Document History:

Title: **Alarm Response Malfunction: Blood, Blood Component, Derivative Storage Equipment and Plasma Thawer**

Site(s): **All DSM sites**

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Signature:			
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Alarm Response Malfunction: Blood, Blood Component, Derivative Storage Equipment and Plasma Thawer

1.0 Principle

To outline the procedure used in the event of alarm activation or equipment malfunction

2.0 Scope and Related Policies

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

3.0 Materials

QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
QC Form- Four Hour Manual Temperature Record: Fridge
QC Form- Four Hour Manual Temperature Record: Freezer
QC Form- Four Hour Manual Temperature Record: Platelet Incubator
Job Aid- Refrigerator Malfunction Instructions
Job Aid- Freezer Malfunction Instructions
Job Aid- Platelet Incubator Malfunction Instructions
Job Aid- Platelet Agitator Malfunction Instructions

4.0 Procedure

Note: All alarms on storage equipment shall be responded to immediately to ensure that corrective action is taken prior to storage equipment reaching unacceptable temperatures.

4.1 Refrigerator Malfunction:

4.1.1 Silence the alarm.

4.1.2 Read and record on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer the temperature of:
- The Continuous Temperature Recording Device (i.e. chart recorder)
- The Digital Controller (Internal Thermometer)
- The Independent Thermometer

4.1.3 Determine if temperatures are outside of acceptable range:
Note: If alarms are responded to immediately the temperature should still be within acceptable range:
- Blood and thawed plasma 1°-6°C.
- Derivatives 2°-8°C (dependent on manufacturer instructions)

4.0 Procedure cont'd

4.1.4 If temperatures are within acceptable range and:
- **4.1.4.1** High alarm was triggered – proceed to 4.1.6
- **4.1.4.2** Low alarm was triggered – proceed to 4.1.7

4.1.5 If temperatures are outside acceptable range (usually due to alarm not being responded to immediately):
- Determine length of time temperature has been outside acceptable range
- Document on QC Form – Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.1.5.1 If less than 30 minutes outside acceptable range:
- High Alarm triggered – proceed to 4.1.6
- Low Alarm triggered -Proceed to 4.1.7 and in addition
  -Quarantine all product affected
  -Consult Charge Tech or designate **or** BTS Medical Director/TM physician on call to determine if product can be considered safe will depend on "time out of range" and "temperatures"

4.1.5.2 If greater than 30 minutes outside acceptable range:
- Proceed to Procedural Note 6.2
- Investigate cause and determine corrective action, why alarm not responded to immediately allowing temperature to exceed acceptable range for greater than 30 minutes

4.1.6 If the temperature indicates that the High Activation alarm has been triggered, ensure that:
- The doors are properly closed
- The temperature –sensing probe is properly seated in the glycerol container
- The power cord is plugged into the electrical outlet

4.1.6.1 Correct the problem and:
- Monitor the temperature every 10 minutes
- Record the temperature of the refrigerator at 10, 20 and 30 minutes, if necessary
- If the temperature returns to acceptable limits within 30 minutes record the details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.1.6.2 If the temperature **does not return** to acceptable limits within 30 minute or the refrigerator appears to be malfunctioning:
Establish that the alternate blood bank refrigerator is functioning properly.
- Remove all products and store them in the alternate blood bank refrigerator
- Refer to procedural note 6.1
- Place sign on malfunctioning refrigerator – clearly indicating it is not working and cannot be used to store product

4.1.7 If the temperature indicates that the Low Activation alarm has been triggered and the refrigerator appears to be malfunctioning:
- Establish that the alternate blood bank refrigerator is functioning properly
- Remove all products and store them in the alternate blood bank refrigerator
- Refer to procedural note 6.1

4.1.8 After the transfer of blood products has been completed, notify the Charge Technologist and/or Maintenance/Service.

4.1.9 Record the details of the malfunction and the corrective action on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer.

4.0 Procedure cont'd

4.1.10 If an alarm sounds on a refrigerator located in a remote location, personnel from those areas shall assess the situation as outlined above and shall notify the blood bank as soon as possible.

4.2 Freezer Malfunction:

4.2.1 Silence the alarm.

4.2.2 Read and record on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer the temperature of:
- The Continuous Temperature Recording Device (i.e. chart recorder)
- The Digital Controller (Internal Thermometer)
- the Independent Thermometer

4.2.3 Determine if temperatures are outside of acceptable range:
Note: If alarms are responded to immediately the temperature should still be within acceptable range.
- Colder than -18°C

4.2.4 If temperatures are within acceptable range - proceed to 4.2.6.

4.2.5 If temperatures are outside of acceptable range (usually due to alarm not being responded to immediately):
- Determine length of time temperature has been outside acceptable range
- Document on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.2.5.1 If less than 30 minutes outside acceptable range – proceed to 4.2.6.

4.2.5.2 If greater than 30 minutes outside acceptable range
- Proceed to Procedural Note 6.4
- Investigate cause and determine corrective action, why alarm not responded to immediately allowing temperature to exceed acceptable range for greater than 30 minutes

4.2.6 If the temperature indicates that the high activation alarm has been triggered ensure that:
- The doors are properly closed
- The temperature-sensing probe is properly seated in the glycerol container (if applicable)
- The power cord is plugged into the electrical outlet

Note: Ensure all products are still entirely frozen (if not – proceed to Procedural Note 6.4).

4.2.6.1 Correct the problem and:
- Monitor the temperature every 15 minutes
- Record the temperatures on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
- If the temperature returns to acceptable limits within 30 minutes, record the details on QC Form- Equipment Malfunction and Corrective Action Record: Storage equipment and Plasma Thawer

4.2.6.2 If the temperature does not return to acceptable limits within 30 minutes and the freezer appears to be malfunctioning:
- Establish that the alternate freezer is functioning properly
- Remove all products and store them in the alternate freezer
- Refer to procedural note 6.3
- Place sign on malfunctioning freezer clearly indicating it is not working and cannot be used to store product

4.0 Procedure cont'd

4.2.7 After the transfer of blood products has been completed, notify the Charge Technologist and/or Maintenance/Service.

4.2.8 Record the details of the malfunction and the corrective action on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer.

4.3 Platelet Agitator Malfunction:

4.3.1 Silence the alarm.

4.3.2 Establish that the backup platelet agitator is functioning properly.
- If no back up platelet agitator available refer to procedural note 6.5

4.3.3 Remove the malfunctioning agitator from the platelet incubator and place the back-up agitator inside, if applicable.

4.3.4 Notify the Charge Technologist and/or Maintenance/Service.

4.3.5 Record the details of the malfunction and the corrective action on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer.

4.4 Platelet Incubator Malfunction:

4.4.1 Silence the alarm.

4.4.2 Read and record on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer the temperature of:
- The Continuous Recording Device (i.e. chart recorder),
- Digital Controller (Internal Thermometer)
- Independent Thermometer

4.4.3 Determine if temperatures are outside of acceptable range.
Note: If alarms are responded to immediately the temperature should still be within acceptable range
- 20-24^{o}C

4.4.4 If temperatures are within acceptable range – proceed to 4.4.6.

4.4.5 If temperatures are outside of acceptable range (Usually are due to alarm not being responded to immediately):
- Determine length of time temperature has been outside of acceptable range
- Document on QC Form: Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.4.5.1 If less than 30 minutes outside acceptable range – Proceed to 4.4.6.

4.4.5.2 If greater than 30 minutes outside acceptable range:
- Proceed to Procedural note 6.6
- Investigate cause and determine corrective action, why alarm not responded to immediately allowing temperature to exceed acceptable range for greater than 30 minutes

4.0 Procedure cont'd:

4.4.6 If the temperature indicates that the high or low alarm has been activated:
- The door is properly closed
- The power switch is turned on
- The power cord is plugged into the electrical outlet

4.4.6.1 Correct the problem and:
- Monitor the temperature every 10 minutes
- Record the temperatures on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
- If the temperature returns to acceptable limits within 30 minutes record the details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.4.6.2 If the temperature does not return to acceptable limits within 30 minutes and the platelet incubator appears to be malfunctioning:
- Remove the platelets and platelet agitator from the incubator and place on an available counter
- If the room temperature is not monitored with a continuous Recording Device, record the ambient room temperature every 4 hours on QC Form- Four Hour Manual Temperature Record: Platelet Incubator
- Place a sign on the malfunctioning Platelet Incubator clearly indicating it is not working and cannot be used to store platelets

4.4.7 After the transfer of platelets has been completed, notify the Charge Technologist and/or Maintenance/Service.

4.4.8 Record the details of the malfunction and the corrective action on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer.

4.5 Plasma Thawer Malfunction:

4.5.1 Turn off and unplug the malfunctioning equipment:
- Place a sign on the malfunctioning plasma thawer clearly indicating it is not working and cannot be used to thaw frozen blood components

4.5.2 Establish that an alternate plasma thawer is functioning properly, if available.
- If alternative not available, refer to MP Procedure - Thawing Frozen Plasma Components

4.5.3 Record the details of the malfunction and the corrective action on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer.

4.5.4 Notify the Charge Technologist and/or Maintenance/Service.

5.0 Reporting

5.1 Ensure all equipment malfunctions and corrective actions have been:
- Documented on QC Form- Equipment Malfunction and Corrective Action Record: Storage equipment and Plasma Thawer
- Reviewed by the Charge Technologist or designate

5.2 Retain all completed equipment malfunction and corrective action records according to Record Retention Policy. (Refer to Appendix 8).

6.0 Procedural Notes

6.1 If an alternate blood bank refrigerator is:

- **Not equipped with a continuous temperature-recording device:**
  - The temperature must be recorded every 4 hours on QC Form- Four Hour Manual Temperature Record: Fridge using a verified thermometer.
- **Not available at Non crossmatch sites**:
  - Blood, thawed plasma and derivatives can be packed as per INV Procedure- Inter-facility Shipping of Blood, Blood Components and Derivatives and transported to an alternate DSM site or discard as per site policy.
  - Notify the Charge Technologist or designate, the BTS Medical Director or designate/TM Physician on call and required site Clinical Practitioner.
  - Refer to DSM policy F100-10-26A -Unscheduled Equipment Downtime checklist.

NOTE: A domestic or commercial refrigerator may not be used for interim storage.

6.2 All blood and thawed plasma, and derivatives that have been stored in a blood bank refrigerator that has exceeded the acceptable temperature range for more than 30 minutes shall be discarded:

- Document in appropriate blood bank log
- Order replacement product as soon as possible
- Notify the Charge Technologist or designate and the BTS medical Director or designate/TM Physician on call
- Refer to DSM Policy F100-10-26A- Unscheduled Equipment Downtime checklist
- Investigate cause and determine corrective action, why alarm not responded to immediately allowing temperature to exceed acceptable range for greater than 30 minutes

6.3 A laboratory freezer that maintains a temperature of -18°C or colder can be used as an alternate freezer.

If it is not equipped with a continuous temperature recording device:

- The temperature must be recorded every 4 hours on QC Form- Four Hour Manual Temperature Record: Freezer using a verified thermometer

6.4 All frozen blood components that have been stored in a blood bank freezer that has exceeded acceptable temperature range for greater than 30 minutes and that have been **partially or entirely thawed** shall be discarded:

- Document in appropriate blood bank log
- Order replacement product as soon as possible
- Notify the Charge Technologist or designate and the BTS medical Director or designate/TM physician on call
- Refer to DSM Policy F100-10-26A- Unscheduled Equipment Downtime checklist
- Investigate cause and determine corrective action, why alarm not responded to immediately allowing temperature to exceed acceptable range for greater than 30 minutes

6.5 If a back up platelet agitator is not available:

- Contact clinical unit to determine if platelets can be transfused immediately
- If unable to transfuse, platelets must be discarded

6.6 All platelets that have been stored in an area (incubator/bench top) that has exceeded acceptable temperature range for greater than 30 minutes shall be discarded:

- Document in appropriate blood bank log
- Order replacement product as soon as possible
- Notify the Charge Technologist or designate and the BTS medical Director or designate/TM physician on call
- Refer to DSM Policy F100-10-26A- Unscheduled Equipment Downtime checklist
- Investigate cause and determine corrective action, why alarm not responded to immediately allowing temperature to exceed acceptable range for greater than 30 minutes