



Alarm systems are checked for functionality initially and at specified periodic intervals.

NOTE: The alarm system must be checked at specified periodic intervals to ensure proper function.

Evidence of Compliance:

- ✓ Records of alarm testing

HSC.22593 Power Failure Back-up

Phase II

The alarms continue to function if the power is interrupted.

NOTE: Alarm systems must have a source of power separate from the house current, in order to allow proper monitoring during power failures. This can be accomplished by a separate circuit, power failure alarm, or battery power.

HSC.22625 Cell Freezers

Phase II



The laboratory monitors and maintains adequate liquid nitrogen (LN2) levels in cell freezers.

NOTE: The system must ensure that an adequate supply of liquid nitrogen is present to maintain optimal cell storage temperature.

Evidence of Compliance:

- ✓ Records of monitoring of LN2 levels

****REVISED** 12/26/2024**

HSC.22775 Thermocycler Temperature Checks

Phase II



Individual wells (or a representative sample thereof) of thermocyclers are checked for temperature accuracy before being placed in service and at least annually thereafter.

NOTE: A downstream measure of well-temperature accuracy (such as productivity of amplification) may be substituted to functionally meet this requirement. For closed systems this function should be performed as a component of the manufacturer-provided preventative maintenance.

Evidence of Compliance:

- ✓ Records of thermocycler verification

REFERENCES

- 1) Saunders GC, et al. Interlaboratory study on thermal cycler performance in controlled PCR and random amplified polymorphic DNA analyses. *Clin Chem.* 2001;47:47-55
- 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR1252(b)].

COLORIMETERS, SPECTROPHOTOMETERS, AND FLUOROMETERS

The following requirements apply to stand-alone instruments; they are not applicable to instruments embedded in automated equipment for which the manufacturer's instructions must be followed.