

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

BAP.09300	Storage Temperature Deviation Procedure	Phase II
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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
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Temperature controlled storage equipment have an emergency power supply.

BAP.09500	Storage Unit Alarms	Phase II
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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
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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.