ASP Advanced Sterilization Products

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

PART 1 A Medical and Chemical Perspective

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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_2O_2) with Plasma Technology in the Chamber Directly Addresses Acute Exposure Risks.** Unlike sterilization methods that rely solely on VH_2O_2, VH_2O_2 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.[1] There are potentially hundreds of thousands of Hospital Sterilization Workers globally with at least 50,000 in the U.S.[2] 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.[3] Hydrogen Peroxide is an odorless vapor[4] 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.”[5]**

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

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.[6] 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.**

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.[4,7] 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.[7]

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;[8,9] 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/m3) for 6 hours a day, 5 days a week for 28 days had no adverse effects, but 10.5 ppm (14.6 mg/m3) and higher resulted in respiratory tract irritation, concentration related necrosis and inflammation of the epithelium in the frontal regions of the nasal cavity.[10]

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.[9,11] 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.[12] 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.[13] 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 (LTEL) of 3 ppm.[14] 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.[15] 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,[16] and Hawaii has STEL of 2 ppm.[17]

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.[18] 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.[19] 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.[20]

Gap in Chronic 8 Hour Exposure Limit

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

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.[20]

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,[20] 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.[18]

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:[21]

- **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.[21]

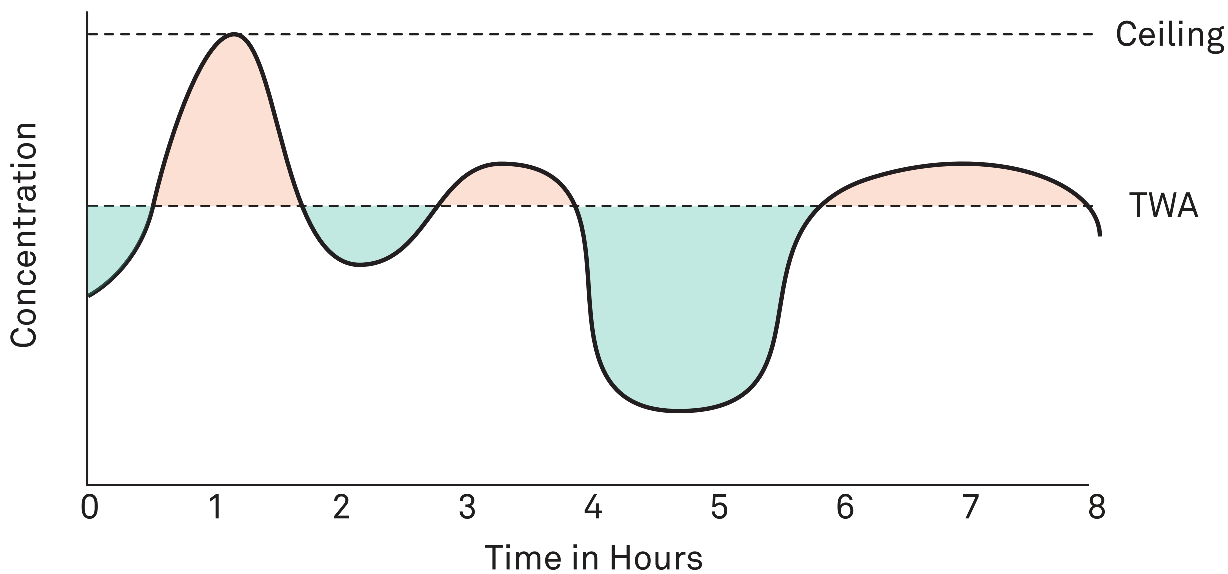


FIGURE 1: Visual demonstration that the time weighted average is not meant to show short term exposure.

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 (H_2O_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.[5] 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.†

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.[3] 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).[22] Reactive Oxygen Species form part of complex biochemical pathways. Oxidative stress causes cell and tissue injury,[23] 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.[24] 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 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.[12] In very severe cases bronchitis or pulmonary edema may occur.[25] Respiratory Rate has been show to increase in as little as 20 minutes of low grade exposure.[11]

Ocular effects

Hydrogen peroxide is an ocular irritant and has been associated with corneal injury with higher exposure.[26] 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.[3]

† Hydrogen peroxide is a strong oxidizing agent (Eo = 1.776 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.[25] 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.[25]

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.[27]

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.[28] Its odor threshold is estimated to be about 0.05ppm.[29] 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[30] for peracetic acid has been established by ACGIH in the USA. However, no OSHA STEL exists for hydrogen peroxide in the U.S.[31] 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.[6]

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."[19]

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.[32] 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.[32,33]

Comprehensive Exposure Limits

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

PARAMETER	FORMALDEHYDE[34,35]
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.[18,36]

Formaldehyde's "pungent, irritating odor"[34] provides some warning properties, though not as pronounced as peracetic acid. The odor threshold for formaldehyde is approximately 0.8 ppm,[37] well above the current ACGIH TLV-TWA of 0.1 ppm[34] 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.[38]

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[39,40]
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.[41]

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 [6]

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:[15,42]

	LIMIT VALUE - 8 - HR TWA		LIMIT VALUE - STEL§	
COUNTRY/BODY	ppm	mg/m³	ppm	mg/m³
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

§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§ 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§ values provide specific protection against respiratory irritation, eye damage, and other acute effects that can occur during brief high-level exposures.

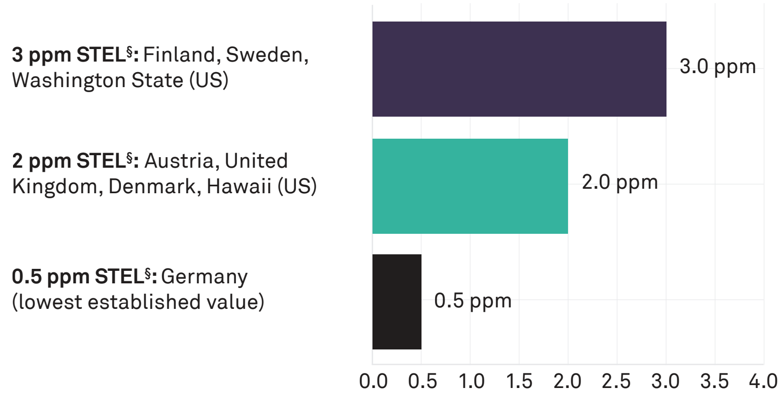
Technological Considerations: European standards acknowledge that certain industrial processes, including sterilization operations, inherently involve peak exposures that exceed TWA limits. STEL§ values provide a framework for managing these exposures while maintaining operational flexibility.

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§ Value Distribution

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



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

§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[42] 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)[25]
- **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 [44]

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.[20] 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.

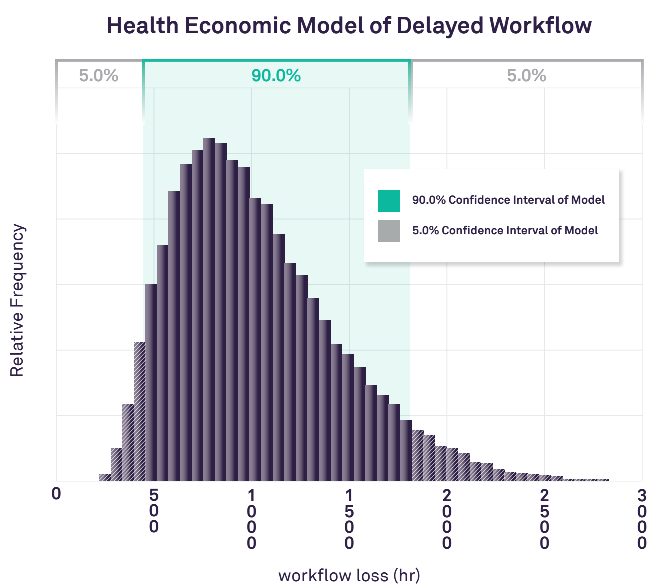
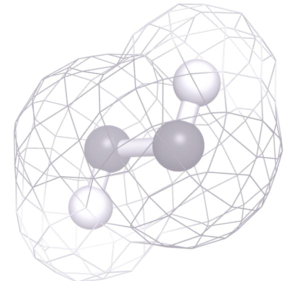


FIGURE 2: Potential annual hours lost waiting for venting

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.[18,36] 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." [45]

> 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 VH_2O_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 VH_2O_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 (VH_2O_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

$$7 \text{ ppm } H_2O_2 = \frac{7 \text{ mol } H_2O_2}{10^6 \text{ mol air}} \times \frac{1 \text{ mol air}}{24.45 \text{ l air}} \times \frac{10^3 \text{ l air}}{1 \text{m}^3 \text{ air}} \times \frac{34.01 \text{ g } H_2O_2}{1 \text{mol } H_2O_2} \times \frac{10^3 \text{ mg } H_2O_2}{1 \text{ g } H_2O_2} = 9.74 \frac{\text{mg } H_2O_2}{\text{m}^3 \text{ air}}$$

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_2O_2, MW ≈ 34 g/mol), plugging in yields the earlier result of ≈7.19 ppm for 10 mg/m³.

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