

STORAGE AND HANDLING OF PRODUCTS CONTAINING RED BLOOD CELLS

I. STORAGE OF WHOLE BLOOD (WB)/RED BLOOD CELLS:

A. GENERAL STORAGE REQUIREMENTS:

The temperature in all areas of a refrigerator used for the storage of products containing 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 WB/Red Blood Cells separated by blood group and Rh type,
2. Crossmatched WB/Red Blood Cells,
3. Autologous Red Blood Cells,
4. Outdated or quarantined WB/Red Blood Cells,
5. Patient samples or reagents.

B. TEMPERATURE MONITORING:

Blood storage units must have a system to monitor temperature continuously and **record the temperature at least every 4 hours** (AABB Standard). 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.

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.

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2. Continuous Temperature Monitoring Systems:

Documentation in the system should include recognition of out-of-range temperatures and corrective actions taken. The alarm should be set to activate prior to the contents reaching unacceptable temperatures so that proper actions can be taken to protect product safety.

C. INTERNAL REFERENCE THERMOMETERS:

Refrigerators:

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. The thermometers should be currently calibrated against a reference thermometer with calibration traceable to a NIST-certified thermometer.

Other product storage areas (freezers, platelet areas):

Reference thermometers should be available and placed in appropriate liquids as back-up for monitoring storage temperatures.

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. Internal Reference Thermometer:

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 acceptable range for the internal reference thermometer or the continuous monitoring system must be explained, initialed and dated.*

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2. Recording Thermometer:

The recording thermometer probe should be checked to make sure it is running/recording 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 acceptable range for the internal reference thermometer or the continuous monitoring system must be explained, initialed and dated.*

3. Variability Between Thermometers/Probes:

The facility should determine the maximum allowable difference between the recording thermometer and back-up/internal reference thermometer readings. The maximum allowable difference should be established after considering the measurement increments and precision claims of the devices, the calibration adjustment factor (if any) for the thermometers, and any standards or regulations that are applicable to your facility. MEDIC recommends no greater than a 2°C allowance for refrigerators, platelet storage areas, and plasma freezers. If the difference between readings is greater than that allowed, calibration and/or repair/replacement of the measuring device may be needed.

4. Daily Inspection:

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

5. 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 (AABB Standard). Longer retention may be required dependent on the standards/regulations applicable to your facility.*

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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 periodically reviewed by a MEDIC representative.*

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 OR MONITORING FAILURE:

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

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 record temperature at required intervals.)
 - 3) Employee who placed red blood cells in temporary storage.
- f. When will equipment be repaired?

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2. Blood Storage Refrigerator Failure:

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

The temperature must be monitored frequently and recorded on form TS13.D (Blood Storage Unit Failure Temperature Documentation) if the refrigerator or cooler is not an approved Blood Storage unit. The frequency of recording this temperature should be determined based on the reliability of the alternate refrigerator/cooler, but MEDIC typically recommends no less frequently than every 2 hours. If your facility has validation records showing acceptable temperature maintenance in the alternate storage area for more than 4 hours, the frequency of temperature reading may be increased to every 4 hours. If product storage temperature is out of the allowable range for a period of time, consult your supervisor and MEDIC regarding acceptability of return and/or transfusion.

- 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 WB/red blood cells placed in temporary storage,
 - 5) Date and time,
 - 6) Employee reporting equipment failure.

3. Electric Recorder (or continuous temperature monitoring system) Failure:

- a. Read manual temperature at least every 4 hours and record on MEDIC TSI3.C (Recorder Failure Temperature Documentation for RBC Storage).
- b. Document failures/actions on Electric Recorder Chart/24 hour monitoring system (when available).

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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) Employee 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) Employee reporting equipment failure.

II. HANDLING WHOLE BLOOD OR RED BLOOD CELLS:

Products containing 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 WB/RED BLOOD CELLS:

Limit the number of WB/red blood cell products 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.

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D. QUESTIONABLE WB/RED BLOOD CELL PRODUCTS:

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,
2. Clearly mark unit to indicate that it is not suitable for issue, stating reason.
3. Include written description of the issue when unit is sent back to MEDIC.

III. HANDLING OF OTHER BLOOD PRODUCTS:

- A. Maintain platelets at 20-24°C with continuous gentle agitation.
- B. Inspect platelets for the presence of swirling prior to issuing, and inspect all products for unusual appearance, leaks, or evidence of contamination.
- C. Maintain frozen plasma products at -18°C or colder, and liquid plasma products at 1-6°C.

IV. TRANSPORTATION OF RED BLOOD CELLS:

A. 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. It is the responsibility of the shipping or issuing facility to ascertain that shipping practices satisfactorily maintain the temperature between 1 and 10°C during transportation.

B. 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.

V. TRANSPORTATION OF PLATELETS OR FROZEN BLOOD PRODUCTS:

- A. Do not use coolant if shipping platelets.

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- B. Platelet temperature should be maintained as close as possible to 20-24°C during transportation and storage.
- C. Use dry ice if shipping frozen components. Products should remain frozen, without any evidence of thawing, during transportation and storage.

VI. REFERENCES:

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.