



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
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Procedure No. RCT-APR-STP-0038	Revision: 1.1	Date: 14 June 2005
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DETERMINATION OF ETHYLENE OXIDE SERVICE LIFE TEST,
AIR-PURIFYING RESPIRATORS
STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by the ethylene oxide service life requirements on gas masks air-purifying respirators submitted for Approval, Extension of Approval, or examined during Certified Product Audits meet the certification requirements set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d) and Subpart I, Section 84.110(c); Volume 60, Number 110, June 8, 1995.

2. GENERAL

This STP describes the Determination of Ethylene Oxide Service Life Test, Air-Purifying Respirators test in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the product passes the test.

3. EQUIPMENT/MATERIAL

3.1. The list of necessary test equipment and materials follows:

- 3.1.1. Miller Nelson Research Model 401 Flow-Temperature-Humidity Control System or equivalent.
- 3.1.2. Interscan Corporation Model 1200 ethylene oxide detector or equivalent.
- 3.1.3. Brooks Rotameter R 215-B equivalent
- 3.1.4. Certified cylinder of 5 parts per million (ppm) ETO in Nitrogen.
- 3.1.5. Gilian Gil-Air-3 Sampling Pump, or equivalent.
- 3.1.6. Vaisala model HMI 31 humidity indicator.
- 3.1.7. Ethylene oxide cylinder, 99% purity.

Approvals:	<u>1st</u> Level	<u>2nd</u> Level	<u>3rd</u> Level
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- 3.1.8. Electronic balance with accuracy of 0.001 grams (g).
 - 3.2. Test fixture for mounting canisters. The test fixture used is specific to each manufacturer. Canisters are tested with their connections glued into the ground glass joint.
 - 3.3. The test chamber consisting of a 12" x 11½" x 7" air tight box, made of ½" plexiglass with 2 hinge type locks on the door opening lined with gasket material. A ½" hole is located on the backside of the test chamber for the introduction of the test concentration and a 1½" hole on the top for the exit of the test fixture and to detect the breakthrough concentration. This fixture is not commercially available.
 - 3.4. Resistance tester consisting of a vacuum source capable of delivering 85 liters per minute (lpm), a 6-inch slant manometer, and a 29/42 female ground glass joint. The resistance testers currently being used are located on the silica dust chamber.
4. TESTING REQUIREMENTS AND CONDITIONS
- 4.1. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the manufacturer's calibration procedure and schedule. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST).
 - 4.2. Normal laboratory safety practices must be observed. This includes safety precautions described in the current ALOSH Facility Laboratory Safety Manual.
 - 4.2.1. Safety glasses, lab coats, and hard-toe shoes must be worn at all times.
 - 4.2.2. Work benches must be maintained free of clutter and non-essential test equipment.
 - 4.2.3. When handling any glass laboratory equipment, lab technicians and personnel must wear special gloves which protect against lacerations or punctures.
 - 4.3. ETHYLENE OXIDE BENCH TEST FOR ESCAPE GAS MASK CANISTERS
 - 4.3.1. Resistance to air flow will be taken before and after each test, 84.126.
 - 4.3.2. Three "as received" canisters (or pairs of canisters) will be tested at 64 lpm, continuous air flow, 50 ± 5 percent relative humidity (RH), approximately 25 degrees Celsius (°C), and 5000 ppm ethylene oxide.
 - 4.3.3. Two canisters or pairs of canisters will be equilibrated at room temperature by passing 25 percent RH air through them at 64 lpm for 6 hours and then testing them at 25 percent RH, approximately 25°C, and 64 lpm continuous air flow containing 5000 ppm ethylene oxide.

4.3.4. Two canisters or pairs of canisters will be equilibrated at room temperature by passing 85 percent RH air through them at 64 lpm for 6 hours and then testing them at 85 percent RH, approximately 25°C, and 64 lpm continuous air flow containing 5000 ppm ethylene oxide.

4.4. PASSIVE END OF SERVICE LIFE INDICATOR

4.4.1. The passive end of service life indicator (ESLI) must clearly indicate that it is a reliable indicator of sorbent depletion at 90% or less of the service life of the canister.

4.5. **Please refer to Material Safety Data Sheets and the NIOSH Health and Safety Manual for the proper protection and care in handling, storing, and disposing of the chemicals and gases used in this procedure.**

5. PROCEDURE

Note: Reference Section 3 for equipment, model numbers and manufacturers. For calibration purposes use those described in the manufacturer's operation and maintenance manuals.

5.1. Follow individual instruction manuals for set up and maintenance of equipment used in this procedure prior to beginning testing. Malfunctioning equipment must be repaired or replaced and properly set up and calibrated before starting all tests.

5.2. After the manufacturer's specified warmup period, calibrate the ETO analyzer using the certified gas cylinder containing the 5 ppm standard as follows:

5.2.1 With a tee in line on the gas cylinder, insert the intake tubing from the analyzer into the tee.

5.2.2 Turn on the 5.0 ppm certified ethylene oxide cylinder.

5.2.3 Wait till the reading stabilizes, and adjust the span control to read 5.0 ppm.

5.3. Set up test equipment as shown in Figure 1. In addition to the humidity reading controlled by the Miller Nelson system, the Vaisala HMI 31 humidity indicator sensor is inserted into the air stream via a tee set-up directly prior to the introduction of the gas. This set up is not shown on Figure 1. The humidity reading obtained at this point takes into account tubing length and outside hood air temperature.

5.4. Turn on:

5.4.1. Miller Nelson Unit.

5.4.2. Air and water supplies.

5.4.3. ETO cylinder.

5.5. Establish the test concentration for 5000 ppm ETO. Set the analyzer to the high scale range of 0-50 ppm.

5.6. Determine the challenge test concentration via a dilution factor method by drawing off 1 lpm test concentration and diluting with a known volume of clean air. By adjusting the rotameter and noting the deflection on the calibrated analyzer, the test concentration can be determined. The volume of clean air required to dilute the 1 lpm of challenge concentration to produce 5000 ppm is calculated as follows:

5.6.1. $C_1V_1 = C_2V_2$ (Where C = concentration and V = volume)

$$5000 \text{ ppm} \times 1 \text{ lpm} = 50 \text{ ppm} \times V_2$$

$$V_2 = \frac{5000}{50}$$

$$V_2 = 100$$

Therefore: $V_2 - V_1 =$ volume of clean air

5.7. Draw off 1 lpm of the ethylene oxide in air test concentration and dilute it with the calculated volume of clean air for the required concentration.

5.8. Insert the intake tubing from the analyzer into the dilution air/gas stream. Adjust the rotameter till the analyzer reads 50 ppm. Note the position of the rotameter float for the concentration being determined.

5.8.1. As an example: A reading of 50 ppm for the dilution of 99 lpm/1 lpm ethylene oxide test concentration results in a factor of 100. By using the following formula the total ETO test concentration can be determined.

$$\text{Dilution factor} \times 50 \text{ ppm reading} = \text{Total ETO test concentration.}$$

5.9. Once the ETO concentration has been established, testing may begin.

5.10. Weigh the canister and record the weight.

5.11. Take inhalation and exhalation resistances of the canister mounted on the facepiece at 85 lpm. See Sections 84.122 Title 42, Code of Federal Regulations, Part 84 for breathing resistance requirements.

5.12. Mount canister onto test fixture and place in testing chamber.

5.13. Direct challenge concentration airflow into test chamber. Start timer. Mount small piece of tygon tubing onto the outlet of the test fixture. Insert intake tubing of detector into a

slit cut into the side wall of the tubing to allow the detector to sample at the flow rate of the detector without interference from airflow back pressure. Monitor and record upstream and downstream temperatures throughout testing. Record breakthrough values and times.

- 5.14. Run test until breakthrough of 1.0 ppm is observed or minimum service life is surpassed.
- 5.15. Dismount canister, weigh and record final weight, and take final inhalation and exhalation resistances.
- 5.16. Shut off ethylene oxide cylinder.
- 5.17. Disconnect ethylene oxide tubing from the rotameter to prevent contaminating the humidity sensor.
- 5.18. Allow clean air to purge through system for 10 - 15 minutes.
- 5.19. Turn off air and water supply to Miller Nelson system.

6. PASS/FAIL CRITERIA

- 6.1. The criterion for passing this test is set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d) and Subpart I, Section 84.110(c); Volume 60, Number 110, June 8, 1995.
- 6.2. This test establishes the standard procedure for ensuring that:

84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in subparts H through L of this part.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

84.110 Gas masks; description.

(c) Gas masks for respiratory protection against gases and vapors other than those specified in paragraph (b) of this section, may be approved upon submittal of an application in writing for approval to the Respirator Branch listing the gas or vapor and

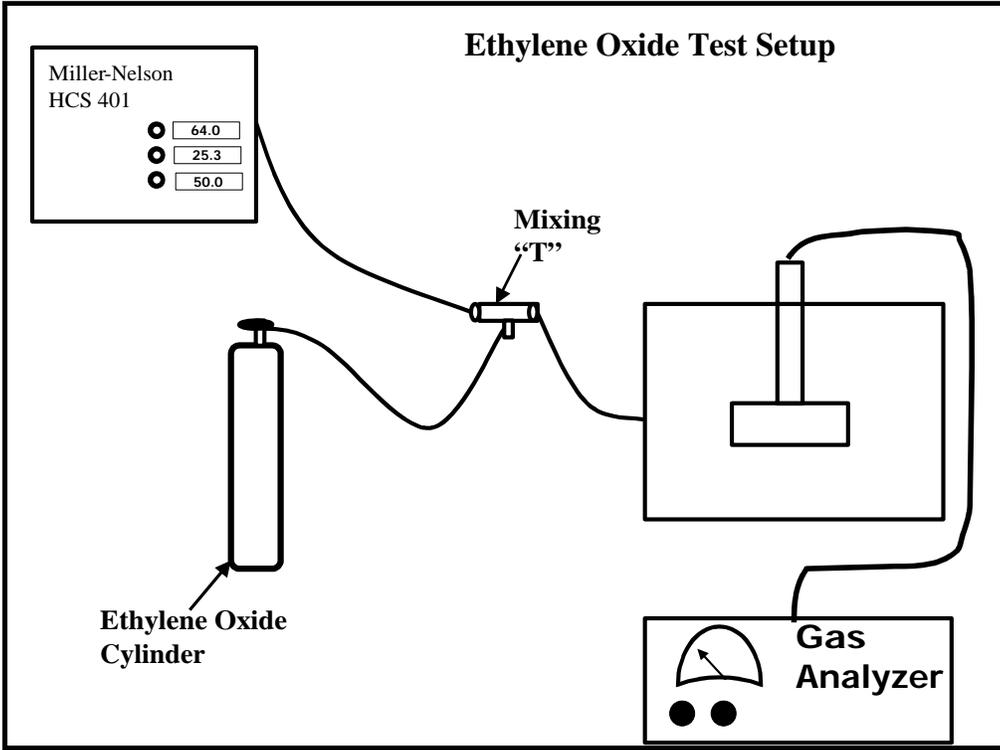
suggested maximum use concentration for the specific type of gas mask. The Institute will consider the application and accept or reject it on the basis of effect on the wearer's health and safety and any field experience in use of gas masks for such exposures. If the application is accepted, the Institute will test such masks in accordance with the requirements of this subpart.

7. RECORDS/TEST SHEETS

- 7.1. All test data will be recorded on the ETHYLENE OXIDE SERVICE LIFE test data sheet.
- 7.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.
- 7.3. All equipment failing any portion of this test will be handled as follows:
 - 7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the RCT Leader and prepare the hardware for return to the manufacturer.
 - 7.3.2. If the failure occurs on hardware examined under an Off-the-Shelf Audit the hardware will be examined by a technician and the RCT Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the RCT Leader, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00.

8. ATTACHMENTS

- 8.1 Bench Top Set-Up
- 8.2 Data Sheet



RB - RESPIRATOR CERTIFICATION TEAM



GAS & VAPOR RESPIRATOR TEST DATA SHEET (Ref.33-48,50,62) STP No.: [____]

Task Number: TN- _____ Gas Name: _____
 Manufacturer: _____ Item Tested: _____

RESISTANCE	Maximum Allowable Resistance (mm of H ₂ O)				Actual Resistance (mm of H ₂ O)				Result
	Inhalation		Exhalation		Inhalation		Exhalation		
			Initial		Initial	Final	Initial	Final	
1									
2									
3									
4									
5									
6									
7									

Overall Results: Pass ___ Fail ___ Comment: _____

WEIGHTS AND AIRFLOWS	WEIGHTS (gm)				Conc. (ppm)	AIRFLOW (Lpm)			
	Con'd					Test Rate		(PAPR Only)	
						RH%	Lpm	Initial	Final
1									
2									
3									
4									
5									
6									
7									

Overall Results: Pass ___ Fail ___ Comment: _____

DATA TABLE	Test Cond.	Final Time (min)	Leakage (ppm)	Temperature (°C)		Corrected Time (min)
				Downstream	Upstream	
1						
2						
3						
4						
5						
6						
7						

Overall Results: Pass ___ Fail ___ Comment: _____
 Was all testing equipment in calibration throughout all testing: Yes ___ No ___
 Signature: _____ Date: _____

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GAS & VAPOR RESPIRATOR TEST DATA SHEET (Ref.33-48,50,62) STP No.: [____]

Task Number: TN- _____ Gas Name:
Manufacturer: _____ Item Tested:

Additional Comments:

Signature: _____

Date:

Revision History

Revision	Date	Reason for Revision
1.0	11 March 2002	Historic document
1.1	14 June 2005	Update header and format to reflect lab move from Morgantown, WV No changes to method