|  |  |
| --- | --- |
| 1.0 | Principle |
|  | To check the alarm system of blood product storage refrigerators and to maintain the refrigerators in good working condition.  |
| 2.0 | Scope and Related Policies |
|  | 2.1 | Equipment used in the collection, processing, serological testing, storage and distribution of blood products shall be maintained in a clean and orderly manner and shall have regular documented calibration and preventative maintenance. Records of maintenance, validation, calibration, malfunction and repair must be kept during the working lifetime of the equipment plus five years.Records must document disposal of equipment also. 9.1 |
|  |  | 2.1.1 | Each piece of equipment must be labelled with a unique identifier.9.1 |
|  | 2.2 | Refrigerators, used for blood product storage shall be validated to maintain a temperature throughout the cabinets within the range recommended by the supplier of the blood product.9.1  |
|  | 2.3 | Equipment used for blood product storage shall be connected to an emergency power supply. The system should be checked monthly to ensure an immediate switch to emergency power supply in the event of a power failure.9.1  |
|  | 2.4 | Audible alarms on temperature monitored equipment shall be located in an area that is staffed at all times. The audible alarm must have a back-up power supply. The alarm and back-up power supply must be checked monthly. This check must be documented.9.1 |
|  | 2.5 | There shall be a procedure for testing the proper functioning of the alarm. The temperature range at which the probe will cause the alarm to ring shall be verified according to manufacturer’s recommendations or at least once annually and documented. Appropriate corrective action shall be taken if required.9.1 |
|  | 2.6 | The alarm shall be set to activate at a temperature that will allow proper action to be taken before the blood or blood components reach undesirable temperature.9.1 |
|  | 2.7 | Refrigerators shall be equipped with an audible alarm which will be activated when the temperature of the liquid in which the temperature sensing device is immersed, reaches the upper or lower limit of the temperature range for the storage of blood products.9.1 |
|  | 2.8 | TML shall have a written procedure outlining actions to be taken when the temperature of a refrigerator falls outside the allowable temperature range.9.1 |
|  | 2.9 | All blood storage equipment needs to be validated prior to being placed into service (on receipt or following repair) to ensure it is functioning as intended.9.1 |
| 3.0 | Specimens – N/A |
| 4.0 | Materials |
|  | **Equipment:** Calibrated thermometersFor alarm probe testing: Solution of ice slush and water in a container  10% glycerol in a container Warm water (12-15°C) in a container**Supplies:** Container (transfer bag, syringe, etc.), similar to the smallest volume of red cells stored in the refrigerator, filled with 10%  glycerol. See Procedural Notes 8.1.  Monthly and Biannual Maintenance Record (QCA.003F1) Receipt Record (QCA.003F2) Malfunction and Corrective Action Record (QCA.003F3) |
|  |
|  |
|  |
|  |
|  |
| 5.0 | Quality Control |
|  | 5.1 | The alarm and back-up power supply must be checked and documented every month. |
|  | 5.2 | Other semi-annual procedures shall include checking air circulation, door seals, cleaning inside, cleaning dust from compressors and testing the alarm probes for upper and lower limits. |
| **6.0** | Procedure |
|  | * 1. The following should be done on the refrigerator monthly. Maintenance should be done following the manufacturer’s instructions and may be performed by departments other than the laboratory (e.g. electrical, biomedical engineering, etc…).
 | * + 1. Check the alarm for sound.
 | * + - 1. Press the "alarm test" button (or pull the plug if there is no special alarm test button). Some models have an indicator light as well as an alarm.
 |
| * + - 1. If the alarm rings (and light flashes, if applicable), record S (satisfactory) on form QCA.003F1.
 |
| * + - 1. If the alarm is malfunctioning, record N (not satisfactory) on QCA.003F1. Notify supervisor and check and record the temperature of the refrigerator manually every 4 hours until the alarm is repaired.
 |
| * + 1. Check the back-up power supply according to the manufacturer’s instructions. If these are unavailable, or if testing is done as a part of the back-up power supply of the hospital (if the electrical outlet is connected to an emergency power supply), proceed to step 6.1.3.
 | * + - 1. Disconnect the refrigerator from the power supply and then remove the back-up power supply (if there is a separate one) to trigger the audible alarm.
 |
| * + - 1. When the back-up power supply is disconnected, there should be a visible or audible signal. Record S (satisfactory) on QCA.003F1.
 |
| * + - 1. If the back-up power supply is not functional, document N (not satisfactory) on QCA.003F1. Notify supervisor and record the temperature of the refrigerator every four hours until the back-up power is restored.
 |
| * + 1. Every 6 months, check the temperature sensors for low and high temperatures according to the manufacturer’s instructions. If these are not available or not described, the following procedure should be done:
 | * + - 1. Place a calibrated thermometer into the container that the temperature sensor is stored in.
 |
| * + - 1. Place the container with the thermometer and temperature sensor into a container of ice slush and water. Close the refrigerator door.
 |
| * + - 1. When the alarm sounds, read the temperature indicated on the digital and/or continuous temperature recorder and on the thermometer in the sensor container.
 |
| * + - 1. Record the low activation temperature on form QCA.003F1.

The alarm should sound when the temperature of the sensor solution reaches 1.5°C. |
| Adjust the set point and repeat testing if the alarm does not sound at 1.5°C. |
| * + - 1. Remove the container with the sensor and thermometer from the slush.
 |
| * + - 1. Document the temperature on the digital and/or continuous temperature recorder and on the thermometer when the alarm stops ringing (it should stop ringing when the temperature of the solution containing the sensing device is above 1.5° C).
 |
| * + - 1. Place the container with the solution, thermometer and sensing device into a container of warm water (12-15°C is ideal). Allow the container to remain in the warm water until the alarm sounds.
 |
| * + - 1. When the alarm sounds, read the temperature on the digital and/or continuous temperature recorder and on the thermometer in the sensor container.
 |
| * + - 1. Record the high activation temperature on form QCA.003F1.

The alarm should sound when the solution containing the sensing device reaches 5.5°C. Adjust the set point to 5.5°C and repeat testing if the alarm does not sound at 5.5°C. |
| * + - 1. Remove the container with the sensor and thermometer from the warm water and return it to the refrigerator.
 |
| * + - 1. Document the temperature on the digital and/or the continuous temperature recorder and on the thermometer when the alarm stops ringing (it should stop ringing when the temperature of the solution containing the sensing device drops below 5.5°C).
 |
| * + - 1. Record the date the alarm probe was checked on form QCA. 003F1.
 |
| * + 1. Clean dust from compressor and other mechanical parts. Record Y (yes) in the result column on QCA.003F1.
 |
| * + 1. Clean the interior and exterior of the cabinet with a disinfectant solution (e.g. Presept, glutaraldhyde, etc.). Record Y (yes) in the result column on QCA.003F1.
 |
| * + 1. Check that there is proper air circulation (fan is working, no obstacles preventing the efficient air flow). Record Y (yes) on QCA.003F1.
 |
| * + 1. Check that the door seals tightly. Adjust gasket as necessary. Record Y (yes) in the result column on QCA.003F1.
 |
| * + 1. Check that the compressor is not leaking. Record N (no) on QCA.003F1 to indicate that the compressor is not leaking.
 |
| * + 1. Record the date and initial the appropriate area on form QCA. 003F1.
 |
| * + 1. If there are any unexpected findings, record corrective actions on form QCA.003F1. Keep a copy of documentation of the work performed, including work done by the maintenance department or servicing.
 |
| * + 1. Report any abnormalities found with the refrigerator to the supervisor.
 |
|  | * 1. Following recommendation from service provider that equipment has been repaired or prior to putting into service (following validation), before storing blood products:
 | * + 1. Place a thermometer in each of two containers filled with 10% glycerol. See Procedural Notes 8.1.
 |
| * + 1. Place one container on the bottom shelf and the other one on the top shelf.
 |
| * + 1. Read and record the temperature for 24 – 72 hours on both thermometers and on the recorder. Record the temperatures on QCA.003F2. See Procedural Notes 8.2.
 |
| * + 1. Test the alarm for sound for 24 – 72 hours. Document S (satisfactory) or N (not satisfactory) in the "alarm sound test" area on QCA.003F2.
 |
| * + 1. Test the alarm probe for low and high temperatures. See step 6.1.3. Record the high and low temperatures on QCA.003F2.
 |
| * + 1. Ensure specific instructions in case of equipment malfunction posted on the refrigerator.
 |
|  | * 1. Immediate Corrective Action for Alarm Sounding on Blood Product Storage Refrigerator
 | * + 1. Silence the alarm.
 |
| * + 1. Read the temperature of the continuous recording device and internal thermometer.
 |
| * + 1. If the temperature is too warm, ensure that the doors are properly closed.
 |
| * + 1. Check the temperature of a red blood cell unit stored close to the top front of the refrigerator. See QCA.009 – Temperature Check of Blood and Blood Components.
 |
| * + 1. If the temperature of the blood bag is warmer than 6°C but colder than 10°C:
 | * + - 1. If a door was ajar, repeated entry caused alarm or the power has failed, correct by closing door, minimizing entry and/or restoring power.
 |
| * + - 1. Set a timer for 15 minutes. Take temperature after 15 minutes.
 |
| * + - 1. If temperature is now within acceptable range, record on QCA.003F3 the corrective action taken.
 |
| * + 1. If temperature is still warmer than 6°C and colder than 10°C, remove all the donor units and store them in an interim refrigerator. See Procedural Notes 8.4.
 |
| * + 1. If the temperature of the blood bag is colder than 1°C or warmer than 10°C:
 | * + - 1. Discard the blood stored closest to the front of the shelf. See IM.005 – Final Disposition of Blood, Blood Components and Other Related Products Not Suitable for Transfusion
 |
| * + - 1. Check the temperature of each red blood cell unit stored next to the unit(s) discarded. See QCA. 009 – Temperature Check of Blood and Blood Components.
 |
| * + 1. Repeat step 6.3.7 until all units have been accounted for (either in an interim fridge or discarded).
 |
| * + 1. Call maintenance immediately after ascertaining the safety of the blood.
 |
| * + 1. Document the response to the off-site alarm. If there was no response, determine the reason.
 |
| * + 1. Record the corrective action on form QCA.003F3 – Maintenance of Blood Product Storage Refrigerators – Malfunction and Corrective Action Record.
 |
| 7.0 | Reporting |
|  | 7.1 | A supervisor must review the results of maintenance and any action taken and document this review. All corrective action should be documented. See Procedural Notes 8.5. |
| 8.0 | Procedural Notes |
|  | 8.1 | Select a container that is the same size as the smallest volume Red Blood Cell (RBC) unit that will be stored in the refrigerator. For example, if RBC units are split in bags of 100 mL, select the same size container (100 mL) to hold the 10% glycerol and the internal thermometer. Or use an approved TML thermometer container. |
|  |  | 8.1.1 | Prepare 100 mL of 10% glycerol.* Add 10 mL of glycerol in a 100 mL volumetric flask
* Fill with water; mix well
 |
|  |  | 8.1.2 | Transfer the 10% glycerol into the container. Use a large syringe if transferring glycerol solution to a donor bag. |
|  |  | 8.1.3 | Cool the solution before using for temperature calibration. |
|  | 8.2 | If the three temperatures are not within 1°C, the recorder should be adjusted. |
|  | 8.3 | When the temperature readings of the two thermometers agree within 1°C, one thermometer may be used. |
|  | 8.4 | If an interim refrigerator is not equipped with a temperature recorder, record the temperature every 4 hours. If an interim refrigerator is not available, blood can be stored in the blood supplier shipping containers for 24 hours. Place completely frozen ice pack(s) in the shipping container(s). See IM.006 - Shipment of Blood and Blood Components/Products Using CBS Shipping Containers. |
|  | 8.5 | Maintenance of equipment may be documented on a computer system, if applicable. |
|  | 8.6 | Equipment should be validated when received and following repair prior to being placed into service. Validation should follow an established protocol and must be documented. Validation includes the following: |
|  |  | 8.6.1 | Installation – checks that electrical and special requirements set out by the manufacturer are met. |
|  |  | 8.6.2 | Operational – shows that the equipment functions as intended with respect to temperature range, alarm, temperature monitoring, and shelving. |
|  |  | 8.6.3 | Performance – demonstrates that the equipment performs as expected using the established facility processes. |
| 9.0 | References |
|  | 9.1 | Standards for Hospital Transfusion Services Version 3 – February 2011. Canadian Society for Transfusion Medicine, 3.1.2, 3.1.3, 3.1.4, 3.1.5, 3.1.8, 3.2.2.1, 3.2.2.2, 3.2.2.3, 3.2.2.4, Appendix A |
|  | 9.2 | Circular of information for the use of human blood and blood components. [www.blood.ca](http://www.blood.ca) |
|  | 9.3 | Kavemeier KG, Ziebell LW, ed. Quality control: a component of process control in blood banking and transfusion medicine. Bethesda MD: American Association of Blood Banks, 1999. |
|  | 9.4 | Roback JD, ed. AABBTechnical Manual, 17th ed. Bethesda, MD: American Association of Blood Banks, 2011: 272,967-968. |
|  | 9.5 | IQMH Requirements and Guidance Information. Version 6.0, December 2013; IV. |

**10.0 Revision History**

|  |  |
| --- | --- |
| **Revision Date** | **Summary of Revision** |
| September 1, 2015 | * Revised name of manual
* Revised numbering in section 2.0
* Changed temperature in section 6.1.3.11 from 6ºC to 5.5ºC
* Updated list of references to include most recent editions
 |