



November 12th, 2009

OSHA Docket Office
US Department of Labor
200 Constitution Avenue NW
Washington DC, 20210

Docket No. OSHA-2009-0035

Re. Standard on Ethylene Oxide (EtO); Extension of the Office of
Management and Budget's (OMB) Approval of Information Collection
(Paperwork) Requirements

Dear Sir,

This letter is in response to OSHA's request for comments on the approval of information collection requirements.

I am Chief Technology Officer and General Counsel with ChemDAQ Inc. I have worked in the gas detection industry for over twenty years, with several of the major gas detection companies. My work has mainly been focused on gas detection technology and I am an inventor on over 25 US patents related to gas detection and I am very familiar with the current state of the art of gas detection.

My employer, ChemDAQ Inc. is a manufacturer of fixed point gas monitors, including instruments that provide continuous monitoring for ethylene oxide, with real time readings and alarms in the event of an exposure to ethylene oxide, automatic calculation of time weighted average readings (TWA) and alerts if the TWA exceeds the OSHA action level as defined in 1910.1047(b) and automatic record keeping.

My response to your request for comments is in the attached memorandum.

Yours sincerely

P. Richard Warburton, Ph.D.
Chief Technology Officer & General Counsel

Memorandum

Prepared by: P. Richard Warburton, Chief Technology Officer & General Counsel,
ChemDAQ Inc.

Date: November 12th, 2009

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Docket No.: OSHA-2009-0035

Comments Solicited by OSHA

OSHA posed four questions for comment regarding the 29 CFR 1900.1047 occupational safety regulations for use of ethylene oxide. The questions were:

1. Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
2. The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
3. The quality, utility, and clarity of the information collected; and
4. Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

Summary of ChemDAQ's Response

- 1) The information collection requirements fail to meet several of the requirements specified in the regulations; the information collected is only marginally useful and fails to satisfy the proper performance of the agency's function which is to promote a safe work environment.
- 2) ChemDAQ Inc. offers no opinion regarding OSHA's estimate of the burden (time and costs) of the information collection requirements.
- 3) The methodology used is to collect ethylene oxide exposure data is flawed because it is misleading and falsely induces users to believe they have satisfied the requirements of the regulations. The choice of information collected is premised on the unreasonable assumption that ethylene oxide emissions from equipment are invariant with time and thus it fails to protect workers from potential exposure to ethylene oxide and fosters a false sense of security.
- 4) Automated and cost effective methods are readily available from several manufacturers that will not only minimize the burden on employers and enhance

worker safety but will also satisfy the regulations in those sections where the current information collection requirements are lacking.

- 5) ChemDAQ recommends that the OMB approval not be granted for the information collection requirements specified in the Ethylene Oxide standard 29 CFR19101.1047 since these information collection requirements as currently implemented fail to fulfill the obligations of the OSH Act of 1970 and fail to adequately promote workplace safety.

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Discussion

- 1) SOLICITATION OF COMMENTS ON WHETHER THE PROPOSED INFORMATION COLLECTION REQUIREMENTS ARE NECESSARY FOR THE PROPER PERFORMANCE OF THE AGENCY'S FUNCTIONS, INCLUDING WHETHER THE INFORMATION IS USEFUL.

The Current and Proposed Information Collection Requirements Fail to Provide Proper Performance of the Agency's Function

The current and proposed information collection requirements fail to satisfy the requirement of 1910.1047(c)(1) that "the employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an (8)-hour time-weighted average (8-hour TWA)."

The procedure under 1910.1047(d)(1)(ii) requires that a *"Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area. ..."* However, the requirement is that *'the employer shall ensure that no employee is exposed ...'* is not achieved by occasional sampling. The word *'ensure'* means *'to make certain of getting or achieving'* [The New Lexicon Webster's Dictionary of the English Language, 1989 Edition]. Equipment for handling ethylene oxide is similar to any other type of equipment in that it can fail, wear out, or be subject to operator error. Showing that there was no ethylene oxide in the employees' breathing zone at one time does not ensure that no employee is exposed to an airborne concentration of EtO in excess of 1 ppm since circumstances at different times will never be identical.

Leaks can and do occur from ethylene oxide sterilizers and other equipment. For example, Health Devices¹ reported an instance where nearby employees were exposed to EtO from a faulty connection to a gas cylinder. Occasional sampling for ethylene oxide may detect a continuous egression of EtO from equipment, but it will not detect the sudden and unexpected emissions resulting from operator error or sudden equipment failure. I know of a large user of ethylene oxide that recently experienced a large and sudden leak of ethylene oxide because a door seal ruptured. It is fortunate that this facility had a continuous ethylene oxide monitor in place at the time that provided an instantaneous alarm. Without this continuous monitor, it is likely that nearby workers would have been exposed to high concentrations of ethylene oxide.

Since these sudden and unexpected leaks can and sometimes do occur, the employer cannot ensure that no employee is exposed to 1 ppm EtO (8 Hr TWA) with the current information gathering requirement of occasional sampling, and thus the recommended sampling procedure does not satisfy the requirement of 1910.1047(c)(1). Therefore taking a representative 8-hour TWA employee exposure determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each

¹ Health Devices Dec 1994;23(12):493; Full text available from http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8234, retrieved 12/5/06



work area does not ensure that no employee is exposed to more than the PEL of ethylene oxide. Therefore the current and proposed information collection requirements fail to satisfy the requirement of 1910.1047(c)(1) and the Current and Proposed Information Collection Requirements Fail to Provide Proper Performance of the Agency's Function.

The current and proposed information collection requirements fail to satisfy the requirements of section 6(b)(5) of the Occupational Safety and Health Act of 1970 and thus the collection methods are failing to provide proper performance of the Agency's function.

Section 6(b)(5) of the Occupational Safety and Health Act of 1970 (OSH Act) states that:

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. ...

The current sampling protocol in 1910.1047 does not account for unexpected leaks of EtO that may occur and thus does not adequately assure that no employee will suffer material impairment. The hazards associated with exposure to EtO are well documented based on the best available evidence [1910.1047(j)(1)(i)].² Cost effective continuous monitoring equipment is available from several manufacturers that will provide alerts in the event of an EtO leak and thus continuous monitoring is not only feasible but readily available. Thus the current information collection methods fail to address the requirements of the OSH Act and the Agency's functions, since OSHA derives its authority from this Act.

The periodic leak surveys required under Section 1910.1047(f)(2)(ii) will not ensure that no employee is exposed to 1 ppm EtO (8 Hr TWA) as required 1910.1047(c)(1) and thus the current information collection requirements fail to address the requirements of section 1910.1047(f)(2)(ii) and these information collection requirements are failing to provide proper performance of the Agency's function

OSHA has recognized in the past that leaks can and do occur and requires use of respirators or continuous monitoring for operations such as changing the tanks on EtO sterilizers. Section 1910.1047(f)(2)(ii) requires that *"The compliance program shall include a schedule for periodic leak detection surveys and a written plan for emergency*

² See for example information available through NIOSH Safety and Health Topic: Ethylene Oxide, available at <http://www.cdc.gov/niosh/topics/ethyleneoxide/>, retrieved 12/15/06

situations, as specified in paragraph (h)(i)³ of this section.” It is well known that leaks can occur in, for example, EtO sterilizers. NIOSH has noted that:

Accidental releases of EtO may occur from several sources, including cartridges, sterilizer discharge lines, and EtO supply cylinders. Single-dose cartridges usually contain 67, 100, or 134 g of EtO, depending on their size. An 8.8-foot³ sterilizer uses a mixture of EtO (12% by weight) and dichlorodifluormethane, and it discharges approximately 150g of EtO into the drain during each purge cycle. A typical large supply cylinder for the 12:88 gas mixture contains 7,000 g of EtO.

Because the odor of EtO cannot generally be detected below approximately 700 ppm,⁴ workers can be exposed to high concentrations of this compound without knowing it. A relatively small quantity of EtO in an average room can create concentrations that are many times the exposure limit. For example, 1 g of EtO can create a concentration of more than 20 ppm in a 10- by 10-foot room with an 8-foot ceiling. [NIOSH, 1989]⁵

In the last two years some of ChemDAQ’s customers have experienced ethylene oxide leaks in hospital sterilization systems, including leaks due to a failure of the exhaust fan, leaks from the exhaust duct work and a recent case of leaks near the rear of a sterilizer (exact source is under investigation).

OSHA recognizes that ethylene oxide emission can and sometimes does occur during operations such as changing of ethylene oxide tanks on sterilizers; [1910.1047(f)(1)(iii)] and requires the use of respiratory protection for such operations [1910.1047(f)(1)(ii)], but without continuous monitoring how is an employee to know when it is safe to remove the respirator, or when it is safe for that employee or other employees to reenter that location without respiratory protection.

Since leaks can and do occur, and leaks are unexpected because to the extent they are predictable, they will be corrected before they occur. Unknown leaks may pose a significant risk of exposure of employees to ethylene oxide. Since the existence and magnitude of a leak is unknown to the employer prior to the next periodic leak survey, periodic leak surveys required under Section 1910.1047(f)(2)(ii) cannot ensure that no employee is exposed to 1 ppm EtO (8 Hr TWA) as required 1910.1047(c)(1). Thus the current information collection requirements fail to provide employee protection against

³ 1910.1047(h)(1)(i) “A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.”

⁴ Citing Clayton, G.D., Clayton F.E. (Eds.) (1978) Patty’s Industrial Hygiene and Toxicology, 3rd Ed. Vol. 2a Toxicology, New York, NY Wiley Interscience, p. 2186.

⁵ Control Technology for Ethylene Oxide Sterilization in Hospitals, September, 1989, DHHS (NIOSH) Publication No. 89-120; available from <http://www.cdc.gov/niosh/89-120.html>, retrieved 12/13/06



exposure to ethylene oxide and thus the collection requirements are failing to provide proper performance of the Agency's function.

The current and proposed information collection requirements fail to satisfy the requirement of 1910.1047(c)(2) "Excursion limit." The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes and thus these information collection requirements are failing to provide proper performance of the Agency's function

The procedure under 1910.1047(d)(1)(ii) requires that "... *Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.*" If an employer follows this procedure, then the employer will fail to "ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes" since this procedure would only function if the employer could be certain that the employee's exposure was consistent from day to day, week to week and year to year. This is an impossibility since this procedure will only measure the normal routine ethylene oxide exposures, it will not measure non-routine exposures. Since any equipment can fail or malfunction there will always be the possibility of non-routine exposures in the workplace. Short term exposures such as leaks from EtO plumbing or from faulty EtO sterilization equipment are inherently unpredictable because to the extent such problems are predictable responsible employers will ensure these problems are rectified in advance. Thus the procedure in section 1910.1047(d)(1)(ii) fails to meet the requirements of 1910.1047(c)(2) that an "*employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.*" Thus the current information collection requirements fail to provide employee protection against exposure to ethylene oxide and thus the collection requirements are failing to provide proper performance of the Agency's function.

Section 1910.1047(d)(4)(ii) Allows an employer to cease monitoring for ethylene oxide thus failing OSHA's mission statement to "assure the safety and health of America's workers by setting and enforcing standards; ... and encouraging continual improvement in workplace safety and health."

The current and proposed information collection protocol fails to meet the proper performance of the Agency's functions and provide information of only limited use. The current information collection requirements in section 1910.1047(d)(2) require only an initial assessment of the ethylene oxide concentration in the workplace atmosphere, but if the concentration of EtO at two initial testing times a week apart is below the action level of 0.5 ppm, then section 1910.1047(d)(4)(ii) allows that further monitoring can be discontinued. Retesting is only required under section 1910.1047(d)(5) if "*whenever there has been a change in the production, process, control equipment, personnel or*

work practices that may result in new or additional exposures to EtO or when the employer has any reason to suspect that a change may result in new or additional exposures.” The allowed discontinuance of further monitoring under section 1910.1047(d)(4)(ii) means that no further monitoring is required despite aging of the equipment, potential employee error etc. This abandonment of the requirement for future monitoring under 1910.1047(d)(4)(ii) means that OSHA is failing its mission “*to assure the safety and health of America's workers by setting and enforcing standards; ...; and encouraging continual improvement in workplace safety and health*”⁶ and is failing to require useful information to be obtained. By not requiring on-going monitoring, it not possible to assess the current status of employee exposure to ethylene oxide and thus OSHA is failing its mission to both assure the safety and health of America's workers by setting and enforcing standards and to encourage continual improvement in workplace safety and health.

The current and proposed information collection requirements fail to satisfy the requirement of 1910.1047(h)(2) that “Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly.”

The current and proposed information collection requirements fail to provide proper performance of the Agency's functions of promoting a safe work environment, fail to meet the requirements of the regulation in section 1910.1047(h)(2) that requires means to alert employees in the case of an emergency release of EtO and fail to produce information that is useful. An emergency is defined in 1910.1047(b) as “*any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of EtO.*”

According to the EPA, the odor threshold for ethylene oxide is 430 ppm,⁷ therefore the ethylene oxide concentration must be at least 800 times the action level of 0.5 ppm in 1910.1047(b) before the ethylene oxide becomes perceptible to human senses. Other sources place the odor threshold at higher values,⁸ probably reflecting variation from person to person. The exposure monitoring of 1910.1047(d) would not detect a leak of ethylene oxide until the next regular leak test of the EtO system under 1910.1047(f)(2)(ii) and the emergency would not be detected unless employees heard the hiss of escaping gas or the concentration of EtO had already exceeded the human odor threshold at which point the employees have been subjected to a hazardous exposure to EtO.

⁶ OSHA's mission statement: available at <http://www.osha.gov/oshinfo/mission.html>, retrieved 12/6/06.

⁷ Ethylene Oxide - Hazard Summary-Created in April 1992; Revised in January 2000; citing J.E. Amoores and E. Hautala. Odor as an aid to chemical safety: Odor thresholds compared with threshold limit values and volatilities for 214 industrial chemicals in air and water dilution. Journal of Applied Toxicology, 3(6):272-290. 1983. Available at <http://www.epa.gov/ttn/uatw/hlthef/ethylene.html#ref7>, retrieved 12/6/06.

⁸ Odor threshold for EtO is 700 ppm; “Healthcare hazard control and safety management” J.T. Tweedy; (2005), CRC Press, p238

The current value for the concentration of ETO which is immediately dangerous to life and health (IDLH) as determined by NIOSH is 800 ppm.⁹ Thus the IDLH concentration is similar magnitude to the odor threshold, with estimates at 430 ppm and 700 ppm (see above) and likely to vary considerably between individuals.¹⁰ Thus even for employees with an acute sense of smell, ethylene oxide will only become perceptible near the IDLH and for less odor-perceptive employees the concentration of ethylene oxide is likely to have exceeded the IDLH before they are able to sense its presence. The NIOSH definition for an immediately dangerous to life or health condition, is a situation

*"that poses a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from such an environment."*¹¹

OSHA's definition of the IDLH is similar: *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.* [1910.120(a)(3)].

Thus an unexpected release of EtO that exceeded the IDLH could be imperceptible to some workers, result in prolonged exposure and yet the employer would still be in compliance with the current information collection requirements. Thus the current information collection requirements fail to *"To assure safe and healthful working conditions for working men and women; by authorizing enforcement of the standards developed under the Act; ..."*¹²

Section 1910.1047(h)(2) requires that *"Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly."* Since OSHA recognizes that leaks can and do occur in 1910.1047(f)(2)(ii), anytime that high concentrations of EtO are being employed there is the possibility of employee exposure to EtO in the event of an emergency. An emergency as defined in 1910.1047(b) reflects the unusual, the unexpected, the uncontrolled release of EtO. The current information gathering requirements of the 1910.1047 regulation not address how section 1910.1047(h)(2) is to be implemented. The requirement of 1910.1047(h)(2) that *"means shall be developed to*

⁹ Documentation for Immediately Dangerous to Life or Health Concentrations (IDLH): NIOSH Chemical Listing and Documentation of Revised IDLH Values (as of 3/1/95), NTIS Publication No. PB-94-195047. Available from <http://www.cdc.gov/niosh/idlh/intridl4.html>, retrieved 12/13/06.

¹⁰ For example in "Human Odor Detectability: New Methodology Used to Determine Threshold and Variation;" James C. Walker¹, Sandra B. Hall², Dianne B. Walker¹, Martin S. Kendal-Reed¹, Alison F. Hood¹ and Xu-Feng Niu²; Chem. Senses 28: 817-826, 2003, the odor threshold to n-amyl acetate was found to vary between individuals by over twenty times. Full text of report available at <http://chemse.oxfordjournals.org/cgi/content/full/28/9/817>

¹¹ Documentation for Immediately Dangerous to Life or Health Considerations (IDLH): Introduction; NTIS Publication No. PB-94-195047; <http://www.cdc.gov/niosh/idlh/idlhintr.html>

¹² "Occupational Safety and Health Act of 1970." Introduction. Public Law 91-596, 84 STAT. 1590, 91st Congress, S.2193, December 29, 1970,, as amended through January 1, 2004. (1).



alert potentially affected employees of such occurrences promptly” requires continuous monitoring for ethylene oxide. Once ethylene oxide has been detected, an alert must be given promptly to potentially affected employees.

The means to satisfy section 1910.1047(h)(2) are readily available from several supplies and consist of a continuous monitor for ethylene oxide that incorporates an alarm system. While the regulation is designed to provide flexibility to the employer regarding the means of satisfying section 1910.1047(h)(2); it would be beneficial if the information gathering requirements ensured the performance of the means employed. Unfortunately the current and proposed information collection requirements do not address section 1910.1047(h)(2) at all and so fail to provide the proper performance of the Agency's functions, i.e. to provide for safe work environments and the information collection requirements fail to meet satisfy the requirements of the regulation in 1910.1047(h)(2).

OSHA has commented before that section 1910.1047(h)(2) is not intended to specify the method of compliance, but merely state the requirements that employers must meet.¹³ This functional approach has many benefits, including avoiding obsolescence as new technology becomes available and giving employers freedom to adapt the best method for their particular application. However, if a standard provides detailed information collection requirements such as those in the subsections of 1910.1047(d), then users are likely to consider satisfaction of these detailed requirements as satisfaction of the much more limited verbiage performance standards such as in section 1910.1047(h)(2), i.e. confusion. Such confusion acts counter to the Proper Performance of the Agency's Function. It would be much more preferable to delete the information requirement sections of for example 1910.1047(d) and replace them with simple direct performance requirements. See Recommendations for Changes to 1910.1047.

The information collection requirements of 1910.1047 emasculate the standard such that it provides less worker protection than does the general air contaminants standard 1910.1000 and thus the informational collection requirements fail to support the proper performance of the Agency's functions.

While ethylene oxide and other carcinogens have their own standards to promote greater safety in the use of these especially hazardous chemicals, in practice, the 1910.1047 standard has in places reduced the required protection due to employees. For example with regard to controlling exposure to toxic gases, the 1910.1000 standard provides that

An employee's exposure to any substance in Table Z-1 [Table Z-1 Limits for Air Contaminants. - 1910.1000 TABLE Z-1], the exposure limit of which is not preceded by a "C", shall not exceed the 8-hour Time Weighted Average given for that substance any 8-hour work shift of a 40-hour work week. 1910.1000(a)(2).

¹³

Standard Interpretations 12/11/1998 - Use of ethylene oxide alarm systems with sensors. From Richard E. Fairfax Director, Directorate of Compliance Programs; To Mr. Darrel Giraud, Florida Area Manager, Kem Medical Products Corp., dated 12/18/1998, available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22664; retrieved 12/13/06.

In contrast the corresponding section for 1910.1047 reads:

"8-hour time-weighted average (TWA)." The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an (8)-hour time-weighted average (8-hour TWA). 1910.1047(c)(1).

Whereas the former requires employers to prevent employee exposure to exceed the time weighted average over **ANY** 8 hour period, the later, for EtO only employers to prevent exposure over **AN** 8 hour period, the period of sampling. This difference is a significant decrease in the duty of an employer to the employees who handle carcinogenic gas (e.g. EtO, PEL 1 ppm) compared to a simple toxic, but non-carcinogenic gas like carbon monoxide (PEL 50 ppm). This reduction in protection for ethylene oxide compared to other toxic air contaminants fails to support the proper performance of the Agency's functions. It is recommended that 1910.1047 be modified to reflect the same exposure control requirements as 1910.1000 (see below).

Recommendations for Changes to 1910.1047

I recommend that the 1910.1047 regulation be modified so that it provides the performance metrics that must be met, but leave out the more confusing and obsolete of the information collection requirements. The changes are intended to address the major flaw with the current information collection requirements in that they imply that there is only a one time or occasional duty to ensure that workers are not exposed to excessive concentrations of ethylene oxide. The proposed changes below reflect a continuing duty on employers to ensure a safe work place (reflecting the General Duty clause of the OSH Act, section 5(a)) and thus a continuing duty to ensure that employee are not exposed to ethylene oxide above the 8 hour and 15 minute TWA limits, similar to the requirements in 1910.1000(b)(1) written for toxic air contaminants. In the suggested changes below text struck out is deleted, text underlined is added and comments in brackets, to the current version of 1910.1047.

1910.1047(c)(1)

"8-hour time-weighted average (TWA)." The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an (8)-hour time-weighted average (8-hour TWA) in any 8-hour work shift of a 40-hour work week. [Modified to reflect the language in 1910.1000(b)(1)]

1910.1047(c)(2)

"Excursion limit." The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a any sampling period of fifteen (15) minutes.

1910.1047(c)(2)



"Excursion limit." The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over ~~a sampling period~~ of fifteen (15) minutes.

Delete sections 1910.1047(d)(1)(ii) to 1910.1047(d)(5)

In summary, the information the proposed information collection requirements are not necessary for the proper performance of the Agency's functions, and furthermore hinder the proper performance of the Agencies functions and additionally these requirements provide scant useful information.

2 SOLICITATION OF COMMENTS ON THE ACCURACY OF OSHA'S ESTIMATE OF THE BURDEN (TIME AND COSTS) OF THE INFORMATION COLLECTION REQUIREMENTS, INCLUDING THE VALIDITY OF THE METHODOLOGY AND ASSUMPTIONS USED

ChemDAQ Inc. expresses no opinion as to the accuracy of OSHA's estimate of the burden of time and costs of the information collection requirements.

3) SOLICITATION OF COMMENTS REGARDING THE QUALITY, UTILITY, AND CLARITY OF THE INFORMATION COLLECTED

The purpose of the 1910.1047 ethylene oxide standard is to promote worker safety from ethylene oxide, a known human carcinogen [IARC]¹⁴ and treated by OSHA as a known or suspected human carcinogen,¹⁵ however the current information collection methodology fails to protect worker safety.

The information gathering requirements only provide limited useful information since they fail to address unexpected emissions of ethylene oxide.

NIOSH recommends the use of continuous monitoring to warn workers of unexpected ethylene oxide emissions.

One time sampling or occasional sampling will not protect against unexpected releases of ethylene oxide, since if ethylene oxide is not being detected at the time of release, warnings will not be given and employees will not be protected. NIOSH recommends the use of continuous monitoring near ethylene oxide sterilizers.

¹⁴ International Agency for Research on Cancer, Overall Evaluations of Carcinogenicity to Humans, List of all agents evaluated to date, As evaluated in IARC Monographs Volumes 1-95. Available from <http://monographs.iarc.fr/ENG/Classification/crthallist.php>, retrieved 12/13/06

¹⁵ Standard Interpretations 10/16/2003 - OSHA-recognized chemicals as carcinogens or potential carcinogens for Hazard Communication purposes. Letter from Richard E. Fairfax, Director Directorate of Enforcement Programs, To Mr. Philip W. Crawford Director Gibbons, Del Deo, Dolan, Griffinger, and Vecchione, Oct. 16, 2003; available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=24730; retrieved 12/12/06. See also 1910.1047(j)(1).

ETO Alarms: Implementing controls for emissions and exposures will reduce the likelihood and severity of exposures; however the potential for an exposure can never be completely eliminated. The possibility of exposures above recommended limits due to accidents or malfunctions will always exist. Accidents can happen, and may involve the release of large amounts of EtO. Because the odor of EtO cannot be detected at concentrations much less than 700 ppm, workers can be exposed to potentially harmful amounts of EtO without knowing it, and sensors and alarms are needed to warn of elevated EtO concentrations....
[NIOSH, 1989]¹⁶

The information gathering requirements focus on initial and thereafter occasional sampling of ethylene oxide, but do not adequately address the unexpected leak or other emission of ethylene oxide. The information thus gathered is of limited use, whereas if the employer were required to ensure that the TWA EtO concentration was always below the PEL, then the employer generated evidence of such compliance would be much more valuable and would provide much better protection for employees.

The current information gathering requirements allow an employer to essentially abandon collection of exposure data absent substantial changes in the work practices.

Section 1910.1047(d)(4)(iii) states that *If the initial monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure to be at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by the initial monitoring.* Thus whereas the 1910.1000 standard requires an employer to ensure exposure does not exceed the TWA PEL, the information gathering requirements of 1910.1047 not only does not require an employer to ensure exposure is below the PEL but grants a waiver from all future monitoring absent substantial changes in work practices. Not only is the information gathered under 1910.1047 of limited value, but 1910.1047(d)(4)(iii) allows essential abandonment of the requirement to gather almost any exposure information at all. For example, whereas an employer using acetone [PEL 1000 ppm]¹⁷ must ensure that employee exposure does not exceed the PEL in any 8 hour work period, and must be able to demonstrate that any employee exposure was below the PEL for any 8 hour shift, an employer using EtO (a carcinogen with a PEL of only 1 ppm) does not under 1910.1047(d)(4)(iii) need to do any further measurement beyond an initial safe value. The current information gathering requirements allow an employer to essentially abandon collection of exposure data absent substantial changes in the work practices and is a much lower standard than for other toxic air contaminants.

¹⁶ Control Technology for Ethylene Oxide Sterilization in Hospitals, September, 1989, DHHS (NIOSH) Publication No. 89-120; available from <http://www.cdc.gov/niosh/89-120.html>, retrieved 12/13/06

¹⁷ Regulations (Standards - 29 CFR), TABLE Z-1 Limits for Air Contaminants. - 1910.1000 TABLE Z-1



The collection of data from only an initial sampling means that the data collected is of very limited utility, and so limited quality and limited clarity. Data from one point in time lacks the quality of data obtained over time. Thus the current and proposed information gathering requirements fail to provide information of adequate quality, utility or clarity.

OSHA already recognizes the advantages of continuous monitoring
OSHA has already recognized this advantage of continuous monitoring and has issued an interpretation that continuous monitors be used in locations of potentially high exposure to ethylene oxide that would otherwise require respiratory protection.

The intent of the requirement at 1910.1047(g), [Respiratory protection and personal protective equipment] to prevent exposure from a situation where potentially high, unexpected exposures could occur, could alternatively be met by providing real-time, continuous exposure monitoring (instantaneous readout), of the area where the EtO tanks are maintained. Such monitors would, additionally, need to be triggered to an emergency alarm for employee evacuation of the area in the event of a leak or sudden release of EtO. In the event of such an emergency, employers must assure that the emergency procedures required under 1910.1047(h) are followed.¹⁸

OSHA later clarified this opinion by stating that it does not apply to the personnel actually changing the ethylene oxide tanks because of the risk of sudden high exposure to ethylene oxide.¹⁹ It would be beneficial to worker safety if the current information gathering requirements matched OSHA's interpretation of the regulations. The failure of the current information gathering requirements to match OSHA's interpretation results in the information gathering requirements having a lower quality, utility and clarity than if the interpretation were included.

4) SOLICITATION OF COMMENTS REGARDING WAYS TO MINIMIZE THE BURDEN ON EMPLOYERS WHO MUST COMPLY; FOR EXAMPLE, BY USING AUTOMATED OR OTHER TECHNOLOGICAL INFORMATION COLLECTION AND TRANSMISSION TECHNIQUES

Review of the Burdens on Employers

¹⁸ Standard Interpretations. Letter from Patricia K. Clark, Director, Directorate Compliance Programs to Mr. George L. Notarianni, Logan Associates, Inc.; Jan. 29, 1992. - Respiratory Protection Under OSHA's Ethylene Oxide (EtO) Standard. Available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=20539; retrieved 12/12/06.

¹⁹ Standard Interpretations 03/01/1993 - Ethylene oxide tank changing operations. Letter from Roger A. Clark, Director, Directorate of Compliance Programs, to Richard F. Andree, CSP, PE, Ph.D., Executive Vice President, Safety and Health Management Consultants, Inc., March 1, 1993, available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21047, retrieved 12/12/06

Direct and Extended Costs Associated with Ethylene Oxide Monitoring and Exposure

There are many costs associated with ethylene oxide exposure of employees, both direct and indirect. The most immediate direct costs are the costs of monitoring for the gas. For badges, the immediate cost is the expense of the badges and their subsequent analysis. The next level of cost is the cost of the medical surveillance, cost of the physician's services and full pay to the employee [1910.1047(i)(1)(ii)] as well as lost production. If employees become ill because of exposure to ethylene oxide, the employer will be responsible for their medical costs, and the costs of replacement workers. There are additional costs associated with increased insurance, workman's' compensation and the bad publicity resulting from poisoned employees. Since ethylene oxide is known to be a tumorigen, mutagen, reproductive effector and a primary irritant²⁰ any resulting injury to the employees including cancer in later life, may give rise to law suits. The total burden on the employer is more difficult to estimate since it depends upon the extend of discovered ethylene oxide exposure and magnitude of any resulting injuries.

Costs Associated with a Continuous Monitor

For a continuous monitor there is usually an initial up-front charge [rental programs are available from some manufacturers] and a recurring maintenance charge that will vary from manufacturer to manufacturer and on the size of monitoring system. If any ethylene oxide emissions are detected, alerts will be given by the monitoring system and employees can be evacuated or the leak corrected before employees had suffered dangerous exposure levels. If an employer can show that there have been no exposures of employees, then medical surveillance is not required and so cost is reduced. *"The employer shall institute a medical surveillance program for all employees who are or may be exposed to EtO at or above the action level, without regard to the use of respirators, for at least 30 days a year."* [1910.1047(i)(1)(i)(A)].

Furthermore, if the presence of a slow leak is detected by a continuous monitoring system, then prompt action may allow the situation to be corrected before employee exposure to EtO becomes an issue. Monitors from several manufacturers include relays and communications ports that allow the monitor to not only alert employees but to, for example, automatically increase the exhaust ventilation at that location so as to remedy a rising concentration of ethylene oxide before it reaches dangerous levels.

Record Keeping can be simplified with many continuous monitors

One of the burdens imposed on employers by 1910.1047(k)(2)(iii) is to "maintain this [exposure] record for at least thirty (30) years, in accordance with 29 CFR 1910.1020 and to make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying [1910.1047(k)(4)(i)]. Recording and archiving exposure records creates a significant administrative burden on employers. Many of the ethylene oxide detection systems include a computer based data acquisition system that will automatically save and back-up the records and allow ready access to the

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The Registry of Toxic Effects of Chemical Substances, Ethylene oxide , RTECS #: KX2450000.
Available at <http://www.cdc.gov/niosh/rtecs/kx256250.html>, retrieved 12/12/06



records at any time. This automatic record keeping can greatly reduce the record keeping burden placed on employers.

If Ethylene Oxide is Monitored with Badges, Then a Continuous Monitor of Some Kind is Also Required

For monitoring employee exposure with badges, the employer provides the badges to the employees who wear them for a shift, typically eight hours. The badges are then collected and sent to a laboratory that analyzes the badges and sends a written report to the employer which is often not received until several days to a couple of weeks later. The employer will then notify any employees that were exposed [1910.1047(d)(7)], arrange for medical examination as necessary [1910.1047(i)(1)(i)(A)] and store the records for at least thirty years. [1910.1047(k)(3)(iii)]. If an employee is in an environment that contains high concentrations of EtO, the badge will record the high exposure, but it will not provide any warning of that high concentration and will not provide any information that would allow the problem to be rectified until the analysis report is received by the employer. Notification of a past exposure from a badge is not a timely response to ethylene oxide exposure.

In order to meet the requirements of 1910.1047(h)(2) *“Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly”* some form of continuous monitor is required. Obviously a badge is unable to meet this requirement since a two week turn around for the laboratory analysis results to be returned to the employer is not prompt. OSHA does not specifically require a continuous monitor *“the performance language of 29 CFR 1910.1047(h)(2) gives employers the flexibility to choose any effective method of alerting employees, including communications systems, voice communication, or a bell or other alarm.”*²¹

However, a prompt alert will require detection of the ethylene oxide emission and timely notice to employees in that vicinity. Since ethylene oxide is not perceptible to human senses until concentrations near or above the IDLH (see discussion above), human senses cannot be used to detect ethylene oxide for purposes of 1910.1047(h)(2). Therefore, some form of automatic monitoring device is needed, but at a minimum it need only detect an unexpected significant release of EtO constituting an emergency. [1910.1047(b)]. The timely notice can be provided by suitable means including *communications systems, voice communication, or a bell or other alarm*. The cost of whatever type of monitor is employed as required by section 29 CFR 1910.1047(h)(2) should also be included in the burden calculations on the employer in addition to badges.

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Standard Interpretations 12/11/1998 - Use of ethylene oxide alarm systems with sensors. From Richard E. Fairfax, Director, Directorate of Compliance Programs, to Mr. Darrel Giraud, Florida Area Manager, Kem Medical Products Corp.; available from, http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22664



The cost of monitoring the engineering controls required in 1910.1047(f)(1)(i) should be included in the calculation of the burden on the employer.

OSHA recognizes the potential hazards from ethylene oxide and requires that the employer *shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA and to or below the excursion limit, except to the extent that such controls are not feasible.* [1910.1047(f)(1)(i)]. However, without monitoring for the ethylene oxide concentration, an employer cannot know whether they have reduced and maintained the employee exposure to or below the TWA and to or below the excursion limit. As NIOSH noted:

Significant EtO exposures may occur if the ventilation system fails or if its performance deteriorates significantly. Without reliable ventilation system monitors and alarms, the sterilizer operator may be unaware of a malfunction. An accidental release of a large quantity of EtO could contaminate other areas of the facility through the general ventilation system. [NIOSH, 1989]²²

This monitoring, whether by badges or electronic instruments would have to be on a frequent or continuous basis to reduce and maintain the employee exposure levels at the TWA or lower. The cost of this monitoring should also be included in the calculation of the burden on the employer.

Continuous Monitoring Provides a Cost Effective Real Time Response to Ethylene Oxide Exposure

There are many companies that manufacture monitors for ethylene oxide and there are of course differences in the features and capabilities of the various systems available. However, a typical system will consist of several monitoring points that are connected to a central PC based data acquisition system. The monitoring points are located at locations where ethylene oxide emission is possible, for example, for a sterilization application, in front of the sterilizer, behind the sterilizer when the gas is plumbed in or cartridges inserted, and where the gas is stored. There may be additional monitoring as required by the application and systems are typically modular to allow for this custom configuration.

Once installed, the employer has varying degrees of maintenance that needs to be periodically performed that vary with manufacturer. Most sensors require periodic calibration to ensure that the monitor's response meets the accuracy requirements [1910.1047(d)(6)] and this often only requires swapping the old sensor for a fresh pre-calibrated sensor, a process that takes a few seconds, though some manufacturers still require calibration with a test gas.

The majority of monitors provide a continuous measurement of the ethylene oxide concentration, and will initiate a real time visual and audible alarms after the monitor detects an ethylene oxide concentration above threshold levels (usually the excursion

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Control Technology for Ethylene Oxide Sterilization in Hospitals, September, 1989, DHHS (NIOSH) Publication No. 89-120; available from <http://www.cdc.gov/niosh/89-120.html>, retrieved 12/13/06

limit [1910.1047(c)(2)]). Most systems also have the ability to calculate 15 minutes and 8 hour time weighted average exposures and to initiate alarms if the exposure exceed the Excursion limit of the permissible exposure limit of 1910.1047(c)(1). Thus these systems provide the means to satisfy section 1910.1047(h)(2) “Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated from the area in the event that an emergency occurs.”

Continuous Monitors Are An Established Reliable Technology

Continuous monitors have been around for many years, though as with any technology they are subject to continuous improvement. In 1986, the EPA listed the principle available technologies for area monitors for ethylene oxide as infrared, gas chromatography, photoionization, and solid state sensors with ranges down to 1 ppm.²³ In 1989, NIOSH recommended the use of continuous monitors and described the then current state of the art as follows:

Relatively inexpensive EtO sensors and alarm systems are available which could alert workers to an emergency situation involving the presence of a high concentration (greater than 20 ppm) of EtO. Other more sophisticated (and more expensive systems have been developed which could detect elevated concentrations on the order of 1 ppm or less. ...

These devices range from simple, low cost, organic vapor sensors to complex gas chromatograph systems.²⁴

In the same year OSHA’s inspectors also agreed that continuous monitoring is required to meet the requirements of 1910.1047(h)(2)²⁵ Since then continuous monitors have

²³ Locating And Estimating Air Emissions From Sources Of Ethylene Oxide; EPA-450/4-84-007L; September 1986; available at <http://www.epa.gov/ttn/chief/le/ethoxy.pdf>; retrieved 12/12/06

²⁴ Control Technology for Ethylene Oxide Sterilization in Hospitals, September, 1989, DHHS (NIOSH) Publication No. 89-120; available from <http://www.cdc.gov/niosh/89-120.html>, retrieved 12/13/06

²⁵ In 1989 the Little Rock Area OSHA Office issued a Notification (OSHA 2-H) for a violation of 29 CFR 1910.1047(h)(2) because the hospital was using a continuous ethylene oxide monitor with the alarm set to 50 ppm instead of the excursion limit. The basis of this decision is 29 CFR 1910.1047(c)(2) which states no employee shall be exposed to an airborne concentration of ethylene oxide in excess of 5 parts of ethylene oxide per million parts of air (5ppm) as averaged over a sampling period of 15 minutes.” However, upon later review by OSHA issued an opinion that stated that the continuous monitor need not be set at the excursion limit or short term exposure limit to satisfy 1910.1047(h)(2) but could be set at a higher value, but declined to set a value. Standard Interpretations; 04/26/1990 - Clarification of 29 CFR 1910.1047(h)(2) Requirements for Emergency EtO Limit; April 26, 1990; Memorandum For: Gilbert J. Saulter, Regional Administrator; From: Patricia K. Clark, Director Designate [Directorate Of Enforcement Programs]; Subject: Clarification of 29 CFR 1910.1047(h)(2) Requirements for Emergency EtO Limit; available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=19968; retrieved 12/12/06



improved greatly and the cost of purchase and ownership has come down. Many hospitals and other users of ethylene oxide have continuous monitors installed demonstrating the feasibility and cost effectiveness of this solution to employee safety, even though the current regulations do not explicitly require continuous monitoring. Cost effective monitors are now routinely available with a resolution of 0.1 ppm, for example systems based on both gas chromatography and electrochemical sensors. OSHA inspectors use infrared and electrochemical based monitors for detecting ethylene oxide in the workplace²⁶ and together with GC, these three technologies are all well established and reliable methods for detecting ethylene oxide in the workplace.

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OSHA Technical Manual, available at http://www.osha.gov/dts/osta/otm/otm_ii/otm_ii_3.html, retrieved 12/12/06