



STEM CELL LABORATORY (STCL)



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Temperature and Environmental Monitoring Systems for the Stem Cell Laboratory

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STCL-EQUIP-021

TEMPERATURE AND ENVIRONMENTAL MONITORING SYSTEMS FOR STCL LABORATORY

1 PURPOSE

- 1.1 To describe the automated monitoring system that provides compliance with set limits for temperature and humidity for applicable equipment and Stem Cell Laboratory space and the appropriate response to each alarm state.

2 INTRODUCTION

- 2.1 The monitoring systems used by the Stem Cell Laboratory are REES Scientific using the Centron Software and Duke's Building Automating System (B.A.S.).
- 2.2 The Centron system monitors any type of input, analyzes the system data for trouble, and ensures, in the event of an alarm, that the appropriate people are notified in a timely manner.
- 2.3 The Centron system provides detailed records of all events encountered.
- 2.4 The Centron node provides records that show periodic readings when conditions are normal. In the event of an alarm, Centron records the time of the alarm, the nature of the alarm, the phone number contacted to report the alarm, and the time the alarm was corrected. Any user, who inhibits, enables, resets an alarm, or changes the program will be identified by name in the audit log.
- 2.5 The Building Automation System (B.A.S.) consists of computerized equipment to monitor, control, and record alarms for major equipment, which includes the following: Fire Alarm System, HVAC System, Building Security System, Emergency Generator System, and Plumbing System (including Medical Gases).

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Stem Cell Laboratory also utilizes the B.A.S. for monitoring of essential equipment that is either currently not covered by REES Scientific or is used as a secondary backup to REES Scientific's monitoring system. B.A.S. provides continuous monitoring but does not track individual equipment temperatures for quality control purposes but rather just alarm states.
- 3.2 The Stem Cell Laboratory Medical Director, Quality Systems Unit, Laboratory Manager, and the participating laboratory staff are responsible for ensuring that requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 B.A.S. Building Automation System
- 4.2 REES REES Scientific Monitoring System
- 4.3 N2 Nitrogen
- 4.4 O2 Oxygen
- 4.5 STCL Stem Cell Laboratory

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 B.A.S.- Building Automation System (919-684-3232 or 681-2365)
- 6.2 REES Monitoring System (609-408-0073 Technical Support)
- 6.3 Barlow Scientific (919-245-1129) – Support for Refrigerators, Freezers, etc.

7 SAFETY

- 7.1 O₂ Depletion alarms are installed in designated freezer locations to warn personnel if there is excess N₂ causing a decreased O₂ level which poses a risk to staff working in close proximity.

8 PROCEDURE

- 8.1 Alert/Alarm set points
 - 8.1.1 The alert/alarm set points for each broad category of equipment is detailed in those applicable SOPs for each.
 - 8.1.2 Permanent changes to any set points in REES require submission of a Change Control Request per COMM-QA-019 with corresponding changes made to this SOP prior to implementing change.
 - 8.1.3 Temporary changes to any set points in REES require submission of a Planned Deviation per COMM-QA-042 prior to implementing change.
 - 8.1.4 Any changes to set points require documentation of comments in REES system.
- 8.2 How the REES alarms are reported (see also STCL-EQUIP-021 *JAI Centron Presidio User Guide*).
 - 8.2.1 During an alarm condition, Centron software examines the alarm instructions on how to respond to the alarm.
 - 8.2.2 The telephone list that is used during an alarm is established in the alarm programming.
 - 8.2.3 The voice system calls each phone number in turn repeating the alarm message for 2 minutes. The alarm message will normally consist of the Centron unit identification number (ie. Node#), the input number of the probe affected, the current reading, and the acceptable range (*if applicable*).
 - 8.2.4 Once Centron receives a response, it communicates an acknowledgement message and logs the following data:
 - 8.2.4.1 The date and time
 - 8.2.4.2 Which input# (sensor) generated the alarm

- 8.2.4.3 The current (alarm) reading
 - 8.2.4.4 Which phone number responded
- 8.2.5 While Centron is going through an alarm sequence, it continues to scan the remaining inputs. Multiple alarm conditions are handled on a priority basis and as determined by user assigned priority rankings.
- 8.3 Alarm Controls
 - 8.3.1 The alarm in Thermogenesis BioArchive is at non-alarm state unless:
 - 8.3.1.1 Hi LN2
 - 8.3.1.2 Ex Low LN2
 - 8.3.1.3 LN2 sensor failure (alarm sensor path interruption)
 - 8.3.1.4 Power failure
 - 8.3.2 The alarm for the MVE LN₂ vapor phase freezer will alarm when:
 - 8.3.2.1 Colder than -190°C (during fill)
 - 8.3.2.2 Warmer than -150°C
 - 8.3.2.3 Temperature sensor has electrical path interruption.
- 8.4 Responses to Alarms
 - 8.4.1 Instructions for REES telephoned alarms
 - 8.4.1.1 *STCL-EQUIP-021 JA4 Quick Guide to Responding to Rees Alarms*
 - 8.4.1.1.1 Press the telephone buttons slowly.
 - 8.4.1.1.2 Do not share passwords.
 - 8.4.1.1.3 Keep telephone numbers in Centron call database current.
 - 8.4.1.1.4 Know which input / probe number refers to which piece of equipment. A current list of inputs is located in the processing area of the STCL.
 - 8.4.1.2 Response to alarms must be documented in REES within 72 hours.
 - 8.4.2 Action Requirements
 - 8.4.2.1 Bring up the alarm control screen by any of the following:
 - 8.4.2.1.1 Double click on the input that is in alarm (Inputs in alarm will be flashing red).
 - 8.4.2.1.2 Click on the alarm button on the tool bar (The button looks like a loudspeaker).

- 8.4.2.1.3 Go to the Alarm menu and select “Specific Alarms”.
 - 8.4.2.2 The Alarm Control box will show the alarm handling instructions for the particular input and allow inhibiting or reset/enabling of the input in question.
 - 8.4.2.3 After an alarm has been responded to, select the running log then select the event (if appropriate).
 - 8.4.2.3.1 Select the “Note” button and answer any questions.
 - 8.4.2.3.2 Add comments and any additional information that might be required.
 - 8.4.2.4 Generate an “Event History for this Node” report in the File menu.
 - 8.4.2.4.1 Select this event.
 - 8.4.2.4.2 Respond to the alarm report there.
 - 8.4.2.5 Response to alarms must be documented in REES within 72 hours.
- 8.4.3 Handling Alarms (see also *STCL-EQUIP-021 JA4 Quick Guide to Responding to REES Alarms*),
 - 8.4.3.1 Inhibit an alarm
 - 8.4.3.1.1 Turn off an alarm for a period of time, after which it automatically enables.
 - 8.4.3.2 Reset/Enable an Alarm
 - 8.4.3.2.1 Allows an inhibited alarm to be brought back online immediately.
 - 8.4.3.2.2 Allows resetting of a latched alarm that has been triggered, a non-latched alarm that has been “acknowledged”, or registering of a “nobody home” condition.
 - 8.4.3.3 Groups of Alarms
 - 8.4.3.3.1 Allows inhibiting of an entire department / group of alarms.
 - 8.4.3.4 Add/Edit Comment
 - 8.4.3.4.1 Allows documentation to be entered during an alarm situation. Critical storage and monitoring equipment related to product manufacturing and storage require entry of a comment whenever an alarm is inhibited in the live system.

- 8.4.3.4.2 Select the alarm event in the running log, go to the ALARM menu, and select "Add/Edit Comment" (if applicable).
- 8.4.3.4.3 Select the event and then select the "Notes" button on the tool bar.
- 8.4.3.4.4 Double click on the event in the running log.
- 8.4.3.4.5 The alarm instructions (when appropriate), with responses and comments, are attached to the running log, along with the name, date and time.
- 8.4.4 Instructions for B.A.S. alarms
 - 8.4.4.1 If a refrigerator, incubator, or freezer alarm status is activated, a B.A.S. employee will refer to the Refrigeration Call List that is on file for the Laboratory.
 - 8.4.4.2 B.A.S. employees have been instructed to notify Laboratory Manager after hours, on weekends, and on holidays when an alarm has been activated.
 - 8.4.4.3 If the alarm is activated after hours and/or the B.A.S. employee is unable to contact a Laboratory Manager at the phone numbers listed, they have been instructed to contact via pager #: 919-970-2751 or cell phone #: 919-812-2521 to report the alarm status.
 - 8.4.4.4 Whenever possible, the staff member should attempt to evaluate and resolve the alarm status immediately. If the staff member cannot resolve the problem, Barlow Scientific should be contacted by calling 919-245-1129. This phone # can be used if/when support is needed after-hours, on weekends, and/or on holidays.
 - 8.4.4.5 The Laboratory Manager should be notified immediately of any problems resulting in the need to relocate cellular products or reagents to ensure that reinforcements (additional staff) are contacted if help is needed in the relocation process.
- 8.4.5 REES printouts generated
 - 8.4.5.1 Global Events Report
 - 8.4.5.1.1 This report is exactly the same as the event report for a node, except that it only shows program changes that were made under Global Option Programming.
 - Event history for this Node, "Node Events" tab, opens Event Selection Options. Enter date or select using drop down calendar.
 - 8.4.5.2 Show All Events
 - 8.4.5.2.1 Shows all events, regardless of type

8.4.5.3 Select by Input Name

8.4.5.3.1 Click on the arrow to display the list of input names. The system will locate the exact records of interest and display them on the screen, color coded by event.

8.4.5.3.2 Alarm events are highlighted in red, pending alarms and inhibited alarms are in yellow, programming changes are in black, and normal readings are in green.

8.4.5.4 Select by Input Number

8.4.5.4.1 Click on the arrow to display the list of input numbers. The system will locate the exact records of interest and display them on the screen, color coded by event.

8.4.5.5 Select by Event Type

8.4.5.5.1 The report will show all instances of that type of event for all inputs in the user's department/group or in the whole node if the user has access to all the node's inputs.

8.4.5.6 Readings Report - All Inputs

8.4.5.6.1 This allows a look at the routine reading samples, within a user's access group, that were logged on any node on any particular date that are on record in the system.

8.4.5.7 Readings Report - Single Input

8.4.5.7.1 This allows the viewing of the readings for a selected time frame for any individual probe in a user's access group.

8.4.5.8 Readings Report – Current Readings

8.4.5.8.1 This allows the viewing of the readings for all inputs in real time.

8.4.5.9 Averages Reports – Single Input

8.4.5.9.1 Show and/or Print individual probe's highs, lows, and averages.

8.4.5.10 Averages Reports – All Inputs

8.4.5.10.1 Show and/or Print highs, lows, and averages.

8.4.5.11 Averages Reports – Mean Kinetic

8.4.5.11.1 Mean Kinetic Temperature Report

8.4.5.12 Graphs – Readings Graphs

8.4.5.12.1 This allows the examining of the daily highs, lows and averages for any point on the system that is in the user's access group, on any particular date.

8.4.5.13 Graphs - Highs, Lows and Averages (Single Probe)

8.4.5.13.1 This allows the viewing of the daily highs, lows and averages for any single input on the system that is in the user's access group, on any particular date.

8.4.5.14 Advanced and Custom Reports

8.4.5.14.1 By selecting a report and optional node, input and department selection number types of report possibilities are available.

8.4.5.15 Other Reports

8.4.5.15.1 Node Program Printout - This prints a description of the entire user program for a user's department for the selected node.

8.4.5.15.2 System Summary - This prints a system overview summary report.

8.4.5.15.3 Export Readings - Exports the readings samples file as a comma delineated text file (Readings.txt)

8.4.5.15.4 Input Names by Number - This shows/prints all of the input names in input number order. A user's access will determine which inputs are printed.

8.4.5.15.5 Alphabetic Input Names - This shows/prints all of the input names in alphabetical order, followed by the input number. The user's access will determine which inputs are printed.

8.4.5.15.6 Master Phone Directory - This prints an alphabetical listing of all of the names and phone numbers that are in the master telephone directory.

8.4.5.15.7 Master Access Code Directory - This prints all of the security codes and names that are on the master directory.

8.4.5.15.8 Advanced and Custom Reports - The Mean Kinetic Temperature takes into account all variations and calculates the constant temperatures that would have produced equivalent spoilage of the samples.

8.4.6 Export Readings

- 8.4.6.1 All historical data is stored in an encrypted database for security and cannot be altered. This function creates a new unencrypted file (readings.txt) on the hard drive that can be used for reporting purposes.

8.4.7 Graph Readings

- 8.4.7.1 Select the input to graph by clicking on the input. Go into the File menu and select "Graph Readings" or click on the Graph button on the tool bar. When the graph window opens, it will automatically show the previous week's data on the graph or the previous dates chosen since the workstation program was launched.
- 8.4.7.2 Change the start and end dates for the graph by clicking on the right or left arrows, or by typing in new dates.
- 8.4.7.3 Graph High, Lows and Averages
 - 8.4.7.3.1 This graphs the daily highs, lows, and averages for a single input in the user's access group, over a period of time.

8.4.8 *STCL-EQUIP-021 JA2 Duke University User's Guide- Building Automation Systems*

- 8.4.8.1 Consists of computerized equipment to monitor, control and record alarms for major equipment, which include the following:
 - 8.4.8.1.1 Fire Alarm System
 - 8.4.8.1.2 HVAC System
 - 8.4.8.1.3 Building Security System
 - 8.4.8.1.4 Emergency Generator System
 - 8.4.8.1.5 Plumbing System (including Medical Gases)

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-EQUIP-021 JA1 Rees Scientific Centron Presidio User Guide
- 9.2 STCL-EQUIP-021 JA2 Duke University Users Guide- Building Automation Systems
- 9.3 STCL-EQUIP-021 JA3 Duke University Users Guide- Hospital Refrigeration
- 9.4 STCL-EQUIP-021 JA4 Quick Guide to Responding to REES Alarm
- 9.5 STCL-EQUIP-013 Alarm System and Instructions in the Event of Equipment Malfunction, Failure, or Repair
- 9.6 STCL-EQUIP-013 JA1 Refrigeration Call List
- 9.7 STCL-EQUIP-014 Instructions for Oxygen Depletion Alarm

- 9.8 STCL-EQUIP-016 Liquid Nitrogen Storage System
- 9.9 STCL-EQUIP-016 FRM1 LN2 Preventative Maintenance Checklist
- 9.10 STCL-EQUIP-016 FRM2 LN2 Distribution System Bi-Annual Checklist
- 9.11 STCL-EQUIP-016 JA1 LN2 Distribution System Preventative Maintenance
- 9.12 STCL-EQUIP-016 JA2 LN2 System Piping Diagram for North Pavilion
- 9.13 STCL-EQUIP-016 JA3 Access Instructions for 2309B Pratt Street Freezer Building

10 REFERENCES

- 10.1 Rees Scientific Centron Presido User Guide 2012
- 10.2 Server-Tower and REES Web Software User Manual Version 1.0

11 REVISION HISTORY

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