User Requirement Specifications
Biosafety Cabinet

Equipment ID:	BF-BSC 01
	BF-BSC 02
	BF-BSC 03
	BF-BSC 04

URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of installation of the Biosafety Cabinet in the Seed Store Room, Seed Preparation Room, Harvest & Purification Room and IPQC room

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1.0 Approval Signature

This document is prepared by the Process, Validation and GMP compliance team of "NNE Pharmaplan India for the project "Revival of BCG Vaccine Laboratory" (**project number:-110729**) of BCG Vaccine Laboratory, Guindy, Chennai under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team and authorized by the appropriate Project Authority.

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2.0 Equipment description

A Biosafety Cabinet (BSC) is the primary barrier protection for individuals working with bio hazardous materials. Procedures that could create airborne biohazards should always be performed in a BSC as it protects workers and the environment from aerosols or droplets that could spread biohazardous material.

Following type of cabinet shall be considered:

Class II A2 type: 60% to 70% air from the positive plenum is re-circulated within the cabinet through high efficiency particulate air (HEPA (H-14)/ULPA filtration and 30% to 40% is discharged to the environment through the exhaust filter (HEPA (H-14) filtration). Velocity of airflow to the work zone creates an ultra-clean environment for product protection.

This cabinet may be used with microbiological activities like culturing, harvesting etc.

- Installation of BSC's must allow access to both supply and exhaust filters for annual certification testing and filter changes:
    - Top of cabinet must be far enough below the ceiling (at least 18") to allow field testing of exhaust flow according to NSF Standard 49.

The Supplier has to provide calibration protocols and guidelines for writing SOPs for recalibration.

All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.10, 4.1.11
- 5.1- Table 2, point 3 FDA guidance for industry for sterilisation equipment.
- ASME
- ISO 8362
- 5.4- Material of constructions –Please refer the section: Specific requirement.
- 5.2.7, 5.2.8

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User Requirement Specifications

Equipment /System	Biosafety Cabinet		
Identification	BF-BSC 01-04	**Document**	URS/BF-BSC 01-04
Effective Date	2014-02-17	**Revision**	05

Note:

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. I n case of an deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options become necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or an information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	Special Instruction a. If no comments against any specification shall be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non compliant and rejected.
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HLL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_110729_IRS_BCG_01
XII.	Refer Tender document with URS; NPI/110729/EQP/TD/06

Specifications	Remarks
3.0 Process Description	
3.1 Input & Charging method	
The product / accessories should be placed inside the BSC through the front grill / panel / movable sash	
3.2 Brief Process Steps	
BSC's are designed to provide both a clean work environment and protection for employees who work with biological hazards: i) The UV lamp the blower in the biosafety cabinet should be switched on for 20 minutes prior to using the BSC. The UV lamp should be switched off but the blower should be kept on till the end of the process ii) The front sash should be opened, the product / accessories to be placed inside and the grill to be closed. iii) BSC's use vertical laminar airflow to create a barrier to airborne particles, such as microorganisms iv) This unit will have a uniquely designed and strategically located high efficiency particulate air filters made of non-woven superior grade pleated media. v) The intake of the air is also derived through primary HEPA (H-14) filters located at the pre filter of the unit. vi) 70% air from the positive plenum is re-circulated and 30% is discharged to the environment through the exhaust filter (HEPA (H-14) filtration)	
3.3 Output & Discharging method	
The product / accessories etc should be removed from the BSC through the front grill / panel / movable door.	
4.0 Productivity Requirement	
4.1 Desired/ suggested capacity	

S.No.	Identification no.	Purpose	Inner Dimension (L x W x H in mm)
1.	BF-BSC 01	Seed Store (BF042) – Seed Ampoule Inoculation	Approx 950 x 800 x 750 or nearest standard Size
2.	BF-BSC 02	Seed Room (BF040) – Sub culturing (test tubes, conical flasks, tuberlin flasks)	1500x 800 x 750 or nearest standard Size
3.	BF-BSC 03	Harvest & Purification Room (BF037) – Harvest, Purification, Final Bulk dilution (Max. Bottle 15L, height - 430mm)	1900 x 800 x 750 or nearest standard Size (Client to confirm)

					Remarks
	4.	BF-BSC 04	IPQC (BF012) – Sample Flasks, conical flasks etc.	1200 x 800 x 750 or nearest standard Size (Client to confirm)	

4.2 Standard batch size	
Not Applicable	
4.3 Change Over Time	
Not Applicable	
4.4 Other Productivity Requirement	
Not Applicable	
5.0 Containment	
Not Applicable	
6.0 GMP Requirements	
6.1 Process control	
a) Differential Pressure	
b) Air Velocity	
c) Speed Control of motor	
6.2 Failure mode detection	
A. Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
a) Emergency stop activated	
b) Blower motor overload	
B. Following condition (not limited to the mentioned below) need only notification to operator for procedural control	
c) Audible and visual alarm for low air flow	
d) The UV lamp shall be interlocked with blower, sash, fluorescent lamp and UV lamp can be switched on only when the front sash is completely closed, otherwise it should give alarm	
e) Change of HEPA filter alarm/ indication	
f) Alarm in case of differential pressure across HEPA filter out of limit	

Specifications	Remarks
g) Alarm shall be triggered if the front door is raised more than safe clear opening during operation	
6.3 In –Process control	
Not Applicable.	
6.4 Level of instrumentation	

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Instrumentation
Differential Pressure	Monitor the pressure drop of the HEPA (H-14) filter w.r.t the ambient pressure	Microprocessor control it should display the actual Velocity in fpm Or m/s.
Air velocity	To maintain the positive and negative plenum of the cabinet	Air velocity sensing device with continuous digital display on the LED
Speed controller	To maintain the stable motor voltage and airflow despite building voltage fluctuations	Micro based speed controller
UV light with Hour meter	UV radiation	UV light with Hour meter

6.5 Batch data display and record printing	
Not Applicable	
6.6 GMP requirements (Others)	
6.6.1 Moving parts between the technical and the clean areas are not permitted. Necessary shafts and moving parts have to be tightly sealed.	
6.6.2 Illumination: i. Unit to be provided with adequate illumination at the work table by means of fluorescent light panel concealed at the upper portion of the unit. ii. The illumination at the work table is to be minimum 400 Lux	
6.6.3 Ultraviolet Light i. Optimal wattage of UV light to be incorporated for sanitization of the chamber area ii. The UV lamp installed shall be mounted out of the operator's line of sight and the radiation output should not be less than 40 microwatts per square centimeter at a wavelength of 254 nanometers (nm). iii. UV light with Hour Meter	
6.6.4 Equipment design must realize zero contamination.	

	Specifications	Remarks
6.7	**Specific requirements**	
6.7.1	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. Motors, etc.	
6.7.2	All switches ergonomically located for operator convenience.	
6.7.3	All setting should be user adjustable.	
6.7.4	HEPA (H-14) (High-Efficiency Particulate Air) shall be provided : • The BSC Class II A2type. Typical efficiency of 99.997% at MPPS, 0.3. • ISO Class 5 needs to be maintained during operation	
6.7.5	Laminated safety glass front sash • Optimum resistance to and filtering of germicidal UV radiation • Higher optical quality and less reflection and glare off of glass surface • High tolerance to heat • The interlayer should dampen the sound significantly • Tilted front panel for operator ease.	
6.7.6	Motorized damper adjustment shall be provide to control in flow and exhaust (i.e. 60%-70% recirculation and 40%-30% exhaust)	
6.7.7	Airflow velocity sensor shall be provided to overcome the filter choking and to maintain the velocity of 0.45m/s ±20%.	
6.7.8	Automatic speed control of motor (VFD) shall be provided to overcome the filter choking and to maintain the velocity of 0.45m/s ±20%.	
6.7.9	Two electrical sockets, (single outlets on 230 volt models), located one on each side and covered with stainless steel covers.	
6.7.10	The interior work area is formed from a single piece of stainless-steel with large radius to simplify cleaning	
6.7.11	Integrated sash proximity contacts sense proper sash position, serve as an interlock for the UV lamp, and activate an alarm if the sash is improper positioned.	
6.7.12	POA test port to be provided.	
6.7.13	Sanitation cycle (germicidal UV radiation) shall be taken care of after resuming power.	
6.7.14	All materials shall be made of durable type and have to be resistant against surface cleaning and wiping disinfecting using common detergents, disinfectants (chlorine free) and 70% Ethanol / IPA	
6.7.15	The work tray shall be integrated with the front air grille, for joint-free construction of SS316	
6.7.16	The main body and support stand to be SS304, min 240 grit. The support stand to be provided with castor wheels with lockers made of non-shedding material.	
6.7.17	All side panels shall be SS304, min 240grit.	

	Specifications	Remarks
6.7.18	The inner Surface of the bio safety cabinets to be SS 304, min 240 grit.	
6.7.19	LED with soft touch keypad shall be provided at the top of the front glass for blower and lights	
6.7.20	**Blower:** a) Blower shall be permanantly lubricated b) Motor Blower assembly MOC: Aluminum	
6.7.21	Preferred make for Motor Blower assembly : Crompton Greaves/ ABB/ GE/ Siemens/EBM-PAPST/Nicotra	
6.7.22	Approved make for filter: Camfil Farr/AAF/Freudenberg	
6.7.23	The following test to be conducted at site during qualification 1. air velocity test 2. Filter Integrity Test 3. Flow Visualization Test (videography) 4. Non-viable Particle Count 5. Recovery Test 6. Lux Level 7. Sound Level	
6.7.24	Internal and external dampers and sealant GMP compliance shall be provided	

7.0 Constraints

7.1 Equipment location and available space

This equipment will be installed in the Bulk Area of Revival of BCG Vaccine Laboratory at BCGVL, Guindy, Chennai.

Equipment Location:

Floor: First Floor - Bulk

Plant: Revival of BCG Vaccine Laboratory, Guindy, Chennai

The equipment location is indicated in the relevant block of the layout enclosed as URS Annex-1.

Physical condition of the rooms:

BSC Seed Store (BF042)

1. Class: EU Class "B" – BSL2
2. False ceiling: 3000 mm
3. Differential Pressure: -15 Pa
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: <55% RH

BSL-2 Seed Room (BF040)

1. Class: EU Class "B" – BSL2
2. False ceiling: 3000 mm
3. Differential Pressure: -5 Pa
4. Temperature maintained: 22 °C ±2 °C
5. Relative Humidity: <55% RH

Harvest & Purification room (BF037)

1. Class: EU Class "B" – BSL2
2. False ceiling: 3000 mm

Specifications	Remarks
3. Differential Pressure: -5 Pa 4. Temperature maintained: 22°C ±2°C 5. Relative Humidity: <55% RH IPQC (BF012) 1. Class: EU Class "D" 2. False ceiling: 3000 mm 3. Differential Pressure: 15 Pa 4. Temperature maintained: 22°C ±2°C Relative Humidity: <55% RH	
7.2 Available Utility	
a) Electricity: _____(Report Requirement) b) Air consumption (from room):_____ (report requirement)	

8.0 Abbreviation

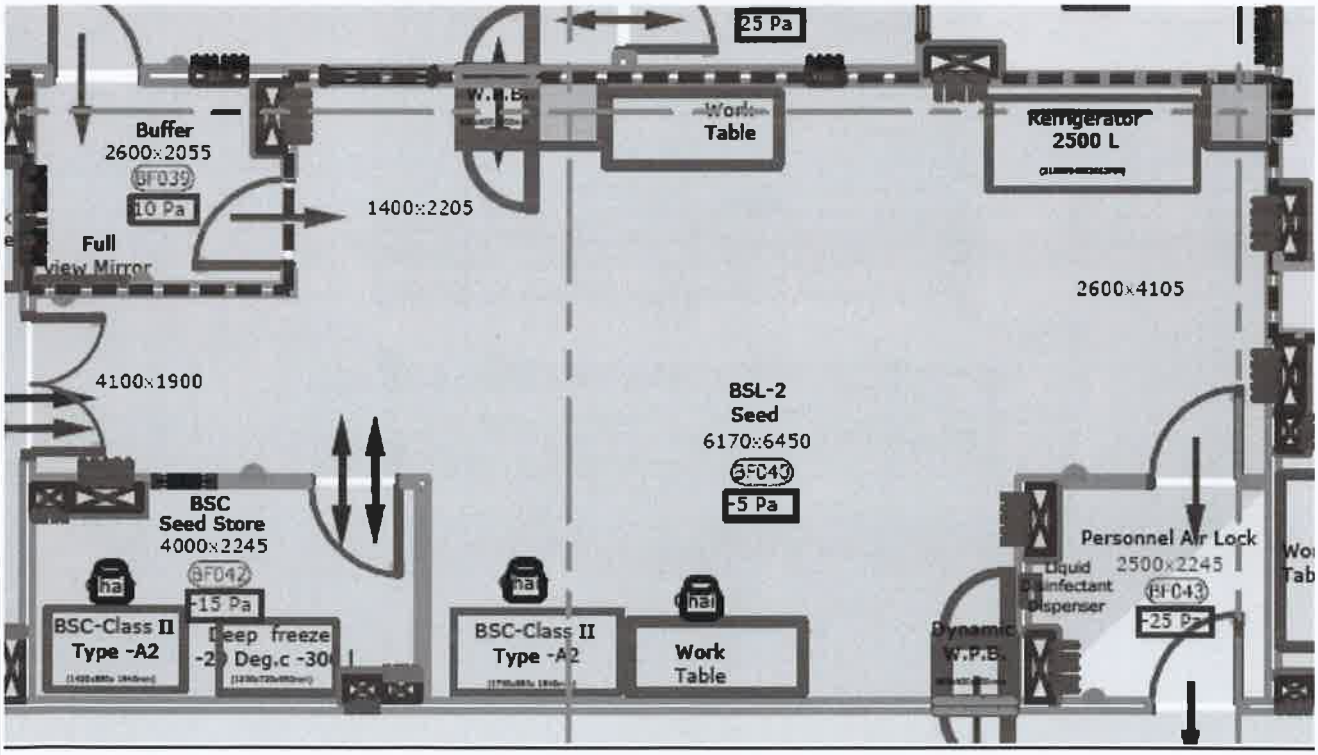
Abbrevation	Definition
BSC	Biosafety Safety Cabinet
BSL	Biosafety Level
GMP	Good Manufacturing Practice
HEPA	High-Efficiency Particulate Air
ISO	International Organization of Standardization
LED	Light Emitting Diode
MPPS	Most Penetrating Particle Size
NPI	NNE Pharmaplan India
NSF/ ANSI	National Safety Foundation/ American National Standard Institute
QA	Quality Assurance
SOP	Standard Operating Procedures
SS	Stainless steel
UV	Ultra Violet

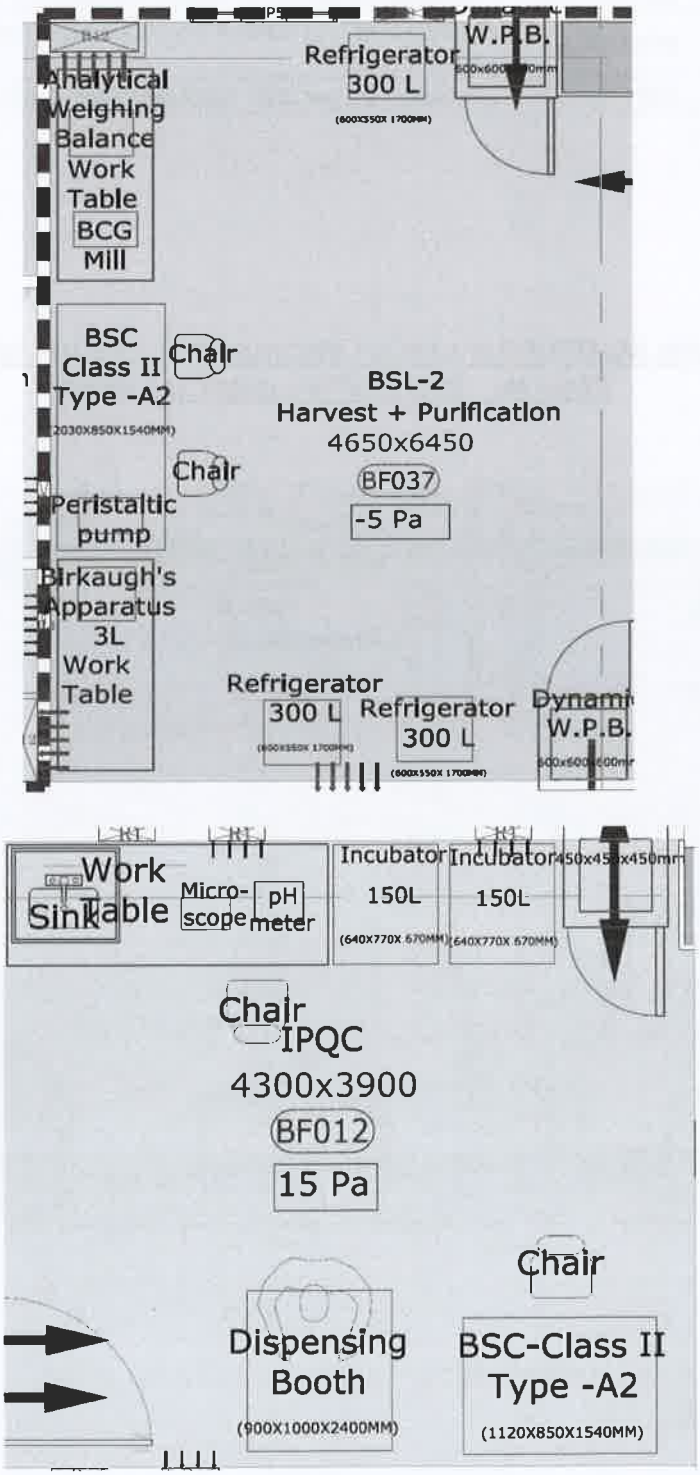
Revision index

Revision	Date	Reason for Revision
00	13.02.2012	First Draft for Client's Review
01	2012-11-16	Format changed as per HLL requirement
02	2013-01-02	Updated as per HLL comments received on 2013-01-02

03	2013-01-10	Updated as per MOM dated 2013-01-10
04	2013-04-22	Updated as per comments received by mail from HLL on 2013-04-09
05	2014-02-17	Updated as per HLL comments received on 2014-02-14

URS ANNEXURE 1: LAYOUT SHOWING THE LAYOUT AREA
Room No.: BF040, BF042, BF037 and BF012




Refrigerator
300 L
(600X550X 1700MM)
W.P.B.
Analytical
Weighing
Balance
Work
Table
BCG
Mill
BSC
Class II
Type -A2
(2030X850X1540MM)
Chair
Chair
BSL-2
Harvest + Purification
4650x6450
BF037
-5 Pa
Peristaltic
pump
Birkaugh's
Apparatus
3L
Work
Table
Refrigerator
300 L
Refrigerator
300 L
(600X550X 1700MM)
Dynami
W.P.B.
Work
Table
Sink
Micro-
scope
pH
meter
Incubator
150L
(640X770X 670MM)
Incubator
150L
(640X770X 670MM)
450x45
x450mm
Chair
IPQC
4300x3900
BF012
15 Pa
Chair
Dispensing
Booth
(900X1000X2400MM)
BSC-Class II
Type -A2
(1120X850X1540MM)