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Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Work Instruction

Title:	**TC Refrigerator Freezer and Platelet Incubator Failure**	**WI Number** SFOWI-0034 **Revision:** 13
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Work Instruction		**Review Period -** 340 **Days**

PURPOSE

It is critical that blood products and reagents are stored within the correct temperature range to ensure their safety and efficacy. The refrigerators, freezers and platelet incubator are equipped with local audible alarms as well as a wireless temperature monitoring system that has an alert light and sound. The alarm system is set to activate prior to storage temperature exceeding unacceptable limits allowing time for corrective actions. In case of a power failure, the emergency power supply (generators) will be automatically initiated. In case of a total power failure (no power and no generator) or unresolved temperature problems, blood products and reagents are to be moved to temporary storage areas that are monitored wirelessly or manually by checking temperature charts or taking temperature every 4 hours. This procedure provides instructions for actions to be taken when storage equipment fails. The Transfusion Service is staffed 24/7 with personnel who are trained to handle storage equipment problems.

QUALITY CONTROL

A. Review of Check Point Corrective Action Log by Blood Bank Supervisor or designee daily.
B. Review of temperature charts on refrigerators, freezers and platelet incubator performed daily and weekly.
C. Alarm Check performed quarterly.
D. CheckPoint Alert Device Activation performed weekly.

EQUIPMENT

A. Refrigerators
B. Freezers
C. Platelet Incubator
D. Laser thermometer
E. Coolers
F. CheckPoint Wireless Temperature Monitoring System

TEMPERATURE ALARM SETPOINTS

High Alarm Setpoint and **Low Alarm Setpoint** are the low and high temperature limits that

when exceeded will trigger an alarm. The low limit is set at 0.5°C above and the high limit is set at 0.5°C below the actual temperature range to allow time for corrective action.

PROCEDURE

A. **Equipment in Transfusion Service**

When there is a failure or when temperature exceeds alarm setpoints, audible and visual alarm will be activated to alert the Transfusion Service staff. The Transfusion Service staff will perform the following steps:

Steps	Action
1	Investigate and correct the problem immediately (e.g. door ajar, door opened for inventory check, alarm check, defrost cycle...). If the alarm is due to low battery or no sensor contact, call Engineer or BioMed (for platelet incubator) **STAT** to resolve problem.
2	Check temperature on Face display, Chart recorder, independent digital thermometer (there is only independent digital thermometer for RT) and CheckPoint.
3	For RT, close room door if too cold or open room door if too warm.
4	Set alarm delay for 15 minutes if problem is not corrected immediately.
5	Document in CheckPoint the following information **every time the alarm is activated**: a. Reason for alarm and corrective action. Enter 'Corrective action in progress' for subsequent alarms of the same problem if temperature is returning to within limits. b. Internal temperature c. Blood products/reagents that may be affected. **NOTE:** Local alarms that may not cause a temperature spike or drop e.g. 'door open', 'low battery', will not trigger a CheckPoint alert so it is unnecessary to document in CheckPoint.
6	For unusual spike or drop in temperature, document the reason for alarm on the temperature recording chart at the time/date when it occurs.
7	If alarm sounds again after 15 minutes and the temperature starts to correct, set alarm delay for another 15 minutes, otherwise go to the next step.
8	If alarm sounds again after the first reset and any of the following applies, call Engineer or BioMed (for platelet incubator) **STAT** for service and locate alternative refrigerator, freezer or platelet incubator. a. Freezer is warmer than -18°C b. Refrigerator is colder than 1°C (reagent refrigerator colder than 2°C) or warmer than 6°C c. Platelet incubator is warmer than 24°C or colder than 20°C d. Room temperature is warmer than 24°C (>25°C for gel cards).
9	If temperature problem cannot be timely resolved (within 15 minutes), relocate blood products and reagents.
10	If after 2 resets, alarm still sounds and there is no obvious problem, call the Engineer or BioMed (for platelet incubator) **STAT** to investigate even if temperature is within limits.
11	If after 2 resets, alarm still sounds and the temperature does not correct (no more than half an hour), call the Engineer or BioMed (for platelet incubator) **STAT** for service and locate alternative refrigerator, freezer or platelet incubator. Relocate blood products and reagents if temperature cannot be

	corrected within 15 minutes.
12	After 2 resets, relocate blood products and reagents if temperature exceeds acceptable limits: a. Freezer is warmer than -18°C b. Refrigerator is colder than 1°C (reagent refrigerator colder than 2°C) or warmer than 6°C c. Platelet incubator is warmer than 24°C or colder than 20°C d. Room temperature is warmer than 24°C (>25°C for gel cards).
13	Use laser thermometer to take temperature of blood products if there is suspicion that the units were exposed overlong to unacceptable temperature. Quarantine blood products if the **temperature of the blood product** exceeds acceptable limits: a. Frozen blood products shows signs of thawing b. RBC is colder than 1°C or warmer than 10°C c. Platelet is warmer than 24°C or colder than 20°C.
14	Quarantine reagents and gel cards if they were exposed overlong to unacceptable temperature (below 2°C or room temperature above 25°C).
15	Perform patient impact assessment if non-conforming blood products or reagents were used prior to discovery. Refer to SFOWI-0155 Unusual Occurrence Management for instructions.

Refrigerators in OR

When there is a failure or when temperature exceeds alarm setpoints, audible and visual alarm will be activated to alert the OR staff who will perform the following steps:

Steps	Action
1	Investigate and correct the problem immediately (e.g. door ajar). Take internal temperature.
2	If temperature is below 1°C or above 6°C, return blood products to Transfusion Service immediately.
3	Notify Transfusion Service at 3-3881 and Engineer STAT if problem cannot be corrected immediately.
4	Document corrective action in CheckPoint with the following information: a. Internal thermometer temperature b. Any obvious problems c. Blood products that may be affected d. Notification of Engineer
5	Transfusion Service will dispense RBCs and thawed plasma in coolers until temperature returns to acceptable limits.

B. **Relocation of Blood Products**

1. Document problem and corrective action in CheckPoint and Blood Bank Communication Log.
2. Use BF0017 Temperature Storage Device Log to document either the manual temperature or temperature chart recorder check (to make sure it is working and the temperature is within range) every 4 hours for equipment not monitored by CheckPoint or when CheckPoint is down.

If	then
Fridge #1 (main RBC	Transfer blood products to Fridge #2.

refrigerator) fails	
Fridge #2 fails	Transfer blood products to the Fridge #4.
Fridge #4 (Autologous blood refrigerator) fails	Transfer blood products and reagents to Fridge #2.
All refrigerators in the Transfusion Service are down	1. Transfer blood products to refrigerators in the main lab. 2. Take temperature manually every 4 hours if they are not monitored by CheckPoint.
All refrigerators in the entire lab are down	1. Transfer O Neg and O Pos RBCs to separate validated coolers. a. Attach a note to indicate cooler expiration time. b. Set a timer to alarm prior to cooler expiration time as reminder to change out the ice-packs in the coolers. c. Transfer A Pos RBCs if there is/are remaining cooler(s) available. 2. Return remaining RBCs to BCP. a. Notify BCP. b. Ask BCP to send boxes with frozen icepacks and cold TSP for packing RBCs. c. Transport blood products via BCP driver or cab. **NOTE: Order RBCs STAT when needed.**
One of the freezer fails	Transfer frozen plasma and cryoprecipitate to the other freezer in the Transfusion Service.
Both freezers fail	1. Transfer frozen products to one of the freezers in the main lab. 2. Take temperature manually every 4 hours if it is not monitored by Check Point.
All freezers in the entire lab fail	1. If problem cannot be timely resolved: a. Start to thaw the following FFP: 6 group O, 6 group A, 2 group B, 6 group AB. b. If there are ongoing or upcoming surgeries, increase the number of units as appropriate. 2. Return remaining frozen products to BCP. a. Notify BCP. b. Request BCP to send boxes with dry ice for packing frozen products. c. Transport blood products via BCP driver or cab. **NOTE: Order frozen products STAT when needed.**
Platelet incubator fails	1. Leave door open or remove agitator and place on counter top. 2. Take room temperature every 4 hours if RT is not being monitored by CheckPoint e.g. due to broken sensor.
Platelet agitator fails	1. Platelets can be off the agitator for a maximum of 24 hours. 2. If problem cannot be timely resolved, return platelets to BCP. **NOTE: Order platelets STAT when needed.**

C. Notification of refrigerators, freezers and platelet incubator failure:

If	Notify
Monday - Friday	1. Transfusion Service Supervisor

(0830 to 1730)	2. Assistant Laboratory Administrative Director
Evenings, night and weekends	1. Transfusion Service Supervisor 2. Assistant Laboratory Administrative Director 3. Transfusion Service Medical Director

D. Handling potential failures:

1. If equipment makes unusual sounds or if there is a possibility of malfunction even though the temperature is within acceptable limits:
   a. Notify Engineer or BioMed (for platelet incubator) to investigate.
   b. Engineer or BioMed will check and inform Transfusion Service personnel if equipment can continued to be used or need to be repaired.

PROCEDURE NOTES

Refer to SFOWI-0055 CheckPoint Temperature System if problem is with CheckPoint e.g. no sensor contact, CheckPoint is down, CheckPoint is not recording temperature, or CheckPoint is recording intermittently.

REFERENCE

A. AABB, Standards for Blood Banks and Transfusion Service, current edition, Bethesda, MD.
B. AABB Technical Manual, current edition, Bethesda, MD.

Associated Documents:

External Documents

Associated Documents:

SFOFCD-0226 -- BF0017 Storage Temperature Log
SFOWI-0033 -- TC Alarm Check of Refrigerator Freezer and Platelet Incubator
SFOWI-0155 -- TQ-Unusual Occurrence Management
SFOWI-0055 -- TC CheckPoint Temperature System
SFOWI-0141 -- TQ-Equipment Repair

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Documents Generated:

Document Revision History:

Revision: 13	**Date Created:** 09/12/2005 **Date of Last Revision:** 06/29/2018	**Last Approval Date:** 06/20/2016

Document Author: Cara H Lim/CA/KAIPERM	**Document Manager:** Richard Chui/CA/KAIPERM

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Approver	New Lab Director	12/3/06
3	Approver	New Lab Director	01/07/07
4	Approver	New Lab Director	7/29/07
5	Procedure and notes	Add wireless temperature monitoring system	1/27/08
6	Procedure and notes	Document reason of alarm on chart as well as Check Point	3/21/10
7	Procedure Approver	Change the upper range of refrigerator 4 from 8 C to 6 C. Change Lab Director	4/24/11 06/01/11

8	Approver	New Lab Director	1/17/13
9	Approver	New BB Medical Director.	11/11/13
10	Title Purpose Quality Control Equipment Procedure Associated Documents	Added Plt Inc. Revised. Revised. Added Alarm Check and CheckPoint Alert Device. New section. Revised entire procedure to align with current practice. Added SFOWI-0033, SFOWI-0055, SFOWI-0155 and BF0017.	7/3/15
11	Procedure B.Table. All refrigerators in the entire lab are down Procedure B.Table. All freezers in the entire lab fail	Added instructions to temporary store RBCs in validated coolers. Added instructions to thaw FFP and order frozen products STAT as needed.	12/3/15 12/7/15
12	Approver	New CLIA Director.	6/16/16
13	Purpose	Added reagents as per long standing practice, storage temperature of reagents is monitored the same as blood products.	6/28/18

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section