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,

or using a graphical recording device). 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.

Evidence of Compliance:

- ✓ QC records for continuous temperature monitoring **OR** records of checks at defined frequency

BAP.09200 Alarm Response Time **Phase I**

Temperature limits for the alarm are established with consideration for anticipated response time.

BAP.09300 Storage Temperature Deviation Procedure **Phase II**

The biorepository follows a defined process for deviations in the storage temperature limits, with an impact assessment when required.

NOTE: Procedures for the handling of biological specimens if storage temperature limits cannot be maintained must be written and included in personnel training. The primary concern is the preservation of specimen. If there is a failure, arrangements must be made for service, and for alternative storage.

BAP.09400 Emergency Power Supply **Phase II**

Temperature controlled storage equipment have an emergency power supply.

BAP.09500 Storage Unit Alarms **Phase II**

There is an audible alarm for each component storage unit, the alarm is continuously monitored 24 hours per day (in biorepository or remote), and the response system to an alarm has been validated.

NOTE: The biorepository should be able to demonstrate how this system works, and that there is a process to ensure a timely response to an alarm.

Evidence of Compliance:

- ✓ Records of response time to the alarm

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

BAP.09600 Alarm System Checks **Phase II**

Alarm system functionality is tested at least semiannually (eg, alarm triggers, ability to communicate, etc.).

NOTE: The Biorepository Director may define policies for more frequent alarm system testing based on the level of risk associated with an alarm system and/or communication failure. Temperature controlled storage unit alarms should be tested without taking specimens outside of their acceptable range. Some ways to perform this testing may include: 1) electronic manipulation of freezer set points to trigger the alarm system, 2) warming or cooling the probe using external measures that do not affect the operating temperature at which the specimens are held, and other acceptable processes. This includes both individual alarms and central monitoring systems.