

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR -80°C LIQUID NITROGEN FREEZERS

CHAPTER: 3-Equipment

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1. REVISION

1.1. Significant changes incorporated in this version include:

- 1.1.1. 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.
- 1.1.2. Added Section 4.2 defining alarm system management terminology.
- 1.1.3. Throughout SOP, references to SF-2-4 and Siemens were revised to align with Scope revisions.
- 1.1.4. In Section 6.1, Appendix C name revised to specify applicability to R3-C156 and correct title to reflect applicability to -80°C LN₂ freezers.
- 1.1.5. Throughout Section 6.1 and in Step 6.3.1, added references to Appendix F, defining Acceptable Ranges in TK 252.
- 1.1.6. Revised Step 6.1.1.3 to define determination of standard acceptable range for SSF-owned freezers.
- 1.1.7. Added Section 6.1.1.5 directives for response to inability to fill freezers and directives to check freezer integrity.
- 1.1.8. Step 6.1.2.1.1 lid defrost courtesy notification directives were deemed unnecessary and removed.
- 1.1.9. Section 6.1.3.2 revised to define that quarterly equipment wipe down includes wiping down the freezer top, handles, lid, and control panel.
- 1.1.10. Step 6.1.4.6.2.1 revised to indicate that the Chart MVE default password may unlock a password-protected freezer.
- 1.1.11. Corrected Step 6.1.4.6.2.7, adding omitted directive that documentation of alarm testing on alarm test worksheet per the alarm system SOP is not required.
- 1.1.12. Added Section 6.1.4.8, annual wipe down of entire freezer procedure.
- 1.1.13. Added Section 6.1.5.4 directives for verification following vendor maintenance.
- 1.1.14. Section 6.1.6.2.9 revised to specify completion of an OOS *Event Report* per SF-1-10, as directed.
- 1.1.15. Added Campus Facility Services contact information in Section 7.
- 1.1.16. Section 9 revised to reflect new title of Appendix E and add Appendix F.

- 1.1.17. Appendix B revised for:
 - 1.1.17.1. New quarterly and annual freezer wipe down procedure
 - 1.1.17.2. Require listing NIST thermometer SSF ID versus serial number to align with SF-3-1 and SF-3-2.
 - 1.1.17.3. Inclusion of alarm functionality test directives applicable to the Sonicu alarm system
- 1.1.18. Appendix C revised to:
 - 1.1.18.1. Specify applicability to R3-C156
 - 1.1.18.2. Reflect that all Vario freezers formerly housed in R3-C156 were moved to TK 252
- 1.1.19. Appendix D revised to reference Appendix F.
- 1.1.20. Appendix E alarm system and SOP references revised to align with revisions referenced in the Scope section.
- 1.1.21. Appendix F added to define acceptance criteria for freezers in TK 252.

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 -80°C liquid nitrogen freezers owned or contracted for storage in the SSF. This procedure satisfies guidance set forth in ISBER.

3. PRINCIPLE

- 3.1. -80°C LN₂ freezers are an energy efficient alternative to ultra-low MRU freezers, with less power consumption and lower operating costs than ultra-low MRUs. -80°C LN₂ freezers provide a consistent temperature profile even with the lid open, minimal increase in temperature when warm samples are introduced, and no thermal load. All -80°C liquid nitrogen freezers owned or contracted for storage in the SSF are supported by Indiana CTSI SSF Staff. The refrigeration 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 personnel operating and maintaining -80°C liquid nitrogen freezers owned or contracted for storage in the SSF. It provides the schedule and procedures for monitoring and maintaining the units and defers response to OOS conditions to SF-1-10 SOP for Out of Specification Condition Notification and Management. Alarming and response is managed via 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. Safety relevant to the liquid nitrogen is addressed in SF-2-2 SOP for LN₂ System and Freezer Room Operations.
- 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
- 5.2. General Purpose Cleaner (Example: Windex)
- 5.3. NIST-traceable thermometer (SF-3-7 SOP for Thermometers)
- 5.4. Timer (SF-3-6 SOP for Timers) or similar device
- 5.5. Cryo approved aprons
- 5.6. Cardboard "slab"

6. PROCEDURE:

6.1. Routine Monitoring and Maintenance

Note: At unit intake, complete/update the SN Specific Acceptable ranges for -80°C LN₂ freezer probe temperature template – R3-C156 (Appendix C) or SN Specific Acceptable ranges for -80°C LN₂ level and probe temperature – TK 252 template (Appendix F) to include by location: S/N, acceptable temperature range.

Note: Routine monitoring and maintenance of a -80°C LN₂ 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 for each probe of each unit.

6.1.1.2. NOTES:

6.1.1.2.1. The Temp A probe measures temperature at the level of the top boxes in the freezer.

6.1.1.2.2. Temp B probe measures temperature at the level of the bottom boxes in the freezer. Temp B temperatures are recorded for informational purposes.

6.1.1.3. Temp A & Temp B Acceptable Range: For each unit, refer to acceptable range criteria documented on the applicable -80°C LN₂ Freezer Daily and Monthly Monitoring and Maintenance Log (Appendix A). The acceptable range criteria are defined for each unit per Appendix C and Appendix F and documented on Appendix A at the time the log is created.

Acceptable Range is generally $\leq -60^{\circ}\text{C}$, unless otherwise defined by the PI for PI-owned freezers or SSF for SSF-owned freezers.

6.1.1.4. If within acceptable range (i.e., normal operating range), record readings and tech initials on Appendix A.

6.1.1.5. If temperature is outside of acceptable range (i.e., action limit range/alarm condition):

6.1.1.5.1. Evaluate integrity of the freezer, checking for abnormal frost buildup on the freezer.

6.1.1.5.1.1. If it is found that the integrity of the unit has been compromised, such as in the case of structural vacuum failure, notify SSF Management as soon as possible. Relocate samples and proceed to fill out an OOS Event Report per SF-1-10 SOP for Out of Specification Response and Notification Management. Discuss with SSF Director to determine further course of action.

6.1.1.5.1.2. If the integrity of the unit has not been compromised, proceed to the next step.

6.1.1.5.2. If temperature is warm because LN₂ cannot be added, evaluate whether the E-Stop has been activated. Reset the E-Stop, if it has been activated. If the E-Stop will not reset, evaluate E-Stop system compressed air pressure per SF-2-2 SOP for LN₂ System and LN₂ Freezer Room Operations, and contact Campus Facility Services as needed for TK 252.

6.1.1.5.2.1. If LN₂ still cannot be added, notify SSF Management as soon as possible. Relocate samples per SF-1-10. Proceed to fill out an OOS Event Report per SF-1-10.

Discuss with SSF Director to determine further course of action, such as contacting Praxair for assistance.

- 6.1.1.5.3. If temperature reaches the action limits stated in Step 6.1.1.3, recheck in 15 minutes to see if the unit recovers to within the parameters.
- 6.1.1.5.4. If unit is recovered, record and accept.
- 6.1.1.5.5. If unit is stable or approaching recovery, repeat Step 6.1.1.5.1 up to 3 times (not to exceed 1 hour.) Record each temperature in the comments section of Appendix A or document temperatures on SF-1-10 Appendix E, OOS Temperature Monitoring Log (Suggested Tool).
- 6.1.1.5.6. If unit reaches acceptable range, record and accept. Hit the Alarm Mute button on the freezer controller to clear the alarm condition.
- 6.1.1.5.7. If unit fails to reach acceptable range after 1 hour but is trending colder, monitor every 30 minutes for up to an additional 2 hours (i.e., a total of 3 hours), recording each temperature as per above. If unit reaches acceptable range, record and accept. Hit the Alarm Mute button on the freezer controller to clear the alarm condition. If unit fails to reach acceptable range, notify SSF Management and correct if possible. If unable to resolve, proceed per SF-1-10. Relocate samples per SF-1-10.
- 6.1.1.5.8. If unit does not reach acceptable range and is NOT trending colder after 1 hour, notify SSF Management and correct if possible. If unable to resolve, proceed per SF-1-10. Relocate samples per SF-1-10.
- 6.1.1.5.9. Document results and any actions taken on the -80°C LN₂ Freezers Daily Monitoring Log (Appendix A).

6.1.2. Monthly

- 6.1.2.1. Visually check the lid for excessive ice build-up and defrost as needed.
- 6.1.2.2. If excessive ice build-up is observed, defrost the lid per the following:
 - 6.1.2.2.1. The lid is placed in the open position.
 - 6.1.2.2.2. The opening of the freezer is covered as completely as possible. If available, use two cryo-aprons. A cardboard slab large enough to cover the freezer opening may be used as a substitute for the cryo aprons.
 - 6.1.2.2.3. Defrost the lid until excessive ice has been removed.
 - 6.1.2.2.4. Monitor Unit temperature every 30 minutes.
 - 6.1.2.2.5. Document completion on Appendix A.
- 6.1.2.3. If no excessive ice build-up is observed, document on Appendix A.

6.1.3. Quarterly

- 6.1.3.1. NOTE: the term “Quarterly” does not represent calendar quarters and is defined in SF-1-1 SOP for Writing, Reviewing, and Maintaining SOPs.
- 6.1.3.2. Wipe down the top, handles, lid, and control panel of each unit with a cloth and general purposes cleaner.
- 6.1.3.3. Record actions, date and initials on the -80°C LN₂ Freezer Quarterly/Annual Maintenance Log (Appendix B).

6.1.4. **Annually**

6.1.4.1. NOTE: Before completing any of the following, consider directives in Section 6.1.5, if applicable.

6.1.4.2. Temperature display calibration verification

6.1.4.2.1. Place a notice on the LN₂ Freezer stating “CALIBRATION IN PROCESS – DO NOT OPEN”.

6.1.4.2.2. Place the probe of an NIST-traceable thermometer (capable of reading within expected range and within calibration limits and time per SOP SF-3-7) inside the unit, as close as possible to the freezer probe.

6.1.4.2.2.1. The freezer probe is located near the top of the racks, in the center of the freezer, within a column of metal.

6.1.4.2.2.2. Place the NIST probe at the level of the top of a rack, as close to the middle of the freezer as possible without allowing the NIST probe to touch anything; this is accomplished by threading the probe through the handle of a rack.



6.1.4.2.3. Wait at least 20 minutes, until thermometer is stabilized.

6.1.4.2.4. Read NIST thermometer.

6.1.4.2.5. Compare NIST thermometer with digital readout of top probe, probe A.

6.1.4.2.6. NOTE: Temp B (bottom probe) temperatures are recorded for informational purposes only, therefore probe B calibration is not verified annually.

6.1.4.2.7. Record the digital readout and the NIST thermometer reading on Appendix B.

6.1.4.2.8. If difference exceeds 10°C proceed as follows:

6.1.4.2.8.1. If unit is SSF owned, notify SSF Management and document as an OOS per SF-1-10. Initiate repair if warranted.

6.1.4.2.8.2. If unit is not SSF owned, notify SSF Management as well as the owner of the unit. Complete an OOS per SF-1-10. Corrective action is the responsibility of the owner.

- 6.1.4.2.9. Record results and actions on Appendix B.
- 6.1.4.3. Check stair's slip resistant strips on each freezer for peeling and cracking
 - 6.1.4.3.1. If repairs are required, notify SSF Management, the SSF (if owned by SSF) or the PI (if PI-owned) to initiate repair.
 - 6.1.4.3.2. Observe and record results on Appendix B.
- 6.1.4.4. Check step assembly
 - 6.1.4.4.1. Verify that the hinges are free of cracks and that all connections are secure.
- 6.1.4.5. Check Styrofoam Lid integrity on each freezer for chipping and cracking
 - 6.1.4.5.1. If repairs are required, notify SSF Management, the SSF (if owned by SSF) or the PI (if PI-owned) to initiate repair.
 - 6.1.4.5.2. Observe and record results on Appendix B.
- 6.1.4.6. Perform a Freezer Alarm Functionality Test per the alarm system SOP to verify that alarm still functions as intended.
 - 6.1.4.6.1. Annual Freezer Alarm Functionality Testing may NOT be waived by any personnel or entity outside the SSF (e.g., GLP biorepository request per SF-1-13, Appendix C submission).
 - 6.1.4.6.2. Activate Unit Alarm Test Function:
 - 6.1.4.6.2.1. On the -80°C LN₂ unit monitor, hit the setup button, if password is required, hit enter four times. If that does not work, enter password 3-4-5-6 (Chart MVE default password). If that does not work, refer to freezer manual or ask PI.
 - 6.1.4.6.2.2. Select temperature menus by hitting the enter button.
 - 6.1.4.6.2.3. Select Temp A; Hit ▲/▼ to scroll until you see alarm test.
 - 6.1.4.6.2.4. To begin alarm test, use the ▲/▼ button to change from 'no' to 'yes'. Hit enter and temperature A will start getting warmer. If temperature begins to return to normal temperature before the alarm system delay has passed, begin alarm test again using Step 6.1.4.6.2.
 - 6.1.4.6.2.5. After alarm test is complete, the temperature will return to actual temperature of -80°C LN₂ freezer and the alarm test function will automatically return to 'no'.
 - 6.1.4.6.2.6. Hit the Alarm Mute button on the freezer controller to clear the alarm condition.
 - 6.1.4.6.2.7. Document completion of testing on Appendix B of this SOP. Documentation of alarm testing on alarm test worksheet per the alarm system SOP is not required.
 - 6.1.4.6.2.8. If alarm does not function as intended, notify SSF Management and complete an OOS per SF-1-10.
- 6.1.4.7. Evaluate freezer for Defrost Necessity:
 - 6.1.4.7.1. Visually check freezer for excessive ice build-up.
 - 6.1.4.7.2. If excessive ice build-up is observed, document results on Appendix B and proceed per Section 6.1.6.
 - 6.1.4.7.3. If no excessive ice build-up is observed, document results on Appendix B.
 - 6.1.4.7.4. NOTE: Selecting "Minimal or no ice build-up in freezer" on Appendix B meets acceptance criteria and defrost is not required.

- 6.1.4.8. Cleaning of Freezer Exterior
 - 6.1.4.8.1. Wipe down the exterior of each unit with a cloth and general purposes cleaner.
 - 6.1.4.8.2. Record actions, date and initials on Appendix B.
- 6.1.5. Alternatively, display calibration verification and other routine maintenance performed by a contractor are acceptable if SSF standards are met (per Section 6.1.4) and/or unit owner accepts vendor documentation and procedure as adequate. Alarm testing must be performed by SSF personnel as described in Step 6.1.4.6 and may not be delegated to a contractor.
 - 6.1.5.1. If calibration verification is completed by contractor, documentation must be provided, including as found and as left temperature data.
 - 6.1.5.2. Documentation must include NIST-traceability of any temperature measurement instrumentation used.
 - 6.1.5.3. If any information was not provided on vendor documents that are required per SSF standards, notify owner of unit to determine if the supplied documentation is acceptable as is.
 - 6.1.5.3.1. If the owner deems the documentation to be acceptable, attach proof of acceptability (i.e. email) and vendor documentation to Appendix B.
 - 6.1.5.3.2. If the owner deems the contractor documentation to be unacceptable, and if the owner does not want the vendor to repeat the calibration (or if the due date is approaching), SSF personnel will attempt to perform the required calibration verification and routine maintenance as described in Section 6.1.4. If the owner does want the vendor to repeat the calibration, ensure that this is completed prior to the due date.
 - 6.1.5.4. After PM completion by vendor:
 - 6.1.5.4.1. Evaluate "as-found" & "as-left" temperatures as documented by the vendor. If "as-found" and/or "as-left" temperatures were not within acceptance criteria, verify probe depth per Section 6.1.5.4.3.
 - 6.1.5.4.1.1. If "as-found" and or "as-left" temperatures could not be brought within specification during the calibration by the vendor and/or remain OOS after probe depth verification, notify SSF Management or owner of unit and complete an OOS Event Report per SF-1-10.
 - 6.1.5.4.2. Confirm settings are as defined in Appendices C and F.
 - 6.1.5.4.3. Verify that the LN₂ temperature probes have not been moved from their original position, by visually inspecting that the probe depth setting marker (an indicator on the probe's cable) is immediately above the opening of the freezer's probe channel entrance.
 - 6.1.5.4.3.1. If the probe depth setting marker is not visible, consult SSF Management. Only at SSF Management direction, remove probe, remeasure appropriate depth, and place a new mark if necessary (using paint, durable ink, or similar) on the LN₂ probe cable at the point at which the probe enters the freezer's probe channel). Cover the probe depth setting marker with clear tape. Alternately, the probe setting can be indicated with duct tape or similar.
 - 6.1.5.4.3.2. Old probe depth setting markers that are found to be out of place must be removed (using appropriate product,

such as environment grade ETOH for latex paint) after new mark has been established.

- 6.1.5.5. All routine maintenance as described per Section 6.1.4 must be completed. If the contractor fails to complete/document required maintenance defined in this SOP, it is the responsibility of the SSF personnel to complete the remainder of the maintenance and document on Appendix B.
- 6.1.6. When indicated by excessive ice build-up, defrost freezer.
- 6.1.6.1. Freezer Defrost Scheduling
- 6.1.6.1.1. **For defrost due to excessive ice build-up discovered by SSF (per Section 6.1.4.7):** Notify owner of findings, request defrost approval, and schedule defrost with qualified vendor. Proceed per Section 6.1.6.2.
- 6.1.6.1.2. **For defrost upon request:** No notification requirement. Schedule defrost with qualified vendor. Proceed per Section 6.1.6.2.
- 6.1.6.1.3. Alternately, owner may schedule defrost with qualified vendor and notify SSF of scheduled service date. SSF proceeds per Section 6.1.6.2.
- 6.1.6.2. Defrost Process:
- 6.1.6.2.1. At least 24-48 hours prior to vendor's scheduled arrival, move samples to SSF back-up freezer(s) (as described in SF-1-10) and disconnect unit from the alarm system (as described in alarm system SOP). Complete page 1 of SF-1-10 Appendix B for sample relocation.
- 6.1.6.2.2. Close LN₂ supply valve to remove LN₂ supply.
- 6.1.6.2.3. Disconnect backup battery.
- 6.1.6.2.4. Disconnect freezer from power supply.
- 6.1.6.2.5. Open hinged lid and leave open until defrosted.
- 6.1.6.2.6. Allow the freezer storage space to warm to room temperature and visible moisture within freezer to evaporate.
- 6.1.6.2.7. Per equipment manual, defrost includes purging the plumbing assembly of moisture, and this process is to be completed by a qualified vendor.
- 6.1.6.2.8. Attach vendor documentation to the -80°C LN₂ Freezer Defrost Log (Appendix D).
- 6.1.6.2.9. Startup after defrost:
- 6.1.6.2.9.1. Upon completion of plumbing assembly purge by qualified vendor, and visual confirmation that cabinet is dry, close lid.
- 6.1.6.2.9.2. Reconnect freezer to power supply.
- 6.1.6.2.9.3. Reconnect battery backup.
- 6.1.6.2.9.4. Turn on LN₂ supply.
- 6.1.6.2.9.5. Allow the freezer to restore to its set temperature.
- 6.1.6.2.9.6. If unit does not reach its set temperature, per Step 6.1.1.5, notify SSF Management and PI (if not SSF owned). Initiate repairs, if necessary, and complete an OOS Event Report per SF-1-10.
- 6.1.6.2.9.7. If unit digital display is within range described in Step 6.1.1.3, perform temperature display calibration verification per Section 6.1.4.2.

- 6.1.6.2.9.8. If freezer restores to its set temperature, reconnect unit to the alarm system and perform a Freezer Alarm Functionality Test per Section 6.1.4.6 to verify that it functions as intended.
- 6.1.6.2.9.9. If alarm does not function as intended, notify SSF Management and complete an OOS Event Report per SF-1-10.
- 6.1.6.2.9.10. Once all acceptance criteria are met and alarm is functional, return samples to the freezer following the procedure defined in SF-1-10.
- 6.1.6.2.10. Daily monitoring must be performed and documented on the day samples are returned to the freezer.
- 6.1.6.2.11. Notify owner that the defrosting procedure has been completed. Complete page 2 of SF-1-10 Appendix B for sample relocation.
- 6.1.6.2.12. Attach both pages of SF-1-10 Appendix B to Appendix D.
- 6.1.6.2.13. Record results and actions on Appendix D.

6.2. Non-Routine Monitoring – Documentation and follow-up of OOS conditions per SOP SF-1-10 (above acceptable range for which there is an audible or visual alarm, but a remote notification 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 6.1.1.3, refer to the -80°C LN₂ Freezer Non-Routine Monitoring Local Alarm Investigation Flowchart (Appendix E), 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 remote alarm has been generated.
 - 6.2.1.1.4. If 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 6.1.1.5.
 - 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 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 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 6.1.1.5.

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:

6.2.1.1.5.3.1. 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 notification alarm is not generated, discontinue monitoring freezer

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

6.2.1.3. Refer to Appendix E for assistance monitoring audible / visual alarming freezers prior to remote notification alarm generation.

6.3. Parameter changes for non-SSF units are documented on Appendix A during the month in which the change is initiated and as defined in SOP SF-1-4.

6.3.1. Appendix C or Appendix F is updated to reflect the new parameters.

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)

7.2. MVE Vario Series with MVE Vario Pro Controller Technical Manual

7.3. Campus Facility Services (CFS) Switchboard: 317-278-1900

8. DOCUMENTATION

8.1. Maintenance and Monitoring Logs are submitted for review to SSF Management and maintained per SF-1-6 SOP for Controlled Document Management.

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

8.3. 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: -80°C LN₂ Freezer Daily and Monthly Monitoring and Maintenance Log (1 Page)

APPENDIX B: -80°C LN₂ Freezer Quarterly/Annual Maintenance Log (1 Page)

APPENDIX C: Template of the SN Specific Acceptable ranges for -80°C LN₂ freezer probe temperature – R3-C156 (1 Page)

APPENDIX D: -80°C LN₂ Freezer Defrost Log (1 Page)

APPENDIX E: -80°C LN₂ Freezer Non-Routine Monitoring Local Alarm Investigation Flowchart (1 Page)

APPENDIX F: Template of the SN Specific Acceptable ranges for -80°C LN₂ freezer probe temperature – TK 252 (1 Page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVE

10.1. N/A

Month:		Year:			
-80°C LN₂ Freezer Daily & Monthly Monitoring and Maintenance Log				Unit ID:	
Date	Temperature (°C)		Both Ranges Acceptable (Y=yes) (N=no)	Initials	Comments / Corrective Actions
	Temp A Acceptable Range: ≤ _____ °C	Temp B* Acceptable Range: ≤ _____ °C			
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		<u>Lid Defrost</u> Defrost Required: <input type="checkbox"/> Yes <input type="checkbox"/> No Defrost Completed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A (Document any unexpected observations in Comments Section) Initials / Date:
28			Y N		
29			Y N		
30			Y N		
31			Y N		
Reviewed By:					

* Recorded for Informational Purposes only

Year: _____

-80°C LN₂ Freezer Quarterly/Annual Maintenance Log				Unit ID: _____		
Quarterly Wipe Down: Top of freezer; handles, lid, control panel	Quarter	Completed Yes / No	Initials / Date	Quarter	Completed Yes / No	Initials / Date
	1	<input type="checkbox"/> Yes <input type="checkbox"/> No		3	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No		4	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Quarterly Wipe Downs Reviewed By:						
Difference: <i>Acceptable Range = +/- 10°C</i>						
Annually	Unit Digital Display (°C)	NIST Temperature (°C)	Acceptable	Initials/Date	Comments / Corrective Actions (required if not acceptable)	
Temperature calibration verification			<input type="checkbox"/> Yes <input type="checkbox"/> No			
NIST SSF ID:		Re-calibration Due Date:				
NIST unit's calibrated range includes temperature being measured					<input type="checkbox"/> Yes <input type="checkbox"/> No	
Annually			Acceptable	Initials/Date	Comments	
Alarm Functionality Test (performed per alarm system SOP)	Completed and Passed:		<input type="checkbox"/> Yes <input type="checkbox"/> No			
	Alarm delay reset to 15 minutes or alarm profile setting returned to "dry contact":		<input type="checkbox"/> Yes <input type="checkbox"/> No			
Freezer Wipe Down	Completed:		<input type="checkbox"/> Yes <input type="checkbox"/> No			
Annually	Observation	Acceptable Range	Acceptable	Initials/Date	Comments / Corrective Actions (required if not acceptable)	
Stair's Slip Resistant Strips Integrity	<input type="checkbox"/> Minimal or no cracking/peeling <input type="checkbox"/> Other. See comments	Minimal or No Cracking or peeling	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Step Assembly	<input type="checkbox"/> Hinges Free of Cracks <input type="checkbox"/> All Connections Secure <input type="checkbox"/> Other. See comments	Hinges Free of Cracks; All Connections Secure	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Styrofoam Lid Integrity	<input type="checkbox"/> Minimal or no cracking/peeling <input type="checkbox"/> Other. See comments	Minimal or No Cracking or Chipping	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Defrost Evaluation	<input type="checkbox"/> Minimal or no ice build-up in freezer <input type="checkbox"/> Other. See comments. If defrost required, proceed to Appendix D	Minimal or no ice build-up in freezer (Defrost not required)	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Non-SOP driven SSF Shared Calendar Updated?		Completed	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Comments:						
Annual Reviewed By:						

SN Specific Acceptable ranges for -80°C LN₂ freezer probe temperature – R3-C156

SN _____
Temp A: °C
Temp B: °C
D1

SN _____
Temp A: °C
Temp B: °C
D2

D3

D4

POST

SN _____
Temp A: °C
Temp B: °C
C1

SN _____
Temp A: °C
Temp B: °C
C2

SN _____
Temp A: °C
Temp B: °C
C3

C4

C5

POST

B1

B2

B3

B4

B5

SN _____
Temp A: °C
Temp B: °C
A1

Effective Date: _____
Obsolete Date: _____

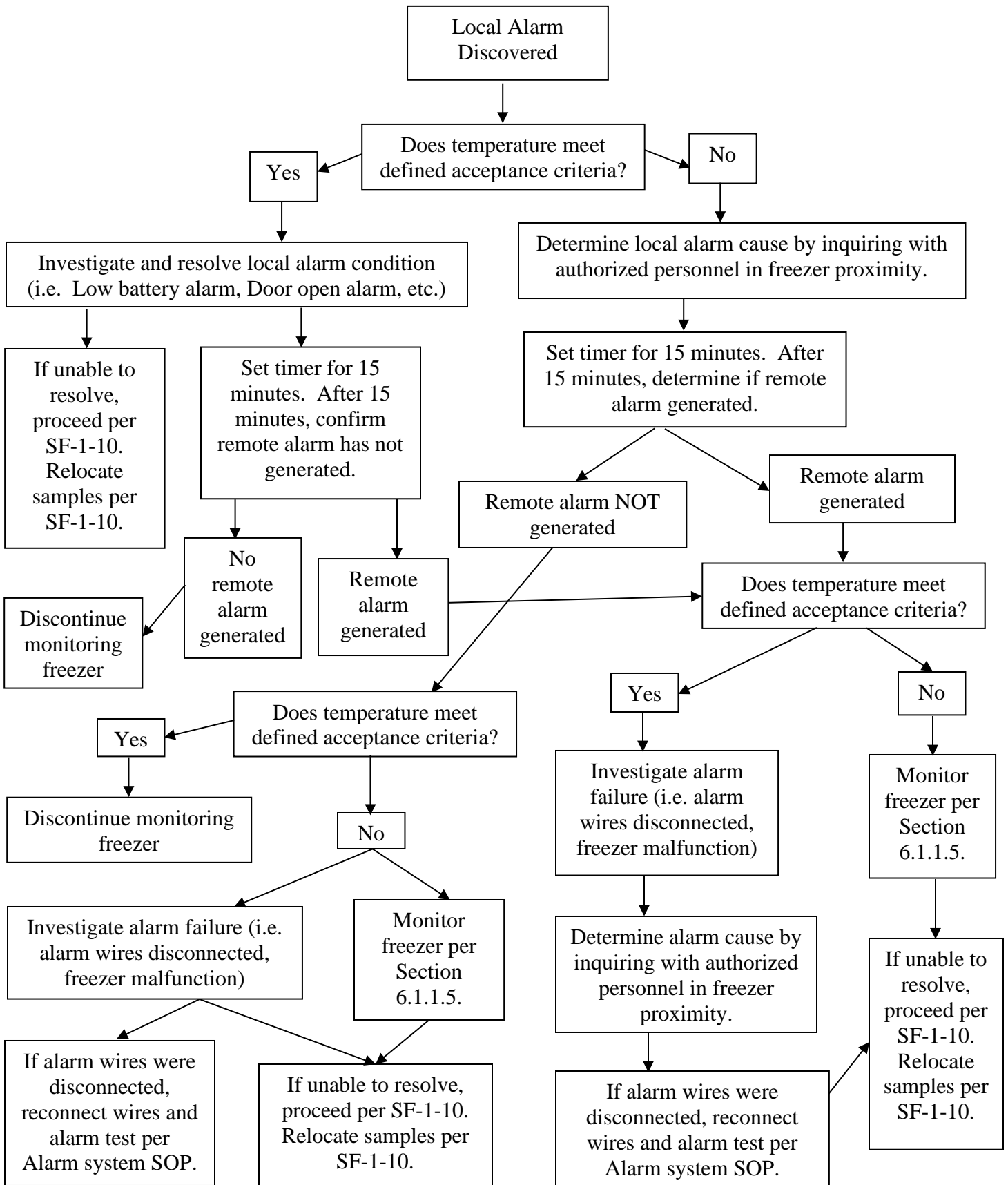
Units with dashed borders are traditional LN₂ freezers.

A2

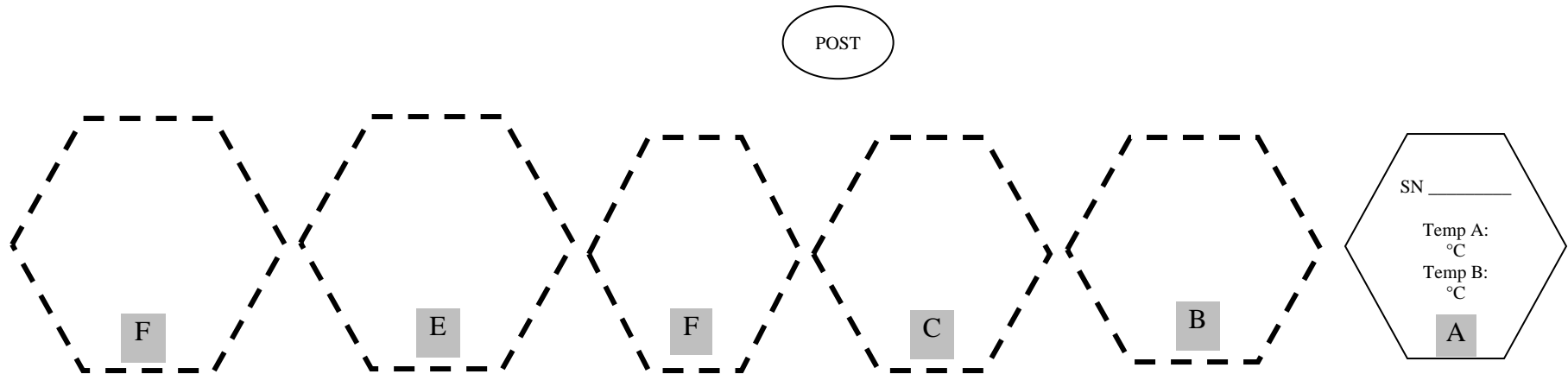
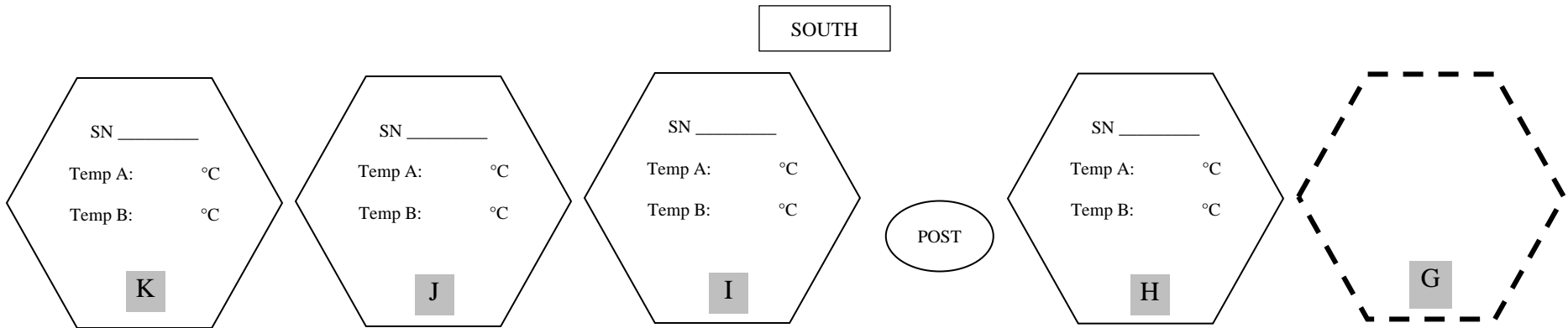
A3

-80°C LN₂ Freezer Defrost Log			
Year: <input type="text"/>		Unit ID: <input type="text"/>	
PI Notified / Defrost Scheduled	Name of Contact(s): Date/Initials:		Date Defrost is Scheduled with Qualified Technician: Date/Initials:
Samples Moved	New Location(s): Date/Initials:	Old Unit Unalarmed: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	
Unit Defrosted	Backup Battery Disconnected: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	Unit Shut Down / Defrosted: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	
Vendor Defrost Completed	Defrost Procedure (Plumbing Assembly Purge) Completed by Qualified Vendor: (Record Unexpected Observations below and attach any documentation provided by vendor to Appendix D) <input type="checkbox"/> Yes <input type="checkbox"/> No Date/Initials:		
Unit Powered On	Unit Turned On: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	Backup Battery Reconnected: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	Verify operating and alarm set points on unit are set as stated per SF-3-16 Appendix C or Appendix F. <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:
Unexpected Observations, if applicable	 Date/Initials:		
Unit Placed Back in Service	Unit Re-alarmed: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	Alarm Functionality Test Completed: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	Alarm Functionality Test Passed: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:
Samples Returned & PI Notified	Samples Returned: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:	Name of Contact(s): <input type="checkbox"/> See "PI Notified" field. <input type="checkbox"/> Changed from "PI Notified" (list contacts): Date/Initials:	Non-SOP driven Freezer Maintenance Spreadsheet and calendar updated: <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, explain in Comment Section) Date/Initials:
Comments / Corrective Actions (required if not acceptable) (Initial & Date all Comments)	 		
Reviewed By:	<input type="text"/>		

-80°C LN₂ Freezer Non-Routine Monitoring Local Alarm Investigation Flowchart



SN Specific Acceptable ranges for -80°C LN₂ freezer probe temperature – TK 252



Units with dashed borders are traditional LN₂ freezers.

Effective Date:
Obsolete Date: