

VERIF. DATE: _____

INITIALS: _____

CP3-ES-0043 FRev. 0B	TITLE: Temperature Control for Sample Storage	Page 1 of 8
DOCUMENT CATEGORY: Administrative		
LEVEL OF USE: Information Level		
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REQUIRED REVIEW DATE (or expiration date for temporary change): 6/2/2028	EFFECTIVE DATE: 10/31/2022	

REVISION/CHANGE LOG				
Revision/ Change Letter	Description of Changes	Pages Affected	Date of Revision/ Change	Approved By (signature on file)
FR0	Revision- Procedure was initially CP4-ES-0043 but is used by multiple functional areas so is being revised to a CP3 procedure. Addressed CAPAs #AI-0005993 and #AI- 0006230. Added NOTE above Section 5.0 clarifying terminology used for thermometers and revised Scope to include other locations to be used for sample storage.	All	5/23/2022	Documentation on File
FR0A	Periodic Review has been completed with no changes identified in procedure technical content. Nonintent change to FA, SMA, SME, Approver and dates has been incorporated per CP3-NS-2001. Date for review cycle has been reset.	All	9/28/2022	
FR0B	Periodic Review has been completed with no changes identified in procedure technical content. Nonintent changes have been incorporated per CP3-NS-2001. Date for review cycle has been reset.	All	6/2/2025	Caleb Kline

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1.0 PURPOSE AND SCOPE

1.1 Purpose

To provide a system for the documentation of temperatures in refrigerators used for sample storage. Certain analytical methods require temperatures of ≤ 6 °C for sample preservation (40 Code of Federal Regulations (CFR) 136.3 or other regulatory guidelines).

1.2 Scope

This procedure applies to anyone performing environmental, waste, and characterization sampling activities for the Deactivation and Remediation (D&R) contractor and subcontractor personnel at the U.S. Department of Energy (DOE)-owned Paducah site. The requirements in this procedure apply to temperature controlled storage areas at locations meeting temperature control standards.

2.0 REFERENCES

2.1 Use References

Federal Register, *40 Code of Federal Regulations Part 136.3*

2.2 Source References

- Program Policy and Structure, *National Environmental Laboratory Accreditation Conference (NELAC)*
- Quality Systems for Analytical Services (QSAS), *Department of Energy*
- SW-846, Volume One, Part Four, *Methods for Analytes and Properties*, September 1994, Rev. 2

3.0 COMMITMENTS

None

4.0 RESPONSIBILITIES

4.1 Sampler

- 4.1.1** Conducts refrigerator temperature checks.
- 4.1.2** Ensures thermometers are within calibration date.
- 4.1.3** Ensures refrigerators are within acceptance limits (0°C to 6°C).
- 4.1.4** Documents nonconformances and actions taken to correct problems with refrigerator temperatures.

NOTE:

Thermometers are considered critical if used to verify specific temperature as required by method. Critical thermometers are National Institute of Standards and Technology (NIST) traceable. Other thermometers are considered non-critical and are **NOT** required to be verified.

Thermometers should be verified in their range of use. Thermometers may be shipped to a qualified vendor for verification.

5.0 GENERAL INFORMATION

NOTE:

Verification does **NOT** have to be performed if critical thermometer is purchased annually.

- 5.1 Ensure critical thermometers are verified annually.
- 5.2 Ship NIST reference thermometer for calibration verification at least every 5 years.
- 5.3 Temperature of refrigerators shall be recorded on CP3-ES-0043-F01, *Daily Weekly Fridge Chart* each work day.

6.0 INSTRUCTIONS

Sampler

6.1 Refrigerators with Temperature Chart Recorders

6.1.1 Confirm proper operation of the refrigerated storage area:

- A. **When** refrigerator is installed for sample storage, **then** place critical thermometer in an area representative of the overall temperature of the refrigerator.

NOTE:

The chart paper must be changed **after** seven consecutive days of continuous recording.

Time, date, and signature must be recorded on chart paper each time chart paper is replaced **or** removed.

- B. Record temperature from temperature chart recorder each work day on form CP3-ES-0043-F01.
- C. Read temperature of critical thermometer each work day **and** record on CP3-ES-0043-F01.
- D. Compare reading on critical thermometer with temperature from chart recorder.
If reading on chart recorder does **NOT** reflect reading on critical thermometer (0°C to 6°C), **then** adjust temperature on chart recorder.
- E. **If** critical thermometer reading is **NOT** within acceptance limits (0°C to 6°C), **then** recheck the critical thermometer in approximately one hour.
- F. **If** critical thermometer reading is still **NOT** within acceptance limits, **then** adjust refrigerator according to manufacturer's instructions **and** bring temperature to within acceptable operating limits.

- G. If adjustment does **NOT** bring temperature into acceptable limits, **then**:
 - Remove samples and place in an acceptable refrigerator.
 - Tag the unit out of service.
 - Contact maintenance for adjustment and/or repair.
- H. Document nonconformances **and** actions taken to correct problem on recorder disc **and** on CP3-ES-0043-F01.

6.2 Refrigerators

6.2.1 Confirm proper operation of the refrigerated storage area.

- I. **When** refrigerator is installed for sample storage, **then** place critical thermometer in an area representative of the overall temperature of the refrigerator.
- J. Read temperature of critical thermometer each work day **and** record on form CP3-ES-0043-F01.
- K. If critical is **NOT** within acceptance limits (0°C to 6°C), **then** recheck the thermometer in approximately one hour.
- L. If thermometer reading is still **NOT** within acceptance limits, **then** adjust refrigerator according to manufacturer's instructions **and** bring temperature to within acceptable operating limits.
- M. If adjustment does **NOT** bring temperature into acceptable limits, **then**:
 - Remove samples and place in an acceptable refrigerator.
 - Tag the unit out of service.
 - Contact maintenance for adjustment **and/or** repair.
- N. Document nonconformances **and** actions taken to correct problem on recorder disc **and** on CP3-ES-0043-F01.

6.3 Thermometer Verification

6.3.1 Verify critical thermometer annually by performing the following:

- A. Place a NIST reference thermometer beside the critical thermometer to be verified **and** let stabilize for 30 minutes.
OR
- B. Perform an ice point check by placing the critical thermometer in an ice bath.
- C. Read **and** record the temperature shown on the critical thermometer after it stabilizes.

NOTE:

Readings are considered the same if they are within the limit of uncertainty for the thermometer.

D. If the reading is **NOT** the same as the NIST reference thermometer for the verification method **or** 0°C for the ice point check, **then**:

1. Calculate the correction factor for the critical thermometer.
2. Note it on the temperature log and calibration label for that critical thermometer.

OR

3. Replace the critical thermometer.

7.0 RECORDS

7.1 Records Generated

The following records may be generated by this procedure:

- Chart paper
- CP3-ES-0043-F01, *Daily/Weekly Fridge Chart*

Forms are to be completed according to CP3-OP-0024, *Forms Control*.

7.2 Records Disposition

The records are to be maintained according to CP3-RD-0010, *Records Management Process*.

Appendix A – Acronyms/Definitions

ACRONYMS

CFR – Code of Federal Regulations

D&R – Deactivation and Remediation

DOE – U.S. Department of Energy

NELAC – National Environmental Laboratory Accreditation Conference

NIST – National Institute of Standards and Technology

QSAS – Quality Systems for Analytical Services

DEFINITIONS

Critical Thermometer – An NIST traceable thermometer used to verify specific temperatures as required by method.

Reference Thermometer – An NIST traceable thermometer that has very high accuracy and can be used to compare accuracy of other thermometers.

Traceability – The ability to relate measurements to national standards or to a nationally accepted measurement system.

Work Day – Day on which work is regularly scheduled. This excludes weekend, holidays, and occasional single days of absence.

CP3-ES-0043-F01 – Daily/Weekly Fridge Chart

Location: _____

Fridge SN# _____

Month/Year: _____

Thermometer ID _____

Acceptance Range (°c) _____

Day	Time	Initials	Thermometer Temp. (°C)	Disc Chart Temp. (°C)	Comments/Weekly Change Out
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
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Signature: _____ Date: _____

Verifier: _____ Date: _____