INTRODUCTION/PRINCIPLE

The EMTECHNOLOGIES Remote-Slit-Sampler (R2S) is a self contained air sampling unit which is designed to determine the presence and level of viable bacteria in environmental air. The R2S sampler employs a base unit (R2S-C) with a vacuum pump and controller means to achieve the required air flow of 60 Standard Cubic Feet of Air per Hour (SCFH) through a narrow sample slit located in the sample conduit on top of the R2S's dome. An agar test plate is placed on a turntable, which resides within the dome. The surface of the agar test plate is adjusted to approximately 2.5 mm below the sample slit. The distance from the slit to the agar test plates surface is critical to proper impingement and capture of the bacterial organisms in the sampled volume of air. The agar test plate is also rotated at a set speed, 1 RPH, during the sample period to allow for easier enumeration of colonies, determination of time of capture and to prevent desiccation of organisms captured. During the sample period, which can range from 0-60 minutes, as set by the operator on the unit's sample timer, the sampled volume of air drawn through the sample slit is impinged upon the agar test plate. Bacterial organisms in the sampled volume of air remain captured on the agar test plate. Upon incubation, the number of viable bacterial organisms recovered from the environment can be counted and CFU per cubic foot of air can be determined.

PURPOSE

This instrument installation qualification, operation qualification and performance verification serves to insure the EMTECHNOLOGIES Remote-Slit-Sampler (R2S) as received meets and performs according to the specifications and tolerances intended by the purchaser as described by the manufacturer. Slit-to-Agar samplers are the industry standard to which other air viable sampling units are currently compared. As such, it is not the intent of this document to prove the bacterial recovery ability of this method of sampling but the document is designed to prove the bacterial recovery abilities of this unit based on the verification and qualification of the proper functionality of the unit and it's components. The basic functionality of the unit will be qualified and verified as is necessary to operate within the scope of Standard Operating Procedure [SOP#], Air Viable Monitoring with the EMTechnologies R2S Sampling Assembly

EQUIPMENT PROCEDURE

Copies of the following Standard Operating Procedures and reference documents shall be on file with [GROUP NAME] and / or Calibration/Repair Services:

- [SOP#]: Air Viable Monitoring with the EMTechnologies R2S Sampling Assembly
- [SOP#]: Calibration of the EMTechnologies R2S Sampling Assembly
- R2S General Information (Specifications and General Maintenance)

EQUIPMENT DESCRIPTION

Equipment

EMTechnologies Remote-Slit-Sampler (R2S) Sampling Assembly, includes (General Description):

Remote-Slit-Sampler Model: R2S.001

- R2S: (Components of White Polycarbonate and Stainless Steel)
  - -Housing and Base
  - -Turntable adjustment mechanism
  - -Turntable
  - -Motor Mount
  - -Turntable Motor (1 RPH)
  - -Electrical Connector
  - -Hose Connector (Barb)
- Dome Assembly:
  - -One Piece Clear Polycarbonate Dome and Sample Throat
  - -Slit to Test Plate Surface, Distance Indicator (Red PC) and mount (White PC)
- Dome-to-Base Seal (Blue Flourosilicone)

Remote-Slit-Sampler Controller Model: R2S-C.001

- Sample Elapsed Timer
- Rotometer (Sample Flow Controller) with Arbitrary Scale of 1 to 10
- 6 or 12 Foot (up to 36 feet) Primary AC Power Supply Cable with GFCI Protection
- 2.4 CFM Linear Vacuum Pump
- Cooling Fan
- Front Panel R2S Vacuum Hose Connector
- Front Panel R2S Power Cable Connector
- Twelve (12) Foot, R2S Vacuum Tubing / Power Cable Assembly

NOTE:
Additional Materials are required to perform this protocol. Refer to [SOP#], Air Viable Monitoring with the EMT R2S Sampling Assembly, for other required materials.

EQUIPMENT REQUIREMENTS

The following are operational and storage requirements for the EMT R2S Sampling Assembly.

- Utilities: Power (AC): 120 V, 60 Hz, 1Amp
- Operating Temperature: 33° F to 100° F
- Storage: Store in a clean dry area with the sample throat of the dome covered (i.e., bioshield, wipe all, stopper, or comparable clean covering)

EQUIPMENT CALIBRATION / MAINTENANCE

The following are Calibration and Maintenance requirements for the EMT R2S Sampling Assembly:

• Calibration is to be performed by qualified personnel per Standard Operating Procedure [SOP#]: "Calibration of EMTechnologies R2S," at regularly scheduled intervals of 6-months.

• Maintenance is to be performed when required by qualified calibration personnel or by other appropriate repair personnel (i.e., EMTechnologies Calibration/Repair Personnel).

EQUIPMENT SECURITY

The EMTechnologies R2S is a portable unit. It will be operated and / or stored in the Quality Control Laboratories or Manufacturing facilities of [COMPANY NAME], [LOCATION]. Equipment will be transported by appropriate personnel between each area or facility. The facilities and each of the areas are access controlled.

CAUTIONS

The operator should not remove any of the covers of the R2S, or R2S-C. All repairs shall be performed by appropriately trained personnel or EMTechnologies Calibration/Repair personnel. All standard electrical hazard safety practices shall be followed when operating the unit.

PROCEDURE

1. Follow and complete the Standard Equipment Verification Checklist:

   1.1 Complete the "Equipment Checklist" section located in Appendix A. Perform and document verification of each step as you proceed.

2. Follow and complete the Performance and Operational Verification Checklist, Appendix B, in a stepwise manner. Perform and document verification of each step as you proceed.

   Note: Refer to Standard Operating Procedure [SOP#]: Air Viable Monitoring with the EMTechnologies R2S Sampling Assembly to perform procedures required to complete Appendix B.

2.1 Complete Section 1, "Calibration / Maintenance Verification"

2.2 Complete Section 2, "Power Up Verification"

2.3 Complete Section 3, "Test Procedure":

3. A second qualified analyst shall review Appendix A and Appendix B following completion of testing.

ACCEPTANCE CRITERIA

Checklist items must indicate a "YES" response for each applicable item. If "NO" is indicated for any applicable item of the checklist, the instrument fails the qualification unless a plausible explanation is given for the item in question. If the instrument fails, the qualification / verification must be repeated after corrections to the equipment have been performed. Documentation of steps completed shall be performed in a stepwise manner by the person performing the qualification / verification.

Appendix-A
STANDARD EQUIPMENT VERIFICATION CHECKLIST

1. Equipment Checklist:

1.1 All equipment as described in the "Equipment Description" Section is present.

___Yes ___No Initial/Date_____

1.2 Model Number of R2S is R2S.001 ___Yes ___No Initial/Date_____

1.3 Serial number of R2S is [SERIAL #] ___Yes ___No Initial/Date_____

1.4 Model Number of R2S-C is R2S-C.001 ___Yes ___No Initial/Date_____

1.5 Serial number of R2S-C is [SERIAL #] ___Yes ___No Initial/Date_____

1.6 Manufacturers calibration documents and certificate agree with Model and Serial numbers.

___Yes ___No Initial/Date_____

COMMENTS_____
_____
_____
_____

Performed By/Date: _____Reviewed By/Date_____

Appendix-B
PERFORMANCE AND OPERATIONAL VERIFICATION CHECKLIST - Section 1

1. Calibration / Maintenance Verification:

Calibration procedures per SOP [SOP#], "Calibration of EMTechnologies R2S Sampling Assembly," verifies the following functionality and includes the following maintenance of the R2S Sampling Assembly:

- Turntable Rotation
- Elapsed time accuracy of sample timer
- 60 SCFH of Airflow through the sample conduit of the dome @ specified flow rate on rotometer for specified lengths of sample tubing (e.g., 6 feet, 12 feet, etc.)

1.1 Calibration sticker indicates current calibration (calibration within 6 months).

___Yes ___No Initial/Date_____

1.1.1 Calibration Date and Due Date on Calibration sticker at time of testing:

_____ / _____ Recorded by: Initial/Date_____

1.2 Current calibration documentation is on file.

___Yes ___No Initial/Date_____

1.3 Calibration report results show unit to be within the following specified operating parameters:
- Turntable rotation is 360° ± 5° in 60 minutes
- Elapsed Timer Accuracy is ± 1 Minute @ 60 minutes
- Calibration shows 60 SCFH ± 5 SCFH are drawn through the sample slit when flow rate is set to specified flow rate on unit's rotometer as documented on the calibration label and report.

___Yes ___No Initial/Date_____

1.4 Attach copy of original manufacturers original calibration reports and current calibration report for the unit (if applicable)

Performed by: Initial/Date_____

COMMENTS_____
_____
_____
_____

Performed By/Date: _____Reviewed By/Date_____

Appendix-B
PERFORMANCE AND OPERATIONAL VERIFICATION CHECKLIST - Section 2

2. Power Up Verification:

2.1 Attach R2S power supply cable to power port on front panel of R2S-C.
Performed by: Initial/Date_____

2.2 Attach R2S power supply cable to connector on R2S.
Performed by: Initial/Date_____

2.3 Attach vacuum tubing to hose connector on front panel of R2S-C
Performed by: Initial/Date_____

2.4 Attach vacuum tubing to hose connector on R2S
Performed by: Initial/Date_____

2.5 Connect primary power supply cord with GFCI to AC Power supply and perform the GFCI Functionality Test as described in the SOP, [SOP#]
Performed by: Initial/Date_____

2.6 GFCI Test shows proper functionality. ___Yes ___No Initial/Date_____

2.7 Turn R2S-C power switch to ON position Performed by: Initial/Date_____

2.8 R2S-C Sample timer display is on ___Yes ___No Initial/Date_____

2.9 R2S-C Cooling Fan is on ___Yes ___No Initial/Date_____

2.10 Pressing START/STOP key pad initiates vacuum pump and sample timer elapsed time countdown.
___Yes ___No Initial/Date_____

2.11 Rotometer shows a volume of air flow ___Yes ___No Initial/Date_____

2.12 Pressing START/STOP key pad again stops the vacuum pump and terminates the sample cycle
___Yes ___No Initial/Date_____

2.13 Turn R2S-C power switch to OFF position Performed by: Initial/Date_____

2.13 R2S-C Sample timer display is off ___Yes ___No Initial/Date_____

2.14 R2S-C cooling fan is off ___Yes ___No Initial/Date_____

COMMENTS_____
_____
_____
_____

Performed By/Date: _____Reviewed By/Date_____

Appendix-B
PERFORMANCE AND OPERATIONAL VERIFICATION CHECKLIST - Section 3

3. Test Procedure:

3.1 Sanitize and set up the R2S Sampling Assembly unit for testing per SOP [SOP#]

Performed by: Initial/Date_____

3.2 Take a 15 minute sample with the unit. Label the test plate with the validation protocol number and serial numbers of the R2S and R2S-C

Performed by: Initial/Date_____

3.2.1 When the set sample period of 15 minutes has been completed on the elapsed sample timer, the elapsed timer audible indicator beeps and the vacuum pump turns off.

___Yes ___No Initial/Date_____

3.2.2 A distance indicator mark (small circular pattern) is present in the center of the plate.

___Yes ___No Initial/Date_____

3.2.3 Air impingement marks are present on the plate's surface and cover the equivalent of 1 quarter of the plate's surface originating near the start line.

___Yes ___No Initial/Date_____

COMMENTS_____
_____
_____
_____

Performed By/Date: _____Reviewed By/Date_____