Shared health
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Document History:

Title: **Storage Equipment Standards: Blood, Blood Components and Plasma Protein Products**

Site(s): **All Shared Health sites**

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Approved by: **Signature:**	Dr. Charles Musuka	**Date:**	07-JAN-2020
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Details of Recent Revision

- Updated derivative to plasma protein product throughout
- 5, Note changed to a bullet
- 10, Notes changed to bullets

Storage Equipment Standards: Blood, Blood Components and Plasma Protein Product

Policies

1. Storage equipment shall be installed as per manufacturer's instructions; ensure an Operator's Manual is available.

2. Equipment shall have a unique identification number (e.g., serial number, facility assigned number) which shall be recorded on all documents related to piece of equipment.

3. Equipment shall be qualified and validated for intended use; documentation of validation must be available on-site.

4. The blood bank/BTS shall have a process for scheduled monitoring, maintenance and cleaning of equipment which 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 plasma protein product (PPP) shall have regular documented calibration.
- Equipment shall be calibrated:
  - Upon receipt
  - After service
  - After relocation
  - At prescribed intervals
- Equipment shall bear a label indicating calibration has been performed and stating the date for next calibration

6. The blood bank/BTS 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 PPP storage shall be connected to an emergency power supply.

8. Refrigerators, freezers and platelet incubators used for blood, blood component and PPP storage shall be able to maintain a temperature throughout the storage device 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 1ºC and 6ºC.

8.2 Refrigerators used for storage of PPP 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 1ºC and 8ºC (for reagent storage, refer to manufacturer's instructions).

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

8.5 Platelet incubators used for storage of platelets shall be maintained at a temperature between 20ºC and 24ºC.

9. Refrigerators, freezers and platelet incubators shall have alarm systems with audible signals:
- Alarm activation points shall be set at temperatures which allow time for appropriate corrective action to be taken before blood, blood components or PPP reach unacceptable temperatures
- Alarm activation points shall be tested quarterly
- The audible alarm shall sound in a location continuously monitored or staffed so 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
- Back-up batteries shall be changed semi-annually, as appropriate
- Checks shall be documented

10. Refrigerators, freezers and platelet incubators with a continuous temperature monitoring device shall, in addition, have the temperature recorded manually with an independent calibrated thermometer once every 24 hours, at a minimum:
- A trained and authorized individual shall record and review temperature records daily. The review shall be documented.
- The charge technologist or designate shall review temperature records weekly and a final review monthly. The review shall be documented.
- The independent calibrated thermometer must be located in a different location than the digital controller.
- For refrigerators, the independent calibrated thermometer shall:
    - Be immersed in 10% glycerol, unless specified otherwise by the manufacturer, which has a volume no greater than the volume of the smallest unit of donor red cells in storage.

11. Storage devices without a continuous temperature-monitoring system shall have the temperature recorded manually with a calibrated thermometer once, at a minimum, every four hours.

12. Refrigerators used for the storage of red cell units 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 red cells, e.g., 10% glycerol.
- All thermometers used in storage devices storing blood, blood components and PPP shall be checked against a certified calibrated thermometer annually and check shall be documented.

13. Equipment used for blood, blood components or PPP storage in a remote location outside of the blood bank/BTS 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.