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AUTHOR:	G938509	**PREVIOUS NUMBER:**	KQE:11.2-3-0001.07
OWNER:	G938509	**CHANGE NUMBER:**	SCPMG-CR-0577

Routine Monitoring and Maintenance of Blood Components Storage Equipment

Purpose

This procedure will describe how to perform maintenance and inspection of the refrigerators, freezers and platelet rotators and record results on the Daily Maintenance and Inspection Form. It also describes the process of performing alarm checks

Policy

- There must be mechanisms in place to determine that reagents, blood and blood components are stored at the appropriate temperature.
- All equipment must be used and maintained according to manufacturer's instructions
  - Refrigerators, validated coolers, freezers and platelet incubators used for the storage of blood and blood components must always be kept clean and spills must be cleaned up immediately.
- Storage devices which store blood or blood components must have a continuous reading chart recorder (or validated automated temperature monitoring system/data logger) or must have the temperature recorded every 4 hours when the recorder or automated system is not functional.
  - Validated coolers (ice chest) or other validated containers are considered storage devices when used to store blood/blood components near the patient (Emergency Department, Operating Room, etc.) on the Medical Center campus.
- There must be a process to alert Transfusion Service staff when storage devices which contain blood or blood components are approaching the limits of the acceptable storage range. This process could be:
  - The integral device alarm which is audible and can be heard 24 hours/7 days a week by laboratory staff.
  - An alarm system which will notify personnel outside of the Transfusion Service (e.g. emergency operator, or to the maintenance/engineering department).
    - These personnel will notify the Transfusion Service when the device is alarming.
  - On line monitoring with local audible alarms and/or system generated alerts (pager, phone call, email) to alert laboratory or other appropriate personnel (Maintenance/Engineering).
  - Recording of temperatures every 4 hours (such as for temporary storage)

Whenever chart is not recording, we must log temps manually every 4 hrs

coolers=storage devices (this is why return units in Cern within 4 hours and temps)

If pager alarms or we are called about a high alarm in L&D/MOR/ CVOR, it is BB responsibility to physically assess the ref and bring products back to BB if necessary

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

- If a storage device is no longer capable of keeping the appropriate temperature range, blood, blood components and/or reagents must be removed from the storage device and stored temporarily in another device that has been calibrated and verified to maintain the appropriate temperature.
  - Document the date/time and temperature when blood, blood components and/or reagents are removed from device.
  - Blood, blood components and/or reagents that are found in storage devices that are NOT within acceptable temperature range must be placed in quarantine.
    - A Quality Improvement Monitoring (QIM) form must be completed.

Document and quarantine as appropriate

Policy-continued

- Upon return from repair and before blood, blood components and/or reagents can be returned to the storage device, the equipment must be validated that it will maintain the appropriate temperature. See *Equipment Validation and Implementation Plan.*
  - Document the date/time and temperature when blood, blood components and/or reagents are placed into device.
- The temperatures, alarms (including chart recording of the alarm event) and response time (for devices that require personnel outside of the Transfusion Service to notify when the alarm occurs) must be checked and those checks recorded on a scheduled basis.
- Equipment malfunctions, failures or adverse events are investigated. A Quality Improvement Monitoring (QIM) report is generated and product/reagents are assessed if acceptable for use.
  - Refer to *Temperature of Out of Range: Refrigerator, Plasma freezer, Platelet Incubator* for more details.
- Double door refrigerators and freezers must have both sides checked daily and both sides must be within acceptable temperature range (they do not need to agree completely).
  - If the double door refrigerator has two independent probes, then the temperatures must be monitored as two separate refrigerators.
  - If there is only one probe, ensure it is in the middle of the refrigerator to be assured it will capture temperature variations on either side.

Log temps every 4 hours for 24 hrs before placing products back in unit

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Equipment and reagents

- Refrigerator, freezer and platelet incubators with continuous recording device
- NIST traceable thermometers
- Bottles or bags to hold the thermometers
- Chart recording papers (not necessary for validated electronically monitored equipment)
- Glycerol, or other validated solution/substance to be used to monitor temperatures
- Plastic containers (2)
- Crushed ice
- Tap water
- Table salt

Acceptable Temperature Ranges	**Refrigerator Low and High Alarms**	**Freezer High Alarm- (Verify with Operator's manual if a Low Alarm is required)**	**Platelet Incubator Low and High Alarms**
To alarm before it reaches an unacceptable temperature	Blood Only: 1°C -6°C Blood and Reagents: 2.0°C – 6.0 °C) Reagents Only: Or 2.0°C – 8.0°C	> -18°C	20°C -24°C
Set alarm(s) to activate at:	Blood Only: ≤ 1.5°C and ≥5.5°C **Blood and Reagents** ≤ 2.5°C and ≥5.5°C Reagents Only: ≤ 2.5°C and ≥7.5°C	-18.5°C or lower	Low activation >20.5°C High activation <22.5°C

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Procedure

Perform the following steps to record information manually on the Daily Maintenance and Inspection form.

Step	Action
1	Obtain Daily Maintenance and Inspection forms yearly from LaboratoryTechno logy Services (LTS) department. • If refrigerators are given a local number that can be added to the top of the form after Transfusion Service Refrigerator #. Using Operator's Manual verifyf requency of cleaning, alarm checks, and other required periodic maintenance are correctlydocum ented on form. • Verify all temperature specifications are correct for storage device. o Acceptable temperature range o Alarm settings • Verify all other preventative maintenance tasks or checks (door ajar) specified in Operator's Manual are documented on form • Make anyupdates /modification to form prior to placing LTS formi n use. o Alternatively, a localf ormm ay be used instead of the LTS generated form. NOTE: Notify LTS of major updates (temperature ranges, periodic maintenance, etc.).
2	Record chart recorder temperature recording in appropriate box.
3	Record temperature fromi nternal thermometer(s) in appropriate box.
4	**Enter "N"** When equipment is not in use, in the dailytem perature column until the unit is returned to service <u>Notes:</u> • Exception, Platelet incubators that are not continuously used. • If an instrument is out of service for a prolonged period, a notation on the back of the form will explain the lack ofentri es. It is not necessary to put N in every date for these long-delayed repairs.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Procedure

Perform the following steps to record information manually on the Daily Maintenance and Inspection form.	
Step	**Action**
4 con't	When equipment is not under direct observation for limited time periods, i.e. in offsite and not used on a week-end or a holiday: • Records must show that recording charts and emergency response times are monitored periodically. • Temperatures must be recorded on days of use.
5	**Enter "R"** When the equipment is sent for repairs, in the daily temperature column until the unit is returned to service. • If the repair takes a long time, put an R in the column and a line through the dailyen try until it comes back, or make a notation of the time the equipment was out of service on the back of the form.
6	**Enter "S"** When the equipment is in storage, in the daily temperature column until the unit is placed into use.
7	Perform daily maintenance tasks indicated on Daily Maintenance and Inspection form. (See Daily Maintenance Section below for appropriate equipment)
8	Performany other periodic maintenance (monthly, quarterly, annually) as indicated on the Daily Maintenance and Inspection form.
9	Verify that temperature is acceptable and dailym aintenance is completed. • Enter initials in appropriate box on form. • If temperature is not acceptable refer to corrective action section below.
10	In the Rev-column at the right end of the form, initial and date the review for the month. The date mayf alloutsi de the margins.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Daily Maintenance Refrigerators

Perform the following steps for **Manual Daily** maintenance of refrigerators

Step	Action
1	**Record Temperatures-** Record the temperature reading of the chart. • There is a separate form for each refrigerator. • Always check to make sure the manual chart has moved since the last temperature recording. (Ensure against the chart being stuck or stopping). • Medical Centers with remote alarm systems (Awarepoint) which continuously monitor the storage device must also show evidence of a daily check by Transfusion Service staff. Record the internal temperature of the refrigerator. • The chart should read ± 2°C of the internal thermometer.
2	**Out of Range** When temperature readings are not within the appropriate range: • Close the door and wait approximately 10-15 minutes for the refrigerator to readjust. If this does not correct the temperature reading, continue. • Remove product/reagents from refrigerator. Place in quarantine and alert manager or designee. Document temperature upon removal on the back of the form for corrective action. • Contact local maintenance department or local contract service(s) if it is a problem with the refrigerator. • See "Not maintain temperature" section at the end of this document.
3	**Corrective Action** Perform corrective action as needed. Record all corrective action on the back of the form. Include dates, initials and short description of the problems.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Daily Maintenance Refrigerators continued

Perform the following steps for **Manual Daily** maintenance of refrigerators

Step	Action
4	**Visual Inspection** Visually inspect the units of blood or blood products available for transfusion for unusual appearance. • Any units that appear very dark or hemolyzed, purple, bubbly or any other abnormal finding must be removed from the general available inventory until investigated. • Arrange stock by expiration date or site specific processes. • Quarantine any units having abnormal appearance
5	After the above actions have been performed and everything is acceptable, initial the column under the appropriate date.

Although this must be performed and signed by AM shift, every shift should assess inventory at beginning of shift (this is product inventory form you initial), **including arranging by expiration date**

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Weekly Maintenance Refrigerators

Perform the following steps for Refrigerator **Weekly** maintenance using **Manual** process

Step	Action
1	**Recording Chart, removal and review** • On a designated day each week, change the recording charts. • Review the chart. Ensure that it has recorded for the entire week, i.e. has not stuck or stopped. • Make sure all unusual temperature recordings are explained on the chart. • Make sure the date and initials of the person who put the chart on the refrigerator is on the chart. • Initial and date the chart when the chart is removed from the refrigerator. • Initial and briefly annotate (if necessary) each out of range "blip". • If there are any problems with the chart bring the problem to the attention of the Manager or designee immediately. Otherwise, store the charts for manager or designee review.

2	**Recording chart, replace with a new chart.**
	• Make sure the chart has the facility name and address and refrigerator name or number.
	  • Initial and date the chart to indicate when and who put the chart on the refrigerator.
	  • Make sure the chart will move freely and is recording properly.

3	**Review of chart** File chart is designated area Manager or designee review is performed at least monthly.
4	If corrective action or repairs are needed on the unit, record an "R" in the date column and describe the action or repair needed on the back of the form.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Quarterly Refrigerators

Perform the following steps for Refrigerator **Quarterly** maintenance using **Manual** process	
Step	**Action**
1	**Alarm Check:** Test the high and low alarms and record on the bottom of the form. • The low alarm should activate at or prior to the allowable temperature limit on the form. • The high alarm should activate at or prior to the allowable temperature limit on the form. • If the alarms are not functioning properly, repeat the test. If they are still out of range, contact the engineering department or the local contract service. • Indicate on the chart that the "blip" for the high and low was due to alarm checks. Initial and date. This test can also be used as the test of the audible alarm (step #4 below). Record that the alarm sounded and thus was OK by initialing and dating the form under Quarterly alarm check.
2	**Emergency response time:** Check to see if the to the alarm check from Step 1 above was less than 30 minutes, if applicable. • If the response time is greater than 30 minutes, contact the Manager. This will need to be reported to the local service that is expected to respond.
3	**Battery Check:** • Test batteries (for chart recorder, audible alarm etc.) is working as recommended by the manufacturer's instructions, • Record the check in the appropriate box at the bottom of the form.

Check pager

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Quarterly Refrigerators Continued

Step	Action
4	**Audible alarm** system check. If the refrigerator has a system to activate the alarm, then: • Flip the alarm toggle, or push the button/pad, which ever applies to turn on the alarm. Once it sounds, it can be turned off immediately. • Inform the emergency response service that a test is being performed, if applicable.
5	**Fluid bottles or bags** Check that they are filled to the appropriate level, if applicable. • Fill the bottles with 10% glycerol or ethylene glycol (depending on manufacturer's instructions) if needed.
6	**Corrective Action** If corrective action is needed, record specifics of that action on the back of the form. • Initial and date the Quarterly alarm checks once the checks are completed.
7	**Final Review** Manager or designee reviews and initials the quarterly checks. The initials signify: • The form is complete, and all initials and temperatures and alarm activations are acceptable. • Corrective action is correctly documented. • Units that have been out of service for a prolonged period are followed-up with the appropriate department, if indicated.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Annual Refrigerators

Perform the following steps for the Annual Refrigerator Alarm Check…	
Step	**Action**
1	**Alarm Probe Verification:** Consult Operator's manual for annual alarm probe tasks.
2	**Interpretation** The temperatures on the probe (digital display) and thermometer (independent thermometer – NIST traceable thermometer) should compare within ± 2°C.
3	**Corrective Action** If the probes/thermometers are outside the approved range (± 2°C), repeat once more. If there is still a problem, contact the refrigerator maintenance department, and check the high and low alarms manually.

Daily Freezer

Perform the following steps for the Manual Daily Freezer Maintenance…	
Step	**Action**
1	**Record Temperatures-** Record the temperature reading of the chart on the appropriate form for each freezer. • Ensure that the chart is moving and has not stuck since the last time it was reviewed.
2.	Record the temperature of the internal thermometer of each freezer. • The chart should read ± 2°C of the internal thermometer. • The internal thermometer should be -18°C or colder. • If the temperature readings are not within the appropriate range, contact Laboratory Technology Services • if it is a problem with the thermometer contact your local maintenance group • if it is a problem with the freezer contract Laboratory Technology Services or the manufacturer

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Daily Freezer, continued

Step	Action
3	If the temperatures are out of range, call the appropriate maintenance department, and record the incident on the back of the form. See "Not maintain temperature" at the end of this document.
4	**Visual inspection** Briefly perform a visual inspection of the interior of the freezer, to be assured it is orderly and the blood products are stored correctly.
5	Initial the column to indicate that you have recorded the temperatures and have inspected the unit and that all checks are OK, or that corrective action has been taken when the checks are not OK.

This is a daily requirement

Weekly Freezer

Perform the following steps for the Manual Weekly Freezer Maintenance…	
Step	**Action**
1	**Recording Chart, removal and review** On a designated day each week, change the recording charts. Review the chart. • Make sure all unusual temperature recordings are explained on the chart. • Make sure there is a date and initial of the person putting the chart on at the beginning of the week. • Initial and date the chart when the chart is removed from the freezer. • Each out of range "blip" must be initialed and briefly annotated. • If there are any problems with the chart bring the problem to the attention of the Manager or designee immediately. Otherwise, forward the charts for Manager or designee review.
2	**Recording chart, replace with a new chart.** • Make sure the chart has the facility name and address and freezer name or number. • Initial and date the chart to indicate when and who put the chart on the freezer. • Make sure the chart will move freely and that there is enough ink. If not, replace ink cartridge.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Weekly Freezer- continued

Step	Action
3	**Ice removal** Check for excessive ice buildup. Remove ice that might impair the seal on the door,or could cause problems in the freezer.
4	**Review of chart** Manager or designee reviews and initials and dates the recording chart. Note: Review may be performed monthly according to local protocol.
5	If any corrective action was needed, or if the unit needs repair, record that information on the back of the form.

Quarterly Freezer

Perform the following steps for the Manual Quarterly Freezer Maintenance…	
Step	Action
1	**Alarm Check:** Test the high alarm and record on the bottom of the form. • The high alarm should activate at a temperature warmer than that set by the manufacturer as the upper limit. The limits of freezers could be set at: –35°C, -25°C or -18°C • If the alarms are not functioning properly, repeat the test. If they are still out of range, contact the maintenance department or local contract service. • This test can also be used as the test of the audible alarm (step #4 below). Record that the alarm sounded and thus was OK by initialing and dating the form under Quarterly alarm check. NOTE: Refer to Operator's Manual for specific instructions on how to perform alarm checks.
2	**Emergency response time:** Check to see if the emergency response time was less than 30 minutes, if applicable. If the response time is greater than 30 minutes, contact the Manager or designee. This will need to be reported to the maintenance department or local contract service.
3	**Battery Check:** • Test battery (if appropriate for the freezer unit) according to manufacturer's instructions. • Record the check in the appropriate box at the bottom of the form

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Quarterly Freezer, continued

Step	Action
4	**Audible alarm**: Check the audible alarm system if the freezer has a system for this and for some reason it was not checked in step #1 above. • Flip the alarm toggle, or push the button, which ever applies to turn on the alarm. Once it sounds, it can be turned off immediately. • Inform the emergency response service that a test is being performed, if necessary. Note: If this check was performed as part of your daily checks, then it has already been performed, and is not a part of the quarterly checks.
5	**Visual Inspection**: Check that the thermometers or sensors are intact, and that the containers in which the temperature sensors are placed in are in good condition (not broken or leaking). • Make sure the door gaskets are intact and that the door(s) shut completely and securely.
6	If any corrective action was needed, record specifics of that action on the back of the form

Annual Freezer

Perform the following steps for the Annual Freezer Alarm Check…	
Step	**Action**
1	**Alarm Probe Verification** Refer to Operator's manual for specific instructions for performing alarm probe verification.
2	**Interpretation** The freezer alarm must activate before the temperature reaches -18 C. The freezer digital temperature should be within ± 2°C of the probe, and the thermometer. Freezers kept at colder temperatures must alarm before reaching -18 °C.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Annual Freezer- continued

Step	Action
3	**Corrective Action** • If any of the reading fall outside of the prescribed limits, notify the Manager and designee and engineering immediately. • Manually monitor temperature every four hours to ensure proper storage. • If the alarm cannot be repaired that day, continue to monitor every 4 hours or move components to another properly monitored device.

Daily Platelet Incubator

Perform the following steps for the Manual Daily Platelet Incubator and Agitator Maintenance…

Step	Action
1	**Record Temperatures-** If applicable, enter the local number of the platelet incubator on the top of the form after Platelet incubator #. Record the temperature reading of the chart, in the appropriate space. Ensure that the chart is moving and is recording as expected. Record the temperature of the internal thermometer of each platelet rotator in the Therm. space for the appropriate day. • The chart should read ± 2°C of the internal thermometer. • The internal thermometer should read between 20°C - 24°C • If the temperature readings are not within the appropriate range, contact Laboratory Technology Services if it is a problem with the thermometer and your local maintenance or contract service if it is a problem with the platelet rotator. • See "Not maintain temperature" section at the end of this document.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Daily Platelet Incubator-continued

Step	Action
2	**Visual Inspection** Inspect the interior of the platelet rotator and the platelets, to be assured it is orderly and the blood products are stored correctly and are not leaking or discolored. Check to make sure the rotator is agitating properly, with no loud noise or scraping.
3	Initial the appropriate row to indicate that you have recorded the temperatures and have inspected the unit and products.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Weekly Platelet Incubator

Perform the following steps for the Manual Weekly Platelet Incubator and Agitator Maintenance

Step	Action
1	**Recording Chart, removal and review** On a designated day each week, change the recording charts. Review the chart. • Make sure the facility name and address and platelet rotator name or # is on the form. • Make sure there is a date and initial of the person putting the chart on at the beginning of the week. • Make sure all unusual temperature recordings are explained on the chart. • Initial and date the chart when the chart is removed from the incubator. • If there are any problems with the chart bring the problem to the attention of the Manager or designee immediately. • Record all corrective action on the back of the form. • Forward the charts for Manager review.
2	**Recording chart, replace with a new chart.** Replace the chart with a new chart. • Initial and date the chart to indicate when and who put the chart on the incubator. • Make sure the new chart has the facility name and address and platelet rotator name or #. Make sure the chart will move freely and that there is enough ink. If not, replace ink cartridge.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Quarterly Platelet Incubator

Perform the following steps for the Manual and Electronic Quarterly Platelet Incubator and Agitator Maintenance…	
Step	**Action**
1	**Alarm Check:** Test the High and Low alarms • The high alarm should activate before the temperature is over 24°C (usually around 23. 5°C). • The low alarm should activate before the temperature is below 20°C (usually around or just below 21°C). Note: NOTE: Refer to Operator's Manual for specific instructions on how to perform alarm checks.
2	**Audible alarm**: Test that the audible alarm sounds when the alarm switch is turned on. Document that check in the appropriate box at the bottom of the form. • If the alarm does not sound, contact the local maintenance department or contract service. Note: Check individual manufacturer instructions. Some models may not have an alarm switch, and checks may need to be performed by unplugging the incubator and listening for the alarm to sound.
3	Check that the thermometers are intact.
4	If any corrective action was needed, record specifics of that action on the back of the form.
5	Clean the inside and outside of the platelet incubator with soap or mild cleaning disinfection solution (germicide) - per manufacturer instructions. This is done as needed.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Not maintaining temperature

Move units, place sign that device is out of order. Document information on equipment daily form. When service is completed, monitor temps every 4hrs for 24 hours before returning products to device.

Perform the following steps when removing product from any storage device when it will not maintain temperature…

Step	Action
1	If the storage device will not maintain temperature for a prolonged period and/or when the temperature is approaching the lower/upper limit of the storage device, the blood products and other temperature sensitive contents (samples, reagents etc.) must be moved to a designated storage container. • Put a conspicuous sign or tape over the storage device to indicate it is "Out of Order" and no products or reagents are to be placed in the device.
2	The designated alternate storage device must be calibrated and shown to maintain temperature at the appropriate temperature for the product.
3	Records of the products moved into the alternate service must be maintained to indicate that these products are appropriate for their intended use.
4	If there is no alternate device to move products to, arrangements must be made to ship the products to another facility or department that can store the product in a regulated and monitored storage container. • These arrangements must be made in advance of any issue and must be re-evaluated at least annually.
5	Upon return of the initial storage device, it must be validated according to the procedure *Critical Equipment Validation-New Installation And After Repairs* before being put back into use.
6	The returned device should run at least a day without products, but with some type of filler – (boxes –something to fill air space) to ensure proper maintenance of temperature. Document when this is completed and when products are returned on the back of the individual equipment maintenance form. • Remove the "Out of Order" sign or tape.
7	Refer to *Temperature Out of Range: Refrigerator, Plasma freezer, Platelet Incubator* for additional steps to take.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Corrective Action

Perform the following steps to take corrective action when alarms fall outside the prescribed unit	
Step	**Action**
1	Notify the Manager or designee and engineering immediately.
2	Manually monitor temperature every four hours to ensure proper storage.
3	If the alarm cannot be repaired that day, then move components to another properly monitored device until it is determined safe to return products.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Manual Alarm Check

Perform the following steps to manually check the alarm activation settings:

Step	Action
1	Refrigerators/Platelet Incubators General Instructions: Prepare a water/ice/salt solution within the acceptable range for the storage device (refrigerator/platelet incubator) being tested. For platelet incubators a large plastic test tube containing water may be cooled and warmed to the appropriate temperature by wrapping a cold or warm gel pack around the test tube. Refer to Operator's Manual for additional instructions.
2	Insert probe and NIST traceable thermometer into mixture and let equilibrate for at least two minutes.
3	**For low alarm activation**: Slowly add ice to the solution, gently agitating. (Or apply cold gel pack to outside of test tube) Record the temperature of the NIST traceable thermometer when the alarm sounds. This is the low alarm temperature. **For high alarm activation**: Slowly add warm water to the solution, gently agitating. (Or apply warm gel pack to outside of test tube) Record the temperature of the NIST traceable thermometer when the alarm sounds. This is the high alarm temperature.
4	Freezers may require a high alarm activation check only. Refer to user's manual for instructions for performing manual alarm check.

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Controlled Documents	Equipment Validation and Implementation Plan Temperature Out of Range: Refrigerator, Plasma freezer, Platelet Incubator Critical Equipment Validation-New Installation And After Repairs
Uncontrolled Documents	AABB Standards, current ed. CAP Requirements, checklist, current ed. Fung, Mark K. Ed. Technical Manual, 19th Ed. AABB,2017
Authors	SCPMG Transfusion Service Managers RegionalBl ood Bank Compliance Officer

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Reviewed and approved by:

PreviouslySigned	August 1, 2001
Virginia Vengelen-Tyler, MBA, MT,ASCP(SBB), CQA(ASQ) Regional Blood Bank Compliance Officer	Date
Signature Collected Electronically	March 8, 2001
Jeffrey D. Shiffer, MD. MedicalDirector –San Fernando ValleySA	Date
Signature Collected Electronically	July 27, 2001
Gary Gochman, MD, Medical Director – Bellflower, Harbor City,Bal dwin Park MSA	Date
Signature Collected Electronically	March 8, 2001
Adriana A. Bedoya, M.D. FCAP, FASCP Medical Director- San Diego –SA	Date
Signature Collected Electronically	May 24, 2001
Joseph Thompson, MD. Medical Director –Los Angeles, West Los Angeles MSA	Date
Signature Collected Electronically	March 13, 2001
David R. Huebner-Chan, MD. Medical Director –Orange County SA	Date
Signature Collected Electronically	July 30, 2001
Dong Quach, MD. Medical Director –Riverside, Fontana MSA	Date

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

DOCUMENT HISTORY PAGE

Effective Date: August 1, 2001

Change type: new, major, minor etc.	Changes Made to Document – Describe	Signature responsible person/Date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ Date	Date change Imp.
New					
Minor	Corrected typo- changed colder to warmer- pg. 9. Only issued corrected pg. 9.	Ginny Tyler 8-20-01	N.A.		
Minor	Page 9- allowed for different manufacturers of freezers with temperatures to -35ºC, -25ºC or other temperatures.	Ginny Tyler 020102	N.A.		
Minor	1) Page 9: clarified that different freezers may be set at different temperatures. 2) Page 12, that the alarm should occur "before" it reaches 20C or 24C. 3) Clarified wording in several spaces.	Ginny Tyler 6/25/02	N.A.		
Minor	1) Correct error on when low alarm should sound- should be 20.5C-21.5C and the high alarm, 22.5C-23.5Con platelet incubator. 2) Added policy on contacting manufacturer if needed, per new 22nd ed. AABB Standards 3.3.1 (4).	Ginny Tyler 10/21/03	N.A.		
Minor	1. Added Irvine 2. Added Work Place Safety No version change needed.	Ginny Tyler 02/18/08	N.A.	N.A.	

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

Minor	Added what to do if the equipment needed repair.	Ginny Tyler 04/17/08	N.A.	N.A.	
Minor, V .06	1. Removed the 0.5C from the platelet as recommended bythe FDA inspector. 2. Added cleaning the Platelet incubator per manufacturer instructions.	Ginny Tyler 06/24/2011	N.A.	N.A.	
	1. Added Electronic monitoring systems- made a separate procedure. 2. Added annual temperature checks.				
Major V.07	1. Changed document into an Electronic and Manual procedure. This is the manual procedure. 2. Added Temperature ranges in a chart to allowed for setting refrigerators at temperatures compatible with reagents and blood storage. 3. Better defined when to remove products from the storage containers. 4. Stated that double door refrigerators need temperature in each compartment OR in the middle of the storage device. 5. Added annual alarm checks	Ginny Tyler 07/06/2012	All gathered by June 28, 2012		

IMP = Implemented

Routine Monitoring and Maintenance of Blood Components Storage Equipment, Continued

MasterControl History of Change:		
Change type: new, major, minor etc.	**Version #**	**Description of Change**
Minor	8	Removed KQE reference Corrected typo Updated authors
Minor	9	Removed references to donor centers Removed KQE reference Added controlled documents section Updated uncontrolled documents. Added statements clarifying completion of Daily Maintenance and Inspection form. Added section on how to perform manual alarm check
Minor	10	Updated title from Routine PM of Blood Components Storage Equipment- Manually Recorded to Routine Monitoring and Maintenance ofBl ood Components Storage Equipment Added instructions to refer to Operator's Manual verify frequencyof cleaning, alarm checks, and other required periodic maintenance are correctly documented on form. Added statement to verify all other preventative maintenance tasks or checks specified in Operator's Manual are documented on form Added instructions to update or create local form to align with Operator's manual Added steps regarding platelet alarm activation