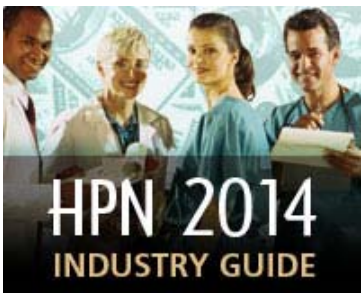
Inside the November Issue

Click the cover above for the online edition, or click below for the digital flip book.

November Cover Story

Quality patient care hinges on quality tool care



Self Study Series

White Papers

Purchasing Connection

Resources

HEALTHCARE PURCHASING NEWS

Follow @HPN_Online

CLINICAL INTELLIGENCE FOR SUPPLY CHAIN LEADE

INSIDE THE CURRENT ISSUE

Having My Say

The importance of monitoring all sterilant gases for employee safety

Low Temperature sterilization with gases and vapors such as ethylene oxide (EtO), hydrogen peroxide (H2O2) and ozone (O3) are essential for the sterilization of heat and moisture sensitive items. While information about EtO and its health hazards has been widely communicated over the years, information about the newer sterilant gases has not been well communicated. This article is intended to provide the reader with important safety information in order to decide the most effective way to monitor their workplace and assure a safe environment for their workers consistent with regulations and standards.

EtO and its dangers as a carcinogen, mutagen, irritant, etc.2 are well known as it has been used as a sterilant gas since the 1950s. In view of EtO's hazards, the Occupational Safety and Health Administration (OSHA) has developed special regulations for its use,2 and both the National Institute of Occupational Safety and Health (NIOSH)3 and Association for Advancement of Medical Instrumentation (AAMI)4 have also developed guidelines for the safe use of EtO. As a result and over time, most users of EtO have become very aware of the need to monitor for it in the workplace.

In 1995 the FDA approved the use of hydrogen peroxide gas plasma from Advanced Sterilization Products, an ozone sterilizer from TSO35 in 2003 and more recently a vapor phase hydrogen peroxide (VHP) sterilizer from STERIS (2007).6 These new sterilant gases offer some significant advantages over EtO, especially in terms of cycle time (4.5 hours for the TSO3 125L,7 55 minutes for STERIS V-Pro,8 and 28 minutes for Sterrad NX,9 compared to ~ 15 hours for EtO); but the newer sterilant gases have more restrictions in terms of material

Show Calendar
HPN Hall of Fame
HPN Buyers Guides
SHOP HPN
FEATURED PRODUCTS
INFORMATION LINK
Classifieds
Issue Archives
Advertise
About Us
Home
Subscribe
Sign up for our
Email Newsletter
GO
Privacy by SafeSubscribe℠
For Email Marketing you can trust
Contact Us

compatibility, penetration of lumens, etc. (Contact sterilizer manufacturers for specific information).

In addition to faster cycle times, some users have come to believe that these newer sterilant gases are safer than EtO and that whereas EtO required monitoring, the newer sterilant gases do not. However, realizing that sterilant gases are selected for their ability to effectively destroy a wide range of biological life, one should expect that exposing personnel to a sterilant gas is potentially hazardous and that exposure to any sterilant gas poses significant health and safety risks.

OSHA has the responsibility to regulate the workplace to promote a safe work environment. The overall goal of the OSHA regulations is set out in Section 5 (General Duty Clause) of the Occupational Safety and Health Act of 1970:

(a) Each employer

> *(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees; …*

More specifically, OSHA has developed Permissible Exposure Limits (PELs) for many common chemicals (including the sterilant gases) which are intended to set the exposure concentration that is safe for most people10 over long term exposure; thus PELs can be used as an indicator of the chronic hazard presented by the individual gases. For most gases, the PEL represents the maximum permissible exposure limit averaged over eight hours, as represented in the table below.

As the table shows, the OSHA PEL for both ethylene oxide and hydrogen peroxide are the same, only 1 ppm; and the PEL for ozone is one tenth of that value, only 0.1 ppm. Additionally, there are other indicators that suggest the hazards of being exposed, and the reliance (or lack thereof) that one can place on the ability to react based on smell.

Gas	OSHA PEL[11]	NIOSH IDLH[12]	Odor threshold
Ethylene oxide	1 ppm	800 ppm	700 ppm[13]
Hydrogen peroxide	1 ppm	75 ppm	Not available
Ozone	0.1 ppm	5 ppm	0.005 -2.0 ppm (detection threshold); 0.1 ppm (recognition)[14]

Also represented in the table is the National Institute of Occupational Safety and Health (NIOSH) immediately dangerous to life and health (IDLH) limits which represent the acute hazards posed by the gases and odor thresholds.

• The odor threshold for Ethylene Oxide is around 700 ppm, therefore one can see that a person can be exposed to EtO 700 times the OSHA PEL before he or she will able to smell it at a concentration close to the IDLH.

• There is no published odor threshold for hydrogen peroxide, but the Agency for Toxic Substance and Disease Registry (Department of Health and Human Services) has determined that Detection of odor [of hydrogen peroxide] does not provide adequate warning of hazardous concentrations.15

• While the initial odor threshold for ozone is below the OSHA PEL, the Canadian Center for Occupational Health and Safety states that detection of the odor is an unreliable method for determining the presence of potentially dangerous concentrations of ozone because of olfactory fatigue.16

As it relates to monitoring, OSHA simply requires that employers ensure that employees are not exposed to the sterilant gases at concentrations exceeding the PEL. OSHA has a policy of stating regulatory goals, but not of specifying the exact means to achieve them. The basis for the policy is to reduce the obsolescence of regulations since generally the goals change more slowly than the technology of compliance. For example, an employer can achieve the goal of not exposing employees by stopping use of ALL sterilant gases and contracting the work to a third party. The general principle is that OSHA sets the goal and the employer must use whatever means are necessary to achieve that goal.

The data above shows that all the sterilant gases are potentially hazardous and none of them can be reliably detected by smell until well above the OSHA PEL. If sterilant gases are going to be used in the workplace, then essentially the only way to meet the requirement that the employer ensures a safe working environment, i.e. ensure (and report) the sterilant gas concentration is below the OSHA PEL, is to use a continuous gas monitor with data capture capabilities.

EtO sterilizers have been in use since the 1950s, and there have been numerous reports of EtO leaks and studies of EtO exposures from sterilizers.17 Hydrogen peroxide gas plasma sterilizers have been around for a shorter time, but there have been many reports of skin contact as well as respiratory contact with hydrogen peroxide vapors.18 The author is not aware of any reports of ozone exposure, but new sterilizers using ozone and other newer sterilant gases have only been cleared by the FDA for marketing in the last few years. While there is no reason to doubt that most companies design and manufacture their sterilizers to the highest standards, leaks have still occurred. As the exposure reports above indicate, it is reasonable to expect that leaks may occur as door seals age, other wear and tear, etc., have taken their toll. This is not a criticism of these manufacturers; the same statement is true for almost any piece of precision equipment. Consequently, there is a significant risk of exposure from any sterilizer employing a sterilant gas and similar safety precautions should be taken, reflective of the safety risks posed by the sterilant gas in use.

Conclusions

Sterilant gases are selected for their ability to destroy a wide range of life forms. Exposure of workers to sterilant gases is therefore potentially hazardous.

Newer sterilant gases such as hydrogen peroxide and ozone have been introduced which offer significant benefits of cycle time over the traditional EtO, but the newer sterilants pose the same or greater risk as EtO based on the OSHA PELs and NIOSH IDLH values.

While OSHA does not mandate the use of a continuous gas monitor for ozone and hydrogen peroxide sterilization processes, it is difficult to see how the legal requirement that employers provide a safe work environment can be satisfied without a continuous monitoring system since leaks cannot be reliably detected by odor until well above the OSHA PELs.

Even though modern sterilizers are made to very high standards, any equipment can sometimes fail and so continuous monitoring equipment should be used with all sterilant gases, and not just ethylene oxide. HPN

P. Richard Warburton is Chief Technology Officer and General Counsel for ChemDAQ Inc, Pittsburgh, PA.

References

1. http://www.cdc.gov/niosh/rtecs/kx256250.html
2. http://www.cdc.gov/niosh/topics/ethyleneoxide/
3. See for example, standard ANSI/AAMI ST:41:1999/(R)2005
"Ethylene oxide sterilization in healthcare facilities: Safety and effectiveness, available from
http://www.aami.org/publications/pdf.html
4. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=7615
5. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=22387
6. http://www.tso3.com/en/products-services/description.php
7. http://www.steris.com/healthcare/documents/3574VProSS.pdf
8. http://www.sterrad.com/Products_&_Services/STERRAD/STERRAD_NX/
9. The OSHA PELs were originally based on the 1968 ACGIH threshold limit values
10.EtO 29 CFR 1910.1047, H2O2, O3 29 CFR 1910.1000, Z-1.
11.http://www.cdc.gov/niosh/idlh/intridl4.html
12.Control Technology for Ethylene Oxide Sterilization in Hospitals, September, 1989, DHHS (NIOSH) Publication No. 89-120; available from http://www.cdc.gov/niosh/89-120.html, retrieved 12/13/06. Citing Clayton, G.D., Clayton F.E. (Eds.) (1978) Patty's Industrial Hygiene and Toxicology, 3rd Ed. Vol. 2a Toxicology, New York, NY Wiley Interscience, p. 2186.
13.http://www.ccohs.ca/oshanswers/chemicals/chem_profiles/ozone/working_ozo.html
14.http://www.atsdr.cdc.gov/MHMI/mmg174.html
15.http://www.ccohs.ca/oshanswers/chemicals/chem_profiles/ozone/working_ozo.html
16.See for example A.D. LaMontagne, J.M. Oakes, R.N. Lopez Turley, Am. J. Public Health 2004 (September), 94(9), 1614 and
17.A.D. LaMontagne, K.T. Kelsey, Am.J. Public Health 2001 (March), 91(3), 412.
18.See for example FDA's Manufacturer and User Facility Device Experience Database, available at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm