

Subject: Minutes of meeting of the Technical Committee for specifications of "Equipment for Blood Banks/Blood Component Separation Units" held on 9th November 2012.

A meeting of the Technical Committee for specifications of "Equipment for Blood Banks/Blood Component Separation Units" was held under the Chairmanship of Dr. B.D.Athani, Addl. DGHS & Medical Superintendent in committee room 5th Floor, at Safdarjang Hospital, New Delhi on 9th November 2012 at 11.00AM.

The following members attended the meeting:

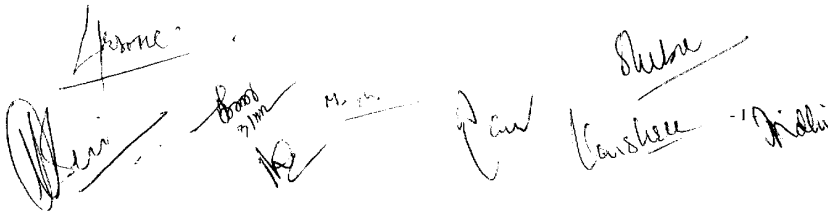
1. Representative from Drug Controller General of India, MOH & FW
2. Representative from ICMR H.Q (looking after HIV/AIDS division)
3. Director, National AIDS Research Institute, Pune
4. Director. National Institute of Biologicals, Noida
5. Dr. Sandhya Kabra, ADG (BS & LS), NACO
6. Dr. Manisha Srivastava, Bhopal Memorial Hospital & Research Center, Bhopal
7. Dr. Vanashree Singh, Indian Red Cross Society, Delhi
8. Dr. Nidhi Bhatnagar, BJ Medical College, Ahmedabad, Gujarat
9. Mr. Alok Jain, Accreditation Officer, Grade III, NABL, Delhi

The agenda of the meeting was as follows:

1. Review of Technical Specifications of Equipment for Blood Banks/Blood Component Separation Units

All the agenda items were discussed in the meeting and representations received from manufacturers with relation to these equipment were reviewed and the following decisions were taken:

Agenda Item No. 1: Review of Technical Specifications of Deep Freezer -40° C

The image shows several handwritten signatures in black ink. From left to right, there are approximately seven distinct signatures. Some are more legible than others, but they appear to be the names of the participants listed in the meeting minutes. The signatures are written in a cursive style.

The committee approved the technical specifications of Deep Freezer -80° C as follows:

1. **Purpose of Equipment:** To freeze and store plasma
2. **Type of Equipment:** Compression freezer with CFC-free refrigerant
3. **Capacity :** As required by the blood bank (e.g. 200/400/600/900 plasma bags of 200 mL. each)
4. **Construction:**
 - Internal: Stainless steel (min. 22g) (S.S. V₂ A- 1.4301)
 - External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness)
 - CFC-free insulation
 - Design: Upright Type
 - Door: Solid door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110°.
 - Insulation and gasket should be silicone.
 - Separate inner doors to prevent cold loss
 - Drawers: Roll out type
 - Heating device on frame to avoid condensation.
5. **Electrical Characteristics:**
 - Input voltage: 220/240V 50HZ
 - A line voltage corrector of appropriate rating should form part of configuration.
6. **Minimum Compressor Starting Voltage:** 22% below nominal Voltage
7. **Internal Temperature Control:**
 - Electronic temperature control
 - Operating temperature reachable lowest up to -45°C with setting accuracy of ±1 °C whatever the load
 - Fan air cooling
 - Automatic defrost within safe temperature range
 - Casing & door should have insulation panel with polyurethane foam > 80mm thickness.

Amme
W. S. S. S.
MD
Shubra
Ganesh
Nidhi
-2-

13. Additional Requirements

- All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
- Complete with comprehensive set of spare parts including a spare compressor, refrigerant gas cylinder etc. and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
- Necessary catalogues, 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
- Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
- Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 2: Review of Technical Specifications of Deep Freezer -80° C

The committee approved the technical specifications of Deep Freezer -80° C as follows:

1. **Purpose of Equipment:** To freeze and store plasma
2. **Type of Equipment:** Compression freezer with CFC-free refrigerant
3. **Capacity :** As required by the blood bank (e.g. 200/400/600/900 plasma bags of 200 mL. each)
4. **Construction:**

[Handwritten signatures and initials]

[Signature] *[Signature]* *[Signature]* *[Signature]* *[Signature]*

- Internal: Stainless steel (min. 22g) (S.S. V₂ A- 1.4301)
 - External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness)
 - CFC-free insulation
 - Design: Upright Type
 - Door: Solid door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110°.
 - Insulation and gasket should be silicone.
 - Separate inner doors to prevent cold loss.
 - Drawers: Roll out type
 - Heating device on frame to avoid condensation.
- 5. Electrical Characteristics:**
- Input voltage: 220/240V 50Hz
 - A line voltage corrector of appropriate rating should form part of configuration.
- 6. Minimum Compressor Starting Voltage: 22% below nominal Voltage**
- 7. Internal Temperature Control:**
- Electronic temperature control
 - Operating temperature reachable lowest up to -86°C with setting accuracy of ±1 °C whatever the load
 - Fan air cooling
 - Automatic defrost within safe temperature range
 - Casing & door should have insulation panel with polyurethane foam > 80mm thickness.
- 8. Refrigeration :**
- Heavy duty hermetically sealed compressor air cooled cascade refrigeration system, maintains inner temperature below -80°C
 - Refrigerant CFC free/ green gas
 - Optional: Access port for CO₂ backup system for refrigeration.
 - Option for duct from equipment to connect to common main duct to throw hot air out of the room.

As per

[Signature]

MSL
[Signature]

Shree
Vanshree -s.

[Signature]

9. External Ambient Temperature: Performs in an ambient temperature of +10 to +40 °C

10. Hold over time: 2 hrs at ambient temperature

11. Cooling Down Time:

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

12. Temperature Monitoring:

- Digital temperature (LED) display with 0.1 °C graduation
- Temperature recording device
- Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system.
- Seven days inkless graphic temperature recorder with range of 0°C to -50°C with data logger, with supply of free charts for a period of warranty.
- Battery backup for alarm and temperature recording device.
- Provision to connect with central (temperature) monitoring system
- Mounted on Lockable Castor wheels
- Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration of alarm.
- Desirable:
 - Noise factor should not exceed 60 decibels.
 - Should have compressor running time < 60 to 70%

13. Additional Requirements

- All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / International standards.
- Complete with comprehensive set of spare parts including a spare compressor, refrigerant gas cylinder etc. and a suitable capacity voltage

Handwritten signature

Handwritten signature

Handwritten signature with 'M14' above it

Handwritten signature with 'Shubra' above it

-6-

Handwritten signature

stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.

- Necessary catalogues, 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
- Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
- Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 3: Review of Technical Specifications of Blood Bank Refrigerator

The committee approved the technical specifications of Blood Bank Refrigerator as follows:

1. **Purpose of Equipment:** A refrigerator for storing whole blood or red cell packs in a blood bank
2. **Type of Equipment:** Compression type refrigerator that uses CFC-free refrigerant gas/ green gas
3. **Capacity:** As required by the blood bank (e.g. 200/400/600/900 blood bags of about 350/450 mL. each)
4. **Construction:**
 - Internal: Stainless steel (min. 22g)
 - External: Corrosion Resistant (CR at least 1mm thickness)
 - CFC-free insulation
 - Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of

Asst. Secy
[Signature]
M. C.
[Signature]
[Signature]
[Signature]
[Signature]

13. Temperature Monitoring:

- Digital temperature (LED) display with 0.1 °C graduation
- Microprocessor based temperature controller with integrated audio visual temperature and power alarm function with digital monitoring display.
- Independent safety thermostat to avoid negative temperatures.
- At least 2 Temperature Sensors: Sensor for temperature monitoring shown on front display, Sensor for managing use of compressor.

14. Temperature recording device

- Visual and audible alarm system indicating unsafe temperatures
- Battery backup for alarm and temperature recording device
- Facility for remote alarm contact
- Seven days graphic temperature recorder with range of -10°C to +20°C with data logger, with supply of free charts for a period of warranty.
- Ideal compressor running time of 27% at room temperature.
- Door locks should be available.
- Audio and visual alarm for variation in temperature
- Interior lighting
- External ambient temperature +10°C to +40°C
- Auto defrosting
- Cooling time – Maximum 13 hours for all the packs to reach below +6°C

15. Certifications:

- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 4: Review of Technical Specifications of Platelet Incubator & Platelet Agitator

The committee approved the technical specifications of Platelet Incubator & Platelet Agitator as follows:

Aswani
Aswani *Aswani* *M.C.* *Aswani* *Aswani* *Aswani* *Aswani* *Aswani*

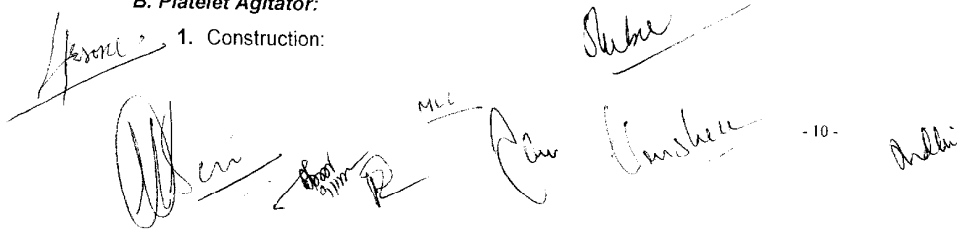
- Purpose of Equipment: To continuously agitate platelet concentrates in an incubator in an even suspension in a plasma bag
- Type of Equipment: Flatbed agitator fitted inside a temperature-controlled incubator operating with CFC-free refrigerant gas and insulation material
- Certifications
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

A. Platelet Incubator

1. Should have a provision to store the agitator.
2. Should have a single transparent outer door for clear visibility.
3. Should be able to maintain a temperature of 22±2°C. Set temperature of 22°C.
4. Should have a digital temperature indicator.
5. Seven day inkless chart recorder with battery back-up for minimum of 2 hours for continuous operation during power failure
6. Single digital temperature sensor for both recording and controlling
7. Should have audible visual high/low alarm for temperature control, battery on/low, sensor failure, agitator off, power failure, compressor and system
8. Should have forced air circulation method for the uniformity of the temperature at all sides of the incubator.
9. Chamber mounted electrical outlet for agitator should be available
10. Power supply: 220-240 volts at 50 Hz.
11. Facility to connect with central (temperature) monitoring system

B. Platelet Agitator:

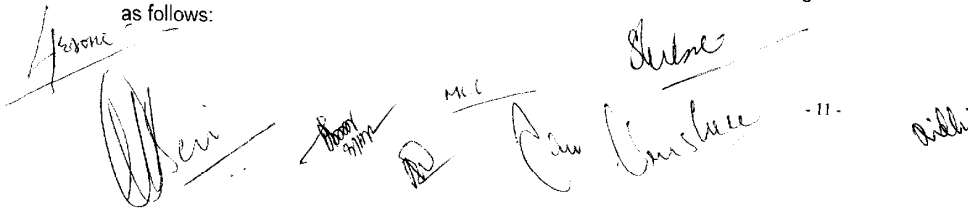
1. Construction:


 A collection of handwritten signatures and initials in black ink. On the left, there is a signature that appears to be 'Asim'. Below it is another signature that looks like 'W. Srin'. To the right of these are several other signatures and initials, including 'M. C.', 'S. K.', 'Anshu', and 'Rishi'. The signatures are scattered across the lower half of the page.

- Internal: Stainless steel (min 304 grade)
 - External: Corrosion Resistant, at least 1mm thickness
 - Capacity: Designed to hold random platelet packs or aphaeresis platelet packs or a mixture of both types (minimum 48 random platelet concentrate packs).
 - Transparent Door
 - Design of Shelves: Shelves are made of non slip, corrosion resistant material, Coated with bacteria resistant material, perforated to ensure air circulation and with sufficient clearance to minimize noise.
 - Gentle side to side agitation at 3.6–4 cm side to side, 60- 70 strokes/ minute
 - Heavy duty ball bearing gear motor for noise less and continuous operation for 24 hours a day throughout the year
 - Motor with internal fan
2. Temperature
 - 7 day chart recorder with free charts till warranty period.
 - Temperature controller with sensor
 3. Refrigeration: Non-CFC air cooled refrigeration
 4. Safety features
 - Audio alarm for temperature fluctuation
 - Auto stop for agitation when the door is opened
 - Power failure alarm
 5. Push buttons switch with pause function for temporary stoppage of the motion.
 6. Power supply: 220-240 volts at 50 Hz.

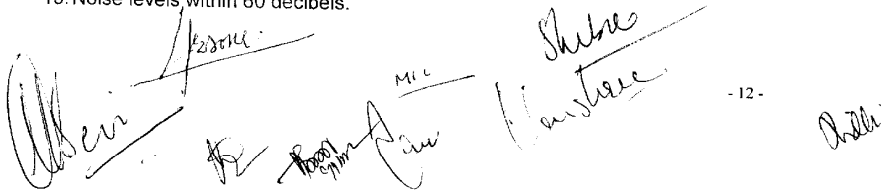
Agenda Item No. 5: Review of Technical Specifications of Refrigerated Centrifuge

The committee approved the technical specifications of Refrigerated Centrifuge as follows:



 A series of handwritten signatures and initials are present below the text. From left to right, they include: a signature that appears to be 'K. S. S.', a signature that appears to be 'S. S.', a signature that appears to be 'M. C.', a signature that appears to be 'S. S.', a signature that appears to be 'S. S.', and a signature that appears to be 'S. S.'. There is also a small '- 11 -' in the middle and another signature 'S. S.' on the far right.

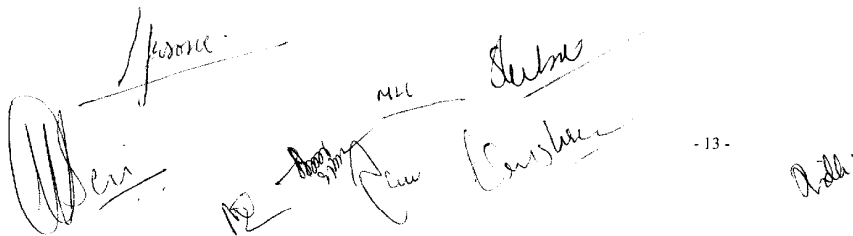
1. For separation of blood components like packed cells, platelet rich plasma, platelet concentrate, plasma
2. Micro processor controlled system to make operation automatic.
3. Programmable memory: Memory with tamper proof facility.
4. Stainless steel chamber: Easy to clean, corrosion resistant with provision of both drain and condensed water collection container.
5. CFC free refrigerant
6. Swing bucket blood bank rotor: With metal buckets, 6 x 2000 mL, wind-shielded. Suitable adapters for 12 blood bags of 350 mL. & 450 mL.
7. Removable plastic cups to hold single/ double/triple/quadruple blood bags with partition in every bucket.
8. Insert with hook adapter to spin buffy coat or small volume of blood and balancing weights for inserts
9. Equipped with automatic lid lock
10. Centrifugal force: 5000-6000 g.
11. Speed variation: Micro processor controlled rotor speed to within 10 rpm of set value. Acceleration and deceleration profiles shall be available.
12. Temperature range: -10°C to +40°C
13. Micro processor controlled rotor temperature within 1°C of set temperature regardless of the centrifuge speed.
14. Programmable time: 0 - 99 minutes with minimum resolution of 1 minute.
15. Digital display of temperature, speed and time. Minimum no. of 3 digit resolution
16. Motor imbalance detection: Automatic shut down of centrifuge if rotor load is out of balance with appropriate indicator. Should incorporate alarms for imbalance detection lid interlock, over temperature, rotor over speed
17. Power requirement: 220/240 volts, 50 Hz. Single phase AC supply.
18. The equipment shall be suitable for operation from 0 to 40°C at 90% Relative humidity. Electronic circuitry shall be tropicalised for this ambient condition.
19. Noise levels within 60 decibels.


 A collection of handwritten signatures and initials in black ink. From left to right, there is a large signature, a signature with 'Kishore' written above it, a signature with 'M.C.' written above it, a signature with 'Shubho' written above it, and a signature with 'Chella' written to its right. The text '- 12 -' is printed in the center of the page.

20. The equipment shall have lockable castors.
21. Protection of data: In event of power interruption or complete failure data should remain stored
22. Should have a provision for external connectivity.
23. It shall have a security lock to prevent unintentional switch off and also unauthorized opening of the equipment.
24. Automatic Line voltage corrector/Voltage Stabilizer: 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(Pt.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
 - a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
 - b. Input voltage: 140 to 280 volts, 50 cycles.
 - c. Output voltage: 220 volts \pm 10% volts. Input-out voltmeter and amperemeter. Protection: high-low voltage cut-off, overload and short circuit protection.
 - d. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (15Amp.).
 - e. Make of the line voltage corrector shall be indicated
25. Certifications:
 - i. Product certification: CE Class II A or US FDA certified
 - ii. Quality Certification: ISO certified
 - iii. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 6: Review of Technical Specifications of Cell Counter (Automated Hematology Analyzer)

The committee approved the technical specifications of Cell Counter (Automated Hematology Analyzer) as follows:


 A collection of handwritten signatures in black ink, including names like 'Sudhakar', 'Sudha', 'Sudha', 'Sudha', and 'Sudha'. The signatures are written over a faint grid or lines.

1. The equipment is meant to determine the count of various blood cells & hemoglobin estimation for the screening of blood donors.
2. Should be a fully automated hematology 3 part differential analyzer with option to print the results with histograms of basic 8 parameters like RBC, WBC, Platelets, Hemoglobin (HGB), MCH and others.
3. Printer: Built-in thermal printer can be connected to external computer and printer.
4. The reportable RBC indices should be: Total RBC, HCT, HGB, MCV, MCH, MCHC and user definable settings for RDW-CV and RDW –SD. RBC count linearly should be above $6.5 \times 10^9/\mu\text{L}$.
5. Reportable platelet indices should be: Total platelet count, MDW and P-LCR.
6. The system should give the differential count as lymphocytes ,mix population and neutrophils in percentage as well as absolute count.
7. Rapid result turnaround time upto 60 samples-per-hour throughput
8. Display: large color LCD, show all parameters and histograms at same screen.
9. Reagents for validation/training up to the time of installation to be provided by the manufacturer free of cost .
- 10.The system should have autoprobe wiper to clean the sample probe automatically after sample aspiration.
- 11.The system should have automatic floating threshold for correct separation of WBC, RBC's and platelets during over lap of microcytosis /large platelets.
- 12.The system should use cyanide free reagents.
- 13.Should be able to perform all blood counts from whole blood and blood components at different dilutions for the purpose of quality control.
- 14.Power supply: 220/240 volts, 50 cycles, single phase, with inbuilt FIE safety against high load voltage.
15. On line voltage corrector of appropriate rating as per standard configuration.
16. **Interface:** USB for printer, mouse and keyboard, internet port.
17. **Storage capability** for detail results including histograms up to 3 months.
18. **Calibration:** three test modes offer auto and manual calibration, provide original calibrator and control.

Handwritten signature

Handwritten signature

Handwritten signature

MS C

Handwritten signature

Handwritten signature

19. **Sample type:** venous blood, peripheral blood, Pre-dilution peripheral blood and various dilutions of blood

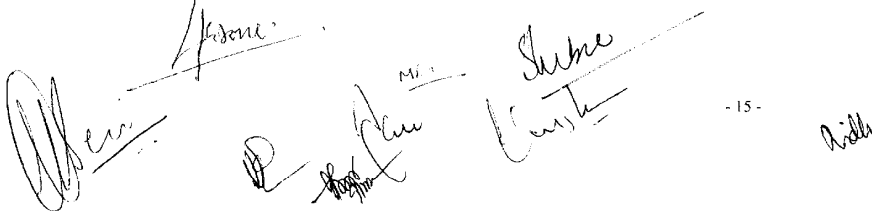
20. Certifications:

- i. Product certification: CE Class II A or US FDA certified
- ii. Quality Certification: ISO certified
- iii. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 7: Review of Technical Specifications of Semi Automated Coagulometer

The committee approved the technical specifications of Semi Automated Coagulometer as follows:

1. Coagulometer measures the blood clotting parameters
2. Should be microcomputer controlled
3. Semi automatic with at least 4 channels optics
4. Based on optical principle with LED
5. Should have integrated / external incubation block with pre – warming positions.
6. Suitable for PT, a-PTT, fibrinogen, thrombin time, factors: II, V, VII, VIII, IX, X, XI, XII, Fletcher, AT-III, Protein C, Protein S, Heparin, STAT
7. Results can be represented in seconds, %activity, ratio, INR g/L and mg/L
8. Should be able to store specific test parameters in the system
9. Should have LCD display
10. Complete system with printer or facility for printer connectivity is required.
11. Should generate the standard curve for factor assays
12. Power input to be 220-240VAC, 50Hz fitted with Indian plug
13. Suitable UPS with maintenance free batteries for minimum 30 minutes back-up should be supplied with the system.
14. Open system for reagent and low reagent consumption

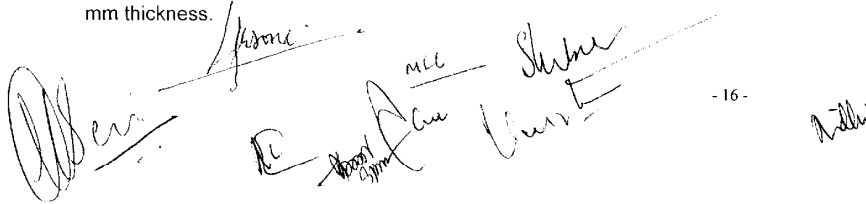
Handwritten signatures and initials are present at the bottom of the page. From left to right, there is a large signature, a signature with 'Ajay' written above it, a signature with 'M.' written above it, a signature with 'Shubh' written above it, and a signature with 'Nishi' written to its right. There are also some other illegible initials and marks.

15. The unit shall be capable of being stored continuously in ambient temperature of 0 - 50deg C and relative humidity of 15-90%
16. The unit shall be capable of operating continuously in ambient temperature of 10 - 40deg C and relative humidity of 15-90%
17. User/Technical/Maintenance manuals to be supplied in English.
18. Certificate of calibration and inspection.
19. List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
20. Reagents for validation, training up to installation to be provided free of cost by manufacturer.
21. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

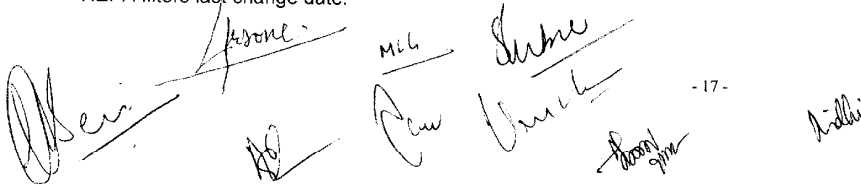
Agenda Item No. 8: Review of Technical Specifications of Laminar Airflow Bench (Bio-Safety Cabinet)

The committee approved the technical specifications of Laminar Airflow Bench (Bio-Safety Cabinet) as follows:

1. Floor model, Horizontal flow, well-lighted, work surface, low vibration and noise, easy to manoeuvre due to castor wheel provision. Over all dimension of work space of approximately 1200 mm x 600 mm x 600 mm.
2. Construction:
 1. Cabinet: Stainless steel sheet of 20 SWG lining
 2. Front Panels: Removable transparent scratch resistant sheet of approximately 6 mm thickness.
 3. Side Panels: Fixed transparent scratch resistant sheet of approximately 6 mm thickness.


 A collection of handwritten signatures and initials in black ink, including names like 'Srinivas', 'Srinivas', 'Srinivas', and 'Srinivas', along with various initials and a signature that appears to be 'Srinivas'.

4. Work Table: Stainless Steel of 20 SWG lining
 5. Pre-Filters: Filtration efficiency of 98% for all types of particles of sizes 8 micron and larger.
 6. HEPA-Filters (fine filters): Filtration efficiency 99.999% for all types of particles of sizes 0.3 micron and larger. Housed in a frame with leak proof gaskets
 7. Motor Blower: Dynamically balanced and specially constructed to suit low noise and vibration with adjustable speed. Motor shall conform to ISS or any international specifications.
 8. Air Velocity: Should not be more than 100 fpm over the work area
 9. Lighting: Fluorescent tube lights with diffuser acrylic to get 120 decalux on work surface.
 10. Ultra-violet light source: Shall be provided
 11. Power supply: 220/240 volts, 50 cycles, single phase. The equipment shall be provided with both 5 Amp and 15 Amp plug units inside the cabinet along with a line voltage corrector of appropriate rating.
 12. Installation, commissioning and trial run will be the responsibility of the supplier
 13. Manometer: Should be provided with appropriate manometer to measure the air pressure
 14. Technical Literature: The firm shall positively submit printed illustrated technical literature/leaflet including the model quoted by them. If quoted model is modified version of their any standard model that also be indicated in the offer.
3. Cabinet information/LCD Display for:
- Exhaust air flow
 - Laminar flow air velocity
 - Cabinet temperature
 - Fans elapsed hour meter.
 - UV elapsed hour meter.
 - HEPA filters last change date.


 A collection of handwritten signatures and initials in black ink. From left to right, there is a large signature 'Beir', a signature 'Asone', a signature 'AG', a signature 'M.G.', a signature 'Sukme', a signature 'Vruch', a signature 'Sant', and a signature 'Nidhi'.

4. Visual and Buzzer alarm message:

- Low exhaust flow.
- Low down flow air velocity.
- Impulsion and exhaust fans malfunction.
- Front window not in right position

5. Filters: HEPA

6. Line Voltage Corrector: On line voltage corrector of appropriate rating as per standard configuration.

7. Certifications:

- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 9: Review of Technical Specifications of Donor Couch

The committee approved the technical specifications of Donor Couch as follows:

1. Blood Donor Couch is a completely automatic enveloping, variable tilt chair and specially designed to make blood withdrawals easier, safe and functional, and also for other diagnostic and therapeutic areas.
2. Variable positioning for either arm with comfortably wide arm-rests with swinging out as well as up and down moving facility.
3. Reclining and upright body positions with a smooth shifting to any position.
4. Both sides should have supporting brackets for material required for blood collection
5. Ergonomically designed comfortable chair type for donor comfort. Mattress should be comfortably cushioned with elegantly thick washable upholstery.
6. Seat, back rest and leg rest size designed for donor comfort. It should have step less electric remote controlled height adjustment
7. Easily tilted to head low position, electrically operated
8. Should be mobile with lockable wheels.

Aben *Shome* *mit* *Shine*
10 *Ch* *Unsh* *Shome*
- 18 - *Nishi*

9. Comfortable working level for the operator. Lifting capacity - Approx 200 kg.

8. Certifications:

- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 10: Review of Technical Specifications of Sterile Connecting Device

The committee approved the technical specifications of Sterile Connecting Device as follows:

1. Should accommodate and weld all types of blood bag tubing in use in our country.
2. The welding should be seamless.
3. Should be capable of joining wet-wet/wet-Dry/ Dry-Dry tubes.
4. Welding should not affect the quality of the tube in terms of its physical and chemical properties and it should not cause hemolysis.
5. It should have LED indicators to display the actual status of the ongoing procedural steps and audio-visual alarm system for any functional irregularities.
6. The welding accessories should be available with the local agent throughout year.
7. The consumable wafer cost per 100 pieces to be taken into account during price evaluation.
8. Compatible UPS with half an hour backup.
9. Power supply 220V, 50 Hz AC.
10. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

[Handwritten signatures and initials]

- 19 -

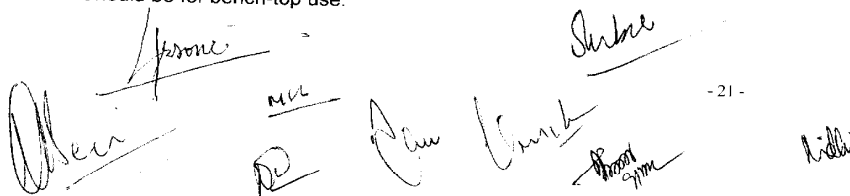
[Handwritten initials]

15. Should have audio visual over-temperature alarm system
16. Should have a system to drain the chamber easily.
17. Should be supplied with a cover to keep the unit covered when not in use
18. Simple to operate, easy to read LED display
19. Drain Line with Shut off valve can be connected to existing plumbing.
20. Power supply: 220-240 volts at 50 Hz, single phase
21. **Accessories:**
 1. Reusable wrap bag – 8 numbers
 2. Frozen plasma bag holder
 3. Compression rack holder
 4. Reference thermometer
22. **Certifications:**
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 12: Review of Technical Specifications of Dielectric Tube Sealer

The committee approved the technical specifications of Dielectric Tube Sealer as follows:

1. Blood Bag Tube Sealer is a compact equipment to seal the Blood Bag pilot tubing.
2. The system should be heavy duty and be able to seal the blood bag etc quickly and effectively.
3. Should be simple to handle
4. System should gently seal the tubing with no hemolysis using radio frequency.
5. Should be capable of making wide seal of 2 mm thickness.
6. Should be for bench-top use.


 A collection of handwritten signatures and initials in black ink. From left to right, there is a large signature 'Abeir', a signature 'Ajroni' with 'mu' written below it, a signature 'Daw' with 'Daw' written below it, a signature 'Shake' with 'Shake' written below it, a signature 'Amad' with 'Amad' written below it, and a signature 'Kilbi' on the far right.

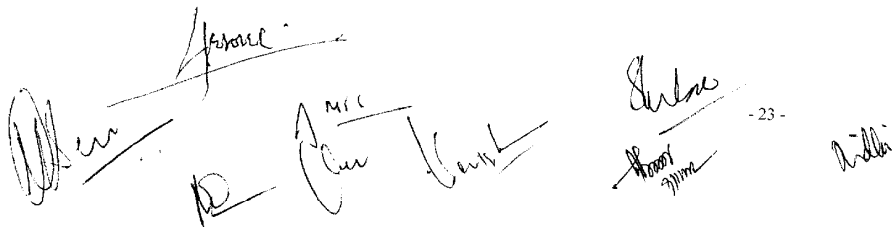
7. The sealing time should not be more than 2 seconds
8. Sealing trigger should be automatic
9. Should also have extended portable hand unit Sealing hand should be with coaxial cable of 1.5-2.0 meter.
10. Should have indication lamps for "Sealing Process" on handle as well as main unit.
11. No warm-up time should be required.
12. Should ensure easy separation of tube segments after the sealing
13. System should run on both mains and battery (more than 10hrs. back up and charger).
14. Back up battery should seal more than 500 seals on PVC- tubes in continuous mode.
15. The unit shall be capable of operating continuously in ambient temperature of 10 - 40° C and relative humidity of 15-90%
16. Power input: 220-240V/ 50 Hz AC Single phase or 380-400V AC 50 Hz Three phase fitted with appropriate Indian plugs and sockets.
17. Suitable Autovoltage corrector with spike protector should be available.
18. Electrodes should be well protected by a cover
19. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I) or Class II type-B device to protect against electric shock.
 - Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Agenda Item No. 13: Review of Technical Specifications of Blood Mixer and Collector

The committee approved the technical specifications of Blood Mixer and Collector as follows:

The image shows several handwritten signatures and initials. From left to right: a signature that appears to be 'Abhinav', a signature 'Ajay', a signature 'Ravi', a signature 'Sudhakar', a signature 'Sudhakar' with '-22-' written below it, and a signature 'Abhinav' on the far right. There are also some smaller initials and marks scattered around.

1. The system is used to collect donated blood from the donor at the same time mixing the blood for quality collection of blood.
2. It is meant for stationary and mobile use. Gentle end to end mixing and control of collection time to give high quality blood suitable for all blood bags.
3. Volume Setting: Pre-selection of volume to be collected. Tarring of bag volume before collection. Tarring range: 0 – 600 g. Automatic storage and recall of set volume. Measure volume with best accuracy
4. LED indication on commencement of collection.
5. LED indication and audible alarm at the end of collection.
6. Indication of time taken for collection.
7. Indication of blood flow with audio alarm when blood flow is higher or lower than desired.
8. Continuous display of collected volume, flow and time during collection
9. Automatic clamping at termination of preset volume collection
10. Automatic release of bag when lifted.
11. Continuous agitation of blood bags during collection: 12 – 16 rpm.
12. Equipment carry case for BCM should be provided for portability.
13. Should operate on mains as well as rechargeable battery. On battery it should operate for a minimum of 5-8 hours.
14. The unit shall be capable of operating continuously in ambient temperature of 10 -40° C and relative humidity of 15-90%
15. Power input to be 220-240VAC, 50Hz,/440 V 3 Phase as appropriate fitted with Indian plug
16. Resettable over current breaker shall be fitted for protection
17. Suitable Automatic Voltage regulator/stabilizer meeting ISI specifications should be supplied. Broad specifications are: Automatic Type Input 150-280V , Output 220 V +/- 7 % , 50 Hz . Single phase, AC with automatic 2-4 sec Cut Off and 6-9 minutes restart delay.. Quick start arrangements for bypassing the start delay. Suitable MCB on input voltmeter and indicators on Front Panel.


 A collection of handwritten signatures and initials in black ink. On the left, there is a large circular signature. To its right are several smaller signatures and initials, including one that appears to be 'M.C.' and another that looks like 'S. S. S.'. On the far right, there is a signature that looks like 'N. S. S.' and the number '- 23 -' written below it.

Input Power Cable with 15 A Plug and six way output terminal strip for two outlets.

18. Certifications:

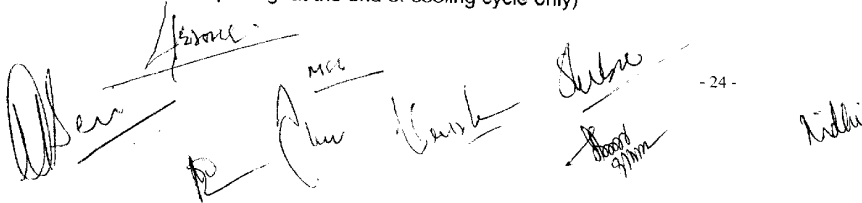
- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I) or Class II type-B device to protect against electric shock.
- Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Agenda Item No. 14: Review of Technical Specifications of Horizontal Pre Vacuum Autoclave

The committee approved the technical specifications of Horizontal Pre Vacuum Autoclave as follows:

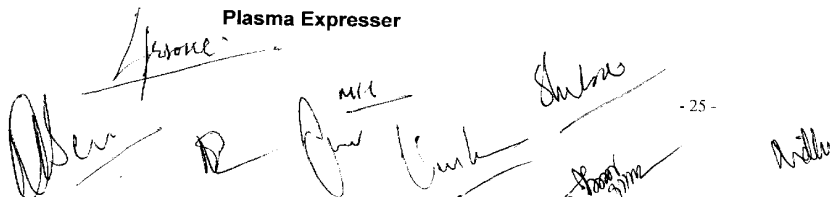
Autoclaves use pressurized steam to destroy microorganisms, and are the most dependable systems available for the decontamination of laboratory waste and the sterilization of laboratory glassware, media, and reagents. For efficient heat transfer, steam must flush the air out of the autoclave chamber. Autoclave to be exclusively designed and used for the treatment/disinfection of bio-medical waste.

1. Capacity minimum 100 liters
2. Sterilization Temperature 121 deg C to 138 deg C
3. Compressed Air 5.0 – 7.0 BAR
4. Should include vacuum cycle, rapid vacuum cycle and non-vacuum cycle with or without drying
5. Tamper-proof control panel with efficient display and recording devices for critical parameters such as time, temperature, pressure, date and batch number etc. (Touch sensitive control panel)
6. Door with front loading. Door to have an locking mechanism (Door to have a safety lock to allow opening at the end of cooling cycle only)

 Several handwritten signatures and initials are present at the bottom of the page. From left to right, there is a large signature, a signature with 'ma' written above it, a signature with 'Chauhan' written below it, a signature with 'Sinha' written above it, and a signature with 'Sharma' written below it. To the right of these signatures is the page number '-24-' and the name 'Rishi' written vertically.

7. Durable stainless steel pressure vessel (chamber) which conforms to the pressure equipment directive (PED). All metal parts in the inner surfaces to be made of SS
8. Multi-program model allowing at least 5 programs to be stored
9. To be supplied with load probe and printer
10. Audible and visible alarms including cycle fault and interruption, sterilization failure, low water level and door unlocked.
11. Should have a communication interface for data transfer to a central data capture system.
12. Should work on 200-250 Volts at 50 Hz
13. Containers for autoclave : Stainless steel containers and pans or autoclavable polypropylene
14. Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle
15. Alarm system
 - a. Independent temperature and pressure monitoring
 - b. Cycle information recovery in the case of power failure or cycle interruption
 - c. Fail Indicator – Indicates cycle failure or interruption
 - d. Door Indicator – Indicates the door is unlocked
19. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I) or ISO standards
 - For indigenous items: should comply with BIS & CPCB standards.

**Agenda Item No. 15: Review of Technical Specifications of Manual
Plasma Expresser**


 A collection of handwritten signatures and initials in black ink. From left to right, there are several distinct signatures, some with horizontal lines underneath. The text '- 25 -' is written in the center-right area. To the far right, the word 'with:' is written vertically.

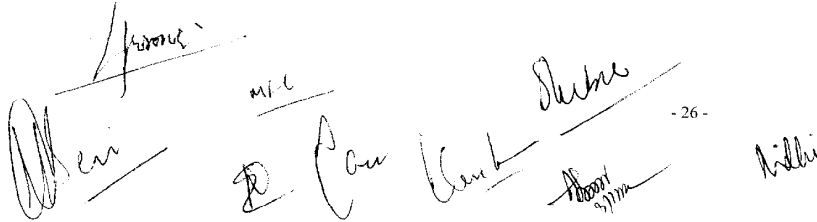
The committee approved the technical specifications of Manual Plasma Expresser as follows:

1. Should be suitable to express blood components (plasma, platelets) from collection container
2. Mode of operation: Manual
3. Front panel should be spring loaded to uniform pressure on container causing transfer of fluid
4. Compression plate should be made of transparent acrylic, durable
5. Metal used for the equipment should be non-corrosive and can be cleaned with antiseptics.
6. Base portion and Vertical surface should be made to have better strength and long lasting performance.
7. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 16: Review of Technical Specifications of Automated Component Processor (Automated Plasma Separator)

The committee approved the technical specifications of Automated Component Processor (Automated Plasma Separator) as follows:

1. The equipment should be able to express the blood components, from primary bag into various satellite bags automatically, after initial manual loading of the bag system on to the machine.
2. The equipment must be compatible with any blood bag including top and top and top and bottom.

A collection of handwritten signatures and initials in black ink. From left to right, there is a signature that appears to be 'A. Keri', a signature 'M. C.', a signature 'C. C.', a signature 'S. K.', a signature 'A. S.', and a signature 'M. L.'. There are also some smaller initials and marks scattered around.

3. The equipment should have built in weighing mechanisms to measure the weight of various components separated (Plasma, Red cells and Platelets).
4. It should give at least one log leucoreduction for red cells and platelets
5. The equipment should have an integrated system of sealing heads and optical sensors to automatically control the flow of various blood components (Plasma, Platelets and red cells) in satellite tubings.
6. The equipment should have a control panel with display system to indicate various procedural steps.
7. The tube sealing should be of radio frequency type.
8. The equipment should have the provision to store and transfer the blood component details including the identification number of the donor unit to a central facility.
9. The equipment should have built in alarm system to indicate the completion of the procedure.
10. Electrical Supply:
 - Voltage – 220 to 240 V AC
 - Frequency – 50/60 Hz
 - Compatible UPS, to complete the ongoing procedure, with a back-up supply for at least half an hour, should be supplied with the equipment.
11. A computer should be supplied having seamless integration with equipment. Any other accessories for its interface with computer should also be supplied along with.
12. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified
 - Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

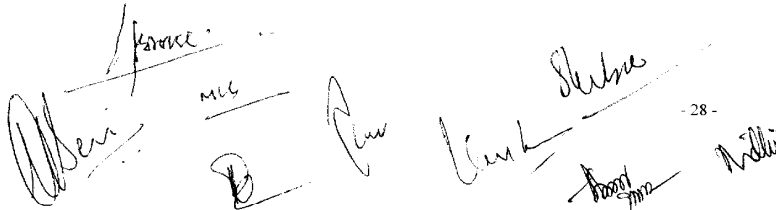
Agenda Item No. 17: Review of Technical Specifications of Refrigerated water bath (Cryobath)

Asone
Ben *M* *Can* *Ch* *Shree*
Asad *Nishi*

- 27 -


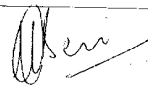
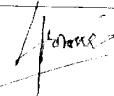
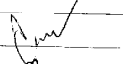
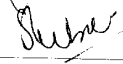

The committee approved the technical specifications of Refrigerated water bath (Cryobath) as follows:

1. For uniform thawing of plasma bags at preset temperature of $4^{\circ} \pm 0.2^{\circ}\text{C}$
2. High capacity pump to facilitate optimum and uniform thawing of plasma
3. Capacity: 10-12 bags per run or per one cycle
4. System to prevent contamination of individual ports during thawing.
5. Microprocessor based controller for precise monitoring and controlling of temperature at $4^{\circ} \pm 0.2^{\circ}\text{C}$.
6. Other requirements:
 - a) Input power supply : 230 + 10% V, 50 Hz, 15A single phase AC
 - b) Power consumption : Maximum 1600 W
 - c) Operating temperature : $3.5^{\circ}\text{C} - 4.5^{\circ}\text{C}$
 - d) Programmable temp. range : $3^{\circ}\text{C} - 50^{\circ}\text{C}$
 - e) Display resolution : 0.1°C
 - f) Temp. controller : Microprocessor based digital controller
 - g) Stainless steel tank of 22 guage & stainless steel lid of at least 20 guage.
 - h) Time taken for one process: Not more than 2 hours for plasma bags store at -40°C .
 - i) Tray: Stainless steel, removable tray of individual compartments for holding plasma bags.
 - j) External dimension (WxDxH) : Should be less than 850 x 500 x 800 mm ($\pm 10\%$)
 - k) Castor wheels: Mounted on lockable castor wheels.
 - l) Temp. Sensing method: Sealed sensor dipped directly in the water.
 - m) Weight : Less than 70kg
 - n) Drain line with shut off valve can be connected to existing plumbing.
7. Certifications:
 - Product certification: CE Class II A or US FDA certified
 - Quality Certification: ISO certified

The image shows several handwritten signatures and initials in black ink. On the left, there is a large signature that appears to be 'Abhinav'. To its right are several smaller initials, including 'mg', 'D', and 'R'. Further right, there is a signature that looks like 'Suresh'. Below this signature are two more initials, 'Raj' and 'Nelli'. The signatures are scattered across the bottom of the page.

- Protection against electric mechanical hazards: Preferably having international safety requirements of EN61010-1.

The representations/complaints received from the manufacturers during the pre-bid meetings for past 5 years have also been examined while finalizing these technical specifications and wherever found necessary suitable modifications have been incorporated.

S.No	Name of the member	Designation	Signature/Date
1	Mr. A.Senthikar	Asst. Drug Controller Representative from Drug Controller General of India, MOH & FW	
2	Dr. Manjula Singh	Scientist -C Representative from ICMR H.Q (looking after HIV/AIDS division)	M/S 21/11/12
3	Dr. Archana Bheri	Research Scientist -III Representative, National AIDS Research Institute, Pune	
4	Dr. G.R.Soni	Dy. Director Representative, National Institute of Biologicals, Noida	
5	Dr. Manisha Srivastava	Associate Professor - Transfusion Medicine Bhopal Memorial Hospital & Research Center, Bhopal	Manisha Srivastava MP
6	Dr. Nidhi Bhatnagar	Associate Professor - Transfusion Medicine IHBT Blood Bank, Civil Hospital, Ahmedabad, Gujarat	Nidhi Bhatnagar 09/11/12
7	Mr. Alok Jain	Accreditation Officer, Grade III, NABL, Delhi	
8	Dr. Sandhya Kabra	ADG (BS & LS), NACO Member Secretary	
9	Dr. B.D.Athani	Addl. DGHS & Medical Superintendent, Safdarjang Hospital, New Delhi Chairman	

10. Dr. Vanshree Singh Director Blood Bank, Vanshree
Indian Med Cross Society -29-
New Delhi.