TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	12.17.2013
Department:	Blood Bank	**Due Date:**	12.31.2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Blood Bank Plasma Freezers
Description of change(s):
Manual alarm checks are no longer required. Electronic alarm checks may be performed every quarter.

Non-Technical SOP

Title	**Blood Bank Plasma Freezers**	
Prepared by	Rowena Vince Cruz	Date: 5/28/2010
Owner	Stephanie Codina	Date: 5/28/2010

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

Frozen plasma and cryoprecipitate products are stored at temperatures ≤ -18°C. Blood product storage freezers must be equipped with a system for continuous temperature monitoring and audible alarm. The alarm must activate at a temperature that will allow proper action to be taken before blood products reach unacceptable conditions. The temperature and alarms are frequently checked to ensure an appropriate temperature is maintained.

2. SCOPE

Thermometers and chart recorders are calibrated prior to initial use and annually thereafter. Temperatures of thermometer, recording device and digital display are recorded daily. Temperature alarm system, power failure alarm, door open alarm and no battery alarm are verified quarterly.

3. RESPONSIBILITY

All blood bank staff members must demonstrate competency for the proper temperature requirements to store frozen blood products, performance and documentation of quality control, and action required when the temperature range is exceeded or the freezer alarm sounds.

4. DEFINITIONS

N/A

5. PROCEDURE

A. General Guidelines

Blood bank freezers:

1. Shall only contain blood components. One shelf may be reserved for temporary storage of patient specimens.
2. Shall be equipped with a visual and audible alarm system, and have continuous temperature monitoring device via a chart recorder. Alarm is set to activate at a temperature that will allow proper action to be taken before components reach unacceptable temperature. The audible alarm sounds within the blood bank where there is 24 hour coverage.
3. Shall be connected to an emergency power source, alarm system has a battery backup.
4. Shall have a calibrated thermometer placed on one of the shelves near the door.
5. Shall have clearly designated areas for:
   a. Plasma separated by ABO groups
   b. Cryoprecipitate

B. Daily Quality Control

Step	Action
1	Verify that the recording chart is positioned at the correct date and time. If not, re-adjust to the correct date and time and document the correction on **both** the front of the recording chart and the Plasma Freezer Temperature Form.
2	Read and record the following temperatures on the "Plasma Freezer Temperature Form." A. Chart recorder read to the nearest whole number (for example, -35) B. Thermometer read to the nearest 0.5 degree (for example, -35.0 or -35.5) C. Digital display read to the nearest 0.1 degree (for example, -35.1 or -35.2)
3	Interpret the freezer's operation. A. S = satisfactory B. U = unsatisfactory. If unsatisfactory, a. Document corrective action on the reverse side of the Plasma Freezer Temperature Form. b. Notify a supervisor if unable to resolve. c. If the temperature is out of range, move the contents of the freezer. Refer to section, "Freezer in Alarm."

C. Weekly Quality Control

Step	Action
1	Weekly QC is performed each Monday.
2	Obtain a new temperature chart. Be sure the new temperature chart is appropriate for the freezer and will record temperatures correctly. A. Stamp the back of the chart with the hospital address stamp. B. Stamp the back of the chart with the "date on" stamp. C. Record "plasma freezer" on the back of the chart to identify the storage containerRecord the current date in the "date on" line. D. Initial the back of the chart next to the date.
3	On the chart recorder, press the "C" (chart change) button until the stylus begins to move to the left, then release the button. The LED will flash to indicate the current temperature range value.
4	When the stylus stops moving, remove the chart know by turning it counter-clockwise, then swing it toward the top of the chart recorder.
5	Gently lift the stylus and remove the current temperature chart.
6	Press the new chart onto the chart recorder. Gently lift the stylus and turn the paper so the pen is on the correct day and time line groove.
7	Hold the chart paper to prevent it from turning while re-installing the chart knob. Turn the knob clockwise until snug.
8	Press and hold the "C" (chart change) button until the stylus starts to move to the right, then release the button.
9	Confirm the stylus is marking the correct temperature on the correct day/time. If not, repeat steps 3-9. Do not try to move or adjust the chart while it is on the recorder.
10	Record the following information on the removed chart and forward the chart to a supervisor or designee for review. A. Date removed B. Tech's initials

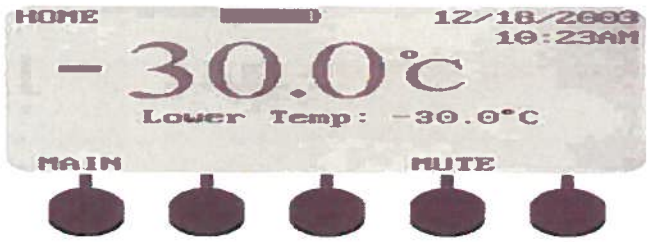
D. Quarterly Quality Control

Step	Action
1	Calibrate the temperature probe to ensure the high temperature alarm is activated properly. A. Remove all probes and cap from the bottle. B. Tape a calibrated thermometer to the temperature probe and place both in the probe bottle. Ensure that at least 2 inches of the probe and thermometer are immersed in solution. C. Close the freezer door and allow the temperature to stabilize for at least 10 minutes. D. Read the temperature of the calibrated thermometer to the nearest 0.5°C and record on the QC form. E. Enter and save the temperature reading in the freezer configuration. a. On the freezer panel, press the first button to go to the "Main Menu." b. Press the "Down" button until "Edit Configuration" is highlighted then press "select." c. Press the "Down" button until "Temperature Calibration" is highlighted then press "select." d. Select the "Upper" temperature probe. e. Press the "Down" button until "Temperature" is highlighted. f. Press the "Inc" and "Dec" buttons until the temperature of the calibrated thermometer displays. g. Press the "down" button until "Store Calibration" is highlighted and press "select." h. Press the "home" key to exit. A message will appear stating that the new calibration is memorized. The current temperature value will change to the value you selected. Verify the value. i. Shortly after the change, the current value temperature may change. This is normal. F. Remove the calibrated thermometer from the probe bottle and replace the cap. Ensure the cap fits tightly to minimize evaporation. G. Replace the probes in the bottle ensure they are immersed in solution at least 2 inches. H. Document the temperature probe calibration on the Plasma Freezer Temperature Form. Notify a supervisor or designee immediately if a problem exists.

Step	Action
2	Test the Power Failure Alarm to ensure it activates in an appropriate amount of time. A. The power failure alarm is normally set at 3 minutes. B. Change the power failure alarm setting to zero minutes. a. From the main menu, press the "down" button until "Edit Configuration" is highlighted. Press "select." b. Press the "down" button until "Alarm Setpoints" is highlighted and press "select." c. Press the "down" button until "Power Failure Timeout" is highlighted. d. Press the "dec" button until the setting is "0 min." e. Press the "back" button. C. Turn off the power to the freezer. a. Turning off the freezer may affect the chamber temperature. Before testing the alarm, take precautions to protect items in the freezer from extended exposure to adverse temperatures. b. During a power failure, the backup batteries continue to provide power to the monitoring system. D. The power failure alarm should activate immediately. a. An audible alarm will sound. b. The "AC Power Failure" message will appear on the HOME screen. E. Turn the power back on. The power failure alarm should clear. F. Change the power failure alarm setting to 3 minutes. a. From the main menu, press the "down" button until "Edit Configuration" is highlighted. Press "select." Press the "down" button until "Alarm Setpoints" is highlighted and press "select." b. Press the "down" button until "Power Failure Timeout" is highlighted. c. Press the "inc" button until the setting is "3 min." d. Press the "back" button. G. Document the alarm failure check on the Plasma Freezer Temperature Form. Notify a supervisor or designee immediately if a problem exists.
3	Test the door open alarm. A. Change the door open timer setting to zero minutes. a. From the main menu, press the "down" button until "Edit Configuration" is highlighted. Press "select." b. Press the "down" button until "Alarm Setpoints" is highlighted and press "select." c. Press the "down" button until "Door Ajar Alarm" is highlighted. d. Press the "dec" button until the setting is "0 min." e. Press the "back" button. B. Open the freezer door. C. The alarm should activate immediately. a. An audible alarm will sound. b. The "Door Open" message will appear on the "HOME" screen.

Step	Action
3 Cont	D. Close the freezer door. The alarm should clear. E. Return the door open alarm to the 3 minute setpoint. a. From the main menu, press the "down" button until "Edit Configuration" is highlighted. Press "select." b. Press the "down" button until "Alarm Setpoints" is highlighted and press "select." c. Press the "down" button until "Door Ajar Alarm" is highlighted. d. Press the "inc" button until the setting is "3 min." e. Press the "back" button. F. Document the Door Open Alarm check on the Plasma Freezer Temperature Form. Notify a supervisor or designee immediately if a problem exists.
4	Test the No Battery Alarm. A. Remove the battery from the battery holder for the monitoring system. B. The "No Battery" alarm should activate. a. An audible alarm will sound. b. The "No Battery" message will appear on the HOME screen. c. Return the battery to the battery holder and the alarm will clear. C. Document the "No Battery" alarm check on the Plasma Freezer Temperature Form. D. Notify a supervisor or designee immediately if a problem exists.
5	Clean the condenser grill and external drain fan. A. Protect the items in the freezer from exposure to adverse temperatures. B. Unplug the freezer to eliminate the potential for electric shock. C. Clean the condenser grill and the drain fan using a soft brush and vacuum cleaner. a. The condenser grill is the finned surface on the rear of the freezer. b. The external drain fan is located on the rear of the freezer, directly above the water evaporation tray. D. Document the cleaning on the Plasma Freezer Temperature Form. E. Notify a supervisor or designee immediately if a problem exists
6	Examine the probe bottles. Clean and refill if necessary.
7	Wipe the interior, exterior, and gasket with a damp cloth and mild soap to clean.
8	To calibrate chart recorder (and any non-certified thermometers) refer to the procedure "Thermometer Calibration and Installation."

E. Semi-annual Quality Control

Step	Action
1	Test the high alarm.  A. Identify the current setting for the high alarm set point. The alarm should activate at a temperature between ≤-20°C. B. From the "MAIN" screen, use the buttons to navigate to and select the "System Alarm Test & Status" option. C. The "System Alarm Test & Status" screen appears. D. Press the "up" or "down" button until the "Start High Alarm Auto Test" option is highlighted. E. Press the "Enter" button. F. The "Home" screen will appear. Under the reading for the upper temperature probe, a "High Alarm Test in Progress" message will appear. G. View the event log to determine the temperature at which the high temperature alarm activated. This should be between -22°C and -20°C. H. Document the alarm check on the Plasma Freezer Temperature Form. I. Notify a supervisor or designee immediately if a problem exists.

F. Freezer in Alarm

Step	Action
1	If the freezer alarm activate, push the alarm silence button to temporarily stop the audible alarm.
2	Determine whether there is an obvious cause for alarm activation and correct. If corrected, make a note on the temperature chart indicating alarm activation and reason. A. Freezer door ajar B. Outlet power failure / unit unplugged C. Freezer failure

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Step	Action
3	If the cause of alarm is not identified or if the problem is not immediately correctable, A. Monitor the internal thermometer temperature of the freezer every **15 minutes** until the alarm stops **or** until all blood products have been removed. Document the temperature on the "Manual Product Storage Temperature" form. B. If the temperature reaches -20°C, all blood products must be relocated to another storage container that will maintain temperatures below -18°C. Blood products can be moved to: a. The Chemistry freezer. However, patient specimens and blood products must be stored on different shelves. b. ARC shipping boxes containing dry ice. c. Transfer to a sister hospital (WAH, SGAH, GEC) d. Contact the blood supplier to attempt to ship products to another hospital. C. Document movement of the blood products on the temperature chart. Include the exact time and tech's initials. D. Place a calibrated thermometer in the temporary storage container with the blood products. E. Monitor the temperature at least every 4 hours. Document the temperature of the temporary storage container on the "Manual Product Storage Temperature" form.
4	A. Notify a supervisor or designee as soon as possible but definitely within 1 business day. B. Notify Quest biomedical engineering if the problem persists or if repairs are needed. C. Notify plant operations if there is a problem with the power supply.
5	When the problem is resolved **and** the freezer temperature returns to the acceptable range, A. Re-activate the alarm B. Return the blood products to the freezer C. Document replacement of blood products on the temperature chart with exact time and initials D. Continue to monitor and document manual temperatures every 4 hours for a minimum of 12 hours.

6. RELATED DOCUMENTS

Form: Manual Product Storage Temperature Form (AG.F51)
Form: Plasma Freezer Temperature Form (AG.F50)
Procedure: Blood Bank Equipment and Maintenance
Procedure: Blood Bank Equipment Record and Repair Instructions
Procedure: Thermometer Calibration and Installation

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7. REFERENCES

1. Roback, J.D., Grossman, B.J., Harris, T., and Hillyer, C.D. 2011. Technical Manual of the AABB, 17th ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, 2012. AABB, 28th ed. AABB Publishing, Bethesda, Maryland.
3. Barry of Helmer Inc.,Freezer Operation Manual, Helmer Freezer, 360086-1 Rev H; issued April 2009.
4. Barry of Helmer Inc., Temperature Chart Recorder Operation and Service Manual, 360076-1 Rev H; issued April 2009.
5. Barry of Helmer Inc., Freezer Service Manual 360087-1 Rev K; issued April 2009.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAH.B507.002, WAB507.003, SGAH.B508.001, WAB508.002		
000	12.9.2013	Section 5: Removed instructions for manual alarm checks; only perform electronic. Updated formatting. Changed acceptable range for alarm activation from -20-22°C to ≤-20°C. Section 6: forms moved from section 9 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina LBarrett	NCacciabeve

9. ADDENDA AND APPENDICES

None