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**

The biorepository performs regular freezer preventive maintenance.

NOTE: Regular preventive maintenance is required to keep units functioning properly. Routine cleaning and maintenance should be done by assigned employees according to a Preventive Maintenance Schedule. Actions should be targeted at elimination of the causes of equipment failure and unscheduled interruptions. This activity involves regular, routine cleaning, lubricating, testing, calibrating and adjusting, checking for wear and tear and eventually replacing components to avoid breakdown.

Evidence of Compliance:

- ✓ Record of employees trained to perform preventive maintenance **AND**
- ✓ Results of all preventive maintenance will be recorded

BAP.08400 Emergency Response Plan **Phase II**

There is an emergency response plan if acceptable temperature ranges for refrigerators and/or freezers are exceeded.

BAP.08500 Specimen Transfer Process **Phase II**

The biorepository has a defined process for maintaining appropriate temperatures in the event of a system failure.

NOTE: There is a plan in place for transfer and back-up storage. For example, having 10% back-up storage containers would be considered best practices for each type of temperature-controlled unit should any one unit suffer an unrecoverable failure. Failure mode analysis should be performed to identify possible root causes of failure. Corrective actions should include service calls to providers for system repair, as applicable. Duration of failure should also be recorded, as well as any potential adverse effects to specimens.

Evidence of Compliance:

- ✓ Temperature and alarm records **AND**
- ✓ Updated specimen location records **AND**
- ✓ Corrective action and preventive action records

*****REVISED** 08/24/2023***

BAP.08600 Liquid Nitrogen Supplies **Phase II**

Adequate liquid nitrogen (LN2) supplies are maintained securely onsite if LN2 is used as refrigerant or coolant for a storage environment.

NOTE: In general, vapor phase storage is the preferred method over storage in the liquid phase of nitrogen because vapor phase provides sufficiently low temperatures to maintain temperatures below the Tg (glass transition temperature), while avoiding safety hazards inherent in liquid phase storage.

The biorepository must have sufficient LN2 supply to fill a spare storage vessel and/or to allow for freezing of specimens in an emergency.

Access to supply tanks stored outside of the laboratory must be limited to trained personnel and authorized individuals (eg, vendors).

Evidence of Compliance:

- ✓ LN2 supply storage within the restricted area of the laboratory **OR** locked supply storage area outside of the laboratory with limited key access

BAP.08700 LN2 Monitoring **Phase II**