

# Hydrogen-Peroxide Emissions Safety in the Sterile Processing Department/ Central Sterile Supply (SPD/CSSD):

PART 1

A Medical and Chemical Perspective



**Ivan Salgo MD, MS, MBA**  
Vice President & Chief Medical & Scientific Officer  
Advanced Sterilization Products

**Richard Warburton PhD, JD**  
Chief Technology Officer  
ChemDAQ

# Key Points

- ▶ **Countries are focusing on updating safety standards to include Short Term Exposure Limits.** Current U.S. exposure limits were published by OSHA in 1971.
- ▶ **Peak Exposure Can Occur During Routine Sterilization Cycles.** Sterilizer door opening can cause short-term hydrogen peroxide concentrations that have been published to spike to 25–40 ppm. This exceeds the ACGIH recommendation of being no more than 5x the 8-hr TWA which would be 5 ppm.
- ▶ **Poor Detectability Increases Risk.** Hydrogen peroxide has poor detectability by smell alone at potentially hazardous concentrations because it is odorless, meaning workers can be exposed to irritant levels without immediate awareness.
- ▶ **Acute Exposure can create Physiologic Effects.** Hydrogen peroxide's oxidative properties, while effective for killing microbes, can cause health issues in humans, including respiratory, ocular, and dermal irritation, especially in susceptible populations.
- ▶ **International Consensus on the Need for STELs.** Numerous countries and some U.S. states have adopted Short-Term Exposure Limits (STELs) for hydrogen peroxide, demonstrating international recognition that TWA-only regulations are insufficient for worker protection.
- ▶ **Vaporized Hydrogen Peroxide (VH<sub>2</sub>O<sub>2</sub>) with Plasma Technology in the Chamber Directly Addresses Acute Exposure Risks.** Unlike sterilization methods that rely solely on VH<sub>2</sub>O<sub>2</sub>, VH<sub>2</sub>O<sub>2</sub> with Plasma technology uses a final plasma phase to break down residual hydrogen peroxide, directly mitigating the risk of acute exposures to personnel during door-opening events.
- ▶ **Regulatory Evaluation Is Ongoing in Hydrogen Peroxide Safety.** To ensure a safer working environment, regulations are being updated in many countries with established Short-Term Exposure Limits (STEL) for hydrogen peroxide, complementing the current 8 hour Time-Weighted Average (TWA) standard.





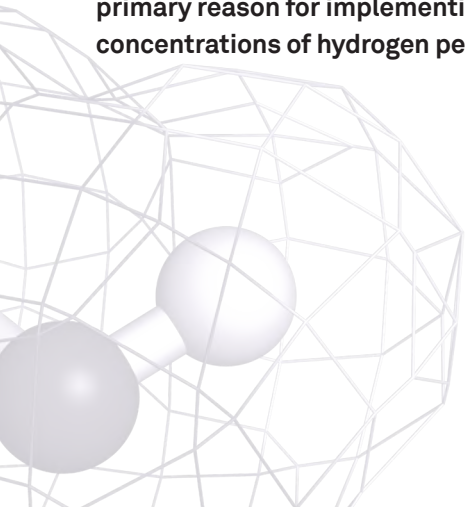
# Introduction

The Sterile Processing Department (SPD) or Central Sterile Services Department (CSSD) represents one of the most critical areas in hospital operations, where the safety of both patients and healthcare workers depends on effective sterilization while maintaining occupational health standards. With over 310 million major surgeries conducted globally each year, sterilization plays a pivotal role in preventing complications, infections, and mortality.<sup>1</sup> There are potentially hundreds of thousands of Hospital Sterilization Workers globally with at least 50,000 in the U.S.<sup>2</sup> This review presents a comprehensive scientific analysis of global hydrogen peroxide emission limits, with a particular focus on short-term exposure limits (STELs). The AAMI ST-58:2024 standard places a specific emphasis on staff safety, requiring facilities to consider safety and efficacy in the use of both liquid chemical sterilants (LCSs) / high-level disinfectants (HLDs) and gaseous chemical sterilizers.<sup>3</sup> Hydrogen Peroxide is an odorless vapor<sup>4</sup> that has acute exposure effects. **The ATSDR (Agency for Toxic Substances and Disease Registry) notes that regarding hydrogen peroxide vapor, “Detection of odor does not provide adequate warning of hazardous concentrations.”<sup>5</sup>**



**“Detection of odor [smell] does not provide adequate warning of hazardous concentrations of hydrogen peroxide vapor.”<sup>5</sup>**

Findings indicate a widespread disparity among major occupational health organizations regarding the long-term Time-Weighted Average (TWA) exposure limit for hydrogen peroxide. As demonstrated later, the 50-year-old OSHA limit is only indicative for an 8-hour shift of chronic low-level exposure. Opening a sterilizer door is an acute exposure event. Additional expert positions, for example, by the American Conference of Governmental and Industrial Hygienists (ACGIH) suggest that **acute exposure be limited to no more than five times the 8-hour Time-Weighted Average.<sup>6</sup>** The **primary reason for implementing STELs are rooted in the acute health effects associated with brief exposures to high concentrations of hydrogen peroxide, including respiratory irritation and eye irritation.**

A decorative graphic in the bottom left corner showing a complex, interconnected network of white lines forming a spherical, crystalline or molecular structure. Two larger, semi-transparent spheres are integrated into the structure, one at the bottom left and one slightly above and to the right of it.



# History of Hydrogen Peroxide Standards

This analysis highlights that current U.S. federal regulations on hydrogen peroxide exposure rely on half century old data, with limits based on a 1957 study and a 1968 assessment. Prior to the 1950s, it was generally believed that inhaling the vapors from 90% hydrogen peroxide at room temperature for a short time such as cleaning up a spill did not present a respiratory hazard.<sup>4,7</sup> However, studies such as the one by Oberst et al on animals showed that prolonged exposure of dogs to low concentration around 7 ppm resulted in nasal discharge, mild irritation in the bronchioles and bleaching of the hair.<sup>7</sup>

In 1946 the American Conference of Governmental Industrial Hygienists (ACGIH) published its first list of Maximum Allowable Concentrations, which later became the Threshold Limit Values (TLVs) for Chemical Substances, calculated as 8-hour TWA. Based on the research by Oberst and others, the proposed TLV for hydrogen peroxide in 1956 was 1 ppm;<sup>8,9</sup> and this value was subsequently adopted. In 1970, the workplace safety laws in the United States were overhauled with the passage of the Occupational and Safety Act, which created the Occupational Safety and Health Administration (OSHA). OSHA's role was (and still is), to issue standards for occupational safety and to enforce them. OSHA adopted the 1968 ACGIH TLVs to become the OSHA Permissible Exposure Limits (PELs), a legally enforceable standard and the new PEL for hydrogen peroxide was 1 ppm, calculated as an 8-hour (TWA). The OSHA PEL for hydrogen peroxide today is still 1 ppm. More recent testing with rats has shown that exposure to 2.1 ppm (2.9 mg/m<sup>3</sup>) for 6 hours a day, 5 days a week for 28 days had no adverse effects, but 10.5 ppm (14.6 mg/m<sup>3</sup>) and higher resulted in respiratory tract irritation, concentration related necrosis and inflammation of the epithelium in the frontal regions of the nasal cavity.<sup>10</sup>

Since the 1950s, much more research have been conducted on the effects of hydrogen peroxide vapor exposure. Acute exposure to 2.2 ppm has been found to cause mild irritation in the respiratory tract but 0.5 ppm was not found to have any observable adverse effects in healthy volunteers.<sup>9,11</sup> Although most inhalation exposures have milder presentations, acute exposures to the vapors from highly concentrated hydrogen peroxide solutions has been shown to lead to more severe respiratory distress which include dyspnea, inflammation of mucous membranes and even pulmonary edema post exposure.<sup>12</sup> Because of frequent exposures to higher concentrations for short periods can average above the TWAs, the data suggests that multiple brief high exposures may be more harmful than a low constant exposure for the same TWA.

Several studies have been conducted to look at the short-term effects of hydrogen peroxide exposure. Mastrangelo et al assessed the effect of brief hydrogen peroxide exposures (< 30 min) over the 8-hour TWA in beverage workers and found that the effects lasted for more than a year and recommended that a STEL be introduced for hydrogen peroxide.<sup>13</sup> In 2002 Gagnaire et al studied the short term effects of hydrogen peroxide exposure and recommended a short term exposure limit (15 min TWA) of 10 ppm and a Long Term Exposure Limit (LTE) of 3 ppm.<sup>14</sup> Occupational exposure organizations have also recognized the need for a STEL for hydrogen peroxide. Several countries have introduced a STEL for hydrogen peroxide. The UK introduced its STEL of 2 ppm prior to 1987, and it remains this value today.<sup>15</sup> Even though the US-OSHA does not have a STEL for hydrogen peroxide, Washington State in the U.S. also has a STEL of 3 ppm,<sup>16</sup> and Hawaii has STEL of 2 ppm.<sup>17</sup>

The CDC's guideline sets an Immediate Danger to Life and Health (IDLH) at 75 ppm and an 8-hour exposure limit at 1 ppm, last reviewed in 2014.<sup>18</sup> Organizations have cited that these exposure limits are incomplete for acute exposure.



OSHA recognizes that many of its standards are outdated and encourages users to employ more current occupational exposure limits such as those issued by the ACGIH.<sup>19</sup> Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time. Regulations relying solely on 8-hr TWA measurements for gases and vapors like hydrogen peroxide do not adequately protect workers from acute exposure risks. Although acute effects from peak exposures are documented, neither the ACGIH nor OSHA have set STEL values for hydrogen peroxide. In contrast, some European countries, as well as some U.S. states (Washington and Hawaii), have established short term exposure limits.<sup>20</sup>





# Gap in Chronic 8 Hour Exposure Limit

Peak exposures during sterilizer door opening can reach 25-40 ppm for brief periods.<sup>20</sup> Without STEL protection, workers may experience dangerous acute exposures while remaining in compliance with TWA-based regulations.<sup>20</sup>

The acute nature of these exposures presents particular concern because traditional TWA measurements fail to account for the intensity and potential harm of brief, high concentration exposures. The resulting symptoms represent not merely discomfort but indicators of physiological stress that can affect worker performance and health.

The SPD/CSSD environment presents unique exposure scenarios that differ significantly from other occupational settings where hydrogen peroxide might be encountered. As discussed earlier, unlike industrial applications where exposure might be more predictable and controlled, SPD/CSSD operations involve repeated cycles of sterilization with varying loads, creating dynamic exposure conditions throughout the workday. These dynamic circumstances also rely on consistent ventilation air exchanges per hour. Exposure right at the sterilizer and nearby can create physical conditions of elevated short term exposure.

The temporal pattern of these exposures compounds their significance. SPD/CSSD workers typically process multiple loads throughout their shifts, creating repeated exposure events that may not be adequately captured by traditional 8-hour TWA measurements.



**A worker might experience several brief exposures to concentrations exceeding 10-20 ppm during door opening events, yet their calculated 8-hour TWA might remain below the OSHA PEL of 1 ppm.<sup>20</sup>**



# Exposure to Hydrogen Peroxide Vapor in Healthcare

AAMI Standard ST58:2024 calls specific attention to staff safety and chemical sterilant vapor. The document discusses ventilation throughout the standard. These include:



## AAMI Standard ST58:2024 (P16 section 3.1):

*Traffic control; engineering controls (adequate ventilation and hazard containment); ergonomics; and proper equipment installation, operation, and maintenance can reduce unnecessary or inadvertent exposure of personnel, patients, and visitors to chemical sterilants/high-level disinfectants.*



## AAMI Standard ST58:2024 (P24 section 3.4.9):

*It should be noted that increasing the general room ventilation is usually not a cost-effective way to reduce hazardous vapor exposure levels because of the large amount of air that must be moved, heated, and cooled.”*

This standard emphasizes staff safety with respect to ventilation as well as “reducing unnecessary exposure”. Exposure entails not simply chronic low levels of exposure as measured by OSHA’s 8 hour TWA but also many jurisdictions’ adoption of a STEL.

Typically, in a hospital setting, workers are not exposed to constant levels of hydrogen peroxide vapor, rather they are exposed intermittently when opening the door of hydrogen peroxide sterilizers to remove the sterilized load. If there is any residual hydrogen peroxide vapor in the sterilizer chamber, then the vapor cloud will be released, and it typically rises because a hydrogen peroxide sterilizer is warmer than room temperature after the cycle. **This odorless vapor cloud is released directly into the face of the sterile processing technician when they retrieve the load from the chamber.** A standard hydrogen peroxide sterilizer cycle is about 28 minutes (varies with manufacturer) and in a busy sterile processing department with multiple sterilizers running almost continuously, **the technician may receive multiple brief exposures in a day.** The concentrations in the chamber at the end of the cycle vary greatly with manufacturer and maintenance status of the sterilizer. The concentration of hydrogen peroxide vapor released at the end of the cycle can reach 25 to 40 ppm,<sup>20</sup> this varies with manufacturer. The current OSHA PEL is 1 ppm calculated as an 8-hour TWA. These brief exposures usually do not exceed the OSHA PEL, but the literature discussed below suggests that acute exposure to higher concentrations can be harmful. This review article will analyze the scientific and regulatory history of the occupational exposure limits for hydrogen peroxide and show that there is a benefit to having a STEL as well as the 8-hour TWA for chronic exposure.<sup>18</sup>

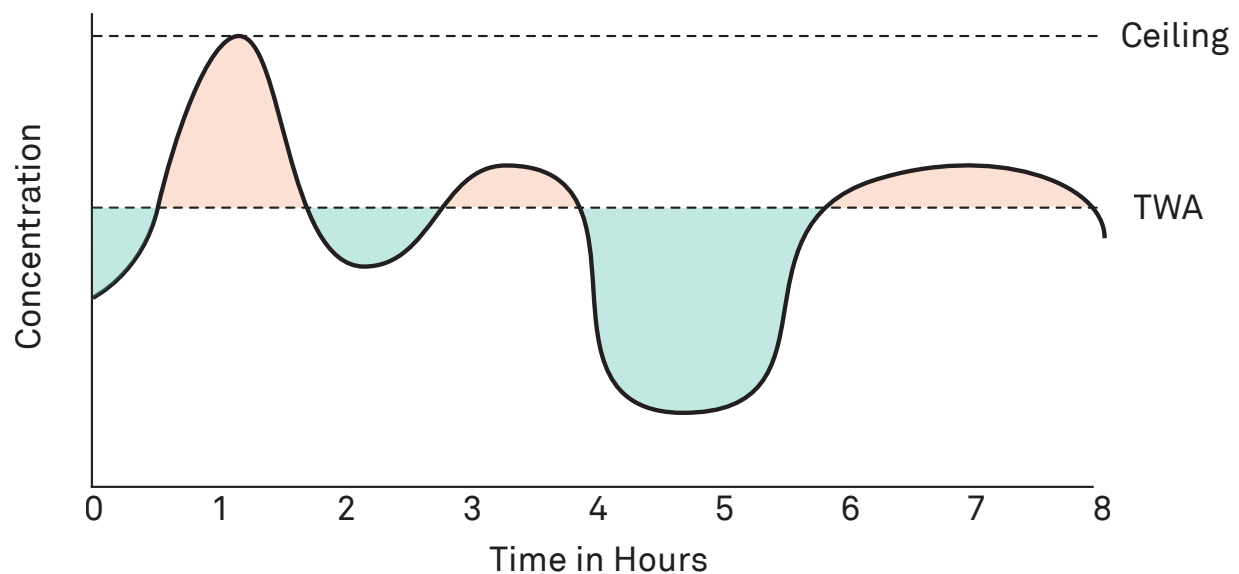
**TWA-STELs are given for contaminants for which short-term hazards are known.**



To understand workplace exposure standards, it is helpful to be familiar with the following key terms, as defined by professional organizations. They give these three definitions:<sup>21</sup>

- **Time-weighted Average (TWA) concentration:** The concentration of a contaminant averaged over a workday (usually 8 hours long). It's measured in a workplace by sampling a worker's breathing zone for the whole workday. ACGIH recommends that the TWA should not be exceeded for up to an 8-hour workday during a 40-hour workweek.
- **Ceiling value:** A concentration of a toxic substance in air that ACGIH recommends should not be exceeded at any time during the workday. This value is often used in conjunction with the TWA.
- **Short-term Exposure Limit (STEL) value:** A TWA concentration over 15 minutes that ACGIH recommends not to exceed—even if the 8-hour TWA is within the standards. TWA-STELs are given for contaminants for which short-term hazards are known.

NOAA and the ACGIH show in their graph below, that the Chronic Time Weighted Average does not measure acute exposure. In fact, it averages out acute emissions as shown in their graph below.<sup>21</sup>



**FIGURE 1:** Visual demonstration that the time weighted average is not meant to show short term exposure.

In other words, **use of the 8 hour TWA represents an incomplete assessment of the Occupational Health and Safety exposure to personnel.**

The regulatory framework does not consider **sensitive populations, including workers with pre-existing respiratory conditions, and pregnant employees.** International guidelines increasingly recognize the need for additional protection factors for vulnerable workers.

A useful analogy involves driving for eight hours at an average speed of 50mph (80kph). Although brief periods of speeding at 110mph (177kph) may still result in an acceptable overall average, those instances nonetheless can lead to hazardous driving conditions. Consequently, **the average speed alone can obscure intermittent periods of elevated risk.**



# Health Effects of Hydrogen Peroxide Exposure

Hydrogen peroxide ( $\text{H}_2\text{O}_2$ ) presents unique challenges in the hospital SPD/CSSD environment due to its colorless, odorless nature at concentrations that can cause immediate health effects. Detection of odor by smell does not provide adequate warning of hazardous concentrations.<sup>5</sup> Understanding these acute effects is crucial for establishing appropriate exposure limits and emergency response protocols. The importance of wearing appropriate PPE is essential to protecting eyes and skin.<sup>†</sup>

The health effects of hydrogen peroxide exposure in SPD/CSSD environments manifest through multiple pathways. Contact of hydrogen peroxide solutions can cause severe irritation of the eyes, nose, throat, lungs and gastrointestinal tract.<sup>3</sup> Health symptoms represent not merely discomfort but can be an indicator of physiologic stress.

Important health exposure scenarios can occur when SPD/CSSD workers open sterilizer chambers immediately after cycle completion.

## Hydrogen Peroxide Oxidative Effects: Microbiocidal Activity and Human Cell Effects

The mechanism by which Hydrogen Peroxide destroys microbiocidal life is through oxidation. Cellular injury is brought about by oxidizing the lipid (fat) of cell membranes, oxidizing proteins, and creating free radicals that attack deoxyribonucleic acid (DNA).<sup>22</sup> Reactive Oxygen Species form part of complex biochemical pathways. Oxidative stress causes cell and tissue injury,<sup>23</sup> which means that the oxidative effect is welcome in destroying germs but also can affect humans as outlined next.

## Respiratory System Effects

Inhaling hydrogen peroxide vapors leads to irritation of the nose, throat, and respiratory tract.<sup>24</sup> While the PEL is defined over 8 hours, studies at shorter periods already show respiratory effects. In a study involving human volunteers exposed to hydrogen peroxide aerosol for 4 hours, the threshold for respiratory tract irritation was found to be  $10 \text{ mg/m}^3$ , which is equivalent to **7.19 ppm (refer to Appendix 1 for calculation)**. Hydrogen peroxide causes toxicity via three main mechanisms: corrosive damage, oxygen gas formation and lipid peroxidation.<sup>12</sup> In very severe cases bronchitis or pulmonary edema may occur.<sup>25</sup> Respiratory Rate has been shown to increase in as little as 20 minutes of low grade exposure.<sup>11</sup>

## Ocular effects

Hydrogen peroxide is an ocular irritant and has been associated with corneal injury with higher exposure.<sup>26</sup> Healthcare workers may experience eye irritation from vapor exposures well below concentrations that cause direct contact damage. The threshold for eye irritation from vapor exposure is significantly lower than for direct contact, making eye protection essential during sterilizer operations and maintenance activities. When working around hydrogen peroxide vapor, appropriate eye protection, such as safety goggles or a face shield, is recommended to prevent irritation or injury.<sup>3</sup>

<sup>†</sup> Hydrogen peroxide is a strong oxidizing agent ( $E_0 = 1.776 \text{ V}$  vs. Standard Hydrogen Electrode) and as such it is a primary irritant, in that it primarily causes damage at the site of exposure. Exposure of liquid hydrogen peroxide causes bleaching of skin with prolonged exposure resulting in blistering depending on the concentration and contact duration.



## Skin effects

Skin (dermal) exposure to dilute solutions may cause whitening of the skin, whilst more concentrated solutions can cause severe irritation and corrosion.<sup>25</sup> Skin contact with hydrogen peroxide produces concentration-dependent effects ranging from temporary whitening to severe chemical burns. Dilute solutions cause characteristic whitening or bleaching of the skin due to microembolism caused by oxygen bubbles in the capillaries.<sup>25</sup>

Occupational in SPD/CSSDs dermal exposure typically occurs through accidental contact during sterilizer maintenance, solution handling, or equipment cleaning. Even brief contact with high-concentration solutions can result in tissue damage, making proper personal protective equipment essential for all personnel working with hydrogen peroxide sterilization systems.

## Workers with Pre-existing Conditions

Healthcare workers with pre-existing respiratory conditions, including asthma, chronic obstructive pulmonary disease (COPD), or chemical sensitivities, may be at increased risk for severe reactions to hydrogen peroxide exposure. These individuals may experience symptoms at concentrations below those that affect healthy workers, necessitating additional protective measures or work restrictions. Exposure to cleaning products and disinfectants is associated with risk of developing Chronic Obstructive Pulmonary Disease.<sup>27</sup>

The irritant properties of hydrogen peroxide can exacerbate existing respiratory conditions, potentially leading to severe bronchospasm or respiratory distress in susceptible individuals. Medical surveillance programs should include assessment of respiratory status and consideration of work restrictions for high-risk employees.



# Comparison with Peracetic Acid (PAA) - The Detectable Sterilant

Peracetic acid has a characteristic “strong, pungent, acrid odor” that is detectable at very low concentrations.<sup>28</sup> Its odor threshold is estimated to be about 0.05ppm.<sup>29</sup> This odor serves as an important safety feature, alerting workers to the presence of potentially harmful vapors before reaching concentrations that could cause health effects. Human smell is subject to fatigue and so it cannot quantify exposure levels over periods of time. The ability to smell PAA provides an immediate indication of exposure that can prompt workers to take protective action or evacuate the area.

In contrast, hydrogen peroxide is essentially odorless until concentrations reach levels that are high enough to cause noticeable irritation, though the hydrogen peroxide concentration where respiratory irritation begins (approximately 7 ppm; See Appendix 1) is well below the concentration where that irritation is perceived. This lack of warning properties means that workers may be exposed to potentially harmful concentrations without immediate awareness, making engineering controls and monitoring systems more critical for hydrogen peroxide than for PAA.

The regulatory framework for peracetic acid demonstrates a more stringent approach to acute exposure. A STEL of 0.4 ppm<sup>30</sup> for peracetic acid has been established by ACGIH in the USA. However, no OSHA STEL exists for hydrogen peroxide in the U.S.<sup>31</sup> due to many of OSHA’s PELs being based on older data. This disparity is concerning given that hydrogen peroxide exposures in healthcare settings can exceed 5 ppm during sterilizer operations.<sup>6</sup>

**According to OSHA, “OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA’s PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time.”<sup>19</sup>**





# Comparison with Formaldehyde\*

Formaldehyde’s uses as a sterilant within clinical settings within the United States is extremely limited, and was excluded from the CDC’s list of methods of sterilization and disinfection in the Guideline for disinfection and sterilization in healthcare facilities, 2008.<sup>32</sup> Nonetheless, it has both a TWA and the STEL. The comprehensive regulatory framework for formaldehyde demonstrates how hazardous chemicals can be effectively regulated with both TWA and STEL limits. Formaldehyde is an alkylating rather than oxidizing agent.<sup>32,33</sup>

## Comprehensive Exposure Limits

Formaldehyde regulation includes both TWA and STEL limits from multiple agencies, providing protection against both chronic and acute exposures:

| PARAMETER         | FORMALDEHYDE <sup>34,35</sup> |
|-------------------|-------------------------------|
| OSHA PEL-TWA      | 0.75 ppm (8-hr)               |
| OSHA PEL-STEL     | 2 ppm (15 min)                |
| Action Level      | 0.5 ppm                       |
| NIOSH REL-TWA     | 0.016 ppm (up to 10-hr)       |
| NIOSH REL-Ceiling | 0.1 ppm (15 min)              |
| ACGIH TLV-TWA     | 0.1 ppm (8-hr)                |
| ACGIH TLV-STEL    | 0.3 ppm (15 min)              |
| IDLH              | 20 ppm                        |

The formaldehyde regulatory framework demonstrates several important principles that could be applied to hydrogen peroxide regulations. The establishment of both TWA and STEL limits recognizes that irritant chemicals require protection against both chronic and acute exposures. The action level triggers additional monitoring and medical surveillance, providing early warning of potentially problematic exposures.

Both formaldehyde and hydrogen peroxide are potent respiratory and ocular irritants. However, formaldehyde regulation has evolved to incorporate decades of research on irritant effects, while hydrogen peroxide regulation remains based on ACGIH’s 1968 knowledge.<sup>18,36</sup>

Formaldehyde’s “pungent, irritating odor”<sup>34</sup> provides some warning properties, though not as pronounced as peracetic acid. The odor threshold for formaldehyde is approximately 0.8 ppm,<sup>37</sup> well above the current ACGIH TLV-TWA of 0.1 ppm<sup>34</sup> meaning that workers can be exposed to harmful concentrations without odor detection.



# Comparison with Ethylene Oxide

Ethylene oxide (EtO) provides a relevant regulatory precedent for hydrogen peroxide vapor because both are used as gaseous sterilants in healthcare and both present staff exposure risks; however, ETO is classified as a human carcinogen by IARC.<sup>38</sup>

## Comprehensive Exposure Limits

Ethylene oxide regulation includes both TWA and STEL limits from multiple agencies, providing protection against both chronic and acute exposures:

| PARAMETER                 | ETHYLENE OXIDE <sup>39,40</sup> |
|---------------------------|---------------------------------|
| OSHA PEL-TWA              | 1 ppm (8-hr)                    |
| OSHA PEL-STEL             | 5 ppm (15 min)                  |
| OSHA PEL-Ceiling          | Not established                 |
| Action Level              | 0.5 ppm                         |
| NIOSH REL-TWA             | <0.1 ppm                        |
| NIOSH REL-Ceiling         | 5 ppm (10 min)                  |
| IDLH                      | 800 ppm                         |
| Carcinogen Classification | IARC-1, OSHA-Ca                 |

The ethylene oxide regulatory framework demonstrates several important principles that could be applied to hydrogen peroxide regulation. The establishment of both TWA and STEL limits recognizes that potential exposure to hazardous vapors requires protection against both chronic and acute exposures. The action level triggers additional monitoring and medical surveillance, providing early warning of potentially problematic exposures.

Both ethylene oxide and hydrogen peroxide are potent respiratory and ocular irritants. However, just as the case with formaldehyde, ethylene oxide regulation has evolved to incorporate decades of research on irritant effects, while hydrogen peroxide regulation remains based on 1968 [ACGIH 1968] knowledge.

Ethylene oxide has an odor, but like hydrogen peroxide, the odor recognition threshold for ethylene oxide (~500 ppm) is far above the ACGIH TLV of 1 ppm (8 hr TWA) meaning that workers can be exposed to harmful concentrations without odor detection.<sup>41</sup>

# Rationale for Adopting Short-Term Exposure Limits for Hydrogen Peroxide

The American Conference of Governmental Industrial Hygienists advocates a Threshold Limit Value – Short Term Exposure Limit if there is supporting data.

“Transient increases in workers’ exposure levels may exceed 3 times the value of the TLV–TWA level for no more than 15 minutes at a time, on no more than 4 occasions spaced 1 hour apart during a workday, and **under no circumstances should they exceed 5 times the value of the TLV–TWA level when measured as a 15-min TWA.** In addition, the 8-hour TWA is not to be exceeded for an 8-hour work period).” – ACGIH <sup>6</sup>

This would translate into a 5 ppm 15 min TWA STEL. In fact, several geographies have an even tighter STEL for hydrogen peroxide. (see Geographic Survey)

## Geographic Survey of STEL Values

European countries have independently established STEL values for hydrogen peroxide, demonstrating international recognition of the need for peak exposure protection.<sup>15,42</sup>

| COUNTRY/BODY             | LIMIT VALUE - 8 - HR TWA |                   | LIMIT VALUE - STEL <sup>§</sup> |                   |
|--------------------------|--------------------------|-------------------|---------------------------------|-------------------|
|                          | ppm                      | mg/m <sup>3</sup> | ppm                             | mg/m <sup>3</sup> |
| Austria*                 | 1                        | 1.4               | 2                               | 2.8               |
| Denmark*                 | 1                        | 1.4               | 2                               | 2.8               |
| Finland*                 | 1                        | 1.4               | 3                               | 4.2               |
| Germany (DFG/AGS)*       | 0.5                      | 0.71              | 0.5                             | 0.71              |
| Ireland*                 | 1                        | 1.5               | 2                               | 3                 |
| Poland*                  |                          | 0.4               |                                 | 0.8               |
| Sweden*                  | 1                        | 1.4               | 2                               | 3                 |
| Switzerland*             | 1                        | 1.4               | 2                               | 2.8               |
| USA - Washington State** | 1                        | 1.4               | 3                               |                   |
| USA - Hawaii***          | 1                        | 1.4               | 2                               | 3                 |
| United Kingdom*          | 1                        | 1.4               | 2                               | 2.8               |

<sup>§</sup>15 min average value

\*Source: <https://ilv.ifa.dguv.de/limitvalues/33433>

\*\*<https://app.leg.wa.gov/wac/default.aspx?cite=296-841-20025> (Search: Hydrogen Peroxide)

\*\*\*<https://labor.hawaii.gov/hiosh/files/2012/12/12-60-General-Safety-Health-Requirements.pdf> (Search: Hydrogen Peroxide)

\*\*\*\*Every effort has been made to ensure accuracy. Please verify with the most up to date source when using.



## Regulatory Rationale

The establishment of STEL<sup>§</sup> values in European countries reflects several key considerations that have not been addressed in U.S. regulations:

**Acute Health Protection:** European regulators recognize that TWA limits alone cannot protect workers from the immediate health effects of peak exposures. STEL<sup>§</sup> values provide specific protection against respiratory irritation, eye damage, and other acute effects that can occur during brief high-level exposures.

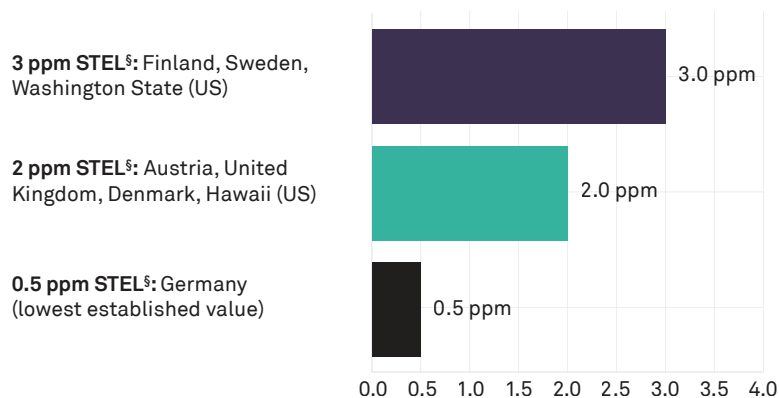
**Technological Considerations:** European standards acknowledge that certain industrial processes, including sterilization operations, inherently involve peak exposures that exceed TWA limits. STEL<sup>§</sup> values provide a framework for managing these exposures while maintaining operational flexibility.

**Scientific Updates:** European exposure limits incorporate recent toxicological research, including studies on concentration-response relationships, mechanism of action, and vulnerable populations. This scientific basis contrasts with U.S. limits that remain based on 1968 knowledge.

## Comparative Analysis of International Standards

### STEL<sup>§</sup> Value Distribution

The international STEL<sup>§</sup> values for hydrogen peroxide cluster around 2-3 ppm,<sup>42,43</sup> with most jurisdictions selecting values within this range:



This convergence around a 2-3 ppm STEL<sup>§</sup> suggests international consensus on appropriate peak exposure protection levels, based on similar interpretation of available health effects data.

<sup>§</sup>15 min average value

## Several clear trends emerge from international hydrogen peroxide regulation:



### Universal STEL Recognition:

Countries establishing new or updated hydrogen peroxide standards consistently include STEL values, recognizing the inadequacy of TWA-only protection.



### Conservative Approach:

International STEL values are generally 2-3 times<sup>42</sup> the TWA limit, providing substantial protection against peak exposures while maintaining operational flexibility.



### Scientific Basis:

Recent international standards cite current toxicological research rather than historical precedent, incorporating modern understanding of hydrogen peroxide health effects.



### Healthcare Focus:

Many international standards specifically consider healthcare applications, recognizing the unique exposure patterns associated with sterilization operations.

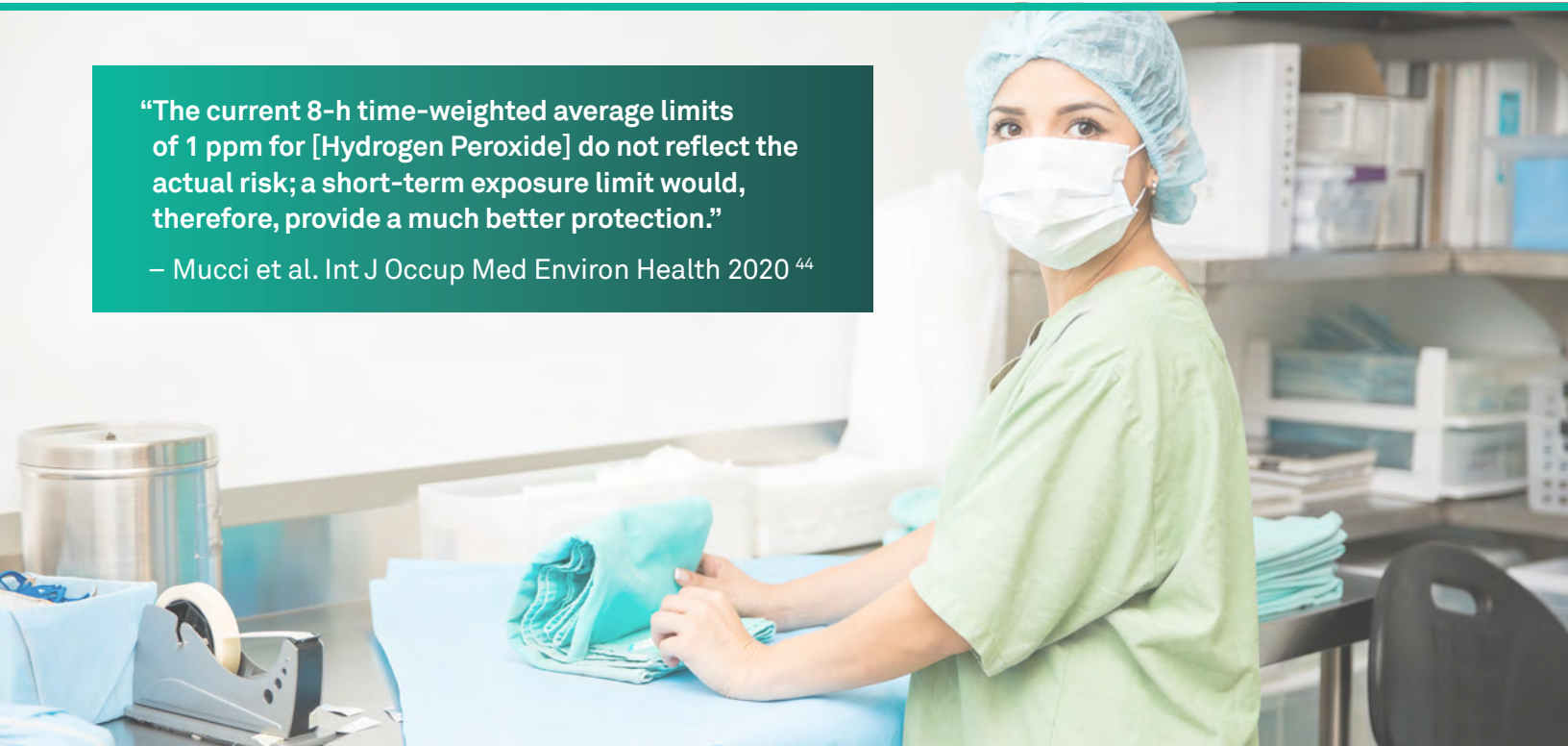
The international convergence of 2-3 ppm STEL values reflects scientific consensus on appropriate peak exposure protection levels. This consensus is based on:

- **Respiratory irritation thresholds** identified in human volunteer studies (7 ppm)<sup>25</sup>
- **Concentration-response relationships** from occupational exposure studies
- **Acute health effects data** from case reports and epidemiological studies
- **Technological feasibility** assessments from sterilization equipment manufacturers

The scientific basis for international STEL values provides a strong foundation for updating U.S. standards to provide equivalent worker protection.

**“The current 8-h time-weighted average limits of 1 ppm for [Hydrogen Peroxide] do not reflect the actual risk; a short-term exposure limit would, therefore, provide a much better protection.”**

– Mucci et al. Int J Occup Med Environ Health 2020<sup>44</sup>





# Fugitive Emission Can Hinder Workflow

From a practical standpoint, elevated acute hydrogen peroxide emissions may delay SPD/CSSD operations if a staff member walks away from the sterilizer to allow it to vent. This has Health Economic impact for productivity. The literature has shown that there are differences in short term hydrogen peroxide emission with different sterilization technologies.<sup>20</sup> Short term emissions can hinder workflow depending on the acute concentration present upon door opening.

The hidden costs of high-emission sterilization systems include not only direct safety compliance expenses but also the opportunity costs associated with reduced operational efficiency, increased liability exposure, and the management attention required to address ongoing safety challenges. The following workflow table is a hypothetical projection of potential delayed operations in time due to unaddressed fugitive emissions.

## Modeling Hypothetical Delays Due to Fugitive Emissions

To evaluate the trade-offs between allowing fugitive emissions to dissipate and the time lost while waiting for an area to ventilate, we conducted a Monte Carlo simulation. This simulation estimated the annual range of workflow hours lost under different scenarios. The key assumptions included the number of cycles per day per machine, the operating calendar for the year, and the total number of sterilizers in use. We modeled potential delay times of 15–25 minutes to represent the time lost due to ventilation delays. These assumptions are summarized in the table below, and a uniform distribution was applied in the simulation.

| PARAMETER                                     | LOW | MID | HIGH |
|-----------------------------------------------|-----|-----|------|
| Cycles / Day / Machine                        | 2   | 3   | 5    |
| Days per Week of Operation                    | 4   | 5   | 6    |
| Work Weeks per Year                           | 48  | 50  | 52   |
| # Sterilizers in SPD                          | 2   | 4   | 5    |
| Potential delay per sterilizer due to venting | 10  | 15  | 25   |

TABLE 1: Hypothetical Assumptions

Monte Carlo analysis works by repeatedly sampling random values from the defined assumptions in Table 1 and then computing the total annual delay for each simulated scenario. By running thousands of such scenarios, we obtained a distribution of possible annual delays, as shown in the graph below.

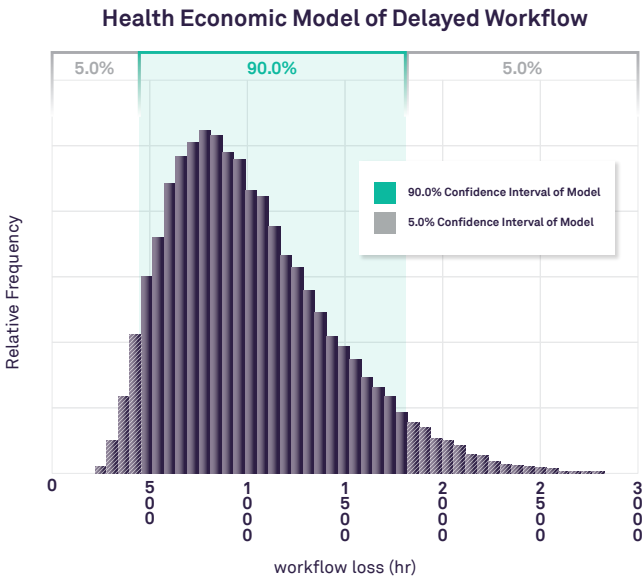
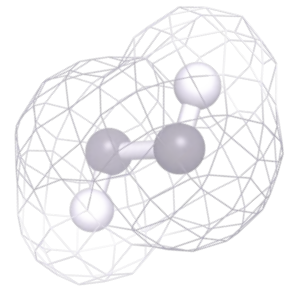


FIGURE 2: Potential annual hours lost waiting for venting

The results provide an estimate of how much workflow can be lost. Depending on the assumptions, the department may lose hundreds of hours per year, with some scenarios approaching 2,000 hours annually. The graph shows that, with 90 percent confidence, the annual loss falls between approximately 465 and 1,812 hours in this simulation.

Finally, the annual economic impact can be estimated by multiplying the number of lost hours by the cost per hour of idle time while waiting for sterilizers to ventilate.



# Summary

The global evolution of occupational safety standards is already moving toward more comprehensive protection that addresses both chronic and acute exposure hazards. The occupational exposure limits for hydrogen peroxide in the U.S. are at least 50 years old and rely on research from the 1950s and 1960s.<sup>18,36</sup> It has become apparent since then that acute exposure poses health effects to the skin, eyes and respiratory system. Some U.S. states and several other countries have implemented a STEL for hydrogen peroxide.

Many facilities are implementing advanced hydrogen peroxide vapor monitoring systems and low-emission sterilization technologies to keep their workforce safe, and position themselves ahead of these regulatory trends. The newly announced The Joint Commission Accreditation 360 promotes data driven improvements: “Promotes the use of data, performance metrics, and evidence-based practices, specifically shifting the focus from observation to outcome-focused measures.”<sup>45</sup>

As our understanding of the effects of acute exposure improve, the international trend toward more short term exposure limits is expected to continue. This trend is consistent with promoting a culture of safety for hospital staff.

The integration of monitoring data with quality management systems creates opportunities for continuous improvement in both safety and operational efficiency. The data-driven approach enabled by modern monitoring systems supports the evidence-based practice expectations of accrediting organizations while providing objective feedback on the effectiveness of safety interventions.

Coupling these insights with actionable solutions is the next step toward advancing occupational safety in sterile processing environments. Modern monitoring systems and low-emission sterilization technologies, including vaporized hydrogen peroxide with plasma-phase decomposition, represent practical strategies to mitigate acute exposure risks while improving workflow efficiency. By leveraging data-driven monitoring and advanced sterilization platforms, healthcare facilities can not only protect staff but also strengthen compliance and operational resilience.

## Checklist:

☐

Does your institution understand the ongoing global enhancements in  $\text{VH}_2\text{O}_2$  short term exposure limit development?

☐

Is your staff aware that hydrogen peroxide is odorless at levels relevant to occupational exposure and hence is undetectable without sensors?

☐

Do you monitor for peak exposure events such as sterilizer door opening?

☐

Exposure can affect breathing, eyes and skin. Is your staff trained in occupational safety and the use of personal protective equipment?

☐

Do you have procedures in place that ensure compliance with AAMI ST-58 and The Joint Commission?



# Glossary

- ▶ **American Conference of Governmental Industrial Hygienists (ACGIH):** Publishes Threshold Limit Values (TLVs) for workplace chemicals.
- ▶ **American Industrial Hygiene Association (AIHA):** Early AIHA research informed the first IDLH values used by NIOSH.
- ▶ **Binding Occupational Exposure Limit Value (BOELV):** Legally-enforceable EU exposure limit recommended by SCOEL and adopted by the European Commission.
- ▶ **Chronic Obstructive Pulmonary Disease (COPD):** Pre-existing lung condition that can be exacerbated by hydrogen-peroxide exposure.
- ▶ **Control of Substances Hazardous to Health Regulations (UK) (COSHH):** UK regulations under which HSE publishes Workplace Exposure Limits (WELs).
- ▶ **Derived No-Effect Level (DNEL):** EU risk-assessment benchmark derived by ECHA for chemical safety assessments.
- ▶ **Destruction & Removal Efficiency (DRE):** Percentage of a contaminant eliminated by an abatement device, e.g., a plasma reactor.
- ▶ **European Chemicals Agency (ECHA):** Maintains registration dossiers and DNELs for chemical substances.
- ▶ **European Union (EU):** Sets indicative or binding occupational exposure limits via the European Commission.
- ▶ **U.S. Food & Drug Administration (FDA):** Oversees medical-device reports (MAUDE) and recognizes  $\text{VH}_2\text{O}_2$  sterilization.
- ▶ **Health and Safety Executive (UK) (HSE):** Publishes Workplace Exposure Limits (WELs).
- ▶ **Immediately Dangerous to Life or Health (IDLH):** NIOSH hazard value; for hydrogen peroxide it is 75 ppm.
- ▶ **Indicative Occupational Exposure Limit Value (IOELV):** Non-binding EU limit that member states must consider.
- ▶ **Local Exhaust Ventilation (LEV):** Engineering control that captures contaminants at source.
- ▶ **Long Term Exposure Limit (LTEL):** 8-hour time-weighted average exposure limit used to control prolonged or chronic exposure to hazardous substances.
- ▶ **Manufacturer and User Facility Device Experience (MAUDE):** FDA database for device-related adverse events.
- ▶ **National Institute for Occupational Safety & Health (NIOSH):** Issues Recommended Exposure Limits (RELs) and IDLHs.
- ▶ **Non-Thermal Plasma (NTP):** Cold-plasma technology used to decompose hydrogen peroxide in exhaust streams.
- ▶ **Occupational Exposure Limit (OEL):** Umbrella term for regulatory or advisory airborne limits such as TWA, STEL, or Ceiling.
- ▶ **Occupational Safety & Health Administration (OSHA):** U.S. agency that promulgates and enforces Permissible Exposure Limits (PELs).
- ▶ **Permissible Exposure Limit (PEL):** OSHA-enforceable eight-hour TWA exposure limit.
- ▶ **Personal Protective Equipment (PPE):** Protective gear such as respirators, gloves, and goggles.
- ▶ **Recommended Exposure Limit (REL):** NIOSH guidance exposure value.
- ▶ **Reactive Oxygen & Nitrogen Species (RONS):** Highly reactive species produced in plasma reactors that oxidise hydrogen peroxide or VOCs.
- ▶ **Scientific Committee on Occupational Exposure Limits (SCOEL):** EU committee advising on IOELVs and BOELVs.
- ▶ **Short-Term Exposure Limit (STEL):** 15-minute exposure limit used to control peak irritant exposures.
- ▶ **Threshold Limit Value (TLV):** ACGIH advisory exposure limit.
- ▶ **Time-Weighted Average (TWA):** Eight-hour average exposure metric used in OELs.
- ▶ **Vaporized Hydrogen Peroxide ( $\text{VH}_2\text{O}_2$ ):** Sterilization technology designated by FDA as Established Category A.
- ▶ **Volatile Organic Compound (VOC):** Often treated in the same plasma systems that abate hydrogen peroxide.
- ▶ **Workplace Exposure Limit (WEL):** UK occupational exposure limit issued by HSE.



## Appendix 1:

### Assumptions:

*Ideal Gas – Temperature = 25°C*

$$7 \text{ ppm H}_2\text{O}_2 = \frac{7 \text{ mol H}_2\text{O}_2}{10^6 \text{ mol air}} \times \frac{1 \text{ mol air}}{24.45 \text{ l air}} \times \frac{10^3 \text{ l air}}{1 \text{ m}^3 \text{ air}} \times \frac{34.01 \text{ g H}_2\text{O}_2}{1 \text{ mol H}_2\text{O}_2} \times \frac{10^3 \text{ mg H}_2\text{O}_2}{1 \text{ g H}_2\text{O}_2} = 9.74 \frac{\text{mg H}_2\text{O}_2}{\text{m}^3 \text{ air}}$$

### Notes

- This derivation assumes ideal gas behavior, which is reasonable for dilute concentrations in air.
- The constant 24.45 is specific to 25°C and 1 atm; at 20°C, it's approximately 24.04 L/mol, and at 0°C (STP), it's 22.4 L/mol.
- For hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>, MW ≈ 34 g/mol), plugging in yields the earlier result of ≈7.19 ppm for 10 mg/m<sup>3</sup>.

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# Hydrogen-Peroxide Emissions Safety in the Sterile Processing Department/ Central Sterile Supply (SPD/CSSD)

**PART 2**

Visualize the Invisible: Elevating Safety through Gas  
Monitoring and Plasma Technology



**Ivan Salgo MD, MS, MBA**  
Vice President & Chief Medical & Scientific Officer  
Advanced Sterilization Products

**Richard Warburton PhD, JD**  
Chief Technology Officer  
ChemDAQ, Inc.



# Table of Contents

Key Points ..... 02

Key Scientific Methodology Points ..... 03

Introduction ..... 04

**SECTION 1**

The Clinical Evidence— What Hydrogen Peroxide Vapor Exposure Does to  
Healthcare Workers Over Time..... 05

**SECTION 2**

The Regulatory Imperative—AAMI ST58: 2024 and Accreditation 360 ..... 06

**SECTION 3**

“Wait-to-Vent”—Why the Most Common Response is Counterproductive ..... 08

**SECTION 4**

The Potential Operational and Economic Cost of Hydrogen Peroxide Vapor Fugitive Emissions ..... 09

**SECTION 5**

Continuous Monitoring—Making Hydrogen Peroxide Vapor Fugitive Emissions Visible ..... 11

**SECTION 6**

Plasma Technology—Minimizing Hydrogen Peroxide Vapor Fugitive Emissions  
Before the Door Opens..... 13

**SECTION 7**

The Closed-Loop System—Monitoring + Plasma as a Natural Evolution ..... 15

Conclusion ..... 17

Institutional Readiness Checklist ..... 18

Glossary..... 19

References ..... 20



# Key Points

- ▶ **As established in Part 1 of this series, hydrogen peroxide vapor fugitive emissions are high concentration peaks, not steady-state elevations.** The primary occupational hazard in the SPD/CSSD is not chronic background exposure but the brief, high-concentration plumes of hydrogen peroxide vapor released during chamber door opening. An 8-hour TWA does not effectively capture or control this risk. Due to the risk of brief but high concentration exposures, many countries have adopted a Short-Term Exposure Limit (STEL).
- ▶ **The “Wait-to-vent” approach potentially creates inefficiency in the department.** Allowing staff to step back and wait for hydrogen peroxide vapor to dissipate is a behavioral workaround that depends on perfect compliance. Odor is not a reliable safety monitor [Hydrogen Peroxide | Medical Management Guidelines | Toxic Substance Portal | ATSDR “Odor does not provide a warning of hazardous concentrations.”] <sup>[1]</sup>. Under production pressure, adherence to wait-to-vent practices could become inconsistent over time, potentially causing significant annual workflow losses and negatively impacting staff safety. Repeated exposure to an invisible, odorless hazard—managed by waiting and individual judgment rather than objective measurement, lessens the culture of safety that modern standards (AAMI ST58 and The Joint Commission 360) instill. Another aspect is that human error may be an issue if waiting-to-vent periods create distraction from workflows.
- ▶ **Continuous monitoring provides objective, real-time data to better protect staff.** Hydrogen peroxide vapor is odorless at hazardous concentrations, therefore reliance on smell alone is not an adequate safety measure. Only continuous monitoring with real-time displays can identify acute exposure events, giving SPD/CSSD staff the information needed to stay safe and informing preventive maintenance decisions.
- ▶ **Plasma technology decomposes residual hydrogen peroxide into water and oxygen before door opening.** Vaporized hydrogen peroxide ( $\text{vH}_2\text{O}_2$ ) with plasma decomposes residual chamber hydrogen peroxide to water and oxygen before the door opens, reducing door-plane fugitive emission peaks approximately 19-fold versus non-plasma systems.

## Summary:

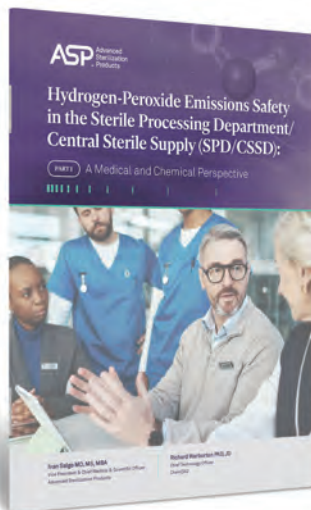
**Together, continuous monitoring and plasma create an integrated safety system. Monitoring detects and quantifies hydrogen peroxide vapor events. Plasma reduces them at the source. Together they form a detect–analyze–intervene–verify cycle that satisfies AAMI ST58:2024’s engineering control mandate and generates the outcome data that Joint Commission Accreditation 360 rewards.**

# Key Scientific Methodology Points

## Hydrogen-Peroxide Emissions Safety in the Sterile Processing Department/ Central Sterile Supply (SPD/CSSD):

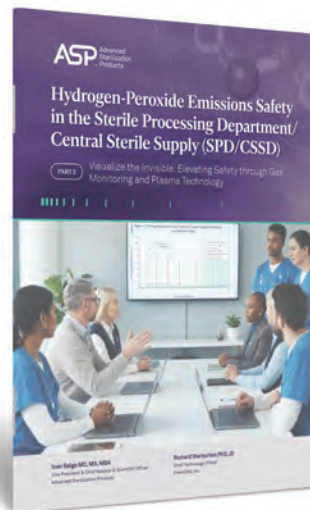
### PART 1

A Medical and Chemical Perspective



### PART 2

Visualize the Invisible: Elevating Safety through Gas Monitoring and Plasma Technology



## Both Emissions White Papers Parts 1 and 2 contain information:

- ▶ Derived from **Scientific Peer Reviewed Journal Evidence**
- ▶ Derived from **Regulatory Body Released Devices**
- ▶ Derived from **Real Time Measurements of Emissions**
- ▶ Listing of **Emerging International Governmental Standards** (Short Term Exposure Limits)

# Introduction

Low-temperature sterilization using  $\text{vH}_2\text{O}_2$  is essential for processing heat-sensitive surgical instruments in the modern Sterile Processing Department (SPD) / Central Sterile Supply Department (CSSD). It is effective, rapid, and widely adopted. However when vapor emissions are insufficiently mitigated, they can present a safety challenge for staff.

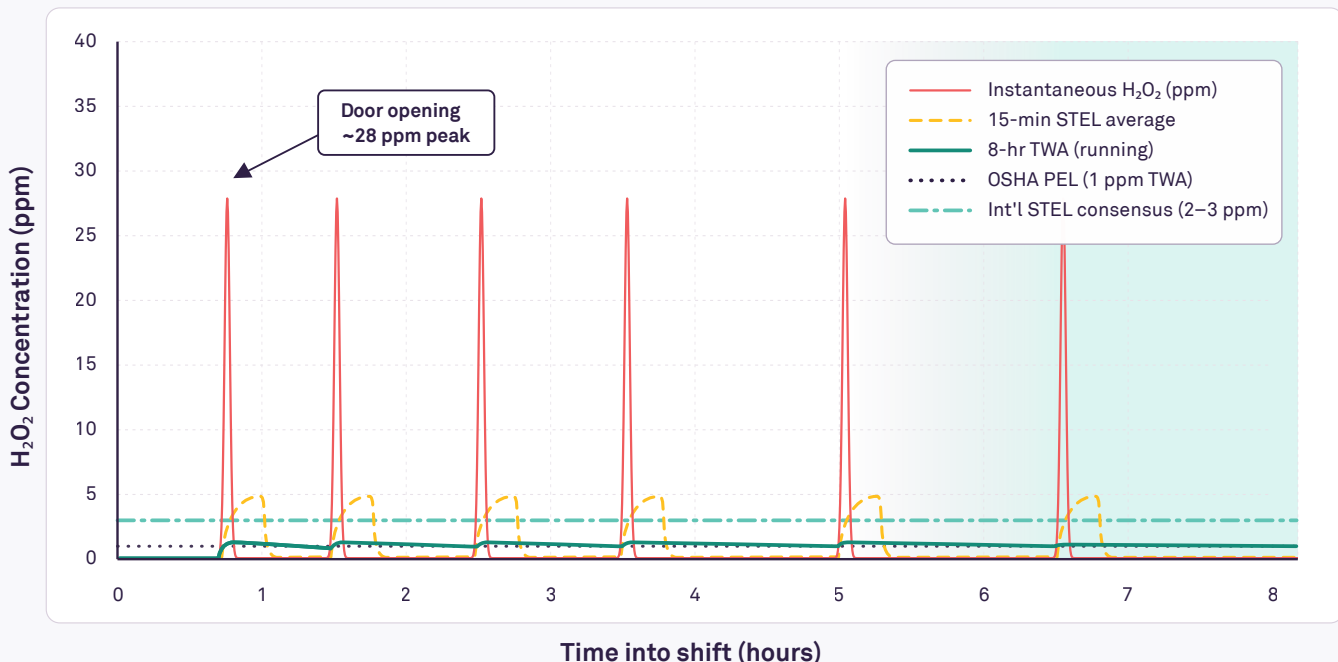
Hydrogen peroxide vapor fugitive emissions are the  $\text{vH}_2\text{O}_2$  that escape the sterilizer boundary into the occupational environment—primarily when the chamber door is opened after cycle completion, but also through equipment that may need maintenance <sup>[2]</sup>.

This paper presents the integrated response to hydrogen peroxide vapor fugitive emissions: the two-pillar **Peak Emissions Management (PEM) framework built on continuous electrochemical monitoring and plasma-phase decomposition technology**. It also addresses a dimension that occupational hygiene data alone cannot fully capture: the operational, economic, and environmental costs of the most common informal response to hydrogen peroxide vapor fugitive emissions—the “wait-to-vent” workaround.



“Detection of odor does not provide adequate warning of hazardous concentrations of hydrogen peroxide vapor.” <sup>[1]</sup>

Figure 1. The Blind Spot: Peak  $\text{H}_2\text{O}_2$  Vapor Fugitive Emissions vs. the 8-Hour TWA



**FIGURE 1.** Illustrative simulation of six door-opening events across an 8-hour shift, modeled on the peak concentration range (25–40 ppm) reported by Cornelia & Warburton <sup>[2]</sup> for non-plasma sterilizers; actual values vary by sterilizer model, maintenance status, and room ventilation. The 15-minute STEL average (orange) briefly exceeds the international 2–3 ppm consensus. The 8-hour TWA (teal) remains below 1 ppm throughout—demonstrating how TWA-only monitoring is structurally blind to acute fugitive emission exposure.

# The Clinical Evidence— What Hydrogen Peroxide Vapor Exposure Does to Healthcare Workers Over Time



## A Landmark Prospective Study in JAMA Network Open

The safety case is supported by prospective epidemiological evidence. The key study, Dumas et al., followed 73,262 female nurses over 6 years. The findings may have important implications for occupational health and safety programs. Weekly occupational use of many germicidal chemicals was associated with a **35% increased risk** of developing physician-diagnosed Chronic Obstructive Pulmonary Disease (COPD) (adjusted hazard ratio [AHR] 1.35), independent of smoking status and asthma history. Hydrogen peroxide specifically was associated with a **29% increased COPD incidence risk** among nurses who have high-level exposure. The authors estimated that approximately **12% of COPD cases among female nurses were attributable to occupational disinfectant exposure** <sup>[3]</sup>.



High-level exposure to glutaraldehyde, bleach, hydrogen peroxide, alcohol, and quaternary ammonium compounds was significantly associated with increased risk of COPD incidence.

— Dumas et al. <sup>[3]</sup>

Associations were not modified by smoking or asthma status.

— Dumas et al. <sup>[3]</sup>

# The Regulatory Imperative— AAMI ST58:2024 and Accreditation 360

Part 1 reviewed the health effects associated with hydrogen peroxide vapor exposure, including respiratory, eye, and skin irritation during short-duration peak exposure events <sup>[3,4,5]</sup>. Recognition of these acute exposure risks has contributed to the growing adoption of Short-Term Exposure Limits (STELs) and increasing emphasis on engineering controls and exposure monitoring within healthcare environments <sup>[6]</sup>.

## AAMI ST58: 2024: Engineering Controls Over Dilution Ventilation

ANSI/AAMI ST58: 2024—Chemical Sterilization and High-Level Disinfection in Health Care Facilities, is the profession's current consensus standard for low-temperature sterilization. Its approach to hydrogen peroxide vapor fugitive emission control has become markedly more explicit with each revision, and two provisions are particularly consequential <sup>[7]</sup>:



### AAMI ST58: 2024 | Selecting Vapor Monitoring Equipment or Services (Annex P, Section P.4):

*“All managers of locations where chemicals are used have clearly defined responsibilities to monitor and minimize worker exposure to chemical vapors.”*



### AAMI ST58: 2024 | Vapor Monitoring (Annex I, Section I.7):

*“Vapor monitoring is recommended if there is the potential for the hydrogen peroxide vapor concentration to exceed the OSHA recommended permissible exposure limits. Emissions from properly operated and maintained chemical vapor sterilizers should be well below the OSHA PEL, but sterilizers and exhaust systems, as with any other complex equipment, can and sometimes do fail. If monitoring is deemed necessary, continuous personal and area monitors for hydrogen peroxide are commercially available. Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide gas below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping.”*



As outlined in Part 1, occupational exposure limits are largely derived from historical Threshold Limit Values (TLVs) and remain primarily based on 8-hour time-weighted averages (TWAs), many of which date back to the late 1960s and early 1970s. While effective for controlling cumulative exposure, TWAs do not fully account for short-duration concentration peaks that may result in acute effects. Toxicological data for hydrogen peroxide highlight this limitation. Although exposures to 2.1 ppm (2.9 mg/m<sup>3</sup>) have not been associated with adverse effects in animal models, higher concentrations ( $\geq 10.5$  ppm [14.6 mg/m<sup>3</sup>]) have been linked to respiratory irritation and tissue damage <sup>[8]</sup>, underscoring the importance of transient peak exposures. To address this, many countries and professional organizations have incorporated Short-Term Exposure Limits (STELs) to better reflect real-world exposure scenarios. However, some regulatory frameworks continue to rely on legacy limits established more than 50 years ago. Occupational Safety and Health Administration (OSHA), for example, acknowledges that many Permissible Exposure Limits (PELs), largely adopted in the early 1970s and not substantially updated since, are outdated and not sufficiently protective of worker health <sup>[9,10]</sup>.

## Accreditation 360: Outcome-Based Governance and Data-Driven Continuous Improvement

In 2025, The Joint Commission launched Accreditation 360, shifting evaluation from episodic audits to continuous, measurable performance improvement <sup>[11]</sup>. For hydrogen peroxide vapor fugitive emission management, this has a key implication:

**Longitudinal sensor data, closed-loop corrective action, and measurable emission reduction support implementation of environmental safety engineering controls.**

Further, Accreditation 360 emphasizes the importance of daily processes and practice, rooted in data and metrics, that create compliance and high reliability as opposed to an endless cycle of reaction to audit findings and recommendations <sup>[11]</sup>.



# “Wait-to-Vent”—Why the Most Common Response Is Counterproductive

## The Workaround and Its Unintended Consequences

When a non-plasma  $\text{vH}_2\text{O}_2$  sterilizer cycle ends and staff perceive a hydrogen peroxide vapor fugitive emission risk, a commonly reported informal response is to open the sterilizer door, step back, wait, and let the hydrogen peroxide vapor fugitive emissions dissipate into the room before retrieving the load. Some people have moved the sensor back to avoid detecting the plumes of  $\text{H}_2\text{O}_2$  rising up the front of the sterilizer door, but doing so only masks the problem, like putting tape over a smoke alarm.

Minor delays at the individual level can escalate into major disruptions at the institutional scale. Even short venting delays across multiple cycles, compounded across multiple sterilizers running near-continuous cycles throughout a workday can potentially translate into a quantifiable loss of productive workflow hours (see Figure 2 on pg. 10) and many SPD/CSSD institutions may not account for this.

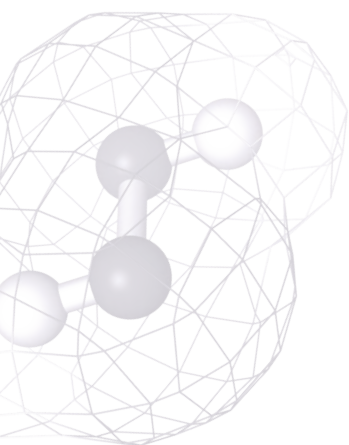
The wait-to-vent approach creates uncertainty in exposure levels. The consequences compound over time:

*Vigilance stress.*

Without sensor data, staff face a recurring judgment—

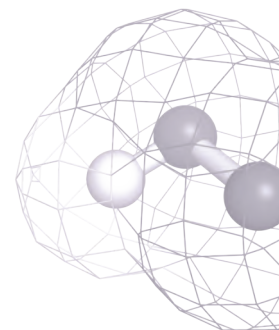
“Have I waited long enough?”

—with no objective answer.



# The Potential Operational and Economic Cost of Hydrogen Peroxide Vapor Fugitive Emissions

## A Quantifiable Impact Assessment



The workflow cost of hydrogen peroxide vapor fugitive emission venting delays is straightforward to estimate and transparent to audit. For example, if personnel spend an additional 15 minutes per cycle waiting to clear the sterilizer, the following formula can be used:

$$\text{Lost hours/year} = (\# \text{ sterilizers}) \times (\text{cycles/day/sterilizer}) \times (\text{days/week}) \times (\text{weeks/year}) \times (\text{delay min/cycle}) \div 60$$

The two mid-range examples below show this scale:

| SCENARIO                           | PARAMETERS                                                                     | LOST HOURS/YEAR |
|------------------------------------|--------------------------------------------------------------------------------|-----------------|
| Mid-size SPD/CSSD                  | 4 sterilizers × 3 cycles/day × 5 days/week × 50 weeks/year × 15 min/cycle ÷ 60 | 750 hours       |
| Larger, higher-throughput SPD/CSSD | 5 sterilizers × 5 cycles/day × 6 days week × 52 weeks/year × 15 min/cycle ÷ 60 | 1,950 hours     |

**TABLE 1.** Illustrative hydrogen peroxide vapor fugitive emission venting delay calculations using the leader-ready formula. Parameters are representative; each facility should apply its own values.

These point estimates are consistent with the Monte Carlo simulation conducted for Part 1 of this series, which modeled a full probability distribution across low, mid, and high parameter ranges. That simulation yielded a 90% confidence interval of approximately 465 to 1,812 annual hours lost, with a central estimate near 1,100 hours lost. If staff multitask to gain back efficiency, they risk potentially increasing error rate with unnecessary multitasking.



**465 hrs**

Annual venting delay (5th percentile)



**~1,100 hrs**

Annual venting delay (central estimate)

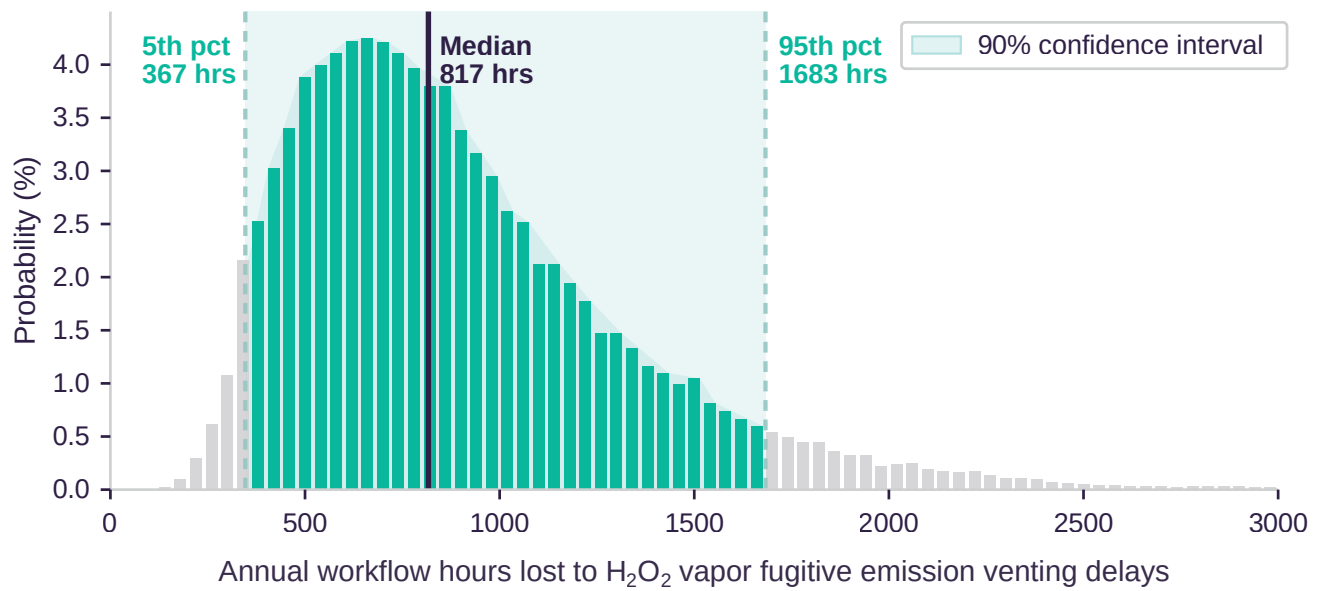


**1,812 hrs**

Annual venting delay (95th percentile)



### Monte Carlo Simulation: Annual SPD Workflow Hours Lost to Hydrogen Peroxide Vapor Fugitive Emission Venting Delays



**FIGURE 2.** . Monte Carlo simulation result: annual SPD workflow hours lost to hydrogen peroxide vapor fugitive emission venting delays (90% confidence interval). Central estimate ~817 hours/year; 5th–95th percentile range 367–1,683 hours.

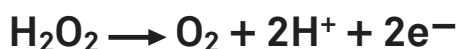
# Continuous Monitoring— Making Hydrogen Peroxide Vapor Fugitive Emissions Visible

## The Technology: Electrochemical Sensing in the SPD/CSSD

Direct-reading electrochemical sensors represent the validated, peer-reviewed standard for real-time  $\text{vH}_2\text{O}_2$  monitoring in SPD/CSSD environments <sup>[6,7]</sup>. These instruments function as specialized monitoring devices that generate an electrical signal proportional to the hydrogen peroxide vapor concentration in the air. This signal is digitally processed to provide a quantitative reading of the hydrogen peroxide concentration in ppm; and if the concentration is above alarm threshold limits, a visual and auditory alert is generated, giving staff and managers a clear, real-time reading. Many continuous monitors also provide rolling 15-min and 8hr TWAs with data logging.

### Electrochemical Reaction

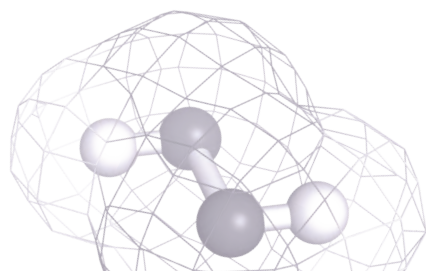
At the working electrode, hydrogen peroxide undergoes oxidation:



The resulting electron flow generates a measurable current proportional to  $\text{H}_2\text{O}_2$  concentration.

Modern sensors achieve: <sup>[12]</sup>

- ▶ **Low Detection Limits** — enabling consistent, reliable accuracy below all established occupational exposure thresholds.
- ▶ **Fast Response Times** — capturing the full peak and decay profile of each hydrogen peroxide vapor fugitive emission event.
- ▶ **Appropriate Operating Range** — spanning peak emissions, TWA, and STEL monitoring needs across the full spectrum of SPD/CSSD sterilizer operation.
- ▶ **Minimal cross-sensitivity** — to alcohols, aldehydes, and other SPD/CSSD related vapors, ensuring selective detection of hydrogen peroxide. This helps minimize false alarms.

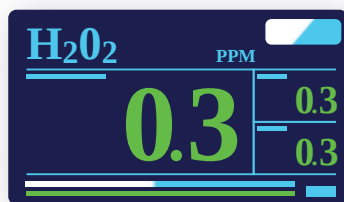




# Deployment, Data, and the Real Time Feedback Loop

Fixed sensors at breathing-zone height (1.2–1.5 meters) adjacent to each sterilizer door, combined with simple to use monitors for task-based and maintenance assessments, create a robust hydrogen peroxide vapor fugitive emission surveillance network. The value of this network extends far beyond regulatory compliance:

- ▶ **Risk management.** Objective, timestamped documentation of hydrogen peroxide vapor fugitive emission events provides defensible evidence of exposure control effectiveness, and of timely corrective action when thresholds are exceeded.
- ▶ **Staff training.** Showing staff environmental conditions with objective measurement data creates a deep understanding of safety conditions. This reinforces the requirement to follow existing safety protocols.
- ▶ **Continuous Improvement.** Continuous logs of concentrations over time, peak frequency, STEL compliance rates, and corrective action correlations satisfy AAMI ST58:2024's environmental monitoring expectations and provide exactly the longitudinal outcome evidence that Accreditation 360 promotes.



# ⚡ Plasma Technology— Minimizing Hydrogen Peroxide Vapor Fugitive Emissions *Before the Door Opens*

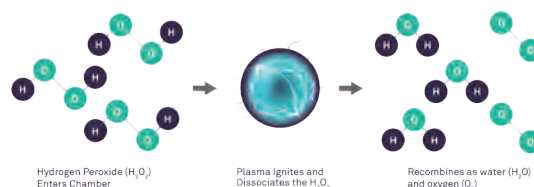
## The Engineering Solution to Source Emissions

Monitoring makes hydrogen peroxide vapor fugitive emissions observable. Plasma technology enables rapid decomposition prior to chamber opening, minimizing staff exposure and eliminating the need for extended venting delays. The FDA recognizes plasma technology as “plasma is used to aid in removal of the sterilant [vH<sub>2</sub>O<sub>2</sub>] from the chamber”<sup>[13]</sup>, and the underlying mechanism explains why it is the most effective source-control approach available.

The plasma phase occurs within the sealed chamber as the final step of the cycle. An electrode (antenna) within the sealed sterilizer chamber applies radiofrequency (RF) energy to the chamber volume. This electromagnetic field ionizes residual hydrogen peroxide vapor and water molecules, creating a non-thermal (cold) plasma. Once the electric field is turned off, the plasma ceases to exist and water vapor and oxygen gas remain from the hydrogen peroxide in the chamber.

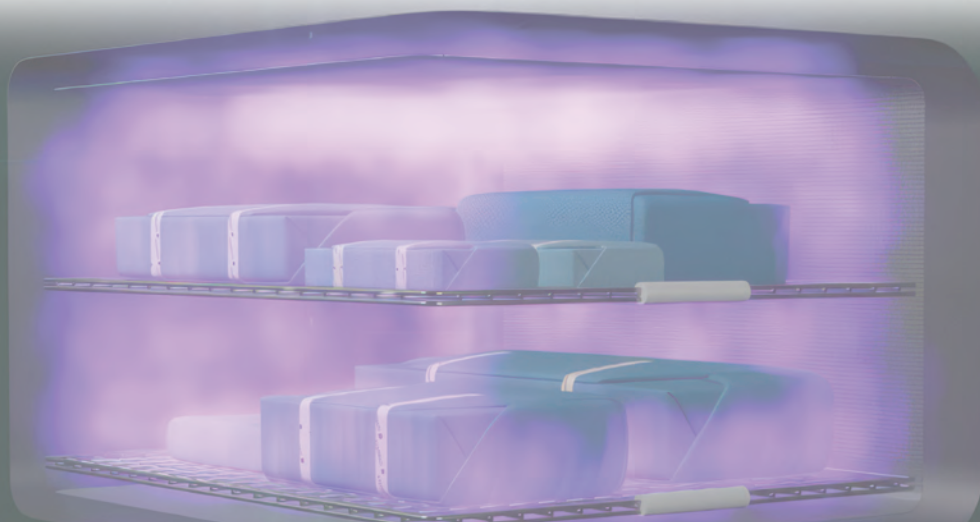
### Decomposition Sequence

- ▶ **Primary dissociation (electron impact):**  $e^- + \text{H}_2\text{O}_2 \rightarrow 2\cdot\text{OH} + e^-$
- ▶ **Radical recombination (gas-phase):**  $2\cdot\text{OH} \rightarrow \text{H}_2\text{O} + \frac{1}{2}\text{O}_2$
- ▶ **Net result:**  $\text{H}_2\text{O}_2 \rightarrow \text{H}_2\text{O} + \frac{1}{2}\text{O}_2$  (water vapor and oxygen—both harmless)



Chamber hydrogen peroxide concentration is reduced from the post-sterilization phase level to extremely low levels<sup>[2]</sup>, yielding door-plane hydrogen peroxide vapor fugitive emission concentrations that are very low.

Longitudinal occupational monitoring has confirmed approximately 19-fold lower peak exposures in plasma-equipped SPD/CSSDs compared with non-plasma systems, despite both meeting the OSHA 8-hour TWA PEL<sup>[2]</sup>.





## Margin of Safety: Sterilization and Staff Protection Work in Sequence

The sterilization phase of a  $\text{vH}_2\text{O}_2$  plasma cycle uses hydrogen peroxide concentrations well above the minimum needed to achieve the required Sterility Assurance Level. **This provides additional Margin of Safety<sup>[14]</sup>**. The plasma phase then converts the residual hydrogen peroxide—which has already done its job—into water and oxygen.



**The higher vapor concentration increases the margin of safety of the sterilization process, supporting patient safety.**

By utilizing the plasma phase, in-chamber plasma technology provides a dual benefit: supporting patient safety while minimizing staff exposure to fugitive emissions.



Higher organism microbiocidal activity +  
Decreased Hazard to People, Environment, and Instruments  
**= Plasma is the Pivotal Enabler**



# The Closed-Loop System— Monitoring + Plasma as a Natural Evolution

The cornerstone of LEAN is continuous improvement which includes the PLAN-DO-CHECK-ACT cycle. This can be applied to Peak Emissions Management (PEM) and the following framework <sup>[15]</sup>.

## Detect, Analyze, Intervene, Verify

Monitoring alone quantifies the hydrogen peroxide vapor fugitive emission problem but does not solve it. Plasma alone solves the problem but cannot prove it. Together, they create a closed-loop Peak Emissions Management (PEM) system with four operating phases (see Figure 3 on pg. 16):

**Detect.** Continuous electrochemical sensors capture each hydrogen peroxide vapor fugitive emission event in real time—instantaneous peak, decay profile, STEL accumulation—which can be tagged to cycle, sterilizer, and shift.

**Analyze.** Longitudinal data identifies patterns: identify which sterilizers produce higher hydrogen peroxide vapor fugitive emission peaks, which load types or configurations correlate with exceedances, and whether maintenance events affect performance.

**Intervene.** Data-driven interventions—equipment selection favoring plasma technology, targeted maintenance, protocol adjustments, and ventilation optimization—are implemented with a clear before/after measurement design.

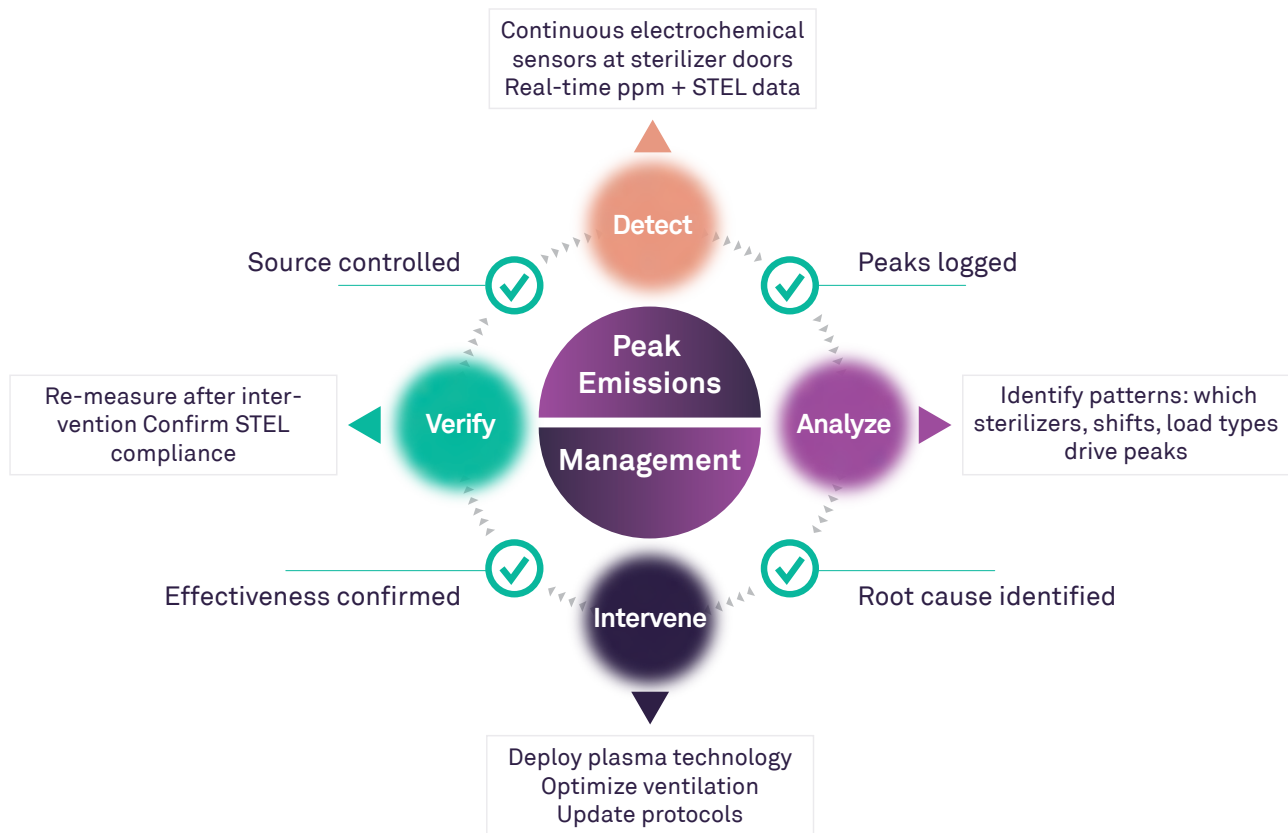
**Verify.** Post-intervention monitoring confirms that hydrogen peroxide vapor fugitive emission peaks have been reduced, STEL compliance has improved, and the intervention has delivered the expected benefit. This closed loop continuous improvement is what Accreditation 360 promotes. This cycle continuously repeats, ensuring the dual goals of patient and staff safety are met.





**Proactive management** beats reactive guessing.

**Closed-Loop Peak Emissions Management (PEM) System**  
Detect → Analyze → Intervene → Verify



**FIGURE 3.** The closed-loop Peak Emissions Management (PEM) framework: Detect (continuous electrochemical monitoring) → Analyze (pattern identification) → Intervene (plasma technology, protocol changes) → Verify (post-intervention re-measurement). This cycle satisfies both AAMI ST58:2024 engineering control requirements and Accreditation 360 continuous improvement expectations.



# Conclusion

Hydrogen peroxide vapor fugitive emissions are a documented occupational hazard. Peak concentrations of 25–40 ppm <sup>[2]</sup> may occur with every non-plasma door opening, far exceeding widely accepted thresholds, with large-scale prospective data linking disinfectant exposure to COPD.

An integrated, comprehensive response is not just needed – it is readily available. Continuous electrochemical monitoring makes hydrogen peroxide vapor fugitive emissions visible—providing the real-time data, longitudinal trends, and closed-loop verification that AAMI ST58:2024 and Accreditation 360 require.  $\text{vH}_2\text{O}_2$  with plasma technology significantly reduces fugitive vapor emission to well below globally adopted thresholds.

**Lower hydrogen peroxide vapor fugitive emissions. Higher margin of sterilization safety. Measurable STEL compliance. Stable, data-driven workflow. Promoting a Culture of Safety for Staff.**





# Institutional Readiness Checklist

- ☐ Is your staff aware that **hydrogen peroxide vapor is odorless** at concentrations that may cause physiological harm? This makes sensor based monitoring of hydrogen peroxide vapor beneficial for safety.
- ☐ Do you **use continuous electrochemical sensor monitoring at a breathing-zone height** to help protect staff safety?
- ☐ Has your facility established **internal STEL targets of 2–3 ppm** (15-min time-weighted average) consistent with the international regulatory consensus?
- ☐ Is **monitoring data integrated with your EHS system** and available as longitudinal, outcome-focused evidence for Accreditation 360 survey presentation?
- ☐ Does your capital equipment evaluation process include **documented hydrogen peroxide vapor fugitive emission performance** relative to staff safety as a formal selection criterion?
- ☐ Does your SPD/CSSD operate **vH<sub>2</sub>O<sub>2</sub> with plasma in-chamber sterilization technology**, eliminating hydrogen peroxide vapor fugitive emissions at the source rather than relying on a wait-to-vent workaround?
- ☐ Have you quantified the annual workflow hours lost to **hydrogen peroxide vapor fugitive emission venting delays** in your SPD/CSSD using the leader-ready formula in Section 4 (page 9)?
- ☐ Is there a defined **continuous improvement cycle**—detect, analyze, intervene, verify—for hydrogen peroxide vapor fugitive emission management, with regular data review and documented corrective actions?



# Glossary

- ▶ **Chronic Obstructive Pulmonary Disease (COPD):**  
Pre-existing lung condition that can be exacerbated by hydrogen-peroxide exposure.
- ▶ **Environmental, Health and Safety (EHS):** a discipline designed to protect healthcare workers, patients, and the community from workplace hazards while ensuring regulatory compliance.
- ▶ **U.S. Food & Drug Administration (FDA):**  
Oversees medical device reports (MAUDE) and recognizes  $vH_2O_2$  sterilization.
- ▶ **Occupational Safety & Health Administration (OSHA):** U.S. agency that enforces Permissible Exposure Limits (PELs).
- ▶ **Peak Emissions Management (PEM):** a framework built on continuous electrochemical monitoring and plasma decomposition technology.
- ▶ **Permissible Exposure Limit (PEL):** OSHA-enforceable eight-hour TWA exposure limit.
- ▶ **Short-Term Exposure Limit (STEL):** 15-minute exposure limit used to control peak irritant exposures.
- ▶ **Time-Weighted Average (TWA):** Eight-hour average exposure metric used in Occupational Exposure Limit (OEL).
- ▶ **Vaporized Hydrogen Peroxide ( $vH_2O_2$ ):** Sterilization technology designated by FDA as Established Category A.



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