The Essentials of Sterilant Gas Monitoring

Occupational safety in the use of sterilant gases

by P. Richard Warburton, PhD, Esq.

Objectives

1. Describe how exposure to sterilant gases can be hazardous to health and the relative hazards posed by each gas.
2. Discuss the exposure limits for the sterilant gases set by the federal government's Occupational Safety and Health Administration (OSHA) and the legal duty on employers to provide a safe work environment.

3. Discuss the limitations of the human sense of smell for detecting sterilant gases and know that smell is an unreliable means for detecting leaks.
4. Identify the main methods for detection of sterilant gases in the work place and features to look for in selecting a gas monitoring system.

Test Questions

True or False. Circle the correct answer.

1. All sterilant gases are harmful to humans upon exposure since sterilant gases are designed to destroy biological life.
   True False
2. There are no OSHA regulations for hydrogen peroxide.
   True False
3. Of the principle detection technologies used for sterilant gases, only electrochemical sensors are used to detect ethylene oxide (EtO), hydrogen peroxide and ozone.
   True False
4. The hydrogen peroxide solution used in a sterilizer is the same concentration as found in the grocery store 3 percent brown bottles.
   True False
5. Hydrogen peroxide is safer than EtO based on both the OSHA permissible exposure limits (PEL) and the National Institute of Occupational Health and Safety (NIOSH) immediate danger to life and health (IDLH) level.
   True False
6. Badges do NOT provide a real time alert of exposure to sterilant gases, only an average historical exposure at a later time.
   True False

Many thanks to the team at 3M Health Care for working with *Managing Infection Control* to provide the following accredited course. IAHCSMM has awarded one (1) contact point for completion of this continuing education lesson toward IAHCSMM recertification. The CBSPD has preapproved this inservice for one (1) contact hour for a period of five (5) years from the date of publication, and to be used only once in a recertification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 96.

Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of *Managing Infection Control*.

7. A well designed sterilant gas safety program should include engineering controls, best work practices, personnel protective equipment (PPE) and gas monitoring.
   True False
8. Gas monitors are not needed for sterilant gases since almost everyone can smell the gas if there is a leak and take preventative action.
   True False
9. OSHA requires that employees be promptly alerted in the event of a significant release of EtO.
   True False
10. Of the sensor technologies commonly used to monitor sterilant gases only metal oxide semiconductor (MOS) sensors are available for ethylene oxide, hydrogen peroxide and ozone.
   True False

Introduction

Understanding the importance of disinfection and sterilization constitutes one of the major advances in medicine, and continues to be an essential component of modern healthcare. Sterilization and disinfection continues to be at the forefront of today's challenges with healthcare-associated infections (HAIs) being a major issue.[1,2,3] The sterile processing department in most hospitals is probably the least visible, yet one of the most important areas regarding patient safety. There are many occupational dangers in healthcare as supported by the Bureau of Labor Statistics, and sterile processing has its unique challenges.[4] This article will focus on occupational safety in the narrow field related to the use of sterilant gases.

There are many ways to kill a broad spectrum of pathogens and heat/steam is by far the most common method used. However for those articles which are heat and steam sensitive, that is not an option and so low temperature gas sterilization is the preferred method in healthcare.

Sterilant gases are designed to destroy a wide range of pathogens including the more resistant spore forms of bacterial. Any gas capable of doing so with high sterilization efficacy is obviously going to be very hazardous to anyone exposed to it; therefore prevention of exposure and prompt warning in the event of a leak is critical. There are three sterilant gases that

Exposure to sterilant gases is most likely to occur via either the dermal (through the skin) route or inhalation.

have received FDA approval in the United States, ethylene oxide (EtO), hydrogen peroxide (including hydrogen peroxide gas plasma) and ozone. These are discussed below.

Legal Duty of Employer to Protect Employees

A safe work environment is in everyone's best interest. The 1970 Occupational Health and Safety Act, General Duty Clause, Section Five, places the burden on the employer to make the work place safe, even where there are no specific regulations.

> *"(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;"*[5]...

However, for the sterilant gases listed above, there are additional regulations that include specific exposure limits for each gas. These are discussed below.

Hazards of exposure to sterilant gases

There are essentially four basic variables to consider when evaluating the hazard of exposure to sterilant gases; the means by which the exposure occurs, the duration of exposure, the concentration of the sterilant gas and of course the nature of the gas itself. Exposure to sterilant gases is most likely to occur via either the dermal (through the skin) route or inhalation. Skin contact with liquid hydrogen peroxide is a great risk because the hydrogen peroxide used for sterilization is a vapor as opposed to being a true gas as with EtO and ozone, and so there is a risk that hydrogen peroxide solution will either not evaporate properly or the vapor will condense to form the liquid. There are many reports of skin contact with hydrogen peroxide, which can cause severe skin damage if the contact is prolonged. Examples of these reports can be found in the FDA's MAUDE database, a database that summarizes user reported adverse events involving medical devices since 1993.[6]

Concentration is the key to toxicity. While exposure to 3 percent hydrogen peroxide from the local grocery store is generally considered to present little risk of injury, sterilizers use much higher concentrations. The Advanced Sterilization Products Sterrad® line of sterilizers use cartridges with approximately 60 percent hydrogen peroxide solution. The Sterrad® NX series internally concentrates this solution to about 90 percent to increase efficacy and allow shorter cycles times. The new V-Pro® Vaporized Hydrogen Peroxide sterilizer from Steris® Corporation starts from approximately 35 percent solutions of hydrogen peroxide. At these high concentrations, the hydrogen peroxide will cause rapid injury to the skin upon contact and so there is a big difference with respect to risk between the hydrogen peroxide used for sterilization and the grocery-store 3 percent solution. Hydrogen peroxide also presents an inhalation risk and similarly, the primary risk of exposure to ozone and EtO is through inhalation.

Concentration, Exposure Risk and Regulation

The sterilant gases are well known chemicals and their hazardous effects are well documented. Exposure limits have been established in order to define what would be considered safe for most people. Permissible exposure limits (PELs) have been established by OSHA, and most of them were adopted from the 1968 Threshold Limit Values (TLVs) of the American Conference of Governmental and Industrial Hygienists (ACGIH).[7] The ACGIH selects TLVs as the maximum exposure limit for which most people can work eight hours a day, 40 hours a week continuously without significant harm.

As more data has become available, some of the OSHA PELs have been modified. For example, in the 1970s EtO was considered to be moderately toxic, an eye, skin and respiratory system irritant, and prolonged skin contact was known to cause delayed burns.[8] At that time the OSHA PEL was set at 50 parts per million. By the 1980s EtO was identified as a known animal carcinogen and suspected human carcinogen.[9] In 1984 based in part on this information, the OSHA 1910.1047 standard for EtO was issued which reduced the PEL to 1 ppm.[10] EtO is now classified as a known human carcinogen by the International Agency for Research on Cancer (IARC).[11] As with all carcinogens the risk depends on cumulative exposure. In contrast to EtO, the OSHA PELs for hydrogen peroxide and ozone have not changed since they were adopted, since their main hazardous effects as primary irritants have long been known.

Another index has been established by the National Institute of Occupational Safety and Health (NIOSH). NIOSH makes recommendations, which OSHA considers when passing laws. NIOSH uses its own established threshold of exposure which is referred to as the IDLH.[12] This is the level at which exposure is considered to be Immediately Dangerous to Life and Health. OSHA defines an immediately dangerous to life or health concentration as follows:

> *"An atmospheric concentration of any toxic, corrosive or asphyxiant substance that poses an immediate threat to life or would cause irreversible or delayed adverse health effects or would interfere with an individual's ability to escape from a dangerous atmosphere."*[13]

The OSHA PELs can be viewed as the exposure limits that refer to long term chronic exposure whereas the IDLH relates to the effects of acute exposure. The OSHA PELs and NIOSH IDLHs for the common sterilant gases and, for reference, two other toxic gases are shown in the table below.

Chemical Name	Chemical Formula	OSHA PEL (ppm)[14]	NIOSH IDLH (ppm)[15]
Ozone	O3	0.1	5
Hydrogen Peroxide	HOOH	1.0	75
Ethylene oxide	CH2OCH2	1.0	800
Hydrogen cyanide	HCN	10	50
Carbon monoxide	CO	50	1,200

From this table it can be seen that hydrogen peroxide and ethylene oxide have identical OSHA PELs (1 ppm), but the IDLH for hydrogen peroxide is far lower (acute effects occur at a lower concentration), less than one tenth that of ethylene oxide.

Ozone is one of the strongest oxidizing agents known and consequently is a very severe irritant. The NIOSH IDLH for ozone is 5 ppm, 15 times lower than hydrogen peroxide and 160 times lower than ethylene oxide. The OSHA PEL is only 0.1 ppm, similar to the Environmental Protection Agency's National Ambient Air Quality Standard for ground level ozone concentration of 0.075 ppm.[16] It is common knowledge that ozone is harmful; there are Action Ozone Days in some communities; where residents are discouraged from regular activities like mowing the grass or driving to help keep the concentration of ozone in the atmosphere from increasing.

The table above also shows the OSHA PEL and NIOSH IDLH for two other well known toxic gases in order to provide a simple comparison to the sterilant gases. From this table it can be seen that hydrogen peroxide and ethylene oxide are 10 times more toxic than cyanide gas (hydrogen cyanide) and 50 times more toxic than carbon monoxide, based on the OSHA PELs. As discussed above, sterilant gases are specifically selected for their ability to destroy a wide range of pathogens at low temperature with high efficiency.

Requirement for Monitoring

OSHA has a policy of writing regulations to state what the exposure limits are, but not how to achieve them. The rationale for this policy is that OSHA does not want its regulations to become obsolete as technology moves forwards and it does not want to limit an employer to a method that may not be the best approach for that application. For most gases, OSHA does not specifically state that the gases must be monitored; instead OSHA says for example:

> *"An employee's exposure to any substance in Table Z-1, the exposure limit of which is not preceded by a "C", shall not exceed the 8-hour Time Weighted Average given for that substance any 8-hour work shift of a 40-hour work week."*[17]

This requirement places the burden on the employer to ensure that this standard is met by whatever means is most appropriate to limit exposure to a particular gas. One employer may stop using that gas and contract that task out to another organization, and another employer may use the gas, but employ added ventilation and continuous monitoring in order to meet the standard.

OSHA has a policy of writing regulations to state what the exposure limits are, but not how to achieve them.

The OSHA regulations for carcinogens such as EtO are much more detailed than for other gases and actually specify the need for monitoring, as may be seen for example in the ethylene oxide standard. Even in this standard, OSHA does not specify a technology, but simply says that if ethylene oxide is going to be used, then it must be monitored. Any means of monitoring can be used so long as they meet the requirements of the standard, including ensuring that employees are not exposed above the excursion limit over 15 minutes, over the PEL over eight hours[18] and that they are warned promptly in the event of a major leak.[19]

Human Senses are Unreliable Indicators of Sterilant Gas Leaks

There is no human sense that can reliably detect the sterilant gases at low levels. Sterilant gases are invisible and there is no way to smell them until the gas is at an unsafe level. The odor threshold for EtO is around 700 ppm, 700 times higher than the OSHA PEL of 1 ppm. There is no published odor threshold for hydrogen peroxide, but the odor threshold is roughly estimated to be around 100 ppm, also much higher than the OSHA PEL of 1 ppm. While the odor threshold for ozone of 0.01 to 0.05 ppm is lower than the OSHA PEL (0.1 ppm); prolonged ozone exposure can result in olfactory fatigue.[20] After exposure to ozone, the human nose becomes increasingly less sensitive to the smell of ozone and therefore smell is an unreliable indicator for ozone.

Safe Use of Sterilant Gases

Sterilant gases can be safely used if suitable precautions are taken. The first level of defense is the design of the gas sterilizers. Sterilizer manufacturers go to great lengths to design products that are as safe a possible. However, sterilizers as with any electro-mechanical device can fail and leaks sometimes occur. The risks of exposure to attending personnel can be minimized by observing the following recommendations:

- Regular preventive maintenance is essential to ensure that the sterilizer is operating at peak performance, both from an efficacy and safety standpoint.

- Use of engineering controls such as forced ventilation as recommended by the sterilizer manufacturer; and required by regulations and standards. There are resources and professional organizations to assist in the development of such controls. The Association for the Advancement of Medical Instrumentation (AAMI) has issued several standards that specify recommended operating practices for gas sterilization.[21]

- Use of appropriate personal protective equipment (PPE) to reduce the risk of exposure to sterilant gases. The sterilizer manufacturers provide information as to what PPE should be used.

- Good work practices and employee training are an essential part of the safety regime. This training should be considered an ever changing and ongoing endeavor as the needs and demands of the industry are continually changing. Ensuring good work practices, such a cracking a sterilizer door and waiting enough time for any residual sterilant gas to disperse before removing the load; is the responsibility of every conscientious team member of the sterile processing department. NIOSH has issued several bulletins regarding the safe use of EtO, and taking similar precautions with the other sterilant gases is prudent.[22]

- Installing a suitable gas monitoring system to provide early warning in the event of a leak. Having early warning is essential so the appropriate response can be executed. The goal of any gas monitoring system should be to provide sufficient warning that action can be taken

BEFORE workers are exposed to the sterilant gas, not just provide a historical record that an exposure has taken place.

Features to Look for in a Gas Detection System

As discussed above, detection of sterilant gases by human senses is not a reliable means to provide notice of a leak. Both ethylene oxide and hydrogen peroxide have no odor at the OSHA PEL and ozone causes olfactory fatigue. Therefore; some form of automated gas monitoring system is necessary. Below are listed five of the more important criteria to consider in selecting a gas monitoring system.

1. **Continuous Monitoring**: Sterilant gas leaks by their very nature are unpredictable; the monitoring should therefore be continuous since the time when the gas monitoring system will be most needed is unknown. The only safe option is to have a continuous gas monitor that provides ongoing monitoring whenever the sterilizer is in use. It is critically important to position the monitor close to the sterilizers as well as to monitor the storage area for the EtO.

2. **Sensitivity:** The lower detection limit should be suitable to give adequate protection. The OSHA PELs have been determined as the maximum safe concentration averaged over eight hours. For EtO, there is also a 15 minute time weighted average exposure limit (Excursion limit of 5 ppm).[18] This means that for any 15 minute period the exposure to EtO must not exceed 5 ppm. Obviously, any gas detection system must be able to detect leaks below the OSHA PEL, otherwise an imperceptible but dangerous condition may exist and may continue to persist for some time if no warning is available. Generally, it is considered prudent to have a monitor resolution at least five times smaller than the minimum threshold. Thus if the minimum threshold is 1 ppm, then the monitor should have a resolution of at least 0.2 ppm.

3. **Alarm Response Time:** The alarm system must give a rapid warning of a leak. Obviously, for ethylene oxide, if the gas monitoring system is going to provide monitoring to prevent exposures in excess of the 15 minutes excursion limit, then the response time of the gas monitoring system must be significantly faster than 15 minutes. The ethylene oxide standard also requires that:

   > *"where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly."*[19]

   OSHA defines an EtO emergency as "any occurrence such as, but not limited to equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of EtO."[23] An emergency condition corresponds to a major leak and in such an instance, people need to be warned in seconds not after 15 minutes. Therefore the gas monitor must be able to initiate an alarm in seconds upon exposure to a high concentration of sterilant gas.

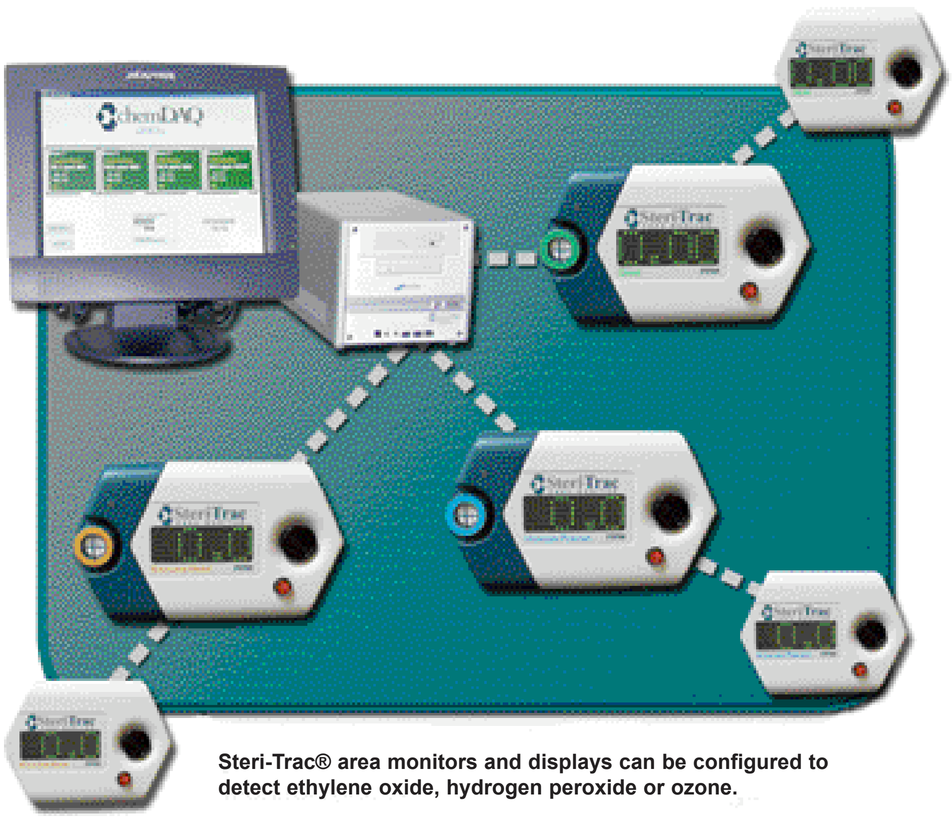
Even though the OSHA regulations for hydrogen peroxide and ozone do not specifically require a prompt warning in the event of a leak, acute exposure to these gases is more hazardous than EtO, based on their IDLH values and thus prompt warning is required upon sudden release of ozone and hydrogen peroxide as well. During the sterilization cycle, the concentration of sterilant gas is typically between 4 percent and 10 percent by volume (1%=10,000 ppm) for all three sterilant gases; and so even very small releases can result in significant concentrations for nearby personnel.

4. **Cross Sensitivity**: Typically sterile processing areas often contain other vapors, most commonly; alcohols. It is important that the sterilant gas monitor not respond to these interferences otherwise false alarms will result. False alarms are a waste of time and money. While the false alarm is investigated, throughput is disrupted and the supply of sterile surgical instruments can be interrupted. They also present a problem in desensitizing the staff of the sterile processing area to the alarm. Once they have lost confidence in the alarm they will not respond appropriately when the alarm does sound, perhaps during a true emergency, potentially placing themselves and others at risk.

5. **Maintenance and Calibration**: The monitor must be simple to use and simple to maintain, If the monitor is not simple to use and simple to maintain, then many users who see their careers and talents extending beyond servicing a gas monitor, will focus their efforts elsewhere. However in practice the maintenance burden necessary to maintain gas monitors in sound operating condition varies with the sensor technology employed and the design of the particular monitor. Therefore it is a good idea to get information from the manufacturers about what is required for maintenance before selecting a gas monitoring system.

The most important part of maintenance is calibration. Calibration serves as a basic function check that the monitor is operating correctly and ensures that the displayed gas concentration matches the true value. Unfortunately, many installed sterilant gas monitors are not regularly calibrated. The traditional method of calibration was for someone to walk around to each monitor and apply first zero air (clean air) and then test gas that contains a known concentration of the target gas from small compressed gas cylinders. While this approach does work, it has several drawbacks apart from the cost of the disposable calibration gas cylinders, the time to perform the operation, and keeping track of the monitor calibration schedule.

The biggest problem with traditional calibration is that the method is prone to error. Errors in calibration can be due to expired gases, contaminated tubing or user



Steri-Trac® area monitors and displays can be configured to detect ethylene oxide, hydrogen peroxide or ozone.

Sterilant gases are hazardous because they are selected to efficiently render all pathogens nonviable, but as with other hazardous chemicals they can be used with appropriate care.

error. Calibration errors tend to be more likely with more reactive gases because the more reactive gases have a greater tendency to react or adsorb on the surfaces in the tubing and other gas delivery equipment or with contaminants in the tubing, etc. Reactive gases generally are more hazardous and so the OSHA PEL is lower and so the concentration at which they are used is reduced. Reaction and adsorptions become more significant both as the reactivity of the gases increase and the concentration of the gas decrease; making calibration errors even more likely.

Manufacturers have tried to simplify the calibration process, and reduce calibration errors by simplifying and or semi-automating the process or by saving the end user from having to calibrate at all by providing a calibrated sensor exchange service.[24] This last approach has the advantage that the sensors are all calibrated under controlled factory conditions minimizing calibration errors.

Gas Sensor Technologies

Many gas sensor technologies have been developed, but only a few are regularly used for sterilant gas monitoring and these are briefly described below.

Badges

Badges are not a sensor technology, but are included here because of their widespread use. The badge contains a chemical that reacts with the target gas, thus fixing it on the badge. Badges are worn throughout a shift, collecting any target sterilant gas that they are exposed to. The badge is then later analyzed and the cumulative exposure result is returned in the form of a report. The time for the result to come back can be hours to weeks depending on whether the analysis is performed in-house or by an outside laboratory.

Badges are a simple, very reliable and sensitive technology. Unfortunately they are not designed to protect or alert in real time. They provide no warning in the event of a leak and only provide a historical record of the time weighted average magnitude of the leak. Therefore, badges do not satisfy the OSHA EtO standard for promptly alerting employees in the case of a major leak. Badges are available for many different gases.

Metal Oxide

Metal oxide semiconductor (MOS) sensors are excellent sensors for natural gas leaks and for detecting flammable gases. The target gas causes a change in the electrical resistance of the sensing element which provides the detected signal. MOS sensors have several advantages. The sensors have long life, are low cost, relatively fast response times and the sensors are very durable. These sensors work well as gross leak detectors for ethylene oxide, for example, for finding which joint in a gas line is leaking.

The resolution of most MOS sensors is usually not low enough to detect EtO at 1 ppm concentrations and thus MOS sensors are unsuitable in determining if the EtO concentration exceeds the OSHA PEL. Since MOS sensors are designed to detect flammable gases, they are prone to interferences and hence false alarms from other easily oxidized gases such as alcohols. MOS sensors are unable to detect hydrogen peroxide or ozone.

Gas Chromatography

Gas chromatography (GC) offers very good sensitivity (< 0.1 ppm EtO) and GCs for EtO are usually very specific, but this specificity can be lost if the columns are damaged. Compared to other gas detection technologies, GCs tend to be maintenance intensive, requiring frequent calibration. This burden has been reduced by the use of automated calibration systems in which a compressed gas cylinder of (~ 10 ppm) EtO calibration gas is permanently connected to the GC; though users are sometimes concerned about leaks from the EtO calibration gas cylinder which remains connected all the time.

Another drawback is that the GC is not a continuous monitor, but rather a sample then analyze device. If a multipoint GC based system is deployed, then the GC will sequentially sample each point. If the sample time per point is three minutes and there are four points, then the cycle time will be 12 minutes. Therefore, if there is a leak, the response time will be up to 12 minutes before an alert is provided. The GC is thus not a good method for ensuring that prompt warning in the case of a major leak as is required by OSHA.[19] GC based monitors are only available for EtO, and are not available for either ozone or hydrogen peroxide.

Electrochemical

Electrochemical sensors are probably the most widely used technology for toxic gas detection. The target gas enters the sensor usually through a membrane to the working electrode, where it is oxidized or reduced. The resulting electrical current provides the measured signal. Sensors and monitors are available for EtO, ozone and hydrogen peroxide. The sensors have low detection limits (0.1 ppm for EtO and hydrogen peroxide, and 0.01 ppm for ozone). Electrochemical sensors respond quickly (seconds) upon exposure to high concentrations of the target sterilant gas. Cross sensitivity has been a major drawback for EtO sensors since the sensors also respond to other easily oxidizable gases, especially alcohols. This problem can be solved by means of a chemical filter that prevents these interferent gases from reaching the sensor.[25] Cross sensitivity is not usually an issue for hydrogen peroxide or ozone sensors. Electrochemical sensors require periodic calibration, typically three to four times a year.

Other Characteristics

In addition to the sensor technology specific characteristics listed above, users should also consider whether the system is modular. The configuration of the monitoring system components should be flexible and it should also be capable of monitoring all of the sterilant gases used in the department simultaneously. Many sterile processing departments are adding a hydrogen peroxide or ozone sterilizer to complement their EtO sterilizer because the former two technologies offer much faster through put, but lack the very broad material compatibility of EtO. Modular systems often also offer advantages of redundancy, if part of the system were to fail then the other components continue to function and provide protection.

The ability to record exposure records over time and to generate reports is very valuable and several manufacturers

Sterile Process and Distribution CEU Information

CEU Applicant Name ____

Address____

City___________________________ State________ Zip Code ______________

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding Certification contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call 908-788-3847 or visit the Web site at www.sterileprocessing.org.

IAHCSMM has awarded one (1) Contact Point for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to one year from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. **KEEP A COPY OF YOUR RECORDS**.
6. Submit this form and the answer sheet to:
   Workhorse Publishing
   Managing Infection Control
   PO Box 25310, Scottsdale, AZ 85255-9998
7. For questions or follow-up, contact craig@manageinfection.com.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of *Managing Infection Control*'s receipt of the application.

Application

Please print or type.

Name____

Mailing Address____

City, State, Country, Zip ____

Daytime phone (   )____

Position/Title____

Social Security or Nursing License Number ___________________________

Date application submitted ____

Signature ____

Offer expires July 2013

On a scale of 1-5, 5 being Excellent and 1 being Poor, please rate this program for the following:

1) Overall content __________________
2) Met written objectives ______________
3) Usability of content ________________

<07/08>

provide software and hardware to accomplish this goal. In addition, most users want a gas monitor that will calculate the time weighted average exposures in addition to providing the real time gas concentration, and providing user adjustable alarms levels that correspond to the OSHA PELs.

In selecting a gas monitoring system it is important to ensure that the system will meet all the needs of that facility. In addition to the basic gas monitor, manufacturers offer other features such as remote displays, calibration service programs, etc. that improve the performance of the gas monitoring system or simplify its use. Users of sterilant gas monitors should ensure that they are fully informed before making a purchasing decision and therefore anyone considering purchasing a gas monitoring system is advised to contact the manufacturers of the various sterilant gas monitoring systems so that they can make an informed decision, and seek references from current users.

Conclusions

Sterilant gases are hazardous because they are selected to efficiently render all pathogens nonviable, but as with other hazardous chemicals they can be used with appropriate care. This care includes regular maintenance of the sterilizers, engineering controls, PPE, good work practices and a continuous gas monitoring system that is capable of detecting the sterilant gas whether it is EtO, hydrogen peroxide or ozone to the OSHA permissible exposure limit. ✛

ANSWERS

1. T	6. T
2. F	7. T
3. T	8. F
4. F	9. T
5. F	10. F

References

1. http://www.bls.gov/iif/oshwc/osh/os/ostb1236.pdf
2. http://www.usatoday.com/money/industries/health/2006-11-20-infections-usat_x.htm
3. http://www.wahsingtonpost.com/wp-dyn/content/article/2007/09/21/AR2007092101842.htm
4. http://www.bls.gov/iif/oshwc/osh/os/ostb1236.pdf
5. Occupational Safety and Health (OSH) Act of 1970, Sec. 5.
6. Manufacturer and User Facility Device Experience Database; available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm.
7. Federal Register, 36 Fed. Reg. 10466, 10503 (1971).
8. Hazardous Chemicals Data, 1975, National Fire Protection Association, NFPA 49.
9. Control Technology for Ethylene Oxide Sterilization in Hospitals, September, 1989 DHHS (NIOSH) Publication No. 89-120.
10. FR 49:25734; 06/22/1984 Final Rules for 1910.1047.
11. http://monographs.iarc.fr/ENG/Classification/crthallist.php
12. http://www.cdc.gov/niosh/idlh/intridl4.html
13. Code of Federal Regulations. 29 CFR 1910.120.14.
14. Code of Federal Regulations. 29 CFR 1910.10000, Table Z-1. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9992
15. http://www.cdc.govv/niosh/idlh/intridl4.html
16. http://ww.epa.gov/air/ozonepollution/standatds.html
17. Code of Federal Regulations. 29 CFR 1910.1000(a)(2).
18. Code of Federal Regulations. 29 CFR 1910.1047(c).
19. Code of Federal Regulations. 29 CFR 1910.1047(h).
20. Canadian Centre for Occupational Health and Safety. Working safely with Ozone, available at: http://www.ccohs.ca/oshanswers/chemicals/chem_profiles/oxone/workingozo.html.
21. "Ethylene oxide Sterilization in Health Care Facilities: Safety and effectiveness ANSI/AAMI ST41:1999; Chemical Sterilization and high-level disinfection in healthcare facilities. ANSI/AAMI ST58: 2005. Additional standards available at www.aami.org.
22. http://www.cdc.gov/niosh/topics/ethyleneoxide
23. Code of Federal Regulations. 29 CFR 1910.1047(b).
24. ChemDaq's sensor exchange program. http://www/chemdaq/com.
25. ChemDAQ's Inc's Spot-on® chemical filter. http://www/chemdaq/com.

Richard Warburton is chief technology officer and general counsel for ChemDAQ Inc., a manufacturer of sterilant gas monitoring equipment. He has been with ChemDAQ for about five years and has more than 20 years experience with the development of gas monitoring equipment. His Ph.D. in Chemistry is from the University of Southampton, United Kingdom and his J.D. is from Duquesne University in Pittsburgh. Dr. Warburton is member of the Pennsylvania Bar and is a registered patent attorney.

70-2010-7120-9