Clinical and Translational Support Laboratory

Alarm System Management and Response

SOP/WI No.: CTSI-CRC-PL-106

Department: Processing Laboratory

Version No.: 03

Effective Date: 05 Jan 2017

Supersedes: CTSI-CRC-PL-106-02 Effective Date: 01 Oct 2014

Page No: 1 of 10

Review Period: 2 Years

	Revised by	Reviewed by	Approved by
Name	Robert Orr	Diana Spiegel	Christie Orschell
Job Title	Laboratory Manager	Quality Manager	Director
Signature	RO	DSpiegel	Christie M. Orschell
Date	23 Dec 2016	28 Dec 2016	Dec 29, 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Clinical and Translational Support Laboratory (CTSL) to manage the alarming and notification parameters for CTSL owned units in response to out-of-specification conditions detected by the Smart-Vue alarm system in RI 2632 and the Sensaphone alarm system in UH 5582C and to define the procedure to be followed by CTSL personnel when an alarm notification is received.

2. SCOPE

The SOP applies to CTSL personnel assigned to install wiring, activate new alarm modules, maintain and update settings in each system and acknowledge and respond to units in alarm status located in University Hospital room 5582C and Riley Hospital room RI 2632. Alarming is managed by 2 separate systems. The Sensaphone system is utilized in University Hospital room 5582C and the Smart-Vue monitoring system is utilized for units in Riley Hospital room RI 2632.
The alarms set point parameters are defined in section 6.3.2.1.6. The alarm points for the CTSL are limited to Mechanical Refrigeration Units.

3. RESPONSIBILITIES

3.1. CTSL personnel are responsible for compliance with this procedure when setting up alarm points and responding to alarm conditions.

4. DEFINITIONS

4.1. Principle: Specimen storage, even on a temporary basis, must involve continuous monitoring of critical systems in order to safeguard the specimens and to remain in compliance with GCP. This is accomplished in the CTSL via programmable electronic monitoring and alarm devices designed to transmit alarm notifications for each individual alarm tag to specific destinations defined by the CTSL. The methods for alarm notification include pagers and phones. Effective systems for maintaining specimen integrity also require that changes are incorporated by a thoughtful, defined, and recorded procedure and alarms are responded to appropriately and, thus, these must also be defined.

CTSL: Clinical and Translational Support Laboratory	ICTSI: Indiana Clinical and Translational Sciences Institute
SOP: Standard Operating Procedures	SSF-Specimen Storage Facility

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-CLN-030 Handling of SOP Deviations
5.2. CTSI-CTSL-PL-301 Mechanical Refrigeration Units
5.3. CTSI-CTSL-LG615 CTSL Alarm Description and Response Log
5.4. CTSI-CRC-PL-105 Out of Specification Condition and Notification Management

6. PROCEDURE

6.1. Management of CTSL Personnel "on-call" status
  6.1.1. CTSL Personnel are "on-call" from approximately 5:30PM to 7:00 AM on work days and 24 hrs on days personnel are not scheduled to work and as needed to provide 24 hour/7 day per week coverage. If the on-call person is unable to respond it is the responsibility of this person to notify management or, if unable to reach management, notify other staff to arrange for alarm response to be covered.
  6.1.2. The CTSL Operations Manager manages the on-call schedule. Conflicts are referred to the CTSL Director.

6.2. Alarm system management – **Sensaphone Alarm Monitoring System.** All following instructions are based on the Sensaphone Model 1104 manual which can be found online (see link in 7. Reference below). Additional copies (electronic and hard) of the manual are maintained in the equipment records.
  6.2.1. Installation of alarm wires and alarm point activation.
    6.2.1.1. Connect alarm wires to the normally open position of the alarm output of each unit if possible. A normally closed connection is acceptable as the alternative.
    6.2.1.2. Connect alarm wires to inputs on the Sensaphone per manual section 5.1.
    6.2.1.3. Set the configuration (normally open or normally closed) on the Sensaphone per manual section 5.1.1.
    6.2.1.4. If activating a new alarm point or resetting an alarm point configuration, follow manual section 3.3, section 5.1 and section 5.2.
    6.2.1.5. Set the AC power failure alarm settings per section 5.8.
    6.2.1.6. Set recognition time to 15 minutes per section 5.9.1.
  6.2.2. System settings
    6.2.2.1. The alarm system phone number in the CRC is 278-7367. This is the number the on call pager will receive during an alarm notification.
    6.2.2.2. Set "Input Recognition Time" for each alarm setpoint to 15 minutes according to manual section 5.3.
    Note: The 15 minute recognition time only pertains to units that alarm as soon as an alarm parameter has been exceeded. Adjust the "Input Recognition Time" so that the delay (recognition time) between alarm activation of the refrigeration unit and the start of alarm notification of

personnel will not exceed 15 minutes (+/- 3 minutes) when setting up units with built in delay periods.

6.2.2.3. Set the "Call Delay" to 0 minutes per manual section 4.8.

6.2.2.4. Set the "Intercall Time" to 30 minutes per manual section 4.11.

6.2.2.5. Set the "Max Calls" to the system limit of 255 per section 4.12.

6.2.3. Call Tree – The Sensaphone system can call up to 4 numbers in succession with a delay between calls ("Intercall Time" – see 6.2.2.4). This call pattern will repeat until the maximum number of calls is reached ("Max Calls" – see 6.2.2.5)

6.2.3.1. Set the dial out telephone numbers per manual section 4.2.

6.2.3.1.1. Dial out number #1 – CTSL on-call pager.

6.2.3.1.2. Dial out number #2 – CTSL on-call pager.

6.2.3.1.3. Dial out number #3 – Specimen Storage Facility on-call pager #1.

6.2.3.1.4. Dial out number #4 – CTSL management contact number.

6.3. Alarm system management – **Smart-Vue Alarm Monitoring System.**

6.3.1. All operations, including setup and maintenance, of the Smart-Vue system are covered by the Smart-Vue Software User Manual (version dated January 2011). The manual can be accessed by clicking on the "Help" tab within the Smart-Vue software and is also available at https://static.thermoscientific.com/images/D21582~.pdf

6.3.1.1. Username and password for Smart-Vue system – refer to Chapter 3 "Managing Users" of the Smart-Vue Software User Manual (version dated January 2011).

6.3.1.1.1. Log on to the alarm system host PC by using university username and password.

6.3.1.1.2. Username of authorized personnel who have access to the Smart-Vue software will be first initial and last name with no spaces and lower case letters only.

6.3.1.1.3. Initial password will be set up by management.

6.3.1.1.4. Upon initial login by the new user, a prompt to change the new user's password will appear and must be completed before accessing the system for the first time.

6.3.1.2. Configuration and management of alarm system modules (sensors) – refer to chapter 4 of the Smart-Vue Software User Manual (version dated January 2011).

6.3.1.2.1. Adding a module (sensor) to the system must be done by manual entry only (section 4-28).

6.3.1.2.2. Module name will be the same as the identification of the refrigeration unit the module is assigned to monitor.

6.3.1.2.3. Module will be placed in the tree structure based upon its location (Module group name will be based upon the

room/location of the monitored refrigeration unit). Refer to section 4-24 "Managing the tree structure".

6.3.1.2.4. Replacement of module battery will be performed annually at a minimum or if battery power reaches 25% capacity. Refer to section 4-38 for battery replacement procedure.

6.3.1.2.4.1. Before replacing the battery, download data from the module. Refer to chapter 5, section 5-63.

6.3.1.2.4.2. Contact management if module cannot upload data to the main system prior to removing the battery.

6.3.1.2.5. Module parameters under Sensor settings tab – Refer to 4-43 Configuring Sensors (modules)

6.3.1.2.5.1. Set Transfer Interval to 1 hour.

6.3.1.2.5.2. Set Measurement interval to 15 minutes.

6.3.1.2.5.3. Set Unit to correct sensor type (temperature PT100 for refrigeration unit sensors)

6.3.1.2.5.4. Ensure the Mobile module box is not checked.

6.3.1.2.5.5. Set number of attempts before "error absence" is displayed to 10.

6.3.1.2.5.6. Verify sensor name is correct.

6.3.1.2.5.7. Ensure Automatic module reconnection via SDP is not checked.

6.3.1.2.6. Alarm parameters - Alarm settings tab (in Sensor Settings) – Refer to Chapter 6 "Configuring and Managing Alarms"

6.3.1.2.6.1. ULT (-80.0°C) Freezer alarm settings

6.3.1.2.6.1.1. Set High Alarm to -60.0°C.

6.3.1.2.6.1.2. Set Low Alarm to -95.0°C.

6.3.1.2.6.1.3. Set both delays to 15 minutes.

6.3.1.2.6.1.4. Set spontaneous transmission tries to 15

6.3.1.2.6.1.5. Set delay between unsuccessful alarm transmissions to 60 seconds.

6.3.1.2.6.1.6. Ensure Enable alarm limit, Sensor fault alarm and Low battery alarm boxes are checked.

6.3.1.2.6.1.7. Ensure Disable spontaneous alarm transmission and Automatic module reconnection via SDP are unchecked.

6.3.1.2.6.2. -20.0°C Freezer alarm settings

6.3.1.2.6.2.1. Set High Alarm to -20.0°C.

6.3.1.2.6.2.2. Set Low Alarm to -40.0°C.
6.3.1.2.6.2.3. Set both delays to 15 minutes.
6.3.1.2.6.2.4. Set spontaneous transmission tries to 15
6.3.1.2.6.2.5. Set delay between unsuccessful alarm transmissions to 60 seconds.
6.3.1.2.6.2.6. Ensure Enable alarm limit, Sensor fault alarm and Low battery alarm boxes are checked.
6.3.1.2.6.2.7. Ensure Disable spontaneous alarm transmission and Automatic module reconnection via SDP are unchecked.

6.3.1.2.6.3. 4.0°C Refrigeration alarm settings
6.3.1.2.6.3.1. Set High Alarm to 8.0°C.
6.3.1.2.6.3.2. Set Low Alarm to 2.0°C.
6.3.1.2.6.3.3. Set both delays to 15 minutes.
6.3.1.2.6.3.4. Set spontaneous transmission tries to 15
6.3.1.2.6.3.5. Set delay between unsuccessful alarm transmissions to 60 seconds.
6.3.1.2.6.3.6. Ensure Enable alarm limit, Sensor fault alarm and Low battery alarm boxes are checked.
6.3.1.2.6.3.7. Ensure Disable spontaneous alarm transmission and Automatic module reconnection via SDP are unchecked.

6.3.1.2.7. Review all module settings by clicking on Settings status under the Reports tab if a new module has been added to the system or if any module settings have been modified.
6.3.1.2.7.1. Print a copy of the settings status report (Chapter 10, section 10-111). Review, sign and date next to each module name.
6.3.1.2.7.2. If any module settings are found to be incorrect, notify management and document as an SOP deviation per CTSI-CRC-QA-004 Handling of SOP Deviations.

6.3.2. Call Tree – The Smart-Vue Alarm Monitoring System will contact personnel per the pattern described below until the alarm has been acknowledged at the control

panel. The method for configuration of the call tree is located in Chapter 7 "Configuring and testing alerts".

6.3.2.1. The following steps list the minimum required contacts for each group. Additional contacts may be added to each group as required.

6.3.2.1.1. CTSL group

6.3.2.1.1.1. CTSL group email

6.3.2.1.1.2. CTSL on-call pager (via SMS)

6.3.2.1.1.3. Operations Manager secondary contact

6.3.2.1.2. System admin contact group

6.3.2.1.2.1. Operations Manager cell phone

6.3.2.1.3. SSF contact group

6.3.2.1.3.1. SSF on-call pager #1

6.3.2.1.3.2. SSF on-call pager #2

6.3.2.2. Each group of modules will be assigned at least one contact group to be notified when an alarm condition is present. Refer to section 7-88 "Configuring alerts for groups and receivers".

6.4. Alarm response.

6.4.1. **Sensaphone Alarm Monitoring System** (UH5582C)

6.4.1.1. Acknowledge alarms according to manual section 6.1.

6.4.1.2. Evaluate alarm situation and respond per CTSI-CRC-PL-301 Mechanical Refrigeration Units.

6.4.1.3. Responding technicians will notify CTSL management if resolution of alarm condition cannot be obtained.

6.4.1.4. Document alarm and response on CTSI-CRC-PL-LG614 CTSL Alarm Description and Response Log.

6.4.2. **Smart-Vue Alarm Monitoring System** (RI 2632)

6.4.2.1. Evaluate alarm situation and respond per CTSI-CRC-PL-301 Mechanical Refrigeration Units.

6.4.2.2. Disable alarm notification at the Smart-Vue PC per the Acknowledging Alarms section 6-80.

6.4.2.2.1. Select alarm from the alarm list by double clicking on the line or clicking the red acknowledgement button (stop sign with exclamation point)

6.4.2.2.2. Enter Cause of Incident either by typing in the box or selecting from drop down list.

6.4.2.2.3. Enter corrective action. Document OOS number if available at this time.

6.4.2.2.4. Disable sensor only if the freezer requires repair and all samples will be removed immediately. This can also be done on the Sensor settings window after samples have been removed.

6.4.2.3. Responding technicians will notify CTSL management if resolution of alarm condition cannot be obtained.
6.4.2.4. Document alarm and response on CTSI-CRC-PL-LG614 CTSL Alarm Description and Response Log.

6.5. Function Verification and Maintenance – Weekly, monthly and annual verifications will be documented on CTSI-CRC-PL-LG619 Smart-Vue Alarm System Verification and Maintenance Log
6.5.1. Weekly
6.5.1.1. Alarm notification test – refer to section 7-96
6.5.1.1.1. Choose a freezer module from the tree
6.5.1.1.2. Select "High Limit Alarm" from the dropdown box under the "Select remote to be tested"
6.5.1.1.3. Document the time the page, email and call were received on the printed report.
6.5.1.1.4. If any expected alert is not received, notify management and document as an SOP deviation per CTSI-CRC-QA-004 Handling of SOP Deviations.
6.5.1.1.5. Initial, date and retain the completed report.
6.5.1.2. Battery power check – refer to section 8-102
6.5.1.2.1. Print the results of the battery power check.
6.5.1.2.2. Verify that each module's battery power is greater than 25% by placing a check mark next to each measurement.
6.5.1.2.3. Replace batteries that have 25% capacity or less per section 4-38.
6.5.1.2.4. Document the battery change on the printed battery power report.
6.5.1.2.5. Initial, date and retain the completed report.
6.5.1.3. Wireless performance test – refer to section 8-100
6.5.1.3.1. Print the results of the wireless performance test.
6.5.1.3.2. If any value in the Power column is less than 30%, initiate an out of specification per CTSI-CRC-PL-105 Out Of Specification Response and Notification Management and relocate any specimens in the unit to a backup until resolution has been obtained.
6.5.2. Monthly
6.5.2.1. Run an alarm report per section 10-112. Verify that each alarm noted on the report has been documented and resolved per section 6.4 of this SOP.
6.5.3. Annually
6.5.3.1. Perform calibration verification for each module per section 6.2.4.1 of CTSI-CRC-PL-301 Mechanical Refrigeration Units.

6.5.3.2. Run a Settings Report per section 10-112 to verify all settings of each module meet specifications described in steps 6.3.2.1.5 and 6.3.2.1.6 of this SOP.

6.6. Documents

6.6.1. Alarm responses are documented on CTSI-CRC-PL-LG614 CTSL Alarm Description and Response Form.

6.6.1.1. Printed alarm reports from the Smart-Vue alarm system will be attached to the appropriate CTSI-CRC-PL-LG614 CTSL Alarm Description and Response Form.

6.6.1.2. CTSI-CRC-PL-LG614 CTSL Alarm Description and Response Forms will be reviewed monthly by CTSL Management.

6.6.2. Weekly, monthly and annual verifications will be documented on CTSI-CRC-PL-LG619 Smart-Vue Alarm System Verification and Maintenance Log

6.6.3. Out of specification condition responses are managed through CTSI-CRC-PL-105 Out Of Specification Response and Notification Management

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

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

7. REFERENCES

7.1. Sensaphone Model 1104 manual (version 1.43) - http://www.sensaphone.com/legacy-products/1104Manual.pdf

7.2. Smart-Vue Alarm Monitoring System manual (version dated January 2011) - The manual can be accessed by clicking on the "Help" tab within the Smart-Vue software and is also available at https://static.thermoscientific.com/images/D21582~.pdf

8. APPENDICES

n/a

9. AMENDMENT HISTORY

Date of Amendment:	09 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-006

Details of Amendment:	Updated to footer file location; Updated the SOPs in 5.2 and 6.6.5.;Updated 6.6.5 with correct SOP number;Removed step 6.3.1.1.5;