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.

Inspector Instructions:

	• Spectrophotometer policy or procedure • Sampling of manufacturer required system checks
	• Filters (clean, not scratched or deteriorated)

HSC.23137 Absorbance/Linearity **Phase II**

Absorbance and/or linearity fluorescence is checked and recorded at least annually or as often as specified by the manufacturer, with filters or standard solutions.

Evidence of Compliance:

✓ Records of absorbance and linearity checks at required frequency

HSC.23324 Filter Photometers **Phase II**

Filters (filter photometers) are checked at least annually to ensure they are in good condition (eg, clean, free of scratches).

Evidence of Compliance:

✓ Records of filter checks at defined frequency

HSC.23511 Spectrophotometer Checks **Phase II**

Spectrophotometer (including ELISA plate readers) wavelength calibration, absorbance and linearity are checked at least annually (or as often as specified by the manufacturer), with appropriate solutions, filters or emission line source lamps, and the results recorded.

NOTE: Some spectrophotometer designs, eg, diode array, have no moving parts that can alter wavelength accuracy and do not require routine verification. The manufacturer's instructions must be followed.

Evidence of Compliance:

✓ Records of spectrophotometer checks at required frequency

HSC.23698 Stray Light **Phase II**

Stray light is checked at least annually with extinction filters or appropriate solutions, if required by the instrument manufacturer.

Evidence of Compliance:

✓ Records of stray light checks at required frequency