

# Safe Use of Chemicals for Sterilization in Healthcare

P. Richard Warburton

One of the paradoxes of modern healthcare is that while we have increased both life expectancy and quality of life for patients, the same healing environment has the potential to be a dangerous work area, and the tools of the trade could, if mishandled, pose health hazards for caregivers and hospital staff.

According to the Bureau of Labor Statistics, in 2007, there were 670,600 injuries and illnesses in the healthcare and social assistance industry, with an injury and illness rate of 5.6 per 100 full-time workers compared with 4.2 for all of private industry. There was also a decline in cases between 2003 and 2007, and the majority of cases were due to injuries caused by lifting and other physical tasks.

However, there are many other potential causes of injury in healthcare. In addition to slip and falls, sprains from lifting, and punctures from sharp instruments, healthcare workers are also at risk of exposure to harmful substances and chemicals (including sterilants and high-level disinfectants). This article focuses on this smaller, but no less significant group, with chronic exposure to low doses and complex mixtures of chemicals and hazardous agents.

It is important to be aware of potential hazards in the sterile processing environment, avoid unnecessary exposure to toxins, and prevent chronic and acute health hazards. Being knowledgeable about these chemicals, instituting good work practices, wearing appropriate personal protective equipment, and engineering controls in the environment can all help

minimize the exposure of healthcare staff to chemicals such as disinfectants and sterilants.

Disinfectants are chemical mixtures designed for their ability to kill a broad range of microbial life, including most bacteria, viruses, and parasites; whereas sterilants are designed to kill all microbial life including bacteria in resistant sporoidal form. Both disinfectants and sterilants need to be broad-spectrum biocides, and almost by definition, any chemical mixture with broad biocidal properties is likely to be hazardous to workers who are exposed to it.

Sterilants and disinfectants tend to fall into several chemical categories. The most common category is oxidants, including hydrogen peroxide, sodium hypochlorite (bleach), peracetic acid (PAA), and ozone. Another common group is the alkylating agents including ethylene oxide (EO), formaldehyde, and other aldehydes.

## Low-temperature Sterilization And Disinfection

The most common method of sterilization is heat or steam, and if devices can withstand heat and moisture, steam is the preferred method.<sup>2</sup> For devices sensitive to high temperatures, chemical sterilization or high-level disinfection is required. During liquid chemical sterilization, the device is immersed in a liquid formulation for the length of time needed to

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achieve sterilization. Liquid sterilization and high-level disinfection use a variety of active chemical agents, the most widely used including dialdehydes like glutaraldehyde and o-phthalaldehyde (OPA), and oxidizing agents like hydrogen peroxide and PAA.

Gas sterilization is achieved by placing medical devices within a sealed chamber and exposing them to high concentrations of reactive gases or vapors for a specified time. The most common gas sterilization method used today is hydrogen peroxide, as used in Advanced Sterilization Products' Sterrad® line of sterilizers. Ethylene oxide is still widely used, and additionally, sterilizers using hydrogen peroxide gas and hydrogen peroxide/ozone have more recently become available.

Modern sterilizers are designed and produced to exacting standards, with multiple safety features incorporated in them. As part of the 510(k) FDA approval process for a new sterilizer, which is considered a Class II medical device,<sup>3</sup> the manufacturer must submit data showing that the sterilizer is safe for the operators using it.<sup>4,5</sup> Potential exposures can sometimes occur due to malfunction, wear and tear, user error, and failure of engineering controls.

### **Occupational Safety and Health Administration Regulations**

The Occupational Safety and Health Administration (OSHA) has a responsibility to promulgate workplace safety standards and to enforce them under the 1970 Occupational Safety and Health Act (OSH Act). OSHA has permissible exposure limits (PELs) for some of the sterilant and high-level disinfectant chemicals. OSHA often partners with state agencies, which will enforce the more stringent of the federal or state laws.<sup>6</sup>

A common misconception among general hospital staff is that a chemical must be harmless if there is no OSHA PEL. This is incorrect, as only a few compounds have PELs compared to the approximately 8,300 chemicals in significant commercial use,<sup>7</sup> out of the more than 64 million chemicals recognized by the American Chemical Society's (ACS) abstract service.<sup>8</sup> In particular, newer compounds in service as sterilants and high-level disinfectants, such as OPA and

peracetic acid, were not in significant use before the 1970s and therefore do not have PELs. However, health and safety hospital staff are aware of OSHA regulations and exposure levels.

Under the OSH Act, employers have a duty to ensure that the workplace is safe. OSHA can enforce this requirement under the so-called General Duty Clause.<sup>9,10</sup> Where there are no OSHA PELs employers should look for other recognized standards or appropriate safety information (from for example the American Conference of Governmental Industrial Hygienists or ACGIH, and the National Institute for Occupational Safety and Health or NIOSH) to determine the maximum exposures limits that are recognized as safe.

Even for compounds with OSHA PELs<sup>11,12</sup> many of the PELs have not been revised since they were first introduced in 1971 by adoption of the 1968 Threshold Limit Values (TLVs) of ACGIH. Forty years later, about 400 of the current 630 PELs need revision, and another 200 new chemicals warrant addition to the list.<sup>13</sup> OSHA is planning to review the PELs starting in 2012.<sup>14</sup>

OSHA air contaminant exposure limits for hydrogen peroxide apply in a hospital setting<sup>15</sup> as they would in a food-processing facility. The exposure risk may vary with occupational setting, but the effects of exposure to a specific concentration of a particular chemical are the same regardless of industry. While employers have a duty to provide a safe work environment, employees should understand the properties of the chemicals they are using, and take appropriate care to avoid exposure to these compounds.

### **Hazards of Sterilants and Disinfectants**

Exposure to all of these chemicals poses potential immediate and long-term risks to workers. Sterilant chemicals fall into two main groups; alkylating agents and oxidizing agents.

#### **Alkylating Agents**

Alkylating agents include ethylene oxide, (EtO), formaldehyde and the dialdehydes. All alkylating agents used in healthcare are primary irritants, and the gases and vapors from these compounds are irritating to the eyes and respiratory system if in sufficient concentration. Contact with liquids can cause irritation to eyes or skin. EO and formaldehyde are also known human carcinogens.<sup>16,17</sup>

Manufacturers have changed the chemical composition of the sterilants and disinfectants as potential exposure risk data has been collected. Half a century ago, formaldehyde solution was the primary high-level disinfectant in use. As the hazardous properties of formaldehyde became better recognized (the chemical is toxic, a sensitizer, and a carcinogen<sup>18,19</sup>), and the regulatory environment developed<sup>20</sup> alternatives such as glutaraldehyde were used. Formaldehyde is still widely used as a tissue preservative, and formaldehyde gas is still used for gas sterilization, although the gas is no longer significantly used in healthcare in the United States and Canada.

With widespread adoption, glutaraldehyde was also found to be linked to health issues.<sup>21,22</sup> The chemical is an irritant, sensitizer, and causes occupational asthma. Regulatory agencies and other organizations issued warnings<sup>23,24</sup> and glutaraldehyde is being replaced by newer chemicals such as OPA. Like glutaraldehyde, OPA is a dialdehyde, and so has similar chemical and disinfectant properties.

OPA is more reactive and can be used at lower concentrations<sup>25</sup> and OPA has a lower vapor pressure so the inhalation exposure risk to OPA is less. However, OPA is an irritant and like glutaraldehyde,<sup>26</sup> has been known to cause occupational asthma.<sup>27</sup> Dermal exposure is a concern for both compounds. There is no OSHA PEL for glutaraldehyde, but the ACGIH has a ceiling limit of 0.05 ppm;<sup>28</sup> and there is currently no OSHA PEL or ACGIH limit for OPA.

### Oxidizing Agents

All oxidizing agents are primary irritants. Their vapor can cause irritation to the eyes and respiratory system, and the liquid may cause bleaching or irritation of the skin, depending on the concentration and extent of contact.

The OSHA PEL for hydrogen peroxide is 1 ppm, calculated as an eight-hour, time-weighted average (TWA),<sup>29</sup> which is well below the odor threshold (greater than 100 ppm). The International Agency for Research on Cancer (IARC) does not consider hydrogen peroxide to be a carcinogen, and the ACGIH classifies hydrogen peroxide as an animal carcinogen, with unknown relevance to humans.<sup>30</sup>

Peracetic acid is finding widespread use in healthcare as a high-level disinfectant, as well as

in other industries, such as food processing, for aseptic packaging and disinfection. PAA is a more effective disinfectant than hydrogen peroxide, and is potentially more hazardous than hydrogen peroxide.<sup>32</sup> Its greater efficacy and higher toxicity<sup>33</sup> is probably because PAA is less affected by the protective catalyzing enzyme than hydrogen peroxide,<sup>34</sup> and to a lesser extent, because PAA is a moderately stronger oxidizing agent than hydrogen peroxide.<sup>35</sup>

At present, there is neither an OSHA PEL nor an ACGIH TLV for PAA; though the ACGIH is currently reviewing PAA.<sup>36</sup> The U.S. Environmental Protection Agency (EPA) has issued Acute Exposure Guide Lines (AEGs) for PAA, but it is important to distinguish between AEGs—based on rare, typically accidental exposure to a particular chemical, and not subchronic or chronic data and which are designed to protect the general public—from PELs, TLVs, RELs, etc., which are based on frequent low-level workplace exposure levels.

AEGs are roughly defined as the time-weighted exposure which will not cause any long-term effects (AEG 1), serious health effects (AEG 2) or death (AEG 3).<sup>37</sup> The definition for AEG 1 is similar to the definition for the ACGIH TLV value,<sup>38</sup> upon which the OSHA PELs were based. The eight-hour TWA AEGs for PAA<sup>39</sup> are: AEG 1 = 0.52 mg/m<sup>3</sup> (0.17 ppm), AEG 2 = 1.6 mg/m<sup>3</sup> (0.51 ppm) and AEG 3 = 4.1 mg/m<sup>3</sup> (1.3 ppm). The AEG 1 concentration may be an adequate exposure limit, based on the recommendations made by Gagnaire et al.<sup>40</sup>

The current exposure limits for the more common sterilant chemicals are summarized in Table 1. Only the OSHA PELs have the force of law, whereas the other exposure limits are recommendations.

Compound	OSHA PEL (ppm)	NIOSH REL (ppm)	ACGIH TLV (ppm)	EPA AEG 1 (ppm)
Ethylene Oxide	1 (8 hr TWA) 5 (15 min TWA)	< 0.1 (8 hr TWA) 5 ceiling	1 (8 hr TWA)	No AEG 1
Hydrogen Peroxide	1 (8 hr TWA)	1 (8 hr TWA)	1 ppm (8 hr TWA)	n/a
Peracetic Acid	n/a	n/a	Under review	0.17 (8 hr TWA)
Glutaraldehyde	n/a	0.2 ceiling	0.05 ceiling	n/a
o-Phthalaldehyde	n/a	n/a	n/a	n/a

n/a—not available, TWA—time weighted average

**Table 1.** Exposure standards for common sterilization chemicals in the workplace (PEL, REL, and TLV) and for the general population (AEG).

### Odor: An Unreliable Indicator of the Presence of Chemical Vapor

- The odor threshold of any compound varies greatly between individuals.
- An individual's day-to-day health varies. For example, nasal congestion is not conducive to repeatable smelling of gases and vapors near the odor threshold.
- Prolonged exposure to too many gases or vapors causes olfactory fatigue; the temporary inability to distinguish an odor after repeated or prolonged exposure to the airborne compound.
- Even if the individual can smell the gas or vapor, few people are able to quantitatively assess the concentration of the gas or vapor by smell to determine whether the relevant PEL has been exceeded.

All oxidizing agents are primary irritants.

### Questions to Ask About the Risk of Exposure to Sterilization Chemicals

- What sterilant chemicals are used in that facility, and what are the hazards associated with them?
- What potential failures (such as sterilizer malfunctions, incorrect work practices, and failed engineering controls) can cause exposure to sterilant chemicals, and what is the likelihood of these failures occurring?
- If a leak of a sterilant chemical does occur, how will it be detected; and how will people know when it is safe to return?

**The best method for a hospital sterile processing plant is probably different than that for a titanium pickling plant, even if they are both using hydrogen peroxide.**

### Risk of Exposure

Chemical suppliers have a very difficult and probably impossible task: to produce an effective, broadly biocidal disinfectant/sterilant that poses no risk to people who are exposed to its liquid or vapor. These two demands are contradictory, but by careful selection of compounds, well-designed equipment, effective engineering controls, and good work practices, exposure risk can be managed. The overall risk is a combination of the hazards presented by the chemical, and the probability of exposure of personnel to that chemical.

The OSHA sets performance goals, such as permissible exposure limits for gases and vapors, and the employer determines the best methods to achieve these goals. The best method for a hospital sterile processing plant is probably different than that for a titanium pickling plant, even if they are both using hydrogen peroxide.

Of the main questions to ask about the risk of exposure to sterilization chemicals, most facilities can answer the first question easily by looking at their material safety data sheet collection. The second question is more difficult because it concerns the modes of equipment failures, and how likely these failures are to occur.

Facilities may wish to consult with industrial hygienists, biomedical engineering, equipment manufacturers, and others. The answer to the third question depends on the properties of the chemicals involved, including whether they are even perceptible at potentially harmful concentrations. If there is a significant risk of exposure and the chemicals are not perceptible, then an automated means to detect the leak should be used.

Using EO as an example, OSHA requires that “where there is the possibility of employee exposure to EO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly.”<sup>48</sup> OSHA does not define what concentration constitutes an emergency, but says that 50 ppm would be consistent with this standard.<sup>49</sup> The odor threshold for EO is between 300 to 700 ppm.<sup>50</sup> Thus, 100 ppm of gaseous ethylene oxide would be imperceptible, and workers could be

exposed without knowing it. For EO, the OSHA PEL is only 1 ppm, calculated as an eight-hour TWA, and so even a minor leak could result in excessive exposure without detection.

One of the most common ways to automatically and quantitatively detect sterilant gases and vapors is to use a continuous monitor, which is commercially available, and measures concentrations of EO, hydrogen peroxide, ozone, PAA, and glutaraldehyde, relevant to the OSHA PELs and other exposure standards discussed earlier.

However, it is equally important to mitigate risks of exposure as it is to detect accidents. Sterile processing staff should remain aware of risk of exposure to low levels of hazardous chemicals, including, by their very nature, chemicals used in sterilization of medical instruments.

Major leaks of sterilant gases and liquids rarely occur when well-designed systems are in place to protect users, modern equipment and efficient engineering controls reduce the risk of exposure; monitoring systems provide warning if there are leaks; and good work practices prevent leaks and enable people to deal with any leaks that do occur safely.

Employers should develop specific procedures and work practices to be employed in the event of a chemical spill or leak. These procedures may involve, for example, evacuation, or clean-up, depending on the needs and capabilities of the particular facility, and the chemicals involved.

### Summary

Chemical sterilization is necessary for temperature sensitive items that cannot be sterilized with steam. These chemical sterilants are by their nature hazardous; otherwise, they would not function well. Modern sterilizers and associated equipment are designed so that these chemicals can be used safely. Whether through mechanical failure, wear and tear, or user error, leaks do sometimes occur. The maximum chemical exposure is determined by OSHA permissible exposure limits, if available, and if not available, employers should use recognized standards.

Employers have a duty to ensure a safe work environment and take appropriate action to mitigate potential risks. Employers should therefore assess the hazards of the chemicals used, the potential modes for leakage, means for identifying leaks and the risk of exposure of

employees. Ideally, work practices and procedures should be developed by healthcare facilities so that sterile processing employees know what to do in case of a chemical leak or spill, and how to safely use these chemicals to ensure their own, and patient safety. ■

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AST and AAMI share many common issues related to health care. Many of the AST Standards of Practice drew upon AAMI Standards for information and utilized them as primary references.

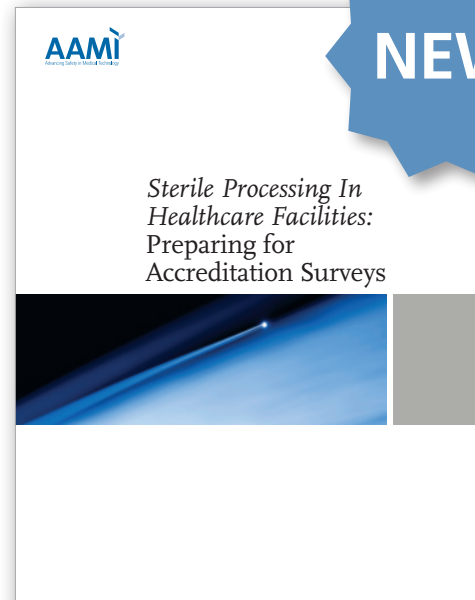
In turn, many of the AST Standards of Practice are relevant to AAMI. AST Standards related to surgical attire cover Laundering Scrub Attire; Wearing the Lab Coat and Cover Apparel; and Head and Shoe Covers in the OR. AST Standards related to sterilization and disinfection cover Decontamination of Surgical Instruments and Packaging Material and Preparing Items. Standards related to aseptic technique cover Surgical Drapes; Skin Prep; and Monitoring Sterility.

To see all of the AST Standards of Practice, visit [www.ast.org](http://www.ast.org) and enter [http://www.ast.org/educators/standards\\_table\\_of\\_contents.aspx](http://www.ast.org/educators/standards_table_of_contents.aspx)

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