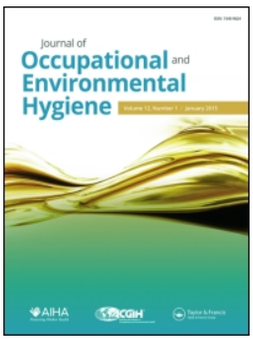

Journal of Occupational and Environmental Hygiene

ISSN: 1545-9624 (Print) 1545-9632 (Online) Journal homepage: http://oeh.tandfonline.com/loi/uoeh20

Assessing hydrogen peroxide vapor exposure from hospital sterilizers

Robert Cornelia & P. Richard Warburton

To cite this article: Robert Cornelia & P. Richard Warburton (2017) Assessing hydrogen peroxide vapor exposure from hospital sterilizers, Journal of Occupational and Environmental Hygiene, 14:9, 150-157, DOI: 10.1080/15459624.2017.1335401

To link to this article: http://dx.doi.org/10.1080/15459624.2017.1335401

Accepted author version posted online: 21 Jun 2017.
Published online: 21 Jun 2017.

JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL HYGIENE
2017, VOL. 14, NO. 9, D150–D157
https://doi.org/10.1080/15459624.2017.1335401

Taylor & Francis
Taylor & Francis Group

CASE STUDY

Assessing hydrogen peroxide vapor exposure from hospital sterilizers

Reported By
Robert Cornelia and P. Richard Warburton

ChemDAQ Inc., Pittsburgh, Pennsylvania

ABSTRACT

This study examines the hydrogen peroxide concentrations measured near four models of hydrogen peroxide sterilizers, from two manufacturers, monitored in seven hospitals across the U.S. and Canada over several years. The results showed that the majority of sterilizers do not emit hazardous levels of hydrogen peroxide and none of them exceeded the OSHA PEL of 1 ppm (8-hr time-weighted average (TWA)), however several of the sterilizers exceeded 3 ppm, the short-term exposure limit in two states: Washington and Hawaii. One hospital found brief concentrations of 25–40 ppm hydrogen peroxide from 4 hydrogen peroxide sterilizers each time they opened the sterilizer at the end of its cycle. Although not exceeding the OSHA PEL, these exposures are of concern since this concentration is roughly half the NIOSH IDLH of 75 ppm, and operators in a busy hospital environment may receive these exposures multiple times a day.

KEYWORDS

Emissions; gas monitor; hydrogen peroxide; leaks; occupational exposure; sterilizer

Introduction

The recognition that the underlying cause of pathogenesis is microbial organisms is one of the greatest advances in medicine, but controlling pathogens remains a challenge to this day. The Center for Disease Control and Prevention estimated that in 2011 there were almost 722,000 hospital acquired infections in acute care hospitals in the U.S., resulting in approximately 75,000 deaths.[1] Effective chemical sterilants play a vital role in controlling infection in healthcare.

A good sterilant chemical must be a broad-spectrum biocide (able to effectively kill fungi, viruses, bacteria, even in the sporoidal form), have good penetrating power, good chemical compatibility with equipment materials, and be environmentally friendly. Hydrogen peroxide is one of the few chemicals that meets these requirements. It is an efficient biocide and the vapor has good penetrating ability, especially when helped by the lumen cycles in modern sterilizers. Hydrogen peroxide breaks down to oxygen and water that is safe for the environment and leaves no patient-adverse residues on equipment.

Most sterilization of reusable medical devices in healthcare is achieved using steam, but for temperature-sensitive devices, chemical methods are used. Ethylene oxide sterilizers were introduced in the 1950s and hydrogen peroxide sterilizers in the 1980s and the latter are the predominant method of chemical sterilization in hospitals today.

Modern sterilizers are highly engineered, incorporate many safety features, and are made to very high standards, but normal wear and tear, malfunctions, failure of engineering controls, and user error can sometimes occur. There have been many anecdotal reports about operators being exposed to fugitive hydrogen peroxide vapors from sterilizers, including, for example, in the Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.

For Advanced Sterilization Product's (ASP's) Sterrad*® sterilizers, there were ~400 reports of odors from sterilizers in 2014. Reports include a few mild cases of burning eyes and respiratory irritation.[2–4] In prior years, there have been a number of cases of skin burns from residual liquid hydrogen peroxide, especially where the cycle was aborted.[6] There have also been several reports where operators complained of respiratory problems around the sterilizer.[7–10]

For the Steris V-Pros**, the other and more recently FDA-approved hydrogen peroxide sterilizer in the U.S. market, there were approximately 20 reports in the FDA MAUDE database in 2014. The majority of these reports were from skin burns resulting from contact with residual liquid hydrogen peroxide on the load. There were also

CONTACT P. Richard Warburton rwarburton@chemdaq.com ChemDAQ Inc, 300 Business Center Dr., Pittsburgh, PA 15205.
*Sterrad® is a registered trade mark of Advanced Sterilization Products, Irvine, CA.
**V-Pro™ is a trademark of Steris Corporation, 5960 Heisley Road, Mentor, OH 44060.

reported cases of minor irritation from vapors, and one due to a mechanical fault.[11]

There was one report from 2014 in which a hydrogen peroxide monitor was placed above a Steris V-Pro sterilizer and the monitor would go into alarm at the end of the cycle (presumably when the door was opened) resulting in the department being evacuated. This report is troubling because the sterilizer manufacturer's representative addressed this problem by telling the hospital to move the gas monitor away from the sterilizer,[12] but it is unlikely that this advice is the corporation's official policy.

Yoshida and Kobayashi[13] performed an investigation into emissions from hydrogen peroxide sterilizers, responding to user complaints of irritation to eyes and throat in a Japanese hospital and found significant leaks of hydrogen peroxide from the exhaust of one Sterrad 200 sterilizer. Leaks were found to be between 1 and 200 hundred ppm and were later identified as caused by a broken filter near the vacuum pump. Yoshida and Kobayashi also found residual hydrogen peroxide in the sterilizer chamber at the end of the sterilization cycle of about 10 ppm for an Amsco V-Pro sterilizer (manufactured by Steris Corporation) and 34 ppm from a Sterrad 100S. Their study clearly indicates that mechanical issues can occur with hydrogen peroxide sterilizers and that these issues can cause the sterilizer to emit significant amounts of hydrogen peroxide, well above the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of 1 ppm calculated as a time weighted average over 8 hr.[14]

The effects of hydrogen peroxide exposure in the workplace have been studied for many years and the current OSHA PEL of 1 ppm was derived from the 1968 American Conference of Governmental Industrial Hygienists' (ACGIH) threshold limit value (TLV) of 1 ppm, also calculated as an 8-hr time-weighted average (TWA).[15] In addition to being a strong oxidant, the ACGIH classifies hydrogen peroxide as a "known animal carcinogen, with unknown relevance to humans."[16] The ACGIH TLV for hydrogen peroxide has not changed since the 1950s, when it was established based on tests with dogs that found that prolonged exposure to only a few ppm hydrogen peroxide vapor could result in irreversible lung damage.[17] There has been some discussion about the need for a short-term exposure limit (STEL) for hydrogen peroxide[18,19] and two states, Washington[20] and Hawaii[21], have established STEL values of 3.0 ppm (15-min TWA). Outside the U.S. several countries have STELs for hydrogen peroxide including the United Kingdom, which has a STEL of 2 ppm.[22]For assessing the measured concentrations, 1 ppm as a 8-hr TWA, 3.0 ppm as a 15-min TWA and 5 ppm instantaneous levels were chosen as the standards for this study.

The goal of this article is to report the concentrations of hydrogen peroxide vapor found near hydrogen peroxide sterilizers in hospitals over a period of several years of regular use, to determine what a typical risk of exposure to hydrogen peroxide is in a healthcare environment from use of hydrogen peroxide sterilizers.

Methods

Hydrogen peroxide concentrations were measured using a ChemDAQ Steri-Trac® hydrogen peroxide monitor. The ChemDAQ monitor comes in two versions, one with an integral sensor and the other with a remote sensor connected back to the wall mounted monitor by a cable. This latter configuration is typically used for hydrogen peroxide monitoring with the remote sensor being placed on the top of the sterilizer. In most installations, each sterilizer has its own sensor, located above the door or sometimes one monitor will be placed between two closely spaced sterilizers. These monitors can be used as stand-alone devices or they can be interfaced with a ChemDAQ DAQ® computer for data acquisition, TWA calculations and alarms, reports, graphs, data export, etc.

The data used for this study was collected and provided by seven different hospitals across the U.S. and Canada (labeled A–G) that use the ChemDAQ gas monitoring system as part of their workplace safety program. The monitors are on 16 hydrogen peroxide sterilizers of various models in regular use. The data collection period ranges from one to four years. The ChemDAQ gas monitoring system stores both the raw data and the TWA values. Even though the ChemDAQ monitors output a reading every second, for file size management the automatically stored data are recorded with a resolution of one point every 15 min if the reading is below the lower alarm level and one point every 20 sec if the reading is above the lower alarm level. The graphs below show the complete data sets of instantaneous readings, except where the graph indicates that the TWA data are plotted.

These data are summarized and for some sterilizers plotted in the graphs shown below. At each location, each gas monitor corresponds to an area (Area 1, Area 2, etc., as shown on the graphs). If a hospital has monitors for multiple gas types (e.g., ethylene oxide and peracetic acid), only the areas corresponding to hydrogen peroxide are included here. The sterilizers models used in

Table 1. Summary of hydrogen peroxide readings.

Sterilizer Model	Hospital (area)	Time (yrs)	Max (ppm)	Mean(b) (ppm)	Median (ppm)	SD (ppm)
200	E(2)	2.3	0.9	0.002	0	0.016
200	E(3)	2.3	0.1	0.000	0	0.003
		Average	**0.5**	**0.001**	**0**	**0.010**
NX	B(5)	1.7	0.3	0.004	0	0.021
NX	B(6)	1.7	0.3	0.001	0	0.009
NX	F(2)	4.4	3.3	0.001	0	0.138
NX	F(3)	4.4	3.1	0.001	0	0.119
		Average	**1.8**	**0.002**	**0**	**0.72**
100S	A(4)	2.9	3.3	0.003	0	0.066
100S	B(2)	1.7	5.7	0.063	0.2	0.693
100S	B(3)	1.7	10.6	0.069	0	0.581
100S	C(2)	2.3	1	0.011	0	0.046
100S	D(3)	3.2	0.7	0.015	0	0.047
100S	E(1)	2.1	12.4	0.068	0	0.640
100S	F(4)	4.4	3.9	0.003	0	0.124
		Average	**5.4**	**0.033**	**0.03**	**0.31**
V-Pro	G(1)	2.3	24.6	0.048	0	0.989
V-Pro	G(2)	2.3	36.6	0.062	0	1.441
V-Pro	G(3)	2.3	42	0.043	0	1.349
V-Pro	G(4)	2.3	32.7	0.059	0	0.855
		Average	**34.0**	**0.053**	**0**	**1.16**

this study were Sterrad models 100S, 200, and NX from Advanced Sterilization Products and V-Pro from Steris Corporation.

Results

Sterrad 100S

The data from Hospital A using a Sterrad 100S showed several brief moments when the hydrogen peroxide concentration exceeded 1 ppm, but the exposure never exceeded the factory default instantaneous low alarm of 5 ppm, the 15-min TWA of 3 ppm, nor the 8-hr TWA of 1 ppm. From a fugitive hydrogen peroxide vapor perspective, this sterilizer is performing well. A summary of the data from all the sterilizers may be found in Table 1.

The second hospital, Hospital B with a Sterrad 100S, had a large number of small hydrogen peroxide concentration readings. The 8-hr TWA exceeded 1 ppm once and twice exceeded the 15-min TWA 3 ppm. The monitor would have gone into alarm several times, assuming the instantaneous low alarm was still at the factory default value of 5 ppm. It may be seen from Figure 1 that the hydrogen peroxide emission varies over time, suddenly increasing around October 2012. Increasing hydrogen peroxide vapor concentrations may indicate that the sterilizer requires or will soon require preventative maintenance. Gas monitoring can often be used to detect certain maintenance issues before they become significant enough to be observed by other means.

The second hydrogen peroxide monitor at Hospital B (shown in Figure 2) exceeded 3 ppm 15 min. TWA several times, and exceeded 1 ppm 8 hr. TWA several times.

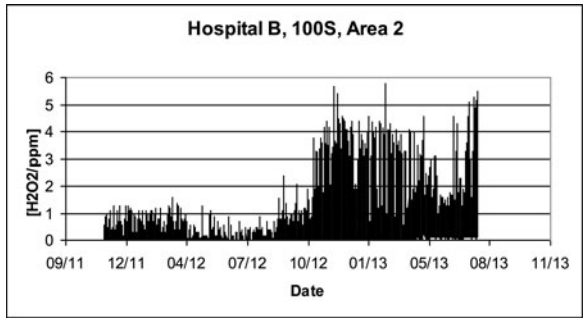

Figure 1. Sterrad 100S, Hospital B.

It may be seen that the increase in the fugitive hydrogen peroxide concentration increases for Area 3 is similar to that seen for Area 2. This conformity arises because it is common practice in a busy hospital to have more than one sterilizer lined up next to each other. If one sterilizer starts to emit hydrogen peroxide vapor then this vapor is often also detected by the monitor on the adjacent sterilizer.

The monitor on a Sterrad 100S from Hospital C showed a maximum instantaneous reading of 1 ppm, and did not exceed either 3 ppm 15-min TWA, nor 1 ppm

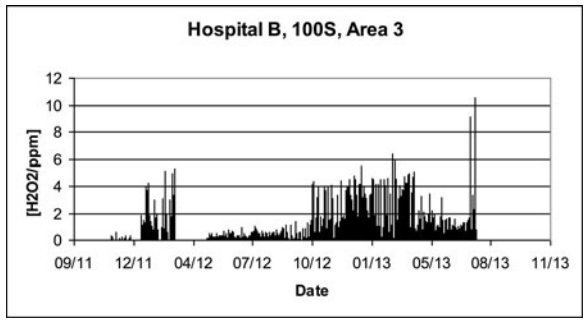

Figure 2. Sterrad 100S, Hospital B.

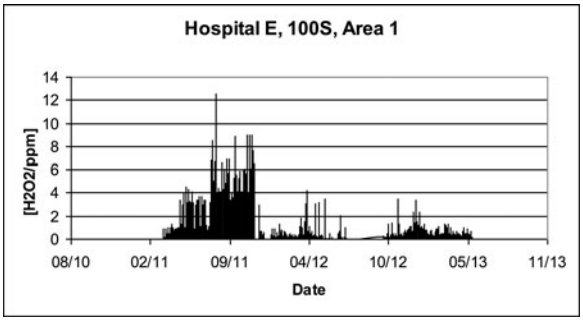

Figure 3. Sterrad 100S, Hospital E.

8-hr TWA. From a fugitive hydrogen peroxide vapor concentration perspective, this sterilizer is performing well.

The monitor on a Sterrad 100S from Hospital D showed a maximum instantaneous reading of 0.7 ppm, and did not exceed either 3 ppm 15-min TWA nor 1 ppm 8-hr TWA. However, the gas monitor was located at the back of the sterilizer and so would be unable to adequately detect any hydrogen peroxide emissions from the front of the sterilizer that are potentially in the breathing zone of the operators. The maximum readings were lower than the readings from the other 100S sterilizers.

Figure 3 shows the hydrogen peroxide concentration data for a Sterrad 100S in Hospital E. The maximum instantaneous reading was over 12 ppm, and the measured hydrogen peroxide concentrations exceeded 3 ppm 15-min TWA 6 times, but did not exceed 1 ppm 8-hr TWA. The hydrogen peroxide concentrations appear to increase over time and then decrease. The cause of the sudden decrease around December 2011 is not known but is suspected to be due to maintenance.

Sterrad 200

Figure 4 shows the hydrogen peroxide concentration data from a Sterrad 200, also from Hospital E. The instantaneous reading did not exceed 1 ppm. From a hydrogen peroxide vapor concentration perspective, this sterilizer is performing well. A second Sterrad 200 at Hospital E behaved similarly.

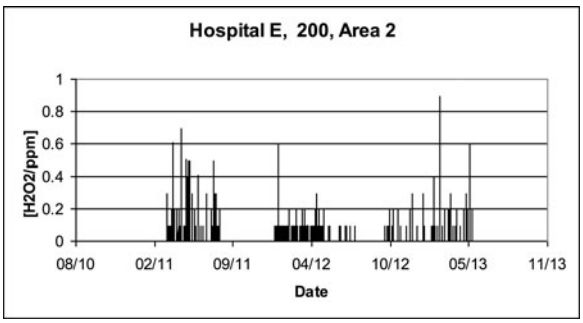

Figure 4. Sterrad 200, Hospital E.

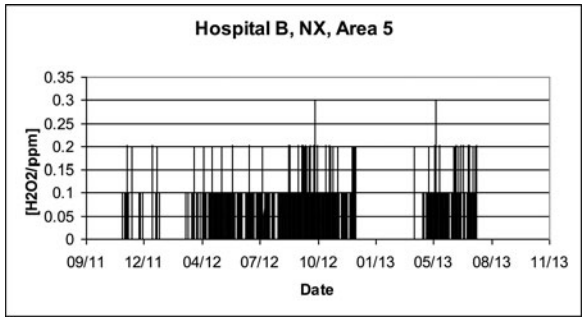

Figure 5. Sterrad NX, Hospital B.

Sterrad NX

Hospital B has two Sterrad NX sterilizers and their hydrogen peroxide concentrations were small, as shown for one of them in Figure 5. Both Sterrad NX sterilizers at Hospital B show minimal hydrogen peroxide concentrations. The instantaneous concentration values are at or below 0.3 ppm. From a hydrogen peroxide vapor concentration perspective, these sterilizers are performing well.

The two data sets for Sterrad NX sterilizers from Hospital F are generally similar to each other (one is shown in Figure 6), again probably because the two sterilizers are adjacent to each other. The hydrogen peroxide concentration from the NX sterilizer in Areas 2 and 3 did not exceed the 5 ppm instantaneous value, nor did it exceed 3 ppm 15 min. TWA, and it exceeded 1 ppm 8-hr. TWA only one time. The time and duration of this event were similar indicating that both monitors were responding to the same event, most likely from adjacent the hydrogen peroxide sterilizers as discussed above.

All three monitors showed only one time when the 8-hr TWA of 1 ppm was exceeded. Plotting the 8 hr. TWA data for all three areas on reduced time scale shows that all three monitors were responding to the same event. No details of this event are available.

Steris V-Pro

Significant hydrogen peroxide vapor concentrations were observed by Hospital G, a busy hospital which had four

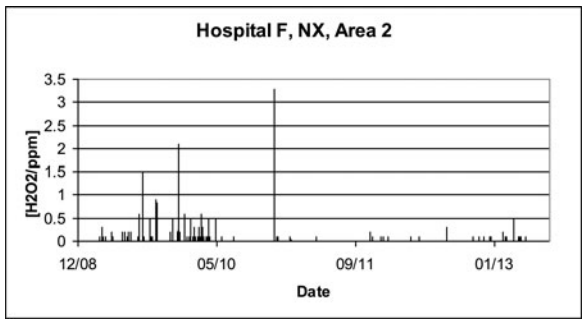

Figure 6. Sterrad NX, Hospital F.

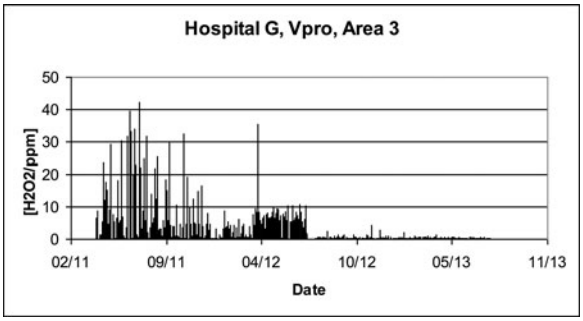

Figure 7. V-Pro Sterilizer, Hospital G.

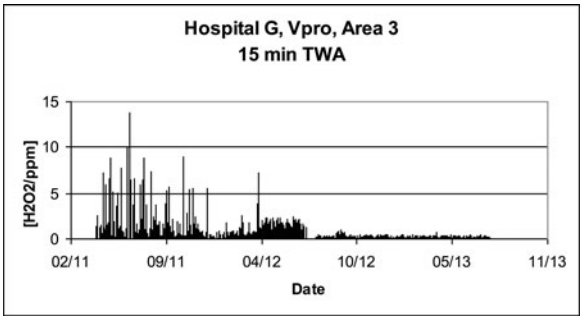

Figure 8. 15-min TWA V-Pro-Sterilizer, Hospital G.

V-Pro Sterilizers in the same room next to each other. For about the first year, hydrogen peroxide peak concentrations in the range of 20–25 ppm (Area 1), 20–37 ppm (Area 2), 30–42 ppm (Area 3), and 20–32 ppm (Area 4) were observed. One of these data sets is shown in Figure 7. For these sterilizers, the hydrogen peroxide was detected at the end of the cycle when the door was opened to remove the load. The 15-min TWA for the same data set is shown in Figure 8. For all four sterilizers, the hydrogen peroxide concentrations frequently exceeded the 3 ppm 15-min TWA, but did not exceed the 1 ppm 8-hr. TWA. The emissions occurred briefly during the day, as seen in Figure 9, typically lasting approximately 15–20 min.

Discussion

Hydrogen peroxide is the most widely used low temperature sterilant in use in U.S. hospitals and in hospitals of many other countries as well. In addition to being effective, it is environmentally friendly in that if released into the environment, hydrogen peroxide rapidly breaks down to water and oxygen. This high reactivity that makes it environmentally friendly also makes it an effective sterilant and underlies its occupational hazards.

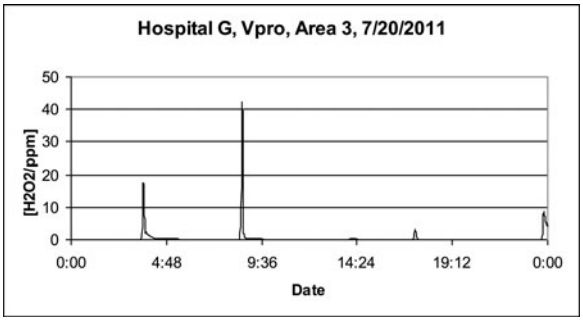

Figure 9. Same data as Figure 7, expanded scale to one day.

ASP's Sterrad 100S

This work horse of sterile processing was first introduced in the 1990s and is still widely used today. None of the sterilizers tracked gave concentrations exceeded 1 ppm TWA over 8 hr, but several of them gave short-term concentrations of several ppm. The hydrogen peroxide vapor concentrations appear to vary over time, but the cause was not determined.

ASP's Sterrad NX

ASP's Sterrad NX sterilizers start with 59% hydrogen peroxide and internally concentrate it to over 90% in order to produce a more potent sterilization vapor and thus a shorter cycle time.[23] Despite the higher internal hydrogen peroxide concentration, the vapor concentration measured above the door was, with only a few momentary exceptions, below that of the 100S sterilizer and the instantaneous peaks were typically only fractions of a part per million. From a hydrogen peroxide vapor concentration perspective, the Sterrad NX sterilizers in this study performed very well.

Steris Corporation's V-Pros

The four new Steris V-Pro sterilizers at Hospital G were located next to each other in a small room with a continuous monitor for hydrogen peroxide placed on top of each sterilizer (Areas 1–4). All four sterilizers emitted hydrogen peroxide vapor with a measured concentration in the 25–40 ppm range when the door was opened at the end of the cycle. The hospital was very concerned about the high hydrogen peroxide concentrations, but the manufacturer determined the sterilizers were functioning correctly.

In the short term, the hospital resolved the problem by instructing the employees to open the sterilizer at the end of each cycle, and step away until the hydrogen peroxide monitor indicated it was safe to unload the sterilizer. While the TWA exposures frequently exceeded 3 ppm over 15 min, there is no STEL permissible exposure limit (PEL) in the U.S. outside of Hawaii and Washington and there was almost no exposure exceeding the OSHA PEL of 1 ppm TWA over 8 hr. Therefore, these measured concentrations did not exceed the legal occupational exposure limits.

Even if the 3 ppm STEL is not a legal requirement in 48 states, it should serve as a flag for potential exposure risk for two reasons. The first is that Hospital G had four sterilizers in a row and if they were run and unloaded sequentially, then the operator may potentially receive a higher cumulative exposure than the individual monitors suggest. The other reason is that hydrogen peroxide has a National Institute of Occupational Safety and Health (NIOSH) immediately dangerous to life and health (IDLH) value of 75 ppm.[24] Some of the measured hydrogen peroxide vapor concentrations are close to half the IDLH and presumably the operators would have been subject to repetitive exposures, had they not been using the hydrogen peroxide monitors as described above to limit their exposure.

The ACGIH states the following.

> *Excursions in worker exposure levels may exceed 3 times the TLV-TWA for no more that a total of 30 minutes during a workday, and under no circumstances should they exceed 5 times the TLV-TWA, provided that the TLV-TWA is not exceeded.*[25]

The ACGIH TLV for hydrogen peroxide is 1 ppm, 8-hr TWA, and according to these guidelines, the maximum exposure to hydrogen peroxide should be no more than 5 ppm. Clearly, some of the exposures recorded here exceed this value and so even though the TWA exposures do not exceed the legal PEL, the exposures should be flagged as potentially harmful to employees.

Using the hydrogen peroxide monitors as an indicator of when it was safe to approach the sterilizer was only a short-term fix and in July 2012, the sterilizers were relocated to a custom-made room with an exhaust vent located immediately above the sterilizer. It can be seen from the graphs for Hospital G that the hydrogen peroxide readings dropped significantly after the relocation. After the move, with the added exhaust ventilation the hydrogen peroxide peak concentrations were around 5 ppm.

Summary of data

The data for the sterilizers is summarized in Table 1. These data sets are for continuous monitoring and so data are being collected even when the sterilizer is not in use, and so as may be expected the median value for all but one of the sterilizers is zero. The mean values of the hydrogen peroxide vapor concentrations are also well below 0.1 ppm for the same reason. The mean exposure was calculated as the sum of the concentration multiplied by the time interval, divided by the total time the monitor was in service. This method was used because a simple mean of the concentrations would read high because the monitors record data at different rates depending on whether the gas concentration is above or below the alarm level, and so would skew the data in favor of higher values. The median and the standard deviation were however based on the simple measured concentrations and not adjusted for the different time intervals.

Table 1 also shows that the statistical metrics vary by sterilizer type, though the sample sizes are small. The Sterrad 200 have the lowest average maximum value with 0.5 ppm, followed by the NX (average max = 1.8 ppm), the 100S (average max = 5.4), and the V-Pros have the highest with 34 ppm. The average mean and standard deviation values follow similar patterns. Even though the sample size is small, these values do appear to be in similar magnitude groups for each sterilizer type.

Personal and area monitoring

The monitors used in this study are fixed point area monitors and so it should be noted that a recorded high hydrogen peroxide concentration does not mean that employees were exposed over this time, simply that there was hydrogen peroxide in the air at the concentrations recorded. The purpose of area monitoring is to inform people what is in the air so that they can take appropriate action to prevent personal exposure.

If, for example, the hydrogen peroxide monitor reading increases for a short while when the sterilizer door is opened, many employers, such as Hospital G, develop work practices that require operators to open the door, step away and only unload the sterilizer once the reading has returned to safe levels. Hydrogen peroxide has almost no odor and so absent a continuous monitor for hydrogen peroxide, operators would not be aware of any exposure to hydrogen peroxide from fugitive emissions until they experienced the irritation or other health effects resulting from over exposure.

Effect of sensor placement

The placement of the sensor is important for getting an accurate reading of the hydrogen peroxide vapor concentration. For most hydrogen peroxide sensors, the vapor enters the monitor's sensor by diffusion. Monitors can only measure the concentration of the hydrogen peroxide vapor immediately adjacent to the sensor. If there is a vapor leak, then the gas is transported to the sensor by diffusion and air movement.

If the vapor has a point source, then the concentration away from the source will decrease greatly with distance (volume of a sphere increases with the cube of the radius). If there are air currents, then the concentration of the vapor may vary depending on the direction of the air currents. Therefore, it is important to place the sensor close

to the source and in such a way as to measure the vapor concentration in or close to the breathing zone of the sterilizer operator. Most of the hydrogen peroxide emissions occur from residual vapor when the door opened and the maximum occupational exposure is likely to occur as the operators reach in to empty the sterilizer load since the open door is close to the operator's breathing zone.

Based on the above considerations, the best place to locate a hydrogen peroxide monitor near a sterilizer is directly over the door. Most of the sterilizers are operated at above room temperature (~50°C is typical) and so warm vapors released on opening the door will rise to the sensor. However, it is likely that the concentration inside or at the entrance to the sterilizer will be higher.

Most of the hospitals in this study reported that the sensor was either flush with the front of the sterilizer or set back, up to 6 in. The only exception was Hospital D which reported its sensor was set at the back of the sterilizer which explains why the recorded exposures are significantly lower than those of hospitals using similar sterilizers. If the sensor is pushed back to the back of the sterilizer, then the response to any hydrogen peroxide in the operator's breathing zone will be significantly reduced. Just as with the FDA report cited above, some sterilizer service representatives have recommended that the sensor be moved back as a solution to the monitor showing high hydrogen peroxide readings, but obviously, preventing the sensor from detecting the hydrogen peroxide vapor emissions does not solve the problem and may put workers at further risk.

It should also be noted that the concentrations of hydrogen peroxide measured by the sensors are not just a function of the sterilizer, but also the ventilation and air exchange rates, as can be seen when the sterilizers at Hospital G were moved to a location with a dedicated exhaust directly above each sterilizer. These sterilizers are typically used in sterile processing/central services where there is a requirement to have at least 10 air exchanges per hour.[26] Thus, some of the differences from one data set to the next may be a result of differences in ventilation rather than hydrogen peroxide emission rates from the sterilizers.

Conclusions

This study has demonstrated that hydrogen peroxide sterilizers are generally safe to use and when operating properly do not present a significant hydrogen peroxide vapor hazard to the operators. However, sometimes due to wear and tear, operator error, failed engineering controls, or other factors, the hydrogen peroxide emissions can sometimes reach higher than acceptable concentrations and the tendency to emit hydrogen peroxide varies with the model. Continuously monitoring for the hydrogen peroxide concentration informs operators and the facility if hazardous levels exist so they can take appropriate action to prevent occupational exposure.

References

[1] **CDC**: "Healthcare-associated Infections (HAIs)." Available at http://www.cdc.gov/HAI/surveillance/ (accessed February 5, 2015).

[2] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad 100s Sterilizer Sterrad Equipment (MLR) "Burning eyes and skin rash." FDA MAUDE Report Number 2084725-2009-00322, 100S, 5/26/09. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1395919 (accessed March 16, 2015).

[3] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad NX Sterilizer Sterrad Equipment (MLR) "Watery eyes and a bothersome throat." FDA MAUDE Report Number 2084725-2009-00236, NX, 3/25/09. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1386859 (accessed March 16, 2015).

[4] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad NX Sterilization System Sterilizer "Difficulty breathing, burning eyes, and a foreign taste in her mouth." FDA MAUDE Report Number 2084725-2008-00100, 3/4/08. Available from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1025087 (accessed March 16, 2015).

[5] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad 200 Sterilization System Double-Door Unit with Stainless Steel Exterior Sterrad Equipment (MLR) "eye and throat irritations." FDA MAUDE Report Number 2084725-2009-00081, 200, 2/13/09. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1315493 (accessed March 16, 2015).

[6] **FDA**: "Food and Drug Administration, Medical Device Recalls, Class 2 Recall, STERRAD NX Sterilizer, Posted February 8, 2008, recall number Z-0848-2008." Available from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/resCollection_2.cfm?ID=66413&CREATE_DT=2008-02-08 (accessed March 16, 2015).

[7] **FDA**: "Food and Drug Administration MAUDE Adverse Event Reports: Advanced Sterilization Products Sterrad NX Sterilizer Sterrad Equipment (MLR), Report No. 2084725-2009-00421." 6/19/09. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1414393 (accessed March 16, 2015).

[8] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad 200 Sterilization System Double-Door Unit with

Stainless Steel Exterior Sterrad Equipment (MLR)." Report No. 2084725-2009-00287. 4/16/09. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=1386882 (accessed March 16, 2015).

[9] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad 100s Sterilizer Sterrad Equipment (MLR)." Report No. 2084725-2009-00291, Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1391745 (accessed March 16, 2015).

[10] **FDA**: "Food and Drug Administration MAUDE Adverse Event Report: Advanced Sterilization Products Sterrad 100nx Sterilizer Sterrad Equipment (MLR)." Report No. 2084725-2009-00276. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=1378493 (accessed March 16, 2015).

[11] **FDA**: "Food and Drug Administration, MAUDE Adverse Event Report: STERIS MEXICO, S. DE R.L. DE C.V. V-PRO 1 PLUS STERILIZER." FDA MAUDE Report Number, 3005899764-2014-00071. 8/27/14. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=4042489 and report number 3005899764-2014-00026 (accessed March 16, 2015).

[12] **FDA**: "Food and Drug Administration, MAUDE Adverse Event Report: Steris Mexico, S. DE R.L. DE C.V. V-PRO MAX Sterilizer." FDA MAUDE 3005899764-2014-00103, Event date 9/17/2-14. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=4174968 (accessed March 16, 2015).

[13] **Yoshida, R., and H. Kobayashi**: "Problems on Hydrogen Peroxide Sterilisation — New Proposal for Safety and Effective Use." Presented at the Annual WFHSS and JSMI Conference 2012 13th World Sterilization Congress. November 23, 2012. Available at http://www.wfhss.com/html/conf/wfhss-conference-2012/lectures/wfhss_conf20121121_lecture_sp_s702_en.pdf (accessed February 5, 2015).

[14] "Toxic and Hazardous Substances, TABLE Z-1 Limits for Air Contaminants." *Code of Federal Regulations*, Title 29, Part 1910, section 1000 TABLE Z-1 2017.

[15] **OSHA**: Permissible Exposure Limits - Annotated Tables, US Occupational Safety & Health Administration." Available at https://www.osha.gov/dsg/annotated-pels/ (accessed March 18, 2015).

[16] **ACGIH**: 2014 Guide to Occupational Exposure Values, Compiled and published by ACGIH. Available at https://www.acgih.org/forms/store/ProductFormPublic/2014-guide-to-occupational-exposure-values.

[17] **Oberst, F. W., C. C. Comstock, and E. B. Hackley**: Inhalation toxicity of ninety per cent hydrogen peroxide vapor, acute, subacute and chronic exposures of laboratory animals. *Arch. Indust. Occup. Hyg. 10*:319–327 (1954).

[18] **Mastrangelo, G., R. Zanibellato, E. Fadda, J. H. Lange, L. Scoizzato, and R. Rylander**: Exposure to hydrogen peroxide and eye and nose symptoms among workers in a beverage processing plant. *Ann. Occup. Hyg. 53*(2):161–165 (2009). Available at http://www.rmaoem.org/Pdf%20docs/H2O2%20exp%20in%20bev%20proc%20wkrs.pdf (accessed March 16, 2015).

[19] **Gagnaire, F., B. Marignac, G. Hecht, and M. Héry**: Sensory irritation of acetic acid, hydrogen peroxide, peroxyacetic acid and their mixture in mice. *Ann. Occup. Hyg. 46*(1):97–102 (2002). Available at http://annhyg.oxfordjournals.org/content/46/1/97.full (accessed March 16, 2015).

[20] **Washington State Legislature**: "Permissible Exposure Limits (PELs)." WAC 296-841-20025. Available at http://apps.leg.wa.gov/wac/default.aspx?cite=296-841-20025 (accessed March 16, 2015).

[21] **HIOSH**: "Hawaii Administrative Rules, Title 12, Department of Labor and Industrial Relations, Subtitle 8, Hawaii Occupational Safety And Health Division, Part 2, General Industry Standards, Chapter 60, General Safety And Health Requirements." Available at http://labor.hawaii.gov/hiosh/files/2012/12/12-60-General-Safety-Health-Requirements.pdf (accessed March 16, 2015).

[22] **HSE**: "EH40/2005 Workplace Exposure Limits." Published 2011. Available from http://www.hse.gov.uk/pubns/books/eh40.htm (accessed March 12, 2015).

[23] **Sterrad**: "Sterrad NX Installation Requirements and Product Specifications, Advanced Sterilization Products Inc. (2012)." Available at http://www.aspjj.com/us/sites/www.aspjj.com.us/files/AD-53417-01-US_STERRAD-NX-Install-Specs.pdf (accessed March 18, 2015).

[24] **The National Institute for Occupational Safety and Health (NIOSH)**: "Chemical Listing and Documentation of Revised IDLH Values (as of 3/1/95)." Available at http://www.cdc.gov/niosh/idlh/intridl4.html (accessed March 16, 2015).

[25] **ACGIH**: "2014 TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices." ACGIH. p. 5.

[26] **Association for Advancement of Medical Instrumentation Standard**: ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3: 2012 & A4:2014 (Consolidated text) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Section 3.3.6.4 Ventilation."