I. STORAGE OF RED BLOOD CELLS:

A. GENERAL STORAGE REQUIREMENTS:

The temperature in all areas of a refrigerator used for the storage of Red Blood Cells must be maintained between 1 and 6°C, and should have a fan for circulating air or be of capacity and design to ensure that the designated temperature is maintained. The interior should be clean and adequately lighted. There should be separate areas in the refrigerator, or separate refrigerators, clearly designated and labeled for:

- 1. Uncrossmatched Red Blood Cells separated by blood group and Rh type,
- 2. Crossmatched Red Blood Cells,
- 3. Autologous Red Blood Cells,
- 4. Outdated or quarantined Red Blood Cells,
- 5. Patient samples or reagents.

B. TEMPERATURE MONITORING:

Blood storage refrigerators must have a system to monitor temperature continuously or **record the temperature at least every 4 hours.** The sensor for these systems should be on a high shelf, in a container filled with approximately 250 ml of liquid.

1. Electric Recorder Charts:

The electric recorder charts should be changed at the end of the period for which they record and labeled to identify:

- a. The facility,
- b. The storage unit,
- c. The date and the identity of the tech starting the record,
- d. The date and the identity of the tech ending the record,
- e. Supervisory review.

2. Temperature Variation:

Any temperature variation from normal or omissions (skips) must be explained in writing on the chart beside the tracing, the date and time of variation and the initials of the person making notation.

C. INTERNAL REFERENCE THERMOMETERS:

The internal reference thermometers should be in containers filled with approximately 250 mL of liquid (water is okay). One should be near the top and another near the bottom (on the highest and lowest shelf red blood cells are stored on) of the refrigerator.

D. DAILY RECORDS:

Personnel in the blood bank and laboratory areas should be constantly aware of the status of all blood component storage units and the blood components stored in them.

1. <u>Internal Reference Thermometer:</u>

The reference thermometer(s) of each blood storage refrigerator should be read and the temperature recorded **at least once daily** or on each shift per the policy in your blood bank.

NOTE:

Remember that any omissions or reading outside of the 1-6°C range for the internal reference thermometer or the electric recorder chart must be explained, initialed and dated.

Recording Thermometer:

The recording thermometer should be checked to make sure it is running properly. It should be set at the right time of the correct day and the temperature should correspond with a reference thermometer inside the blood storage unit. The temperature shown should be recorded **at least once daily** or on each shift per the policy in your blood bank.

NOTE:

Remember that any omissions or reading outside of the 1-6°C range for the internal reference thermometer or the electric recorder chart must be explained, initialed and dated.

NOTE: If there is a difference of more than $1^{\circ}C$ between

reference thermometer reading and recorder temperature reading, the recorder and the reference thermometer

should be calibrated.

2. <u>Daily Inspection:</u>

As a part of the daily inspection of the blood storage refrigerator it is desirable to examine all stored units. Blood or blood components that are questionable for any reason should be quarantined until their disposition is decided by the appropriate personnel.

3. Supervisor Review and Notification:

All records should show evidence of review by the supervisor for completeness and acceptability.

NOTE: Temperature records should be retained as

part of the blood bank records for at least

ten years.

Inform the supervisor of any blood or blood storage unit problems. It is important that any problems be corrected immediately.

NOTE: Temperature records will be reviewed by MEDIC

Representative periodically during the year.

E. ALARMS:

All blood component storage units should be equipped with audible alarms that alert personnel of potentially hazardous temperature conditions.

1. Alarm Checks:

Regulatory and accreditation agencies require validation with periodic checks to establish reliability.

2. Documentation:

Document all alarm checks by recording the date and initials of the person performing check.

F. EQUIPMENT FAILURE:

Each hospital transfusion service must develop a plan to deal with any malfunction or failure of the blood storage refrigerator or the electric recorder.

1. Requirement for Documentation:

It is absolutely necessary that you document every move in the event of an equipment failure.

- a. What happened?
- b. Why did it happen?
- c. When did it happen?
- d. Who discovered the problem?
- e. Disposition of blood components?
 - 1) Date and time placed in temporary storage.
 - 2) Temperature of temporary storage. (Remember to read temperature at required intervals.)
 - 3) Technologist who placed red blood cells in temporary storage.
- f. When will equipment be repaired?

DOCUMENT - DOCUMENT - DOCUMENT - DOCUMENT

2. Blood Storage Refrigerator:

a. In the event of equipment malfunction or failure, remove red blood cells from blood storage refrigerator and return to MEDIC or you may place red blood cells in another acceptable refrigerator temporarily.

The temperature must be monitored every thirty (30) minutes and recorded on form TS13.D (Blood Storage Unit Failure Temperature Documentation) if refrigerator is not an approved Blood Storage Refrigerator.

- b. Notify MEDIC immediately by FAX using MEDIC TSI3.B (Equipment Failure/Malfunction Report) of:
 - 1) Equipment failure or malfunction,
 - 2) Action taken,
 - 3) Expected time of repair,
 - 4) Unit numbers of all red blood cells placed in temporary storage,
 - 5) Date and time,

6) Technologist reporting equipment failure.

3. Electric Recorder:

- Read manual temperature at least every 4 hours and record on MEDIC TSI3.C (Recorder Failure Temperature Documentation for RBC Storage).
- b. Document action on Electric Recorder Chart.
- c. Notify MEDIC immediately by FAX using MEDIC TSI3.B (Equipment Failure/Malfunction Report) of:
 - 1) Equipment failure or malfunction,
 - 2) Action taken,
 - 3) Expected time of repair,
 - 4) Date and time,
 - 5) Technologist reporting equipment failure.

4. Alarm:

- a. Notify MEDIC immediately by FAX using MEDIC TSI3.B (Equipment Failure/Malfunction Report) of:
 - 1) Equipment failure or malfunction,
 - 2) Action taken,
 - 3) Expected time of repair,
 - 4) Date and time,
 - 5) Technologist reporting equipment failure.

II. HANDLING RED BLOOD CELLS:

Red blood cells should not remain at room temperature unnecessarily. Acceptable red blood cell temperature limits are 1-6°C during storage and 1-10°C during transportation.

A. PROCESSING RED BLOOD CELLS:

Limit the number of red blood cells processed at one time. **Do not** leave units at room temperature while processing.

B. ISSUE FOR TRANSFUSION:

Transfusion should either be started or the unit returned to the blood bank refrigerator within the time limit that ensures proper storage temperatures as established by the hospital.

C. INSPECTION OF RED BLOOD CELLS:

It is desirable to examine all stored blood or blood components periodically, and it is required that each unit be inspected immediately before issue for transfusion, shipment to other facilities or returned to MEDIC for reissue.

D. QUESTIONABLE RED BLOOD CELLS:

Blood units that are questionable for any reason should be quarantined until the responsible person decides their disposition. If you have unit(s) not suitable for transfusion, you should:

- 1. Notify MEDIC Laboratory,
- 2. Clearly mark unit to indicate that it is not suitable for issue, stating reason.

III. TRANSPORTATION OF RED BLOOD CELLS:

A. COMMERCIAL CARRIER REQUIREMENTS:

Both Interstate Commerce Regulations and CLIA Regulations require enclosure of blood products in a secondary container (leak-proof plastic bag) before being placed in shipping container.

B. SHIPPING CONTAINERS:

Sturdy containers, well-insulated with cardboard or Styrofoam and/or coolers will maintain shipping temperatures between 1 and 10°C if they contain adequate cooling material. In an insulated container, the temperature can be considered to be in the acceptable range as long as unmelted ice remains in the box and is in contact with the blood. It is the responsibility of the shipping or issuing facility to ascertain that shipping practices satisfactorily maintain the temperature below 10°C during transportation.

C. COOLANT:

Ice should be placed above the blood because cool air moves downward. Cubed wet ice may be better than chipped or broken ice for long distance shipments of blood because it melts slowly. In boxes shipped long distances or at high environmental temperature, the volume of ice should at least equal that of the blood.

IV. <u>REFERENCES:</u>

Code of Federal Regulations, Title 21, Parts 600.15, 606.60, 606.160, 610.53 and 640.11. Washington, D.C.: U.S. Government Printing Office, current edition.

Standards for Blood Banks and Transfusion Services. Bethesda, MD: AABB current edition.

Technical Manual, Bethesda, MD: AABB current edition.