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Document Contact	Teresa Lovins: Supv, Laboratory
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Storage Equipment Alarms and Temperature Deviations in Blood Bank - Troy

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document describes the appropriate actions that should be taken when an equipment alarm or temperature deviation occurs.

II. CLINICAL SIGNIFICANCE:

A. In the clinical laboratory, the use of refrigeration designed for storing temperature-sensitive patient samples and reagents is important for maintaining their integrity and sustaining regulatory compliance.

B. Storage within the correct temperature range is critical for providing accurate test results and reducing the risk of financial loss due to temperature excursions. Reagents, for example, must be stored according to manufacturer's instructions, and the temperature should be monitored daily.

C. The Blood Bank is required to safeguard that blood components, reagents, derivatives, samples, and critical materials are handled and stored in a manner and at temperatures that prevents damage and limits deterioration.

III. POLICIES:

A. The Blood Bank is required to maintain evidence of corrective action taken when acceptable temperature ranges for temperature-dependent equipment and environmental temperatures are exceeded, including evaluation of contents of refrigerators and freezers for adverse effects.

1. Therefore, when an equipment alarm or temperature deviation occurs, Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations,* must be documented and appropriate actions must be taken as described throughout this document.
    a. This form includes space to document the initial, 30-minute, and 1-hour temperatures listed below:
        i. Internal thermometer
        ii. External display
        iii. Temperature graph
        iv. Temp Trak®

B. The supervisor or designee will document an internal variance for all alarms and temperature deviations that result in manual temperature monitoring, or moving stored items to an alternate location, or when deemed necessary by the Medical Director.

IV. PROCEDURE:

For each scenario described below, perform the appropriate actions described.

A. **Open Door Alarm**
    1. Close the door that is causing the equipment to alarm.
        a. If the alarm stops immediately, no further actions are required.
        b. If the alarm does not stop immediately or if the alarm reactivates, then document the alarm on Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations*.
            i. If the alarm stops within one hour and the temperature readings at one hour are within the acceptable storage temperature range, then no further actions are required.
            ii. If the alarm does not stop after one hour or if the alarm reactivates, then initiate manual temperatures, enter a variance and email the Supervisor or Lead Medical Technologist about the event.

B. **Audible or Visual Equipment Alarm**
    1. Document form Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations*.
        a. If the alarm stops within one hour and the temperature readings at one hour are within the acceptable storage temperature range, then no further actions are required.
        b. If the alarm does not stop after one hour or if the alarm reactivates, then initiate manual temperatures, enter a variance and email the Supervisor or Lead Medical Technologist about the event.

C. **Manual Temperature Monitoring**

1. Manual temperatures are documented on Transfusion Medicine form, *Manual Temperature Monitor.*
2. Manual temperatures are obtained from the equipment's external temperature display to minimize temperature fluctuations caused by repeated opening and closing of equipment doors.
    a. If the external display is malfunctioning (does not reasonably correlate with the initial reading from the calibrated thermometer inside the equipment), then manual temperatures should be obtained from the internal thermometer.
    b. If the internal thermometer is used for manual temperature monitoring, a notation should be made on the form.
    c. Manual temperatures must be recorded every 15 minutes while an audible or visible alarm is occurring.
    d. Manual temperatures must be recorded every 4 hours when no audible or visible alarms are occurring.
    e. The technologist must document that the timer has been reset for the next reading.
3. Manual temperature monitoring may be discontinued only by the Medical Director, Supervisor, or a Lead Medical Technologist.

D. **Equipment Temperature Outside of Acceptable Storage Temperature Range**

1. If at any time the temperature is outside of the acceptable storage temperature range then the contents must be moved immediately to an alternate storage device with the exception of the Jewett freezer defrosting cycles.
2. Manual temperature monitoring must be initiated, using Transfusion Medicine form, *Manual Temperature Monitor.*

E. **Jewett Plasma Freezer Defrost Cycle**

1. The defrosting process on the Jewett plasma freezer initiates automatically in response to a built-in timer and is set for one defrost cycle every six hours.
    a. The defrost cycle is 20 minutes and terminates automatically if during defrost the evaporator coil temperature exceeds 15°C.
    b. If the temperature of the freezer exceeds -18°C due to the defrosting process but returns to the acceptable storage temperature range (-65°C to -18°C) within 15 minutes, then no additional actions are required.
    c. If the temperature of the freezer exceeds -18°C (the high end of the acceptable storage temperature range) for more than 15 minutes due to the defrosting process, then proceed as follows:
        i. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations.*
        ii. If the temperature still exceeds -18°C after 30 minutes, then the contents must be moved immediately to an alternate storage

device.

iii. Manual temperature monitoring must be initiated using Transfusion Medicine form, *Manual Temperature Monitor.*

F. **Room Temperature Outside of an Acceptable Storage Temperature Range**

1. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations.*
2. Adjust the thermostat to the desired temperature.
3. If unable to adjust temperature to the acceptable range within one hour, request service from Facilities Management.
4. If the room temperature is outside of the acceptable storage temperature for any reagent (as indicated by the manufacturer's insert), then the reagent should be placed in quarantine.
5. The supervisor or designee will obtain excursion study data from the manufacturer to determine the appropriate disposition of the reagent.

G. **Room Humidity Outside of Acceptable Range**

1. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations*.
2. Place a service request for Facilities Management at https://intranet.beaumont.org/departments-services/facilities-and-biomed.

H. **Temperature Graph not Marking or is Marking Outside of the Acceptable Storage Range**

1. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations.*
2. Compare the readings of the temperature graph with the internal thermometer, external display, and Temp Trak® to verify that the graph is adjusted correctly.
3. If the graph needs adjustment, refer to Transfusion Medicine procedure, *Preventative Maintenance of Temperature Monitored Equipment.*
4. After comparing the temperature readings, it may be necessary to refer to the procedure section, V.D. *Equipment Temperature Outside of Acceptable Storage Temperature Range.*

I. **Temp Trak® Sensor Alarm**

1. Temp Trak® sensors display green when the temperature is within acceptable range.
2. If a Temp Trak® sensor displays a blue color (too cold) or a red color (too warm), then the following actions should be taken:
    a. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations.*
3. If the Temp Trak® alarm clears (turns green) within one hour and the temperature

readings at one hour are within the acceptable storage temperature range, then no further actions are required.

4. If the Temp Trak® alarm does not stop (stays blue or red) after one hour or if the alarm reactivates, then initiate manual temperatures.

J. **Temp Trak® Missed Communications**

1. If Temp Trak® has a missed communication state, then recheck the system within 2 hours. If the missed communication has cleared within 2 hours, then no further actions are required.

2. If Temp Trak® has a missed communication state for 2 or more hours, then contact Facilities Management and document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations*.

K. **Storage Equipment Malfunctioning**

1. If the storage equipment is malfunctioning and there appears to be a risk of damage to the stored items or environment, then perform the following:
    a. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations*.
    b. Move the stored items to the appropriate alternate storage location.

L. **Moving Items to Appropriate Alternate Storage Devices**

1. Document Transfusion Medicine form, *Storage Equipment Alarms and Temperature Deviations*.
2. Initiate manual temperature monitoring.
    a. Manual temperatures are documented on Transfusion Medicine form, *Manual Temperature Monitor*.
3. Appropriate Alternate Storage Devices
    a. Refrigerators
        i. The preferred alternate refrigerator is another temperature-monitored refrigerator located within the Blood Bank.
        ii. If there is no space in a Blood Bank temperature monitored refrigerator, the Chemistry walk-in refrigerator is maintained at 4.5°C and is the alternate backup.
        iii. Manual temperature monitoring must be initiated.
    b. Platelet incubator
        i. The platelet agitator may be removed from the incubator and placed on a Blood Bank counter (room temperature is monitored by Temp Trak®).
        ii. Note the differences between the acceptable temperature ranges for platelets vs. room temperature. Therefore, if the agitator is removed from the incubator, then manual room

temperature monitoring must be initiated to ensure that platelets are stored at their acceptable temperature range.

iii. The room temperature thermostat may require slight adjustment in this case.

iv. Note also that a backup platelet agitator is in storage.

c. Freezer

i. Potential alternate storage devices are located in Microbiology and Chemistry.

a. Before moving items to an alternate freezer, verify that the temperature range is acceptable.

b. If no freezer space is available or cannot be made available at Troy, then obtain large quantities of dry ice. Potential sources of dry ice are Versiti, Corewell Health William Beaumont University Hospital, and specimen processing.

c. Maintain a small but adequate inventory of frozen plasma and cryoprecipitate on-site in an appropriate shipping box with an appropriate amount of dry ice.

d. Replenish dry ice as needed to ensure that intact dry ice and vapors are present in the box.

e. Arrange for the transfer of the remaining inventory to another facility (e.g., the Corewell Health William Beaumont University Hospital Blood Bank or another Corewell Health Blood Bank).

M. **Returning Items to Permanent Storage Device from Alternate Storage Device**

1. Items should be returned to their permanent storage device as soon as possible after the permanent storage device has been repaired or replaced.
2. Authorization from the Medical Director, supervisor, or a Lead Medical Technologist is required to return items to their permanent storage device from an alternate storage device.
3. Prior to returning the items, the temperature of the permanent storage device should be monitored for 24 hours and should be within the acceptable storage temperature range for 24 hours.
4. Preventative maintenance should be performed prior to returning the items; refer to Transfusion Medicine policy, *Preventative Maintenance of Temperature Monitored Equipment.*
5. Document Transfusion Medicine form *Revalidation of Blood Bank Temperature Monitored Equipment.*

V. 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* and *Laboratory General Checklist*, current editions.

Attachments

Manual Temperature Monitor-CHE.pdf

Storage Equipment Alarms and Temperature Deviations -CHE.pdf

Approval Signatures

Step Description	Approver	Date
	Masood Siddiqui: Staff Pathologist	7/1/2024
	Ryan Johnson: OUWB Clinical Faculty	7/1/2024
Policy and Forms Steering Committe (if needed)	Teresa Lovins: Supv, Laboratory	7/1/2024
	Teresa Lovins: Supv, Laboratory	7/1/2024

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