Document History:

Title: **Storage Equipment Standards: Blood, Blood Components and Derivatives** **Site(s): All DSM sites**

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Signature: 

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Storage Equipment Standards: Blood, Blood Components and Derivatives

Policies

1. All Storage Equipment shall be installed as per manufacturer's instructions, ensuring an operator's manual is available.

2. Equipment shall have unique identification.
- The unique identification number (e.g. serial number or facility assigned number) shall be recorded on all documents related to the piece of equipment.

3. Equipment shall be qualified and validated for its intended use and have documented validation testing.

4. The BTS/ Blood Bank shall have a process for scheduled monitoring, maintenance and cleaning of equipment.
- The process shall include: frequency of checks, check methods, acceptance criteria and actions to be taken for unsatisfactory results.

5. Equipment used in the storage and distribution of blood, blood components and derivatives shall have regular documented calibration. Equipment shall be calibrated:
- Upon Receipt
- After Service
- After Relocation
- At prescribe intervals

Note: Equipment shall bear a label indicating that calibration has been performed and specifying the date for recalibration.

6. The BTS/ Blood Bank shall have a written procedure outlining actions to be taken when the temperature of a refrigerator, freezer, incubator for platelet storage or plasma thawing device is outside the acceptable temperature range.

7. Equipment used for blood, blood component or derivative storage shall be connected to an emergency power supply.

8. Refrigerators, freezers and platelet incubators used for blood, blood component and derivative storage shall be able to maintain a temperature throughout the storage device that is within the range recommended by the supplier of the product.

8.1 Refrigerators used for storage of blood and blood components shall be maintained at a temperature between 1°C to 6°C.

Policies cont'd

8.2 Refrigerators used for storage of derivatives shall be maintained at a temperature between 2°C to 8°C.

8.3 Refrigerators used for reagent or specimen storage shall be maintained at a temperature between 1°C to 8 °C (for reagent storage refer to manufacturer's instructions).

8.4 Freezers used for storage of blood components shall be maintained at a temperature of - 18°C or colder.

8.5 Freezers used for reagent or specimen storage shall be maintained at a temperature of -18°C or colder.

8.6 Platelet incubators used for storage of platelets shall be maintained at a temperature between 20°C to 24°C.

9. Refrigerators, freezers and platelet incubators shall have alarm systems with audible signals.

- Alarm activation points shall be set at temperatures that allow time for appropriate corrective action before the blood, blood components or derivatives reach unacceptable temperatures.
- Alarm activation points shall be tested quarterly.
- The audible alarm shall sound in a location that is continuously monitored or staffed so that corrective action can be taken immediately.
- The audible alarm shall be tested weekly.
- The audible alarm shall have a back-up power supply.
- The alarm battery back up power supply (power failure alarm) shall be checked at least monthly.
- Backup batteries shall be changed semi-annually.
- Checks shall be documented.

10. Refrigerators, freezers and platelet incubators with a system to monitor the temperature continuously shall have in addition, the temperature recorded manually with an independent calibrated thermometer a minimum of once per day.

- A trained and authorized individual shall record and review temperature records daily. The review shall be documented.
- The Charge Technologist or a designate shall review temperature records weekly and a final review monthly. The review shall be documented.

Note: The independent calibrated thermometer must be located in a different location than the digital controller.

Note: For Refrigerators – the independent calibrated thermometer shall: be immersed in 10% glycerol that is no greater than the volume of the smallest unit of donor red cells in storage. If it is immersed in a significantly smaller volume it should not be too sensitive to the change in temperature.

11. Storage devices that do not have a continuous temperature-monitoring system shall have the temperature recorded manually with a calibrated thermometer a minimum of once every 4 hours.

Policies cont'd

12. Refrigerators used for the storage of red cell components shall have a calibrated temperature-sensing device immersed in a fluid that is no greater than the volume of the smallest unit of donor red cells in storage. The heat transfer characteristics of the fluid shall be similar to blood, e.g., 10% glycerol.
- All thermometers used in storage devices that store blood, blood components and derivatives shall be checked against a certified calibrated thermometer annually and check shall be documented.

13. Equipment used for blood, blood components or derivative storage in a remote location outside of the BTS/blood bank shall conform to all relevant standards.

14. The ambient temperature of open storage areas shall be recorded manually with a calibrated thermometer a minimum of once every 4 hours if a continuous temperature monitoring system is unavailable.

15. Platelet agitators should allow for adequate mixing as well as appropriate gas exchange through the walls of the platelet bag.

16. Equipment malfunctions shall be investigated, followed up and reported on appropriate forms.
- Equipment malfunction /corrective action records shall be retained according to Record Retention Policy.

17. Storage Equipment validation records shall be retained according to Record Retention Policy.

18. All Storage Equipment QC records (temperature recording charts, temperature records, maintenance records/ checklists) shall be retained according to Record Retention Policy.