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Response to an Alarm Condition - Dearborn Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and procedures that will enable the Blood Bank staff to appropriately respond to an alarm caused by an abnormal temperature.

II. SCOPE:

A. The policies and procedures of this document are applicable when a storage device's alarm is activated.

B. During a general power outage, refer to the Transfusion Medicine policy, Blood Bank Emergency Management Plan.

III. PRINCIPLE:

A. The Blood Bank is required to ensure that blood components, tissues, derivatives, samples, and critical materials are handled and stored in a manner that prevents damage and limits deterioration. These temperatures are defined in the *Quality Control* section of this document.

B. For storage of blood components, the temperature must be continually monitored and must be recorded at least every four hours.

C. Blood Bank refrigerators 1, 2, 3, & 5 are continuously monitored refrigerators that are equipped with temperature chart recorders and internal alarm systems to detect any variations outside the required temperature range. The alarms on 2, 3 & 5 are connected to a remote alarm panel that sounds in the main laboratory area. Blood Bank 1 is a refrigerator that is used to store reagents, manufactured products, quarantined reagents and proficiency materials. Blood Bank 2 is currently used to store emergency issue blood products, thawed plasma, unprocessed red blood cells, crossmatched red blood cells, select pediatric units, and autologous/directed red

blood cells. Bank 3 is used primarily for reagents, and patient and proficiency specimens. Blood Bank 5 is currently used to store current patient specimens, available packed cells, red blood cells with testing in process, selected Rhogam and quarantined blood products. Blood Bank 4 is a refrigerator that is used to for long term patient specimen storage, donor blood segments, and expired panels/reagents for selected cell testing.

D. The plasma freezer is used to store fresh frozen plasma, cryoprecipitate, and some frozen patient samples. It is equipped with a temperature chart recorder and an internal alarm system to detect any variations outside the required <-18C range. This alarm is also connected to a remote alarm panel that sounds in the main laboratory area.

IV. DEFINITIONS:

A. Beaumont Health Facilities/Biomedical Department: department which performs repairs and some maintenance of equipment for Beaumont Health.

B. Designee: The Blood Bank Supervisor

V. POLICIES:

A. Documentation of a Variance Report

1. A variance will be completed and submitted to the Supervisor/Lead Technologist any time that the storage device's alarm has been active for 30 minutes or longer regardless of the kinds of items stored in the device.
2. The technologist shall document the actions taken, as indicated in the applicable Procedure section.

B. Considering whether to Move Items from One Storage Device to Another

1. When an alarm from a storage device is activated, consider the following factors when considering whether to move the stored items from one storage device to another:
    a. The possible reason that the alarm was activated in the first place.
    b. Whether the temperature is trending closer to the acceptable range.
    c. Whether the observed temperature is within the acceptable range for the storage device and items stored in the device; refer to the *Quality Control* section of this document.
    d. The amount of time that has passed since the first alarm activation.
    e. The immediate availability of a suitable storage device where the items could be moved.
    f. The kinds of items stored in the device (blood components, reagents, dry ice, etc.).
    g. Refer also to Consulting the Medical Director or Designee before Moving Stored Items or after One Hour of Alarm Activation, below.

C. Consulting the Medical Director before Moving Stored Items or After 1 hour of Alarm Activation

1. The Medical Director (MD) or designee will be consulted:
    a. Before moving blood components, or reagents from one storage device to another, or
    b. If storage device alarm has been active for one hour without resolution.
2. This communication and the MD's instructions will be documented on the variance.
    a. Examples of directions that the MD may provide follow:
        i. If the temperature (as indicated by the storage device's external temperature display or the internal thermometer that is stored inside the device) is outside of the acceptable range (see the Quality Control section), then the MD will most likely instruct the Blood Bank to move any stored blood components.
        ii. If the temperature is normal or is trending back towards the acceptable range yet the MD may instruct the Blood Bank to wait longer before moving any stored items and to record the temperature at specified intervals; e.g., every 15 minutes until it returns to the acceptable range.
        iii. The MD may instruct the Blood Bank to proceed to Manual Temperature Monitoring so that manual temperature(s) will be taken every 4 hours.
        iv. The MD may instruct the Blood Bank to take the device out of service; tag the device with *Equipment out of Service* form on the device until service provided from Beaumont Health Biomedical Department or contracted vendor.

D. Initiation of Manual Temperature Monitoring

1. Temperatures must be monitored manually every 4 hours in the following situations:
2. If the storage contents of a device are relocated to another device which is not actively monitored.
3. If a request by MD to initiate manual temperature monitoring of the storage device is so directed in response to Consulting the Medical Director before Moving Stored Items
4. This activity will be documented on the the *Manual Temperature Monitor Form* and submitted with variance report for review. Refer to Transfusion Medicine policies, Manual Temperature Monitoring and Variance Reporting.

E. Return of Device to Operations

A. Before quarantined reagent/control inventory can be returned for use, they must be evaluated for adverse effects as follows:

    1. Check one bottle/pack for each lot/shipment of reagents by testing with appropriate

control.

2. If control results are within acceptable ranges, the contents may be taken out of “quarantine”.
3. If control results are not acceptable do not use reagents/control material and notify manager.
4. Control/Calibrators used on automated equipment must pass manufacturer’s calibration criteria.
5. Verify stability requirements of any stored samples. Those that fall outside are to be discarded and reported to manager for follow up and incident reporting.
6. The results of this evaluation are documented using “Temperature Failure Evaluation and Report Form”

VI. QUALITY CONTROL:

The following table indicates the storage device, the acceptable temperature range, and the items that are stored in the equipment:

Storage Device	Items Stored	Acceptable Temperature Range
Blood Bank Refrigerator # 1	Blood Bank Reagents, Rhogam, Proficiency specimens	2° - 6° C
Blood Bank Refrigerator # 2	Blood Product Storage	1° - 6° C
Blood Bank Refrigerator # 3	Blood Bank Reagents, Specimens, Proficiency specimens	2° - 6° C
Blood Bank Refrigerator # 4	Blood Bank Reagents, Specimens	2° - 6° C
Blood Bank Refrigerator # 5	Blood Product Storage, Rhogam and Specimens	1° - 6° C
Blood Bank Freezer	Blood Product Storage, Retained Specimens	Below ¯18° C
Platelet Incubator # 1	Blood Product Storage	20° - 24° C

VII. PROCEDURE:

A. Response to an Alarm

Upon the First Alarm Activation

1. Attempt to ascertain the reason that the alarm was activated, (i.e. door left ajar, the door was open for a few minutes while searching for a blood product, probe not in place).

2. If door is observed ajar, close immediately to silence the alarm. If the temperature alarm appears to be a result of a recent activity in the device disable the alarm and set a timer for 15 minutes and minimize access to the device.
3. Observe and document the temperature as indicated on the storage device's external temperature display. If temperature is not within acceptable range confirm temperatures of internal thermometers stored inside the device.
4. If temperature range of the device is within acceptable range proceed to step 6.
5. If temperature range of the device is outside acceptable range, consider whether to move the stored items to another storage device. Refer to the policy *Considering whether to Move Items from One Storage Device to Another.*
6. After 15 minutes, re-enable the alarm if applicable to determine whether the alarm re-activates.
    a. If the alarm does not re-activate after 15 minutes, then the investigation is complete. If the alarm re-activates, proceed to step 7.

Upon the Second Alarm Activation

1. Disable the alarm and set the timer for additional 15 additional minutes.
2. Document the alarm condition on the Temperature Evaluation and Documentation Form.
3. Observe and document the temperature as displayed on the storage device.
    a. If the temperature is not within acceptable range confirm temperatures of internal thermometers stored inside the device.
        i. Consider the likelihood that the temperature probe inside of the storage device has been moved during inventory management.
        ii. Reposition the probe to determine whether the temperature returns to the acceptable range.
        iii. Consider the possibility that the storage devices alarm needs a battery replacement; notify the Lead Medical Technologist/ Supervisor or Beaumont Health Biomedical/Facilities for this replacement.
    b. If temperature of the device is still outside the acceptable temperature range, consider whether to move the stored items to another storage device. Refer to the policy *Considering whether to Move Items from One Storage Device to Another.*
4. After 15 minutes, re-enable the alarm if applicable to determine whether the alarm re-activates.
    a. If the alarm does not re-activate after 15 minutes, then the investigation is complete.
    b. If the alarm re-activates, consult with MD for direction on whether to move items from one storage device to another. Refer to the policy *Consulting the Medical Director before Moving Stored Items*
        i. Document this communication on the Temperature Evaluation and Documentation Form.
5. If the items are moved to another storage device, then the action should be recorded on the Temperature Evaluation and Documentation Form. .
    a. Document the consultation with the Medical Director or designee.

b. Document the alarm follow up actions.

c. Initiate manual temperature monitoring on the alternate storage device *Manual Temperature Monitor* form. Refer to Transfusion Medicine policy, Manual Temperature Monitoring.

d. Submit an internal variance report complete with device name, asset tag, alarm code condition, notifications and instructions from Medical Director or designee and all follow up actions. Refer to Transfusion Medicine policy, Variance Reporting

B. Moving Stored Items

Refrigerator Disruptions

1. If any blood product refrigerator is not functioning properly and is inadequate for storage (temperature is outside the acceptable temperature range of 1-6C) of blood products or RhoGAM:
    a. Medical Director or Supervisor should be notified prior to moving the contents of this refrigerator.
    b. Blood Bank staff should transfer the contents into another monitored blood bank refrigerator.
    c. Use shelves or bins to keep the crossmatched red blood cells (RBCs) separated based on the recipient blood type.
    d. If there are no monitored blood bank refrigerators available, the blood product should be transferred to an alternative refrigerator in the laboratory which has the same storage temperature as blood bank refrigerators.
    e. Moving the blood product inventory (RBCs, thawed plasma) should be top priority followed by reagents
    f. Manual temperatures of the alternative refrigerators will be taken at least every four (4) hours. Refer to Transfusion Medicine policy, Manual Temperature Monitoring.
    g. If there are no refrigerators on-site that are suitable for storage of blood products, then blood products should be packaged up in blood supplier shipping boxes with wet ice (6 pounds of wet per 20 units) both above and below the packaged products (blood products should be contained in a sealed bag with absorbent material in it). Blood products can be sent to other Beaumont Health facilities or back to the blood supplier for storage at their facilities.

Freezer Disruption

1. If there is a problem with any of the freezers that store blood products, Blood Bank staff should use carts to carefully transfer the contents of the malfunctioning freezer to a different freezer for temporary storage.
2. There are multiple freezers that are set up with different temperature ranges that can be used as back-ups. Freezer temperatures must be verified and maintained prior to using alternate freezers.
3. If there are no additional freezers to use as back-ups, then frozen blood products and should

be temporarily stored in Styrofoam coolers or fresh frozen plasma (FFP) transport boxes containing dry ice.

4. Manual temperatures of the alternative storage device will be taken at least every four (4) hours using the *Manual Temperature Monitor* form.
5. Frozen FFP can be sent to other Beaumont Health facilities or back to the blood supplier for temporary storage.

VIII. REFERENCES:

1. AABB, *Technical Manual*, current edition.
2. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
3. College of American Pathologists, *Transfusion Medicine Checklist*, current edition.

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	6/14/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	6/11/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	6/9/2022
	Kimberly Geck: Dir, Lab Operations B	6/9/2022
	Kelly Sartor: Supv, Laboratory	6/9/2022
	Kelly Sartor: Supv, Laboratory	6/9/2022