BAP.07900 Temperature Set Points **Phase I**

High and low temperature set-points have been established that are appropriate for each storage environment.

BAP.08000 Proper Temperature **Phase I**

There is evidence that all temperature-controlled storage units maintain the proper temperature throughout the unit.

NOTE: On all temperature-controlled storage units, temperature mapping must be performed on a periodic basis to ensure that the proper temperature is maintained throughout. There must be records that such readings have been taken. Unrestricted air circulation within the unit reduces the potential for warmer or colder areas that may have detrimental effects on blood/component units without detection by the monitoring system. This requirement also applies to liquid nitrogen (LN2) storage units (vapor phase only).

Temperature mapping must be performed and recorded for each new temperature controlled storage unit prior to being placed in service and periodically for freezers currently in service. The frequency of mapping is determined by the director/designee as well as the review of the data generated.

BAP.08100 Refrigerator/Freezer Temperature **Phase II**

The biorepository monitors and records refrigerator/freezer temperatures daily, as defined in written procedure.

NOTE: Storage temperature of biospecimens must be appropriate for the type of tissue and its means of preservation. Failure to adhere to requirements could result in a unit not being suitable for the purpose for which it was intended.

This checklist requirement applies to refrigerators/freezers containing reagents or biological specimens. "Daily" means every day (seven days per week, 52 weeks per year). The biorepository must define the acceptable temperature ranges for these units. If temperature(s) are found to be outside of the acceptable range, the biorepository must record appropriate corrective action, which may include evaluation of contents for adverse effects.

The two acceptable ways of recording temperatures are: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). If the records are manually obtained, the identity of the individual recording the temperature(s) must be recorded (recording the initials of the individual is adequate).

The use of automated (including remote) temperature monitoring systems is acceptable, providing that biorepository personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. There must be records showing daily functionality of the system.

BAP.08200 Walk-in Storage Criteria **Phase II**

Walk-in storage systems have the following:

1. **Dual compressors**
2. **Internal safety release**
3. **Non-slip floor covering**
4. **Interior oxygen and CO_2 monitoring system, when required**

BAP.08300 Freezer Preventive Maintenance **Phase II**