Guide to Gas Detection in Healthcare in the United States

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Introduction

Biocidal chemicals play a vital role in modern life and their application has allowed significant advances in reducing infection in healthcare. However the use of sterilants and high level disinfections presents a risk to those people performing these essential tasks and gas monitoring is a part of the means to ensure that these chemicals can be used safely.

Occupational Exposures

Toxic gas or vapor concentrations are typically measured in parts per million (ppm) or in mg/m^3. A ppm is a fractional concentration, i.e. if the concentration of peracetic acid is 1 ppm, then of every million molecules in the air, one of them is peracetic acid.

For most toxic gases, the effect of exposure is cumulative and thus most exposures are assessed as time weighted averages (TWAs), such that an exposure of 1 ppm for 8 hours is the same exposure as 8 ppm for 1 hour, or 32 ppm for 15 minutes. The 8 hour limit is sometimes called a long term exposure limit (LTEL).

For some vapors, such as peracetic acid, a high concentration for a short time is more harmful than the equivalent lower concentration for a longer time. For these gases, a shorter (15 minute) TWA is used, often called a short term exposure limit (STEL). Some gas exposures are measured on their instantaneous value, for example OSHA has a permissible exposure limit ceiling for chlorine of 1 ppm.

The ChemDAQ gas monitoring system offers instantaneous concentrations, STELs and 8 hour TWAs, with the instantaneous value on the monitor display and the DAQ® computer provides instantaneous levels, STELs and 8 hour TWAs and associated alarms..

<u>Occupational Exposure Limits</u>

The United States has two federal government agencies related to occupational safety. The National Institute of Occupational Safety and Health (NIOSH) and the Occupational Safety Administration (OSHA). The NIOSH performs research and has developed Recommended Exposure Limits (RELs) for many compounds. The current values are available in the NIOSH Pocket Guide to Chemical Hazards[1] and the RELs are often quoted on safety data sheets etc.

NIOSH also produces a list of Immediately Dangerous to Life and Health Limits (IDLHs) for many chemicals.[2] These relate to the exposure that would cause serious injury or serious impairment preventing escape. For example the IDLH for ethylene oxide is 800ppm, but for the more corrosive hydrogen peroxide it is 75 ppm.

[1] The guide can be search at http://www.cdc.gov/niosh/npg/

[2] A list of NIOSH IDLHs is available at http://www.cdc.gov/niosh/idlh/intridl4.html

NIOSH IDLH Values and Odor Thresholds

Compound	NIOSH IDLH[3]	Odor Threshold
Ethylene Oxide	800 ppm	430 ppm[4]
Hydrogen Peroxide	75 ppm	Very Little smell, no odor threshold reported[5]
Ozone	5 ppm	0.01 to 0.05 ppm[6]

Odor thresholds are at best estimates since the odor threshold varies from person to person and for any given person from day to day, especially if they are congested with a cold or allergies. In addition, the odor of many gases such as ozone is subject to olfactory fatigue meaning that a once pungent odor fades into the perceptual background on continued exposure; also meaning that slowly increasing concentrations may not be perceived.

OSHA is the US regulatory and enforcement agency. It has promulgated a series of occupational exposure limits called permissible exposure limits (PELs). The OSHA PELs are the legal exposure limits throughout the US, though some states may have additional or tighter exposure limits. For example, Washington State[7] and Hawaii[8] both have 3 ppm short term exposure limits for hydrogen peroxide.

OSHA PEL Values[9]

Compound	8 Hr Exposure Limit (ppm)	15 Minutes Exposure Limit (ppm)
Ethylene Oxide	1	5
Hydrogen Peroxide	1	n/a

Another important occupational safety organization is the American Conference of Government Industrial Hygienists (ACGIH). Each year the ACGIH publishes their list of Threshold Limit Values (TLV) for chemical and biological exposures. The ACGIH is highly respected to the point that most of the OSHA PELs were taken from the 1968 ACGIH TLVs and several countries including some Canadian provinces directly reference the TLVs in their occupational exposure laws.[10]

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3 http://www.cdc.gov/niosh/idlh/intridl4.html
4 http://www.epa.gov/ttn/uatw/hlthef/ethylene.html
5 http://www.atsdr.cdc.gov/MHMI/mmg174.pdf
6 http://www.cdc.gov/niosh/docs/81-123/pdfs/0476.pdf
7 http://apps.leg.wa.gov/wac/default.aspx?cite=296-841-20025
8 http://labor.hawaii.gov/hiosh/files/2012/12/12-60-General-Safety-Health-Requirements.pdf,
9 29 CFR 1910.1000 Tbl . Z-1 and 29 CFR 1910.1047 (EtO)
10 The sources of the occupational exposure limits for the Canadian Provinces have been summarized as of June 2013 in http://blog.chemdaq.com/?p=88

ACGIH TLVs[11]

Compound	8 Hr Exposure Limit (ppm)	15 Minutes Exposure Limit (ppm)
Ethylene Oxide	1	5
Hydrogen Peroxide	1	n/a
Peracetic Acid	n/a	0.4 ppm

The ACGIH recently announced a new TLV for peracetic acid. Peracetic acid is widely used as a biocide in healthcare, food and other industries and until this announcement there were no occupational exposure limits for it. ChemDAQ developed the first monitor for peracetic acid vapor.

The ChemDAQ monitor can easily detect PAA at the STEL (monitor range 0 to 6 ppm, minimum detection limit 0.04 ppm). Peracetic acid is used as an equilibrium mixture with acetic acid and hydrogen peroxide and so there is always hydrogen peroxide vapor present to some extent with peracetic acid. Peracetic acid and hydrogen peroxide are chemically similar and so this hydrogen peroxide can potentially cause interference on the sensor. **The ChemDAQ peracetic acid monitor includes a proprietary chemical filter that prevents cross sensitivity to hydrogen peroxide.**

The Environmental Protection Agency (EPA) has also issued exposure limits for peracetic acid (and many other chemicals) known as acute exposure guideline levels (AEGLs). There are three levels of AEGL, roughly translated as irritating (AEGL 1), irreversible harm (AEGL 2), and fatal (AEGL 3).[12] The AEGL 1 for peracetic acid is 0.52 mg/m^3 (0.19 ppm).[13] It should be noted that the AEGLs are intended to give guidance to emergency responders and so apply to a single exposure, not repeated exposure as with an occupational exposure limit.

[11] ACGIH 2014 Guide to Occupational Exposure Values
[12] http://www.epa.gov/oppt/aegl/pubs/define.htm
[13] http://www.epa.gov/oppt/aegl/pubs/results80.htm

Applicable Regulations
The healthcare workplace comes under the same occupational safety laws as other employers. Below is a very abbreviated overview of the US workplace legal framework. [14]

There are three main levels of safety laws that are designed to work together:

1. Federal statutes: Occupational Safety and Health (OSH) Act of 1970
2. Federal regulations, such as the OSHA Hazard Communication Standard, OSHA Airborne Contaminants Standard
3. Many states and cities have their own occupational safety laws, most parallel OSHA's but some are more restrictive.

Occupational Safety and Health Act (1970)
The OSH Act (1974) created a legal duty for employers to provide a safe work environment, created OSHA and NIOSH and provided the authority to OSHA to develop and enforce occupational safety regulations (OSHA standards).

In particular, section 5a (so called General Duty Clause) of the OSH Act reads:

> *Each employer (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees; (2) …* [15]

OSHA can prosecute employers under the General Duty Clause if a dangerous situation poses a risk to employees that is not addressed by a specific regulation.

OSHA Regulations
The standards most relevant to chemical safety in healthcare are:[16]

- 1910.38 & 39 Emergency Action and Fire Prevention
- 1910.132 to 138 Personal Protective Equipment (gloves respirators etc.)
- 1910.1000 Air Contaminants (lists OSHA PELs for many compounds)
- 1910.1200 Hazard Communication (on the basis that informed workers are safe workers, the standard requires labeling of chemicals, safety datasheets, and training for employees and written plan. Of particular relevance to gas detection, the standard requires employees to be

[14] The scheme below is intended to give a brief overview; it should not be taken as legal advice. Please consult a lawyer if you have any specific questions.
[15] https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=OSHACT&p_id=2743
[16] https://www.osha.gov/pls/oshaweb/owasrch.search_form?p_doc_type=STANDARDS&p_toc_level=1&p_keyvalue=1910

trained to determine if there is a leak of a hazardous chemical into the work area and how they should respond.[17]

- 1910.1047 Ethylene oxide standard (special rules for EtO, with a large overlap with the Hazcom standard)
- 1910.1048 Formaldehyde standard (special rules for CH_2O, with a large overlap with the Hazcom standard)
- 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories (similar to Hazcom standard but for Labs).

The use of sterilant and other biocidal chemicals is essential to modern healthcare and gas detection provides a means to enable employers to use these chemicals and their associated equipment safely.

Accreditation Bodies

The largest accreditation organization in the US is the Joint Commission, formerly called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which accredits and certifies more than 20,000 health care organizations and programs in the United States.[18] The Joint Commission develops its own standards which include chemical safety:

> Standard EC.02.02.01 - The [organization] manages risks related to hazardous materials and waste. Some of the relevant elements of this standard are copied below:
>
> - The hospital maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates.
> - The hospital has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures and implements its procedures in response to hazardous material and waste spills or exposures.
> - The hospital minimizes risks associated with selecting, handling, storing, transporting, using, and disposing hazardous chemicals.
> - The hospital minimizes risks associated with selection, handling, storage, transport, use, and disposing hazardous gases and vapors.
> - Note: Hazardous gases and vapors include, but are not limited to, glutaraldehyde, ethylene oxide, …
> - The hospital monitors levels of hazardous gases and vapors to determine that they are in safe range. Note: Law and regulation

[17] 29 CFR 1910.1200(h)(3)(i)

[18] http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx

determine the frequency of monitoring hazardous gases and vapors as well as acceptable ranges.[19]

Until recently, the federal government held that a hospital that met Joint Commission accreditation met the Medicare Conditions of Participation and so the Joint Commission had a near monopoly on accreditation. Since 2008 several other organizations have also been accrediting healthcare facilities.[20]

Overview of the ChemDAQ Steri-Trac® System

The ChemDAQ gas monitoring system is modular so that it can be tailored to each customer's needs; and is made up of the following main components.

- Monitor: the monitor connects to the sensor module and displays the current gas concentration. It also has two instantaneous alarms, high and low. Under normal conditions, the display is green, turns yellow for low alarm and red for high alarm. A horn sounds an alert if the low or high alarms are reached. The monitors also contains two relays, each triggered by the alarm level, that can be used to interface with air handlers, strobes etc. The monitor can operate as a stand-alone instrument or it can be connected to the DAQ computer.

  Monitors are currently available for peracetic acid, hydrogen peroxide, ethylene oxide, ozone, oxygen and combustible (LEL). The latter two are primarily used in commercial applications. Each monitor is configured for a specific gas, but can be factory reconfigured for a different gas.

- Sensor Module: the sensor module contains the gas sensor, circuitry to support it, chemical filters (if applicable) and an internal battery to enable fast start-up when the sensor module is initially installed. The sensor module plugs into the monitor and passes the current gas readings to the monitor. The sensor module connects directly on to the monitor or via a remote sensor mount.

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[19] Joint Commission 2009 Accreditation Requirements Chapters Accreditation Program: Hospital

[20] http://en.wikipedia.org/wiki/Joint_Commission

- Sensor Calibration (SXP)®: The ChemDAQ sensor modules, like all gas sensors, require periodic calibration as a basic function check of operation and to ensure that the output matches the actual gas concentration. Field calibration is often problematic, especially with reactive gases such as peracetic acid and hydrogen peroxide. Instead ChemDAQ provides a calibration service for all users of ChemDAQ equipment. ChemDAQ tracks the date since the last calibration, contacts the customer and sends factory calibrated sensors. The customer swaps the sensors (very simple), and returns the old sensors to ChemDAQ; where the chemical filters are replaced (peracetic acid and ethylene oxide), the batteries recharged and the sensors recalibrated. All calibrations are performed using the target gas, which for hydrogen peroxide and peracetic acid means generating and analyzing the test gas before the sensor modules can be calibrated.

- Remote Displays: The remote displays look somewhat like the monitor but without the connector for the sensor mount. The remote display is used to warn approaching people of a gas or vapor leak before they enter the area. The remote display mirrors the monitor display and horn alarm status. One monitor can be connected to and power up to three remote displays.

- DAQ® Computer: The DAQ is a computer that receives data from the monitors (any combination of gases), calculates the time weighted average (TWA) values of the exposure and displays the instantaneous and TWA values and alarms if the TWA's exceed preset alarm limits. The DAQ also warns if a channel is approaching the TWA limit (impending alarms). The DAQ also has graphing, reports and can export the data as a .csv (text) file for import into Excel or other spreadsheet or to an SQL data for real time interfacing to building systems.

The DAQ can operate up to four zones, each with up to 8 monitors, thus a single DAQ can be connected to up to 32 different monitors of any gas combination offered by ChemDAQ.

Certifications

The Steri-Trac is certified by Metlabs to the UL & CSA standards for electrical safety 61010-10 and FCC EM interference/susceptibility (47 CFR part 15 subpart B). The Steri-Trac sensor module is certified as intrinsically safe by Intertec (www.intertek.com) to UL standards 913, 60079-0, 60079-11 and CSA C22, no. 157; for use in a hazardous atmosphere; Class 1, Div 1, Groups C & D, and T3.

For Europe and other parts of the world, the ChemDAQ Steri-Trac also has a CE mark for electrical safety and EMI. The electrical safety and EMI testing was performed and is certified by Met labs (www.metlabs.com), to EN standards 61010-10 and EN ICES-003. The Steri-Trac system is not currently ATEX certified for use in hazardous/classified areas (where there is a risk of explosion), but we will be applying for ATEX later this year.

In the intrinsic safety configuration the sensor module is placed in the classified area and is isolated from the monitor located in a safe location, by a barrier box.

Placement of Monitors

An area monitor, as the name suggests, is intended to monitor an area to determine if and when it is safe for people to be there. If the concentration of the target gas is too high, then the area monitor will provide an alert and workers can correct the problem or leave the area. If an area is evacuated, the monitor serves to both warn others not to enter the affected area and to show when it is safe to return.

Area monitors should be placed close to potential sources of the gas or vapor being monitored, so for example if the gas[21] is hydrogen peroxide used for hospital sterilization, then the monitors should be placed close the sterilizer. An area monitor should detect the gas before it reaches the people working in the area. The monitors should be placed at a height similar to breathing zone for most people, typically about five feet (1.5 m) off the floor. The sensor or sampling point should be open to air and not covered or blocked.

Range of Monitor

A common question is how far can a gas monitor detect gas, and the accurate answer for diffusion type sensors is that the sensors detect only the gas that reaches them. It is possible to model the gas diffusion in static air, but the results are of little use because this model does not apply to real life. In a typical hospital sterilization department with large air turnovers (e.g. > ~10 turnovers/hr) it is difficult to predict how far the gas will travel because of the rapid turbulence of the air. Gas detection instrument manufacturers use a rule of thumb that gas monitors have a maximum radius of detection of about 4 feet (1.2 m) and so two gas monitors should be no more than 8 feet apart (~3m).

Distance Between Monitors

However, the optimum design of the gas monitoring system must take into account the placement of the gas sources, e.g. (sterilizers), abators and ventilation relative to the operator. If the operator is very close to the gas source, then the gas monitors should be closer. For example if the only gas source is 10 feet away from the operator and the monitor is between the gas source and the operator, that one monitor will suffice since the gas has to pass the monitor to reach the operator. If however, the gas source is close to the operator, such as a hospital sterilizer immediately in-front of the operator, waiting to be unloaded, then a monitor four feet way would be ineffective. In this last scenario, the monitor should be placed as close as possible to the sterilizer door, and in many cases it is preferably placed directly over the door.

[21] In normal usage, a compound in the air is considered to be a gas if the boiling point of the compound is below ambient temperature, but a vapor if the boiling point is above ambient. In this report the terms gas and vapor are used interchangeably.

Hospital Chemical Sterilizers and Reprocessors

Wall mounted Small Sterilizers

We are often asked about the best placement of a monitor on or near a small sterilizer of the type commonly used in hospitals. These sterilizers are about the size of a home dishwasher and may be either free standing or wall mounted.

If the sterilizer is wall mounted, then we recommend placing a monitor on the wall close to the front of the sterilizer. Sterilizers can potentially leak from the door when it is opened and so we need a monitor close by to provide suitable warning. This is particularly true in situations where users regularly open the sterilizer door and reach in to remove the load. Ideally, the monitor is closer to the gas source than the operator, but for operations such as unloading a sterilizer, the monitor should be placed as close as possible.

If there is a risk of leakage from the back of the sterilizer, then a monitor should be placed there as well. A monitor at the back is especially important where the rear of one or more sterilizers is in a utility space, such that any leak may build up in there and affect anyone entering the area.

Free Standing Small Sterilizers

If the sterilizer is a free standing unit, the sensor should be placed above the door (ChemDAQ's remote sensor) and have a monitor on a nearby wall. If above the door is not possible, then as close to the front of the sterilizer as possible. Sterilizers can sometimes emit gas or vapor when the door is first opened after a cycle. We have seen 30 to 40 ppm hydrogen peroxide be emitted by some sterilizers each time the door was opened, significantly higher than the OSHA PEL of 1 ppm (8 hr TWA)[22] and similar magnitude to the NIOSH Immediately Dangerous to Life and Health value (75 ppm).[23]

Where there are several free standing sterilizers in a row, the best configuration is to have a sensor over every door to provide protection as described above. In some cases, finances that a monitor is placed between each pair of sterilizers. This configuration will detect major leaks of gas or vapor but will not provide warning against small releases of gas or vapor when the sterilizer is opened. If the sub-optimal configuration is used, then work practices should be adopted to ensure that operators are not exposed, for example, at the end of a cycle open the door and wait a short time for any vapors to disperse before emptying the load.

Endoscope Reprocessors

[22] 29 CFR 1910.1000; Tabl Z-1.

[23] http://www.cdc.gov/niosh/idlh/intridl4.html, retrieved 2/12/14

Many endoscope reprocessors etc. have tops that open and so it is not easy to mount a sensor on top of them. In these cases, the sensor should be mounted as close as possible, where it is not in the way. The sensor may be wall mounted or mounted to a post. Typically, the sensor and monitor are mounted on the wall behind the reprocessor but if space is limited then the sensor should be mounted as a remote sensor with the monitor located at a convenient location further away, but where it can easily be seen by the operator. As with the free standing sterilizer, if the sensor is located further back from the reprocessor it is advisable to step back when opening the lid at the completion of a cycle for a moment to allow any vapors to disperse before removing the endoscope.

Placement of Remote Displays

The purpose of gas monitoring is to prevent employee exposure and remote displays play a valuable role. If there is an area monitor in a room, where there is a the potential for a major gas or vapor leak, such that there would be a significant risk to anyone walking into the room, then a remote display on the entrance way makes sense. The remote display is connected to the monitor and mirrors the display on the monitor. Thus a person about to enter the room can see at a glance what the gas/vapor concentration is inside and act accordingly. The remote display is located wherever it will most easily be seen. Typical locations are above the door, or next to the door. If the door has window in it, such that a person outside about to enter can easily read the monitor display, then the remote display is normally not needed.

Placement of DAQ

The placement of the DAQ needs to serve several purposes. In normal operation, the DAQ calculates and if necessary sounds the TWA alarms and so the DAQ must be placed near the work area. In addition, for routine practice of printing reports etc., the DAQ should be in a convenient location. However, in the unlikely event of a major leak where the work area is evacuated, the DAQ should still be accessible in order to determine when it is safe to return.

If the DAQ is located in the manager's or supervisor's office, this location may be a problem in an emergency situation if the office is within the affected area. One solution is to place remote video displays in the work area so that operators can see the TWA values and receive the alarm and the DAQ itself can be placed further away. The remote video display mirrors the DAQ's display and so shows the current and TWA exposures for all monitors. Some facilities place a remote video display in the security office so that current gas readings and alarm statuses are available to emergency responders. Another solution is to use a second computer in a remote location and connect to it to the DAQ using

commercial remote access software such as PC anywhere. The advantage of this second approach is that operators can use the other functions of the DAQ (reports, data export, configuration screens) as if they were in front of it.

Work Practices

As previously discussed above incorporating the gas detection system into work practices is important for improving workplace safety and enabling the safe use of the biocidal chemicals.

Some sterilizers may release vapors when they opened at the end of the cycle. For gases such as hydrogen peroxide that have essentially no smell, the monitor provides a reliable way to determine that the concentration is safe. If the remote sensor is placed above the door, then workers can step away from the sterilizer after opening the door and return once the monitor says it is safe to do so. Even for vapors such as peracetic acid which has a smell, few people's noses are sufficiently calibrated to be able to determine the concentration from odor and so determine if the level above or below safe levels.

It is important that the remote sensor be placed above the door and not be pushed back since the plume of gas coming from the sterilizer is likely to completely pass by a sensor that has been pushed away, but the person leaning in to unload the sterilizer may not be so fortunate.

Some users have pushed the sensor back because it kept responding whenever they opened the sterilizer door. Moving the sensor only masks the problem, it does not fix it. It is far better to get the sterilizer serviced (sometimes small gas/vapor leaks are an indicator that maintenance is required) and if that fails to solve the problem, then adapt work practices as discussed previously to crack the door open and use the monitor to tell employees when they can safely approach to unload the sterilizer.

Another common question is whether a monitor for heavier gases and vapors should be placed low because the gas sinks in air. Those who did Chemistry may remember the experiments with pouring heavy gases and vapors like nitrogen dioxide and bromine that form brown clouds that sink to the floor. In some applications where the air is static (man-holes, grain silos and other confined space entry) stratification of gases by mass is an important issue. People who go down manholes sometimes put their monitors at ankle height while descending, so that they will hear an alarm before their head reaches that level. For most common applications with high air turnover, the air turbulence is so great that stratification is not significant. The monitors should therefore be placed at breathing height.

In conclusion, area gas monitors should be placed near the sources of gas so that they can inform people whether it is safe to be in the area and when it is safe to return to an area after a release of gas or vapor. The monitors should be placed at breathing height, ~ 5 feet (1.2m). Every facility is different and so your ChemDAQ representative will work with you to design a system that meets your needs.

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