



**US Environmental Protection Agency
Office of Pesticide Programs**

**Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD**

**Standard Operating Procedure for
Monitoring Environmental Parameters of Incubators,
Refrigerators, Freezers, Laboratories and Sample
Storage Rooms**

SOP Number: QC-05-09

Date Revised: 10-28-15

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Title	Monitoring Environmental Parameters of Incubators, Refrigerators, Freezers, Laboratories and Sample Storage Rooms
Scope	Describes the operation and maintenance of the Environmental Monitoring and Alarm System (EMAS) which is a computer-based system designed to collect environmental data electronically for incubators, refrigerators, freezers, laboratories and sample storage rooms. Data are collected through a network of wireless environmental monitoring devices that use radio frequency to transmit and receive data about current environmental conditions.
Application	Describes how to archive data generated by the EMAS and the procedure for the manual collection and recording of environmental data in the event that the EMAS is malfunctioning.

	Approval	Date
SOP Developer:	_____	_____
	Print Name: _____	
SOP Reviewer	_____	_____
	Print Name: _____	
Quality Assurance Unit	_____	_____
	Print Name: _____	
Branch Chief	_____	_____
	Print Name: _____	

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TABLE OF CONTENTS

<u>Contents</u>	<u>Page Number</u>
1. DEFINITIONS	3
2. HEALTH AND SAFETY	3
3. PERSONNEL QUALIFICATIONS AND TRAINING	3
4. INSTRUMENT CALIBRATION	3
5. SAMPLE HANDLING AND STORAGE	4
6. QUALITY CONTROL	4
7. INTERFERENCES	4
8. NON-CONFORMING DATA	4
9. DATA MANAGEMENT	5
10. CAUTIONS	5
11. SPECIAL APPARATUS AND MATERIALS	5
12. PROCEDURE AND ANALYSIS	6
13. DATA ANALYSIS/CALCULATIONS	7
14. FORMS AND DATA SHEETS	7
15. REFERENCES	7

<p>1. Definitions</p>	<ol style="list-style-type: none"> 1. ASTM = American Society for Testing and Materials 2. ISO 17025 = The main standard used by testing and calibration laboratories, and issued by the International Organization for Standardization (ISO). ISO 17025 is used to implement a quality system aimed at improving the ability of a lab to consistently produce valid results. 3. Input # = EMAS number designation for probe which collects environmental data. 5. Unit # = Microbiology Laboratory Branch (MLB) number designation for each piece of equipment (incubator, refrigerator or freezer) for which environmental data are collected. 6. Target Temperature = Temperature prescribed in Microbiology Laboratory SOPs or research protocols for incubators, refrigerators, freezers, laboratories and sample storage rooms. 7. Period-End Alarm Limits = Exclusive range of environmental measurement limits (e. g., temperatures, percent humidity, percent CO₂, etc.) which are set programmatically in the EMAS system which define whether a probe is within the normal (acceptable) range. If a probe is outside the normal range, it is in alarm status.
<p>2. Health and Safety</p>	<p>Not applicable</p>
<p>3. Personnel Qualifications and Training</p>	<ol style="list-style-type: none"> 1. Lab personnel need to be familiar with the operation of the EMAS. Lab personnel should be knowledgeable about printing and reading the EMAS Specified Period Averages Report (Highs, Lows, and Averages Report for a specified time period, see example in Attachment 1). 2. Selected lab personnel are authorized to manage and retrieve data for the EMAS.
<p>4. Instrument Calibration</p>	<ol style="list-style-type: none"> 1. A reputable vendor calibrates the EMAS sensors yearly against ISO 17025 accredited instruments via service contract. The correction factors for each sensor are entered into the system by the vendor's technical staff. The calibration certificates are kept on file in room B209 with the most recent Rees Calibration Protocol Report notebook for the EMAS instruments. 2. See SOP EQ-02, Calibration of Thermometers, for calibration and accuracy point check requirements for thermometers specified in section 11.4. These thermometers may be used temporarily to monitor temperatures when the EMAS system is not functioning

	properly (see section 12.5). Use only units which have been calibrated or point checked as per SOP EQ-02.
5. Sample Handling and Storage	Not applicable
6. Quality Control	<ol style="list-style-type: none"> 1. For quality control purposes, the required information is documented on the appropriate forms. 2. Calibration certificates and point check calibration records of thermometers are maintained in a notebook, which is archived in the laboratory's file room D217.
7. Interferences	When an EMAS sensor or the entire EMAS is not functioning, follow the procedures listed in Section 12.5.
8. Non-conforming Data	<ol style="list-style-type: none"> 1. Any deviation from the standard procedures will be documented in the Environmental Monitoring and Alarm System Incident Log (see section 14) and investigated. The reasons for any difficulties achieving and maintaining the target temperature will be determined and the appropriate corrective action will be taken by the laboratory staff. If the problem cannot be determined or corrected, a service technician will be called in to evaluate the situation and to initiate the service on the equipment. 2. If the temperature or humidity of the sample storage room or area is not within the target temperature or humidity range, building authorities will be contacted to initiate adjustments/repairs to the air supply system. 3. If the temperature or humidity of the sample storage room or area deviates significantly from target temperature or humidity ranges for an extended period, Office of Enforcement and Compliance Assurance (OECA) may be contacted for advice on sample retention/disposal. 4. Disaster Recovery Plan: The EMAS monitoring devices use small, low voltage batteries as back-up power and are unaffected by power loss. The monitoring devices are supported by repeaters which help transmit data from the probes back to the EMAS computer which converts the data into information. The repeaters have a 24 hour battery backup to prevent data loss in the event of a disaster. The EMAS computer, which is on the Environmental Science Center's (ESC) emergency back-up power, has a battery back-up that will last a minimum of 6 hours and up to 24 hours. When the battery back-up on the EMAS computer is engaged, a telephone alarm will

	<p>be triggered. In addition to the battery back-up, the EMAS daily backs up all data and files needed for the EMAS to function to a thumb drive plugged into the EMAS computer.</p>
<p>9. Data Management</p>	<ol style="list-style-type: none"> 1. The EMAS Specified Period Averages Report will be printed on a daily basis. For weekends, holidays and days when the ESC is closed for any reason, the report should be printed on the next working day for each calendar day. The reports are filed in a notebook kept by the assigned analyst. 2. The EMAS Incident Log (see section 14) is kept in a notebook kept by the assigned analyst. 3. The Incubator, Refrigerator, Freezer Manual Temperature Recording Form and Sample Storage Room Manual Temperature/Humidity Recording Form (see section 14) for manual recording (when an EMAS or the entire EMAS is not functioning) are kept in room B209. 4. Completed report forms, logs and temperature record forms are archived on a yearly basis in notebooks kept in secured file cabinets in room D217. Archived data are subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives. 5. A list of MLB incubators, refrigerators and freezers is maintained electronically using a Microsoft Word table. The list also contains the target temperature and period-end alarm limits associated with each piece of monitored equipment. A hard copy (Attachment 3) of the updated list with effective dates will be filed in the front of the notebook containing the EMAS Specified Period Averages Report.
<p>10. Cautions</p>	<ol style="list-style-type: none"> 1. If an incubator, refrigerator, or freezer is known to be empty or not used regularly, the EMAS alarm may be inhibited or designated as "not in use". 2. The alarm for laboratory room temperature and humidity sensors (not including sample storage rooms) may be inhibited for a night, weekend or other non-work day (holiday, snow day, etc.) since recording temperature of these areas during non-work hours is not critical.
<p>11. Special Apparatus and Materials</p>	<ol style="list-style-type: none"> 1. The EMAS is a computer-based system which monitors several types of inputs, analyzes for outputs outside the established acceptable range and ensures that the appropriate lab staff members are notified by telephone when the measured parameter is outside of its acceptable range. The EMAS is loaded on a stand-alone computer (EMAS Computer) in Room B209 and is password

	<p>protected. The system is on the building's backup power system and also has a six hour battery backup.</p> <ol style="list-style-type: none"> 2. The EMAS probes are placed in incubators, refrigerators, freezers, laboratories and sample storage rooms managed by the Microbiology Laboratory Branch with the exception of room D122. 3. See Attachment 3 for a list of monitored equipment and associated target temperatures and period-end alarm limits. 4. In the event when the EMAS or a sensor is not working: <ol style="list-style-type: none"> a. Thermometers (see SOP EQ-02, Calibration of Thermometers) are used to monitor temperatures of individual incubators, refrigerators and freezers. b. Humidity/temperature meters are used to monitor temperature and humidity of rooms.
<p>12. Procedure and Analysis</p>	<ol style="list-style-type: none"> 1. The EMAS Specified Period Averages Report (Highs, Lows, and Averages Report for a specified time period, see example in Attachment 1) is printed for each calendar day. This report reflects the status of the system from 8:00 a.m. of the previous day to 8:00 a.m. of the current day. For weekends, holidays and days when the ESC is closed for any reason, the EMAS Specified Period Averages Report will be printed on the next working day for each 24 hour period starting at 8:00 a.m. and ending at 8:00 a.m. the next day. The Input Reading Graphs may also be printed for a specific input for a current day if there is a need to look at real-time data due to the critical nature of a study. A report printed in this situation does not need to be filed. 2. To print the report, check the box marked "ALL AVG" for the "Highs, Lows, and Averages Report." The report option window will appear. Select "Average Over Specified Time Period," fill in date and time, click "OK" and print the file (e.g., print two pages/sheet). 3. Assigned analysts will review the report, focusing on the Specified Period Averages Report for laboratory inputs. See Attachments 1 and 3. Any lows or highs which are underlined in this report were outside of the alarm limits. Refer to the Input Reading Graphs for the underlined input. If a value was outside of an alarm limit for more than four hours for incubators, refrigerators and freezers, this will be noted in the Environmental Monitoring and Alarm System Incident Log Form (see section 14) and any corrective action taken (temperature of unit adjusted, door closed tightly, etc.). The report

	<p>should be initialed, dated and filed.</p> <p>4. When an analyst is contacted by telephone that a sensor is out of period-end alarm limit range, follow the instructions in Attachment 2 (EMAS: Instructions for Telephoned Alarms) to inhibit or reset the probe.</p> <p>5. When an EMAS sensor or the entire EMAS is not functioning, the temperature of the affected instruments will be recorded manually by reading either thermometers or the humidity/temperature meters once daily each working day, excluding holidays and days when the ESC is closed for any reason. Record the data on the appropriate Incubator/Refrigerator/Freezer Manual Temperature Recording Form (see section 14) or Sample Storage Room Manual Temperature/Humidity Recording Form (see section 14). See Sections 11.4 and 4.2. On weekends, holidays and days when the ESC is closed, the reason may be noted why the temperature was not recorded under “Maintenance and Notes” on the form.</p>
13. Data Analysis/ Calculations	None
14. Forms and Data Sheets	<p>1. Attachment 1: Example of EMAS Specified Period Averages Report</p> <p>2. Attachment 2: EMAS: Instructions for Telephoned Alarms</p> <p>3. Attachment 3: List of MLB Incubators, Refrigerators, Freezers and Sample Storage Rooms Covered by EMAS</p> <p>4. Test Sheets. Test sheets are stored separately from the SOP under the following file names:</p> <p>Environmental Monitoring and Alarm System Incident Log Form QC-05-09_F1.docx</p> <p>Incubator/ Refrigerator/ Freezer Manual Temperature Recording Form QC-05-09_F2.docx</p> <p>Sample Storage Room Manual Temperature/Humidity Recording Form QC-05-09_F3.docx</p>
15. References	<p>1. Rees Scientific Centron Environmental Control and Monitoring System User Manual located in room B209.</p> <p>2. Rees Scientific Centron Environmental Control and Monitoring System Validation Protocol located in room B209.</p> <p>3. Rees Scientific Monitoring Instrumentation Access Control in room B209.</p>