

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-05-11

Date Revised: 10-29-21

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Title	Monitoring Environmental Parameters of Incubators, Refrigerators, Freezers, Laboratories and Sample Storage Rooms
Revisions Made	Minor editorial changes for clarification purposes.
	• Section 1, shortened the definition for "Period-End Alarm Limits" to remove language pertaining to "acceptable"/"normal range".
	• Section 10, added "equipment not currently containing temperature critical items" to items for which EMAS alarm ranges may be widened to prevent activation of an EMAS alarm.
	• Section 12, deleted section 5.b., "On weekends, holidays and days when the ESC is closed, note the reason why the temperature was not recorded under "Maintenance and Notes" on the form" (Incubator/Refrigerator/ Freezer Manual Temperature Recording Form).

SOP Number Title	SOP Number: QC-05-11 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), 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 wireless technology 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.

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1.	Definitions	1. ASTM = American Society for Testing and Materials	
		2. ISO 17025 = The main standard used by testing and calibration laboratories; 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 (e.g., incubator, refrigerator or freezer) for which environmental data are collected.	
		5. 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 CO ₂ , etc.) which are set programmatically in the EMAS system.	
	Health and Safety	Not applicable	
	Personnel Qualifications and Training	Lab personnel should 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.	
-	Instrument Calibration	1. A reputable vendor calibrates the EMAS sensors annually 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. Use only units which have been calibrated or point checked as per SOP EQ-02.	
5.	Sample	Not applicable	

	Storage		
6.	Quality Control	1.	For quality control purposes, the required information is documented on the appropriate form(s) (see section 14).
		2.	Maintain thermometer calibration certificates and point check calibration records in a notebook and archive it 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	1.	Management of non-conforming data will be consistent with SOP ADM-07, Non-Conformance Reports.
	Data	2.	Document any deviation from the standard procedures in the Environmental Monitoring and Alarm System Incident Log (see section 14). Determine the reasons for any difficulties achieving and maintaining the target temperature. Note the appropriate corrective action taken by the laboratory staff. If the problem cannot be determined or corrected, call in a service technician to evaluate the situation and to initiate the service on the equipment.
		3.	If the temperature or humidity of the sample storage room or area is not within the target temperature or humidity range, contact building authorities to initiate adjustments/repairs to the air supply system.
		4.	If the temperature or humidity of the sample storage room or area deviates significantly from target temperature or humidity ranges for an extended period, contact the Office of Enforcement and Compliance Assurance (OECA) for advice on sample retention/disposal.
		5.	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 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.
9.	Data	1.	File the EMAS Incident Log Form (see section 14) in a notebook

Management		kept by the assigned analyst.
	2.	File 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) in a notebook.
	3.	Archive completed report forms, logs and temperature records 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.
	4.	Maintain a list of MLB incubators, refrigerators and freezers electronically. The list also contains the target temperature and period-end alarm limits associated with each piece of monitored equipment. File a hard copy (Attachment 3) of the updated list in the front of the notebook containing the EMAS Specified Period Averages Report.
10. Cautions	1.	It is permissible to widen the EMAS alarm ranges for inputs associated with empty and, unused equipment, as well as equipment not currently containing temperature critical items in order to prevent activation of an EMAS alarm. The alarm for laboratory room temperature and humidity sensors (not including sample storage rooms) may be inhibited for a night, weekend or other non-workday (holiday, snow day, etc.) because recording temperature of these areas during non-work hours is not critical.
11. Special Apparatus and Materials	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 protected. The system is on the building's backup power system and also has a six hour battery backup.
	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 or available:
		a. Use thermometers (see SOP EQ-02, Calibration of

Thermometers) to monitor temperatures of individual incubators, refrigerators and freezers. b. Use humidity/temperature meters to monitor temperature and humidity of rooms. 12. Procedure and 1. Print the EMAS Specified Period Averages Report (Highs, Lows, and Averages Report for a specified time period; see example in **Analysis** Attachment 1) 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, print the EMAS Specified Period Averages Report 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. Print the Input Reading Graphs 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 report (e.g., print two pages/sheet). 3. Review the report, focusing on the Specified Period Averages Report for laboratory inputs. See Attachments 1 and 3. Any lows or highs underlined in the report were outside of the alarm limits for more than four hours. 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, note the occurrence in the Environmental Monitoring and Alarm System Incident Log Form (see section 14), as well as any corrective action taken (temperature of unit adjusted, door closed tightly, etc.). Initial, date, and file the report. 4. When an analyst is contacted by telephone that an input is out of period-end alarm limit range, follow the instructions in Attachment 2 (EMAS: Instructions for Telephoned Alarms) to inhibit or reset the input. 5. When an EMAS input or the entire EMAS is not functioning, manually record the temperature of the affected instruments 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.		
		a. 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). (Refer to Sections 4.2 and 11.4).		
13. Data Analysis/ Calculations	None			
	1.	Attachment 1: Example of EMAS Specified Period Averages Report		
Sheets	2.	2. Attachment 2: EMAS: Instructions for Telephoned Alarms		
	3.	Attachment 3: List of MLB Incubators, Refrigerators, Freezers and Sample Storage Rooms Covered by EMAS		
	4.	Test Sheets. Test sheets are stored separately from the SOP under the following file names:		
		Environmental Monitoring and Alarm System QC-05-11_F1.docx Incident Log Form		
		Incubator/ Refrigerator/ Freezer Manual QC-05-11_F2.docx Temperature Recording Form		
		Sample Storage Room Manual QC-05-11_F3.docx Temperature/Humidity Recording Form		
15. References	1.	Rees Scientific Centron Environmental Control and Monitoring System User Manual located in room B209.		
	2.	Rees Scientific Centron Environmental Control and Monitoring System Validation Protocol located in room B209.		
	3.	Rees Scientific Monitoring Instrumentation Access Control in room B209.		