necsa
We're in your world
South African Nuclear Energy Corporation SOC Limited

Document Title	SPECIFICATION: BSL-3 MOBILE LABORATORY
Number	PRE-BSL3LAB-SPE-18001; REV3.0
Date	2019-03-28

APPROVAL & DISTRIBUTION

	NAME	SIGNED	DATE
Prepared	D van der Merwe Graduate in training R&D/Radiochemistry		2019/04/03
Reviewed	M Prinsloo Chief Technical Officer R&D/Radiochemistry		2019/04/03
Reviewed & Accepted	Dr. JR Zeevaart Chief Scientist R&D/Radiochemistry		2019/04/03
Approved	J Hanekom Head: PRE PES / PRE		2019/04/03
Distribution	PRE Records, Necsa intranet, OR list names of persons		

[1]

[1] See electronic revision history and approval block

TABLE OF CONTENTS PAGE

APPROVAL & DISTRIBUTION 1

1 INTRODUCTION 3

1.1 SCOPE OF PROJECT 3
1.2 OBJECTIVES 3
1.3 DESCRIPTION 3

2 APPLICABLE DOCUMENTS 3

2.1 NECSA DOCUMENTS 3
2.2 LEGISLATION 3

3 ABBREVIATIONS AND ACRONYMS 4

4 SCOPE OF WORK 4

4.1 SERVICES 4
4.2 DELIVERABLES 4

5 ASSOCIATED ACTIVITIES AND REQUIREMENTS 5

5.1 PROJECT MANAGEMENT 5
5.1.1 COMMUNICATION PERIOD 5
5.1.2 POINT OF CONTACT 5
5.1.3 REQUIREMENTS FOR REPORTING 5
5.2 QUALITY MANAGEMENT 5
5.3 PROJECT CONTROLS 6
5.4 CONFIGURATION MANAGEMENT 6
5.4.1 DOCUMENTS AND RECORDS 6
5.4.2 DOCUMENTATION OF CHANGES 6
5.5 ACCESS TO INFORMATION 6

6 SCHEDULE OF MILESTONES 6

7 RECEIVABLES 6

8 REQUIREMENTS APPLICABLE TO DELIVERABLES 6

8.1 HARDWARE 6
8.2 VENTILATION 9
8.3 LIGHTING 10
8.4 COMMUNICATION 10
8.5 FIRE PROTECTION AND ALARMS 10
8.6 COMMISIONING 11

9 APPENDIX A: PRELIMINARY LAYOUT 12

10 APPENDIX B: AUTOCLAVE SPECIFICATION 13

11 APPENDIX C: REFRIGERATION SPECIFICATION 14

12 APPENDIX D: FREEZER SPESIFICATION 15

13 APPENDIX E: INCUBATOR SPECIFICATION 16

14 APPENDIX F: SPECIFICATION FOR TECHNIPLAST IVC CAGES AND RACKS 18

15 APPENDIX G: SUMMARY OF RECOMMENDED BIOSAFETY LEVELS FOR INFECTIOUS AGENTS: 20

1 INTRODUCTION

1.1 SCOPE OF PROJECT

The project encompasses the manufacturing and installation of a Biological Safety Level 3 (BSL-3) facility as a modular containment laboratory conforming to requirements of BSL-3, and its installation and commissioning on the Pelindaba site.
Radiation monitoring requirements are excluded from the scope and shall be identified and added to the facility at a later stage by Necsa.
Animals handled in this facility will include mice, rats and guinea pigs.

1.2 OBJECTIVES

The objective of this procurement specification is to enable the acquisition of a fully functional BSL-3 mobile, containerised laboratory. Note that any requirement below that contradicts with BSL-3 certified laboratory requirements shall be superseded by the BSL-3 requirements.

1.3 DESCRIPTION

This system is a modular containment laboratory that meets the BSL-3 standard. The BSL-3 standard addresses the safe handling and containment of airborne pathogens (that can cause serious diseases or death).
As part of a Preclinical Imaging facility (PCIF) the BSL-3 laboratory is required to be constructed as a fully furbished containment system within a mobile container. Its purpose is to allow the safe transferal of infected animal study organisms into the PCIF in P-1700 (room G-65), while containing any possible spread of microbial pathogens such as Mycobacterium tuberculosis.
The system is to be positioned between buildings P-1600 and P-1700. A preliminary position has been identified on the south-western corner of P-1700. The laboratory is essentially self-sufficient, with the exception of the need for an external power connection, water, telephone, panic connection and a fire alarm. The system needs to be moved at a later stage to a next location.

2 APPLICABLE DOCUMENTS

2.1 NECSA DOCUMENTS

The Necsa SHEQ-INS system documents are broadly applicable. Prior to finalization of contract, it will be required to go through a checklist of applicable documents. It is not foreseen that any unusual or onerous additional requirements will be imposed, provided that general best practices are followed, and the stringent requirements for BSL-3 laboratories are fully met.
The Necsa SHEQ-INS documents are available on request, but are too numerous to include as addendum or to list here.

2.2 LEGISLATION

All South African legislation, as well as treaties and protocols to which the South African Government is a signatory, are applicable to the extent that they impact on the care and use of animals for scientific purposes. In particular, but not to the exemption from other legislation, the following Acts of Parliament must be considered.

The Animal Protection Act 72 of 1962 is applicable, as it impacts on design considerations for the housing and treatment laboratory animals.
In addition, the South African National Standard – The Care and Use of Animals for Scientific Purposes, SANS 10386:2008, shall be applicable.
Section 68 of The National Health Act 61 of 2003 is applicable; see also Government Notice R178 applicable to this Act.
Hazardous Biological Agents Regulation, 1390, 2001.
Apart from specific requirements with respect to BSL-3 facilities, all requirements of the Occupational Health and Safety Act 85 of 1993 (and amendments) shall apply to general workplace conditions.
The SANS Code of Practice for the Wiring of Premises No. 0142 of 1981, as amended.

The local Municipal by-laws and regulations as well as the regulations of the local Supply Authority.
The local Fire Regulations.
The Standard Regulations of any Government Department or public service company where applicable.
Other relevant SANS regulations pertaining to HVAC and Electrical installations. SANS 1238 and SANS 10173 are included for reference

The supplier of the BSL-3 laboratory shall ensure that the facility conforms to all legal requirements, even if not specifically listed in this document.
The supplier shall ensure that any certification and quality requirements are identified and incorporated, during all phases applicable to realization of this facility, prior to hand-over.

3 ABBREVIATIONS AND ACRONYMS

The main abbreviations and acronyms are listed below (others are added in the text of this document)

AHU	Air Handling Unit
BSC	Biological safety cabinet
BSL	Biological Safety Level (see appendix G for a summary of different levels)
FMEA	Failure Mode and Effect Analyses
HAZOP	Hazard and Operability Study
HVAC	Heating, Ventilation and Air Conditioning
IVC	Individually Ventilated Cages
PLC	Programmable Logic Controller
UDF	Uni-directional Flow (same as the BSC laminar flow cabinet)
UPS	Uninterrupted Power Supply

4 SCOPE OF WORK

4.1 SERVICES

The scope of work shall include all basic and detail design, except for provision of utilities up to battery limits. For the purposes of tendering, the battery limits shall be defined as the connection points of site utilities to the isolation point on the BSL-3 facility. In the case of electrical supply, this will be the connection point for the electrical feed cable to the distribution board.
In the case of water, it will be the connection on the external point of an isolation valve. In the case of civils and structural, the plinths and other civil work will be deemed Necsa responsibility, while the specifications and design shall be provided by the BSL-3 contractor.
The services to be included are:

- Attendance of NECSA design review and safety studies (including HAZOP, FMEA studies);
- IQ (Installation Qualification), OQ (Operational Qualification), PQ (Performance Qualification) and DQ (Design Qualification) documentation;
- IR, OR, PR and DR reports (reports associated with the 4 qualifications above);
- Training of Necsa nominated persons and assistance with standard operating procedures– include tariff base;
- Commissioning;
- Operational and maintenance support for 3 years after commissioning

4.2 DELIVERABLES

The deliverables shall include the following:

i) Fully equipped BSL-3 mobile laboratory conforming to suitable quality requirements associated with the risk of the facility when in operation, including, but not limited to requirements of this specification.
ii) Design documentation pack that contains at least the following content:
   a. System description;

b. Specifying documentation for all equipment, including drawings, performance curves, material specifications, ranges, seals, connections and any other data necessary to enable acquisition of an equivalent item, should the original not be available as a standard off-the-shelf item;
c. Proof of conformance to all BSL-3 requirements in design, including design calculations, specification and selection of components, quality plans for all affected items
d. Proof that risk is managed to acceptable levels (e.g. redundancy and failure conditions evaluated and managed);
e. Commissioning, operating and maintenance manuals (including critical spares list and maintenance schedule);
f. All diagrams and descriptions relating to utilities and ancillary systems, including but not limited to: air and water piping, instrumentation, electrical distribution, HVAC and communication.

iii) Factory acceptance test report (certified).
iv) Site acceptance test report (template to be provided before commissioning; completion to be done in collaboration with the client).

5 ASSOCIATED ACTIVITIES AND REQUIREMENTS

5.1 PROJECT MANAGEMENT

The BSL-3 contractor shall appoint a project manager, whom shall be expected to attend on average bi-weekly (or as differently agreed upon by the parties) progress meetings at Necsa or at the manufacturing site as required. The following additional requirements shall apply.

5.1.1 COMMUNICATION PERIOD

All communication from the client to the BSL-3 contractor shall be acknowledged within 2 days. The period for reply upon queries or instructions is 5 days, including raising objections or counter-queries. In addition, the BSL-3 contractor shall notify Necsa of site or design related issues within 5 days of discovery. If the BSL-3 contractor fails to communicate or respond within the above time frames, the BSL-3 contractor shall be deemed to agree with the instruction or specification as communicated by Necsa, and shall not have recourse to registration of scope changes or compensation events. In the event that a resolution cannot be reached within 5 days, both parties shall co-operate and agree on a reasonable time frame. However, the first communication must happen within the 5 day period.

5.1.2 POINT OF CONTACT

The BSL-3 contractor shall designate a single contact person, to whom all communication from Necsa shall be directed. Necsa shall designate a single contact person, to whom all communication from the BSL-3 contractor must be directed. For the purposes of project execution, it is preferable that the contact person is also the project manager.

5.1.3 REQUIREMENTS FOR REPORTING

The BSL-3 contractor shall be required to provide bi-weekly progress reports that include the following:
i) Design progress
ii) Procurement progress
iii) Manufacturing and assembly progress
iv) Expenditure and float to date

5.2 QUALITY MANAGEMENT

The BSL-3 contractor shall provide a project quality strategy (including design control), and main equipment and systems shall be subject to individual quality plans. These are especially relevant to items that perform safety or statutory functions. The quality plans shall provide appropriate hold points for testing, witnessing or acceptance by Necsa, and must be approved by Necsa before acquisition proceeds.
The design authority for the BSL-3 facility shall be the BSL-3 contractor, implying that ultimate responsibility for compliance with BSL-3 regulations and other legislation remains with the BSL-3 contractor

5.3 PROJECT CONTROLS

The BSL-3 contractor shall provide a financial plan prior to commencement of work. This shall include all provisions for authorization of expenditures, and the rates and schedule for compensation.
A full project schedule in MS Project Professional 2013 format shall be presented to Necsa for approval within 2 weeks (10 days) of contract award. The schedule shall be the basis for evaluation of compensation in the case of delays, scope changes or early termination of the contract. It is therefore critical that all activities and main procurement items are captured appropriately.

5.4 CONFIGURATION MANAGEMENT

5.4.1 DOCUMENTS AND RECORDS

All documents shall be uniquely numbered. The signage of documents may be done either electronically, provided that an accredited system is used. Alternatively, documents may be signed physically, and the original kept in safe and accessible storage for at least 50 years. If the BSL-3 contractor, as design authority, is not able to comply with document storage requirements, the original documents shall be handed over to Necsa in a structured and accessible file system.
Necsa shall be provided with electronic copies of all signed documents in PDF format, as well as editable electronic copies in native format, preferably MS Word 2013 (or later) and MS Excel 2013 (or later).
Drawings shall be provided in MS Microstation, AutoCad or open industry standard, to be accepted by Necsa prior to contracting.

5.4.2 DOCUMENTATION OF CHANGES

All engineering changes prior to the basic design freeze point (after consolidation of HAZOP review recommended changes) shall be controlled according the BSL-3 contractor document system. All subsequent changes shall follow an engineering change procedure, as per Necsa specification, and may invoke further engineering and project controls, including review and scope change.

5.5 ACCESS TO INFORMATION

No restrictions are foreseen.

6 SCHEDULE OF MILESTONES

- Kick off meeting one week after conclusion of SLA
- Acceptance of design of the BSL-3 container including all specifications by Necsa
- Location installation specifications to be agreed upon
- Manufacturing and subsequent commissioning on the contractor site
- Approval of Necsa installation site
- Installation
- On site commissioning at Necsa

7 RECEIVABLES

The BSL-3 Contractor shall receive from Necsa, prior to contracting:

i) Site layout drawing of the applicable area for installation
ii) List of available utilities
iii) Copies of applicable SHEQ-INS documents
iv) Access permits and safety induction training (1/2 day) for all project personnel

8 REQUIREMENTS APPLICABLE TO DELIVERABLES

8.1 HARDWARE

I. The laboratory must consist of high-quality room construction with special consideration given to joints, finishes, and penetrations

II. All connections, services and shutoffs (steam, water, and natural gas) must be external to containment and located in the utilities room. The laboratory must be designed for ease of maintenance, so that access to critical mechanical equipment (ventilation ducts, fans, piping, etc.) is outside containment.

III. The BSL-3 laboratory shall be constructed into a standard ISO shipping container, length 20 ft., width 8 ft., height 8.5 ft. The air handling unit shall be added **outside** of the ISO shipping container and **enclosed** in the lockable utilities room to protect equipment from the environment.

IV. The facility must have gas-impermeable walls, ceilings, and floors.

V. Ceilings shall be monolithic.

VI. The ceiling must be high enough over the Class II biological safety cabinet (BSC) to allow for a canopy/thimble connection or the opening of canopy/thimble door(s).

VII. Interior walls of 50 mm polystyrene, enveloped in 0.58mm Cromadec coated metal sheeting (white). Ceiling panels of container should consist of 79 mm polystyrene enveloped in 0.58mm Cromadec coated white metal sheeting; intersections of panels are sealed with non-shrinking sealant to ensure the lining is watertight (seepage of water through crevices, shall not be possible, also see IV). Panels can be cleaned by means of disinfectant and cloth. The isolator unit contains no windows

VIII. The laboratory shall have no holes where animals can escape and shall allow only one door to open at a time therefore an interlocking system is required operated by central power supply with a back-up battery Thereby preventing loss of negative pressure in containment area. A battery backup ensures that interlock is functional during power disruptions

IX. A 1.5 m wide, 1.2 m deep leak proof roof (on the outside of the container) covering the main entrance shall be fitted to the container.

X. A 1.5 m wide, 1.2 m deep leak proof roof (on the outside of the container) covering the dual port (pass-through hatch) system shall be fitted to the container allowing for operation of the ports.

XI. The BSL-3 laboratory shall have a personnel entrance/exit airlock, making direct access into the main laboratory impossible. The airlock shall have a footprint of 900 x 1200 mm. Both doors shall open outwards, for purposes of emergency exit, and shall be self-closing. The three doors will be equipped with emergency break glass (must be easily maintainable or replaceable) to automatically unlatch all three doors.

XII. Doors inside the suite should allow for an approximately 6 mm clearance underneath the door for directional airflow.

XIII. Doors of the change room should be fixed with ventilation grids, sizes of grids will be determined by contractor as to allow the air changes and pressure cascades to be maintained.

XIV. Doors and frames must be of solid finish construction, hardware appropriate for high-use, and kick plates (300mm stainless steel) should be fixed on all doors.

XV. Wall-door frame connection should be made airtight at time of frame installation with non-shrinking sealant

XVI. The entrance airlock shall open into a change room, with a width of 1200 mm, and length the remainder of container width. The change room door shall open to the inside of the change room itself (not into the laboratory), for purposes of emergency exit. The change room shall be fitted with a PPE/clothes rack and changing bench. Provision must be made for storage of 3 individual PPE sets.

XVII. Coat hooks (5) to be fitted and powder coated steel frame bench to serve as gowning bench in change room to be included.

XVIII. Floors must be easily cleaned, with chemical-resistant flooring *i.e.* vinyl with a slip-resistant, smooth, hard finish.

XIX. Flooring shall be seamless/welded vinyl minimum 3 mm; Light blue suggested in the lab areas and light brown in entrance and change rooms, covering wall to wall (100 mm high) and coved in corners (not hollow *i.e.* use bird's beak coving) with a radius of 50 mm for corners.

XX. Work surfaces, floors, walls, and ceilings must be designed, constructed, and finished to facilitate easy cleaning and decontamination.

XXI. The laboratory floor shall form a bunded area to contain water leaks and associated spread of contamination, this implies a retaining barrier/wall at the entrance door to the laboratory, integrated with the flooring (at least 50 mm high).

XXII. The laboratory shall be fitted with one Autoclave conforming to specifications attached hereto (Appendix B).

XXIII. Space should be allocated in the laboratory for one IVC cage wash station (domestic dustbin) see Appendix A.

XXIV. The laboratory shall be equipped with a wash basin that contains a hands free hot-cold water, pre-mixing faucet, 316 stainless steel sink (single sink-right, ± 600mm x 400mm x 250mm) and dry rack.This should be installed at the same level as the work bench and preferably adjacent to it. The sink must be accompanied by a paper towel dispenser and a hands-free soap dispenser mounted within easy reach. An extra cold water tap (¾ inch) should be installed next to the basin faucet for the use of the wash station and one water tap/shut off valve for the autoclave.

XXV. Movement space from the sink to the exit door shall be open and uncluttered.

XXVI. A 10 L under counter hot water boiler (kwikot) located beneath the basin should be installed.

XXVII. The laboratory shall be equipped with a work bench (900 mm high) made of 316L stainless steel (minimum 38 x 2 sq.) tubing with a Trespa (16 mm) counter top. 600 mm deep.

XXVIII. The laboratory work bench shall be fitted with one set of steel powder coated under counter drawers (4) and an under counter cabinet with removable and adjustable shelving (2) adjacent to the drawers. The cabinet should have double doors minimizing the space required for opening. Fixed casework, if used, must be sealed/caulked to the walls on installation to facilitate cleaning and prevent harbourage for vermin or a box frame should be used to be sealed off with bird's beak coving.

XXIX. Fixed casework, if used, should be installed before the coved flooring so that the coving can extend up toe-kicks (100 mm high as previously mentioned).

XXX. The laboratory shall be fitted with 300 mm deep steel powder coated cabinets and equipped with removable/adjustable shelves (1). The cabinets shall be mounted against the wall for the remainder of the wall length after the incubator has been installed. Clear Polycarbonate 5 mm slide panels should be used for opening and closing.

XXXI. The laboratory shall be fitted with an under counter refrigerator conforming to specifications attached hereto (Appendix C).

XXXII. The laboratory shall be fitted with a counter top single-door freezer (Appendix D) on a roller table for ease of access

XXXIII. The laboratory shall be fitted with a 50 - 60 L incubator (Appendix E) mounted above the fridge and freezer with reinforced support.

XXXIV. Compressed gas cylinders should be secured with 2x gas cylinder brackets

XXXV. The laboratory shall be equipped with an IVC (individually ventilated cages) rack to house animals. The cage rack shall make provision for at least 36 individual cages capable of housing rodents and guinea pigs. The specific IVC rack shall be Techniplast, Green Line, and fully compatible with Techniplast cages conforming to specifications attached hereto. The IVC cage size = 904 cm^2. (Green line GR900). See appendix F for a component breakdown for the IVC system. The identified components shall be included as part of the facility.

XXXVI. The IVC shall be equipped with an air handling unit (AHU) comprising humidity control and filtration. The AHU shall be a Techniplast Clima Flow, or superior unit, and fully compatible with the Techniplast IVC rack. The IVC AHU shall exhaust to the HVAC system.

XXXVII. The laboratory shall be equipped with a five foot (1500 mm) Class II BSC laminar flow cabinet, according to BSL-3 quality requirements. Exhaust air from the laminar flow cabinet shall be filtered through dual HEPA filters in series, and shall be combined with exhaust air from the rest of the BSL-3 facility.

XXXVIII. The necessary documentation for all equipment installed *i.e.* Autoclave, IVC racks and AHU, Fridge, Freezer, incubator, HVAC system, HEPA filters and Class II BSC should be provided this includes but is not limited to equipment service and maintenance plans, warranties, local representative contact details to receive training and validation certificates.

XXXIX. The laboratory shall be fitted with a dual port (pass-through hatch) system. One port shall be large enough in size to accommodate the autoclave canister. The sizes estimated for the top port = (600 w x 700 l x 500 h) and a bottom port (600w x 700 l x 750 h). The bottom of the latter shall be 250 mm above floor level (if possible). Each port shall have manual interlocks on the external and internal doors. The internal door shall have a glass window, to allow observance inside the airlock. The internal cavity shall provide for surface sterilization of objects that are transferred. Method(s) of sterilization shall conform to BSL-3 requirements, and must be approved by Necsa prior to installing. Visible Lighting (separate from UV-C for sterilization purposes), adjustable from 20 to 0 lux, shall be provided for the internal cavity. The two ports shall be vertically stacked, with the entry-port at the top. The door opening shall be 500 mm (high) by 600 mm (wide) on both sides.

XL. All HEPA filters shall be removable via bag-out, and shall fit the autoclave for sterilisation prior to disposal.

XLI. HEPA filter housings must be no more than five-feet high in order to facilitate filter change-out.
XLII. When HEPA filters are installed, a magnehelic gauge or other pressure-monitoring device must be installed, with the display placed in the most accessible location that is practical, to measure pressure drop across the filters.
XLIII. The electrical supply, ventilation, cooling and Pressure of the container shall be monitored via latest auto-bleep or similar system communicating to a designated cell phone in the event of electrical failure.
XLIV. A UPS is required to supply back-up power to the control system (BMS), door interlocks and emergency lights.
XLV. For the BMS allow for 100 m cabling to G-70.
XLVI. An external backup power supply is required for the IVC AHU unit (estimate = 6 kVA).
XLVII. All liquid effluent from the facility (sink) must be accumulated in autoclave glass bottles (x2) both fitted with shutoff valves to allow ease of operation (when one is full it can be shutoff and the other one can be opened).
XLVIII. All penetrations must be perpendicular to the surface and must be sealed to be water tight.
XLIX. Penetrations must be sealed with non-rigid, non-shrinking, silicone or latex sealant, pipes must be rimed with rubber at these sites before securing in place.
L. All pipes into the BSL-3 laboratory should be secured to prevent movement.
LI. Fixtures must be resistant to corrosion of bleach and other disinfectants.
LII. Backflow to utility supply must be prevented.
LIII. All pipes, gas lines and ventilation must be identified by use of labels and tags and flow direction should be indicated.
LIV. Access control system making use of tokens (no electronic logging required).

8.2 VENTILATION

I. The laboratory shall be ventilated by filtered air.
II. In most cases, the HVAC system should be Constant Air Volume (CAV)
III. No recirculation of air is allowed and the filtration shall conform to BSL-3 requirements.
IV. The outside exhaust must be dispersed away from occupied areas and air intakes, the exhaust must be HEPA-filtered (to effectively remove infectious agents prior to release from facility) and discharged upwards at a velocity greater than 3,000 fpm, the directed air should be protected from rain water intake
V. Treatment of supply air is also through a HEPA filter which effectively protects the environment in the event of reverse air flow during mechanical failures
VI. The air balance must accommodate biological safety cabinet canopy/thimble connection or Class II cabinet exhaust requirements.
VII. The BSL-3 lab must not become positively pressured if the exhaust system fails. Whenever possible, electrically interlock the supply and exhaust fans.
VIII. Exhaust ductwork must not be positively pressurized.
IX. Supply and exhaust dampers should be gas-tight and closable from outside the facility to facilitate decontamination with gaseous paraformaldehyde.
X. Local visual and audible ventilation system failure alarms are required for laboratory personnel.
XI. Air supply diffusers must be located so that airflow at the biological safety cabinet face is unaffected (laminar diffusers preferred).
XII. Ductwork should be gas-tight 316 stainless steel up to the HEPA filter (if present).
XIII. If the exhaust ductwork is welded, recommend welded joints for all connections except for the damper(s) (use flange and bolt connections for quick change-out in the future).
XIV. Coil units (for supplemental cooling) should not impact cleaning or provide a breach of containment.
XV. Limit elbows whenever possible to reduce the amount of background noise generated
XVI. The system shall allow for at least 6 air changes per hour in the laboratory area.
XVII. The pressure inside the facility shall be negative with respect to the atmosphere to always ensure air flow inwards towards the facility (in event of leaks or door opening)
XVIII. Filters on the extraction side of the HVAC, in the utility area, shall also be safe change filters to avoid direct contact with filters and spread of contamination/pathogens during maintenance actions. The exchanged filters shall preferably fit into the autoclave for sterilization prior to decay and disposal. However, if the filters need to be larger for practical reasons, the filters can instead be stored in a

safe place until suitable decay is achieved prior to sterilisation at a dedicated facility (not on Necsa site). The anticipated replacement frequency of these filters is once in 5 years.

XIX. Inlet air shall also be filtered to reduce the frequency of replacement of outlet filters.

XX. Climate control shall be provided. Air temperature shall be controllable between 20 and 30 °C, within 2 °C of set point. Normal set point shall be 22 °C. Environmental extremes to be designed for are:
Winter night temperature: -5 °C
Summer day temperature: 40 °C

XXI. Additional meteorological data are to be obtained from the South African Weather Service.

XXII. Air flow shall be sustained from clean towards potentially contaminated areas. This must be ensured by pressure differential and linear velocity of flow from one area to another. Pressure differential for each volume or area must be instrumented, and indicated both locally and remotely. The reference for each measurement shall be to atmosphere.

XXIII. A validation certificate should be available for the airflow system which must be verified annually

XXIV. Air pressure within laboratory room is maintained at negative pressure of 35 ± 2Pa while air in the change room is maintained at a negative pressure of 15 ± 2.5Pa and the entrance lock is maintained at 0Pa to ensure unidirectional airflow from the outside to inside of laboratory.). The HVAC system shall be automated to control pressure differentials, adjusting to loading on the filters.

XXV. Adjustment after opening and closing of doors shall not exceed 90 seconds.

XXVI. Aerosol penetration shall not exceed 0.01 % of upstream concentration under sustained conditions.

8.3 LIGHTING

I. Light fixtures must be flush mounted with bottom service entry.

II. The illumination shall provide for 4 separate lighting settings. These are:
   i. Off (total darkness) 18:00 to 06:00
   ii. Night cycle entry only: deep red light (100-160 lux) 18:00 to 06:00
   iii. Animal housing light cycle (270-375 lux) 06:00 to 18:00
   iv. Maintenance override cycle: no animals present (> 900 lux)

III. Service utilities area: > 900 lux upon switching on

IV. Emergency lighting in all three areas sufficient to evacuate personnel.

V. The animal housing room must be sufficiently light insulated, such that personnel movement and normal activities during daylight hours do not cause fluctuations in illumination levels. In addition, the maintenance cycle must be locked out (via physical lock or pass code), so that it cannot be accidentally set during the normal cycle, when animals are present.

8.4 COMMUNICATION

I. The container shall be equipped with three fixed line telephones (Telkom), one in each room.

II. The laboratory shall be equipped with one CCTV camera covering the main room, with visible and infrared capability, and infrared illumination for use during the dark cycle. The purpose is to monitor the laboratory in case of emergencies, for purposes of personnel and animal wellbeing. The camera stream shall be communicated to a Necsa control room. Wireless is preferred but in the case of cabling, allowance must be made for 200 m from source to monitor.

III. Fire alarms shall be both local and routed to the Necsa emergency centre (Necsa fire brigade).

IV. The laboratory needs to be equipped with a speaker connected to the Necsa PA system.

8.5 FIRE PROTECTION AND ALARMS

I. The laboratory shall be equipped with two SANS/SABS approved 5kg CO_2 fire extinguishers (SANS 1910) – one mounted inside the main laboratory, as well as one mounted on the outside wall near the access door inside a weather box.

II. The facility shall be equipped with fire sensors and alarms for the main laboratory as well as utility areas.

III. The alarm signal shall be cabled to the nearest building fire alarm panel (usually situated in the foyer of the building). Allow for 200 m cabling. From the fire alarm panel of the building, the existing communication to the Necsa Fire Brigade control room shall be utilised to communicate fire alarms to the Necsa Fire Brigade.

IV. The facility shall be equipped with a panic button that will alert Necsa emergency response personnel to an emergency. The button shall be situated within the main laboratory area, near the exit door. The signal shall be cabled to a Necsa control room, with allowance for a distance of 200 m. Further communication to the Necsa emergency response personnel will be initiated from the Necsa control room.

V. Failure of the HVAC system (ventilation failure and when differential pressure drops below a certain point) shall alarm in the Necsa control room.

8.6 COMMISIONING

I. A properly designed and constructed bio-containment facility, including its structural and mechanical safety systems, must meet predetermined performance criteria and be operational upon completion of construction. The integrity of the critical components of the biological containment systems shall be verified by the testing and certification requirements listed below (II-IX).

II. Certification of the facility, including structural components and safety systems, must be included as part of the overall commissioning processes normally undertaken to verify that the design and construction meet applicable standards, and that the facility can operate in accordance with the design intent.

III. Commissioning testing must also be performed without degradation to the facility or mechanical system that is being tested.

IV. All equipment and materials should be tested/evaluated prior to installation; duplicate testing is recommended.

V. Integrity of seals must be demonstrated by visual inspection.

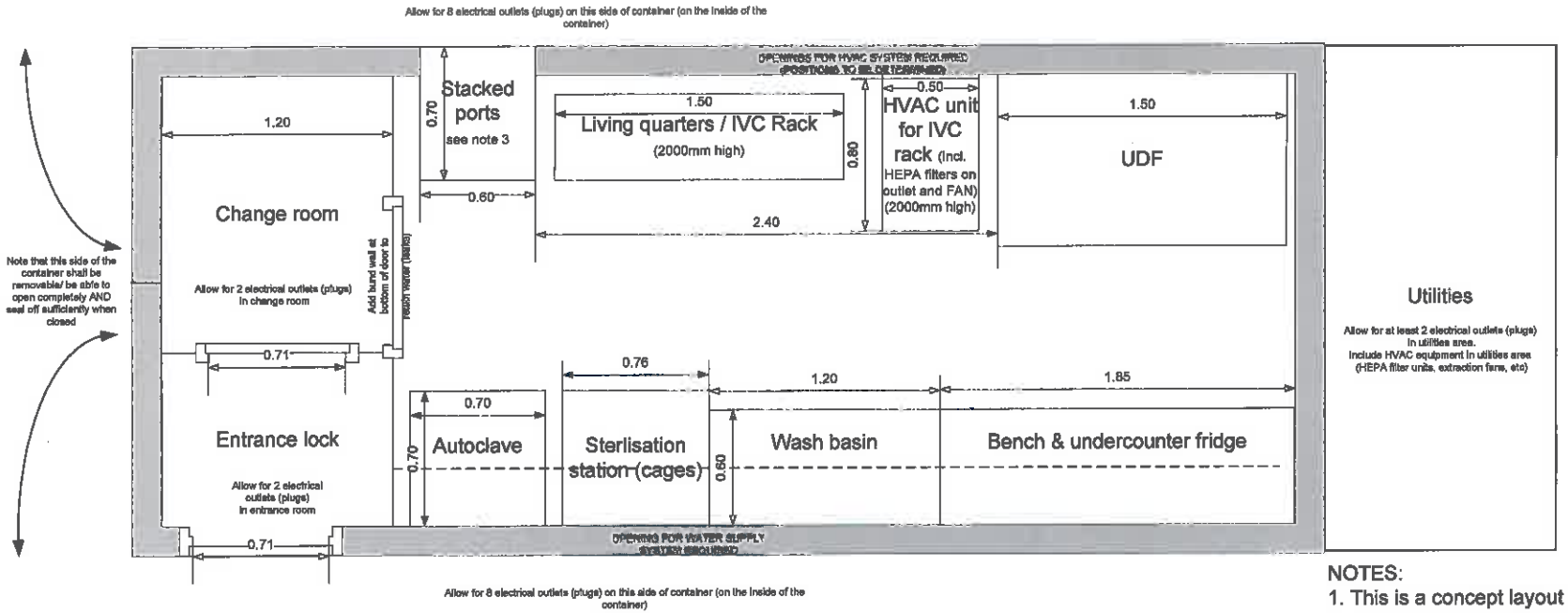
VI. The autoclave installation must be concluded with a performance qualification (PQ).

VII. The autoclave must be tested to verify that it meets specified standards:
   a. Thermometers are calibrated
   b. Clocks and timers are calibrated
   c. Biological indicators are used to verify the autoclave's effectiveness

VIII. The operation of backflow preventers must be verified

IX. The ventilation system must be tested by:
   a. Measurements of airflow at each supply and exhaust diffuser
   b. Smoke testing to visually verify limited turbulence at face of BSC
   c. Smoke testing to visually verify airflow from areas of low hazard to areas of higher hazard
   d. Verification that air system failure alarms (exhaust, supply, room pressure) function and annunciate properly

9 APPENDIX A: PRELIMINARY LAYOUT



NOTES:
1. This is a concept layout and changes to this might be acceptable (e.g. a mirror image or minor layout changes); The contractor shall supply the construction and as-built drawings during the next design phases
2. HVAC openings for supply and return air ducts are not indicated yet
3. Top hatch: (600x700x500(height)); Bottom hatch: (600x700x750(height)), 250mm from floor.

SCALE: 1:25

10 APPENDIX B: AUTOCLAVE SPECIFICATION

TECHNICAL SPECIFICATION:

The system shall have a chamber volume of approximately 23 liters.

The system shall allow for sterilization temperatures of 121°C and 134°C.

The system shall have a test for vacuum leakage.

The minimum vacuum level shall be 100 mbar.

The system preferable shall have an LCD display.

The chamber material shall be of stainless steel.

The chamber dimensions shall be approximately 260 x 420 (mm).

The system shall be able to operate on a 220 V 50/60 Hz power supply.

The system shall have a validation port.

The system shall have a warning system to inform the operator of possible heater failure, sensor failure, high temperature, high pressure etc.

11 APPENDIX C: REFRIGERATION SPECIFICATION

The refrigerator shall be a single door upright refrigerator.

The refrigerator shall be of the under-counter type with the following approximate dimensions:

Height maximum 850 mm;

Width approximately 595 mm;

Depth approximately 635 mm.

The capacity of the refrigerator shall be approximately 152 liters.

The voltage of the refrigerator shall be 220 – 240 V.

The refrigerator shall have temperature indication.

The refrigerator shall be able to maintain temperatures of 2-8 °C.

The system shall allow for temperature logging.

The refrigerator shall be lockable.

Serviced in South Africa

Comprehensive Fridge Warranty

Compressor warranty

12 APPENDIX D: FREEZER SPESIFICATION

The freezer shall be a single door, single compartment, stainless steel unit.

With the following approximate dimensions:

Height approximately 506 mm;

Width approximately 385 mm;

Depth approximately 710 mm.

The capacity of the freezer shall be approximately 52.6 liters.

The voltage of the refrigerator shall be 110 – 240 V.

The freezer shall have temperature indication.

The freezer shall be able to maintain temperatures to -30°C.

The system shall allow for temperature logging.

The freezer shall be lockable.

Serviced in South Africa

Comprehensive Fridge Warranty

Compressor warranty

13 APPENDIX E: INCUBATOR SPECIFICATION

General Specifications CELCULTURE CO_2 Incubators

CCL-050B-8

TEMPERATURE	
Temp. Control Method	Direct heat & air jacket using Microprocessor PID
Temp. Range, °C	Amb. +3 to 60
Temp. Uniformity, °C	<± 0.2*
Temp. Accuracy, °C	<± 0.1
Recovery Time** (after 1 min. door opening, 98%from initial value)	4 mins
Ambient Temp. Range	18 to 34°C (64 to 93 °F)
CO_2	
CO_2 Control System	Microprocessor PID
CO_2 Range, % CO2	0-20
CO_2 Accuracy, % CO2	± 0.1
CO_2 Sensor	Infrared (IR) Sensor*** / TC Sensor
CO_2 Recovery Time*** (after 1 min. door opening, 98% from initial value)	Standard Unit: 8 minutes Suppressed O2 model: 8 minutes
O_2 SPECS (FOR SUPPRESSED O2 MODEL)	
O_2 Control System	Microprocessor PID
O_2 Range, % O2	1-20.7%
O_2 Accuracy, % O2	± 0.1
O_2 Sensor	Galvanic Cell Type
O_2 Recovery Time (after 1 minute door opening)	At 1.0% O_2 by volume: 10 minutes at 1.0% O_2
HUMIDITY	
Humidification Method	Humidity pan
Humidity Range, % RH	Up to 97%

PHYSICAL CONSTRUCTION

Interior Volume	50 L (1.8 cu.ft.)
External Dimensions (W x D x H)	500 x 500 x 655 mm
	(19.7" x 19.7" x 25.8")
Internal Dimensions (W x D x H)	345 x 375 x 390 mm
	(13.6" x 14.8" x 15.4")
Shipping Weight	70 kg (154.3 lbs)
Shipping Dimensions (W x D x H)	660 x 660 x 890 mm
	(26.0" x 26.0" x 35.0")
Number of Shelves	2
Maximum No. of Shelves	4
Shelves Area (W x D)	310 x 310 mm (12.2" x 12.2")
Max. Load per Shelf	4 kg/shelf (8.8 lbs/shelf)
Available Electrical Configuration	220 - 240 VAC, 50 / 60 Hz, 1Φ, 3.4 A
	110 - 130 VAC, 50 / 60 Hz, 1Φ, 7.0 A
Maximum Power Consumption	372 watts
Power Consumption 37°C	37 watts
Interior Material	Stainless steel, type 304

CONTAMINATION CONTROL

Contamination Control Methods	1) Main body is electrogalvanized steel with ISOCIDE antimicrobial coating;
	2) Moist 90°C OVERNIGHT decon. cycle (HPA validated);
	3) 0.2 micron in-line filter for gas inputs;
	4) ULPA filter****

* Data recorded under optimum factory setting conditions

** For temperature not exceeding 37°C

*** For CO2 not exceeding 5.2%. Recovery time with TC sensor is longer.

****Not available for 50L

14 APPENDIX F: SPECIFICATION FOR TECHNIPLAST IVC CAGES AND RACKS

The following must be included:

		RACK AND CAGES FOR RATS	
2GR28CPSU		**2GR28 RACK PRE-ASSEMBLED** Single Sided Rack 2GR28 Pre-assembled with 28 H-Temp Polysulfone cage bodies, filter tops and stainless steel lids Note: 2 Bottles and 2 Bottle Caps needed per cage	1
32864N	ACBT0312SU	**WATER BOTTLE DD 340ML** H-Temp Polysulfone Water Bottle with Silicone Ring -Graduated 300/312 ml (full loaded 340 ml)	56
32860N	ACCP3421GM	**S/S CAP** Stainless Steel Bottle Cap with silicone seal	56
32861N	ACPCP24GM	**GREEN CARD HOLDER DD** Green Plastic Universal Card Holder	28
ACSCVF33GM		**INTERCONNECTION KIT DD** Note: 2 interconnection kits needed per each rack	2
		AIR HANDLING UNIT TO NOTIFY WHEN POWER RESTORED	
BOXUNWFEU		**WIFLOW AIR HANDLING UNIT** Wi Flow - 220/240V 50/60Hz (equipped with Schuko Plug) - to be controlled by any portable device (not included) - ONE 2 ONE included - Pre-arranged for GUARDIAN	1
GUARDIAN		**ONE TIME SOFTWARE LISENCE FEE**	1
GUARDMAINTAIN		**ANNUAL SOFTWARE LICENSE FEE** Annual Software License fee including maintenance and upgrading of the GUARDIAN System. One license required for each GATEWAY or WiFlow connected to the GUARDIAN.	1
		ACCESSORIES TO CONVERT CAGES FOR MICE	
GM900LID		**GR900 S/S LID FOR MICE**	28
ACCP6521GM		**GR900 S/S BOTTLE CAP FOR MICE**	56
		ACCESSORIES TO CONVERT CAGES FOR GUINEA PIGS	
GR900GPLID		**S/S LID TO BE USED FOR GUINEA PIGS** GR900 Stainless Steel Lid for Guinea Pigs (to be used with feeder GR965GPFH)	6

GR965GPFH	**FOOD HOPPER FOR GUINEA PIGS** Stainless Steel feeder for Guinea Pigs (to be used with GR900GPLID)	6
	UPS	
269c	**UPS, DELIVERY AND INSTALLATION** 3kVA HT1103L UPS + SNMP, and with external battery to give 100w load for 6 hrs. Delivery, connection and commissioning (AC cables and switchgear by others)	1

15 APPENDIX G: SUMMARY OF RECOMMENDED BIOSAFETY LEVELS FOR INFECTIOUS AGENTS:

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	■ No primary barriers required. ■ PPE: laboratory coats and gloves; eye, face protection, as needed	Laboratory bench and sink required
2	■ Agents associated with human disease ■ Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: ■ Limited access ■ Biohazard warning signs ■ "Sharps" precautions ■ Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: ■ BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials ■ PPE: Laboratory coats, gloves, face and eye protection, as needed	BSL-1 plus: ■ Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	BSL-2 practice plus: ■ Controlled access ■ Decontamination of all waste ■ Decontamination of laboratory clothing before laundering	Primary barriers: ■ BSCs or other physical containment devices used for all open manipulations of agents ■ PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed	BSL-2 plus: ■ Physical separation from access corridors ■ Self-closing, double-door access ■ Exhausted air not recirculated ■ Negative airflow into laboratory ■ Entry through airlock or anteroom ■ Hand washing sink near laboratory exit
4	■ Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments ■ Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level ■ Related agents with unknown risk of transmission	BSL-3 practices plus: ■ Clothing change before entering ■ Shower on exit ■ All material decontaminated on exit from facility	Primary barriers: ■ All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit	BSL-3 plus: ■ Separate building or isolated zone ■ Dedicated supply and exhaust, vacuum, and decontamination systems ■ Other requirements outlined in the text