

**UC Davis Health
Sacramento, CA
Department of Pathology and Laboratory Medicine**

***THERMOMETER QUALITY CONTROL &
CERTIFIED THERMOMETERS***

Technical Procedure 735.T

PURPOSE:

To outline the process used by the Department of Pathology and Laboratory Medicine to ensure new thermometers are calibrated-certified before being put into service. To outline process for verification of centralized temperature monitoring systems.

PROCEDURE:

Thermometers are purchased as calibrated-certified thermometers and do not require validation or quality control prior to use.

A. Certified Thermometers

1. New certified thermometers must have a Certificate of Calibration that includes the following information:
 - a. Certificate Number (must also be stamped on thermometer)
 - b. Test temperature
 - c. Date of calibration and date calibration is due
2. When thermometer is put into service, the Certificate of Calibration must be maintained in the lab section.
3. Note the date the unit is put into service.
4. Note the equipment which is being monitored (refrigerator, freezer, heat block, etc.).
5. The technical section must make sure that the thermometer is replaced prior to the date of expiration.
6. Thermometers should be periodically evaluated for damage (e.g. separation of columns). Thermometers with obvious damage should be replaced.
7. Tracking Certificate expiration date is monitored by the technical sections.
8. Humidity monitors and or humidity monitor/thermometers are certified, certificates will be maintained. The expiration dates are monitored in the same way as thermometers.

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B. Verification of METASYS® Centralized Temperature Monitoring System:

METASYS® by Johnson Controls is the electromechanical environmental control system overseen by Plant Operations & Maintenance (PO&M). **METASYS®** continuously and remotely monitors temperatures of many laboratory refrigerators and freezers. **METASYS®** for Validated Environments (MVE) meets FDA regulations (Title 21 CFR Part 11).

1. **METASYS®** temperature system is verified by Plant Operations & Maintenance who compare the temperatures recorded by **METASYS®** against manually recorded temperature readings.
 - a. **METASYS®** temperature data can be compared to manual temperature readings in real time.
 - b. **METASYS®** temperature data can also be verified retrospectively by downloading temperature data points and comparing them to records of manually recorded temperatures.
 - c. Acceptable temperature variations are established based on the temperature range of the unit being monitored.

2. **METASYS®** alarms are monitored and documented by PO&M and laboratory staff. Alarms are reviewed by lab staff to ensure equipment is functioning as expected and appropriate actions are taken for equipment.

REFERENCES:

College of American Pathologists (CAP) checklist; current edition

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PROCEDURE HISTORY

Date	Written/ Revised by	Review/Revision	Approved Date	Approved By
8/93	D. Shelby	New	8/93	D. O'Sullivan
8/94	D. Shelby	Revised	8/94	D. O'Sullivan
4/96	D. Shelby	Annual Review	4/96	D. O'Sullivan
10/96	D. Shelby	Annual Review	10/96	R. Green
12/97	D. Shelby	Annual Review	1/98	R. Green
7/99	D. Shelby	Annual Review	7/99	R. Green
11/00	D. Shelby	Annual Review	11/00	R. Green
12/01	D. Shelby	Annual Review	12/01	R. Green
8/02	D. Shelby	Annual Review	8/02	R. Green
9/03	D. Shelby	Annual Review	9/03	R. Green
11/04	L. Blalock	Revised	11/04	R. Green
11/05	D. O'Sullivan	Annual Review	11/05	R. Green
9/06	D. O'Sullivan	Annual Review	9/06	R. Green
9/07	D. O'Sullivan	Annual Review	9/07	R. Green
9/08	D. Wright	Revised	9/08	R. Green
7/09	D. Wright	Revised	7/09	L. Howell
8/10	D. Wright	Revised	8/10	L. Howell

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Date	Written/ Revised by	Review/Revision	Approved Date	Approved By
10/12	T. Cox	Revised: added Addm A & Omega System	10/12	L. Howell
10/14	T. Cox	Revised: removed addendum; added humidity monitor; added example	10/14	L. Howell
10/16	E. Villadolid/ S. Okimura	Biennial Review	10/16	L. Howell
10/18	E Villadolid	Biennial Review	11/18	L. Howell Via OnBase
10/20	E. Villadolid/ N. Kaur	Revised: Add verification by PO&M and updated header/references	10/20	L. Howell Via OnBase