Indiana University Health	**Original Creation Date:** 11/01/2016	**Publication Date:** Not Set
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** Not Set
	Category: Lab Methodist, Lab Riley, Lab University	
	Education: Level 3	
Approval Signatures: No Users		

Blood, Reagent, and Supply Storage/Monitoring

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Reference # 25105

I. PURPOSE

The purpose of this procedure is to provide guidelines and instructions for: a) identifying storage conditions for blood products, reagents, and supplies, b) monitoring blood products, reagents and supply storage; c) managing alarms from the automated monitoring system.

II. SCOPE

The procedure applies to all blood bank monitored storage devices. All Blood bank team members will comply with this procedure.

III. STATEMENTS/REQUIREMENTS

A. All blood products, reagents, and supplies that are stored in refrigerators at University, Methodist, and Riley hospitals are monitored 24/7 by the Rees Monitoring System.

   1. Preventive maintenance and calibration of the REES system is performed annually by the vendor.

   2. The validation is performed every 365 days +/- 30 days.

B. The REES Master Input (Attachment 1) lists all current storage devices, REES input #s, and alert limits set for each alarm.

C. Each hospital blood bank has a dedicated REES computer.

D. All blood products stored by LifeLine are monitored 24/7 by Sonicu.

   1. LifeLine staff are responsible for monitoring temperatures and responding to alarms.
   2. Preventative maintenance and calibration of the Sonicu system is performed annually by the vendor.
   3. Quarterly reports will be sent to Blood Bank QA including temperature excursions with corrective actions.

E. Thermometers and thermocouples/alarms are placed in containers of solution approximately equal to the smallest volume of blood/reagent stored in the refrigerator. This small volume assures rapid detection of temperature change so that appropriate action can be taken before the blood supply is compromised.

F. Instructions for corrective actions in the event of equipment failure are posted on the appropriate piece of equipment in the Blood Bank and are posted at the outlying refrigerator locations (see Job Aid: BBQC-JA002 Management of Refrigerators in Alarm , Job Aid: BBQC-JA003 Management of Freezers in Alarm and Job Aid: BBQC-JA007 Blood Component Refrigerator Alarm System (Outlying Refrigerators): If Alarm Sounds.

G. All refrigeration unit alarm systems are supported by separate circuits, power failure alarm or battery power

H. All refrigeration units are connected to emergency power sources and/or alarm systems that provide alarm alert prior to product loss

I. Number of probes and probe placement:

Type	# of Probes	Placement
Upright refrigerator, single or double door	2	Top and bottom
Under-counter refrigerator	1	On topmost shelf where blood is stored
Upright freezer	1	Topmost shelf where product is stored

J. Because the Rees system provides 24/7 monitoring and records temperatures every 4 hours, chart recorders are not required on any storage device.

K. Contact Facilities/Maintenance for the hospital where the equipment is located.

L. Blood products, reagents, and supplies may not be returned to an out-of-control storage area/device until problem has been resolved and temperature monitored for 24 hours to assure that proper storage temperatures are maintained.

M. Audible alarms on storage units should remain enabled. Audible alarms may sound before the Rees system logs an alarm event and may provide the opportunity to recognize a problem before unacceptable temperatures are observed.

N. All individuals are responsible for ensuring that blood products, reagents, and supplies are stored appropriately. Acceptable storage conditions can be found on blood product, reagent, and supply labels and package inserts. Use caution with refrigerated reagents to ensure that the appropriate refrigerator type is used.

O. Blood product and reagent storage is configured as follows. Alarm set points are configured to alarm under conditions that will allow proper action to be taken before blood components and reagents reach unacceptable conditions.

Storage Unit Type	Acceptable Range	Alarm Set Points (Low/High)
Platelet Incubator	20-24°C	20.5°C /23.5°C
Refrigerator for blood products and reagents that can be stored as cold as 1°C	1-6°C	1.5°C /5.5°C
Refrigerator for blood products and reagents that cannot be stored below 2 °C	2-6°C	2.5°C /5.5°C
Freezer	-18°C or below	-50.0°C /-20.0°C
Room Temperature – Labs	18-25°C	18.5°C/24.5°C
Room Humidity	15-80%	16%/79%

VI. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

CAP: College of American Pathologists

REES EMS: REES Scientific e-Centron Environmental Monitoring System

V. EQUIPMENT/RESOURCES

Storage devices
REES EMS

VI. PROCEDURE

A. Alarm status is communicated by the Rees system using an automated phone list.

1. Listen to the message and alarm details and:
    a. Press **0** to acknowledge the alarm.
    b. Enter your ID code (the same as your IU Health Employee Number) and press **#**.
    c. Follow the voice prompts to inhibit the alarm.
    d. Press **5** to end the call.
    e. If you have acknowledged the alarm via the phone, you are responsible for ensuring that comments have been documented in the REES system.

B. Evaluate the storage unit.

1. At the first notification, the Form: BBQC-F044 Temperature Alarm Sign must be placed on the storage unit.
    a. **NOTE:** Each storage unit has a laminated sign attached to the side by magnet or Velcro. The sign should be moved to the front of the storage unit when needed and returned to the side when done. Signs are laminated and may be written on using a marker. The writing can be erased using an alcohol wipe.
    b. If a sign is not already present, then obtain a new Form, document the Storage Unit ID and the date and time of alarm activation. Attach the sign to the front of the Storage Unit.
    c. If a sign is already present, then note the date and time of the original notification.
    d. Blood products and reagents must be moved from refrigerators and platelet chambers after 30 minutes and freezers or storage rooms after 60 minutes of unresolved alarm.
2. Investigate for obvious reasons for the temperature alarm and correct if applicable.
    a. If the storage unit is at a remote location (i.e. Riley refrigerators), it is acceptable to call the floor and ask for someone to check the refrigerator to see if the door has been left open, or if they know that someone recently was accessing the refrigerator and may have left it open for a period of time. If the responsible floor cannot identify a reason for the alarm, then it may be necessary to go to the refrigerator and check for potential reasons for malfunction.
    b. If the door has been left open, either accidentally or purposefully (i.e. loading with new product or reagents), then close the door.
    c. Check for reasons that might indicate that products and reagents should be moved immediately. For example, is the fan running? Does the equipment have power?

draft

3. Login to the Rees system using your username and password and add a comment to the alarm acknowledgement:
    a. Review the alarm location.
    b. Access the Reports/Graphs tab and select **Node Events**.
    c. Refer to Job Aid: BBQC-JA 021 Resolving REES Alarms.
    d. Job aids will be available at each bench location.
    e. When the temperature alarm is resolved, the Rees system will not call.
        i. Periodically review instruments with the Temperature Alarm form attached for alarm status.
        ii. If >30 minutes have elapsed from the time on the form, login to the Rees software and check the alarm status.
        iii. Alarms that are acknowledged (yellow) should keep the sign attached **unless** the probe has been inhibited awaiting repair and the problem is now resolved.
        iv. Management will login to the Rees system and enable the alarm after completion of repairs.
        v. Probes that have returned to normal status are green. The sign may be removed and discarded.
        vi. If the Rees system requires Technical Support (i.e. broken probe, battery warnings):
            1. Call 609.406.0073
            2. Identify as Customer Number CLA006.
            3. Technical Support will require the Input Number and Node ID (Blood Bank is Node 2).
4. If the Rees system cannot be used to log 4-hour readings for a storage device:
    a. Notify all DPLM Blood Bank staff, via e-mail, that the storage device is being monitored via chart recorder.
    b. Install a paper chart recorder Job Aid: BBQC-JA004 Installing and Removing Chart Recorders on the device. Record on each new chart the following information:
        i. Facility's address (stamp available or pre-imprinted).
        ii. Equipment identification / location.
        iii. Date beginning recording.
        iv. Initials of person placing new chart on recorder.
    c. Allow the chart recorder to run at least 1 hour.
        i. On the chart, near Day of Inspection, record temperature reading indicated by recording pen/" top" thermometer reading and tech initials.
        ii. Perform Step B.4 daily until the Rees probe or system is placed back into service, then remove the chart recorder from the instrument and return to the Blood Bank for Supervisor Review and filing.
    d. For persistent alarms, determine if products/reagents need to be moved using the decision algorithm.

Type	If temperature…	Then…
Refrigerator	Returns within 30 minutes	No action needed

	Does not return within 30 minutes	Move all items to another monitored refrigerator; then call Facilities/Maintenance. **NOTE:** Temporary Cooler Storage for Surgery, see Transport Cooler Management SOP BBCP-018.
Freezer	Returns within 60 minutes	No action needed
	Does not return within 60 minutes	**OPTION 1:** Move all blood/components to another monitored freezer; then call Facilities/Maintenance. **OPTION 2:** Freezers may be packed with dry ice to maintain temperature until problem can be fixed. Dry ice can be obtained from Chemistry, Airgas sales (317-632-7106), Versiti, American Red Cross.
Platelet Chamber	Returns within 30 minutes	No action needed
	Does not return within 30 minutes	Move all items to another monitored platelet chamber (i.e. at another site), and then call Facilities/Maintenance. **NOTE:** Platelets may not be stored in the open laboratory because the temperature monitoring is set for reagent and supply storage (18-25°C).
	Returns within 60 minutes	No action needed
	Does not return within 60 minutes	Evaluate supplies and reagents stored at room temperature to verify the upper and lower storage limits. Some items may need to be moved based on their acceptable range and the current temperature.

i. When blood products, supplies, or reagents are moved, log into the Rees system.

ii. Access the Reports/Graphs tab and select **Node Events**.

iii. In the Event Selection Options dialog box, enter the current date. In the bottom row (Select by Event Type), click on the drop-down and select the **Alarm Messages** option.

iv. Click OK. The Event History window appears.

v. Find the yellow **Ack Rcvd** message that corresponds to the most recent alarm for the device. The Add/Edit a Comment Dialog Box appears.

vi. In the comments box, indicate the date and time that blood, reagents, or supplies were moved.

vii. Log out of the Rees system.

C. Management review of 4-hour logs and alarm activations/corrective action.

1. Review each day Monday through Friday. Monday reviews include Friday, Saturday, and Sunday.
2. The day after a holiday, the review for the day before the holiday and the day of the holiday is completed.
3. Review the 4-hour Log.

    a. Access the Reports/Graphs tab, and select Readings Reports ? All Inputs

b. Enter the date range of interest and select **OK**.

c. The Reading Samples report will display. Scroll through the data, making note of any unacceptable readings (highlighted in red) or missing readings (----------).

d. Press **Print Preview**, re-select the date range, and click **OK**.

e. Use the **Next Page** button to scroll through all of the pages in the Report.

f. Press the **Close** button. The message "Do you want to mark the records you have viewed as Reviewed, Approved, or Rejected?" appears. Click **Yes.**

g. Click the radio button next to **Reviewed**. Enter a comment about unacceptable or missing readings, enter your username and password, and click **OK.**

h. You are returned to the Reading Samples log, and the dates and times reviewed are highlighted in green. Scroll through the applicable dates and times to ensure that the entire date range is green.

i. To see who performed the review, return to the Reading Samples report and left click on the time highlighted in green. The history of review is displayed.

4. Review the Alarm Activations.

a. Access the Reports/Graphs tab, and select Events > Node Events

b. Enter the start review date. Click the radio button next to **Select by Event Type** and select **Alarm Messages** from the drop-down box.

c. Click **OK.**

d. If any **In Alarm** events are observed, click on the event to review the comments.

i. If all comments are acceptable, then check the "Investigation closed" box and click OK.

ii. If any comments are unacceptable, make corrections as needed, follow up with staff, and follow deviation process.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition.

AABB Standards, current edition.

IX. FORMS/ APPENDICES

Forms

Form: BBQC-F044 Temperature Alarm Sign

Attachments

Attachment 1: REES Master Input Chart

Job Aids

Job Aid: BBQC-JA002 Management of Refrigerators in Alarm

Job Aid: BBQC-JA003 Management of Freezers in Alarm

draft

Job Aid: BBQC-JA007 Blood Component Refrigerator Alarm System (Outlying Refrigerators): If Alarm Sounds

Job Aid: BBQC-JA004 Installing and Removing Chart Recorders

Job Aid: BBQC-JA 021 Resolving REES Alarms

X. APPROVAL BODY

None

PROCEDURE #:

BBQC-021

draft