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| Purpose | The Viewpoint is a wireless temperature and environmental parameters monitoring system used to monitor appliances and locations that must be maintained within specific operating conditions. The System measures parameters such as temperature and humidity, which stores the data electronically in a central SQL database.This procedure describes the operating procedures for recording temperatures of equipment, refrigerators, freezers, including room temperature and humidity measuring devices for the laboratory using the Viewpoint Monitoring System. |

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| Policy | A digital thermometer or probe with a high/low alarm function is used to continuously monitor parameters such as temperature, humidity, and CO2 readings. A visual flashing strobe alarm is triggered if these parameters deviate from the established ranges.* The Digital Viewpoint Monitoring probes are calibrated annually by the manufacturer.
* A flashing light alert occurs if the parameter is above or below the min/max limit set for each equipment or location. This corresponds to a red flashing alert on the designated PC indicating which instrument or device needs to be addressed.
* Staff must determine which instrument is activating the alarm by opening the Viewpoint application on the designated PCs.
* Staff must respond to the alarms in a timely manner by manually checking the internal temperature of the equipment/location in question and recording the temperature in the Viewpoint t application. If temperature is not within operational range clear the alarm by selecting the equipment to access the alarm resolution tab.
* If the alarm cannot be resolved for temperature or humidity, contact Engineering for troubleshooting or repair and document in Viewpoint application.
* Staff must respond and address alarms for environmental temperature and humidity monitoring by investigating the reason for the parameter to be out of compliance, taking the necessary corrective action steps, and documenting in the Viewpoint application.
* During normal operating hours for Flow Cytometry Laboratory (FCL), the staff in this department will be responsible for addressing alarms for Flow Cytometry laboratory only.
* Outside of Flow Cytometry laboratory operating hours and including holidays, designated main laboratory staff will be responsible for addressing and resolving alarms.
* Daily maintenance check is performed by a CLS/MLT to perform function check and identify number of asset(s) that are currently on alarm and/or inhibited. Daily maintenance check is rotated between all shifts and is assigned on their designated monthly QC assignments( AM shift: JAN, APR, JUL, & OCT; PM shift: FEB, MAY, AUG, & NOV; GY shift: MAR, JUN, SEPT, & DEC). see Viewpoint Temperature Maintenance Log Form in Master Control.
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| System Checks |  |

 | The following tasks are performed below.Flow Cytometry (FCL) staff to address these checks within their department during their normaloperating hours. Otherwise, Main Laboratory staff perform the checks for the department. |

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| **System Checks** |
| **Action** | **Accountability** | **Description** | **Notes & Comments** |
| Review that ***all assets*** are functioning properly | * CLS OR MLT
 | Document review and findings in the Viewpoint Temperature Maintenance Log Form | Daily maintenance check is rotated between all shifts and is assigned on their designated monthly QC assignments |
| Address***Current Alarms Daily*** | * CLS or MLT
* Lead CLS
* Main Lab Manager
* FCL Manager
 | File Corrective Action and close alarm.**Do NOT** inhibit alarm without informing a Manager or lead CLS. | All alarms must be cleared from the Home window. Documentation is stored in the Viewpoint application. Main Lab staff to address alerts for Flow Cytometry outside of normal operating hours. |
| Review and Address **Inhibited Alarms *Daily*** | * Main Lab Manager
* FCL Manager
 | Management to verify if any alerts should remain in Inhibited status or can be cleared. | Management task to be done daily, excluding weekends and holidays. |
| Run a***Corrective Action******History Report Monthly*** | * Main Lab Manager
* FCL Manager
 | Verify all open alerts have been satisfactorily closed and corrective action has been taken. | Management report to be run and reviewed monthly. Reports should cover the time since last review. This review is stored electronically and may be printed. Printed reports may be retained by management in designated file or binder. |

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| Procedure | Follow the steps below for **Addressing Alerts**

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| **Step** | **Action** |
| 1.
 | The red flashing box with alert symbol displays the equipment name, tag ID, last time updated and the value that is out of range. |
| 1.
 | Investigate the equipment or environment to determine the cause of the alert. Take note of the parameter in question. |
|  | Click the equipment name to display the chart and select ‘Alarm Resolution’ tab to address the alarm. |
|  | Select how would you like to resolve the selected alarm.* Inhibit Alarm and Mute Notifications – Select if equipment is not operational and if issue will not be resolved right away. Proceed to Step 5a
* File Corrective Action and Close Alarm- Select if issue has been resolved and equipment is operational. Proceed to Step 5b
 |
|  | 1. Inhibit Alarm and Mute Notifications: Document reason for inhibiting the alarm(s) and corrective actions taken to resolve the issue. Identify how long to inhibit the alarm. Click ‘Inhibit Alarm’. *To update an Inhibited equipment, click filter ‘Inhibited’ under the home window and follow steps 3 - 5.*
2. File Corrective Action and Close Alarm: You can select common causes of the alarm or free text if it not in the selection provided. Document necessary corrective actions taken that resolved the problem. Click ‘Close Alarm’.

***Note: An electronic signature is required to sign off the corrective action documentation. It is important to address alerts in a timely manner. The program will not repeat an alert for the same equipment if such an alert already exists.*** |

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| Other Alerts | In addition to measurement value alerts, such as high and low temperature, other alert messages are:* **Probe Unplugged:** If the sensor is transmitting but the probe is unplugged, or if the temperature is out of range for the sensor, a series of black dots will appear at the bottom of the chart.
* **Wireless Device Stopped Communication**: If a repeater or Access Point stopped communicating.
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| Corrective Action History Report | Follow the steps below to review and address Corrective Action History Report, performed at least monthly.

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| **Step** | **Action** |
| 1.
 | Click on *Reports window* |
| 1.
 | Select on ***Corrective Action History*** |
|  | Select Group desired for report. |
|  | Select Asset Name or All Assets |
| 1.
 | Identify time span that will be covered on your report |
|  | Click ‘Create PDF Report’, a window will pop-up to confirm the email that the report will be sent for review. Click ‘Confirm’. |
|  | Open pdf file from your email, print report and sign-off review. File report in the ViewPoint Corrective Action History binder. |

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| Validations/ Calibrations | * Temperature measurement and control devices must be calibrated annually in order to prove their accuracy over the full operating temperature range.
* Digital devices are covered by calibration certificates from the device manufacturer. These certificates are valid for a defined period of time.
* The Laboratory Director must sign the validation.
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| Author(s) | Rosalie FajardoAlvin Castillo |