



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Quality Control of temperature monitoring

A New England blood banker reports that his facility uses a REES temperature monitoring system to monitor all product storage and manufacturing areas. According to the inquiring blood banker, the Code of Federal Regulations 21:606.60(b) applies to this type of monitoring system. However, he would like input from the e-Network as to the **proper frequency** that such a system should be validated/calibrated.

The following response was received.

ADDENDA Dec. 17, 2001

1. According to a responding blood banker, in his experience the REES system must be **validated on site by each facility using it**. The user should validate **each probe** by the 'fire & ice' method " using a calibrated thermometer when the system is installed and whenever changes are made (i.e., changing out a probe, sensor, or changing the set points for high and low readings). One must be able to validate that each sensor will do exactly what it was meant to do. Validation records must be kept on file for review by FDA. The responding blood banker states that the REES System probes are capable of being calibrated to within 0.2C of the alarm points. The responding blood banker reported that his facility routinely **re-calibrates the probes at least once a year** routinely, and **each time they changed out a probe**.

ADDENDA Jan. 28, 2002

2. **A blood banker from a community blood collection center in Michigan** reports that **the entire central alarm monitoring system should have a complete validation at a minimum of every 3 years** to demonstrate that the system is operating properly. **Any repairs** to the monitoring system should be evaluated to determine if a full or partial validation to the system is needed. This would also **include software upgrades and hardware changes**.

ADDENDA Jan. 30, 2002

3. **A blood banker in Illinois** wrote that it is his hospital's practice to **contract with the vendor** to validate the entire system, hardware and software, twice yearly. Alarm tests are performed quarterly (e.g. fire and ice testing) on each monitored unit. Validation at this frequency has prevented system failures by detecting them prior to a true issue developing. He adds that **the Rees System (12 bit) has a resolution of 0.1 degrees C, not 0.2 degrees**, as suggested by the responding blood banker in reply #1 above. Early versions were 8 bit and had a resolution of 0.4 degrees C. The Rees probes can be calibrated to the same tolerance as any NIST traceable thermometer.

Please submit comments to the [e-Network Forum](#).



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Ira A. Shulman, MD
CBBS e-Network Forum Editor & Moderator

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Posted: December 15, 2001

Addenda: Dec. 17, 2001; Jan. 27 & 30, 2002