AABB Standards Chat Volume 11

In the previous standards chat, we discussed the use of equipment including monitoring, maintenance, and calibration. In this chat we will discuss storage devices and alarm systems for the storage devices.

* 1. **Storage Devices for Blood, Blood Components, Reagents, Tissue, and Derivatives**

**3.6.1** Storage devices shall have the capacity and design to ensure that the proper temperature is maintained. Standard 5.1.8.1.3 applies.

* (Standard 5.1.8.1.3 states, “For storage of blood or blood components, the temperature shall be monitored continuously and recorded at least every 4 hours.”)
* All blood product freezers and refrigerators as well as the platelet incubator have continuous chart monitoring.
* The *Supplier Qualification* policy describes our process for ensuring our equipment meets requirements and outlines our criteria for choosing suppliers. Parameters include, but are not limited to the following criteria: licensure, certification, or accreditation, review of supplier-relevant quality documentation and/or quality summary reports, results of audits or inspections, market position, and after sale support.

**3.6.2** Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored.

* The *Blood Product Freezer and Blood Storage Refrigerators* and *Platelet Incubator Helmer PC3200i Quality Control* policies explain our processes for monitoring these storage devices.
* All blood product freezers and refrigerators as well as the platelet incubator have continuous chart monitoring. Daily manual temperature checks are recorded for all blood storage devices as part of daily QA. Included in these daily checks is ensuring the chart recorder is recording properly.
* Both the *Blood Product Freezer and Blood Storage Refrigerators* and *Platelet Incubator Helmer PC3200i Quality Control* policies state that manual temperature recordings must be recorded every 4 hours on a Manual Temperature Recordings Form when chart recording and/or digital temperature recordings are not functioning.
* Blood Bank has a maintenance contract with a contracted service to perform quarterly alarm calibrations, repairs, and adjustments on the temperature surveillance monitoring and recording modules.

**3.6.3** If storage devices utilize liquid nitrogen, either the liquid nitrogen levels or temperature shall be monitored.

* This standard does not apply to our blood bank as we do not use liquid nitrogen freezers.

**3.7 Alarm Systems** Storage devices for blood, blood components, tissue, derivatives, and reagetns shall have alarms and shall conform to the following standards:

**3.7.1** The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, tissue, derivatives or reagents reach unacceptable conditions.

* The platelet incubator is set to alarm when the temperature falls to 20.5⁰C and when it rises to 23.5⁰C, this is 0.5⁰C from the low and high acceptable temperatures of 20-24⁰C.
* Blood Bank freezers and refrigerators located in the blood bank also have an alarm check performed daily to ensure the alarm is operational as well as alarming at the proper set point.
* Freezer and refrigerators all alarm before the device reaches the defined lower or upper temperature range limit. This allows time to evaluate the situation prior to deviating from acceptable temperatures.

**3.7.2** The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches an unacceptable level.

* This standard does not apply to our blood bank as we do not use liquid nitrogen freezers.

**3.7.3** Activation of the alarm shall initiate a process for immediate action, investigation, and appropriate corrective action. Standard 5.1.3 applies.

* Policy states that if the freezer temperature rises above the alarm set point, the situation shall be evaluated and the temperature will be monitored hourly. If the freezer temperature cannot be maintained, products are moved to another monitored freezer.
* Policy also states that if the refrigerator temperature remains outside of the tolerance limits of 1⁰C- 6⁰C, the blood products will be moved to another operating monitored blood bank refrigerator within the Blood Bank. Plant Operations will be called to investigate the issue and BB leadership will be notified via Transfusion Service Quality Assurance Work Report Form.
* When the platelet incubator alarms and appropriate temperature cannot be maintained, products can be moved to ambient air storage with manual temperature monitoring every 4 hours. If ambient air temperature is not between 20-24⁰C, BB Leadership is notified and provides guidance on product storage.

The goal of the AABB Standards Chat is to increase staff awareness as to their purpose and how they impact the Blood Bank’s policies and procedures. If you have a question about AABB standards, please see a member of BB Leadership.