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No. F-8( )RMSC/EPM/M-1/2019-20/NIB-476/4799 Dated: 15/09/2020

CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject: Amended Technical Specification and revised bid schedule of item 1.Blood Bank Refrigerator (300 Blood Bag Capacity) 2. Deep Freezer (-) 80 Degree C (Cap. 250 Plasma Bags) 3. Contact Blast Freezer, under No. F-8( ) RMSC/EPM/M-1/2019-20/NIB-476/3556 date: 18.02.2020

In reference to subject cited above NIB-476, various representation received from the firms and issues raised by the bidder are examined by the competent authorities and technical committee. The following clarification/corrigendum/addendum is issued for inclusion in bid document of items as below:-

Revised Technical Specification of Blood Bank Refrigerator (300 Blood Bag Capacity)-

1. Purpose of Equipment
    1. A refrigerator for storing whole blood.
    2. Must be designed specifically for blood bank use. Commercial or modified commercial refrigerators for other purpose are not acceptable.
2. Type of Equipment

    Approved standard electrical Blood bank refrigerator that uses a compressor circulating CFC-free refrigerant / green gas.
3. Quality Standard
    1. Should have built in temperature recorder and controller positioned at Eye level for better visibility and monitoring.
    2. Must have uninterrupted digital electronic temperature circular chart recorder with 21 days days memory with print facility / six inch, 24×7-day, ink-less pressure sensitive circular chart recorder and accuracy should be +/- 1 degree Celsius with supply of free charts for a period of Guaranty.
    3. Should have a digital temperature probe/RTD located in the top portion of the chamber in a liquid medium bottle for accurate temperature measurement.
    4. Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
    5. Quoted model should be compliant with European CE (Notified Body)/US FDA/BIS (Valid documentation should be submitted in technical bid).
    6. Equipment must meet electrical safety specifications of IEC 60601-1.
4. Capacity
    1. At least 300 Whole Blood standard blood bags/250 double bag with Whole Blood standard blood bags.
5. Construction
    1. Outside C. R. (Corrosion Resistant) Sheet at least 1 mm thick.
    2. Inside stainless steel of at least 22 G.
    3. Insulation 50-70 mm thick, foaming agent CFC free.
    4. Glass door with full visibility of unit Door without door opening. Thickness of door should be 50-70 mm.
6. Drawers
    1. Stainless steel, scratch resistant Drawers perforated to ensure good air circulation.
    2. Roll out type.
    3. At least four or more in number.
7. Door
    1. Glass door with full visibility of units without opening door.

2. Automatic/Magnetic closing at 90^0 closer.
3. Door opening audio and visual alarm.
4. Door lock should be available.

8. Electrical characteristics
   1. Compatible with Input voltage: 240V 50 Hz Single phase AC.
   2. Equipment shall be supplied with external Servo Voltage Stabilizer with input voltage rating 90-280 V and 50 Hz.
   3. The Compressor running time should be maximum of 35%.
   4. At room temperature of 25°C should be able to maintain at ideal compressor running time of 27%.
9. Internal Temperature
   1. Blood Bank Refrigerator should have inside temperature range of 2°C - 6°C.
   2. User parameter settings: Set point, High alarm point, low alarm point, buzzer off time, C/F unit display choice.
   3. Whatever the load, setting accuracy less than or equal to 0.5°C (preferably 0.1°C).
   4. Should ensure frost free performance thereby avoiding either freezing or heating. If defrosting function used, temperature should not go outside range specified above.
   5. Four hours battery backup for thermograpic recording (Chart Recorder) display and alarm.
10. External Ambient Temperature:
    1. Can perfectly maintain internal temperature as above at full load in an ambient temperature of +10 to at least +40 °C (± 2°c).
11. Hold-Over Time
    1. A full load (At least 300 Whole Blood standard blood bags/250 double bag with Whole Blood standard blood bags) at +4 °C (±1 °C) should take * more than 1.5 hours to rise to above +6 °C if power off without opening the door at room temperature 22°C(±2 °C).
12. Cooling Down Time.
    1. A full load of blood packs at +25 °C takes a maximum of 6 Hrs for all packs to reach +6 °C.
13. Should have flicker free CFL lamp for uniform lighting and better visibility of samples inside the cabinet.
14. Should have Audible and visual High and Low temperature alarm & power fail alarm as a standard feature with alarm silence button.
15. Provision to connect with central (Temperature) monitoring system / facility of wireless data transfer facility & storage of temp. data on cloud, with continuous accessibility of data on PC or laptop and on smart phones with internet facility.
16. Guarantee: Three years on equipment from the date of installation.
17. CMC: CMC will be given @ 5 % of net rate - exclusive GST (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years.
18. The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
19. Installation will be done by supplier free of cost.
20. The service engineer should be based in Rajasthan.
21. Demonstration of equipment is must for final technical approval.

Other terms and condition to be covered during guarantee period by the supplier:-

- Response time- < 48 Hours after logged the complain in complain portal.
- Service hours- As per health facility schedule.
- Preventive Maintenance Schedule (PM)-As per OEM (Mention PM Schedule).
- Calibration Schedule – As per OEM (Mention Schedule).
- Up time- 95% (346 Days).
- Technical & Application Support, Demonstrations & Trainings - As & when required.
- Toll Free No-

- Life of the equipment- As per OEM.

Revised Technical Specifications of item (-) 80 degree C Deep freezer (Cap. 250 Plasma Bags)

1. The Deep Freezer should achieve low temperature of -80 degree C.
2. Should be heavy duty refrigeration system, maintenance free, with hermetically sealed refrigeration compressors reliable refrigeration with minimum noise & vibration.
3. Must have uninterrupted digital electronic temperature circular chart recorder with 21 days memory with print facility / six inch, 24×7-day, ink-less pressure sensitive circular chart recorder and accuracy should be +/- 1 degree Celsius with supply of free charts for a period of Guaranty.
4. Provision to connect with central (Temperature) monitoring system / facility of wireless data transfer facility & storage of temp. data on cloud, with continuous accessibility of data on PC or laptop and on smart phones with internet facility.
5. Should have a chart range of -100 degree Celsius to +50 degree Celsius.
6. Construction of double wall with efficient insulation to minimize temperature loss, inner chamber should be made of SS 304 grade non corrosive stainless steel & outer made of high quality C/R sheet.
7. Equipment shall be supplied with external Servo Voltage Stabilizer with input voltage rating 90-280 V and 50 Hz.
8. Hold over time - 2 Hrs at ambient temp.
9. External ambient temp. - Can perfectly maintain internal temperature as above at full load in an ambient temperature of +10 to at least +25 °C.
10. Cooling down time –

- A full load of plasma packs at +25 °C takes at least 5 hr for all packs to reach below -5°C.
- A full load of plasma packs at +25 °C takes maximum 30 hrs for all packs to reach below -20 °C.

11. Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
12. Quoted model should be compliant with European CE (Notified Body) /US FDA/BIS (Valid documentation should be submitted in technical bid).
13. The Deep Freezer should be vertical upright with a capacity to hold minimum 250 plasma bags of 250 ml.
14. Should have eye level display of temperature.
15. Should have handle for opening the door.
16. Should have audio alarms for the following: Temperature High/Low, Power Failure/ Battery low, door open.
17. Should have battery back-up for monitoring of cabinet temperature for 8 hrs (for full charge) by sealed maintenance free battery.
18. Should have at least 3 Height Adjustable/Fix trays (4 Compartments).
19. Should have display of 3*7 Segment LED/LCD display of working status of equipment at eye level.
20. Should have lockable heavy duty caster wheels.
21. Should have stainless steel trays.
22. Noise factor should not exceed 60 decibel.
23. Should have Microprocessor based digital temperature controller.
24. Should have high density polyurethane or equivalent gaskets.
25. Should have 12.5 cm foamed in PUF insulation in exterior walls.
26. Should have triple rubber gasket sealing.
27. Should have hot line around the mouth of the cabinet which prevents condensate formation.
28. Should have 4 stainless steel interior compartment doors with magnetic latches ensure storage and less cold air loss during opening and closing of the doors.
29. Should have caster wheels as standard feature.

30. Should have temperature controller with 0.1 degree Celsius with battery backup.
31. Should have rust free stainless steel door hinge makes the door open up to an angle of 135 degrees.
32. Should have well located appropriate/proper ventilation facility which helps in better condensation process.
33. Storage rack should be easily removable.
34. Rear clamps ensure the correct distance from walls, thereby ensuring good air circulation.
35. Guarantee: Three years on equipment from the date of installation.
36. CMC: CMC will be given @ 5 % of net rate - exclusive GST (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years.
37. The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
38. Installation will be done by supplier free of cost.
39. The service engineer should be based in Rajasthan.
40. Four Preventive Maintenance services during Guarantee and CMC period are essential.
41. Demonstration of equipment is must for final technical approval.

Other terms and condition to be covered during guarantee period by the supplier:-

- Response time- < 48 Hours after logged the complain in complain portal.
- Service hours- As per health facility schedule.
- Preventive Maintenance Schedule (PM)-As per OEM (Mention PM Schedule).
- Calibration Schedule – As per OEM (Mention Schedule).
- Up time- 95% (346 Days).
- Technical & Application Support, Demonstrations & Trainings - As & when required.
- Toll Free No-
- Life of the equipment- As per OEM.

Revised Technical Specification - Contact Shock/Blast Freezer/ snap freezer

1. **Purpose/ Objective of Equipment**
   For rapid freezing to core temperature of plasma bag below -30 °C in just 45 minutes to prevent decay of plasma coagulation factor at(-70 to -80) °C storage of Plasma Bags as per drug and cosmetic act
2. Compression type blast freezer that uses CFC free refrigerant gas.
3. **Capacity:**
   Up to 24 standard plasma bags(up to 250 ml) for Contact/Blast freezing/ Storage up to 100 bags, bag store should be horizontal
4. **Construction:**
   a) Vertical upright type. But bag should store/ keep at flat portion.
   b) Construction of double wall CFC free PUF (Polyurethane foam min 125 mm) Insulated with efficient insulation to minimize temperature loss, outer surface temperature should not lower 10 deg from ambient temp,after 5 hrs at chamber temp (-70- to -80), Surface Temperature of body at From the 200 mm gate, inner chamber should be made for SS 304 grade non corrosive stainless steel & outer made of high quality Corrosion resistance sheet with powder coated scratch less. Documents should be submitted,shuold be rtd calibration port to access external check to compare on calibrator.
   c) Should have Trouble free cleaning and disinfection facilities.
   d) Should have handle for opening the door life time comfortable and suitable to all men/women height, flush type.
   e) Should have at least 4 shelves. Arrangement for plasma bag should be flat position at plate.
   f) Should have high quality silicon gasket or equivalent gaskets not to hard at -80 deg c
   g) Should have triple silicon rubber gasket sealing for long life.
   h) Should have hot line around the gate of the cabinet which prevents condensate formation.

i) Separate refrigeration of the fixed cover plate and the electrically adjustable working surface of the upper and lower plates.
j) Should have rust free door hinge makes the door open up to an angle of 120°.
k) Should have well located ventilator which helps in better condensation process.
l) Should be heavy duty refrigeration system, maintenance free, with hermetically sealed refrigeration compressors reliable refrigeration with minimum noise & vibration.
m) Inner doors with magnetic/mech latches ensure storage and less cold air loss during opening and closing of the door.

5. **Refrigeration**
   a) Refrigeration design should be as per minimum 60/40 % on/off cycle,precool temp time should within90 minutes, should not 55 dbat 2meter from machine
   b) Can perfectly maintain internal temperature as above at full load in an ambient temperature of $+10^0$ C to at least $+40^0$ C.
   c) A full load of blood packs at -35^0 C ($\pm 5^0$ C) and chamber temp (-75) should take at least 6 hours to rise to above -20^0 C, if power off.
   d) A full load of blood plasma packs at $+25^0$ C should take a maximum of (-30) hours for all the packs to reach below -(-30^0 C)
   e) Refrigeration cycle should be declared with dq documents
6. **Internal Temperature Control & Recording**
   a) Must have at least(7.1" to 12") inch, user friendly touch screen self explanatory LCD display, USB Support, weekly non editable electronic circular temperature chart recorder with range of -150^0 C to $+10^0$ C, and accuracy should be $\pm 0.1^0$ C, for clear visual($\pm 1^0$ C)
   b) In weekly non editable electronic circular temperature chart recorder, to view previous two weeks and current week chart should be store in the memory, validation port should available.
   c) Working temperature range -70° C to -80° C as per drug act
   d) Microprocessor based electronic temperature control, Operating temperature reachable lowest up to -80^0 C with setting accuracy of $\pm 1^0$ C (preferably ± 0.1° C). Calibration
   e) Should have user friendly microprocessor controlled programmable digital temperature indicator & controller to ensure the usage.
   f) Should have a chart range of -150 degree Celsius to +10°C. with higher and lower uses marking.
   g) Freezing time depending on load and ambient temperature should be 30 to 60 minutes to core temperature of FFP of 250 ml.
   h) Energy consumption per freezing cycles should not be more than 0.8 kWh (unit).
   i) Should have battery back-up for monitoring of cabinet temperature for 12 hrs (for full charge) by sealed maintenance free battery.
   j) Should have microprocessor based temperature controller with integrated audio visual temperature and power failure alarm with digital monitoring display to comply drug and cosmetic act.
7. **Feature of system**
   a) screen visual :

      should be view single graph, scroll all graph history ,high-low temperature, gate status, specific (equipment ID, equipment name, sr no),view of circular weekly graph of current and previous two weeks, can view in excel sheet also,
   b) Graph visual :

      Should be weekly circular chart with high, low, and safe using range for specific product-fresh frozen plasma etc

      Must have automatic e-mailing facility to mail the weekly digital temperature chart recorder at every weekend & must also have a Manual e-mail option to send e-mail whenever wanted. Daily e-mail of all processes in excel sheet(i.e-deposit,withdrawl,balance etc),can view on any system, should not require any life time external software

c) Data download : should have Barcode Reader: To scan and update the process data. by pen drive and auto mail
d) Provision to connect with central (Temperature) monitoring system / facility of wireless data transfer facility & storage of temp. data on cloud, with continuous accessibility of data on PC or laptop and on smart phones with internet facility.
e) About instruments : Information sheet for installed date, calibration status, preventive maintenance planned and done date etc
f) Maintenance: auto mailing system should be on events at three mails (i.e.- pre planned calibration due date, preventive maintenance, all data should show on screen about equipment details (i.e- date of installation, model, calibration plan and done, preventive maintenance plan and don. High voltage, low voltage control and visual information on screen should available. Electronic fuse should be available.

8. **Electrical safety**
Equipment shall be supplied with external Servo Voltage Stabilizer with input voltage rating 90-280 V and 50 Hz.

9. **Quality Standard**
a) ISO 13485 or IEC 61010 certification specific for the product should be submitted, along with that equipment should meet electrical safety specification of IEC 610101 (as relevent), CE conformity/usdfda aproved/UL listed with chain of documents.
b) Quality certification: ISO 9001
c) Electrical Safety: Equipment meets electrical safety specification such as that of IEC 61010
d) CFR 21 CMPLAINCE
e) IP-20 COMPLAINCE

10. **TRAINING AND INSTALLATION**
a) Pre-installation : Pre-installation requirements should be declared
b) Training of staff : Training of staff (medical paramedical, technicians) OPTIONAL (Depending upon scope of work order)

11. Quoted model should be compliant with European CE (Notified Body)/US FDA/BIS (Valid documentation should be submitted in technical bid).
12. Guarantee: Three years on equipment from the date of installation.
13. CMC: CMC will be given @ 5 % of net rate - exclusive GST (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years.
14. **Additional Requirements**
a) Validation and Calibration reports should have traceability to applicable national and international standards.
b) Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer should be supplied with the system free of cost with the system.
c) The make, rating, model, description, specifications, price quantity of each item should be furnished separately.
d) Necessary catalogues, technical write up in English, should be attached with the offer both in hard and electronic copies and should at least 4 installation similar products in INDIA with user satisfaction.
e) Demonstration and continued comprehensive training for lab staff and support services till familiarity with the system.
f) Should provide a set of equipments for calibration (eg Thermometer) and routine preventive Maintenance as per manufacturer documentation in service/technical manual.

Other terms and condition to be covered during guarantee period by the supplier:-

- Response time- < 48 Hours after logged the complain in complain portal.
- Service hours- As per health facility schedule.
- Preventive Maintenance Schedule (PM)-As per OEM (Mention PM Schedule)

- Calibration Schedule – As per OEM (Mention Schedule)
- Up time- 95% (346 Days)
- Technical & Application Support, Demonstrations & Trainings - As & when required
- Toll Free No-

Life of the equipment- As per OEM

Revised bid schedule:-

- E-bids are invited as per following revised time schedule:-

Existing Dates			Extended Dates		
Last date & time for sale of bid form	**Last date & time of receipt of bid form**	**Date & time of opening of technical bid**	**Last date & time for sale of bid form**	**Last date & time of receipt of bid form**	**Date & time of opening of technical bid**
24.09.2020 11:00 a.m.	**24.09.2020 6:00 p.m.**	**25.09.2020 11:00 a.m.**	**29.09.2020 11:00 a.m.**	**29.09.2020 6:00 p.m.**	**30.09.2020 11:00 a.m.**

It is also clarified that information of award of contract shall be communicated to all participating bidders on the website www.rmsc.nic.in and sppp.raj.nic.in. Please note that individual bidder will not be intimated."

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

Executive Director (EPM)
RMSCL, Jaipur