

Our commentary on OSHA's Small Business Guide for Ethylene Oxide

On 30 April 2009, OSHA released a comprehensive document entitled "Small Business Guide for Ethylene Oxide." This new publication is available as a [spiffy pdf](#) (14.2 MB) or as a more browsable [web page](#). The agency considers it to be a "guidance document," in that it is advisory in nature, is informational in content, and is intended to assist employers in providing a safe and healthy workplace.

No new regulations are introduced in this work. All of the required actions presented in the document are based on OSHA's EtO standard ([29 CFR 1910.1047](#)).

What is meant by "monitoring" in the OSHA document

Certain statements are made in Section 2 of the document, entitled "Exposure Monitoring," that merit some clarification. Bear in mind that according to OSHA's Office of Chemical Hazards and Office of Health Enforcement, the document must reflect what is in the regulations, and represents the minimum requirements that would achieve compliance. Note also that some of the language in 29 CFR 1910.1047 dates back to 1984.

Let us examine portions of Section 2A ("Understanding OSHA's EtO Exposure Monitoring Requirements")...

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.

The OSHA EtO standard requires employers who have EtO present in their workplace to conduct personal monitoring unless they are specifically exempt from the requirement. 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.

It is important to note that "monitoring" in the context of the OSHA publication does NOT refer to the sort of 24/7 continuous area monitoring for EtO, most often performed in hospital SPDs (Sterile Processing Departments). Rather, it refers to relatively short-term testing of either the employee's breathing zone (personal monitoring), the workplace at large and in different locations (area monitoring), or periodic testing of potential point sources (leak detection).

Thus, by these definitions, and within the context of only meeting the minimum requirements, area monitoring would not be a substitute for personal monitoring. However, it is clear that SPD customers and others within health care have chosen to exceed the bare minimum requirements for over 20 years—and with good reason.

Unlike chemical plant environments, with few employees who might be exposed to EtO, SPD occupancies put all employees near a potential hazard. While SPD managers could follow the personal monitoring guidelines described in Section 2B of the document, even after initial screening was done (typically many years earlier), this would be expensive and impractical.

Most hospitals do not have their own industrial hygienists, and would thus have to contract out this service, as often as every three months. Moreover, it is quite cumbersome to determine excursion values via manual personal monitoring.

Emergency leaks of EtO

So-called "emergency leaks" of EtO are discussed in Section 3 of the document. The only practical method of handling this contingency is with a continuous ethylene oxide monitoring system. In the early days, these systems were referred to as catastrophic leak detectors, and based on their poor sensitivity, the name was apt. True enough, these old detectors, using metal oxide semiconductor sensors, could not substitute for personal monitoring, as defined in the document.

But, that was then, and this is now. Most good present-day EtO monitoring systems have sufficient sensitivity to accommodate the 1 ppm Eight-Hour Time-Weighted Average (8-hour TWA), and the 5 ppm Excursion Limit (15-minute). These are the two Permissible Exposure Limits, or PELs. Of course, such systems would also be able to respond quickly to emergency leaks.

Continuous monitoring with data acquisition

Sufficient sensitivity is only one part of the equation. The PELs must also be calculated, and this means that monitoring data from the system is acquired, stored, and processed. Most of our EtO monitor customers also install Arc-Max[®], Interscan's data acquisition, archiving, and reporting package.

Accuracy, as stipulated in the OSHA document

The guideline, set forth in accordance with 29 CFR 1910.1047(d)(6) is as follows:

- i) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of EtO at the 1 ppm TWA and to within plus or minus 35 percent for airborne concentrations of EtO at the action level of 0.5 ppm.
- ii) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 35 percent for airborne concentrations of EtO at the excursion limit.

Accuracy of modern continuous monitoring systems is far better than this, and can be as good as ± 2 percent, ultimately limited to the accuracy of the calibration standard. The notion of "confidence level" is not particularly relevant to continuous monitoring systems, unless one is referring to a validation of the calibration itself.

Other content in the OSHA document

Our commentary has mostly addressed the "Exposure monitoring" section of the document but it contains a good deal more material. Other sections cover such topics as exposure reduction/prevention, employee information and training, medical surveillance, and what a medical exam must include.

Your takeaway

In the SPD—and that is where the majority of EtO exposure happens—virtually all occupancies employ continuous monitoring systems. These systems greatly surpass OSHA's minimum requirements, but do so in a manner that is far more cost-effective than the methods detailed in the document.

Since the new OSHA document had to reflect 29 CFR 1910.1047 in a literal sense, describing improvements in continuous monitoring technology was beyond its scope.

If you have any questions about this article or the OSHA document, please [contact us](#).

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