Minutes of Meeting of Technical Specification Committee of "equipment, test kits and drugs for the National Viral Hepatitis Control Program (NVHCP) and other related programs" on 18th October, 2024 at Central Seminar Room, NCDC, Delhi

A meeting of the Technical Specification Committee for finalizing the specification of "equipment, test kits and drugs for the National Viral Hepatitis Control Program (NVHCP) and other related programs" was held on 18th October, 2024 from 10:00 AM to 12:00 PM at Central Seminar Room, NCDC, Delhi under the chairpersonship of Prof. (Dr.) Sunita Sharma, Director Professor of Pathology (LHMC). The member secretary welcomed the committee members. The committee was apprised about the program and need for modification in the technical specification of these equipment through a presentation by the member secretary.

The following members attended the meeting.

1. Prof. (Dr.) Sunita Sharma, Director Professor of Pathology (LHMC)-chairperson (nominee of DGHS)
2. Dr. Kavita S. Lole, Scientist G and Head, Hepatitis, National Institutes of Virology (ICMR), Pune
3. Dr. Rajesh Sharma, Scientist Grade III, Representative of Director, National Institute of Biologicals, Noida
4. Dr. Aashish Choudhary, Department of Microbiology, Representative of Dr. Lalit Dar, AIIMS, New Delhi
5. Prof. (Dr.) Vandana Roy, Director Professor, Department of Pharmacology, MAMC, Delhi
6. Prof. (Dr.) Vaishali Bhardwaj, Professor, Gastroenterology, PGIMER & RML Hospital, New Delhi — could not attend
7. Prof. (Dr.) S. Anuradha, Director Professor, Medicine, MAMC, Delhi
8. Dr. Sandhya Kabra, Deputy Commissioner, NVHCP & Addl. Director Head, Viral Hepatitis, NCDC, Delhi
9. Dr. Partha Rakshit, Joint Director, NVHCP & Viral Hepatitis, NCDC, Delhi
10. Dr. Monil Singhai, Joint Director, Representative of Director, NCDC, Delhi
11. Dr. Preeti Madan, Joint Director, NVHCP & Member Secretary, Technical Specification Committee of equipment, test kits and drugs under NVHCP

The agenda of the meeting was as follows:

Agenda 1: To modify the existing technical specifications of Fully Automated Immuno Analyser

Fully Automated Immuno Analyser

System shall have the facility to test immunoassays for anti- Hepatitis A/Anti-Hepatitis E, Hepatitis B surface antigen, Anti-Hepatitis C, Anti-Hepatitis B core. There should be a provision of up gradation of the system for infectious/non-infectious markers.

Technical Specifications

1. Fully automated, bench top/floor analyser to perform the qualitative and quantitative assays from serum and plasma samples.
2. System should be discrete, fully sensitive random access with a provision to test STAT samples.
3. System should be based on chemiluminiscence, enhanced CLIA/ electro CLIA/ latest chemiluminescence etc. technology for measuring the assays with very high sensitivity, specificity and linearity.
4. Onboard loading capacity should be at least 50-60 samples or more at one time with a procedure for continuous loading.
5. System should have throughput of at least 80 tests/hr and the machine should have provision for up-gradation.
6. System should have reagent slots for a minimum of 15-20 assays.
7. System should have on-board cooling facility to maintain the temperature of the reagents.
8. Sample volumes should be < 350 µl per test for each type of test User defined onboard sample dilution is needed.
9. System must use mechanisms to prevent any carryover contamination to have reliable patient results.
10. System to use latest mixing probe technology to mix the samples and reagents to have complete uniformity with clot detection facility.
11. Flexibility to use different sample containers like primary tube with different sizes; sample cups etc for easy processing.
12. Systems should have the facility to test infectious and non-infectious markers.
13. On-board reagent stability should be up to two months and calibration of the parameter should be typically lot based. Calibration frequency should be as per quality control requirements/lot specific. No daily calibration should be required by the system to conserve reagents.
14. System should have on-board windows-based data control work station with (Thin Film Transistor) TFT LCD/LED colour touch screen monitor for programming the tests and entering the patient data.
15. System should have the facility to store minimum of 2000 test results.
16. System should have external laser printer to take printout of patient results and QC reports.
17. On-board barcode scanner for easy operation needed.
18. Two-way interface with LIS.
19. System should have comprehensive software with calibration management, management of internal control, management of external control and customized patient data management. System must have extensive quality control like Westgard rules, Levey – Jennings graphical representation.
20. The system should be upgradable. If the system gets redundant, the system needs to be upgraded/replaced free of cost. In case the system is upgraded, the equipment will be the property of the institution/consignee site. In case, new equipment is installed at any time on account of obsolete/redundant system of the existing equipment, the same shall be

returned to the firm on completion of 5 years from date of installation of the first equipment (which will be the property of the institution).

21. All materials required for maintenance, calibration and upgrades including software would be provided free of cost.
22. System should have facility to collect both liquid and solid waste for disposal.
23. Power supply 220-240V AC, 50Hz.
24. Company should provide a backup system (throughput of at least 80 tests/hour) using same kits and consumables. In case the equipment stops functioning beyond the admissible downtime, the firm needs to provide free of cost backup for carrying out testing by either providing another machine for the interim period or backup for testing of samples must be ensured.
25. UPS-microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer compatible with the system with maintenance free batteries with desired backup for carrying out the test i.e. run time including incubation time as per the suitability of equipment with additional 15 minutes of run time.

General specifications:

1. Satisfactory working report of the quoted/similar model from a government institute/government hospitals should be provided.
2. The manufacturer should specify installation qualifications, Operational Qualifications and performance qualifications. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Efficiency, other factors such as distortion etc as applicable also be furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2-meter cord at input and fitted with plugs of appropriate rating (5/15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty). However, the quoted CMC rate will not be included in financial evaluation. Warranty should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line

voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating :10KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.

8. Certifications:
   a. Product Certification: CE Class II A or US FDA certified
   b. Quality Certification: ISO certified
   c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Additional requirements
   a. Bidder to be responsible for site preparation (minor modifications), installation, commissioning, trial run etc of the system in laboratory. All reagents to make the machine functional along with trial runs (minimum of 100 tests for each parameter) to user satisfaction should be provided free of cost.
   b. Lab staff should be comprehensively trained on all the operational function of equipment and provided certificate, Satisfactory working report of machine will only be provided once the lab staff is trained to our satisfaction
   c. The supplier should be authorized dealer for the principal firm & should produce original certificate for the same.
   d. The principal firm should provide certificate stating the machine is brand new.
   e. All related plumbing for installation with suitable diameter pipes for input as well as drain should be done by company if required. Also suitable/compatible water treatment plant system and storage tank should be provided if required. It is the responsibility of the vendor to maintain the water quality for equipment irrespective of the quality of the tap water supplied in the site.
   f. The HBsAg, anti-HCV, Anti-HEV/Anti-HAV, Anti-HBc test provided must be compatible with equipment (Model) quoted in this tender and the rate quoted must be inclusive of all accessories to run the test and validated calibrator and positive & negative control of stability of calibration for a minimum of 4 weeks. The firm should provide controls/calibrators free of cost which should be sufficient for 4 runs per month. In case additional controls / calibrators are required, the cost of the same may be mentioned for purchase and the same will not be considered for financial evaluation. All the consumables and reagents required for running of tests shall be included in the cost quoted per test.
   g. The tests should have minimum shelf life of 4 months for each type of test i.e. HBsAg, Anti-HEV/Anti-HAV, Anti-HBc test at the time of delivery to the consignee site. The minimum shelf life for anti-HCV test should be 3 months at the time of delivery to the consignee site.
   h. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

The committee approved the technical specification of the Fully Automated Immuno Analyser and agreed for procurement of the same under reagent rental model wherein the

kits procured for hepatitis diagnostic assistance as per algorithm or use in the program would be compatible with the platform

Agenda 2: To modify the existing technical specifications of Elisa Reader and Elisa Washer

Elisa Reader

Technical Specifications

1. Should be able to support all plate formats U bottom, V bottom and flat bottom with reading capacity of 1 to 96-well microplates individually
2. Optical systems: Xenon Flash Lamp
3. Detection: Absorbance based.
4. Reading Time: < 7 seconds for 96-wells.
5. Wavelength range: To cover 340 nm to 750 nm and should have monochromatic based system.
6. Suitable LCD display
7. Wave length selection should be double monochromatic with 1nm increment
8. System should have capability to do qualitative, quantitative, kinetics with any formulae including validation, transformation, and factors and floating cut off.
9. Should have linear measurement range of: 0-4 OD (optical density)
10. Resolution: 0.001Abs.
11. Photometric Accuracy: 1%±1%
12. Should have a resolution of 0.001 OD
13. Repeatability: 0.5% +/- 0.005 OD
14. Photometric method-single /dual
15. Should have facility for sorting at least 50 assay protocols
16. Should be capable of doing multi standard tests and controls
17. Should have blanking facility-air wise and well wise
18. System should perform self-check before every measurement and should have automatic calibration before each plate reading and facility for storage of calibration curves.
19. Power requirements: 220-240 V AC, 50Hz
20. Inbuilt shaking mode
21. PC based system.
22. PC requirements: Intel core i5 processor, 2 GB RAM, 500GB hard disc, LED monitor 17'', USB PORT, key board and mouse, Microsoft Window with MS office licensed
23. PC software packages (windows compatible and should be licensed) for on board data analysis.
24. Two way interface with Laboratory information System
25. Compatible UPS-microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer

General Specifications

1. Satisfactory working report of the quoted/similar model from three government institutes/government hospitals (from last two years) should be provided.

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2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications at site. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm and the original product catalogue must be available on the company (manufacturer) website. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (5/15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty). However, the quoted CMC rate will not be included in financial evaluation. Warranty should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: As per the requirement of the equipment. However, atleast 1 KVA
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification: CE Class II A or US FDA certified
    b. Quality Certification: ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Additional requirements:
    a. Cover for the instruments to be provided
    b. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

Elisa Washer

Technical Specifications

1. Should have capability to wash flat, U or V bottom microplates
2. Fully automatic plate washer
3. Should have removable and autoclavable plate carrier
4. Should have strip selection option which allows to wash selected strips only
5. Should have inbuilt vacuum and dispensing pumps/peristaltic pumps to ensure accurate and quiet washing.
6. Dispensing and aspirating needles should be separate
7. Washer should have 8 channel wash head
8. Should have 2-4 independent liquid channels
9. Wash volume per well should be programmable
10. Should have more than 50 wash programme memory
11. Programmable washing time, volume and soaking time
12. Should have residual volume of <5µl
13. Alarm for monitoring the overflow and wash solution
14. Should provide additional 2 numbers- each of wash buffer bottle and waste bottle along with the tubing
15. Compatible UPS- microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer
16. Power input 220-240VAC, 50 Hz

General Specifications

1. Satisfactory working report of the quoted/similar model from three government institutes/government hospitals (from last two years) should be provided.
2. The manufacturer should provide Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm and the original product catalogue must be available on the company (manufacturer) website. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (5/15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty).

However, the quoted CMC rate will not be included in financial evaluation. Warranty should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.

a. Complete with comprehensive set of spare parts.
b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: As per the requirement of the equipment. However, atleast 1 KVA
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification: CE Class II A or US FDA/ IVD/ BIS certified
    b. Quality Certification: ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Additional requirements:
    a. Cover for the instruments to be provided.
    b. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

The committee decided that Elisa Reader and Elisa washer will be procured together to ensure the compatibility

The committee approved the technical specification of the Elisa Reader and Elisa Washer

Agenda 3: To modify the existing technical specifications of Table Top Centrifuge (swing out)

Table Top Centrifuge (swing out)

Technical Specifications

1. Body should be made of strong fabricated & corrosion resistant steel.
2. Microprocessor controlled with touch keypad LED.
3. Display of time and speed with digital display.
4. Control panel – for start/stop switch, dynamic brakes and protective fuses.

5. Swing out rotor with 24 tubes of atleast 15 ml capacity with suitable adaptors for 10 ml,7 ml and 5 ml round bottom vacutainers.
6. Autoclavable rotors
7. Automatic rotor recognition and automatic imbalance detector. Programmable speed with separate short spin key (in seconds).
8. Brushless maintenance free motor drive with low noise levels less than 60 dBA at max speed with exact speed pre selection and display. Speed range from 500-4000 rpm accuracy 1 rpm with increment of 100.
9. Double lid locking system for maximum safety.
10. Automatic imbalance cut out, rotor over speed protection feature
11. Multiple acceleration/breaking time modes will be available. (Like Low, Medium and High)
12. Stable speed output even under unstable voltage conditions.
13. The unit should be capable of operating in ambient temperature of 10-40°C and relative humidity of 15-90%.
14. Power supply requirements: Supply voltage: 220-240 V, AC, 50 Hz.

General Specifications

1. Satisfactory working report of the quoted/similar model from three government institutes/government hospitals (from last two years) should be provided.
2. The manufacturer should specify Installation qualifications, Operational qualifications and Performance qualifications on site. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm and the original product catalogue must be available on the company (manufacturer) website. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (5/15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty). However, the quoted CMC rate will not be included in financial evaluation. Warranty should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.

6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: As per the requirement of the equipment. However, atleast 3 KVA
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification: CE Class II A/ US FDA/ IVD/ BIS certified
    b. Quality Certification: ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

The committee approved the technical specification of the Table Top Centrifuge (Swing Out)

Agenda 4: To modify the existing technical specifications of Lab Refrigerator

Lab Refrigerator

Technical Specifications

1. Capacity 300-400 Litres
2. Temperature range: 2-8° C
3. Internal: Durable unbreakable interior stainless steel
4. External: Durable rust free exterior. MS powder coated, scratch free
5. Should have one transparent door with light inside main chamber. Door with lock.
6. Inbuilt roller mounted / wheels required
7. Microprocessor based controller
8. Control panel with temperature alarm, on/off switch, digital thermometer, temperature display with 0.1^0C graduation
9. Refrigerant: CFC / HCFC free/Natural refrigerant should be environment friendly
10. Stainless steel trays, with minimum four adjustable shelves Adequate circulation of air to ensure even cooling by duct system
11. Electronic automatic temperature control and automatic Frost free cooling with Evaporator fan for uniform cooling
12. Hermetically sealed heavy duty compressor unit. Should have all the accessories required for the functioning of the equipment.
13. Power supply requirements: Supply voltage: 220-240 V, AC, 50 Hz.

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General specifications:

1. Satisfactory working report of the quoted/similar model from three government institutes/government hospitals (from last two years) should be provided.
2. The manufacturer should specify installation qualifications, Operational Qualifications and performance qualifications. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm and the original product catalogue must be available on the company (manufacturer) website. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (5/15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty). However, the quoted CMC rate will not be included in financial evaluation. Warranty should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: As per the requirement of the equipment. However, atleast 3 KVA
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification: CE Class II A/ US FDA/ IVD/ BIS certified
    b. Quality Certification: ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

The committee approved the technical specification of the Laboratory Refrigerator

Agenda 5 : To modify the existing technical specifications of Deep Freezer (-20^{0}C) Vertical Deep Freezer (-20^{0}C) Vertical

Technical Specifications

1. Internal minimum capacity 300 to 400 L
2. Temperature Range up to -20^0 C to -25^0 C (adjustable)
3. Vertical Cabinet (upright mode)
4. Outer Panels: Outer panels are made of GI coated/ CPRCA sheet/Stainless steel
5. Interior Panels: Interior panels are made of Stainless steel
6. Adjustable feet for leveling with lockable castor wheels.
7. Door: Standard hinged door with Double gasket seal between the door and the cabinet. Single solid door with (PU) polyurethane Insulated or Vacuum Insulated
8. Door closing and locking Adjustment: Self closing door with key door lock.
9. Control System: Micro-processor-based temperature controller with digital temperature display LED/LCD with temperature recorder.
10. Temperature monitoring:
    a. Digital temperature (LED) display with 0.1^{0}C graduation
    b. Temperature recording device: temperature recorder with data logger compatible with LIS
    c. Microprocessor control for operation with integrated audio-visual temperature alarm function with digital monitoring display. There should be a method to check alarm system.
    d. Provision to connect with central (temperature) monitoring system. Provision of output through freezer for remote monitoring purpose
    e. The temperature indicator of deep freezer shall be calibrated with the help of master calibrator which shall be certified for its accuracy by NABL approved lab.
11. Insulation: High density polyurethane or equivalent gaskets - double seal silicon, fungus resistant
12. Trays: Adjustable stainless steel trays with perforated design
13. Inner shelf: 4-6 shelves/ drawers.
14. Refrigeration system
    a. Refrigerant: CFC / HCFC free/Natural refrigerant should be environment friendly
    b. Should be environment friendly with an enhanced condenser and washable condenser filter for optimum cooling:
    c. Heavy Duty refrigeration system, maintenance free, hermetically sealed compressor (s), noise free and vibration free
    d. Compressors (s) should have with evaporators and cooling fans.
    e. Refrigeration System Alarm: It should also have audio visual Electronic Alarm System independent of power supply for malfunction warning.

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15. Security lock to prevent unintentional switch off shall be supplied
16. Alarm for audible & visual fault acknowledgement, low & high temperature audio visual alarms, condenser fault alarm, remote contact alarm, open door alarm, clean filter indicator and power failure alarm.
17. Noise factor should not exceed 60 dBA
18. System should include racks/ boxes/ plastic crates two for each shelf, additionally, 40 storage boxes should be supplied of which 20 boxes should have capacity to accommodate 81 spaces of 2ml in each box and 20 boxes shall have capacity to accommodate 100 spaces of <2ml in each box.
19. The unit shall be capable of operating continuously in ambient temperature of 10- 40^{0}C and relative humidity of 15-90%.
20. Power Supply: Power input to be 220-240V AC, 50Hz
21. Resettable over current breaker shall be fitted for protection.
22. Maintenance free temperature backup system to retain temperature in subzero condition for period of minimum 1 hour with full load and in close door conditions in case of power failure or any other shut down.
23. Back up of 30 minutes with 5 KVA UPS

General Specifications:

1. Satisfactory working report of the quoted/similar model from three government institutes/government hospitals (from last two years) should be provided.
2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm and the original product catalogue must be available on the company (manufacturer) website. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty). However, the quoted CMC rate will not be included in financial evaluation. Warranty should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.

6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: As per the requirement of the equipment. However, atleast 5 KVA
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification: CE Class II A/ US FDA/ IVD/ BIS certified
    b. Quality Certification: ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

The committee approved the technical specification of the DEEP Freezer (-20 0 C) Vertical

Agenda 6: To modify the technical Specifications of Deep Freezer (- 80^{0}C) Vertical

Deep Freezer (- 80^0 C) Vertical

Technical Specifications

1. Internal minimum Capacity: 400- 500L
2. Temperature range: -65^{0}C to -85^{0}C
3. Internal: Stainless steel (minimum 22g) (S.S. grade 304)
4. External: Solid Outer Cabinet Corrosion Resistant (at least 1 mm thickness) adjustable feet for leveling with lockable castor wheels.
5. Design: Upright Type
6. Door: Triple silicon section seal, fitted with decompression valve facility to lower air pressure inside the freezer for easy door opening. Self -closing door with key door lock adjustable feet for leveling (optional casters). Casing & door should have vacuum insulation technology. Advanced remote monitoring: Should have independent High / Low alarm, Door open alarm, and power failure alarm;
7. Refrigeration:
    a. Dual Compressors with evaporators
    b. Refrigerant: CFC / HCFC free/Natural refrigerant should be environment friendly
    c. Optimized cascade freezing technology. High efficiency, energy saving, environmental friendly, industry-grade refrigeration compressor, CFC free refrigeration with an enhanced condenser and washable condenser filter for optimum cooling.

d. Heavy duty hermetically sealed dual compressor air cooled cascade refrigeration system, maintains inner temperature below -80^{0}C

8. External Ambient Temperature: Performs in an ambient temperature of +10 to +40^{0}C
9. Temperature Monitoring:
    a. Electronic temperature control
    b. Operating temperature reachable lowest up to -86^0 at room temperature of 35^{0}C with settling accuracy of $\pm 1^0$ C whatever the load.
    c. Digital temperature (LED) display with 1°C graduation
    d. Temperature recording device: temperature recorder with data logger compatible with LIS
    e. Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system.
    f. Provision to connect with central (temperature) monitoring system. Provision of output through freezer for remote monitoring purpose
10. The temperature indicator of deep freezer shall be calibrated with the help of master calibrator which shall be certified for its accuracy by NABL accredited lab.
11. Alarm for audible & visual fault acknowledgement, low & high temperature audio visual alarms, condenser fault alarm, remote contact alarm, open door alarm, clean filter Indicator and power failure alarm.
12. Noise factor should not exceed 60 dBA
13. Power supply:
    a. Power input to be 220-240V AC,50Hz
    b. Resettable over current breaker shall be fitted for protection.
    c. Maintenance free temperature backup system to retain temperature in sub zero condition for period of minimum 5 hours with full load and in close door conditions in case of power failure or any other shut down.

General specifications:

1. Satisfactory working report of the quoted/similar model from three government institutes/government hospitals (from last two years) should be provided.
2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national/international standards.
3. Original product catalogue should be provided by the firm and the original product catalogue must be available on the company (manufacturer) website. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (15Amp)
5. 5 years warranty including preventive maintenance (twice in a year). The bidder to also provide per year rate of CMC for next five years (i.e. after completion of 5 years warranty). However, the quoted CMC rate will not be included in financial evaluation. Warranty

should commence only after delivery of satisfactory working report. Warranty shall include UPS, all supplementary equipment and accessories provided along with equipment.

a. Complete with comprehensive set of spare parts.
b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS:9815 with latest amendments or equivalent international standards fitted with voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating :10KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high -low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification: CE Class II A/ US FDA/ IVD/ BIS certified
    b. Quality Certification: ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Technical specifications will be validated through an onsite physical demonstration of the quoted machine (if desired) before opening of the financial bid.

The committee approved the technical specification of the Deep Freezer (-80 ^{0} C) Vertical

Agenda 7: To modify the existing technical specifications of Hepatitis B Immune Globulin (HBIG)

Hepatitis B Immune Globulin (HBIG)

Technical Specifications

1. Each injection contains hepatitis B immunoglobulin 100 IU
2. Number of mL per vial: 0.5/1.0 ml
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (Intramuscular injection) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry date

General specifications

1. Standard Shelf Life: atleast 18 months at the place of dispatch to the consignee

2. Primary Container: one vial/pre-filled syringe with 0.5/1.0 ml
3. Label: It should be glazed label in accordance with the statutory requirements as per Drug and Cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as "Government of India Supply, Not for Sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices
4. It should be tested negative for HBV, HIV, HCV which will be printed on each unit packet

The committee approved the specification of HBIG

Meeting ended with vote of thanks to the chair.

Dr. Hema Gogia, Assistant Director, Program division, NCDC		Dr. Preeti Madan, Joint Director, NVHCP & Member Secretary	
Dr. Partha Rakshit, Joint Director, NCDC & NVHCP		Dr. Rajesh Sharma, Representative of Director, National Institute of Biologicals, Noida	
Dr. Monil Singhai, Representative of Director, NCDC, Delhi		Prof. (Dr.) Vaishali Bhardwaj, RML, Delhi	could not attend
Dr. Aashish Choudhary Representative of Dr. Lalit Dar, AIIMS, New Delhi		Prof. (Dr.) S. Anuradha, Professor, MAMC, Delhi	18/10/24
Prof. (Dr.) Vandana Roy, MAMC, Delhi		Dr. Sandhya Kabra, Deputy Commissioner NVHCP & Additional Director, NCDC	
Dr. Kavita S. Lole, National Institutes of Virology (ICMR), Pune	Attended virtually		
Prof. (Dr.) Sunita Sharma, Director Professor & Chairperson			

18/10/24

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18/10/2024

Gmail Viral Hepatitis NCDC <nvhsp.ncdc@gmail.com>

Minutes - Regarding technical specification committee of equipment, test kits and drugs for NVHCP and other related programs on 18.10.2024 from 10:00 AM to 12:00 PM

KAVITA LOLE <lolekavita37@yahoo.com> Mon, Oct 21, 2024 at 10:49 AM
To: Viral Hepatitis NCDC <nvhsp.ncdc@gmail.com>
Cc: sandhyakabra <sandhyakabra@gmail.com>, Dr Partha Rakshit <partharakshit15@gmail.com>, Preeti Madan <preetimadan07@gmail.com>, hema_gogia <hema_gogia@yahoo.com>, deepikabehal19 <deepikabehal.19@gmail.com>, Mr Uday Kumar <uday140190@gmail.com>

Dear Dr. Gogia,
I have seen the attached minutes of the meeting and concur with the same.
Sincerely,
Kavita Lole

[Quoted text hidden]