INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR LIQUID NITROGEN FREEZERS

CHAPTER: 3-Equipment

SOP #: SF-3-2.11

SUPERSEDES SOP #: N/A

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1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. Corrected erroneous section / step references as needed.
      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. 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 6.1.1.1.3.2.2 response to inability to fill freezers, directing SSF personnel to SF-2-2, since different compressed air systems are used in R3 and TK. Personnel are additionally directed to contact CFS as needed for TK 252.
      1.1.7. Section 6.1.2 revised to define that quarterly equipment wipe down includes wiping down the freezer top, handles, lid, and control panel.
      1.1.8. Step 6.1.4.4.1.1 revised to define Chart MVE default password which may unlock a password-protected freezer.
      1.1.9. Step 6.1.4.4.2 revised to replace alarm testing specific to CBS model freezers with directives to refer to the freezer manual for non-Chart equipment, since the SSF no longer monitors and maintains a CBS freezer and has no non-Chart equipment at this time.
      1.1.10. Added Section 6.1.4.5, procedure directing annual wipe down of entire freezer.
      1.1.11. Section 6.1.5.4.3 revised to clarify directives for indicating appropriate probe depth.
      1.1.12. Added Campus Facility Services contact information in Section 7.
      1.1.13. Section 9 revised to reflect new title of Appendix E and add Appendix F.
      1.1.14. Appendix B revised for
         1.1.14.1. New quarterly/annually freezer wipe down procedure
         1.1.14.2. Inclusion of alarm functionality test directives applicable to Sonicu alarm system
      1.1.15. Appendix C revised to reflect that all Vario freezers moved to TK 252.

1.1.16. Appendix E alarm system and SOP references revised to align with revisions referenced in the Scope section.
1.1.17. 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 liquid nitrogen freezers owned or contracted for storage in the SSF. This procedure satisfies guidance set forth in ISBER. Refer to SOP SF-3-16 for procedures used to maintain and monitor -80°C LN_2 freezers.

3. PRINCIPLE
3.1. All 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 the liquid nitrogen freezers owned or contracted for storage in the SSF. This SOP is applicable to all vapor phase and liquid phase storage units 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 LN_2 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. 70% ETOH
5.4. NIST-traceable thermometer (SF-3-7)
5.5. Timer (SF-3-6)

6. PROCEDURE:
6.1. **Routine Monitoring and Maintenance**
Note: At unit intake, complete/update the applicable SN Specific Acceptable ranges for LN_2 level and probe temperature template – R3-C156 (Appendix C) or SN Specific Acceptable ranges for LN_2 level and probe temperature – TK 252 template (Appendix F) to include, by location: S/N, acceptable temperature range, and LN_2 Levels.

Note: Routine monitoring and maintenance of a 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**
6.1.1.1. Temperature checks

6.1.1.1.1. Observe the temperature from the digital display for each probe of each unit. The Temp A probe measures temperature at the level of the top boxes in the freezer. The Temp B probe (if present) measures temperature at the level of the bottom boxes in the freezer. **Temp B temperatures are recorded for informational purposes only.**

6.1.1.1.1.1. Temp A Acceptable Ranges: For each unit, refer to acceptable range criteria documented on the applicable 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.

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

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

6.1.1.1.3.1. Evaluate integrity of the freezer, checking for leaks as evidenced by abnormal frost buildup or active "dripping" of LN_2 from the freezer.

6.1.1.1.3.1.1. 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.

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

6.1.1.1.3.2. Confirm LN_2 level is within acceptable parameters. If the level is acceptable, proceed to Section 6.1.1.1.3.3.

6.1.1.1.3.2.1. If the level is lower than acceptable parameters, press the start fill button on the unit's control panel.

6.1.1.1.3.2.2. If LN_2 cannot be added using the start fill button, 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 LN_2 System and LN_2 Freezer Room Operations, and contact Campus Facility Services as needed for TK 252.

6.1.1.1.3.2.3. If LN_2 still cannot be added, notify SSF Management as soon as possible. Proceed to fill out an OOS Event Report per SF-1-10. Discuss with SSF Director to determine further course of action, such as

manually filling the unit via a transfer hose, contacting Praxair for refill assistance, or relocating samples.

6.1.1.1.3.3. If both the integrity of the unit is intact and the LN_2 level is within acceptable parameters, the unit should recover over time.

6.1.1.1.3.3.1. Monitor the unit within 4 hours of receiving the remote alarm to verify that the temperature has returned to acceptable parameters, clearing the alarm on the freezer control panel by pressing the alarm mute button.

6.1.1.1.3.3.2. If the unit has not recovered within 4 hours but is approaching recovery, SSF personnel change the warm probe's high alarm level to approximately 2˚ warmer than the probe's current temperature reading. Clear the alarm condition on the freezer control panel by pressing the alarm mute button. Document actions on Appendix A and initiate an OOS Event Report per SF-1-10. When recovered to acceptable temperature, return the probe's high temperature alarm to defined PI-defined high alarm value, documenting actions on Appendix A.

6.1.1.1.3.3.3. If the unit has not recovered within 4 hours and is NOT approaching recovery, Initiate an OOS Event Report per SF-1-10. SSF personnel change the warm probe's high alarm level to approximately 2˚ warmer than the probe's current temperature reading. Clear the alarm condition on the freezer control panel by pressing the alarm mute button. Document actions on Appendix A. Discuss with SSF Director to determine further course of action. When recovered to acceptable temperature, return the probe's high temperature alarm to defined PI-defined high alarm value, documenting actions on Appendix A.

6.1.1.1.4. Document results and any actions taken on the LN_2 Freezers Daily Monitoring Log (Appendix A).

6.1.1.2. LN_2 Level

6.1.1.2.1. Observe the liquid nitrogen level from the digital display for each unit.

6.1.1.2.1.1. Acceptable Range: For each unit, refer to acceptable range criteria documented on the applicable 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.

6.1.1.2.1.2. If the freezer is filling, stop the fill before documenting the LN_2 level to ensure an accurate reading.

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

6.1.1.2.3. If LN_2 level is < 0.5 inch below minimum acceptable LN_2 level, record and accept. Fill the freezer by pressing the manual fill button on the unit's control panel.

6.1.1.2.4. If LN_2 level is ≥ 0.5 inch below minimum acceptable LN_2 level (i.e., action limit range/alarm condition):

6.1.1.2.4.1. Take a manual reading (per Step 6.1.3.1). Document both the display and manual readings.

6.1.1.2.4.2. Fill the freezer if necessary, following Steps 6.1.1.1.3.2.1-6.1.1.1.3.2.3.

6.1.1.2.4.3. Notify SSF Management. Document OOS condition per SF-1-10.

6.1.1.2.5. LN_2 levels above the acceptable range are defined as overfills. Overfills may pose a danger to the specimens within the affected unit and are a potential danger to samples, staff, equipment and/or the facility, given the hazardous nature of Liquid Nitrogen that is not adequately contained. Overfills must be monitored carefully to mitigate potential dangers.

6.1.1.2.5.1. If the LN_2 level is < 1.0 inch above the maximum acceptable LN_2 level, no action required. Record and accept.

6.1.1.2.5.2. If the LN_2 level is ≥ 1.0 inch above the maximum acceptable LN_2 level (i.e., action limit range/alarm condition), or in response to a local or remote alarm, proceed as follows:

6.1.1.2.5.2.1. Close supply valve for affected freezer and affix signage to unit to indicate disconnect.

6.1.1.2.5.2.2. Verify level per Section 6.1.3.1.

6.1.1.2.5.2.3. Notify PI and SSF Management, including SSF Director, and indicate which boxes, if any, are submerged.

6.1.1.2.5.2.4. Document OOS condition per SF-1-10.

6.1.1.2.5.2.5. Additionally (in the event of a remote alarm) increase the high level LN_2 alarm set point to be sufficiently above the PI-specified level to ensure that other daisy-chained units can continue to communicate with the alarm system. Affix signage to the unit to indicate this change in alarm set point. Document all actions on the OOS Event Report and the impacted unit's temperature log (Appendix A).

6.1.1.2.5.2.5.1. If PI has documented directives on file with the

SSF to prohibit LN_2 level set point changes, disconnect malfunctioning unit from alarm system and notify PI.

6.1.1.2.5.2.6. Once the LN_2 level has returned to normal, the supply may be turned back on. Return the high LN_2 level alarm set point to the PI-specified value. Remove applicable signage. Document actions on the OOS Event Report and the impacted unit's temperature log (Appendix A).

6.1.1.2.5.2.7. If more than one overfill event is documented for a given unit within a 3 month period, the SSF Director contacts the PI to discuss the plan for adequate resolution.

6.1.1.2.6. Press the Alarm Mute button on the freezer controller once the level returns to acceptable parameters to clear the alarm condition.

6.1.1.2.7. Document results and any actions taken on the LN_2 Freezers Daily Monitoring Log (Appendix A).

6.1.2. **Quarterly**

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

6.1.2.1. Wipe down the top, handles, lid, and control panel of each unit with a cloth and general purposes cleaner.

6.1.2.2. Record actions, date and initials on LN_2 Freezer Quarterly, Semi-Annual, and Annual Monitoring and Maintenance Log (Appendix B).

6.1.3. **Semi-Annually**

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

6.1.3.1. Digital Liquid Nitrogen Level Display Verification

NOTE: For liquid phase LN_2 units, the clearest reading is likely obtained when the freezer's liquid level is allowed to get as close to its lower acceptable level limit as possible before performing the verification.

6.1.3.1.1. Open lid.

6.1.3.1.2. Clean black ruler by spraying with 70% ETOH. It is not necessary to allow the alcohol to evaporate.

6.1.3.1.3. Place black ruler into open slot in carousel.

6.1.3.1.4. Insert ruler to bottom of tank.

6.1.3.1.5. Leave ruler in for a minimum of 5 seconds.

6.1.3.1.6. Remove ruler.

6.1.3.1.7. Read the ruler at the point where the white vapor is present on the black. If the white vapor line is not visible, wave the ruler back and forth until line becomes visible.

6.1.3.1.8. Compare level to digital readout.

6.1.3.1.9. Acceptable range is $\pm$ 1 inch.

6.1.3.1.10. If difference exceeds 1 inch, LN_2 level is not within acceptable range.

6.1.3.1.10.1. If unit is SSF-owned, notify SSF Management and correct if possible. Initiate repair if warranted.

6.1.3.1.10.2. If unit is not SSF-owned, notify SSF Management as well as the owner of the unit. Corrective action is the responsibility of the owner.

6.1.3.1.10.3. Document OOS conditions per SF-1-10.

6.1.3.1.11. Record results on Appendix B.

6.1.4. **Annually**

NOTE: Before completing Sections 6.1.4.1 – 6.1.4.3, consider directives in Section 6.1.5, if applicable.

NOTE: Annual Freezer Alarm Functionality Testing, as described in Section 6.1.4.4, may NOT be waived by any personnel or entity outside the SSF (e.g., GLP biorepository request per SF-1-13 SOP for Housing GLP Collections, Appendix C submission).

6.1.4.1. Temperature display calibration verification

6.1.4.1.1. Place a notice on the LN_2 Freezer stating "CALIBRATION IN PROCESS – DO NOT OPEN".

6.1.4.1.2. Place the probe of an NIST-traceable thermometer capable of reading within expected range inside the unit, as close as possible to the freezer probe. The probe and thermometer must be within calibration limits and time per SF-3-7 SOP for Thermometers.

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

6.1.4.1.2.2. 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.

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

6.1.4.1.4. Read NIST thermometer

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

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

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

6.1.4.1.8. For units where the acceptable criteria of the top probe is -150°C or warmer, the calibration verification is successful if the difference between the two readings is no more than +/- 10°C.

6.1.4.1.8.1. Document on Appendix B if the results are acceptable.

6.1.4.1.8.2. If the verification does not pass, notify SSF Management and the owner of the unit, if applicable. Document as an OOS Event Report per SF-1-10.

6.1.4.1.8.3. If unit is SSF owned, initiate repair. If not SSF owned, corrective action is the responsibility of the owner.

6.1.4.1.9. For all other units, determine whether or not the temperature calibration verification is successful by following the instructions on

Appendix D and utilizing the Excel LN_2 temperature display verification spreadsheet calculator located in the shared folder. Performance of the calculation listed below (and in the spreadsheet calculator) will yield a "True" result if the verification passes and "False" result if the verification fails:

|NIST reading-unit digital display| ≤ |-132-freezer probe warm limit|-5

6.1.4.1.9.1. Glass phase of pure water (Tg) is -132°C per ISBER Best Practices 4th Edition.

6.1.4.1.9.2. Document on Appendix B if the equation is true and if results are acceptable.

6.1.4.1.9.3. If the equation is true, the freezer probe is within acceptable range of the NIST thermometer probe.

6.1.4.1.9.4. If the equation is false, the freezer probe is not within acceptable range of the NIST thermometer probe.

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

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

6.1.4.1.10. Record results and actions on Appendix B.

6.1.4.2. Check stair's slip resistant strips on each freezer for peeling and cracking

6.1.4.2.1. If repairs are required, notify SSF Management to initiate repair (SSF if owned by SSF or PI if PI-owned).

6.1.4.2.2. Observe and record results on Appendix B.

6.1.4.3. Check Styrofoam Lid integrity on each freezer for chipping and cracking

6.1.4.3.1. If repairs are required, notify SSF Management to initiate repair (SSF if owned by SSF or PI if PI-owned).

6.1.4.3.2. Observe and record results on Appendix B.

6.1.4.4. Perform a Freezer Alarm Functionality Test per the alarm system SOP to verify that alarm still functions as intended.

6.1.4.4.1. **Activating Unit Alarm Test Function on most Chart MVE freezers:**

6.1.4.4.1.1. On the LN_2 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 manual or ask PI.

6.1.4.4.1.2. Select temperature menus by hitting the enter button.

6.1.4.4.1.3. Select Temp A; Hit setup button to scroll until you see alarm test.

6.1.4.4.1.4. To begin alarm test, use the up arrow 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 6.1.4.4.1.4.

6.1.4.4.1.5. After alarm test is complete, the temperature will return to actual temperature of LN_2 freezer and the alarm test function will automatically return to 'no'.

6.1.4.4.1.6. Press the Alarm Mute button on the freezer controller to clear the alarm condition.

6.1.4.4.2. Activate Alarm Test Function on another brand freezer per the freezer's manual.

6.1.4.4.3. 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.

6.1.4.4.4. If alarm does not function as intended, notify SSF Management and complete an OOS Event Report per SF-1-10.

6.1.4.5. Cleaning of Freezer Exterior

6.1.4.5.1. Wipe down the exterior of each unit with a cloth and general purposes cleaner.

6.1.4.5.2. 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 Sections 6.1.3 and 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 Section 6.1.4.4 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 Sections 6.1.3 and 6.1.4. If the owner <u>does</u> 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. 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.

6.1.5.4.2. Ensure that the "as-found" LN_2 levels as documented by the vendor were within acceptance criteria. If the "as-found" LN_2

values 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.

6.1.5.4.3. Once temperatures and level are within normal parameters, verify that the LN_2 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 LN_2 depth 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 6.1.3 and 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. **As Needed**

6.1.6.1. In event of OOS Temperature, unexplained by freezer access, proceed as follows:

6.1.6.1.1. Verify that probe hasn't moved from set position, by verifying that the probe depth setting marker (an indicator on the probe's cable) is immediately above the putty that is insulating the channel entrance.

6.1.6.1.2. If probe is correctly located, complete temperature calibration verification per Step 6.1.4.1.

6.1.6.1.3. If neither attempt solves the OOS Temperature, proceed per below.

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

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

6.2. **Non-Routine Monitoring** – Documentation and follow-up of OOS conditions per 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 and LN_2 level against acceptance criteria per Steps 6.1.1.1.1 and 6.1.1.2.1, refer to the LN_2 Unit Non-Routine Monitoring Local Alarm Investigation Flowchart (Appendix E), and proceed per the following steps:

6.2.1.1. If temperature and/or level 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 and level against acceptance criteria.
6.2.1.1.4.2. If temperature or level does not meet acceptance criteria:
6.2.1.1.4.2.1. Proceed per Section 6.1.1.1.3 (for OOS temperature) and/or Sections 6.1.1.2.4 and 6.1.1.2.5 (for OOS level).
6.2.1.1.4.2.2. If unable to resolve, proceed per SF-1-10; Contact SSF Director to determine next course of action.
6.2.1.1.4.3. If both temperature and level meet acceptance criteria, attempt to clear the local alarm by pressing the alarm mute button on the unit's controller. If this action clears the alarm condition, no further action is necessary. However, if the alarm condition remains:
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; Contact SSF Director to determine next course of action.
6.2.1.1.5. If remote alarm has NOT generated:
6.2.1.1.5.1. Check temperature and level against acceptance criteria.
6.2.1.1.5.2. If temperature or level does not meet acceptance criteria:
6.2.1.1.5.2.1. Proceed per Section 6.1.1.1.3 (for OOS temperature) and/or Sections 6.1.1.2.4 and 6.1.1.2.5 (for OOS level).
6.2.1.1.5.2.2. Investigate alarm failure per Steps 6.2.1.1.4.3.1 through 6.2.1.1.4.3.3.
6.2.1.1.5.2.3. If unable to resolve, proceed per SF-1-10; Contact SSF Director to determine next course of action.

6.2.1.1.5.3. If temperature and level meet acceptance criteria, no further action is necessary. Clear the local alarm, if applicable, on the unit by pressing the alarm mute button on the control panel.

6.2.1.2. If temperature and level meet acceptance criteria:

6.2.1.2.1. Investigate and resolve alarm condition (i.e. low battery level alarm). Clear the local alarm on the unit by pressing the alarm mute button on the control panel.

6.2.1.2.1.1. If unable to resolve, proceed per SF-1-10. Contact SSF Director to determine next course of action.

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, no further action is necessary. Clear the local alarm on the unit, if applicable, by pressing the alarm mute button on the control panel.

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 E for assistance monitoring local alarms prior to remote 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 SF-1-4 SOP for Managing Storage Space.

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. 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 Controlled Document Management SOP.

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 OOS Response and Notification Management SOP.

9. APPENDICES

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

APPENDIX A: LN_2 Freezer Daily and Monthly Monitoring and Maintenance Log (1 Page)

APPENDIX B: LN_2 Freezer Quarterly, Semi-Annual, and Annual Monitoring and Maintenance Log (2 Pages)

APPENDIX C: SN Specific Acceptable Ranges for LN_2 Level and Probe Temperatures – R3-C156 (Template, 1 Page)

APPENDIX D: Temperature Display Calibration Verification Spreadsheet (3 Pages)

APPENDIX E: LN_2 Unit Non-Routine Local Alarm Investigation Flowchart (1 Page)

APPENDIX F: SN Specific Acceptable Ranges for LN_2 Level and Probe Temperatures – TK 252 (Template, 1 Page)

10. COLLABORATING BIOBANK PERSONNEL TRAINING

10.1. N/A

Month: **Year:**

LN_2 Freezer Daily & Monthly Monitoring and Maintenance Log

Unit ID:

Date	Temperature (°C) Top Probe *Acceptable Range:* ≤ _____ °C	Temperature (°C) Bottom Probe* *Acceptable Range:* N/A	LN_2 Level inches Acceptable _____ - _____ Inches	All Ranges Acceptable (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:

*Recorded for informational purposes only.

Year:

LN_2 Freezer Quarterly, Semi-Annual, & Annual Monitoring and 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	☐Yes ☐No		3	☐Yes ☐No	
	2	☐Yes ☐No		4	☐Yes ☐No	

Comments:

Quarterly Wipe Downs Reviewed:
(Initials / Date)

Semi-Annually		LN_2 Level Digital Display:	LN_2 Level Manual Reading:	Difference: *Acceptable Range ≤ 1 inch*	Accept-able?	Initials/ Date	Non-SOP driven Maintenance spreadsheet and calendar updated?	Initials/ Date	**Reviewed by: (initials/date)**
	Month								
Liquid Nitrogen Level Display Verifi-cation					☐ Yes ☐ No		☐ Yes ☐ No		
					☐ Yes ☐ No		☐ Yes ☐ No		

Comments:

1. ANNUAL: Temperature Verification: **Unit ID: _____**

Complete for units with upper acceptable limit = *colder than -150°C* **☐ check if N/A**

Temperature calibration verification	Unit Digital Display	NIST Temperature	Is the following equation true? **|NIST reading-unit digital display| ≤ |-132-freezer probe warm limit|-5**	Acceptable? (only if equation is true)	Initials/ Date	Comments / Corrective Actions (required if not acceptable)
NIST SSF ID:			Re-calibration Due Date:		Calibrated Range:	
			☐ Yes ☐ No	☐ Yes ☐ No		

Complete for units with upper acceptable limit = *-150°C or warmer* **☐ check if N/A**

Temperature calibration verification	Unit Digital Display (°C)	NIST Temperature (°C)	Difference: Acceptable is within +/- 10°C	Acceptable?	Initials/ Date	Comments / Corrective Actions (required if not acceptable)
NIST SSF ID:			Re-calibration Due Date:		Calibrated Range:	
				☐ Yes ☐ No		

2. ANNUAL: Alarm Functionality Test and Other Maintenance:

Complete for ALL units

Alarm Functionality Test (performed per alarm system SOP)	Completed and Passed:	☐Yes ☐No	Comments / Corrective Actions:
	Alarm delay reset to 15 minutes or alarm profile setting returned to "dry contact":	☐Yes ☐No	
	Initials/Date:		
Freezer Wipe Down	Completed:	☐Yes ☐No	
	Initials/Date:		

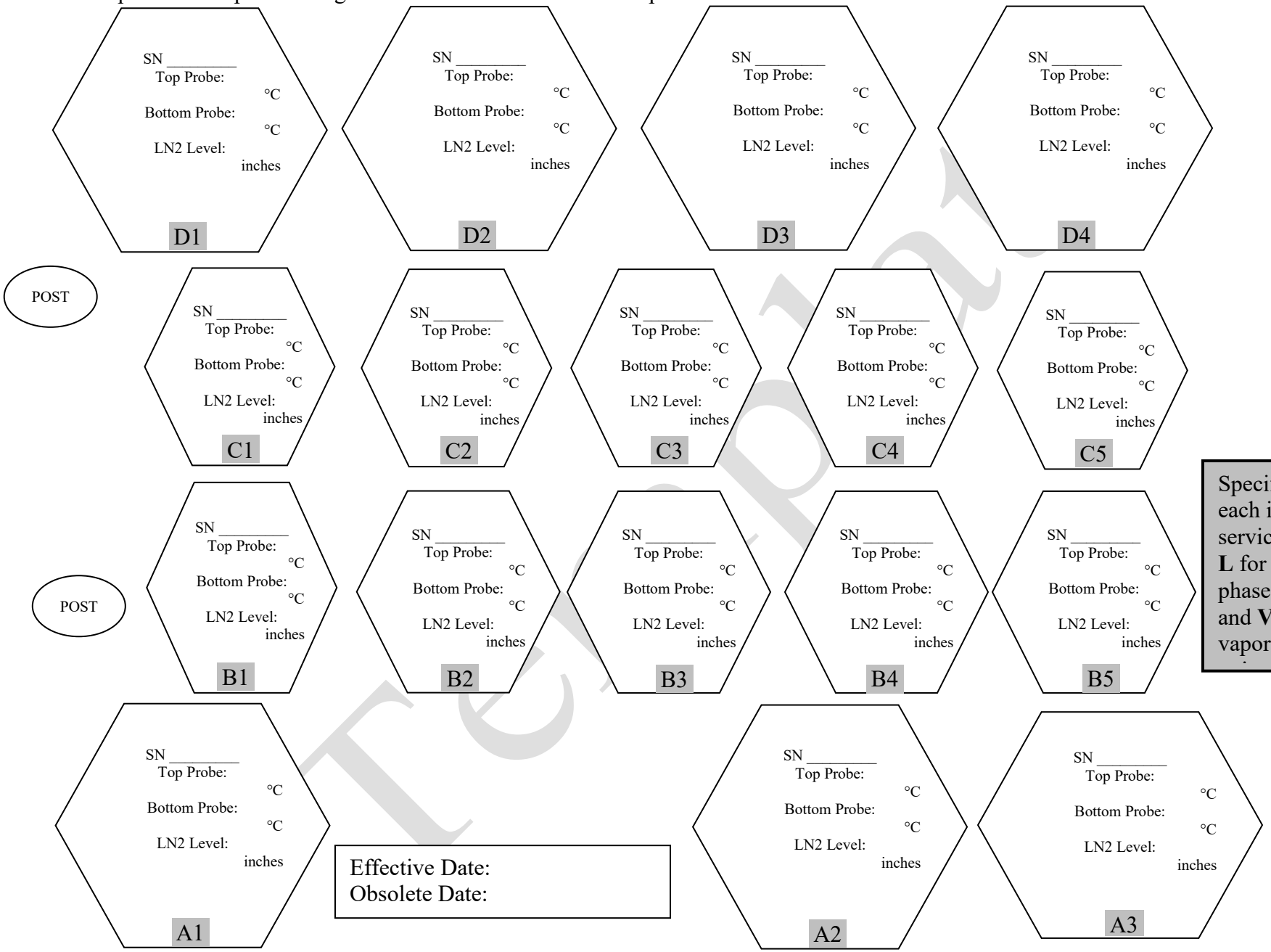
Other Maintenance	**Observation**	**Acceptable Range**	**Acceptable**	**Initials/ Date**
Stair's Slip Resistant Strips Integrity	☐Minimal or no cracking/peeling ☐Other. See comments	Minimal or No Cracking or peeling	☐ Yes ☐ No	
Styrofoam Lid Integrity	☐Minimal or no cracking/peeling ☐Other. See comments	Minimal or No Cracking or Chipping	☐ Yes ☐ No	

Comments:

Non-SOP driven Maintenance spreadsheet and calendar updated?	☐ Yes ☐ No	Initials/date:

Annual Reviewed:
(Initials / Date)

SN Specific Acceptable Ranges for LN_2 Level and Probe Temperature – R3-C156



Temperature Display Calibration Verification Spreadsheet
Instructions for completion

	Before Beginning:
	Ensure the unit has not been opened recently (signage placed prior to verification process)
	Ensure the NIST-traceable unit is calibrated at -196 °C
	Ensure the NIST-traceable unit is within its calibrated due date
	Ensure that the NIST-traceable unit equilibrates for the allotted time define in the SOP
Step #	**NOTE: Step numbers correspond to steps listed in spreadsheet, but are performed in the order listed:**
1	Enter the unit ID by typing in the spreadsheet
2	Enter the unit S/N by typing in the spreadsheet
6	Enter the temperature from the NIST-calibrated unit as a negative number in the yellow box
7	Enter the temperature from the unit's digital display as a negative number in the blue box ******(record the value from the top probe if the freezer has two probes)***
8	Enter the warm probe's warm limit temperature as a negative number in the green box
N/A	Print the spreadsheet
N/A	Print the spreadsheet again after selecting "display formulas" from the menu bar
N/A	Document the following on the spreadsheet that **does not contain the formulas**
3	Record Technician Initials by hand
4	Record Date of Calibration verification by hand
5	Enter any pertinent comments by hand
9	Circle the result as Pass or Fail
10	Submit both pages for review & signature (On the page that does not contain the formulas)

Temperature Display Calibration Verification Spreadsheet

Example Spreadsheet – Blank

SOP SF-3-2 LN2 Freezer Verification of Temeprature Display Calibration

1. Unit ID:	
2. Unit S/N:	
3. Tech ID *(Handwritten)*:	
4. Date Performed *(Handwritten)*:	
5. Comments:	

|NIST reading-unit digital display| ≤ |-132-freezer probe warm limit|-5

****ENSURE ALL VALUES ARE ENTERED AS NEGATIVE NUMBERS**

6. NIST Temperature Reading	°C			
7. Unit Digital Display	°C	0	≤	127
8. Freezer Warm probe limit	°C		TRUE	

9. Circle Calibration Result:

True = Pass

False = Fail

10. Verification Step

Verified as Accurate By: *(enter handwritten initials/date)*
Initials:
Date:

Example Spreadsheet - Completed

SOP SF-3-2 LN2 Freezer Verification of Temeprature Display Calibration

1. Unit ID:	*XYY*
2. Unit S/N:	*123456789*
3. Tech ID *(Handwritten)*:	*ABC*
4. Date Performed *(Handwritten)*:	*01.02.2099*
5. Comments:	*None*

|NIST reading-unit digital display| ≤ |-132-freezer probe warm limit|-5

****ENSURE ALL VALUES ARE ENTERED AS NEGATIVE NUMBERS**

6. NIST Temperature Reading	-120 °C			
7. Unit Digital Display	-185 °C	65	≤	33
8. Freezer Warm probe limit	-170 °C		FALSE	

9. Circle Calibration Result:

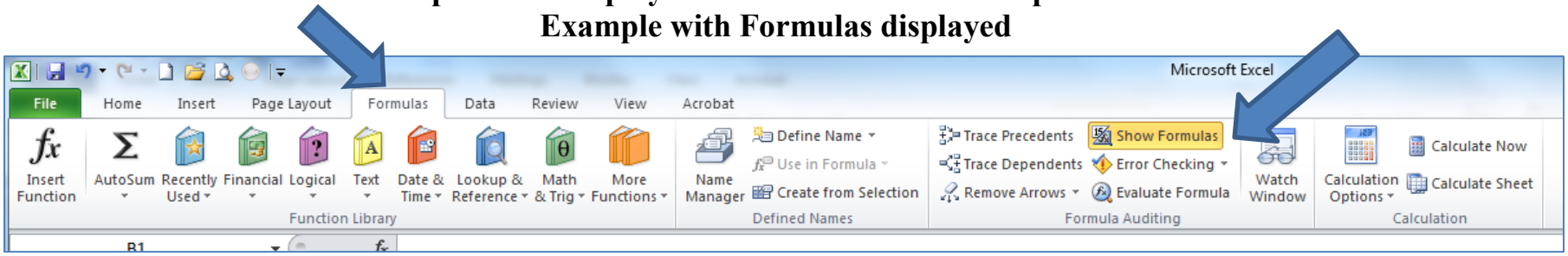
True = Pass

False = Fail

10. Verification Step

Verified as Accurate By: *(enter handwritten initials/date)*
Initials: *XYZ*
Date: *01.03.2099*

Temperature Display Calibration Verification Spreadsheet
Example with Formulas displayed



SOP SF-3-2 LN2 Freezer Verification of Temeprature Display Calibration

1. Unit ID:
2. Unit S/N:
3. Tech ID *(Handwritten)*:
4. Date Performed *(Handwritten)*:
5. Comments:

|NIST reading-unit digital display| ≤ |-132-freezer probe warm limit|-5

****ENSURE ALL VALUES ARE ENTERED AS NEGATIVE NUMBERS**

6. NIST Temperature Reading		°C		
7. Unit Digital Display		°C	=ABS(C13-C14) ≤	=ABS(-132-C15)-5
8. Freezer Warm probe limit		°C	=OR(E14<G14,E14=G14)	

9. Circle Calibration Result:

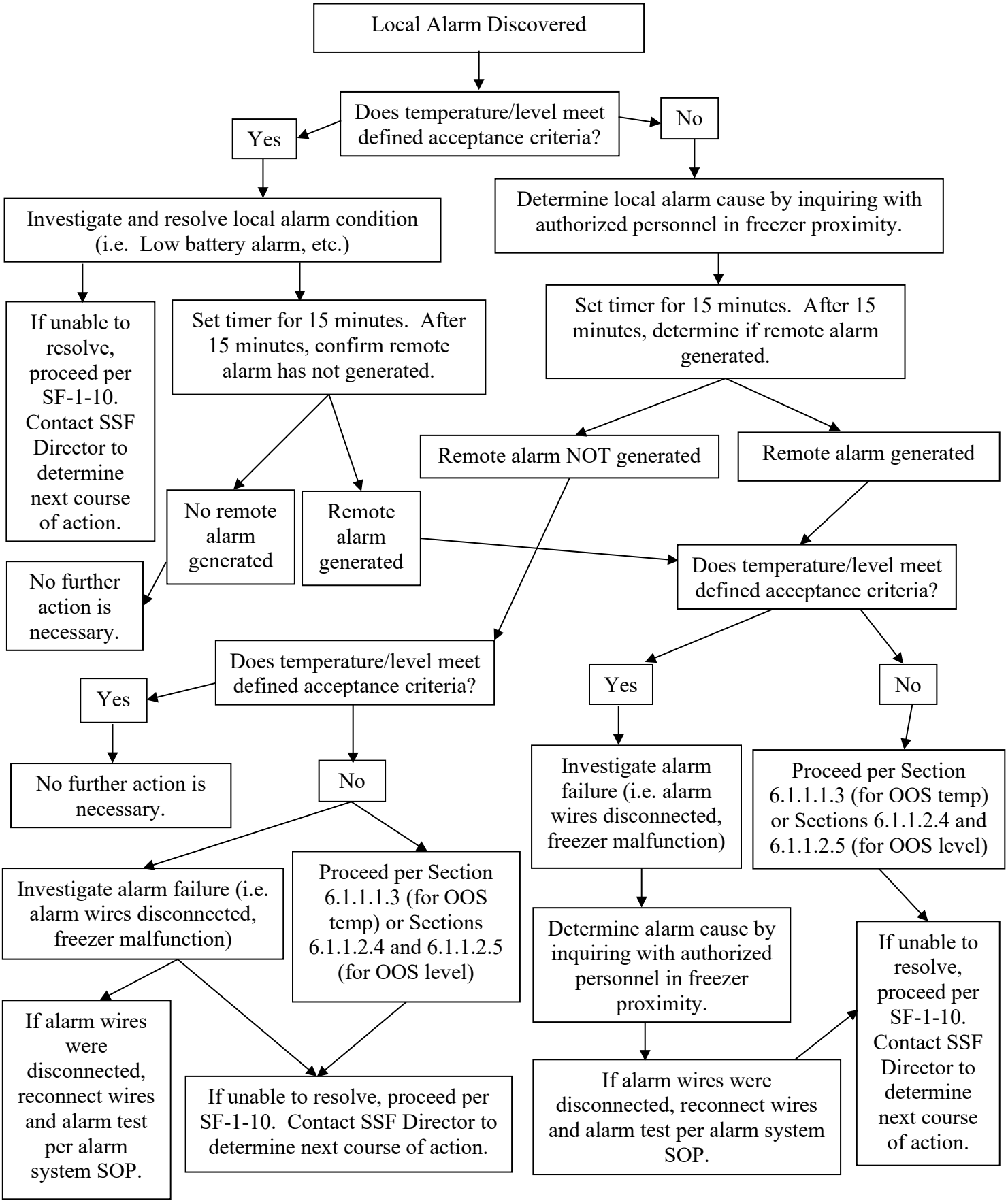
True = Pass

False = Fail

10. Verification Step

Verified as Accurate By: *(enter handwritten initials/date)*
Initials:
Date:

LN_2 Unit Non-Routine Monitoring Local Alarm Investigation Flowchart



SN Specific Acceptable Ranges for LN_2 Level and Probe Temperature – TK 252