INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR OUT OF SPECIFICATION (OOS) RESPONSE AND NOTIFICATION MANAGEMENT

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-10.11

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SUPERSEDES SOP #: N/A

AUTHORED BY: Michael D. Smith DATE: 12-29-21
Indiana CTSI SSF Staff

REVIEWED BY: [signature] DATE: 04 JAN 2022
Indiana CTSI SSF Director

QA APPROVAL: [signature] DATE: 01.27.2022
Quality Compliance Specialist

1. REVISION
   1.1. Significant revisions incorporated in this document include:
      1.1.1. Section 4.1 revised to define that alarming and response is managed by SF-2-4 and/or other validation 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 4.8 defining alarm system management terminology
      1.1.3. Added Annex IV, TK facilities in Section 5
      1.1.4. Throughout SOP, references to SF-2-4 and Siemens were revised to align with Scope revisions.
      1.1.5. Section 6.1.3, revised to:
         1.1.5.1. Add directives for new Appendix A LN_2 storage unit level OOS event verifications
         1.1.5.2. Indicate that Appendix A is exclusive to storage units OOS events, with non-storage unit OOS events moved to the new Appendix F
         1.1.5.3. Reflect the name change of Appendix A
         1.1.5.4. Correct error indicating that Description of Unit contents were in Section 1 not Section 2.
      1.1.6. Section 6.1.5.4, added to direct documenting LN_2 value opening, sign removal, and LN_2 level return to normal level on Appendix A.
      1.1.7. Added directives to use the new Appendix F, Non-Storage Unit OOS Event Report, for non-storage unit OOS events in Section 6.2.
      1.1.8. Section 9, updated to reflect the name change of Appendix A and the addition of Appendix F.
      1.1.9. Modified Appendix A as follows:
         1.1.9.1. Name changed from Out-of-Specification (OOS) Event Report to Storage Unit Out-of-Specification (OOS) Event Report.
         1.1.9.2. Revised to reflect that Non-Storage Unit OOS move to Appendix F

1.1.9.3. Added Sections 3a and 9 for documenting LN_2 Unit Overfills and Low-Level Events

1.1.10. Appendix D alarm system and SOP references revised to align with revisions referenced in Scope Section and move title from header to body to align with other SOPs.

1.1.11. Added the new Appendix F

2. PURPOSE

2.1. This SOP establishes a procedure to investigate and respond to out-of-specification (OOS) conditions per the Indiana CTSI Specimen Storage Facility (SSF) Standard Operating Procedures. This procedure satisfies guidance set forth in ISBER as related to OOS conditions and notifications.

3. PRINCIPLE

3.1. OOS events have the potential to impact the quality of the specimens stored in the SSF. Therefore, when an OOS is detected, there must be a defined and documented investigation and response that immediately minimizes the ongoing impact, evaluates the existing impact, notifies applicable personnel, and addresses an approach toward preventing a recurrence. This SOP defines the process of investigating, documenting, and responding to OOS results.

4. SCOPE

4.1. This SOP applies to the SSF Staff and the SSF Director, and, as applicable, the Quality Compliance Specialist who investigates, documents, and reviews the OOS condition that has reached the level of referral to this SOP. The OOS limits, the investigation, and the response to conditions that are rectified prior to escalation to the point of referral to this SOP are managed entirely by the applicable facility and/or equipment SOP. The alarming plan and notification parameters are defined in the Alarm Systems Management and Response SOP (SF-2-4) and/or other validated alarm system and the SOP(s) corresponding to that alarm system.

4.2. SOPs which are applicable to and may demand referral to this SOP include the entirety of Chapter 2 (Facility) and Chapter 3 (Equipment) SOPs.

4.3. OOS events involving freezer units for which there is sponsor signed documentation authorizing the SSF to manage as exceptions to SSF SOPs (e.g., NGVB GLP units) may be managed by this SOP, or may be excluded from the scope of this SOP. Refer to the appropriate SF-1-13 Appendix C for guidance.

4.4. OOS events involving freezer units undergoing alarm testing/validation are excluded from the scope of this SOP.

4.5. Both pages of Appendix B of this SOP must be completed for any temporary specimen relocation managed by SSF personnel.

4.6. Appendix B is optional when collaborating biobank personnel manage relocation of their own samples to another freezer which they own. However, SSF personnel must be present and manage relocation if samples are to be relocated to an SSF-owned freezer (See Step 4.5).

4.7. Sample relocation during the defrosting of mechanical refrigeration units is documented on Appendix B of this SOP as defined in the SOP for Mechanical Refrigeration Units (SF-3-1), however, defrosting is not considered to be an OOS event and is not logged or documented as such.

4.8. Alarm Management Definitions:

4.8.1. Local Alarm: Alarm issued from freezer (audible, visual, or both)

4.8.2. Remote Alarm: Alarm recorded and communicated from validated alarm system

4.8.3. Alarm System: The SSF's validated alarm system

5. MATERIALS
   5.1. One or more SSF Ultra Low Mechanical Refrigeration Units located in C135, IB 097/MS-B046 Cage, MS-B037, and TK 246 are identified as SSF back-up freezers and provide back-up storage for a minimum of 10% of samples housed in the respective rooms.
   5.2. One or more SSF Liquid Nitrogen Freezer Units located in C156 and TK 252 are identified as back-up storage and provide a minimum storage capacity for 75,000 specimens.

6. PROCEDURE
   NOTE: As needed, refer to Appendix D for assistance in identifying a specimen storage unit OOS event.
   6.1. **Procedure for OOS conditions involving specimen storage units:** equipment SOPs SF-3-1 (Mechanical Refrigeration Units), SF-3-2 (Liquid Nitrogen Freezers), and SF-3-16 (-80 LN_2 Freezer Units):
      6.1.1. **Sample Relocation** (as directed by SF-3-1, SF-3-2, or SF-3-16):
         6.1.1.1. If the OOS event does not require sample relocation, proceed to Section 6.1.2.
         6.1.1.2. In the event of OOS high temperatures, power failures, mechanical failures, or other OOS conditions which threaten sample safety and integrity, first relocate samples per below.
         6.1.1.3. **Quickly** move specimens to a back-up unit or another approved unit owned by the same PI and disconnect alarm of the OOS unit per alarm system SOP.
         6.1.1.4. Request additional SSF personnel to assist as needed.
         6.1.1.5. Place signage on the faulty unit to indicate "ALARM DISCONNECTED - DO NOT USE FOR SAMPLE STORAGE" (or similar).
         6.1.1.6. As specimens are being relocated, concurrently complete relocation details on OOS Specimen Relocation Record (Appendix B, page 1).
         6.1.1.7. Notify the appropriate PI personnel, if applicable.
         NOTE: Handwritten documentation and/or printed labels may be used to document Unit IDs on all forms referenced in this SOP.

      6.1.2. **Initiate the OOS event** in the OOS Occurrence Log (Appendix C).
         6.1.2.1. The OOS Occurrence Log serves as a Table of Contents for the OOS Event Reports and is used to summarize the initiation/completion of OOS events.
         6.1.2.2. Record the date on which the OOS is initiated.
         6.1.2.3. Assign an OOS number as follows:
            6.1.2.3.1. O-yy-xx where:
               6.1.2.3.1.1. O = indicates an OOS event
               6.1.2.3.1.2. yy = indicates the last two digits of the current calendar year.
               6.1.2.3.1.3. xx = assigned sequentially (beginning at 01) throughout each calendar year.
            6.1.2.3.2. Reference the OOS number on any applicable equipment maintenance log (e.g., SF-3-1, Appendix C for MRUs).
            6.1.2.3.3. Write a brief description of the OOS (to include initials/date of the individual recording the description).
            6.1.2.3.4. Record the Location ID and serial number of the unit.
               6.1.2.3.4.1. Location ID is defined as the room number where the storage unit is located followed by the outlet ID (as described in the section of SF-1-4 regarding Freezer Assignment and Postings). For example, freezer located in C135 plugged into outlet A6 has a location ID of C135-A6.

6.1.3. Record information on the Storage Unit OOS Event Report (Appendix A, page 1).
6.1.3.1. Reporting Information (Section 1) defines the specific information for MRU, LN_2, and Ambient storage units that displays an OOS condition.
6.1.3.2. Description of Unit (Section 2) defines storage unit type and:
6.1.3.2.1. Storage Schema Defined: Select whether the PI has provided a specimen map with the unit or not.
6.1.3.2.2. Electronic Specimen Location Management:
6.1.3.2.2.1. If specimen locations are managed by CTSI's Specimen Management System (SMS), request that CTSL record relocation information in the SMS.
6.1.3.2.2.2. For specimens that are being transferred to a backup unit on a temporary basis (e.g., pending maintenance on the affected unit), relocation information need not be recorded in the SMS.
6.1.3.2.2.3. If specimen locations are managed by a PI-managed electronic system, defer to PI personnel for electronic system updates.
6.1.3.2.3. Unit Info: Document the Location ID, serial number, and the owner of the freezer/controlled environment storage unit.
6.1.3.3. Description of OOS Event (Section 3)
6.1.3.3.1. OOS Description: Document the exact data pertinent to the OOS (e.g., temperatures over time) until the specimens are moved or until the issue is resolved.
6.1.3.3.1.1. OOS Temperature Monitoring Log (Appendix E) is an optional, suggested tool to document OOS temps for storage units. If utilized, attach to Appendix A for the final report.
6.1.3.3.2. Liquid Nitrogen Storage Units Only (Section 3a)
6.1.3.3.2.1. If unit is OOS due to LN_2 level: Record a manual LN_2 level reading and the freezer's display level at the time of the manual level LN_2 reading.
6.1.3.3.2.2. If the OOS is due to a high LN_2 level, document closure of the Liquid Nitrogen supply valve, posting of signage per SF-3-2, and the New/Temporary high level alarm value (if applicable).
6.1.3.4. PI Personnel Notified (Section 4) defines that notification of PI personnel is not applicable or, if applicable, defines the sequence of contacts.
6.1.3.4.1. For empty SSF-owned back-up units, formal notification does not need to be documented. Select "Notifications Not Required".
6.1.3.4.2. For PI-owned storage units, SSF-owned rental storage units, or SSF-owned back-up storage units containing PI-owned samples, document the name of the PI personnel, the time and date of notification, and the mode of contact.
6.1.3.4.2.1. If PI personnel are to be involved in the physical relocation of samples or provide direct oversight, but are not responsive, notify SSF Director or Associate Director for guidance.
6.1.3.4.2.1.1. If neither PI personnel, SSF Director, nor Associate Director is able to be contacted, proceed with sample relocation, and record

attempts for notification (Date, Time, Contact method) on Appendix A.

6.1.3.5. Relocation (Section 5)

6.1.3.5.1. Document the date and start time of the relocation, if applicable.

6.1.3.5.2. Document completion of the Relocation Record (Appendix B, page 1) following relocation.

6.1.3.5.3. Indicate that the alarm has been disconnected, if applicable, per alarm system SOP.

6.1.4. Determine if Repair/Follow-up Actions are required via investigation of the event.

6.1.4.1. Record if any follow-up (e.g. equipment repair) actions are required on the OOS Occurrence Log (Appendix C).

6.1.4.2. Begin to record follow-up actions, if any, on the OOS Event Report (Repair/Follow-Up Actions section (Section 6), Appendix A, page 2).

6.1.5. When repair or other follow-up is complete and unit is verified to be functional and has returned to acceptable temperature parameters:

6.1.5.1. Complete the Repair/Follow-Up Actions section (Section 6) on Appendix A, page 2.

6.1.5.1.1. Attach a copy of any follow-up documentation (e.g., repair paperwork from outside vendors) to Appendix A.

6.1.5.2. Reconnect the alarm, if applicable, and perform an alarm test per alarm system SOP. Document completion in the Alarm Testing section (Section 7) on Appendix A, page 2.

6.1.5.2.1. If alarm test fails, contact SSF Management for directives.

6.1.5.2.2. N/A selections are limited to OOS conditions on facility SOPs and equipment SOPs other than those defined in Section 6.1 per Step 6.2.2.1.

6.1.5.2.3. Record actions on the freezer log (SF-3-1 Appendix A or C, SF-3-2 Appendix A, or SF-3-16 Appendix A) to include documentation that the alarm was tested successfully and that the unit is being returned to service. Remove "ALARM DISCONNECTED" signage (referenced in Step 6.1.1.5) from unit.

6.1.5.3. Return samples, if applicable. As specimens are being relocated, concurrently complete relocation details on the Relocation Record (Appendix B, page 2).

6.1.5.3.1. Document completion in the Return to Primary Unit section (Section 8) on Appendix A, page 2.

6.1.5.3.2. If sample return occurs over multiple days, attribution of all dates and start times of sample return is required:

6.1.5.3.2.1. Create an additional Relocation Record (Appendix B, page 2) for each date as a best practice.

6.1.5.3.2.2. Document each date in the Additional Return Dates section on Appendix A, page 2. Add pagination to additional Appendix B, page 2s (e.g. 2a, 2b, 2c, etc.).

6.1.5.3.2.3. Notify freezer owner, if applicable, that the specimens are being returned to the primary unit.

6.1.5.4. LN_2 Unit Overfill Events (Section 9): Document LN_2 supply valve opening, signage removal, and return of the LN_2 high level alarm to the defined value.

6.1.6. Complete the OOS Event Report (Appendix A, page 2), OOS Attribution section (Section 10), adding applicable comments.

6.1.7. Complete the OOS Occurrence Log (Appendix C) with date that the follow-up was completed, if applicable, and any comments.
6.1.8. Send the completed OOS Forms to the SSF Director for review.
6.1.9. Upon the SSF Director Review of Appendix A, document the OOS Close-out date on Appendix A (Section 11) and Appendix C.
6.1.9.1. The close-out date is defined as being the date on which the review was performed and the OOS was approved by the Director.
6.1.10. Provide affected PI with a copy of the applicable OOS forms if requested (Appendix A).

6.2. **Procedure for OOS conditions involving facility SOPs and equipment SOPs other than those listed in Section 6.1:**
6.2.1. Upon discovery of the OOS event, follow procedure under Sections 6.1.2.1-6.1.2.3 for initiating an OOS occurrence on the OOS Occurrence Log (Appendix C).
6.2.2. Record initial information regarding date/time the OOS event was discovered, alarm type (if applicable), description of the equipment/facility involved (e.g., serial number, SSF assigned number, and/or other identifying information), and the OOS description on a Non-Storage Unit OOS Event Report (Appendix F).
6.2.3. Determine if follow-up is required via investigation of the event.
6.2.3.1. Record if any follow-up actions are required on the OOS Occurrence Log (Appendix C).
6.2.3.2. Begin to record follow-up actions, if any, on the OOS Event Report (Appendix F).
6.2.4. When repair or other follow-up is complete:
6.2.4.1. Complete the Repair/Follow-Up Actions and OOS Attribution sections on the OOS Event Report (Appendix F).
6.2.4.1.1. Attach a copy of any follow-up documentation (e.g., repair paperwork from outside vendors) to Appendix F.
6.2.4.2. Complete documentation per Steps 6.1.7-6.1.8.
6.2.4.3. Send the completed OOS Forms to the SSF Director for review and close-out per Steps 6.1.9-6.1.10.

6.3. The Appendix C is retained in the Facility Manager's Office and is reviewed minimally on a quarterly basis to determine the resolution status of all OOS events currently open at the time of review.
6.3.1. An assessment of each OOS is made, and any new information that has not been added to the OOS forms is then added.
6.3.1.1. If there are no changes to the OOS, this is documented on Appendix C via numbered footnote.
6.3.2. Additionally, each OOS event is reviewed for instances of recurrence within the year prior to the event in question.
6.3.2.1. Any recurrences are investigated accordingly.
6.3.3. The completion of the quarterly reviews is documented as applicable on the bottom of each page of Appendix C for the year.

7. REFERENCES
7.1. ISBER Best Practices (current version)
7.2. CTSL Email – ctslab@iupui.edu

8. DOCUMENTATION
8.1. Documents are maintained per SF-1-6 Controlled Document Management SOP.
8.2. Deviations are managed per SF-1-9 Deviation Management SOP.

9. APPENDICES
   9.1. The current version of each of the following appendices are used to guide and/or implement this SOP:
   APPENDIX A: Storage Unit OOS Event Report (2 Pages)
   APPENDIX B: OOS Specimen Relocation Record (2 Pages)
   APPENDIX C: OOS Occurrence Log (1 Page)
   APPENDIX D: OOS Decision Tree for Freezer/Refrigerator Units (1 Page)
   APPENDIX E: OOS Temperature Monitoring Log (Suggested Tool) (1 Page)
   APPENDIX F: Non-Storage Unit OOS Event Report (1 Page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES
   10.1. N/A

INDIANA CTSI Clinical and Translational Sciences Institute	**Storage Unit Out-of-Specification (OOS) Event Report**	**OOS #** O-_____-_____ *O-yy-xx*

1. Reporting Information	Event Date:	Initiating Technician (*Initials*):
Report Date:	Event Time: (AM / PM)	

Alarm Type Received: ☐ N/A ☐ High Temp ☐ Power Failure ☐ Other: _____

Total Pages _____ *(Including this form)*	**Attachments**		☐ Other Documentation (*Describe*) ☐ N/A
	☐ Notification Correspondence	☐ N/A	
	☐ Alarm Log	☐ N/A	
	☐ Equipment Log	☐ N/A	
	☐ OOS Temp Monitoring Log	☐ N/A	
	☐ Approval Correspondence	☐ N/A	
	☐ Other Correspondence	☐ N/A	

2. Description of Unit

Storage Unit Type:	**Storage Schema Defined?**	**Electronic Specimen Location Management:**	**Unit Info.**
☐ MRU Unit ☐ LN_2 Unit	☐ Yes ☐ No	☐ CTSI's SMS ☐ PI-managed ☐ N/A	Location ID: _____ S/N: _____ Owner: _____

3. Description of OOS Event

OOS Description *(Include Initials/Date)*:

3a. LN_2 Unit Overfill or Low-Level Event ☐ N/A

Freezer Display level: _____	Manual LN_2 level: _____	Initials/Date_____
☐ N/A – Low Level Event	LN_2 Supply Valve Closed ☐ Yes ☐ No	Signage Posted ☐ Yes ☐ No
	New / Temporary High Level Alarm Value _____	Initials/Date_____

4. PI Personnel Notified ☐ Not Required (Empty SSF back-up unit)

	Name: Date/Time: (AM / PM)	Contacted via: ☐ Phone ☐ Email Tech Initials/Date:
☐ N/A	Name: Date/Time: (AM / PM)	Contacted via: ☐ Phone ☐ Email Tech Initials/Date:
☐ N/A	Name: Date/Time: (AM / PM)	Contacted via: ☐ Phone ☐ Email Tech Initials/Date:
☐ N/A	Name: Date/Time: (AM / PM)	Contacted via: ☐ Phone ☐ Email Tech Initials/Date:

Comments *(Include Initials/Date)*:

5. Relocation: ☐ N/A

Date: Time: (AM / PM)	Relocation Record Completed (App B, pg. 1) Tech Initials/Date: Unit Alarm Disconnected: ☐ Yes ☐ No Disconnect Date: Tech Initials/Date:

6. Repair/Follow-Up Actions Required	**OOS #** *(O-yy-xx)* O-_____-_____ ☐ N/A
Repair Initiation Date:	Repair Completion Date:
Repair Description *(Include Initials/Date)*:	
Follow-Up/Comments *(Include Initials/Date)*:	

7. Alarm Testing ☐ N/A

Unit Alarm Reconnected and Passed Alarm Testing: ☐ Yes ☐ No

Test Date: Tech Initials/Date:

8. Return to Primary Unit ☐ N/A

Initial Return Date Date: Time: (AM / PM)	Relocation Record Completed (App B, pg. 2) Tech Initials/Date: _____

Additional Return Dates ☐ N/A

Date: Time: (AM / PM)	Date: Time: (AM / PM)	Date: Time: (AM / PM)	Date: Time: (AM / PM)	Date: Time: (AM / PM)

9. LN_2 Unit Overfill Event ☐ N/A

LN_2 Supply Valve Opened ☐ Yes ☐ No	Signage Removed ☐ Yes ☐ No	High Level Alarm Returned to Defined Value (per SF-3-2 Appendix C or F or SF-3-16 Appendix C or F) ☐ Yes ☐ No	Initials/Date: _____

10. OOS Attribution/Comments

Cause/Attribution *(Include Initials/Date)*:

11. Close-out

SSF Director Review / OOS Close-out Date *(Initials/Date)*:

INITIAL RELOCATION

Date__________ Time __________ Original Unit ID__________________ Owner_______________ PI Defined Storage Schema: □ Yes □ No

SSF Personnel Involved in Relocation ___________________________________ ___________________________________

Other Personnel Involved in Relocation ___________________________________ ___________________________________

OOS # (if applicable) ____________________

Relocation Details: **Document contents either by rack number or by brief description of materials and the quantity of each (e.g., 3 cryoboxes, 4 bags of blood tubes, etc.). For relocation to or from units that do not follow this location format as displayed below, design a separate diagram using the back of this form.*

Relocation/Backup Unit ID________________ (if multiple relocation units are warranted, use additional forms and define as continuation)

Original Shelf #:	**Original Location 1**	**Original Location 2**	**Original Location 3**	**Original Location 4**	**Original Location 5**	**Original Location 6**	**Original Location 7**	**Backup Shelf #:**
	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	
	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	
	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	
	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	
	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	
	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	Backup Location___ Contents:	

Reviewed By (*Initials/Date*):_______________________________________

RETURN TO ORIGINAL UNIT

Date__________ Time __________ Original Unit ID__________________ Owner_______________ PI Defined Storage Schema: ☐ Yes ☐ No

SSF Personnel Involved in Relocation ___________________________________ ___________________________________

Other Personnel Involved in Relocation ___________________________________ ___________________________________

OOS # (if applicable) ___________________

Relocation Details: * *Document contents either by rack number or by brief description of materials and the quantity of each (e.g., 3 cryoboxes, 4 bags of blood tubes, etc.). For relocation to or from units that do not follow this location format as displayed below, design a separate diagram using the back of this form.*

Relocation/Backup Unit ID________________ (if multiple relocation units are warranted, use additional forms and define as continuation)

Backup Shelf #:	**Backup Location 1**	**Backup Location 2**	**Backup Location 3**	**Backup Location 4**	**Backup Location 5**	**Backup Location 6**	**Backup Location 7**	**Original Shelf #:**
	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	
	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	
	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	
	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	
	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	
	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	Original Location___ Contents:	

Reviewed By (*Initials/Date*):_______________________________________

INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

Year_____ Page____ of____

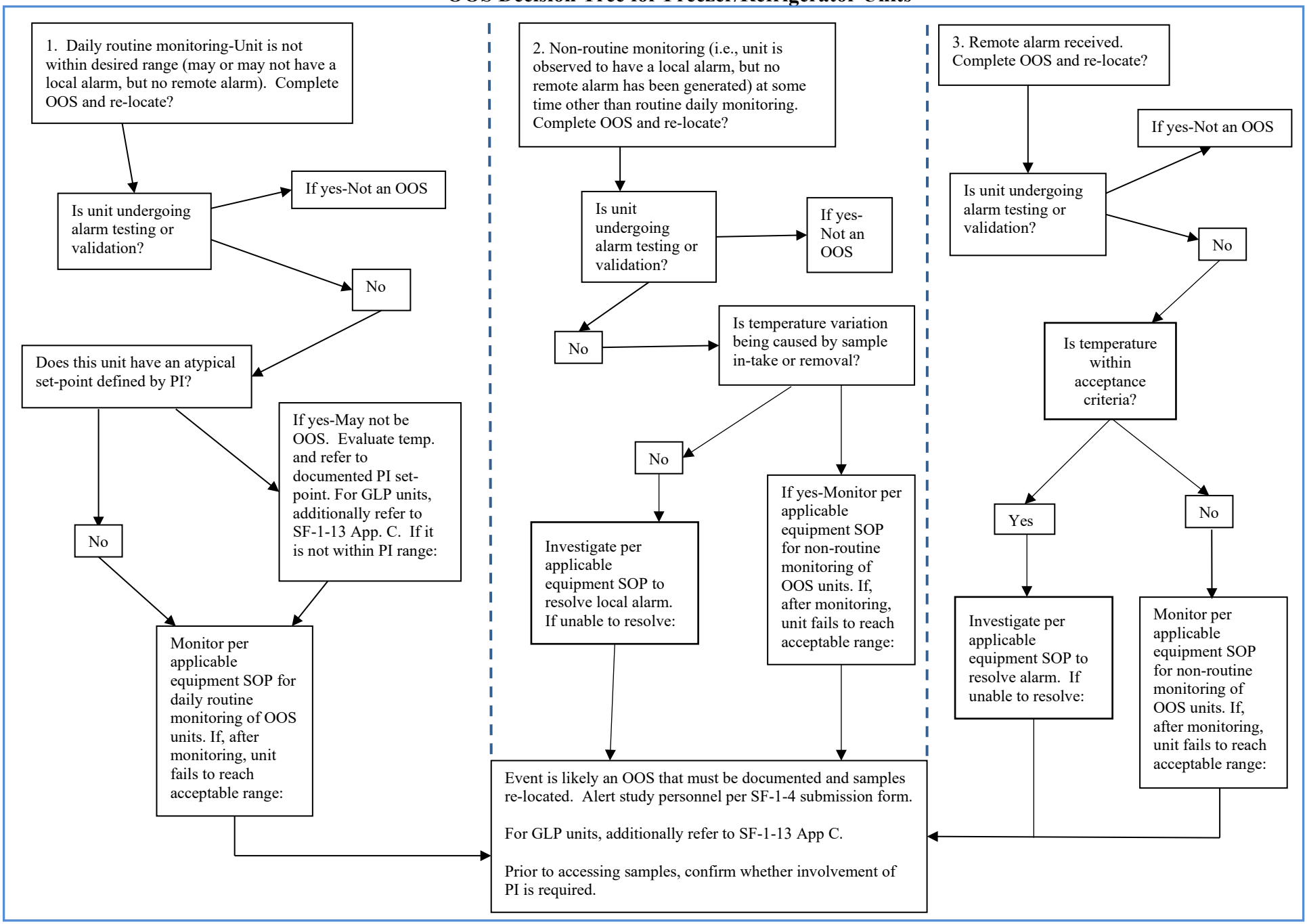
	Date Initiated	OOS # Assigned (O-*yy-xx*)	OUT-OF-SPECIFICATION (OOS) Event Description (Initials/date)	Storage Unit Location ID and SN (if applicable)	Follow-Up Req'd	Follow-Up Complete Date/By	Comments (Initials/Date)	Close-Out Date By: Date/ Initials
1		O-___-___			❑ No ❑ Yes	❑ N/A Follow-up Complete Date: Initials:		
2		O-___-___			❑ No ❑ Yes	❑ N/A Follow-up Complete Date: Initials:		
3		O-___-___			❑ No ❑ Yes	❑ N/A Follow-up Complete Date: Initials:		
4		O-___-___			❑ No ❑ Yes	❑ N/A Follow-up Complete Date: Initials:		
5		O-___-___			❑ No ❑ Yes	❑ N/A Follow-up Complete Date: Initials:		

Quarterly Review of Open OOS Occurrences:

Q1: ☐Yes ☐N/A date/initials_____ Q3: ☐Yes ☐N/A date/initials_____

Q2: ☐Yes ☐N/A date/initials_____ Q4: ☐Yes ☐N/A date/initials_____

OOS Decision Tree for Freezer/Refrigerator Units



OOS Temperature Monitoring Log (Suggested Tool)				
OOS #	O - ____ - ____	Time	Temperature (°C)	Initials
Unit ID:		(AM / PM)		
Date:		(AM / PM)		
Freezer Type:	☐ MRU ☐ LN_2	(AM / PM)		
Monitoring:	☐ High temperature ☐ Low temperature	(AM / PM)		
Alarm Set Point (°C):		(AM / PM)		
Notes:		(AM / PM)		
		(AM / PM)		
		(AM / PM)		
		(AM / PM)		
		(AM / PM)		

INDIANA CTSI Clinical and Translational Sciences Institute	**Non-Storage Unit Out-of-Specification (OOS) Event Report**	**OOS #** O-_____-_____ *O-yy-xx*

1. Reporting Information	Event Date:	Initiating Technician (*Initials*):
Report Date:	Event Time: (AM / PM)	

Alarm Type Received: ☐ N/A ☐ High Temp ☐ Other: _____

Total Pages _____ *(Including this form)*	**Attachments**		☐ Other Documentation (*Describe*)	☐ N/A
	☐ Notification Correspondence	☐ N/A		
	☐ Alarm Log	☐ N/A		
	☐ Equipment Log	☐ N/A		
	☐ Approval Correspondence	☐ N/A		
	☐ Other Correspondence	☐ N/A		

2. Description of Equipment/Facility

☐ Equipment *(Describe)*: _____

☐ Facility *(Describe)*: _____

3. Description of OOS Event

OOS Description *(Include Initials/Date)*:

4. Repair/Follow-Up Actions Required

☐ N/A

Repair Initiation Date:	Repair Completion Date:

Repair Description *(Include Initials/Date)*:

Follow-Up/Comments *(Include Initials/Date)*:

5. OOS Attribution / Comments

Cause/Attribution *(Include Initials/Date)*:

6. Close-Out

SSF Director Review / OOS Close-out Date *(Initials/Date)*: