Environmental Protection Agency

§ 63.364 Monitoring requirements.

(a) (1) The owner or operator of a source subject to emissions standards in §63.362 shall comply with the monitoring requirements in §63.8 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this section.

(2) Each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer’s written specifications or recommendations for installation, operation, and calibration of the system.

(b) For sterilization facilities complying with §63.363(b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

(1) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in §63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated; or

(2) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, and use a liquid level indicator to measure the
§ 63.365 Test methods and procedures.

(a) Performance testing. The owner or operator of a source subject to the emissions standards in §63.362 shall comply with the performance testing requirements in §63.7 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this section.

(b) Efficiency at the sterilization chamber vent. The following procedures shall be used to determine the efficiency of all types of control devices used to comply with §63.362(c), sterilization chamber vent standard.

(1) First evacuation of the sterilization chamber. These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

(i) The amount of ethylene oxide loaded into the sterilizer \( (W_c) \) shall be determined by either:

(A) Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 0.1 lb. Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas.

(B) Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to...