Unit Procedure

Mechanical Refrigeration Units

SOP No./WI No.: CTSI-CRC-PL-301

Department: Processing Laboratory

Version No.: 02

Effective Date: 05 Jan 2017

Supersedes: No.: CTSI-CRC-PL-301-01 Effective Date: 08 May 2014

Page No: 1 of 7

Review Period: 2 years

	Written by	Reviewed by	Approved by
Name	Robert Orr	Diana Spiegel	Christie Orschell
Job Title	Operations Manager	Quality Assurance Manager	ATP Director
Signature			
Date	28 Dec 2016	28 Dec 2016	Dec 29, 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) defines the procedures used in the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL) to maintain and monitor the refrigeration/freezer units in the CTSL.

2. SCOPE

This SOP applies to CTSL personnel operating and maintaining the refrigeration/freezer units located in the CTSL facility. It provides the schedule and procedures for monitoring and maintaining the units and defers response to out of specification (OOS) conditions to the CTSI-CRC-PL-105 "Out of Specification Condition and Notification Management". Response to alarms from the units is managed per the alarm and monitoring CTSL-CRC-PL-106 "Alarm System Management and Response.

3. RESPONSIBILITIES

The laboratory staff is responsible for appropriate operation and maintenance of mechanical refrigeration units.

4. DEFINITIONS

4.1. Principle: All refrigeration/freezer units owned by CTSL are supported by CTSL Staff. The units store samples for which defined storage conditions are critical. Routine monitoring and maintenance is important to minimize risk of the units failing to maintain specified storage conditions and for quickly detecting out of specification (OOS) conditions.

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	OOS: out of specification
PI: Principal Investigator	PL: Processing Lab
NIST: National Institute of Standards and Technology	SOP: Standard Operating Procedure

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 "Document Control and Management"
5.2. CTSI-CRC-CLN-030 "Handling of SOP Deviations"
5.3. CTSI-CRC-PL-121 "General Safety"

5.4. CTSI-CRC-PL-105 "Out of Specification Condition and Notification Management"
5.5. CTSI-CRC-PL-106 "Alarm System Management and Response

6. PROCEDURE

6.1. Material:
- 6.1.1. Cleaning cloth
- 6.1.2. General purpose cleaner (Example: Windex)
- 6.1.3. NIST- traceable thermometer (CTSI-CRC-PL-306 Thermometers)

6.2. Routine Monitoring and Maintenance
- 6.2.1. Daily Temperature Checks
  - 6.2.1.1. Observe the temperature reading from the digital display of the unit. Alternatively, observe the temperature reading on the unit's SmartVue device if the freezer display is not functioning.
  - 6.2.1.2. Acceptable temperature ranges:
    - 6.2.1.2.1. Refrigerators 2-8 °C
    - 6.2.1.2.2. Standard Freezers ≤ -20°C
    - 6.2.1.2.3. Ultra-Low Freezers ≤ -60°C
  - 6.2.1.3. If the observed temperature reading is within acceptable range, record the reading, the date and tech initials on the CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log.
  - 6.2.1.4. If the observed temperature is outside the acceptable range, set a reminder to re-check in approximately 15 minutes. Document initial reading and time of reading on unit's CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log in the comments section.
    - 6.2.1.4.1. If unit has recovered, record current temperature reading and mark as acceptable.
    - 6.2.1.4.2. If unit is approaching recovery (not reached acceptable level but is cooling), repeat step 6.2.1.4 up to 7 times (i.e. for two hours). Record each subsequent temperature reading and time of reading on the unit's CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log in the comments section.
    - 6.2.1.4.3. If unit fails to reach acceptable level after step 6.2.1.4.2, notify CTSL management; relocate samples to backup space and record event per CTSI-CRC-PL-105 Out of Specification Condition Notification and Management.
    - 6.2.1.4.4. Document results and any actions taken on the unit's CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log.

6.2.1.4.5. If no alert of the temperature excursion was received from the alarm system within acceptable parameters (i.e. – after the preset system delay of 15 to 20 minutes), investigate cause and document per CTSI-CRC-CLN-030 Handling of SOP Deviations.

6.2.2. Monthly

6.2.2.1. Wipe down the outside of the unit with a cloth and general purpose cleaner.

6.2.2.2. Record date of wipe down on the unit's CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log.

6.2.3. Annually

6.2.3.1. Record all actions and observations on CTSI-CRC-PL-FM507 Mechanical Refrigeration Unit Annual and Biannual Monitoring and Maintenance form and note date of maintenance on the unit's CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log in the comments section.

6.2.3.2. Temperature display calibration verification

6.2.3.2.1. Place a notice on the unit that states "Calibration Verification in process- DO NOT OPEN".

6.2.3.2.2. Place an NIST- traceable thermometer probe inside the unit as close to the unit's temperature probe as possible and close the door.

6.2.3.2.2.1. A unit's probe is often located in the lower half of the unit, attached to one of the walls, and is typically covered with a metal or plastic structure for protection.

6.2.3.2.3. Wait until thermometer reading has stabilized prior to recording any results.

6.2.3.2.4. Record temperature reading from NIST thermometer, the unit's SmartVue temperature monitoring device and the temperature reading from the unit's display. Readings should be taken at approximately the same time.

6.2.3.2.5. Compare NIST thermometer reading with the unit's digital readout reading.

6.2.3.2.5.1. If the difference between the NIST thermometer and unit's readings exceeds +/- 2˚C for 2-8˚C or +/- 3˚C for -20 ˚C or colder units, notify CTSL management.

6.2.3.2.5.2. Correct unit's display reading per manufacturer's manual so NIST reading and display reading are the same.

6.2.3.2.5.3. If correction is not possible, determine if relocation of specimens is required, initiate repair and document per CTSI-CRC-PL-105 Out of Specification Condition and Notification of Management.

6.2.3.2.5.4. If the difference between the NIST thermometer and SmartVue readings exceeds +/- 2˚C for 2-8˚C or +/- 3˚C for -20 ˚C or colder units, notify CTSL management.

6.2.3.3. Other maintenance

6.2.3.3.1. Clean filter by vacuuming or replacing filter material.

6.2.3.3.2. Vacuum condenser, taking care not to damage or dent the condenser fins or connections

6.2.3.3.3. Check door gaskets for damage.

6.2.3.3.4. Replace backup batteries as needed

6.2.3.3.5. If service is required, document findings and contact CTSL management for further instructions.

6.2.4. Biannually (every two years)

6.2.4.1. Defrost Freezers

6.2.4.1.1. Record all actions and observations on CTSI-CRC-PL-FM507 Mechanical Refrigeration Unit Annual and Biannual Monitoring and Maintenance form and note date of maintenance on the unit's CTSI-CRC-PL-LG606 Mechanical Refrigeration Unit Daily and Monthly Monitoring and Maintenance Log in the comments section.

6.2.4.1.2. Relocate all samples from freezer marked for defrost to a backup freezer. Document relocation using CTSI-CRC-PL-FM501 OOS Response Form and CTSI-CRC-PL-FM502 OOS Specimen Relocation Record.

6.2.4.1.3. Prevent unit from activating the alarm system during the defrost procedure (as described in CTSI-CRC-PL-106 Alarm System Management and Response).

6.2.4.1.4. Open all freezer doors, disconnect the power cord from the wall or freezer, unplug the backup battery and leave unit open until all ice and snow has melted.

6.2.4.1.5. Protect freezer and surrounding space from excessive water runoff by placing absorbent materials (towels or other

absorbent) in and around the freezer. Focus on ensuring water does not enter areas with electrical components.

6.2.4.1.6. Upon completion of defrost, wipe down the internal compartment of the freezer.

6.2.4.1.7. Close all doors, reconnect power supply to freezer, reconnect the backup battery and turn the freezer back on.

6.2.4.1.8. Allow the freezer to return to its set temperature overnight. If time allows, let freezer maintain normal operating temperatures for a minimum of 24 hours before proceeding to next step.

6.2.4.1.9. Ensure alarm system has been reactivated per CTSI-CRC-PL-106 Alarm System Management and Response and return samples to the freezer following the procedure defined in CTSI-CRC-PL-105 Out of Specification Condition and Notification Management.

6.2.4.1.10. Document return of samples to original unit on the CTSI-CRC-PL-FM501 OOS Response Form and CTSI-CRC-PL-FM502 OOS Specimen Relocation Record initiated in step 6.2.4.1.1.

6.2.4.1.11. Attach copies of the completed CTSI-CRC-PL-FM501 OOS Response Form and CTSI-CRC-PL-FM502 OOS Specimen Relocation Record to the unit's CTSI-CRC-PL-FM507 Mechanical Refrigeration Unit Annual and Biannual Monitoring and Maintenance form.

6.2.4.1.12. Record the defrost procedure and all findings on CTSI-CRC-PL-FM507 Mechanical Refrigeration Unit Annual and Biannual Monitoring and Maintenance.

6.2.5. Alternatively, performance of the display calibration verification and other routine maintenance by a contractor is acceptable upon receipt of documentation that meets CTSL requirements per this SOP.

6.2.5.1. Documentation of calibration verification must include NIST-traceability of the instruments used.

6.2.5.2. Attach documentation to the unit's CTSI-CRC-PL-FM507 Mechanical Refrigeration Unit Annual and Biannual Monitoring and Maintenance form.

6.3. Non-routine Monitoring

6.3.1. If the temperature of unit is found to be out of acceptable range defined in 6.2.1.2 and alerts have not been received from the temperature monitoring system, immediately initiate an investigation per CTSI-CRC-PL-105 Out of Specification Condition Notification and Management.

6.3.2. Report any and all signs of damage to CTSL management. If management is not immediately available and damage requires the relocation of specimens, initiate an OOS investigation per CTSI-CRC-PL-105 Out of Specification Condition Notification and Management.

6.4. Documentation:

6.4.1. Retain copies of all repair documentation in the CTSL equipment maintenance records

6.4.2. Documents are maintained per CTSI-CRC-QA-003 Document Control and Management.

6.4.3. Deviations are managed per CTSI-CRC-CLN-030 Handling of SOP Deviations.

7. REFERE"NCES

None

8. APPENDICES

8.1. CTSI-CRC-PL-FM507 "Mechanical Refrigeration Unit Annual and Biannual Monitoring and Maintenance form"

9. AMENDMENT HISTORY

Date of Amendment:	16 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-010
Details of Amendment:	Updated to footer file location; updated the SOPs in 5.2 and 6.5.2; Entire SOP revised for clarity; Removed action limits and updated response procedure in 6.2; added SmartVue temp calibration verification in step 6.2.3.2; revised section 6.2.4.1 defrost procedures for clarity and increased sample security; revised 6.3 non-routine monitoring section to better define process and responsibilities.