Clinical and Translational Support Laboratory

Out of Specification Condition and Notification Management

SOP No./WI No.: CTSI-CRC-PL-105

Department: Processing Laboratory

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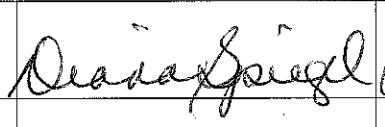
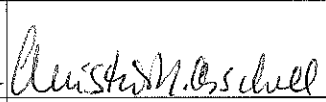
Signature			
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1. OBJECTIVE

This procedure establishes a procedure to investigate and respond to out-of-specification (OOS) conditions per the Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

2.1. This Standard Operating Procedure (SOP) applies to the CTSL staff and the CTSL Director, and, as applicable, the study or quality assurance personnel who are involved in the investigation, documentation and review for the OOS condition that has reached the level of referral to this SOP.
2.2. OOS events involving units undergoing alarm testing/validation are excluded from the scope of this SOP.
2.3. Sample relocation during the defrosting of mechanical refrigeration units is documented on CTSI-CRC-PL-FM502 OOS Specimen Relocation Record as defined in the CTSI-CRC-PL-301 Mechanical Refrigeration Units. However, defrosting is not considered to be an OOS event and is not logged or documented as such.

3. RESPONSIBILITIES

CTSL personnel are responsible for following the procedure defined in this SOP.

4. DEFINITIONS

4.1. Principle: OOS events have the potential to impact the quality of the material stored in the CTSL. 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

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	PL: Processing Lab
PI: Principal Investigator	OOS: Out of Specification
SOP: Standard Operating Procedure	

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 Document Control and Management
5.2. CTSI-CRC-CLN-030 Handling of SOP Deviations
5.3. CTSI-CRC-CLN-031 Handling Protocol Deviations
5.4. CTSI-CRC-PL-121 General Safety
5.5. CTSI-CRC-PL-301 Mechanical Refrigeration Units
5.6. CTSI-CRC-PL-106 Alarm System Management and Response

6. PROCEDURE

6.1. Materials required:
  6.1.1. Back up freezers - may be located in the CTSL, the Specimen Storage Facility (SSF) or in another campus facility(provided their monitoring/alarming is compliant with CTSL's standard practices for specimen storage).
6.2. Determine if OOS Requires Relocation of Specimens. (If the event is a freezer/refrigerator unit temperature that is in question, refer to Appendix A- OOS Decision Tree for Freezer/Refrigerator Units to determine whether or not OOS documentation is warranted/samples need to be relocated).
6.3. **Relocation required** (i.e., the OOS event is the temperature of a specimen storage unit, such as a -80˚C freezer):
  6.3.1. Quickly move specimens to a back-up unit and disconnect alarm of the OOS unit per CTSI-CRC-PL-106 Alarm System Management and Response.
  6.3.2. Initiate the OOS event in the CTSI-CRC-PL-LG603 OOS Occurrence Log.
  NOTE: The OOS Occurrence Log serves as a Table of Contents for the OOS Response Forms and is used to summarize the initiation/completion of OOS events.
    6.3.2.1. Record the date on which the OOS is initiated
    6.3.2.2. Assign an OOS number (CT-O-yy-xx) as follows:
      6.3.2.2.1. CT-O = the OOS event occurring within the CTSL
      6.3.2.2.2. yy= the last two digits of the current calendar year
      6.3.2.2.3. xx= the number assigned to each occurrence sequentially beginning at 01 throughout each calendar year.
    6.3.2.3. Write a brief description of the OOS
    6.3.2.4. Record information on CTSI-CRC-PL-FM501 OOS Response Form
      6.3.2.4.1. OOD Date and Time defines the date and time CTSL Personnel were notified that the OOS condition had escalated to referral to this SOP.
      6.3.2.4.2. Unit ID defines the specific info for a freezer/controlled environment storage unit or descriptive info for other OOS.

If a CTSI owned specimen storage unit, identify the PI's who own the specimens affected and record.

6.3.2.4.3. Complete the OOS description column to include the exact data pertinent to the OOS (e.g., temperatures over time) until the specimens are moved or until the issue is resolved.

6.3.2.4.4. PI Personnel Notified defines that the notification of PI personnel is not applicable or, if applicable, defines the sequence of contacts.

6.3.2.4.4.1. If PI personnel are to be involved, but are not responsive, notify CTSL Director for guidance.

6.3.2.4.4.2. If the CTSL Director is not able to be contacted, proceed with the move and record attempts for notification (date, time and contact method) on CTSI-CRC-PL FM501 OOS Response Form.

6.3.2.4.5. Request additional CTSL personnel to assist as needed.

6.3.2.4.6. If specimen locations are managed by the CTSI Data/Specimen Management System, record relocation information in the database.

6.3.2.4.7. Complete the Relocation Column and indicate that the alarm has been disconnected, if applicable, per CTSI-CRC-PL-106 Alarm System Management and Response. (Applicable only for events involving a specimen storage unit).

6.3.2.5. Record relocation details on CTSI-CRC-PL-FM502 OOS Specimen Relocation Record.

6.3.2.6. Begin to record Follow-up actions, if any, on CTSI-CRC-PL-FM501 OOS Occurrence Log.

6.3.2.7. Record follow-up actions, if any, as requires on CTSI-CRC-PL-LG603 OOS Occurrence Log.

6.3.3. When repair is complete and unit is verified to be functional, reconnect original unit to alarm per CTSI-CRC-PL-106 Alarm System Management and Response and, if applicable, return samples:

6.3.3.1. Complete the Follow-up actions on CTSI-CRC-PL-FM501 OOS Response Form.

6.3.3.2. Complete the "Returned to Primary Unit" column of CTSI-CRC-pl-FM501 OOS Response Form.

6.3.3.2.1. Indicate that the alarm has been reconnected, if applicable, per CTSI-CRC-PL-106 Alarm System Management and Response.

6.3.3.2.2. Record actions on the freezer log to include the parameter for monitoring prior to returning specimens to unit and documentation that alarm functions as intended.

6.3.3.3. Complete Page 2 of CTSi-CRC-PL-FM502 OOS Specimen Relocation Record.

6.3.4. Complete CTSI-CRC-PL-FM501 OOS Response Form with summary of cause of OOS and applicable comments.

6.3.5. Complete CTSI-CRC-PL-LG603 OOS Occurrence Log with date that5 the follow-up was completed, if applicable, and any comments.

6.4. **No Relocation required:** (i.e., the OOS event is something other than the temperature of a specimen storage unit):

6.4.1. Complete CTSI-CRC-PL-FM501 OOS Response Form as described above.

6.4.2. Follow applicable SOP for investigation and record all relevant information including Cause and Comments.

6.5. Send the completed OOS Forms to the CTSL Manager for review. If CTSL manager is author of the OOS form, present OOS to the CTSL Director for review.

6.6. Provide PI(s) for affected samples with a copy of the applicable OOS forms (CTSI-CRC-PL-FM501 OOS Response Form), if applicable.

6.7. The CTSI-CRC-PL-LG603 OOS Occurrence Log is retained in the CTSL

6.7.1. OOS documents initiated during the calendar year are reviewed quarterly to determine the resolution status of the recorded events.

6.7.2. Document quarterly review by providing initials and date of review at bottom of each log page.

6.7.3. Any OOS that are not completed or still require follow up past the date of the quarterly review will be highlighted and a comment must be added with proposed follow up/completion date.

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

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

6.10. Protocol deviations are managed per CTSI-CRC-CLN-031 Handling Protocol Deviations

7. REFERENCES

None

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment: 08 Dec 2016

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Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-005
Details of Amendment:	Updated to footer file location; updated the SOPs in 6.9, 6.10, 5.2, and 5.3; 6.1.1 modified for clarity; 6.5 modified to allow manager to review OOS unless manager is author; 6.7.2 and 6.7.3 added to further define and clarify quarterly review process