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**

LN2 daily usage and LN2 levels are monitored and recorded for each storage container.

NOTE: The interval for monitoring of usage must be based on the requirements of the instruments.

Evidence of Compliance:

✓ Records of usage monitoring, as applicable

BAP.08800 Storage Containers Approval **Phase II**

All specimen storage containers have been approved for use under intended storage conditions.

NOTE: Refer to contact supplier specification sheet for valid use conditions.

TEMPERATURE MONITORING AND ALARMS

Inspector Instructions:

READ	• Sampling of temperature logs • Sampling of records of alarm trigger response • Sampling of alarm system testing records
OBSERVE	• Active alarm systems in place • Availability of emergency power supply
ASK	• What do you do when a storage container alarm triggers? • What is the biorepository's contingency plan if the alarm system fails? • What do you do if a unit cannot maintain appropriate temperature?
DISCOVER	• Select a storage container that has had a temperature failure and follow the process from notification to response and final corrective action

BAP.09100 Temperature Checks **Phase II**

Temperatures are checked and recorded on each day of use, specifying the unit and location for all temperature dependent instruments and equipment.

NOTE: Controlled-temperature devices used must have temperatures recorded at least daily for units that are within the prescribed temperature range, and at least every 15 minutes if outside of that range.

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,