Document History:

Title: **Temperature Monitoring: Blood, Blood Component and Plasma Protein Product (Derivative) Storage Equipment**

Site(s): All DSM sites

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#	Details of Revisions:	Approval:	Date:
1	New Document	C Musuka	31-MAR-2011
2	• Revised title and throughout to “plasma protein products (derivatives) • 4.1.4 and 6.2 revised for fridge/platelet incubator within 2ºC and freezer within 5 ºC	C Musuka	03-FEB-2017
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Temperature Monitoring: Blood, Blood Component and Plasma Protein Product (Derivative) Storage Equipment

1.0 Principle

To monitor and record the temperature of blood, blood component and plasma protein product (derivative) storage equipment

2.0 Scope and Related Policies

Refer to Policy Storage Equipment Standards: Blood, Blood Components and Derivatives.

3.0 Materials

Independent thermometer for each piece of equipment
Continuous temperature-recording chart (i.e. Chart Recorder)
QC Form- Daily/Weekly/Monthly Maintenance Checklist
QC Form- Daily Temperature and Weekly/Monthly Maintenance Record: Fridge
QC Form- Daily Temperature and Weekly/Monthly Maintenance Record: Freezer
QC Form- Daily Temperature and Weekly/Monthly Maintenance Record: Platelet Incubator
QC Forms- Four Hour Manual Temperature Record: Fridge/Freezer/Platelet Incubator
QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.0 Procedure

4.1 Daily: Temperature Monitoring (Fridge/Freezer/Platelet Incubator):

4.1.1 Perform daily temperature checks of the blood, blood component and plasma protein product (derivative) storage
equipment:

- Read and record the temperature obtained from the continuous temperature-recording chart a minimum of once per day on the applicable Daily Temperature and Weekly/Monthly Maintenance Record QC Form

- Read and record the digital controller (internal thermometer) temperature a minimum of once per day on the applicable Daily Temperature and Weekly/Monthly Maintenance Record QC Form

***Note**: If equipment has both an upper and lower digital controller both temperatures must be documented.*

- Read and record the independent thermometer temperature a minimum of once per day on the applicable Daily Temperature and Weekly/Monthly Maintenance Record QC Form
  - The location must be documented on the applicable Daily Temperature and Weekly/Monthly Maintenance Record QC Form.

***Note**: The independent thermometer shall be located in different location than the digital controller.*
***Note:** The independent thermometer may be moved throughout the equipment front to back shelf to shelf.*

4.0 Procedure cont'd

4.1.2 For open storage areas and equipment **without** a continuous temperature monitoring system:
- Read and record the digital controller (internal thermometer) temperature where applicable and the independent thermometer temperature every 4 hours on applicable Four Hour Manual Temperature Record QC Form

4.1.3 Verify that the temperature has remained within the acceptable temperature range since the last temperature check. Refer to procedural note 6.1:
- If the temperature is outside the acceptable range refer to QC Procedure- Alarm Response Malfunction

4.1.4 Compare the temperatures of the digital controller (internal thermometer), the independent thermometer, and the continuous temperature recording chart.
- For fridge and platelet incubator the temperatures must be within 2°C of each other
- For freezer the temperatures must be within 5°C of each other
  - If the temperature readings are not within acceptable temperature range of each other, refer to procedural note 6.2.

4.2 Weekly: Change Continuous Temperature-Recording Chart (Fridge/Freezer/ Platelet Incubator)

4.2.1 Remove the completed temperature chart and record the following:
- Stop date and time
- Initial

4.2.2 Select a new temperature chart for storage equipment:
- Ensure the replacement chart is the correct type and size for the equipment that is being monitored

4.2.3 On a new temperature chart, record the following:
- Start date and time
- Initial
- Storage equipment identification (make and serial number).

4.2.4 Install with the new temperature chart according to manufacturer's instructions.

4.2.5 Position the temperature chart to match the start date and time:
- Ensure the temperature recorded by the pen on the device is within ± 1°C of the internal temperature

4.2.6 Review the completed chart to ensure that the temperatures recorded have remained within the acceptable range for the appropriate storage conditions:
- Review must be performed by Charge Technologist or designate
- Confirm deviations outside the acceptable range on the temperature graph have been documented and initialed
- Investigate any unexplained deviations

4.2.7 Document charts changed on appropriate:
- QC Form- Daily Temperature and Weekly/Monthly Maintenance Record
- QC Form- Daily/Weekly/Monthly Maintenance Checklist

5.0 Reporting

5.1 Ensure required documentation complete on:
- QC Form- Daily/Weekly/Monthly Maintenance Checklist
- QC Forms- Daily Temperature and Weekly Maintenance Record: Fridge/Freezer/ Platelet Incubator
- Temperature Recording Chart

5.2 A trained and authorized individual shall record and review the temperatures daily.

5.3 The Charge Technologist or designate shall review temperature records weekly and final review monthly:
- This review shall be documented on QC Forms- Daily Temperature and Weekly/Monthly Maintenance Record: Fridge/Freezer/Platelet Incubator

5.4 Retain all competed QC records according to Record Retention Policy. (Refer to Appendix 8).

6.0 Procedural Notes

6.1 Acceptable temperature ranges for blood, blood component and derivative storage equipment are:

Equipment	Acceptable Temperature Range
Refrigerator	1 to 6°C (red blood cells, thawed plasma) 1 to 8°C (specimen storage) 2 to 8°C (plasma protein products-derivatives)
Freezer	-18°C or colder
Platelet Incubator	20 to 24°C

Note: *For acceptable temperature range for reagent storage – refer to manufacturer's instructions.*

6.2 If the temperature of the internal thermometer, the independently calibrated thermometer and the continuous temperature recording device are **not within** acceptable temperature range of each other:
- For fridge and platelet incubator within 2°C of each other
- For freezer within 5°C of each other

6.2.1 Determine whether the chart is recording correctly (improper installation, etc.).

6.2.2 Determine whether the digital read-out is functioning correctly. (check probe placement, etc.).

6.2.3 Verify the internal thermometer with a calibrated thermometer.
- Read and record the temperature of the calibrated thermometer after 1 hour.

6.2.4 Document on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer.

6.2.5 If unable to resolve, contact Charge Technologist or Designate.