereafter the unit and contents will be sterilised with vaporized H202. During operation the isolator will maintain Grade A conditions with first air protection in the critical zone and unidirectional airflow that sweeps over and away from exposed products during processing. Viable and non-viable monitoring will take place during operations. The decontamination cycles will run automatically once

selected. All critical information will be recorded printable and available for review.

Definitions & Abbreviations

- GMP Good Manufacturing Practice
- GEP Good Engineering Practice
- GAMP Good Automated Manufacturing Practices
- WHO World Health Organisation
- MCC Medicines Control Council
- PIM Pharmaceutical Inspection Convention and Co-operation Scheme
- USP Unites States Pharmacopeia
- EU European Union
- OHSA Operational, Health & Safety Act
- PLC Programmed Logic Controller
- SCADA Supervisory Control and Data Acquisition
- QA Quality Assurance
- SANS South African National Standards
- SAHPRA South African Health Products Regulatory Authority
- PIC/S Pharmaceutical Inspection Co-operation Scheme
- FAT Factory Acceptance Test
- IQ/OQ/PQ installation qualification, operational qualification and performance qualification, respectively.

PART A – CONTRACT

DETAILED SPECIFICATIONS

1. Bidder Responsibility

The appointed bidder is responsible for the delivery of the entire project and the management of maintenance thereafter for five years.

The bidders must design, manufacture and install suitable air ducting in order to connect the isolators to an existing air extraction system of the facility.

The bidder must provide all documentation including third party warranties to flow through to iThemba LABS.

iThemba LABS project management reserves the right to reject any specialist subcontractor that does not meet the special requirements of the facility.

2. Sterility Testing Isolator - Specifications

Point	Specification	Meets Specification ❑ Yes ❑ No	Remarks
2.1.	General		
2.1.1.	The purpose of this document is to specify minimum requirements for design, manufacturing, testing, and performance guarantee for the sterility testing isolator equipment for iThemba LABS at the Cape Town site. The sterility testing unit will be used for sterility testing of sterile radiopharmaceuticals. The unit is to operate at a negative pressure to the environment.		
2.1.2.	The following cGMP-requirements have to be considered in design, execution and documentation of the sterility testing isolator equipment: ▪ EU Guidelines to Good Manufacturing Practice ▪ Medicinal Products for Human and Veterinary Use ▪ European Pharmacopoeia (FT)		

	▪ US-Pharmacopoeia (USP) ▪ The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 4 ▪ Good Automated Manufacturing Practice (GAMP5) ▪ ISO 14644-1 2015 ▪ ISO 14644-2 2015 ▪ PIC/S ▪ cGMP		
2.1.3.	The following technical regulations have to be met in the design, execution and documentation of the sterility testing isolator equipment: ▪ Directive and LVD (Low Voltage Directive). We comply to these requirements. ▪ Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery ▪ Council Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits ▪ EN 60073, Basic and safety principles for man-machine interface, marking and identification - Coding principles for indicators and actuators		
2.1.4.	Safety, operability, and easy maintainability are designed in by the supplier as of prime importance for the whole machine.		
2.1.5.	The supplier ensures that the equipment is adequately designed and constructed and where necessary guarded.		
2.1.6.	The supplier provides training for operating personnel during Factory Acceptance Testing (FAT), Start-up, and Site Acceptance Testing (SAT).		
	The language of the documentation will be English.		
2.2.	Project Description		

2.2.1.	The scope of delivery is for a sterility testing isolator, for the aseptic sterility testing of sterile radiopharmaceuticals. The isolator is to be a fully closed environment, it must meet Grade A class requirements at rest and in operation and must operate at a negative pressure. This document applies to the Nuclear Medicine Department of iThemba LABS at their Cape Town site. The sterility testing isolator is to include: ▪ Full laminar airflow ▪ Integrated Vapour-Phase Hydrogen Peroxide (VPHP) sterilization and bio-decontamination unit for sterilisation of unit and components. ▪ Dedicated loading racks/baskets for material loading. ▪ Suitable for testing vials, ampoules, syringes, cartridges and others. ▪ Panel PC HMI Control System fully compliant for CFR21 Part11 and Data Integrity requirements. ▪ Glove tester ▪ Integrated peristaltic Merck Millipore pump for sterility testing. ▪ Integrated viable and non-viable monitoring systems. ▪ HEPA H14 1st stage exhaust filtration. • Bag in bag out system to control contamination ▪ HEPA H14 2nd stage exhaust filtration. • Bag in bag out system to control contamination ▪ Scada interface predisposition ▪ Main chamber for testing with glove ports and ▪ Preloading chamber The isolator and all the integrated parts/components/ equipment must be cGMP, 21 CFR Part 11 compliant, and have the relevant validation and IQ/OQ/PQ to be performed and documentation to be provided.		
2.2.2.	The system must be capable of continuous monitoring of particles in the isolator.		

2.2.3.	Particle counter The system must have an integrated data management application for the running and monitoring of the conditions in the isolator. Non-viable counts at 0.5 um and 5.0 um must be available per cubic foot and counts per cubic meter. ▪ cGMP compliant ▪ 21 CFR Part 11 compliant ▪ Integrated system ▪ IQ/OQ/PQ documents to be provided		
2.2.4.	The isolator must provide integrated equipment for pressure differential, temperature, and humidity monitoring. ▪ cGMP compliant ▪ 21 CFR Part 11 compliant ▪ Integrated system ▪ IQ/OQ/PQ documents to be provided		
2.2.5.	The isolator must provide a unit for the bio-decontamination of the working zone and transfer lock airlock using vaporised hydrogen peroxide. Exhausted gas, post decontamination, must be over a suitable catalyst to render gases safe. Automatic and repeatable decontamination process in an aseptic environment This integrated system must reach the target for the decontamination process: log 6 reduction. It must be a validated system. Documentation must be provided. ▪ cGMP compliant ▪ 21 CFR Part 11 compliant ▪ Integrated system ▪ IQ/OQ/PQ documents to be provided Note: Pipe to HVAC (regeneration air outlet)		
2.2.6.	The isolator must provide an integrated sterility pump unit for sterility testing with the required vacuum removal of waste. Must be suitable for testing radiopharmaceuticals. VHP resistant		

	Compatible with sterile Merck Millipore media bottles ▪ GMP compliant ▪ 21 CFR Part 11 compliant ▪ Integrated system ▪ IQ/OQ/PQ documents to be provided ▪ VPHP COMPATIBLE On-site annual maintenance		
2.2.7.	All equipment to be hydrogen peroxide compatible / resistant		
2.3.	Performance		
2.3.1.	Installation (in South Africa) of the isolator will be prepared and executed by the supplier		
2.3.2.	Installation Qualification (IQ) and Operational Qualification (OQ) of the isolator according to Annex 15 of EU Guide of GMP will be executed by supplier. Adequate protocols have to be provided for the test phase in maximum 4 weeks in advance of acceptance testing.		
2.3.3.	Particle counting unit must have a minimum performance of counting 1 cubic foot per minute.		
2.3.4.	Decontamination cycles must be under 2 hrs.		
2.4.	Design		
2.4.1.	The system must have sufficient glove ports for the easy manipulation of products and equipment, by a single operator.		
2.4.2.	The isolator must have been provided with a mechanism, and pressure decay test for the integrity test of the working area chamber and glove ports.		
2.4.3.	The isolator must consist of an operation chamber, a decontamination chamber, and a sterilisation unit capable of delivering a sterilant to both chambers simultaneously and independently.		
2.4.4.	Iso kinetic probe to be supplied with the system, linked to a particle monitoring system for 0.5um, 5.0um and at per minutes counts and cubic meter counts. Protective covers of AISI 316l stainless steel shall be provided for protection during cleaning and sanitisation.		

2.4.5.	Viable monitoring platform or station must be available, situated at the highest risk position of operation. ▪ GMP compliant ▪ 21 CFR Part 11 compliant ▪ Integrated system ▪ IQ/OQ/PQ documents to be provided ▪ VPHP COMPATIBLE		
2.4.6.	Piping shall be pharmaceutical grade and resistant to chemical sanitisation. (VPHP COMPATIBLE)		
2.4.7.	In the event of equipment malfunction or loss of utilities, the unit contains all necessary protection devices to ensure that the machine is always in a safe condition without consequential damage. *Vacuum system to prevent backflow with valve type arrangement*		
2.4.8.	All relevant instruments shall be delivered calibrated. The supplier shall provide calibration protocols and calibration instructions.		
2.4.9.	All relevant instruments shall be calibrated with a three-point calibration (if applicable) on-site (full loop calibration).		
2.4.10.	Calibrating / Recalibrating of all measuring process relevant instruments must be done at the installed place. Instrument devices shall be located in accessible positions to enable service and cleaning. Certificates to be provided.		
2.4.11.	Equipment baskets with associated hooks to be provided in 316L ss for the hanging of components and kits.		
2.5.	Installation		
2.5.1.	The scope of the delivery includes the setup of the unit and execution.		
2.5.2.	All wiring and pipework are to be installed in specified cable trays.		
2.5.3.	All vacuum pipes are to be installed in cable trays.		
2.5.4.	Machine dimensions to allow access to the site of installation Door Opening: 0.740 m X 1.940 m		

2.5.5.	Dimensions (for isolator and sanitisation unit) Space available Length: 2.5 m Width: 0.820 m Height: 2.65 m		
2.5.6.	Air extraction ducting are to be supplied and installed by a suitably experienced specialist subcontractor for connecting the isolator air outlet with the existing air extraction system of the facility whilst maintaining the general air quality requirements of the cleanroom.		
2.6.	Controls and Instrumentation		
2.6.1.	The unit must have its own local control system and an operator panel (HMI). The operator must be able to notice, to check and to acknowledge the relevant alarms on the operating panel.		
2.6.2.	The control system has to be developed according to GAMP byes CJI no 5 and has to fulfil Annex 11, EU GMP Guide. Fail-safe principle has to be applied.		
2.6.3.	Profibus /ethernet connection to SCADA has to be provided. UPS to carry the system for 30 mins to allow controlled shutdown.		
2.6.4.	All relevant data must be stored and printed in a GMP compliant, and 21 CFR Part 11 compliant manner.		
2.6.5.	The program shall provide appropriate alarm signals for out-of-range values, time expiry, program errors, emergency stop, other hazard operation modes, cable breakage, network communication errors.		
2.6.6.	A machine alarm in case of malfunction between PLC/PC and controllers (transfer of set parameters) has to be released		
2.6.7.	A machine alarm in case of malfunction of controllers has to be released		
2.6.8.	All GMP-critical data and alarms (with time of occurrence) shall be printed and stored in a GMP-compliant way The facility for a reprint of a specific test must be available. The print-outs must have archival quality. The number of channels shall comply with the number of		

	GMP critical data. 21 CFR Part 11 compliant		
2.6.9.	In case of a system disaster (e.g. replacement of the control system) a procedure must be provided to recover the whole system including all configurations. During and after a disaster recovery, the system has to stay in a safe status.		
2.6.10.	A paperless recorder shall be offered. Electronic records shall meet the requirements of PIC's annexure 11: ▪ Computer generated audit trail ▪ Backup & Restore ▪ Archiving Retrieval ▪ And other applicable requirements related 21 CFR Part 11 compliant		
2.6.11.	All used software (PLC/PC programming and visualization system) must be developed and documented according to internal supplier guidelines. System must register, produce and issue data, which include 1 yes Li different states of process and equipment, measurements, alarms and any other relevant information in an appropriate manner, conform to current GAMP regulations. The software version must be available as a backup within iThemba LABS. A version control system for the software including application software has to be provided. The change Control procedure has to start with version 1		
2.6.12.	PIC's Annexure 11: Following requirements are to be met: ▪ Password protection and different access levels ▪ Enforced minimum password length and format ▪ Unique user IDs ▪ Passwords automatically expiry after given time ▪ Automatically log-out after given time 21 CFR Part 11 compliant		

2.6.13.	The PLC/PC shall provide for a minimum of four levels of security: ▪ Operators (operating level) ▪ Supervisor (system setting) ▪ Technicians (calibration, maintenance) ▪ Administrator (system) These levels will be accessed by using password functionality. Access to each level is based on individual passwords and authorization. (These password levels define the access level and alarm clearance access level) 21 CFR Part 11 compliant		
2.6.14.	It is forbidden for level one (operator) to three (technician) to have the possibility to change system configuration. It is also forbidden to have the possibility to delete or change electronic records or UID's. Electronic records have to be handled as raw data. 21 CFR Part 11 compliant		
2.6.15.	Operators: Operator functions include process data input and limited process related actions. 21 CFR Part 11 compliant		
2.6.16.	Supervisors: Supervisor functions include all operator functions, plus a screen protected supervisor password that allows setting the control system status (automatic / manual) and process set parameters. 21 CFR Part 11 compliant		
2.6.17.	Technicians: Technician functions include operator functions for process data input and limited process related actions. In addition, the technician's functions will provide an access to maintenance and development screens. 21 CFR Part 11 compliant		
2.6.18.	Administrator: Master function includes all other functions and the password setting for each level. 21 CFR Part 11 compliant		
2.6.19.	The electrical connection for the counter units must be: 230V, 50 Hz Single Phase		

2.6.20.	The electrical connection for the vacuum units must be: 230V, 50 Hz Single Phase		
2.6.21.	The detector unit must be protected in a housing, the panels have to be built flush, and easy to clean.		
2.6.22.	All instrument parts are easily accessible for maintenance purposes.		
2.7.	Material Requirements		
2.7.1.	Flexible instrument lines are of Polyamide or Rislan for pneumatics and detector tubing. If not, material is to be specified.		
2.7.2.	Isokinetic probe and lid to be AISI 316L, stainless steel		
2.7.3.	Unit and surfaces must be resistant to cleanroom sanitisers such as IPA and H202 for surface disinfection.		
2.7.4.	All internal metal surfaces are 316L stainless steel. Shielding requirements for sterility isolator ▪ Front section/Window/Visor – all parts to be supplied with the maximum shielding offered ▪ Waste Compartment – additional 25 mm lead equivalent all sides and base ▪ Base/Floor of isolator (if staff are to sit with legs beneath the unit) 25mm lead shielding equivalence across entire base (shielding can be mounted externally beneath the unit) Lead shielding to be clad in stainless steel. No gaps or penetrations permitted through lead shielding or adjacent sheets of shielding material.		
2.8.	Documentation		
2.8.1.	The following documentation requirements are a minimum standard which need to be offered. ▪ P&ID, Valve and Wiring Diagrams ▪ Operation and Maintenance Manual ▪ IQ and OQ Protocols Validation documents for the isolator and for each integrated instrument IQ, OQ, and PQ documents for the isolator and each		

	integrated instrument. Calibration certificates for all equipment.		
2.8.2.	Qualification package in the English language. The system qualification documentation provides complete verification that the machine including and installation including all components is in compliant with the internal order and/or the valid specification. The qualification is based on Appendix D5 of the GAMP 5 guideline. It is further based on Annex 15 of the EU-GMP guide to Good Manufacturing Practices for Medicinal Products and the PICA - document PICTS PI 006. Documentation to include Verification of the personnel in charge of qualification. Test Process Sheet. Passed test section. Failed test section. Test incidents section. Test report (TR): Report with all test results. Comments on test sequences. Description of deviations and open points to be tested. Verification and release of the qualification proceedings		
2.8.3.	IQ: Installation verification of the system (IQ): Documentation verification. Mechanical installation verification. Electrical installation verification. Installation verification of the software versions. Installation verification of the PLC system (IQ): Input and output test of the control system. PLC configuration test.		
2.8.4.	OQ: Functional verification of the system (OQ): Alarm tests. Function tests. Operating terminal test.		
2.8.5.	Technical documentation (TD): Technical data sheets: Index and structuring of all data sheets included. Data sheets of all relevant components of the control system. PLC program with comments. Schematic cross section of detector unit.		

2.8.6.	Documents as paper print-out System instruction manual (two copies). System Maintenance and sanitisation (two copies) Electrical documentation, wiring diagram (two copies). EC Declaration of Conformity for machines with CE marking (one copy). Drawings / Diagrams as print-out or as file (two copies) Layout drawing. Cable layout plan (if necessary). Media connection plan. Documents on that carrier (CD-ROM) Machine instruction manual as PDF (two copies). Instruction manuals for installed purchased parts as PDF -English (two copies). Data sheets of all the recommended lubricants as PDF (two copies). Technical documents (pneumatic circuit diagram,) as PDF - depending on machine type and equipment (two copies): Electrical documentation, wiring diagram as PDF (two copies) Spare part list (one copy).		
2.9.	Safety Requirements		
	All equipment in use must comply with current South Africa Occupation, Health and Safety, and hazardous substances legislation.		

3. Dispensing Isolators - Specifications

The dispensing isolator is to include:

1. Main chamber for final filling of vials with glove ports and a teleplier
2. Preloading chamber for introduction of consumables and component sterilization
3. Integrated Particle counter
4. Dosing pump
5. Integrated dose calibrator
6. Vaporized hydrogen peroxide (VHP) sterilization and bio-decontamination unit for sterilisation of unit and components
7. Controlling HMI

8. Non-Viable Monitoring
9. Viable Monitoring
10. Radiation shielding
11. Consumables and spare parts

Point	Specification	Meets Specification ❑ Yes ❑ No	Remarks
3.1.	General		
3.1.1.	The purpose of this document is to specify minimum requirements for design, manufacturing, testing, and performance guarantee for the dispensing isolator for iThemba LABS at the Cape Town site. The isolator will be used for dispensing ^{123}I Radiopharmaceuticals The unit is to operate at a negative pressure to the environment.		
3.1.2.	The following requirements have to be considered in design, execution and documentation of the isolator and integrated equipment: ▪ EU Guidelines to Good Manufacturing Practice ▪ Medicinal Products for Human and Veterinary Use ▪ European Pharmacopoeia (FT) ▪ US-Pharmacopoeia (USP) ▪ The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 4 ▪ Good Automated Manufacturing Practice (GAMP5) ▪ ISO 14644-1 2015 ▪ ISO 14644-2 2015 ▪ PIC/S ▪ cGMP		
3.1.3.	The following technical regulations have to considered in the design, execution and documentation of the isolator and integrated equipment: ▪ Directive and LVD (Low Voltage Directive). We comply to these requirements.		

	▪ Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery ▪ Council Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits ▪ EN 60073, Basic and safety principles for man-machine interface, marking and identification - Coding principles for indicators and actuators		
3.1.4.	Safety, operability, and easy maintainability must be considered by the supplier and are of prime importance for the whole machine.		
3.1.5.	The supplier ensures that the equipment is adequately designed as per 3.4 and constructed and where necessary guarded.		
3.1.6.	The supplier provides training for operating personnel during Factory Acceptance Testing (FAT), Start-up, and Site Acceptance Testing (SAT).		
3.1.7.	Documentation will be supplied in accordance with section 3.8 Documentation. The language of the documentation will be English.		
3.2.	Project Description		
3.2.1.	The scope of delivery is for a dispensing isolator that allows for the aseptic dispensing of radiopharmaceuticals. The isolator is to be a fully closed environment in GMP Grade A at rest and in operation. The isolator must be Full laminar airflow and operate at a negative pressure. . The dispensing isolator is to include: The dispensing isolator is to include: i. Main chamber for final filling of vials with glove ports and a teleplier ii. Preloading chamber for introduction of consumables and component sterilization iii. Integrated Particle counter		

	iv. Integrated dosing/peristaltic pump for dispensing. v. Integrated dose calibrator vi. Integrated vaporized hydrogen peroxide (VHP) sterilization and bio-decontamination unit for sterilisation of unit and components vii. Panel PC HMI Control System fully compliant for CFR21 Part11 and Data Integrity requirements. viii. Integrated viable and non-viable monitoring systems. ix. Bubble point tester x. Glove tester xi. 2 stage HEPA filters for exhaust filtration xii. SCADA interface predisposition xiii. Radiation shielding The isolator and all the integrated parts/components/equipment must be cGMP, 21 CFR Part 11 compliant, and have the relevant validation and FAT/IQ/OQ/PQ to be performed and documentation to be provided.		
3.2.2.	<u>Particle Counter</u> The system must be capable of continuous monitoring of particles in the isolator. The system must have an integrated data management application for the running and monitoring of the conditions in the isolator. Non-viable counts at 0.5 um and 5.0 um must be available per cubic foot and counts per cubic meter. Particle counting unit must have a minimum performance of counting 1 cubic foot per minute. The system must be an integrated system, cGMP, 21 CFR Part 11 compliant. IQ/OQ/PQ documents to be provided		
3.2.3.	The isolator must be capable of continuous pressure differential, Pressure across all filters, temperature and humidity monitoring. The system must be an integrated system, cGMP, 21 CFR Part 11 compliant.		

	IQ/OQ/PQ documents to be provided		
3.2.4.	The isolator must provide an integrated unit for the bio-decontamination of the pre-chamber, final product dispensing chamber using vaporised hydrogen peroxide. The decontamination process must be validated process, automatic, repeatable and provide a 6-log bio decontamination reduction. Exhausted gas, post decontamination, must be over a suitable catalyst to render gases safe. The unit must be cGMP, 21 CFR Part 11 compliant. IQ/OQ/PQ and validation documents to be provided Note: Pipe to HVAC (regeneration air outlet)		
3.2.5.	The isolator must provide an integrated dispensing pump for dispensing radiopharmaceuticals, a vial crimper, and a vial rubber stopper remover. GMP compliant 21 CFR Part 11 compliant Integrated system IQ/OQ/PQ documents to be provided VPHP COMPATIBLE On-site annual maintenance		
3.3.	Performance		
3.3.1.	Installation (in South Africa) of the isolator will be prepared and executed by the supplier		
3.3.2.	Installation Qualification (IQ) and Operational Qualification (OQ) of the isolator according to Annex 15 of EU Guide of GMP will be executed by supplier. Adequate protocols have to be provided for the test phase in maximum of 4 weeks in advance of acceptance testing.		
3.3.3.	Decontamination cycles should be under 2 hrs.		
3.4.	Design		
3.4.1.	The system must have sufficient glove ports for the easy manipulation of products and equipment, by a single operator.		
3.4.2.	The isolator must be provided with a mechanism, and pressure decay test for the integrity test of the working area		

	chamber and glove ports.		
3.4.3.	The isolator must consist of an operation chamber, a decontamination chamber, and a sterilisation unit capable of delivering a sterilant to both chambers simultaneously and independently.		
3.4.4.	Isokinetic probe to be supplied with the system, linked to a particle monitoring system for 0.5u, 5.0u and at per minutes counts and cubic meter counts. Protective covers of AISI 316l stainless steel shall be provided for protection during cleaning and sanitisation.		
3.4.5.	Viable monitoring platform or station must be available, situated at the highest risk position of operation.		
3.4.6.	Piping shall be food grade and resistant to chemical sanitisation. pharmaceutical grade		
3.4.7.	In the event of equipment malfunction or loss of utilities, the unit contains all necessary protection devices to ensure that the machine is always in a safe condition without consequential damage. Vacuum system to prevent backflow with valve type arrangement		
3.4.8.	All relevant instruments shall be delivered calibrated. Supplier shall provide calibration protocols and calibration instructions.		
3.4.9.	All relevant instruments shall be calibrated with a three-point calibration (if applicable) on site (full loop calibration).		
3.4.10.	Calibrating / Recalibrating of all measuring process relevant instruments has to be possible in the installed place. Instrument devices shall be located in accessible positions to enable service and cleaning. Calibration certificates to be provided.		
3.4.11.	Equipment baskets with associated hooks to be provided in 316L ss for the hanging of components and kits.		
3.5.	Installation		
3.5.1.	Scope of delivery includes the setup of the unit and execution of system function, batch reporting, setting limits.		
3.5.2.	All wiring and pipework to be installed in specified cable trays.		

3.5.3.	All vacuum pipes to be installed in cable trays.		
3.5.4.	Machine dimensions to allow access to the site of installation Door Opening: 2.020 m X 1.140 m		
3.5.5.	Dimensions (for 2 x isolator and sanitisation unit) Space available Length: 5.670 m and Depth: 1.900 m Height: 3 m		
3.5.6.	Air extraction ducting are to be supplied and installed by a suitably experienced specialist subcontractor for connecting the isolator regeneration air outlet with the existing air extraction system of the facility whilst maintaining the general air quality requirements of the cleanroom.		
3.6.	Controls and Instrumentation		
3.6.1.	The unit must have its own local control system and an operator panel (HMI). The operator must be able to notice, to check and to acknowledge the relevant alarms on the operating panel.		
3.6.2.	The control system has to be developed according to GAMP byes CJI no 5 and has to fulfil Annex 11, EU GMP Guide. Fail safe principle has to be applied.		
3.6.3.	Profibus /ethernet connection to SCADA has to be provided UPS to carry the system for 30 minutes to allow controlled shutdown.		
3.6.4.	All relevant data must be stored and printed in a GMP and 21 CFR Part 11 compliant. See 7.6.12 for details.		
3.6.5.	The program shall provide appropriate alarm signals for out-of-range values, time expiry, program errors, emergency stop, other hazard operation modes, cable breakage, network communication errors.		
3.6.6.	A machine alarm in case of malfunction between PLC/PC and controllers (transfer of set parameters) has to be released		
3.6.7.	A machine alarm in case of malfunction of controllers has to be released		
3.6.8.	All GMP-critical data and alarms (with time of occurrence)		

	shall be printed in a GMP/ 21CFR Part 11 compliant way. The facility for a reprint of a specific test must be available. The print-outs must have archival quality. The number of channels shall comply with the number of GMP critical data.		
3.6.9.	In case of a system disaster (e.g. replacement of the control system) a procedure must be provided to recover the whole system including all configurations. During and after a disaster recovery the system has to stay in a safe status.		
3.6.10.	Electronic records shall meet the requirements of PIC's annexure 11: ▪ Computer generated audit trail ▪ Backup & Restore ▪ Archiving Retrieval ▪ And other applicable requirements related		
3.6.11.	All software (PLC/PC programming and visualization system) should be developed and documented according to internal supplier guidelines. System must register, produce and issue data, which include 1 yes Li different states of process and equipment, measurements, alarms and any other relevant information in an appropriate manner, conform to current GAMP regulations. The software version must be available as a backup within iThemba LABS A version control system for the software including application software has to be provided.		
3.6.12.	PIC's Annexure 11: Following requirements are to be met: ▪ Password protection and different access levels ▪ Enforced minimum password length and format ▪ Unique user IDs ▪ Passwords automatically expiry after given time ▪ Automatically log-out after given time		

3.6.13.	The PLC/PC shall provide for a minimum of four levels of security: ▪ Operators (operating level) ▪ Supervisor (system setting) ▪ Technicians (calibration, maintenance) ▪ Administrator (system) These levels will be accessed by using password functionality. Access to each level is based on individual passwords and authorization. (These password levels define the access level and alarm clearance access level)		
3.6.14.	It is forbidden for level one (operator) to three (technician) to have the possibility to change system configuration. It is also forbidden to have the possibility to delete or change electronic records or UID's. Electronic records have to be handled as raw data.		
3.6.15.	Operators: Operator functions include process data input and limited process related actions.		
3.6.16.	Supervisors: Supervisor functions include all operator functions, plus a screen protected supervisor password that allows setting the control system status (automatic / manual) and process set parameters.		
3.6.17.	Technicians: Technician functions include operator functions for process data input and limited process related actions. In addition, the technician's functions will provide an access to maintenance and development screens.		
3.6.18.	Administrator: Master function includes all other functions and the password setting for each level.		
3.6.19.	The electrical connection for the counter units must be: 230V, 50 Hz Single Phase		
3.6.20.	The electrical connection for the vacuum units must be: 230V, 50 Hz Single Phase		
3.6.21.	The detector unit must be protected in a housing, the panels have to be built flush, easy to clean.		
3.6.22.	All instrument parts are easily accessible for maintenance purpose.		
3.7.	Material Requirements		

3.7.1.	Flexible instrument lines are of Polyamide or Rislan for pneumatics and detector tubing. If not material to be specified.		
3.7.2.	Isokinetic probe and lid to be AISI 316L, stainless steel		
3.7.3.	Unit and surfaces must be resistant to cleanroom sanitisers such as IPA and H202 for surface disinfection.		
3.7.4.	All internal metal surfaces are 316L stainless steel, front panel is toughened glass. Shielding requirements for a dispensing isolator ▪ Front section/Window/Visor – all parts including viewing window to be supplied with 25mm lead shielding equivalence ▪ Dose Calibrator Compartment – additional 25mm lead equivalent all sides and base ▪ Waste Compartment – additional 25mm lead equivalent all sides and base ▪ Base/Floor of isolator (if staff are to sit with legs beneath the unit) 25mm lead shielding equivalence across entire base (shielding can be mounted externally beneath the unit) Lead shielding to be clad in stainless steel. No gaps or penetrations permitted through lead shielding or adjacent sheets of shielding material.		
3.8.	Documentation		
3.8.1.	The following documentation requirements are a minimum standard which need to be offered. ▪ P&ID, Valve and Wiring Diagrams ▪ Operation and Maintenance Man2a1 ▪ FAT, SAT, IQ and OQ Protocols ▪ Factory acceptance test report		
3.8.2.	Qualification package in English language. The system qualification documentation provides complete verification that the machine and installation including all equipment is in compliance with the internal order and/or the valid specification.		

	The qualification is based on Appendix D5 of the GAMP 5 guideline. It is further based on Annex 15 of the EU-GMP guide to Good Manufacturing Practices for Medicinal Products and the PICA - document PICTS PI 006. Documentation to include Verification of the personnel in charge of qualification. Test Process Sheet. Passed test section. Failed test section. Test incidents section. Test report (TR): Report with all test results. Comments on test sequences. Description of deviations and open points to be tested. Verification and release of the qualification proceedings		
3.8.3.	IQ: Installation verification of the system (IQ): Documentation verification. Mechanical installation verification. Electrical installation verification. Installation verification of the software versions. Installation verification of the PLC system (IQ): Input and output test of the control system. PLC configuration test.		
3.8.4.	OQ: Functional verification of the system (OQ): Alarm tests. Function tests. Operating terminal test.		
3.8.5.	Technical documentation (TD): Technical data sheets: Index and structuring of all data sheets included. Data sheets of all relevant components of the control system. PLC program with comments. Schematic cross section of detector unit.		
3.8.6.	Documents as paper print-out System instruction manual (two copies). System Maintenance and sanitisation (one copy) Electrical documentation, wiring diagram (one copy). EC Declaration of Conformity for machines with CE marking (one copy). Drawings / Diagrams as print-out or as file (each one copy) Layout drawing.		

	Cable layout plan (if necessary). Media connection plan. Documents on that carrier (CD-ROM) Machine instruction manual as PDF (two copies). Instruction manuals for installed purchased parts as PDF - English (two copies). Data sheets of all the recommended lubricants as PDF (two copies). Technical documents (pneumatic circuit diagram,) as PDF - depending on machine type and equipment (two copies): Electrical documentation, wiring diagram as PDF (two copies) Spare part list (one copy).		
3.9.	Safety Requirements		
	The equipment in use must comply with current South Africa Occupation, Health and Safety legislation. CE mark or equivalent		

Changes to the specifications provided

The project team will conduct meetings with the appointed bidder on matters marked for discussion such as door sizes once more data is provided by the appointed bidder to resolve such matters.

The appointed bidder must clear any unresolved or unclear matter with the project teams as well as bringing to their attention matters impacting the project not listed above when on site.

Compliance Management

The design, construction and validation shall be done in accordance with current Good Manufacturing Practices (cGMP), Good Engineering Practices (GEP) and OHS Act. The isolators shall comply with IThemba LABS in-house Quality Policies and shall satisfy the requirements of SAHPRA/PIC/s and Radiation Safety. The isolators and all the integrated parts/components/equipment must be cGMP, 21 CFR Part 11 compliant, and have the relevant validation and IQ/OQ/PQ to be performed and documentation to be provided.

General Requirements

- Provided a Standard Operating Procedure (SOP) and user manuals for Isolators and all integrated equipment
- Provide training and competency certificates for trainees.
    - Provide detailed schedule for the service maintenance
- Provide local technical support and servicing as and when required for a period of 5 years.
- Maximum lead time for response should be 48 hours (or two working days). Provide certificates for every service and calibrations of isolators and integrated equipment

- Provide Installation, Operational and Performance Qualification documentation.
- Provide CE certification or equivalent for isolators and integrated equipment
- Five (5) year warranty for isolators and integrated equipment

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 a minimum of three (3) contactable written reference letters with contact details from three different clients where the bidder has supplied similar equipment.
   - 1.2. Provide datasheets or manufacturers specification of the proposed Sterility Isolator and dispensing isolators.
   - 1.3. Provide CE certification or equivalent
   - 1.4. Provide project plan (detailing from Manufacturing to commissioning)
   - 1.5. Provide the CVs and qualifications (competency certificate to install the isolators and integrated equipment) of technical teams.
   - 1.6. Provide the CVs and qualifications of the specialist subcontractor for the supply and installation of ducting for the connection of the air outlets of the isolators with the existing air extraction system of the facility
   - 1.7. This document (SBD 1) signed. (Refer to page 55 & 68)
   - 1.8. Bidders Disclosure (SBD 4). (Refer to page 60)
   - 1.9. Preference points claim (SBD 6.1). (Refer to page 63)
   - 1.10. A resolution granting authority to sign documents on behalf of the company to the signatory on every document in the tender bid where required.

CONTRACT PERIOD

Five (5) year contract (commences after commissioning date of the Sterility Testing Isolator and dispensing isolators)

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 38 to page 53

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.

After installation and commissioning, the appointed bidder must ensure that the electrical installation and commissioning comply with the necessary norms to the original requirements, specifications, and safety regulations.

A meeting between the contractor, and the iThemba LABS contract project manager shall take place to confirm that all specifications comply with the specifications.

Warranty (General Condition of Contract Clause No: 15)

- Five (5) year warranty for isolators and integrated equipment and all other equipment forming the installation
- Service Warranty: The appointed service provider must warrant reliability and functionality of this system after installation. As stipulated on GCC 15.1,15.2, and any other additional warranty specified in SCC15.

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

Any service incidental to the operational management of this system is included in the list of incidental services in GCC13.1.

In the event of requiring such 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.

Spares (General Condition of Contract Clause No: 14)

Where spares are required, this are acquired in line with GCC14 and 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 supplies, installs, commissions, and conduct all necessary tests on the systems and submit commissioning reports to the iThemba LABS project manager.
2. iThemba LABS project manager verify the results of tests and commissioning reports against the specifications.
3. The appointed bidder manages all project activities and processes in accordance with accepted industry practice and in consultation with the appointed consulting engineer and iThemba LABS project manager.
4. The appointed bidder will deliver to the site any deliverable required under this contract.
5. 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 compliance upon completion of the installation of all electrical equipment and before the energizing. The electrical installation must be inspected and tested in accordance with Eskom requirements and the Occupational health and safety Act No. 85 of 1993. The installation shall be tested to the satisfaction and approval of Eskom, the appointed consulting Engineer, and the iThemba LABS project manager. The contractor shall submit certificates of tests carried out to prove compliance of the installation.

Contract Due Diligence during the contract period

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

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

The appointed bidder provides the following documentation, as a minimum in hardcopy and electronic format, upon completion of the installation and commissioning: Final layout and design drawings, tests and inspections certificates, comprehensive report, and certificate of compliance.

Payment (General Condition of Contract Clause No: 16)

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

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 electrical installation performed under the contract shall not vary from the prices quoted by the supplier in his 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 will 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 failed parts 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.
Service Warranty	The appointed service provider must warrant reliability and functionality of this system after installation.	As stipulated on GCC 15.1,15.2, and any other additional warranty specified in SCC15.

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 1, 55 to 60, and 68	
Bidder's Disclosure (SBD 4), signed and completed	**M**	❑ Yes ❑ No	Pages 60 to 63	
Preference Points Claimed (SBD 6.1), signed and completed with B-BBEE certificate or sworn affidavit.	**M**	❑ Yes ❑ No	Page 63 to 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 29	

RETURNABLE DOCUMENT CHECKLIST TO QUALIFY FOR EVALUATION

Returnable Documents	Specification			
(M – Mandatory); (O – Optional)	**Submitted**		**Bid Section Reference**	**Reference to Bidder's document**
Bidder Support Due Diligence Eligibility				
Provide datasheets or manufacturers specification of the proposed Sterility Isolator. verifies that bidder can meet the specifications	**M**	❑ Yes ❑ No	Page 29**Error! Bookmark not defined.**	
Evaluate the minimum of three (3) contactable written reference letters or project completion certificates (dated and Signed) with contact details from three different clients where the bidder has supplies similar equipment to establish that the bidders have done similar work to the standard set by iThemba LABS?	**M**	❑ Yes ❑ No	Page 29 and pages 67 to 68	

Pricing Competition Documents				
(M – Mandatory); (O – Optional)	**Submitted**		**Bid Section Reference**	**Reference to Bidder's document**
Pricing (SBD 3.1) in the format provided in this document (separate envelope)	**M**	❑ Yes ❑ No	Page 53 to 55	

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 and Bid Submission Form**

COLLUSION, FRAUD AND CORRUPTION

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

FRONTING

The NRF supports the spirit of broad based black economic empowerment and recognizes that achieving real empowerment is through individuals and businesses conducting themselves in accordance with the Constitution and in

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

DISCLAIMERS

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

GENERAL DEFINITIONS

"B-BBEE" means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act;

"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:**

GENERAL CONDITIONS OF CONTRACT	
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.

GENERAL CONDITIONS OF CONTRACT	
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 National Research Foundation a fully paid up, irrevocable, and non-exclusive licence to use its background intellectual property for the exploitation of this contract to enable the National Research Foundation 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 National Research Foundation 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 National Research Foundation in obtaining statutory protection for the contract intellectual property at the expense of the National Research Foundation wherever the National Research Foundation may choose to obtain such statutory protection. The appointed supplier/party shall procure where necessary the signatures of its personnel for the assignment of its respective contract intellectual property to the National Research Foundation or as the National Research Foundation may direct, and to support the National Research Foundation or its nominee, in the prosecution and enforcement thereof in any country in the world. The appointed supplier/party irrevocably appoints the National Research Foundation to be its true and lawful agent in its own name, to do such acts, deeds, and things and to execute deeds, documents, and forms that the National Research Foundation in its discretion requires in order to give effect to the terms of this clause.
SCC5B	**Confidentiality** The recipient of confidential information shall be careful and diligent as not to cause any unauthorised disclosure or use of the confidential information, in particular, during its involvement with the National Research Foundation and after termination of its involvement with the National Research Foundation, the recipient shall not: a. Disclose the confidential information, directly or indirectly, to any person or entity, without the National Research Foundation's prior written consent. 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 recipient shall ensure that any employees, agents, directors, contractors, service providers, and associates which may gain access to the confidential information are bound by agreement with the recipient both during the term of their associations with the recipient and after termination of their respective associations with the recipient, 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 recipient 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 recipient is able to prove: a. Was independently developed by the recipient prior to its involvement with the National Research Foundation or in the possession of the recipient prior to its involvement with the National Research Foundation; b. Is now or hereafter comes into the public domain other than by breach of this contract by the

	recipient; 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 National Research Foundation, 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 National Research Foundation of such requirement prior to any disclosure. The recipient shall within one (1) month of receipt of a written request from the NRF to do so, return to the National Research Foundation all material embodiments, whether in documentary or electronic form, of the confidential information including but not limited to: a. All written disclosures received from the NRF; b. All written transcripts of confidential information disclosed verbally by the National Research Foundation; and c. All material embodiments of the contract intellectual property. The recipient acknowledges that the confidential information 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 to the recipient, but for the obligations of confidentiality agreed to herein. Except as expressly herein provided, this contract shall not be construed as granting or confirming, either expressly or impliedly any rights, licences or relationships by furnishing of confidential information by either party pursuant to this contract. The recipient acknowledges that the unauthorised disclosure of confidential information may cause harm to the NRF. The recipient agrees that, in the event of a breach or threatened breach of confidentiality, the NRF is entitled to seek injunctive relief or specific performance, in order to obtain immediate remedies. Any such remedy shall be in addition to and not in lieu of any other remedies available at law, including monetary damages.
SCC5C	**Protection of Private Information** The supplier hereby gives the NRF permission, in terms of the Protection of Private 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**
7.1	Within thirty days (30) of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.
7.2	The proceeds of the performance security shall be payable to the purchaser as compensation for any

	loss resulting from the supplier's failure to complete his obligations under the contract.
7.3	The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms: 7.3.1 bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or 7.3.2 a cashier's or certified cheque.
7.4	The performance security will be discharged by the purchaser and returned to the supplier within thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.
SCC7	The additional terms for performance securities as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29-33 are applicable.
GCC8	**Inspections, tests and analyses**
8.1	All pre-bidding testing will be for the account of the bidder.
8.2	If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the purchaser or an organization acting on behalf of the purchaser.
8.3	If there are no inspection requirements indicated in the bidding documents and contract makes no mention, but during the contract period, it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.
8.4	If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.
8.5	Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the supplier shall defray the cost in connection with these inspections, tests, or analyses.
8.6	Supplies and services referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.
8.7	Any contract supplies may on or after delivery be inspected, tested or analysed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies are held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies, which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.

8.8	The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract because of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.
SCC8	Additional inspection procedures as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29 are applicable.
GCC9	**Packing**
9.1	The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.
9.2	The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.
SCC9	Additional packing requirements as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29 are applicable.
GCC10	**Delivery and Documentation**
10.1	The supplier in accordance with the terms specified in the contract shall make delivery of the goods/services. The SCC specifies the details of shipping and/or other documents furnished by the supplier.
10.2	Documents submitted by the supplier specified in SCC.
SCC10	Additional delivery documentation requirements as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29 are applicable.
GCC11	**Insurance**
11.1	The goods supplied under the contract are fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.
SCC11	Professional indemnity insurance cover in accordance with SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29-33 is 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.
15.2	This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.
15.3	The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.
15.4	Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.
15.5	If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take such remedial action as may be necessary, at the supplier's risk and

	expense and without prejudice to any other rights, which the purchaser may have against the supplier under the contract.
SCC15	The additional warranty requirements as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29-33 are applicable.
GCC16	**Payment**
16.1	The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.
16.2	The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfilment of other obligations stipulated in the contract.
16.3	Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.
16.4	Payment will be made in Rand unless otherwise stipulated in SCC.
SCC16	Additional payment terms as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29-33 are applicable.
GCC17	**Prices**
17.1	Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.
GCC18	**Contract amendment**
18.1	No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.
GCC19	**Assignment**
19.1	The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.
GCC20	**Subcontract**
20.1	The supplier shall notify the purchaser in writing of all subcontracts awarded under this contract if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract
SCC20	The requirements of sub-contractor management as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29-33 are applicable.
GCC21	**Delays in supplier's performance**
21.1	Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.
21.2	If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As

	soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.
21.3	No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.
21.4	The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.
21.5	Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.
21.6	Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without cancelling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.
GCC22	**Penalties**
22.1	Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.
GCC23	**Termination for default**
23.1	The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part: 23.1.1 If the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2; 23.1.2 If the Supplier fails to perform any other obligation(s) under the contract; or 23.1.3 If the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract. h
23.2	In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in suc manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.

23.3	Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.
23.4	If a purchaser intends imposing a restriction on a supplier or any person associated with the supplier, the supplier will be allowed a period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.
23.5	Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.
23.6	If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information: 23.6.1 The name and address of the supplier and / or person restricted by the purchaser; 23.6.2 The date of commencement of the restriction 23.6.3 The period of restriction; and 23.6.4 The reasons for the restriction. These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.
23.7	If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.
SCC23	The additional terms of termination as detailed in SPECIAL CONDITIONS OF CONTRACT MANAGEMENT on page 29 are applicable.
GCC24	**Anti-dumping and countervailing duties and rights**
24.1	When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from

	moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which may be due to him
GCC25	**Force Majeure**
25.1	Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.
25.2	If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event
GCC26	**Termination for insolvency**
26.1	The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.
GCC27	**Settlement of disputes**
27.1	If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.
27.2	If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.
27.3	Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.
27.4	Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.
27.5	Notwithstanding any reference to mediation and/or court proceedings herein, 27.5.1 The parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and 27.5.2 The purchaser shall pay the supplier any monies due the supplier.
GCC28	**Limitation of liability**
28.1	Except in cases of criminal negligence or wilful misconduct, and in the case of infringement pursuant to Clause 6; 28.1.1 The supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest

	costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and 28.1.2 The aggregate liability of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.
GCC29	**Governing language**
29.1	The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.
GCC30	**Applicable law**
30.1	The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.
GCC31	**Notices**
31.1	Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice.
31.2	The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice
SCC31	Electronic communication, to the extent it meets the requirements of legal notices, is also permitted.
GCC32	**Taxes and duties**
32.1	A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.
32.2	A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted goods to the purchaser.
32.3	No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid, the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services
SCC32A	The "tax certificate" in clause 32.3's second sentence refers to the documents specified in National Treasury Instruction Note 9 of 2017/18 applicable to public entities and departments.
GCC33	**National Industrial Participation Programme**
33.1	The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.
GCC34	**Prohibition of restrictive practices**
34.1	In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).

GENERAL CONDITIONS OF CONTRACT	
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 3.1**	
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 29-33 are applicable.
4.	**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

No.	QTY	DESCRIPTION	UOM	UNIT PRICE	TOTAL (including VAT)
1. Sterility Testing Isolator including integrated equipment					
1.1.	1	Sterility Testing Isolator including integrated equipment (as per the specifications)	Each		
1.2.	1	Delivery, installation and commission sterility testing isolator, particle counter and integrated equipment.	roll		
1.3.	1	Installation Qualification (IQ) and Operational Qualification (OQ) and Performance Qualification (PQ documents	Each		
1.4.	1	Calibration and servicing for 5 years	Each		

1.5.	1	Training (including competency certificates)	Each		
1.6.	1	Provisional sum for adhoc maintenance and supply of parts (Sterility Testing Isolator, particle counter and integrated equipment).	Each	**R 500 000.00**	**R 500 000.00**
Total price: Sterility Testing Isolator including integrated equipment					
2. Dispensing Isolator including integrated equipment					
2.1.	2	Dispensing Isolator including integrated equipment (as per the specifications)	Each		
2.2.	2	Delivery, installation and commission sterility testing isolator, particle counter and integrated equipment.	Each		
2.3.	1	Installation Qualification (IQ) and Operational Qualification (OQ) and Performance Qualification (PQ documents	Each		
2.4.	1	Calibration and servicing for 5 years	Each		
2.5.	1	Training (including competency certificates)	Each		
2.6.	1	Provisional sum for adhoc maintenance and supply of parts (dispensing isolators and integrated equipment).	Each	**R 500 000.00**	**R 500 000.00**
2.7.	1	Safety file (for item 1 and 2)	Each		
Total price: Sterility Testing Isolator including integrated equipment					
3. Subcontracting amount allowed for the supply and installation of HVAC ducting from the isolators' air outlets to the existing air extraction system of the facility, including profit & attendance.					
TOTAL BID PRICE INCLUSIVE OF VAT AND OTHER TAXES					

PART C - RETURNS

INVITATION TO BID (SBD 1)

Bid Number	NRF/ILABS 70IS/67/2022/23
Closing date and time	**26 April 2023 at 11H00AM**

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

HIGH LEVEL SUMMARY OF BID REQUIREMENTS

SUPPLY, DELIVERY, INSTALLATION AND COMMISSIONING OF RADIOPHARMACEUTICAL STERILITY TESTING AND RADIOPHARMACEUTICAL DISPENSING ISOLATORS INCLUDING MAINTENANCE TO ITHEMBA LABS IN FAURE, WESTERN CAPE, FOR A PERIOD OF FIVE (5) YEARS

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

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

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

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

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

bid/tender/request for quotation process and sets out each party's obligations for executing the contract.	
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	
Date and Time	**Briefing session to be held on the 14th of April 2023 at 11h00am.**
Venue and Address	**iThemba LABS, iThemba LABS, Old Faure Road, Faure, 7131**
Contact Person	**Mr Odwa Mxenge**

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

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

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

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

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

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

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

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

…… ……

Signature Date

…… ……

Position Name of bidder

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

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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**: …… …… ……

REFERENCE LETTER FORMAT FOR BIDDER

Referee Legal Name :	
Bidder's name:	
Bid Number:	NRF/ILABS 70IS/67/2022/23
Bid Description: SUPPLY, DELIVERY, INSTALLATION AND COMMISSIONING OF RADIOPHARMACEUTICAL STERILITY TESTING AND RADIOPHARMACEUTICAL DISPENSING ISOLATORS INCLUDING MAINTENANCE TO ITHEMBA LABS IN FAURE, WESTERN CAPE, FOR A PERIOD OF FIVE (5) YEARS	
Describe the service/work, start date and completion date the above bidder provided to you below	

Criteria/Risks	Below requirements	Meets requirements	Exceeds requirements
Quality of rendered services as measured against your service level			
Satisfied with work done			
Overall Impression	Other comments		
Approximate value of contract			
Would you use the provider again?			❑ YES ❑ NO

Completed by:	
Signature:	
Company Name:	
Contact Telephone Number:	
Date:	

NB: The above reference letter format is optional. The contractor may use their own template as long as the information therein is in line with the one specified in the "**Due diligence of capacity and capability**" or "**Returnable documents**" tables on page 10 and 15, respectively.

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

BID SIGNATURE (SBD 1)

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	