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| 1.0 | Principle | | | | | | | | | |
|  | To check the alarm system of blood product storage freezers and to maintain the freezers 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 | | Freezers 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 alarm rings shall be tested  as per manufacturer 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 | | Freezers 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, 9.2 | | | | | | | |
|  | 2.8 | | TML shall have a written procedure outlining actions to be taken when the temperature of a freezer 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 thermometers  **Supplies:** Monthly andBiannual Maintenance Record (QCA.004F1)  Receipt Record (QCA.004F2)  Malfunction and Corrective Action Record (QCA.004F3)  For alarm probe testing:  Cold water in a container | | | | | | | | | |
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| 5.0 | Quality Control | | | | | | | | | |
|  | 5.1 | The alarm sound and back-up power supply must be checked and documented every month**.** | | | | | | | | |
|  | 5.2 | Other semi-annual procedures should include checking air circulation, door seals, cleaning inside, cleaning dust from compressors and testing the emergency power supply and the alarm sensors for upper and lower limits. | | | | | | | | |
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| 6.0 | Procedure | | | | | | | | | |
|  | * 1. Monthly the following should be done on the freezer. 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 alarm test button). Some models have an alarm indicator light as well as an audible alarm. | | |
| * + - 1. If the alarm rings (and the light flashes, if applicable), record S (satisfactory) on form QCA.004F1. | | |
| * + - 1. If the alarm is malfunctioning, record N (not satisfactory) on QCA.004F1. Notify supervisor and check and record the temperature of the freezer 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 freezer 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 form QCA.004F1.   If the back-up power supply is not functional, record N (not satisfactory) on  QCA.004F1. Record the temperature every | | |
| 4 hours until the back-up power is restored. | | |
|  | * + 1. Every six months, check the temperature sensors for high temperatures according to the manufacturer’s instructions. If these are not available or not described, the following procedure should be followed. | * + - 1. Place a calibrated thermometer into the same container that the temperature sensor is stored in. | | |
| * + - 1. Place the container with the thermometer and temperature sensor into a container of cold water. Close the freezer 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 alarm activation temperature on the appropriate form.   For most freezers, the alarm should sound at -18°C. Adjust the set point to –18°C and repeat testing if the alarm did not sound at –18°C. | | |
| * + - 1. Remove the container with the sensor and thermometer from the cold water. | | |
| * + - 1. Record the temperature on the thermometer when the alarm stops ringing. | | |
| * + - 1. Record the temperature on form QCA.004F1. | | |
| * + 1. Clean dust from the compressor and other mechanical parts. Record Y (yes) in the result column on QCA.004F1. | | | |
| * + 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.004F1. | | | |
| * + 1. Check that there is proper air circulation (fan is working, no obstacles preventing the efficient air flow). Record Y (yes) in the result column on QCA.004F1. | | | |
| * + 1. Check that the door seals tightly. Adjust gasket as necessary. Record Y (yes) on QCA.004F1. | | | |
| * + 1. Check whether the compressor is leaking. Record N (no, compressor is not leaking) on QCA.004F1. | | | |
| * + 1. Record the date and your initials in the appropriate area on form QCA.004F1. | | | |
| * + 1. If there were any unexpected findings, record corrective actions on form QCA.004F1. 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 freezer 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. Check the temperature of the freezer. | | | * + - 1. Place one thermometer on the bottom shelf and another 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.004F2. See Procedural Notes 8.1 and 8.2. | |
| * + 1. Test the alarm for sound for 24 – 72 hours. See step 6.1.1. Record S (satisfactory) or N (not satisfactory) in the "alarm sound test" area on QCA.004F2. | | | | |
| * + 1. Test the alarm probe for high temperature during the week. See step 6.1.3. Record the high temperature on QCA.004F2. | | | | |
| * + 1. Ensure specific instructions in case of equipment malfunction are posted on the freezer. | | | | |
|  | * 1. Immediate Corrective Action for Alarm Sounding on Blood Product Storage Freezer | | | | | * + 1. Silence the alarm. | | | | |
| * + 1. Read and record the temperature of the continuous recording device and internal thermometer. | | * + - 1. If the temperature is –18°C or warmer, determine the cause for the alarm: door ajar or freezer malfunction.   If a door was ajar, proceed to step 6.3.3  If the door is closed completely, a malfunction is the cause for the alarm. Proceed to step 6.3.4. | | |
| * + - 1. If the temperature is warmer than –18°C and the donor units have been partially or entirely thawed, discard them. See IM.005 – Final Disposition of Blood, Blood Components and Other Related Products Not Suitable for Transfusion – Manual Procedure. | | |
| * + 1. If the temperature is –18° C or colder and a door was ajar: | | * + - 1. Close the door and minimize entry. | | |
| * + - 1. Set a timer for 15 minutes. Check the temperature of the freezer after 15 minutes. | | |
| * + - 1. If the temperature remains at –18°C or colder, record the date and the corrective action taken on QCA. 004F3. | | |
| * + - 1. If the temperature does not remain at –18°C or colder, remove all donor units and store them in an interim freezer. | | |
| * + 1. If the freezer is malfunctioning (i.e., does not maintain –18° C or colder and it does not appear that a door was left ajar): | | * + - 1. Establish that the interim freezer is functioning properly. | | |
| * + - 1. Remove all donor units and store them in an interim freezer.   If the interim freezer is not equipped with a temperature recorder, record the temperature every 4 hours. | | |
| * + - 1. Call maintenance immediately after ascertaining the safety of the donor units. | | |
| * + - 1. If there is an off-site alarm, document the response. If there was no response, determine why. | | |
| * + - 1. Record the corrective action on form QCA.004F3. | | |
| 7.0 | Reporting | | | | | | | | | |
|  | 7.1 | | A supervisor must review the results of maintenance and any action taken. Corrective action should be documented, if taken. See Procedural Notes 8.3. | | | | | | | |
|  | 7.2 | | This review must be documented. | | | | | | | |
| 8.0 | Procedural Notes | | | | | | | | | |
|  | 8.1 | | If the three temperatures are not within 1°C, the recorder should be adjusted. | | | | | | | |
|  | 8.2 | | When the temperature readings of the two thermometers agree within 1°C, one thermometer may be used. | | | | | | | |
|  | 8.3 | | Maintenance of equipment may be documented on a computer system, if applicable. | | | | | | | |
|  | 8.4 | | 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: | | | | | | | |
|  |  | | 8.4.1 | | Installation – checks that electrical and special requirements set out by the manufacturer are met. | | | | | |
|  |  | | 8.4.2 | | Operational – shows that the equipment functions as intended with respect to temperature range, alarm, temperature monitoring, and shelving. | | | | | |
|  |  | | 8.4.3 | | 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. | | | | | | | |
|  | 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. AABB Technical Manual, 17th ed. Bethesda, MD: American Association of Blood Banks, 2011: 272, 969-970. | | | | | | | |
|  | 9.5 | | IQMH Requirements and Guidance Information. Version 6.0, December 2013. (IV) | | | | | | | |

**10.0 Revision History**

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| **Revision Date** | **Summary of Revision** |
| September 1, 2015 | * Revised name of manual * Renumbered section 2.0 * Updated list of references to include most recent editions |