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

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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.

Records of appropriate alarm triggering and notification of personnel during normal operations may also be used as evidence of functionality.

Evidence of Compliance:
- ✓ Records of alarm system testing

BAP.09700 Alarm Adjustment **Phase II**

Alarms are adjusted to be triggered before the temperature falls outside the acceptable temperature range.

NOTE: The biorepository defines the acceptable range for specimen storage.

Evidence of Compliance:
- ✓ Records of trigger temperatures during alarm checks **AND**
- ✓ Records of corrective action, when appropriate

BAP.09800 Power Failure Back-Up **Phase II**

The alarms will continue to function if the power is interrupted.

NOTE: Alarm systems must continue to function during a power failure. This may be accomplished by having the alarm on a separate circuit, installing battery power back-up, or having a power failure alarm.

BAP.09900 Off-Site Notification Process **Phase II**

If the monitoring system allows for off-site notification, there is a:

1. **Trained person on-call (24/7) to respond to alarm conditions**
2. **List of phone numbers or alternate means of contact for trained personnel in case the on-call person fails to respond**

BAP.10000 Back-Up Alarm QC **Phase II**

There is a back-up alarm system in place with records of testing at defined intervals.

BAP.10100 Alarm System Monitoring **Phase II**

There is a mechanism for monitoring the alarm system.

BAP.10200 Alarm System Contingency Plan **Phase II**

There is a contingency plan in place for monitoring if the alarm system fails.

NOTE: Downtime procedures should exist and staff should be trained on these procedures. This contingency procedure should be periodically tested.