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OSHA's Renewed Mandate for Regulatory Flexibility Review: In Support of the 1984 Ethylene Oxide Standard

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Background *The Regulatory Flexibility Act of 1980 requires that all federal agencies consider the impact of regulations on small entities. One of the provisions of the Act requires review of regulations every 10 years to determine whether such regulations should be continued without change, rescinded, or amended to make them more effective or less burdensome on businesses. The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 amended and expanded the Regulatory Flexibility Act. Most significantly, SBREFA entitles aggrieved small entities or their representatives (e.g., trade associations) to sue OSHA for failure to fulfill Regulatory Flexibility Act requirements. In response to this new political reality, OSHA held the first public meetings of their kind in June of 1997 to gather information on the ethylene oxide and lock-out/tag-out standards for the purposes of Regulatory Flexibility review.*

Method *This paper presents the development of the Regulatory Flexibility review process and details our analysis of the ethylene oxide standard using OSHA's eight Regulatory Flexibility review criteria.*

Results *Great progress in ethylene oxide health and safety has been made since the promulgation of the standard in 1984, including a considerable decrease in average workshift exposures. Yet, important concerns remain, such as the lack of safer substitutes for EtO's most common uses, the widespread occurrence of accidental exposures to EtO that are not captured by personal monitoring, and the recent increase in the occurrence of catastrophic EtO explosions.*

Conclusions *Because of the considerable study that has been devoted to EtO and to the EtO standard, there is a very strong case for either making the EtO standard more worker protective, or continuing the standard without change while improving outreach and enforcement efforts to address shortcomings. Other valuable standards for which fewer data exist may be inappropriately threatened by the Regulatory Flexibility review process. Importantly, Regulatory Flexibility review could be constructive if accompanied by appropriations to fund sound evaluation studies. Instead, it will likely divert OSHA's limited resources from the numerous urgent health hazards that await initial rule-making. As signified by the designation of "intervention effectiveness research" as one of the 21 priorities on the National Occupational Research Agenda, evaluation studies of OSHA standards and other interventions are urgently needed. The occupational health community's response to this need will play a crucial role in preserving hard-won protections, as well as in developing other urgently needed protections in the future.* Am. J. Ind. Med. 34:95–104, 1998. © *1998 Wiley-Liss, Inc.*

KEY WORDS: ethylene oxide; OSHA; OSHA policy; health standards; intervention effectiveness research; evaluation

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OSHA'S RENEWED MANDATE FOR REGULATORY FLEXIBILITY REVIEW

The Regulatory Flexibility Act of 1980 requires that all federal agencies consider the impact of regulations on small entities (small businesses, small governmental jurisdictions, and nonprofit organizations) (Public Law 96–354, Sept. 19, 1980). This Act required agencies to take specific steps to solicit input from small entities, particularly in the development of new rules and regulations. In addition, the Act provided for the review of regulations every 10 years to evaluate their effectiveness and their impact on small entities. Such reviews would be conducted by the issuing agency to determine whether a regulation should be continued without change, rescinded, or amended to make it more effective or less burdensome. However, questions of interpretation remained, such as whether the review requirement applied only to rules which agencies had determined have ''a significant economic impact'' on a ''substantial number of small entities,'' allowing agencies some discretion in the application of the review requirement.

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Public law 104–121, March 29, 1996) has amended and expanded the Regulatory Flexibility Act. Most significantly, SBREFA has made agencies' compliance with the Regulatory Flexibility Act judicially reviewable. That is, aggrieved small entities or their representatives (e.g., trade associations) are now entitled to file suit against OSHA for failure to perform Regulatory Flexibility review, or to dispute specific Regulatory Flexibility decisions rendered by OSHA. Thus, in addition to its more widely known powers over the development of new standards (which are being exercised for the first time in the context of OSHA's 1997 methylene chloride standard), SBREFA can also be used against standards that are more than 10 years old.

In response to this new political reality, OSHA announced the first public meetings of their kind to gather information on the ethylene oxide and the lock-out/tab-out standards for the purposes of Regulatory Flexibility review. OSHA, May 27, 1997. The meetings were held June 30, 1997, with one half-day devoted to each standard. The comments below detail the analysis we presented to OSHA both orally and in written form in support of the continuation or strengthening of the ethylene oxide (EtO) standard.

Beyond the specific relevance of these comments to the EtO standard, the phenomenon of Regulatory Flexibility review in general should be of great concern to the occupational health community. At a time when OSHA has a considerable backlog of currently unregulated hazards to address, the appropriateness of devoting scarce resources to the review of existing standards without specific cause for such review is questionable.

Because of the wealth of data on EtO exposures, health effects, and the implementation and effectiveness of the standard, there is a strong case for making the EtO standard more worker protective, or at a minimum continuing the standard without change. Other valuable standards for which fewer data are available may be threatened by this new impediment to OSHA action. Importantly, Regulatory Flexibility review would not be an impediment to OSHA if it were accompanied by appropriations to fund evaluation studies of existing standards. Evaluation studies of OSHA standards and other interventions are urgently needed to defend the hard-won occupational health protections in existance today. Indeed, evaluation studies incorporating sound public health principles as well as economic and business perspectives may help to change the opinions of those who short-sightedly argue that OSHA and NIOSH are a burden on, rather than a benefit to, our economy and our nation.

We offer the following point-by-point argument in support of the EtO standard as an illustration of OSHA's Regulatory Flexibility review process and a strategy for responding to it. The identification of intervention effectiveness research as a priority area on the National Occupational Research Agenda (NORA) is helping to focus attention on the urgent need for evaluation research on standards and other interventions [NIOSH, 1996]. The occupational health community's response to this need will play a crucial role in preserving hard-won protections, as well in developing other urgently needed protections now and in the future.

IN SUPPORT OF THE ETHYLENE OXIDE STANDARD

In its request for information relevant to Regulatory Flexibility review of the ethylene oxide standard, OSHA specified eight points for comment to ''assist the Agency in determining whether to retain the standard unchanged or to initiate rulemaking for the purposes of revision or recision'' [OSHA, May 27, 1997]. These eight points are addressed in sequence below. Our comments are based on the published literature and our experiences from an evaluation of the implementation and effectiveness of the ethylene oxide standard in Massachusetts hospitals. As requested by OSHA, these comments draw primarily from information that has become available since the promulgation of the EtO standard in 1984.

1. The Benefits and Utility of the Rule in Its Current Form and, if Amended, in Its Amended Form

In order to understand the benefits and utility of the EtO standard, as well as its feasibility, both the extent of implentation by industry as well as apparent impacts must be examined. We have conducted such evaluations of the EtO standard in almost all EtO-using hospitals in the state of Massachusetts (n = 92) [LaMontagne et al., 1996a,b;

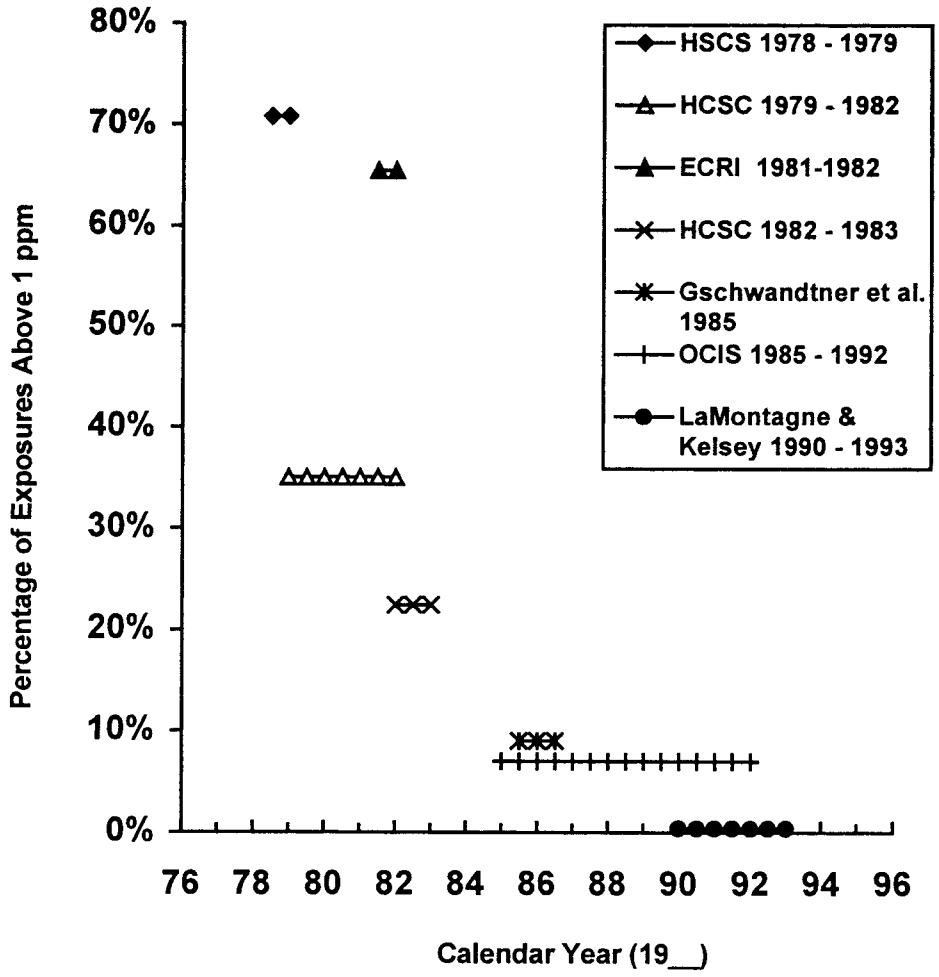

FIGURE 1. Percentages of workshift average EtO exposures above 1.0 ppm: in the health care industry, 1978–1993. Portrays percentages of exposures above 1 ppm 8-hr time-weighted average (vertical) versus calendar year time periods during which samples were collected (horizontal). Each study (horizontal line) represents data from more than 10 hospitals. Data sources: HCSC, Hospital Council of Southern California [Meridian Research, 1992]; ECRI, Emergency Care Research Institute [Meridian Research, 1992]; OCIS, OSHA's Computerized Information Service [Meridian Research 1992]; Gschwandtner et al. [Meridian Research, 1992]; and LaMontagne and Kelsey [1997]. Adapted from LaMontagne and Kelsey [1998].

LaMontagne and Needleman, 1996; LaMontagne and Kelsey, 1997]. The implementation and impact of each of three principal sections of the standard—exposure monitoring, medical surveillance, and worker training—are discussed below.

Exposure monitoring.

By 1993, almost all EtO-using Massachusetts hospitals had implemented personal monitoring requirements for 8-hr (Action Level or AL, and Permissible Exposure Limit or PEL) and 15-min (Excursion Limit or EL) periods, but one-third of hospitals had not installed EtO alarms or implemented other means to alert employees during accidental releases (required under section h-2 of the EtO standard) [LaMontagne and Kelsey, 1997]. In addition, implementation of all exposure monitoring requirements has lagged significantly behind OSHA-specified implementation deadlines [LaMontagne and Kelsey, 1997]. Examination of OSHA citation data from the Integrated Management Information System (IMIS) in parallel with the Massachusetts hospital study data suggested that OSHA enforcement pressure stimulated many hospitals to install EtO alarms [LaMontagne and Kelsey, 1997].

Workshift personal EtO exposures in the healthcare setting have dropped steadily since NIOSH and OSHA attention became focused on EtO hazards during the late 1970s (Fig. 1). However, exposures above the workshift and

15-min OSHA limits continued to occur widely into the 1990s; for example, roughly one-third of Massachusetts hospitals exceeded either the AL or EL one or more times during the 1990–993 period [LaMontagne and Kelsey, 1997]. Importantly, the Massachusetts hospital study also showed that personal monitoring activities have failed to detect the widespread occurrence of accidental exposures during EtO leaks and spills [LaMontagne and Kelsey, 1997]. Accidental exposures are of particular concern for the reasons described under section 8 (see below). Accordingly, we believe that hospitals should be encouraged or required (if the standard is reopened) to improve primary preventive measures, continue workshift monitoring, and increase EL monitoring during EtO cylinder changing and any other processes during which accidental exposures might occur. Improved primary preventive measures include appropriate emergency training (described in below), as well as improved engineering controls for situations in which accidental exposures might be anticipated to occur. For example, a common situation in which accidental exposures occur is the changing of EtO supply cylinders. NIOSH has suggested engineering controls to protect workers during cylinder changes (see Fig. 1 in NIOSH [1989]). Such exhaust hoods can be made with Plexiglas and hinged in the front, thus allowing easy access and viewing during cylinder removal and replacement.

Medical surveillance.

Five specific circumstances or ''triggers'' in OSHA's EtO standard activate requirements for medical surveillance: (1) exposures above the AL for 30 or more days per year, (2) before assignment to areas where exposure may exceed the AL for 30 or more days, (3) exposures during emergencies or accidents, (4) voicing of employee reproductive concerns, and (5) upon job termination or transfer from an area where exposure was at or above the AL for 30 or more days [OSHA, 1984]. Under the current standard, exceeding the EL is not a trigger for medical surveillance. The reason for this is unclear [LaMontagne et al., 1996b]. Since the EL—like the AL/PEL—is health risk-based, we recommend that exceeding the EL for 30 or more days per year be added as a medical surveillance trigger if the standard is reopened.

Medical surveillance for EtO exposure had been provided one or more times by two-thirds of the 92 Massachusetts hospitals in the study as of 1993 [LaMontagne et al., 1996a]. In an analysis of the extent to which OSHA triggers are related to EtO surveillance implementation, it was found that the determinants of providing EtO medical surveillance, in order of decreasing magnitude, were accidental EtO releases, the coverage of medical surveillance issues in worker training, and the existence of voluntary written medical surveillance policies [LaMontagne et al., 1996b]. These findings highlight the interdependence of primary and secondary prevention efforts, with important roles to be played by workers, management, and medical surveillance providers.

Two-thirds of providers reported the performance of all five OSHA-required procedures. However, roughly 25% deficits were reported in taking occupational histories and performing leukocyte differentials. We believe that the observed deficit in history-taking threatens the utility of medical surveillance and should be addressed by improved outreach or other efforts [LaMontagne et al., 1996a].

When provided, the standard states that EtO medical surveillance must include at least a medical and work history, a physical examination, and a complete blood count (CBC) with leukocyte differential [OSHA 1984]. OSHA's requirement for CBC with differential was apparently based on a 1967 report from Ehrenberg and Hallstrom [Ehrenberg and Hallstrom, 1967; OSHA, 1984]. However, more recent occupational studies have found inconsistent relationships (positive, negative, and non) between EtO exposures and hematologic effects [LaMontagne et al., 1993; Schulte et al., 1992, 1995; reviewed in LaMontagne and Kelsey, 1998]. Higher historic exposures may account in part for these discrepancies. Other observations, however, cast further doubt on the utility of the CBC as a screening test in medical surveillance for EtO exposure. These include (1) numerous problems in the use of the CBC as a screening test for any health outcome in asymptomatic, nonpregnant adults; (2) the lack of reliable ''normal'' values, necessitating the collection of blood samples from nonexposed comparison populations and/or group statistical analyses in order to interpret results; and (3) EtO-associated lymphocytosis has been seen principally in symptomatically exposed workers, who could readily be identified as overexposed by observation [LaMontagne et al., 1993]. It is important to note that some recent epidemiologic studies have found effects on hemoglobin, hematocrit, and relative lymphocyte and neutrophil counts at EtO exposure levels below the current PEL [Schulte et al., 1992, 1995]. However, these effects occurred within the range of clinically acceptable values and required multivariate statistical analysis in order to be detected. While these exposure-associated effects are of concern (which could be addressed by lowering exposure limits), their detection by the use of the CBC/differential is problematic. Even if detected, the clinical value of such findings is unclear. Accordingly, if the EtO standard is reopened, we recommend that the CBC/differential be rescinded *as a requirement* and left to the discretion of the attending health care provider. On the other hand, epidemiologic research on the hematologic effects of EtO and their potential relationship to adverse health effects deserves further attention.

Beyond routine hematologic tests, numerous biomonitoring procedures for EtO are being investigated [reviewed

in LaMontagne and Kelsey, 1998]. To date, however, none of these has been adequately developed for practical clinical use. We do not recommend any new EtO biomonitoring requirements at the present time; however, new biomonitoring possibilities should be reviewed carefully if OSHA reopens the standard.

Linking exposure assessment and medical surveillance findings to primary prevention.

EtO medical surveillance is a suitable tool for detecting and managing most acute and some chronic EtO-associated effects, such as burns, neuropathies, or allergic sensitization. However, medical surveillance is not as effective in the detection and management of the principal health concerns driving the 1984 EtO standard, namely carcinogenic and reproductive risks. This highlights the importance of linking EtO medical surveillance to primary prevention efforts. Fukushima et al. [1986] provide an excellent case study in this regard, following up on EtO-related clinical findings with workplace walkthroughs and exposure control interventions. To the extent that detected acute conditions lead to the reduction of exposures, all EtO-associated health risks will decrease. To realize maximal public health impact, the process of medical surveillance itself, independent of medical findings, should also be conducted as worker and management educational interventions, with group results and implications for exposure control communicated to all potentially affected workers, unions, managers, and other interested parties. If the EtO standard is reopened, we recommend the addition of requirements to trigger mandatory reassessments of primary preventive measures when overexposures occur (e.g., accidents, exceeding the AL, PEL, or EL), and when EtO-related health effects are observed. OSHA's recent cadmium standard provides an appropriate model for such requirements.

OSHA's EtO standard uses an AL trigger mechanism for both training and medical surveillance requirements. In the Massachusetts Hospital Study, 30 hospitals exceeded the AL one or more times, and nine of those 30 exceeded the AL for 30 or more working days [LaMontagne and Kelsey, 1997]. Our evaluation results, however, showed no significant relationships between exceeding the AL and providing medical surveillance, or between exceeding the AL and providing worker health and safety training (training was provided by 98% of the 92 hospitals in the study) [LaMontagne et al., 1996b]. Accordingly, we recommend that OSHA reconsider its AL trigger scheme if the EtO standard is re-opened. For instance, we believe that training should be offered to anyone working with or in the vicinity of EtO, independent of the occurrence of exposures in excess of the AL.

Training and other primary preventive measures.

Other primary prevention measures addressed in OSHA's EtO standard include requirements for worker health and safety training, evacuation procedures, and the use of personal protective equipment, as well as recommendations on the use of effective engineering controls. While training has been widely implemented, there are areas for improvement. For example, in the Massachusetts Hospital Study, we observed that two-thirds of hospitals had experienced real or suspected EtO leaks that required the evacuation of workers from the area, yet only one third had ever carried out EtO emergency training drills to prepare for such events. In this instance as well as others, the effectiveness of EtO training could be greatly improved by the use of more interactive or problem-posing methods that apply adult-basic education principles [LaMontagne et al., 1992, 1990]. In addition, numerous excellent practical guides to the prevention and control of EtO hazards are now available and could be cited by OSHA as resources in a nonmandatory appendix to the standard or in an educational outreach publication [NIOSH, 1989; LaMontagne et al., 1990; Mortimer and Kercher, 1989; IPCS, 1985; Reich, 1990; CHEM, 1994b].

Benefits summary.

In summary, the benefits of the rule have been widespread implementation of EtO exposure monitoring, medical surveillance, training, and other primary preventive measures. These have been associated with a steady decrease in workshift EtO exposures. Although we are not aware of any published population-based historical data on excursions above the EL and the occurrence of accidents, we believe that it is likely that these exposures have decreased in parallel with the decrease in workshift exposures. Some specific shortcomings of the rule have been identified together with appropriate and feasible improvements in the standard and other interventions that could be applied to rectify them. Revision of the standard to incorporate some or all these recommendations would further improve the standard's effectiveness without unduly increasing the burden of compliance on industry.

2. Whether Potentially Effective and Reasonably Feasible Alternatives to the Standard Exist

It is possible that revised risk assessments for EtO-associated health outcomes could justify a lowering of exposure limits. For instance, new data have become available [reviewed by LaMontagne and Kelsey, 1998] on human genotoxicity [Mayer et al., 1991; Schulte et al., 1992;

1995], carcinogenesis [Gardner et al., 1989; Kiesselbach et al., 1990; Greenberg et al., 1990; Teta et al., 1993; Steenland et al., 1991; Stayner et al., 1993; Bisanti et al., 1993; Norman et al., 1995; Major et al., 1996; Shore et al., 1993], reproductive health risks [Lindbohm et al., 1991; Rowland et al., 1996; Anon, 1994; Rutledge and Generoso, 1989; Sega and Owens, 1987; Generoso et al., 1986; 1987], and EtO-associated asthma [Wagner and Kollorz, 1987; Deschamps et al., 1992; Dugue et al., 1991; Jacson et al., 1991; Verraes and Michel, 1995]. In particular, genotoxicity and other macromolecular damage have been demonstrated at exposures below the PEL [Mayer et al., 1991; Schulte et al., 1992, 1995], and allergic reactions and asthma could be triggered by exposures below the PEL or EL as well.

Given the continued occurrence of exposures over the AL and EL, as well as the widespread occurrence of accidental exposures, we believe that higher priority should be placed on ensuring compliance with existing exposure limits (e.g., by improving short-term personal monitoring in order to characterize accidental exposures) than on developing new limits that OSHA may or may not be able to enforce.

Although outside of OSHA's current rule-making ability, a feasibility-based approach to controlling EtO exposures deserve mention. Such an approach would set exposure limits based on the lowest levels that are reasonably achievable by industry. For example, the NIOSH recommended occupational exposure limits, which are considerably lower than OSHA's (0.1 ppm TWA per 8 hr, and 5 ppm TWA per 10 min), are probably achievable by most hospitals [Mortimer and Kercher, 1989]. Owing to the current limitations imposed by Supreme Court interpretations of OSHA's ''significant risk'' requirement, however, feasibility-based rule-making is not an alternative open to OSHA at the present time. This currently neglected regulatory alternative deserves reconsideration [LaMontagne, 1997].

3. The Continued Need for the Rule

Substitutes for EtO as a sterilant are currently being pursued, and use reduction opportunities exist (see also Section 6). Some, but not all, hospital sterilization needs can be met with alternatives, such as peracetic acid or hydrogen peroxide systems LaMontagne et al., 1990; CHEM, 1994a]. Given the challenges of developing complete replacements for EtO as a sterilant and chemical intermediate, it appears that EtO will remain a potential occupational hazard for the foreseeable future.

Although exposures have dropped steadily since the passage of the standard (Fig. 1)(see Section 1), exposures that exceed the AL and the EL as well as unmeasured accidental exposures continue to occur widely in hospitals, indicating a need to continue the standard to ensure that the occurrence of such exposures will continue to decrease [LaMontagne and Kelsey, 1997]. Accidental exposures and excursions above the EL are of particular concern because they occur at higher doses and dose rates than workshift level exposures below the PEL. EtO has been shown to cause more damage to macromolecules at high dose rates relative to low, posing greater cancer and reproductive risks per unit dose [Generoso et al., 1986]. This finding was what led, in part, to the 1988 revision of the EtO standard to add the EL [OSHA, 1988]. In addition, high-dose episodic EtO exposures may also pose greater risks of EtO-associated asthma, working through a rapid-onset nonimmunological mechanism [case report by Deschamps et al., 1992].

EtO has also long been known to be potent allergic sensitizer [Bommer and Ritz, 1987; Bommer et al., 1985]. Most of the early studies of EtO allergenic properties were conducted on patients who had been exposed to EtO in medical devices. Similar studies are now being performed on EtO-exposed workers, as for example in an assessment of EtO-human serum albumin antibodies in seven endoscopy nurses [Wagner and Kollorz, 1987]. A number of cases of EtO-associated asthma in healthcare workers have been recently reported that likely represent sentinel cases for the industry [Deschamps et al., 1992; Dugue et al., 1991; Jacson et al., 1991; Verraes and Michel, 1995]. In addition to the nonimmunological mechanism described above, some of these cases have involved an EtO allergic sensitization mechanism (measurable IgE antibodies) [Dugue et al., 1991; Verraes and Michel, 1995]. In support of EtO's likely role in these cases, asthma and rhinitis have been reported to be common features of EtO IgE-mediated allergy in sensitized dialysis patients [Bousquet and Michel, 1991].

Finally, in a recent survey of medical surveillance providers, potentially EtO-related health effects were reported by 10 of 37 respondents [LaMontagne et al., 1996a]. Symptoms and conditions reported (usually more than one per affirmative response) were grouped as follows: mucous membrane irritation (6 of 10), central nervous system effects (5 of 10), peripheral nervous system effects (2 of 10), hematologic effects (1 of 10), and ''blood in urine'' (1 of 10). With the exception of ''blood in urine'', all symptoms or conditions reported have been previously associated with EtO overexposures.

In summary, the lack of safer substitutes for EtO, the continuing occurrence of exposures above the AL and EL as well as unmeasured accidental exposures, and the continuing occurrence of adverse health effects in EtO-exposed workers clearly indicate the continuing need for the EtO standard.

4. The Complexity of the Rule

Streamlining of some of the standard's requirements, as well as the development of plain English compliance guidelines as an outreach material or a new nonmandatory appendix, would reduce complexity and facilitate compli-

ance [LaMontagne et al., 1996a,b; LaMontagne and Kelsey, 1997]. Particular points of confusion for many sterilization department managers include the AL trigger (discussed further in Section 1), the distinction between personal and area monitoring and how they are complementary (discussed in further detail in Sections 7 and 8), how to comply with the ''alert'' requirement (discussed in further detail in Sections 1, 7, and 8), and how long medical surveillance should continue to be provided once it has been triggered for an individual worker [LaMontagne et al., 1996a,b; LaMontagne and Kelsey, 1997].

5. Whether, and to What Extent, the Rule Overlaps, Duplicates, or Conflicts With Other Federal, State, and Local Governmental Rules

EtO is regulated by several other federal agencies. NIOSH has specified more protective occupational exposure limits (0.1-ppm, 8-hr TWA, and 5 ppm 10-min TWA for excursions). However, since these recommendations are not legally enforceable, there is no duplication or conflict. Because of the widespread occurrence of EtO-associated adverse effects in exposed patients, the US Food and Drug Administration (FDA) has set limits for EtO, as well as its two reaction products: ethylene chlorohydrin and ethylene glycol. The U.S. Environmental Protection Agency (EPA) regulates EtO as a pesticide contaminant in foodstuffs, as well as an air pollutant and hazardous waste. EPA is currently completing a special review of EtO's use as a sterilant and fumigant, particularly with regard to the health and safety of applicators. This review was started in 1978; the passage of OSHA's EtO standard in 1984 obviated most of the need for this review. However, EPA has recently refocused attention on this review, with the goal of determining whether there is a need for EPA applicator protection guidelines in the estimated 15 states that have no enforceable worker protection provisions for public employees. This effort would provide an important complement to the OSHA standard, and would not conflict with or duplicate it.

In addition, the EPA is drafting a National Emission Standard for EtO under the Clean Air Act. However, this regulation will affect only large-scale users, such as the chemical industry and commercial sterilization and fumigation plants, and not small scale users such as hospitals. Some state air pollution regulations, however, require abatement of EtO emissions even from small quantity users such as hospitals. Air pollution regulations overlap with the OSHA standard only to the extent that the required pollution control technologies affect exposures in the workplace. With the recent series of EtO explosions in aerosol packaging, medical products, and other plants using EtO on an industrial scale, the EPA is re-examining its requirements to ensure that they are not associated with these extremely serious and sometimes fatal EtO exposures to workers in these plants (''EPA Delays Air Pollution Rules Following 4 Factory Explosions,'' *Washington Post* August 2, 1997, page A2, ''Worker dies, 34 hurt in blast at Elkhart plant,'' *U.S. News* June 24, 1997). These regulatory efforts are a very important complement to the OSHA standard, and pose no conflict or duplication. Under Superfund and Community Right-to-Know, the EPA has classified EtO as an Extremely Hazardous Substance and requires reporting of EtO use for emergency planning, as well as reporting of any release greater than ten pounds. These reporting requirements provide a surveillance mechanism that could be routinely used by OSHA to investigate unusual releases for potential occupational exposures.

6. Information on Any New Developments in Technology, Economic Conditions, or Other Factors Affecting the Ability of Affected Firms to Comply With the Ethylene Oxide Rule

Some important new economic and technological conditions highlight the continuing need for the EtO rule as well as the need to re-focus on EtO safety hazards (the primary emphasis of the standard is on health hazards). The phase-out of ozone-depleting chlorofluorocarbons has significantly increased the price of widely used EtO gas mixtures. Most hospitals use one of two types of EtO: large cylinders containing mixtures of a small percentage of EtO (10–12%) with flame-retardant propellants, and small single-use canisters (roughly 100 g) of 100% EtO. As the favored propellant, Freon, was phased out, the price of gas mixtures rose considerably. The less ozone-depleting replacement gas mixtures remain expensive. This has caused a shift to greater use of 100% EtO—which is highly flammable and explosive. For small-scale sterilizer use (such as in hospitals), the safety record of 100% sterilizers is excellent. Most 100% sterilizers used in hospitals have built-in local exhaust ventilation and run under negative pressure (thus in the event of a leak, air is drawn into the chamber, rather than having EtO pushed out into the work area). OSHA and its compliance officers should be mindful of this trend and more attentive to EtO fire and explosion hazards, particularly where 100% EtO may be used on a large scale. Examples of such industries include chemical manufacturing and medical products manufacturing/packaging.

The potential for routine worker exposures in chemical manufacturing is low because most production and chemical synthesis work with EtO is conducted in enclosed or outdoor operations [LaMontagne and Kelsey, 1998]. In addition, medical products manufacturing exposures appear to be relatively low since the passage of the EtO standard [Steenland et al., 1991]. However, the potential for large explosive or otherwise catastrophic releases in these indus-

tries continues to be of concern, as unfortunately illustrated in the recent series of explosions cited in Section 5 above.

The EtO standard and other regulatory efforts also seem to have had some positive economic impacts on small-scale users of EtO, such as hospitals. In response to heightened awareness of EtO hazards as well as rising prices of EtO gas mixtures, some users have carefully re-examined EtO use and found considerable opportunity for use reduction [see Factsheet 13 in LaMontagne et al., 1990]. For instance, many items commonly sterilized with EtO can be effectively sterilized with steam, which is much cheaper and safer. A Boston hospital recently reduced its EtO usage by more than 75% after determining that many traditionally EtO-sterilized items could be safely and effectively sterilized with steam, resulting in significant hazard reduction as well as cost savings.

7. Alternatives to the Rule or Portions of the Rule That Would Minimize Significant Impacts on Small Businesses While Achieving the Objectives of the Occupational Safety and Health Act

8. The Effectiveness of the Standard as Implemented by Small Entities

These two points, since they both address concerns about the implementation of the standard by small businesses, will be addressed together.

Implementation and effectiveness of the standard in small businesses.

We are not aware of any published studies comparing the implementation and effectiveness of the EtO standard relative to the size of the workplace. In the Massachusetts hospital study, we gathered data on two measures of workplace size. Hospital size, as measured by number of patient beds ranged from 30 to 1,082, with a median of 221 and a mean of 253 ($\pm$180 SD, n = 92) [LaMontagne et al., 1996b]. Focusing closer to where EtO is used in the hospital, we also gathered data on the number of full-time equivalent employees in each hospital's sterilization department (range = 1.5–45.0, median = 7.5, mean = 11.2 $\pm$ 9.4 SD, n = 92).

In multivariate analyses to identify significant determinants of the provision of medical surveillance, neither of our two measures of hospital size was significantly related to providing medical surveillance [LaMontagne et al., 1996b]. In preliminary analyses of the determinants of the three exposure events examined (exceeding the AL, exceeding the EL, and the occurrence of accidental exposures), neither of the two measures of hospital size are related to the occurrence of any of the three exposure events (unpublished analyses by AD LaMontagne and KT Kelsey).

In summary, our analyses have shown that there is no differential in providing medical surveillance relative to hospital size across a statewide hospital population, and similarly, that there is no differential in the likelihood of the occurrence of the three exposure events examined relative to hospital size. This suggests that in the hospital industry, the implementation and effectiveness of the EtO standard is similar across the full range of workplace sizes.

"Alert" requirement.

The lack of clarity over the ''means to alert'' requirement (section h-2) may lead to overspending by employers. Some advertisers of EtO alarm systems (the most common means of fulfilling the alert requirement) have interpreted this requirement in favor of their own interests, recommending sophisticated and expensive alarm systems ($20,000–50,000) that are sensitive to 1 ppm of EtO or lower in order to comply with the OSHA standard [LaMontagne and Kelsey, 1997; CHEM, August 28, 1990]. Accordingly, we recommend that OSHA (1) clarify its interpretation of ''means to alert'' (e.g., if it does not necessarily mean ''get an alarm,'' what are the alternative means of complying?), and (2) clarify that employers using EtO alarms are not required to set their alarms at or below the personal exposure monitoring limits (the PEL, AL, and EL) in order to be in compliance with the standard. Alarms are intended to monitor instantaneous area concentrations, and not time-weighted average personal breathing zone exposures. Alarms that would be triggered in the event of an accidental EtO leak or spill could be reasonably set within the range of 20–100 ppm, as previously recommended by NIOSH [Mortimer and Kercher, 1989]. Alarms that are reliably sensitive to this concentration range of EtO are available and start in the price range of $1,000–2,000. Clarity on these points would prevent small hospitals and other businesses from overspending in response to this requirement.

CONCLUSIONS

The ethylene oxide standard clearly needs to be continued, at a minimum. Alternatively, revision of the standard along the lines recommended above would both improve the standard's ability to protect worker health and safety (e.g., improve training and exposure monitoring efforts to prevent and control accidental exposures), and reduce the burden of implementing the standard in industry (e.g., remove requirement for CBC in medical surveillance, clarify ''alert'' requirements).

There are also alternatives to OSHA rulemaking that could achieve the goals outlined above with equal or perhaps greater effectiveness. These include clarifications of interpretations of unclear requirements, increased enforcement efforts, improved outreach efforts, and improved collabora-

tion with NIOSH. For example, OSHA could publicly state concern about accidental exposures, suggest the need for improved EL and area monitoring efforts, clarify and unify its interpretation of the ''alert'' requirement, and revise its compliance officer enforcement guidelines accordingly. In parallel, if NIOSH were to consider issuing an updated EtO Current Intelligence Bulletin or other outreach material, a very credible, established, and nonthreatening distribution mechanism (not requiring contact with OSHA) could be used to disseminate OSHA's new information. Our findings also suggest that OSHA enforcement improves compliance with the implementation of EtO standard requirements [LaMontagne and Kelsey, 1997] This finding is also supported by common sense and experience with other health and safety standards.

Because of the continuing diminution of OSHA's resources relative to its growing mandate, OSHA's decision on whether to continue or reopen the EtO standard will require a careful balancing of scarce resources against anticipated impact per quantity of resource invested. While we clearly believe that there are important improvements that could be made by reopening the standard, we also believe that continuing the standard as is while implementing the nonrulemaking alternatives outlined above could very well have a greater impact on the prevention and control of EtO exposures and associated health impacts in U.S. workplaces. We believe that OSHA's rulemaking efforts would be expended to greater benefit, and OSHA's statutory mandate better fulfilled, by addressing the numerous urgent health hazards that await initial rulemaking.

REFERENCES

Anon (1994): Reproductive toxicology and occupational exposure: ethylene oxide. In Zenz C, Dickerson OB, Horvath EP (eds): ''Occupational Medicine.'' St. Louis: CV Mosby, pp 851–853.

Bisanti L, Maggini M, Raschetti R, Alegiani SS, Ippolito FM, Caffari B, Segnan N, Ponti A (1993): Cancer mortality in ethylene oxide workers. Br J Ind Med 50:317–324.

Bommer J, Barth HP, Wilhelms OH, Schindele H, Ritz E (1985): Anaphylactoid reactions in dialysis patients: Role of ethylene oxide. Lancet 2:1382–1384.

Bommer J, Ritz E (1987): Ethylene oxide (EtO) as a major cause of anaphylactoid reactions in dialysis [a review]. Artif Organs 11:111–117.

Bousquet J, Michel F (1991): Allergy to formaldehyde and ethylene oxide. Clin Rev Allergy 9:357–370.

CHEM (1994a): Does EtO have a future in hospitals? Healthcare Hazardous Mater Mgnt: The Newsletter of the Center for Healthcare Environmental Management (CHEM) 7:1–6.

CHEM (1994b): Ethylene Oxide. In Segal P(ed): ''Healthcare Environmental Management System.'' Plymouth Meeting, PA 19462, ECRI: III: 1.2.1–1.2.24.

CHEM (August 28, 1990): Inconsistent enforcement of OSHA EtO emergency requirements can cause overspending. In ''CHEM Alert Special Notice.'' Plymouth Meeting, PA, Center for Healthcare Environmental Management (CHEM).

Deschamps D, Rosenberg N, Soler P, Maillard G, Fournier E, Salson D, Gervais P (1992): Persistent asthma after accidental exposure to ethylene oxide. Br J Ind Med 49:523–525.

Dugue P, Faraut C, Figueredo M, Bettendorf A, Salvadori JM (1991): Ethylene oxide-related occupational asthma in a nurse [in French]. Presse Med 20:1455.

Ehrenberg L, Hallstrom T (1967): Hematologic studies on persons occupationally exposed to ethylene oxide. In ''Radiosterilization of Medical Products.'' Report No. SM-92/96.Vienna: International Atomic Energy Agency, pp 327–334.

Fukushima T, Abe K, Nakagawa A, Osaki Y, Yoshida N, Yamane Y (1986): Chronic ethylene oxide poisoning in a factory manufacturing medical appliances. J Soc Occup Med 36:118–123.

Gardner MJ, Coggon D, Pannett B, Harris EC (1989): Workers exposed to ethylene oxide: a follow up study. Br J Ind Med 46:860–865.

Generoso WM, Cain KT, Hughes LA, Sega GA, Braden PW, Gosslee DG, Shelby MD (1986): Ethylene oxide dose and dose-rate effects in the mouse dominant-lethal test. Environ Mutat 8:1–7.

Generoso WM, Rutledge JC, Cain KT, Hughes LA, Braden PW (1987): Exposure of female mice to ethylene oxide within hours after mating leads to fetal malformation and death. Mutat Res 176:269–274.

Greenberg HL, Ott MG, Shore RE (1990): Men assigned to ethylene oxide production or other ethylene oxide related chemical manufacturing: A mortality study. Br J Ind Med 47:221–230.

IPCS (1985): ''Ethylene Oxide Health and Safety Guide.'' Health and Safety Guide No. 16. Geneva: World Health Organization.

Jacson F, Beaudouin E, Hotton J, Moneret-Vautrin DA (1991): Allergy to formaldehyde, latex, and ethylene oxide: Triple occupational allergy in a nurse [in French]. Rev Fr Allergol 31:41–43.

Kiesselbach N, Ulm K, Lange HJ, Korallus U (1990): A multicentre mortality study of workers exposed to ethylene oxide. Br J Ind Med 47:182–188.

LaMontagne AD (1997): Work-related cancers. Cancer Causes Control 8(suppl 1):S35–S38.

LaMontagne AD, Kelsey KT (1997): Evaluating OSHA's ethylene oxide standard: employer exposure monitoring activities in Massachusetts hospitals from 1985–1993. Am J Public Health 87:1119–1125.

LaMontagne AD, Kelsey KT (1998): Ethylene oxide. In Rom WN (ed): ''Occupational and Environmental Medicine.'' 3rd Ed. Philadelphia: Lippincott/Raven Press.

LaMontagne AD, Needleman C (1996): Overcoming practical challenges in intervention research in occupational health and safety. Am J Ind Med 29:367–372.

LaMontagne AD, Kelsey KT, Christiani DC, Plantamura D (1990): ''Ethylene Oxide Health and Safety Manual: Training and Reference Materials on the Safe Use of Ethylene Oxide in Sterilizing Facilities.'' 2nd Ed. Braintree, MA: Center for Occupational and Environmental Medicine, Massachusetts Respiratory Hospital.

LaMontagne AD, Kelsey KT, Ryan CM, Christiani DC (1992): A participatory workplace health and safety training program for ethylene oxide. Am J Ind Med 22:651–664.

LaMontagne AD, Christiani DC, Kelsey KT (1993): Utility of the complete blood count in routine medical surveillance for ethylene oxide exposure. Am J Ind Med 24:191–206.

LaMontagne AD, Mangione TW, Christiani DC, Kelsey KT (1996a): Medical surveillance for ethylene oxide exposure: practices and clinical findings in Massachusetts hospitals. J Occup Environ Med 38:144–154.

LaMontagne AD, Rudd RE, Mangione TW, Kelsey KT (1996b): Determinants of the provision of ethylene oxide medical surveillance in Massachusetts hospitals. J Occup Environ Med 38:155–168.

Lindbohm ML, Hemminki K, Bonhomme MG, Anttila A, Rantala K, Heikkila P, Rosenberg MJ (1991): Effects of paternal occupational exposure on spontaneous abortions. Am J Public Health 81:1029–1033.

Major J, Jakab MG, Tompa A (1996): Genotoxicological investigation of hospital nurses occupationally exposed to ethylene-oxide. Environ Mol Mutagen 27:84–92.

Mayer J, Warburton D, Jeffrey AM, Pero R, Walles S, Andrews L, Toor M, Latriano L, Wazneh L, Tang D, Tsai WY, Kuroda M, Perera F (1991): Biologic markers in ethylene oxide-exposed workers and controls. Mutat Res 248:163–176.

Meridian Research Inc (1992): Ethylene oxide: A case study in hazard identification, OSHA regulation, and market response. Final report. Silver Spring, MD, performed on contract for the Office of Program Evaluation, OSHA, by Meridian Research, Inc.

Mortimer VD, Kercher SL (1989): ''Technical Report: Control Technology for Ethylene Oxide Sterilization in Hospitals.'' DHHS (NIOSH). Report No. 89–120.

NIOSH (1989): ''Current Intelligence Bulletin 52: Ethylene oxide sterilizers in health care facilities—engineering controls and work practices.'' US Department of Health and Human Services (NIOSH).

NIOSH (1996): ''National Occupational Research Agenda.'' US Department of Health and Human Services (NIOSH) Publication No. 96–115.

Norman SA, Berlin JA, Soper KA, Middendorf BF, Stolley PD (1995): Cancer incidence in a group of workers potentially exposed to ethylene oxide. Int J Epidemiol 24:276–284.

OSHA (1984): Occupational exposure to ethylene oxide: final standard. Federal Register 49:25734–25809.

OSHA (1988): Occupational exposure to ethylene oxide; final standard. Federal Register 53:11414–11438.

OSHA (May 27, 1997): Notice of Public Meeting on Review of the Ethylene Oxide Standard (29 CFR 1910.1047). Federal Register 62:28649–28650.

Reich AR (1990): Safe use of ethylene oxide in the hospital environment. In Charney W, Schirmer J (eds): ''Essentials of Modern Hospital Safety.'' Chelsea, MI: Lewis Publishers.

Rowland AS, Baird DD, Shore DL, Darden B, Wilcox AJ (1996): Ethylene oxide exposure may increase the risk of spontaneous abortion, preterm birth, and postterm birth. Epidemiology 7:363–368.

Rutledge JC, Generoso WM (1989): Fetal pathology produced by ethylene oxide treatment of the murine zygote. Teratology 39:563–572.

Schulte PA, Boeniger MF, Walker JT, Schober SE, Pereira MA, Gulati DK, Wojciechowski JP, Garza A, Froelich R, Strauss G, Halperin WE, Herrick R, Griffith J (1992): Biological markers in hospital workers exposed to low levels of ethylene oxide. Mutat Res 278:237–251.

Schulte PA, Walker JT, Boeniger MF, Tsuchiya Y, Halperin WE (1995): Molecular, cytogenetic, and hematologic effects of ethylene oxide on female hospital workers. J Occup Environ Med 37:313–320.

Sega GA, Owens JG (1987): Binding of ethylene oxide in spermiogenic germ cell stages of the mouse after low-level inhalation exposure. Environ Mol Mutat 10:119–127.

Shore RE, Gardner MJ, Pannett B (1993): Ethylene oxide: An assessment of the epidemiological evidence on carcinogenicity. Br J Ind Med 50:971–997.

Stayner L, Steenland K, Greife A, Hornung R, Hayes RB, Nowlin S, Morawetz J, Ringenburg V, Elliot L, Halperin W (1993): Exposure-response analysis of cancer mortality in a cohort of workers exposed to ethylene oxide. Am J Epidemiol 138:787–798.

Steenland K, Stayner L, Greife A, Halperin W, Hayes R, Hornung R, Nowlin S (1991): Mortality among workers exposed to ethylene oxide. N Engl J Med 324:1402–1407.

Verraes S, Michel O (1995): Occupational asthma induced by ethylene oxide. Lancet 346:1434–1435.

Teta MJ, Benson LO, Vitale JN (1993): Mortality study of ethylene oxide workers in chemical manufacturing: a 10 year update. Br J Ind Med 50:704–709.

Wagner M, Kollorz W (1987): Occupational medicine studies of 7 ethylene oxide-exposed endoscopy nursing professionals. Zentralbl Bakteriol Mikrobiol Hyg [B] 185:154–163.