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Ethylene Oxide (EtO): Understanding OSHA's Exposure Monitoring Requirements

Making the Right Decisions - How to Comply with the EtO Standard

U.S. Department of Labor Occupational Safety and Health Administration OSHA 3325-01N 2007

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Purpose

The purpose of this guidance document is to help employers understand how to monitor the quality of the air in workplaces where ethylene oxide (EtO) is processed, used, or handled. Air monitoring is an important activity that can help alert employers when unsafe levels of EtO are present in the air so that they can take steps to reduce employee exposure. EtO can be used more safely if appropriate precautions are taken and if equipment is adequately designed and maintained. This document:

- Clarifies the different types of EtO exposure monitoring,

- Reviews the exposure monitoring requirements in OSHA's EtO rules, and
- Outlines the monitoring decisions that the employer needs to make when employees work in areas where EtO is present.

All of the required actions presented in this document are based on OSHA's EtO standard (29 CFR 1910.1047). This guidance document provides helpful suggestions for complying with §1910.1047 as well.

This guidance document is not a standard or regulation, and it creates no new legal obligations. The guidance document is advisory in nature, informational in content, and is intended to assist employers in providing a safe and healthful workplace. The Occupational Safety and Health Act requires employers to comply with hazard-specific safety and health standards promulgated by OSHA or by a State with an OSHA-approved State Plan. In addition, pursuant to Section 5(a)(1), the General Duty Clause of the Act, employers must provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm. Employers can be cited for violating the General Duty Clause if there is a recognized hazard and they do not take reasonable steps to prevent or abate the hazard. However, failure to implement these recommendations is not, in itself, a violation of the General Duty Clause. Citations can only be based on standards, regulations, and the General Duty Clause.

Background

EtO is used extensively by hospitals and other industries as a sterilizing agent. EtO is a colorless, odorless gas which is both flammable and highly reactive. Most importantly, you cannot smell EtO until it reaches levels that can cause serious harm to human health (NIOSH, 1989). Human and animal studies consistently show that EtO can be hazardous to human health. Short-term exposures to EtO can cause respiratory irritation and lung injury, shortness of breath, headache, nausea, vomiting, and diarrhea. Long-term exposure over many years may cause cancer, reproductive effects, genetic changes, and damage to the nervous system (Lamontagne et al., 1990).

OSHA Requirement for Air Monitoring

The OSHA EtO standard requires employers to conduct personal monitoring unless they are specifically exempt (see "Exemptions" text box at page 10). This guidance document is intended to help employers understand the difference between personal monitoring, area monitoring, and leak detection and why area monitoring is complementary to personal monitoring, but can never be used instead of it.

Clarifying the Different Types of Exposure Monitoring

There are three types of EtO monitoring available for determining levels of EtO in a workplace: 1) personal monitoring, 2) area monitoring, and 3) leak detection (a special type of area monitoring). However, personal monitoring is required to determine if there is compliance with the exposure limits of the standard.

Personal Monitoring

Personal monitoring involves measuring a person's exposure to EtO by testing the air that the person (an employee) would breathe regardless of where the person moves in the workplace. A sampling device is attached to the shirt collar or as close as practical to the nose and mouth of the employee in the employee's "breathing zone" - the hemisphere forward of the shoulders with a radius of approximately six to nine inches - to test airborne EtO concentrations.

The device is worn for a specified period of time. During personal monitoring for EtO, the sample is collected for 15 minutes to test short-term exposure or for the length of a whole work shift (typically 8 hours; see the text box "What if the Work Shift is Not Exactly 8 Hours?" at page 8) to test for average exposures over the course of a workday. These air samples will be referred to here as 15-minute samples and 8-hour samples.

Equipment used for personal monitoring typically includes a "passive diffusion monitor" (a type of clip-on tag that collects EtO), or alternatively a small air pump worn on the employee's belt that pulls a sample of air through a glass tube filled with a substance that captures EtO. These samples typically must be sent to a laboratory for analysis. The accuracy of any method depends to a large degree upon the skills and experience of those who not only collect the samples but also those who analyze the samples.

After the samples have been analyzed, the employer must post monitoring results within 15 days of receiving them, or notify employees of the results in writing. The employer must also mention the steps being taken to reduce employee exposures when the monitoring results indicate that the time-weighted average or excursion limit has been exceeded.

Area Monitoring

Area monitoring is used to show the levels of EtO throughout the general working area and to identify problems and priorities.

Area samples should be taken close to a source of emission in order to evaluate concentrations or the effectiveness of steps taken to control exposure. Alternatively, area samples can be collected at various places in the working area to assess how far EtO might have spread. Equipment used for area monitoring is often mounted on the wall or placed directly on equipment. The monitoring instrumentation can be similar to that used for personal monitoring, or it can be of the "direct-reading" type, which gives an immediate reading of the EtO level. When an employer uses direct reading instruments, nothing needs to be sent to a laboratory but the equipment must be calibrated periodically to ensure accuracy.

A wall-mounted emergency alert system used for area monitoring is one example of a direct-reading area monitor (also see subsection titled "Emergency Alert Provision" at page 18).

Leak Detection

Employers, who are required to create a written compliance program because their employees' exposures are over the permissible exposure limit, must also produce a schedule for routine leak detection surveys. Some businesses that use EtO find it helpful to test equipment such as sterilizers, pipes, tanks, and fittings at least every two weeks to confirm that there are no leaks. Portable EtO gas-detection meters are available to check for leaks around equipment such as sterilizers, tanks, fittings, and pipes that contain EtO. Leak testing is generally performed using hand-held EtO detection meters (a type of portable direct-reading instrument).

The OSHA Exposure Levels

The Federal OSHA regulation on EtO establishes certain allowable exposure levels. This section will explain the terms, units, and exposure levels that require action.

Units of Measure: Exposure levels are reported as concentrations - the volume of EtO per volume of air. This is typically expressed as "parts per million" (also called "ppm"). One part per million means that there is one part of EtO in every million parts of air sampled. Alternatively, the concentration of EtO can also be reported using metric units, in milligrams of EtO per cubic meter of air (mg/m^3). It is important to compare only exposure values that have the same units of measure. For example, only compare exposure results reported as ppm to the OSHA levels for EtO reported in ppm.

Action Level: The "action level" is the 8-hour exposure level that triggers certain actions under OSHA's EtO standard. If an employee's 8-hour sample result is equal to or greater than the action level, the employer must start certain required activities such as exposure monitoring and medical surveillance.

The action level for EtO is 0.5 ppm (which equals $0.9 \text{ mg}/\text{m}^3$).

Permissible Exposure Limit (PEL): This is the exposure level of EtO above which no employees may be exposed to under normal workplace conditions. You should become familiar with two PELs; one for 8-hour samples and one for 15-minute samples.

Eight-Hour Time-Weighted Average (8-hour TWA) - This is an 8-hour (or full work shift) sample that represents the maximum average EtO levels that an employee should be exposed to.

The 8-hour PEL for EtO is 1 ppm (which equals 1.8 mg/m³).

Excursion Limit (15-minute) - This is a 15-minute (short-term) sample that represents the maximum EtO exposure level that an employee may be exposed to for a short period of time.

Rotating employees to different workstations so that they are not exposed to higher EtO levels is not an accepted way of meeting the 8-hour TWA or the Excursion Limit requirement.

The 15-minute Excursion Limit for EtO is 5 ppm (equal to 9 mg/m³).

Both types of samples are important because, taken together, they help employers protect employees over the range of exposure conditions that employees are likely to experience. Actions that an employer must take if these PELs are exceeded are outlined in Tables 3 and 4 at pages 15-17.

What if the Work Shift is Not Exactly 8 Hours?

When you collect an 8-hour sample, OSHA expects you to collect the sample for the length of the whole work shift, no matter how long it is. The shift might be more or less than 8 hours. Although not every sample will be exactly 8 hours, the OSHA action level and 8-hour permissible exposure limit must only be compared to an 8-hour sample result.

To avoid confusion caused by samples collected for more or less time, OSHA allows you to use a simple equation that converts any full-shift sample result to an 8-hour **equivalent result** (also called an 8-hour time-weighted average or an 8-hour TWA result).

$$\text{Equation:} \\ C8 = CA(TA)/T8$$

TA = The actual time during which your sample was collected (in minutes).

CA = The actual result (concentration) for your sample (in ppm).

T8 = 480 minutes (this is the number of minutes in 8 hours).

C8 = The 8-hour equivalent result for your sample (in ppm).

Fortunately, most analytical laboratories will do the calculation for you. Ask the laboratory to "Report the full-shift results as 8-hour time-weighted averages (or 8-hour TWAs)." You do not need to make this arrangement for 15-minute samples, which should always be collected for exactly 15 minutes.

When exposure levels are high, it may be necessary to collect a series of mid-length samples (for example, 1-2 hours each) instead of a single 8-hour sample for an employee. In this case, ask the laboratory to combine all the results from one employee to create a single 8-hour TWA result.

Monitoring Requirements

• What types of monitoring are required to be in compliance with OSHA's EtO standard?

The OSHA EtO standard requires that each employer whose workplace does not meet the "exemption" clause, §1910.1047(a)(2), must perform personal monitoring to show whether EtO exposures are exceeding the 8-hour and/or the 15-minute PEL. The OSHA standard requires that these samples be "representative" of EtO exposures (see "Criteria for Using Results from Similar Work Conditions" text box, at page 11). There are two types of monitoring requirements: *initial* and *periodic*.

Initial Monitoring

• Do I need to collect initial EtO samples?

Yes. If you are not exempt (see "Exemptions" text box at page 10) and there is reason to believe that exposure levels may equal or be above the action level under "expected conditions of operation," then you are required to conduct personal EtO monitoring to accurately measure the airborne concentrations of EtO. Most employers should assume that exposure levels may reach or exceed the action level and that they must conduct exposure monitoring: 1) if their business involves processing, using, or handling products containing EtO; 2) if they are not exempt as described in the Exemption text box; and 3) if they have never conducted personal monitoring.

This level of caution is important because accidental releases of EtO may occur from several sources, including leaking cartridges, sterilizer discharge lines and leaks, or routine changing of EtO supply cylinders. A relatively small quantity of EtO released into an average office-sized space can result in concentrations that are many times above the action level or PEL (NIOSH, 1989; Lamontagne and Kelsey 1998). If there are special circumstances that would suggest that monitoring is not required for your workplace and you need further clarification, we encourage you to contact your local area OSHA office. Locate your local area OSHA office by phone at 1-800-321-OSHA or online at <http://www.osha.gov/html/RAmap.html>.

When carrying out initial monitoring, you must collect both **8-hour samples** (full work shift) and **15-minute samples** (short-term). At least one sample of each type is required for:

- Each work shift,
- Each job classification, and
- In each work area of the workplace.

Exemptions

Is Monitoring Always Required?

No. An employer is exempt from the standard and, therefore, is not required to conduct employee exposure monitoring if "objective data" demonstrates the processing, use, or handling of products containing EtO are not capable of releasing EtO in concentrations at or above the OSHA action level or in excess of the excursion limit under expected conditions that will cause the greatest possible release.

The objective data might include specific information generated by an individual employer or obtained from chemical manufacturers, industry studies, or trade associations that documents why your facility's processing, use, or handling of EtO would not result in workplace concentrations exceeding the action level or excursion limit.

include:

- The source of the objective data,
- The testing protocol, results, and/or analysis of data,
- The exempted operation and corresponding information supporting the exemption, and
- Any other data relevant to the operations, materials, processes, or employee exposures covered by the exemption.

• Do I need to collect initial personal monitoring samples for every single employee, on every work shift?

No. But you do need to determine the exposure level of every employee. If you have only one employee, or just a few who all do different jobs, you need to collect personal samples for each employee. However, if you have two or more employees who do the same job, you may be able to collect personal samples for one of these employees and use the results to document exposure levels for all of these employees. This is known as representative sampling. To decide whether the results for one employee will represent the EtO exposure of other employees in the group, you must evaluate certain criteria (see "Criteria for Using Results from Similar Work Conditions" text box).

If the answer is "no" to any of the questions, you probably need to compare a smaller and more similar group of employees, or conduct individual personal monitoring for each employee. If the answer to all of these questions is "yes," you may use the results from one or more employee to represent the exposure of other employees in the group. However, you must select the employee who is likely to have the highest EtO exposure (due to slight variations in work area, work practices, or experience).

Criteria for Using Results from Similar Work Conditions

- Do the employees do the same work?
- Are their working conditions similar (for example, do the employees use similar equipment and EtO products?)
- Do the employees have similar work practices, with similar EtO control measures?
- Do they work in the same area or in areas with similar air movement patterns?
- Do the employees use the same EtO product for the same amount of time during their shifts?
- Do the employees work the same distance from possible sources of EtO?

You must also keep a record stating your reasons for selecting an employee from one work shift to represent employees on another shift. One way to document the similarity of shifts is by sampling employees on each shift one time to show that the employee exposures are the same on each shift. If the exposures are the same, you can conduct future required periodic sampling on a single shift and consider it representative of all shifts. You may use this option with 8-hour samples and with 15-minute samples.

• Am I permitted to use results of air samples collected at another time or at a different location from my initial monitoring results?

Yes, but the work conditions must have been similar on the two dates, or at the two locations. The text box "Criteria for Using Results from Similar Work Conditions" also applies in this situation. Again, if the answer is "no" to one or more of the questions, it is likely that you must conduct initial monitoring. If the answer is "yes," then OSHA allows you to meet the initial monitoring requirements by using personal monitoring results collected for other employees at an earlier date or at a different location in the workplace. Be sure to keep a document explaining why it was appropriate to use those results.

• Which 15-minute period should I monitor?

You must collect a 15-minute air sample during the portion of the work shift when you think that the employee's EtO exposure will be the highest. You may need to collect several 15-minute samples during the same shift (see text box "Why Is It So Important to Collect 15-Minute Samples?").

Why Is It So Important to Collect 15-Minute Samples?

Research suggests that EtO exposures above the 15-minute OSHA PEL continue to occur in workplaces that are involved in processing, using, or handling products containing EtO. Recent studies have also shown that personal monitoring activities often fail to detect accidental exposures during EtO leaks and spills (Lamontagne et al., 2004; Lamontagne and Kelsey 1998). Therefore, it is important to carefully consider the types of activities for which 15-minute monitoring are most useful. The following examples should provide some guidance:

- A common situation in which accidental exposures to EtO might occur involves changing EtO supply cylinders. Consider collecting 15-minute personal samples while the employees being sampled are replacing EtO cylinders.
- Employees who work directly with, or in close proximity to, EtO sterilizers or similar equipment should be monitored frequently for short-term (i.e., 15-minute) exposures to EtO at the times when they are most likely to experience exposure (such as when the employee opens the door at the end of the cycle, or while EtO is being pumped in or out of the equipment).

Periodic Monitoring

• Do I need to repeat the EtO personal monitoring and, if so, what is the monitoring schedule?

The answer depends on the results of initial personal monitoring for EtO. Under certain situations, a long-term schedule for personal monitoring for EtO must be established. Tables 1 and 2 provide the "periodic monitoring" schedule required by the EtO standard. The personal monitoring results might also trigger other requirements that are listed in Tables 3 and 4, which appear later in this guidance document.

Table 1 - Schedule for OSHA Exposure Monitoring

If your initial employee monitoring results...	Then...
...show that employee exposure is below the 8-hour action level,	Discontinue monitoring for only those employees whose exposures are represented by the initial monitoring.
...are between the 8-hour action level (0.5 ppm) and the 8-hour permissible exposure limit (PEL) of 1 ppm (including the value 0.5 ppm),	Conduct additional 8-hour personal exposure monitoring at least every 6 months.
...are above the 8-hour PEL of 1 ppm or above the 15-minute PEL of 5 ppm,	Conduct additional personal exposure monitoring (either 8-hour or 15-minute, depending on the sample type that initially exceeded the limit) at least every 3 months.

Table 2 - Requirements for Discontinuing Monitoring

If your periodic employee monitoring results had been above the PEL (either the 8-hour	Then...

...are now less than the 8-hour action level (0.5 ppm) and the 8-hour PEL of 1 ppm (including the value 0.5 ppm) for two consecutive tests (these samples must be collected at least 7 days apart, but no more than 3 months apart),	You can decrease the 8-hour personal monitoring frequency from every 3 months to every 6 months. Note: if 15-minute exposures exceed the excursion limit of 5 ppm, you will still need to conduct the 15-minute (excursion limit) monitoring at least every 3 months.
...are now less than the 8-hour action level (0.5 ppm) for two consecutive tests (the samples must be collected at least 7 days apart, but no more than 3 months apart),	You are no longer required to conduct periodic personal monitoring unless a change in the workplace makes additional monitoring necessary.
...now indicate that employee exposures are at or below the 15-minute PEL of 5 ppm (the excursion limit) for two consecutive tests (the samples must be collected at least 7 days apart, but no more than 3 months apart),	You may discontinue 15-minute (excursion limit) monitoring for those employees whose exposures are represented by the initial monitoring.
For definitions of OSHA Exposure Levels, see page 6.	

• **When must I resume air monitoring?**

You must start monitoring again whenever there is a change that may result in new or additional exposures to EtO. Examples of changes that should be evaluated to determine if they may result in new or additional exposures and, therefore, would trigger resuming EtO sampling include:

- Changing EtO process equipment or increasing the volume of EtO used,
- Modifying the exhaust ventilation system,
- Hiring new or inexperienced employees, and
- Changing work practices.

You also must resume sampling any time that you have a reason to suspect that such a change may result in new or additional exposures.

Actions Triggered by Air Sample Results

• **I received air sampling results; now what do I do?**

Tables 3 and 4 provide the lists of actions you need to take as a result of EtO monitoring results that exceed specific levels. These actions are based on the OSHA action level and/or PELs (8-hour and/or 15-minute samples).

Table 3 - Actions Triggered by Air Sample Results				
Result interpretation:	8-hour sample is equal to or above Action Level	8-hour sample is above Permissible Level	15-minute sample is above Excursion Limit	Other OSHA Standards that Apply**
Result value:	0.5 ppm or greater	Above 1 ppm	Above 5 ppm	
Action Triggered by Monitoring Results				
Provide medical surveillance (if employee's exposure is more than 30 days per year)*	Yes	Yes	Not required	1910.1020
Provide information and training	Yes	Yes	Yes	-
Establish a regulated area	Not required	Yes	Yes, also if <i>expected</i> to exceed this level	-
Take steps to reduce exposure levels with engineering controls or other methods	Not required	Yes	Yes	-
Develop and put into action a written compliance program for reducing exposure and establishing a schedule for periodic leak detection	Not required	Yes	Yes	-
Provide respirators	Not required	Yes	Yes	1910.134
Ensure that caution labels are fixed to containers (also when container contents are capable of causing	Yes	Yes	Yes	1910.1200

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