INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR MECHANICAL REFRIGERATION UNITS

CHAPTER: 3-Equipment

SOP #: SF-3-1.12

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SUPERSEDES SOP #: N/A

AUTHORED BY: _____ DATE: 2-15-2022
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1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. Added Annex IV -80C freezer room, TK 246, to Section 4.
      1.1.2. Revised Section 4.1 to define that alarming and response is managed by SF-2-4 and/or other validated alarm system and the SOP(s) corresponding to that alarm system, since Sonicu will replace Siemens for alarm system management in the near future.
      1.1.3. Added Section 4.2 defining alarm system management terminology.
      1.1.4. Throughout SOP, references to SF-2-4 and Siemens were revised to align with Scope revisions.
      1.1.5. Revised Step 6.1.3.2.1 reference to direct recording NIST thermometer's "SSF ID" to align with Appendix D and other freezer equipment SOPs.
      1.1.6. Steps 6.1.4.1.6 and 6.1.5.1.9.1 reworded to enhance clarity.
      1.1.7. Revised Section 6.1.5.1.10 defrost criteria to allow for a second 48-hour defrost before initiating an OOS. A second defrost is standard procedure should a freezer fail to cool after defrost per repair technicians.
      1.1.8. Step 6.1.5.1.13 documentation of relocation directive moved up from Step 6.1.5.1.15 to reflect proper procedure.
      1.1.9. Step 6.1.7.1 revised to specify completion of an OOS *Event Report* per SF-1-10, as directed.
      1.1.10. Section 9 revised to reflect new title of Appendix G
      1.1.11. Appendix B revised to include alarm functionality test directives applicable to the Sonicu alarm system
      1.1.12. Appendix G alarm system and SOP references revised to align with revisions referenced in the Scope section.
      1.1.13. Appendix H revised to reflect minor grammatical changes.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) to maintain and monitor the refrigeration/freezer units owned or contracted for storage in the SSF. This procedure satisfies guidance set forth in ISBER.

3. PRINCIPLE
   3.1. All refrigeration/freezer units owned or contracted for storage in the SSF are supported by Indiana CTSI SSF 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.

4. SCOPE
   4.1. The SOP applies to SSF personnel operating and maintaining the refrigeration/freezer units owned or contracted for storage in the SSF and stored in the Mechanical Refrigeration Unit Storage Room and SSF Storage Room Annexes (R3-C135, R3-C156, IB 097/MS-B046 Cage, MS-B037, and TK 246). Additionally, it applies to SSF personnel operating and maintaining any other refrigeration/freezer units that are not stored in the Mechanical Refrigeration Unit Storage Room which contain SSF managed samples. It provides the schedule and procedures for monitoring and maintaining the units and defers response to OOS conditions to SOP SF-1-10 SOP for Out of Specification Condition Notification and Management. Alarming and response is managed per SF-2-4, SOP for Alarm Systems Management and Response, and/or other validated alarm system and the SOP(s) corresponding to that alarm system.
   4.2. Alarm Management Definitions:
      4.2.1. Local Alarm: Alarm issued from freezer (audible, visual, or both)
      4.2.2. Remote Alarm: Alarm recorded and communicated from validated alarm system
      4.2.3. Alarm System: the SSF's validated alarm system

5. MATERIALS
   5.1. Cleaning Cloth (Example: Swiffer pads, dry or pre-moistened)
   5.2. General Purpose Cleaner (Example: Windex or Swiffer Wet solution)
   5.3. Chart supplies as applicable
   5.4. NIST-traceable thermometer (SF-3-7 SOP for Thermometers)
   5.5. Schumacher 12V Automatic Battery Charger (or similar)
   5.6. OTC 55 Digital Multimeter (or similar), for testing battery voltage
   5.7. Backup battery per freezer manual
   5.8. Timer (SOP SF-3-6) or similar device

6. PROCEDURE
   6.1. **Monitoring and Maintenance**

   NOTE: Routine monitoring and maintenance of a mechanical refrigeration unit (i.e. MRU or unit) is optional if the unit is out of service. A unit is considered "in service" only if it has been alarm tested per the alarm system SOP and is ready to accept samples for storage.

      6.1.1. Daily-Temperature checks
         6.1.1.1. Observe the temperature from the digital display of each unit
            6.1.1.1.1. Acceptable Ranges:
            Refrigerators - Normal Operating Range (Generally 2-8°C*)
            Standard Freezers - Normal Operating Range (Generally <-20°C*)
            Ultra-Low Freezers - Normal Operating Range (Generally <-60°C*)

            * Unless otherwise specified by PI or determined by unit capabilities

Equipment	Temperature Range	Range ID	Additional Monitoring
Ultra-Low Freezer	Alarm Condition (outside acceptable parameters)	Action Limit Range	Monitor for up to one hour, at 15-minute intervals, to: • Reach normal operating range or to ensure trending colder; if trending colder • OR if temperature is within 2 degrees of acceptable range AND the temperature is stable, Monitor for up to 2 additional hours, at 30-minute intervals, until normal operating range
	Normal Operating Range	Acceptable Range	N/A
Standard Freezer	Alarm Condition (outside acceptable parameters)	Action Limit Range	Monitor for up to one hour, at 15-minute intervals, to: • Reach normal operating range or to ensure trending colder; if trending colder • OR if temperature is within 2 degrees of acceptable range AND the temperature is stable, Monitor for up to 2 additional hours, at 30-minute intervals, until normal operating range
	Normal Operating Range	Acceptable Range	N/A
Refrigerator	Alarm Condition (outside acceptable parameters)	Action Limit Range	Monitor for up to one hour, at 15-minute intervals, to: • Reach normal operating range or to ensure trending colder; if trending colder • OR if temperature is within 2 degrees of acceptable range AND the temperature is stable, Monitor for up to 2 additional hours, at 30-minute intervals, until normal operating range
	Normal Operating Range	Acceptable Range	N/A

6.1.1.2. If within acceptable range, record reading and document tech initials on the Mechanical Refrigeration Unit Daily Monitoring and Maintenance Log (Appendix A, if unit equipped with chart recorder, or Appendix C).

6.1.1.3. If outside of acceptable range (i.e., action limit range/alarm condition) refer to the Mechanical Refrigeration Unit Monitoring Decision Tree Flowchart (Appendix H), and proceed per the following steps:

6.1.1.3.1. If temperature reaches the action limits per chart in Step 6.1.1.1, monitor every 15 minutes (not to exceed 1 hour) to see if the unit has recovered or is approaching recovery. Record each temperature in the comments section of SF-3-1 Appendix A (if unit equipped with chart recorder), SF-3-1 Appendix C, or on the SF-1-10 Appendix E, OOS Temperature Monitoring Log (Suggested Tool), if applicable.

6.1.1.3.2. If unit reaches acceptable range, record and accept.

6.1.1.3.3. If unit fails to reach acceptable range after 1 hour and either of the 2 criteria below apply, monitor every 30 minutes for up to an additional 2 hours (i.e., a total of 3 hours of monitoring), recording each temperature as per above.

6.1.1.3.3.1. Applicable criteria:

6.1.1.3.3.1.1. The unit is trending colder

6.1.1.3.3.1.2. The temperature is within 2 degrees of acceptable range and the temperature is stable

6.1.1.3.3.2. If unit reaches acceptable range, record and accept.

6.1.1.3.3.3. If unit fails to reach acceptable level, notify SSF Management and correct if possible. If unable to resolve, proceed per SF-1-10. Relocate samples per SF-1-10.

6.1.1.3.4. Notify SSF Management and proceed per SF-1-10. Relocate samples per SF-1-10 if any of the following apply:

6.1.1.3.4.1. The unit is <u>not</u> trending colder after 1 hour

6.1.1.3.4.2. The unit is <u>not</u> within 2 degrees of acceptable range and stable after 1 hour.

6.1.1.3.4.3. The unit fails to reach acceptable range after 3 hours.

6.1.1.3.5. If the unit trends warmer at any point during the additional 2 hours of monitoring, notify SSF Management and proceed per SF-1-10. Relocate samples per SF-1-10.

6.1.1.3.6. Document results and any actions taken on Appendix A or Appendix C.

6.1.1.4. If the unit is equipped with a chart recorder, assure that the recorder is functional. Refer to the applicable equipment operation manual to address problems if detected.

6.1.2. Weekly

6.1.2.1. Change circular recorders for SSF owned units (if chart recorder equipped) and PI units if the PI provides SSF with necessary supplies for the unit.

6.1.2.1.1. Remove the paper chart and record current temperature of digital readout and note current temperature per circular chart.

6.1.2.1.1.1. Acceptable limit are as follows:
Refrigerators +/- 2°C
Standard Freezers +/- 3°C
Ultra-Low Freezers +/- 5°C

6.1.2.1.1.2. Notify SSF Management if out of specification. Record any actions on the paper chart.

6.1.2.1.2. Document on Appendix A if supplies are not available.

6.1.2.2. Record the following prior to filing:

6.1.2.2.1. Unit ID

6.1.2.2.2. Inclusive dates for the chart record

6.1.2.2.3. Tech initials and date for removal

6.1.2.3. File SSF-owned units circular papers in the SSF Operations Office with Refrigeration unit documents (maintain per SOP SF-1-6 Controlled Document Management) and file non-SSF owned units circular papers in envelope attached to refrigeration unit for the PI's personnel to retrieve.

6.1.2.4. Observe if pen needs to be changed.

6.1.2.4.1. If SSF owned, use from SSF supplies.

6.1.2.4.2. If PI owned, SSF Management notifies PI to provide.

6.1.2.4.3. Record actions in comment.

6.1.3. Quarterly

Note: Quarterly does not represent calendar quarters and is defined in SF-1-1 SOP for Writing, Reviewing, and Maintaining SOPs.

6.1.3.1. MRU Wipe Downs

6.1.3.1.1. Wipe down the outside of the units with a cloth and general purposes cleaner.

6.1.3.1.2. Record actions, date and initials on Mechanical Refrigeration Unit Quarterly Maintenance Log (Appendix D).

6.1.3.2. Mechanical Refrigeration Unit Quarterly Temperature Calibration Verification (document completion on Appendix D)

6.1.3.2.1. Record NIST SSF ID next to the correct quarter.

6.1.3.2.2. Record Re-calibration due date.

6.1.3.2.3. Place a notice on the refrigeration unit stating “Calibration in process – Do NOT open”.

6.1.3.2.4. Place an NIST-traceable thermometer inside the unit, near the freezer’s internal probe, for a minimum of 20 minutes.

6.1.3.2.4.1. Ensure that the NIST-traceable device is being used within its calibrated range and ensure that it has not exceed its calibration due date.

6.1.3.2.4.2. If freezer probe is not visible, consult unit manual or manufacturer to determine location inside unit and place NIST probe as close to the freezer probe’s location as possible.

6.1.3.2.5. After the minimum 20-minute period has elapsed, verify that the thermometer reading has stabilized before proceeding.

6.1.3.2.6. Record unit digital display and stabilized NIST temperature values.

6.1.3.2.7. Compare recorded NIST thermometer value with digital readout value.

6.1.3.2.8. If difference exceeds 3^{o}C for 2-8^{o}C units or 10^{o}C for freezer units proceed as follows:

6.1.3.2.8.1. If unit is SSF owned, notify SSF Management, proceed per SF-1-10 and begin re-calibration investigation per Mechanical Refrigeration Unit Re-Calibration Investigation Form (Appendix E). If investigation proves calibration is necessary, proceed with calibrating the unit (while recording results and actions on Appendix D and Appendix E to match the NIST thermometer per unit instruction manual or other sources. Initiate repair if warranted.

6.1.3.2.8.2. If unit is not SSF owned, notify SSF Management as well as the owner of the unit. Proceed per SF-1-10 and begin re-calibration investigation per Appendix E.

6.1.3.2.8.2.1. If the investigation proves that calibration is necessary, contact the PI of the unit to receive permission to calibrate unit to match NIST probe.

6.1.3.2.8.2.1.1. If the PI grants permission, proceed with calibrating the unit (while recording results and actions on Appendix D and Appendix E) to match the NIST thermometer per unit instruction manual or other sources.

6.1.3.2.8.2.1.2. If the PI denies permission, document as such on Appendix E and notify SSF Management.

6.1.3.2.8.2.2. If the investigation proves that calibration is not required, document rationale and provide to SSF Management for review and approval.

6.1.3.2.8.3. If unit was sent for repair, once returned to facility, allow unit to sit for at least 24 hours per Step 6.1.8. Test the freezer using the NIST thermometer to verify the issue has been resolved. If issue has been resolved, alarm test upon re-connection to alarm via the alarm system SOP. If issue has not been resolved, notify SSF Management and PI (if not SSF owned).

6.1.4. Annually

NOTE: Annual Freezer Alarm Functionality Testing as described in Section 6.1.4.2 **may NOT be waived by PI directives** (e.g., GLP biorepository request per SF-1-13, Appendix C submission).

6.1.4.1. Maintenance (May be performed more frequently if indicated by observation)

6.1.4.1.1. Clean filters for each unit and record actions on Mechanical Refrigeration Unit Annual Maintenance Log, Appendix B.

6.1.4.1.2. Vacuum condensers and clean/vacuum filters for each unit and record actions on Appendix B.

6.1.4.1.3. Check gaskets on each unit for cracks and separations. Record actions on Appendix B**.**

6.1.4.1.4. Replace backup battery, if necessary

6.1.4.1.4.1. Test the voltage of the backup battery with the OTC Series 55 Digital Multimeter (or similar) per the multimeter manual.

6.1.4.1.4.1.1. If the reading on the voltmeter is greater than the battery's defined voltage (i.e. ≥12V for a 7Ah, 12V battery), replacement is not necessary.

6.1.4.1.4.2. Replaced 6V and 12V batteries may be recharged for re-use, utilizing Schumacher 12V Automatic Battery Charger (or similar) per the charger manual.

6.1.4.1.4.3. Some MRUs utilize battery packs as back-up batteries, per the equipment manual. (A battery pack is a set of (preferably) identical batteries or individual battery cells that are configured to deliver the desired voltage.) If a purchased battery pack arrives (a) without lead wires or (b) with loose terminal connections, request that CFS or other qualified vendor (a) secure loose terminal connections on new battery or (b) solder or connect lead wires from the spent battery to the new battery.

6.1.4.1.5. Replace batteries (SSF or PI supplied) on chart recorders if applicable.

6.1.4.1.6. If need for repair is noted, notify SSF Management or PI to initiate repair (contact SSF Management if owned by SSF or PI if PI owned).

6.1.4.2. Perform a Freezer Alarm Functionality Test using the warm-towel method for creating an alarm via the alarm system SOP to verify that alarm still functions as intended. Alarm testing of additional units connected via daisy chain to unit being tested is not required. Document results of alarm testing on Appendix B of this SOP. Completion of an alarm test worksheet per the alarm system SOP is not required.

6.1.4.2.1. If alarm does not function as intended, alert SSF Management and proceed per SF-1-10.

6.1.5. Biennially, if indicated by excessive ice build-up (for <-70°C units only), or if temperature of units over time have come close to or have reached OOS temperatures.
NOTE: The term Biennial is defined in SF-1-1. Document all actions on Mechanical Refrigeration Unit Biennial Maintenance Log, Appendix F.

NOTE: If backup space is limited, consult SSF Management. Document deviation per SF-1-9 if backup space is inadequate to accommodate defrost within the defined time frame.

6.1.5.1. Defrost Freezers

6.1.5.1.1. As a courtesy, owners are generally provided minimally one week notice prior to freezer's scheduled defrost.

6.1.5.1.1.1. Should SSF personnel fail to provide notice one week prior to defrost due date, a deviation (per SF-1-9 SOP for Deviation Management) need not be initiated.

6.1.5.1.1.2. If less than one week is available prior to defrost due date, notify owner of date defrost is planned and that SSF personnel will proceed with defrost unless PI requests otherwise.

6.1.5.1.2. Move samples to SSF back-up freezers or another approved unit under the same PI (as described in SF-1-10) and disconnect unit from the alarm system (as described in the alarm system SOP). Complete page 1 of SF-1-10 Appendix B for sample relocation.

6.1.5.1.2.1. NOTE: Empty racks should not remain in freezer during defrost.

6.1.5.1.2.2. NOTE: Samples should never be stored in unalarmed freezer.

6.1.5.1.3. Disconnect or turn off backup battery, as applicable. Power off unit.

6.1.5.1.4. Place towels on the floor.

6.1.5.1.5. Remove snow from the freezer, ensuring that no samples remain during defrost. (Utilize flashlight, if needed due to obstructed view from vapor, to ensure no samples remain before defrost.)

6.1.5.1.6. Open all freezer doors, external and internal, and leave open until defrosted.

6.1.5.1.7. Wipe down the freezer on the inside to remove any residual liquid.

6.1.5.1.7.1. Freezer must be defrosted for a minimum of 24 hours, though 48 hours is ideal.

6.1.5.1.8. Close doors, internal and external, and power on unit. Reconnect or turn on backup battery.

6.1.5.1.9. Confirm that the unit's settings for operating temperature and high/low alarm set points are still set as documented per the SF-1-4, Appendix D storage agreement for that unit (some units' settings will revert back to factory settings when powered off).

6.1.5.1.9.1. If the settings have changed, adjust them to defined settings per the storage agreement. Consult freezer manual as

needed. Document actions in the Comments section of Appendix F.

6.1.5.1.10. Allow the freezer to restore to its set temperature (most of the time will return to temperature overnight).

6.1.5.1.10.1. If unit does not reach its set temperature, notify SSF Management and defrost freezer for an additional 48 hours.

6.1.5.1.10.2. If unit does not reach its set temperature notify SSF Management and PI (if not SSF-owned) to determine corrective action.

6.1.5.1.10.3. If unit is not SSF-owned, follow the corrective actions approved by the PI. If SSF-owned, turn off unit and initiate repair.

6.1.5.1.10.4. Proceed per SF-1-10.

6.1.5.1.11. If freezer restores to its set temperature, reconnect unit to the alarm system and perform a Freezer Alarm Functionality Test per alarm system SOP to verify that it functions as intended.

6.1.5.1.11.1. If alarm does not function as intended, alert SSF Management and proceed per SF-1-10

6.1.5.1.12. Return samples to the freezer per procedure defined in SF-1-10.

6.1.5.1.13. Complete page 2 of SF-1-10 Appendix B documenting sample relocation.

6.1.5.1.14. Daily monitoring must be performed and documented on the day samples are returned to the freezer.

6.1.5.1.15. Notify owner that the defrosting procedure has been completed.

6.1.5.1.16. Attach both pages of SF-1-10 Appendix B to Appendix F of this SOP.

6.1.5.1.17. Record results and actions on Appendix F (of this SOP).

6.1.6. As needed:

6.1.6.1. Other units may be defrosted per Section 6.1.5 if indicated by excessive ice build-up.

6.1.6.2. Back-up batteries should be changed as indicated by a freezer's low-battery indicator.

6.1.7. Alternatively, performance of the display calibration verification and other routine maintenance by a contractor is acceptable upon receipt of adequate documentation. Documentation of calibration verification must include NIST-traceability of the instrumentation used and "as found" and "as left" temperature data. Attach documentation to Appendix B and/or F, as applicable.

6.1.7.1. Ensure that the "as-found" temperatures as documented by the vendor were within acceptance criteria. If the "as-found" temperatures were OOS, notify SSF Management or owner of unit and complete an OOS Event Report per SF-1-10. If the "as-left" values could not be brought within specification during the calibration by the vendor, initiate repair.

6.1.8. New and repaired freezers should sit at least 24 hours before being plugged in (in case units were not upright while in transit) unless arriving loaded and/or cold.

6.2. **Non-Routine Monitoring** – Documentation and follow-up of OOS conditions per SOP SF-1-10 (above acceptable range for which there is a local alarm, but a remote alarm is NOT generated) that occur at time points other than the routine temperature check:

6.2.1. Upon discovery of local alarm, verify temperature against acceptance criteria per Step 6.1.1.1.1, refer to the Mechanical Refrigeration Unit Non-Routine Monitoring Local Alarm Investigation Flowchart (Appendix G), and proceed per the following steps:

6.2.1.1. If temperature does not meet acceptance criteria:

6.2.1.1.1. Determine cause of alarm condition by asking personnel authorized to access the alarming freezer, in its proximity, what caused the alarm (i.e. sample access).

6.2.1.1.2. Set timer using a timer, computer workstation, personal phone, or other similar device for 15 minutes.

6.2.1.1.3. After 15 minutes, determine if a remote alarm has been generated.

6.2.1.1.4. If a remote alarm has generated:

6.2.1.1.4.1. Check temperature against acceptance criteria.

6.2.1.1.4.2. If temperature does not meet acceptance criteria:

6.2.1.1.4.2.1. Monitor freezer per Section 6.1.1.3.

6.2.1.1.4.2.2. If unable to resolve, proceed per SF-1-10.

6.2.1.1.4.3. If temperature meets acceptance criteria:

6.2.1.1.4.3.1. Investigate alarm failure (i.e. alarm wires disconnected, freezer malfunction, etc.).

6.2.1.1.4.3.2. If alarm wires are found to be disconnected:

6.2.1.1.4.3.2.1. Determine cause by asking personnel authorized to access the alarming freezer, in its proximity, if they accessed area behind freezers or moved the freezer.

6.2.1.1.4.3.2.2. Reconnect the wires and alarm test per alarm system SOP.

6.2.1.1.4.3.3. If unable to resolve, proceed per SF-1-10; Relocate samples per SF-1-10.

6.2.1.1.5. If a remote alarm has NOT generated:

6.2.1.1.5.1. Check temperature against acceptance criteria.

6.2.1.1.5.2. If temperature does not meet acceptance criteria:

6.2.1.1.5.2.1. Monitor freezer per Section 6.1.1.3.

6.2.1.1.5.2.2. Investigate alarm failure per Steps 6.2.1.1.4.3.1 through 6.2.1.1.4.3.2.2.

6.2.1.1.5.2.3. If unable to resolve, proceed per SF-1-10; Relocate samples per SF-1-10.

6.2.1.1.5.3. If temperature meets acceptance criteria, discontinue monitoring freezer.

6.2.1.2. If temperature meets acceptance criteria:

6.2.1.2.1. Investigate and resolve alarm condition (i.e. low battery level alarm)

6.2.1.2.1.1. If unable to resolve, proceed per SF-1-10; Relocate samples per SF-1-10.

6.2.1.2.2. Set timer using a timer, computer workstation, personal phone, or other similar device for 15 minutes.

6.2.1.2.2.1. If remote alarm is not generated, discontinue monitoring freezer.

6.2.1.2.2.2. If remote alarm has generated, proceed per Section 6.2.1.1.4.

6.2.1.3. Refer to Appendix G for assistance monitoring local alarming freezers prior to remote alarm generation.

6.3. Parameter changes for non-SSF units are documented on Appendix A (if unit equipped with chart recorder) or Appendix C during the month in which the change is initiated and as defined in SOP SF-1-4.

6.3.1. Investigator directives regarding non-standard acceptable parameters are listed on SF-1-4 Appendix D, a copy of which is posted on the front of the unit. The original is filed in the Operations Manager's office.

6.4. Retain copies of all SSF-owned unit repair documentation with freezer logs in the SSF Management office.

7. REFERENCES

7.1. ISBER Best Practices (current version)

8. DOCUMENTATION

8.1. Circular charts for non-SSF owned refrigeration units are maintained by owner.

8.2. Frequency terminology is defined in SF-1-1, SOP for Writing, Reviewing, and Maintaining SOPs.

8.3. Documents are maintained per SF-1-6, SOP for Controlled Document Management.

8.4. Deviations are managed per SF-1-9, SOP for Deviation Management.

8.5. Out-of-Specification (OOS) events are managed per SF-1-10, SOP for OOS Response and Notification Management.

9. APPENDICES

9.1. The current version of each of the following appendices is used to guide and/or implement this SOP:

APPENDIX A: Mechanical Refrigeration Unit Daily Monitoring and Maintenance Log (1 Page)
APPENDIX B: Mechanical Refrigeration Unit Annual Maintenance Log (1 Page)
APPENDIX C: Mechanical Refrigeration Unit Daily Monitoring Log (Without Chart Recorder) (1 Page)
APPENDIX D: Mechanical Refrigeration Unit Quarterly Maintenance Log (1 Page)
APPENDIX E: Mechanical Refrigeration Unit Re-Calibration Investigation Form (1 Page)
APPENDIX F: Mechanical Refrigeration Unit Biennial Maintenance Log (1 Page)
APPENDIX G: Mechanical Refrigeration Unit Non-Routine Local Alarm Investigation Flowchart (1 Page)
APPENDIX H: Mechanical Refrigeration Unit Monitoring Decision Tree Flowchart (1 Page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES

10.1. N/A

Mechanical Refrigeration Unit Daily Monitoring and Maintenance Log

Month:_____ Year:_____ Room:_____ Unit ID:_____

Daily Temp °C Acceptable Range:
(Circle applicable) Refrigerators 2-8°C*, Standard Freezers ≤ -20°C*, Ultra Low Freezers ≤ -60°C*
*** Unless otherwise designated by PI: _____°C**

Date	Temp	Chart Recorder Functioning	Initials	Weekly Chart Refrigerators: +/- 2°C, Standard Freezers: +/- 3°C, Ultra Low Freezers: +/- 5°C	Comments/Corrective Actions
1		Y N		**Week 1** Unit Digital: _____° C Chart Value: _____° C Acceptable: □ Yes □ No Chart Changed □ Initials/Date	
2		Y N			
3		Y N			
4		Y N			
5		Y N			
6		Y N			
7		Y N		**Week 2** Unit Digital: _____° C Chart Value: _____° C Acceptable: □ Yes □ No Chart Changed □ Initials/Date	
8		Y N			
9		Y N			
10		Y N			
11		Y N			
12		Y N			
13		Y N		**Week 3** Unit Digital: _____° C Chart Value: _____° C Acceptable: □ Yes □ No Chart Changed □ Initials/Date	
14		Y N			
15		Y N			
16		Y N			
17		Y N			
18		Y N			
19		Y N		**Week 4** Unit Digital: _____° C Chart Value: _____° C Acceptable: □ Yes □ No Chart Changed □ Initials/Date	
20		Y N			
21		Y N			
22		Y N			
23		Y N			
24		Y N			
25		Y N		**Week 5** Applicable: □ Yes □ No Unit Digital: _____° C Chart Value: _____° C Acceptable: □ Yes □ No Chart Changed □ Initials/Date	
26		Y N			
27		Y N			
28		Y N			
29		Y N			
30		Y N			
31		Y N			

Reviewed By:

Mechanical Refrigeration Unit Annual Maintenance Log					
Year: _____				**Unit ID: _____**	
Annual	Observation/Action	Acceptable Range	Acceptable	Initials/ Date	Comments / Corrective Actions (required if not acceptable)
Clean Filters	□Completed. No repairs indicated. □Other (see comments)	Completed. No repairs indicated.	□ Yes □ No		
Vacuum Condenser	□Completed. No repairs indicated. □Other (see comments)	Completed. No repairs indicated.	□ Yes □ No		
Check Gaskets	□Completed. No repairs indicated. □Other (see comments)	Completed. No repairs indicated.	□ Yes □ No		
Replace Backup Battery, if necessary (per Step 6.1.4.1.4)	□Replaced. □Adequate Charge (replacement unnecessary) □Other (see comments)	Replaced OR Adequate charge (replacement unnecessary)	□ Yes □ No		
Replace Chart Recorder Batteries (if applicable)	□Completed. □Not Applicable	Completed.	□ Yes □ No □ Not Applicable		
Alarm Functionality Test (performed per alarm system SOP)		Completed and Passed. Alarm delay reset to 15 minutes or alarm profile setting returned to "dry contact".	□ Yes □ No □ Yes □ No		
Non-SOP driven Annual Spreadsheet and Calendar updated?		Completed.	□ Yes □ No		
Reviewed By:					

Mechanical Refrigeration Unit Daily Monitoring Log

Month_____ Year _____ Room:_____ Unit ID:_____

Daily Temp °C Acceptable Range:
(Circle applicable) Refrigerators 2-8°C*, Standard Freezers ≤ -20°C*, Ultra Low Freezers ≤ -60°C*
*** Unless otherwise designated by PI: _____°C**

Date	Temp °C	Temp Accept. (Y=yes) (N=no)	Initials	Comments/Corrective Actions
1		Y N		
2		Y N		
3		Y N		
4		Y N		
5		Y N		
6		Y N		
7		Y N		
8		Y N		
9		Y N		
10		Y N		
11		Y N		
12		Y N		
13		Y N		
14		Y N		
15		Y N		
16		Y N		
17		Y N		
18		Y N		
19		Y N		
20		Y N		
21		Y N		
22		Y N		
23		Y N		
24		Y N		
25		Y N		
26		Y N		
27		Y N		
28		Y N		
29		Y N		
30		Y N		
31		Y N		

Reviewed By:

Mechanical Refrigeration Unit Quarterly Maintenance Log

Year: _____ Unit ID: _____

Difference:
Acceptable Range
2-8°C units = +/- 3 °C
Other units = +/- 10°C

Quarterly	NIST Unit's SSF ID	NIST Unit's Re-calibration Due Date	NIST unit's calibrated range includes temperature being measured (✓)	Mechanical Unit's Digital Display Temperature (°C)	NIST Temperature *to a tenth of a degree* (°C)	Difference Meets Acceptance Criteria*	Initials / Date
1						☐Yes ☐No	
2						☐Yes ☐No	
3						☐Yes ☐No	
4						☐Yes ☐No	

*Record Time of temperature measurement (T_0) for **all results that do not meet acceptance criteria**.

Q1: T_0 ❑ N/A _____ AM/PM **Q2:** T_0 ❑ N/A _____ AM/PM

Q3: T_0 ❑ N/A _____ AM/PM **Q4:** T_0 ❑ N/A _____ AM/PM

Wipe Down Completed

Q1: Completed ❑ Date/Initials _____ **Q2:** Completed ❑ Date/Initials _____

Q3: Completed ❑ Date/Initials _____ **Q4:** Completed ❑ Date/Initials _____

Comments

Reviewed by:

Mechanical Refrigeration Unit Re-Calibration Investigation Form

Unit ID:_____ Unit Type: ☐ -80°C ☐ -20°C ☐ 2-8°C

SSF Management Notified: ☐Complete Initials/Date:_____

Data Transcribed from Appendix D: Mechanical Refrigeration Unit Quarterly Maintenance Log (T_0)

(T_0) Unit Digital Display: _____° C (T_0) NIST Reading: _____° C Acceptable Difference: _____° C	**Note**: Unless justified below in the comment section, the same NIST unit should be used for the T_0, T_1 and T_2 time points. NIST SSF ID for T_0 _____	(T_0) Transcription documented by _____ Tech ID/Date

Documented Investigation

Data acquired while investigating the need for recalibration: Additional sheets attached? ❑ No ❑ Yes

T_1 (1 to 2 hours after T_0): NIST SSF ID for T_1 _____ (T_1) _____ AM/PM

(T_1) Unit Digital Display:_____°C (T_1) NIST Reading: _____°C

Acceptable: ❑ No ❑ Yes Tech ID/Date _____

T_2 (> 12 hours after T_1): NIST SSF ID for T_2 _____ (T_2) _____ AM/PM

(T_2) Unit Digital Display:_____°C (T_2) NIST Reading: _____°C

Acceptable: ❑ No ❑ Yes Tech ID/Date _____

Recalibration Required :
- ❑ Yes – All three temp readings **not** acceptable
- ❑ No – Explain reason in comments
- ❑ Other – Not recalibration issue - further investigation required

If yes or other, PI Notified: ❑ Complete Agreed to recalibration? ❑ No ❑ Yes ❑ N/A
PI Name: _____ Tech ID/Date:_____

Recalibration Record	As Found Temperature: _____°C	As Left Temperature: _____°C	Initials/Date: _____

Temperature Re-Check

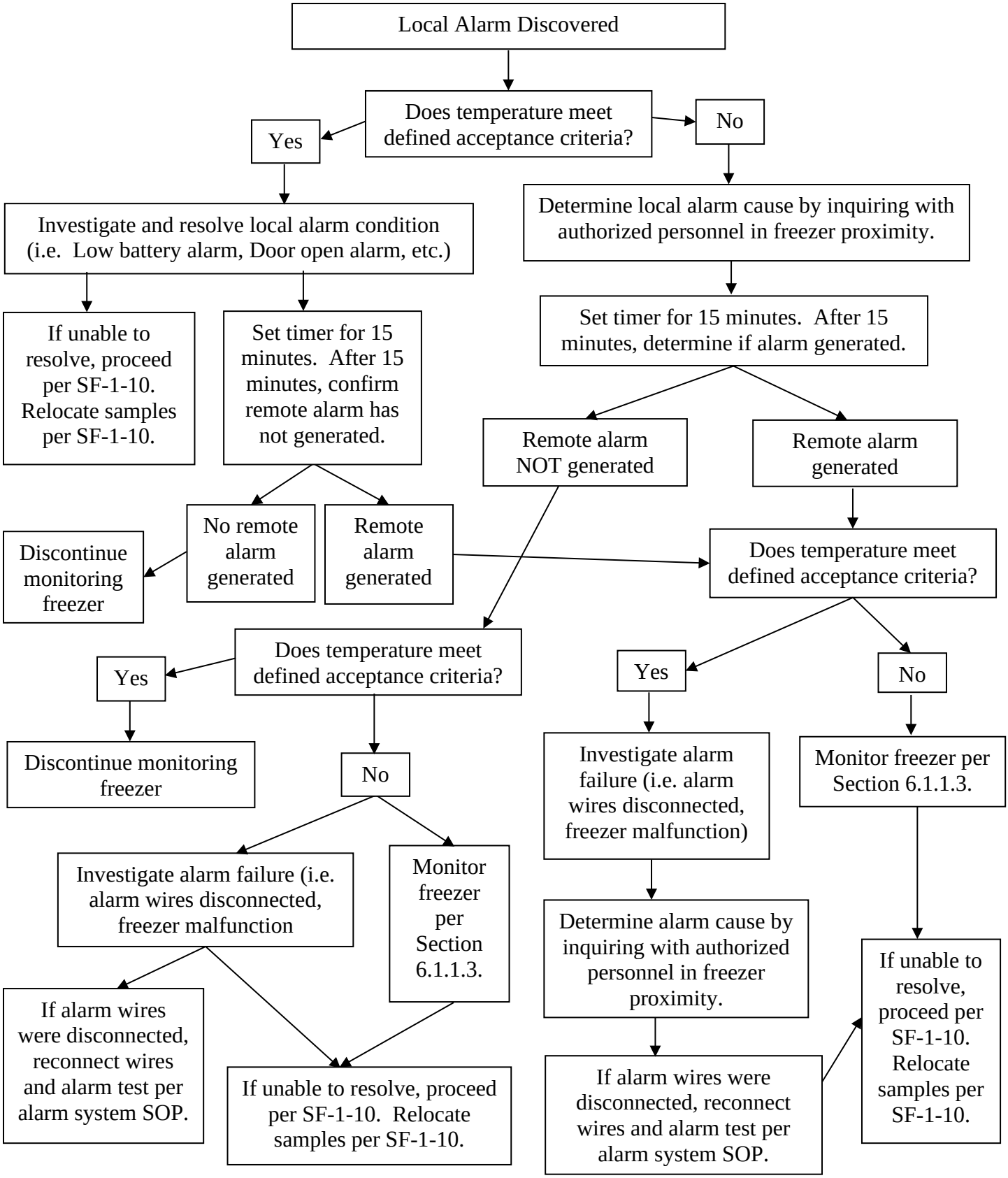
Time Lapsed From Date of Calibration	Date	NIST SSF ID	NIST Re-Calibration Due Date	Unit Digital Display ° C	NIST Temperature ° C	Acceptable (range: +/- ____° C	Initials/Date
Day 1						❑ Yes ❑ No	
Day 2						❑ Yes ❑ No	
1 Week						❑ Yes ❑ No	
1 Month						❑ Yes ❑ No	

Comments

Reviewed By:

Mechanical Refrigeration Unit Biennial Maintenance Log			
Year:		**Unit ID:**	
PI Notified	Name of Contact(s) Date/Initials:		
Samples Moved	New Location(s) Date/Initials:	Old Unit Unalarmed: ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	
Unit Defrosted	Backup Battery Disconnected / Switched Off ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	Unit Turned Off / Defrosted ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	
Unit Powered On	Unit Turned On: ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	Backup Battery Reconnected / Switched On ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	Verify operating and alarm set points on unit are set as stated per the storage agreement for that unit? ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:
Unexpected Observations, if applicable	Date/Initials:		
Unit Placed Back in Service	Unit Re-alarmed: ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	Alarm Functionality Test Completed: ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	Alarm Functionality Test Passed: ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:
Samples Returned & PI Notified	Samples Returned ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:	Name of Contact(s) ☐ See "PI Notified" field. ☐ Changed from "PI Notified" (list contacts): Date/Initials:	Non-SOP driven Biennial Spreadsheet and calendar updated? ☐ Yes ☐ No (If no, explain in Comment Section) Date/Initials:
Comments / Corrective Actions (required if not acceptable) (Initial & Date all Comments)			
Reviewed By:			

Mechanical Refrigeration Unit Non-Routine Monitoring Local Alarm Investigation Flowchart



Mechanical Refrigeration Unit Monitoring Decision Tree Flowchart