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CHEMDAQ, INC. - PROTECTING PEOPLE FROM AIRBORNE TOXINS

DISCUSSION OF STERILANT GAS SAFETY IN HEALTHCARE MONITORING TECHNOLOGIES, INDUSTRY NEWS, OSHA REQUIREMENTS, AAMI STANDARDS, BEST PRACTICES & FDA ADVERSE INCIDENT REPORTS.

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Alarm Levels

One question that we frequently get is where to set the alarm levels for ChemDAQ area Steri-Trac® monitors. ChemDAQ monitors provide two user adjustable instantaneous alarm levels, a low alarm and a high alarm. These alarms activate if the current reading exceeds the alarm threshold values. Normally, if the gas concentration drops below the alarm threshold, the alarm will turn off, but the monitor alarms can be set to latch (requiring someone to push the alarm silence button to reset) if the customers so wishes.

Most users connect their area monitors to a ChemDAQ data acquisition computer (DAQ®) and the DAQ displays both the instantaneous alarms from the monitors as well as calculates and displays the time weighted average (TWA) alarms. The TWA alarms are most commonly calculated as an 8 hr TWA (rolling average), but for some gases, such as ethylene oxide short term exposure limits (STELs) calculated as 15 minute TWAs are also used. I apologize for all the acronyms, but they are widely used in this part of the industrial hygiene world.

Time weighted average exposures are used because the effects of many gases are cumulative, at least over short time periods and OSHA permissible exposure limits (PELs) for most gases are expressed as TWAs. For example the OSHA PEL for ethylene oxide and hydrogen peroxide are both 1 ppm calculated as an eight hour TWA. This limit would therefore be met if a person were exposed to ethylene oxide or hydrogen peroxide at 1 ppm for 8 hours, 2 ppm for 4 hours, 4 ppm for two hours, 8 ppm for 1 hour etc.

The DAQ alarms are set at the OSHA PELs where they are available, but the DAQ also has an impending alarm which provides an alert at 50% of the OSHA PEL. The purpose of this alarm is to notify users that there is problem early so that they can take appropriate action to correct the problem before workers have been over exposed.

The question remains as to where the instantaneous alarms on the monitor should be set. Of the two alarms, the lower one is intended to say there is a problem that needs urgent attention and the latter that there is a dangerous

concentration of gas or vapor and everyone needs to leave the area now. For the low alarm, if there is an OSHA PEL or an 8 Hr TWA Threshold Limit Value (TLV) from the ACGIH, then the instantaneous alarms should be set higher than this value, since the latter is an 8 hr time weighted average. As a rule of thumb, ChemDAQ typically sets the low alarms around five times the OSHA PEL; so for hydrogen peroxide or ethylene oxide, the low alarm is set at 5 ppm. If the gas has a 15 minute STEL, then either the STEL or up to around twice the STEL is an appropriate level for the low alarm. Ethylene oxide has a 15 minutes STEL (excursion limit in OSHA parlance) of 5 ppm. There is no OSHA STEL for hydrogen peroxide, but the state of Hawaii and Washington have STELs of 3 ppm and so an instantaneous alarm level around 5 ppm is reasonable. If the gas or vapor has a ceiling level, then half the ceiling level would be an appropriate low alarm threshold. If a vapor for example has an OSHA PEL of 1 ppm ceiling, a reasonable low alarm for the monitor is between 0.5 ppm. If there are no OSHA PELs for the compound of interest, then other reliable exposure limits should be used. For example, there is OSHA PEL for peracetic acid, nor is there a NIOSH recommened exposure limit or ACGIH TLV (the ACGIH has a proposed STEL of 0.4 ppm). Instead users can refer to the EPA's Acute Exposure Guidelines for peracetic acid. There are three AEGL levels, and loosely AEGL 1 is the concentration at which no serious irritation or harm will occur, AEGL 2 is the level where significant irritation will occur, but full recovery is expected, and AEGL 3 is the concentration where disabling irritation or permanent injury may occur. See the EPA website for more detailed explanations. The AEGL 1 for peracetic acid is 0.17 ppm for 10 minutes to 8 hour exposure and so a low alarm around 0.5 to 0.9 ppm would be reasonable.

The Steri-Trac's alarms are user adjustable since the monitors are often used in different ways. For example, some users of hydrogen peroxide sterilizers have found that when they first open the door there is a release of a high concentration cloud of hydrogen peroxide (~30 ppm sometimes). Unfortunately, the sterilizer manufacturer has indicated that the problem is not easily remedied. Therefore the hospital tells its people to open the sterilizer door at the completion of the cycle, step away and only unload the sterilizer once the monitor shows that it is safe to do so. In this situation, the hospital is using the monitor to keep its people safe, but they do not want the monitor going into alarm every time the sterilizer door is opened. In this situation, it makes sense to raise the low alarm level to a level above the routine exposure since the routine exposure though high is already managed through appropriate work practices.

As mentioned above, emission of hydrogen peroxide is not infrequent on opening the sterilizer door at the end of the cycle for certain models. The sterilizer technicians are sometimes unable to address the problem; perhaps because most of them do not carry gas monitors and so have no way to verify whether a sterilizer is leaking or not beyond internal pressure changes. We have had several cases where the customer has been told by the sterilizer service technician that the problem is that the monitor to 'too sensitive' and that

the sensor should be moved away. The monitors are designed around the OSHA or other established exposure limits, so they are not too sensitive. The best solution is to stop the leak, but if the sterilizer manufacturer is unable or unwilling to correct the problem, another approach is to employ work instructions using the gas monitor to ensure that workers are not over exposed, as discussed earlier. Moving the sensor away from the sterilizer door is not the answer, since the area by the open door is the breathing zone for someone unloading the sterilizer and moving the sensor away just masks the problem.
The alarm levels for the Steri-Trac's high alarm are also user adjustable. The purpose of the high alarm as mentioned earlier is to warn people that there are dangerous concentrations of gas or vapor present and that they should leave the area. Appropriate levels are typically twenty to forty times the OSHA PEL. If there is a NIOSH Immediately Dangerous to Life and Health (IDLH) that falls lower than this value, then the high alarm level should be set to about half the IDLH. If there is no NIOSH IDLH, then other exposure levels or information about the compound can be used to assess the hazard, such as the EPA's AEGL-3 discussed above.

OSHA defines the IDLH as:
An atmospheric concentration of any toxic, corrosive or asphyxiant substance that poses an immediate threat to life or would cause irreversible or delayed adverse health effects or would interfere with an individual's ability to escape from a dangerous atmosphere." [29 CFR 1910.120]
In summary, the instantaneous alarms on the Steri-Trac are user adjustable because the optimum value may depend on how the how the monitor is being used. Most users employ the factory set alarm thresholds that will work well for most applications; but for those users who applications may be a little different from typical, this blog is intended to provide some simple rules of thumb that can be used to select the alarm thresholds.

If you need more information or assistance, please contact ChemDAQ at 800-245-3310 Ext 560.