Evaluating OSHA's Ethylene Oxide Standard: Employer Exposure-Monitoring Activities in Massachusetts Hospitals from 1985 through 1993

ABSTRACT

Objectives. This study characterized exposure-monitoring activities and findings under the Occupational Safety and Health Administration's (OSHA's) 1984 ethylene oxide (EtO) standard.

Methods. In-depth mail and telephone surveys were followed by on-site interviews at all EtO-using hospitals in Massachusetts (n = 92, 96% participation rate).

Results. By 1993, most hospitals had performed personal exposure monitoring for OSHA's 8-hour action level (95%) and the excursion limit (87%), although most did not meet the 1985 implementation deadline. In 1993, 66% of hospitals reported the installation of EtO alarms to fulfill the standard's "alert" requirement. Alarm installation also lagged behind the 1985 deadline and peaked following a series of EtO citations by OSHA. From 1990 through 1992, 23% of hospitals reported having exceeded the action level once or more; 24% reported having exceeded the excursion limit; and 33% reported that workers were accidentally exposed to EtO in the absence of personal monitoring.

Conclusions. Almost a decade after passage of the EtO standard, exposure-monitoring requirements were widely, but not completely, implemented. Work-shift exposures had markedly decreased since the mid-1980s, but overexposures continued to occur widely. OSHA enforcement appears to have stimulated implementation. (*Am J Public Health.* 1997;87:1119–1125)

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Introduction

Systematic study of employer exposure-monitoring activities is needed in order to optimize the implementation of exposure-monitoring recommendations and requirements and to achieve the ultimate public health objectives of occupational health standards—the prevention of hazardous exposures. However, relatively little research has focused on how employers and employees respond to existing Occupational Safety and Health Administration (OSHA) exposure-monitoring requirements and what employers find when they conduct routine exposure monitoring. Improved understanding of industry exposure-monitoring practices under OSHA standards is especially important in light of OSHA's recent consideration of generic exposure-monitoring requirements.[1,2]

An in-depth study was conducted in 1993 to characterize the implementation of OSHA's 1984 ethylene oxide (EtO) standard in all Massachusetts hospitals.[3–6] EtO is used in hospitals to sterilize heat- and moisture-sensitive medical supplies. Health care workers compose the largest group in the estimated 270 000 US workers who are potentially exposed to EtO.[7] EtO is a potent neurotoxin, a known human carcinogen, a potential reproductive hazard, and an allergic sensitizer.[8,9] OSHA promulgated a 6(b) EtO health standard with a 1 ppm permissible exposure limit and 0.5 ppm action level in 1984,[10] and revised the standard in 1988 to add a 5-ppm short-term excursion limit.[11]

The EtO standard requires initial exposure monitoring consisting of worker breathing–zone air samples that are representative of the 8-hour time-weighted average (for permissible exposure limit and action level) and 15-minute short-term exposures of each employee (for excursion limit).[10,11] If the results of such exposure monitoring are below the action level and the excursion limit, then no further personal monitoring is required unless there are process or personnel changes that give reason to suspect changes in EtO exposures. When exposures exceed the action level or excursion limit, employers are required to repeat monitoring at least every 3 months or as often as necessary to evaluate the situation. In addition, employers must develop written plans for emergency EtO situations (leaks, spills, etc.) and ways "to alert potentially affected employees of such occurrences promptly."[10]

An active sampling method for 8-hour–work-shift personal monitoring for EtO was first developed in 1977, but it was cumbersome and required the services of a trained industrial hygienist.[12,13] In anticipation of the announced OSHA rule making on EtO, passive dosimeters for full-shift EtO monitoring were developed commercially by several manufacturers in the early 1980s.[12,14] These small passive dosimeters, or "monitoring badges," are easy to use and are therefore preferred by most employers. By the time the EtO standard came into effect in 1985,

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TABLE 1—Personal Monitoring for EtO Exposure in Massachusetts Hospitals, 1985 through 1983

	1985 through 1993		1990 through 1992			
	Yes/Total	%	Yes/Total	%	Median	Range (No.)
Ever monitored for AL?	87/92	95	75/90	83		
Exceeded AL one or more times?	30/85	35	17/75	23		
Exceeded the AL for 30 or more days one or more times?	9/85	11	6/75	8		
Ever monitored for the EL?	80/92	87	72/90	80		
Exceeded the EL one or more times?	23/80	29	17/72	24		
Accidental EtO release one or more times?	50/92	54	32/90	33		
One or more workers potentially exposed in accidental EtO release one or more times?	46/92	50	29/90	32		
How many times monitored for AL?[a]					19	2–3744 (75)
How many times exceeded AL?[b]					1	1–12 (17)
Percentage of times monitored exceeding AL?[b]					4.0	0.2–33.3 (17)
How many times monitored for EL?[a]					18	1–2808 (72)
How many times exceeded EL?[c]					1	1–25 (17)
Percentage of times monitored exceeding EL?[c]					4.2	0.9–50.0 (17)

Note. AL = action level; EL = excursion limit; EtO = ethylene oxide.
[a]At hospitals where monitoring done.
[b]At hospitals that exceeded AL.
[c]At hospitals that exceeded EL.

the use of passive dosimeters was widespread.[12]

The study described below provides an important complement to other EtO exposure–assessment studies that have focused on scientifically collected exposure data.[15–18] This study takes an evaluation or intervention research[19,20] perspective, focusing on the activities and findings of employers in response to OSHA's mandate for EtO-exposure monitoring. The unit of analysis is the workplace. Thus, in addition to yielding valuable worker-exposure information, this study was designed to examine the behavior of organizations and the dynamics of the implementation of OSHA exposure-monitoring requirements among a population of workplaces. Insights into these areas are needed to improve exposure-monitoring recommendations and requirements, clarify OSHA regulatory language, focus outreach and other communication efforts, and target exposure-reduction interventions.

Methods

Study Design and Population

An in-depth survey (mail, telephone, and on site) of EtO health and safety was conducted among all hospitals in Massachusetts (n = 159). The respondent was the manager of EtO-sterilization operations, most commonly called the "central sterile" manager. The survey covered the period from 1985, when the exposure monitoring sections of OSHA's EtO standard became effective, through 1993, when the survey was conducted. At least 96% of EtO-using hospitals in Massachusetts were recruited into the study.[3] The survey design, procedures and study population and the measures taken to maximize participation and minimize selection and information bias have been described in detail previously.[3,6] For example, key exposure-history questions from the telephone survey were repeated in the on-site interviews, and many initial false-negative responses to overexposure questions were identified and corrected.[4,6]

Variables Measured

Exposure variables. For each hospital, a detailed EtO-exposure history addressing both personal and area monitoring activities was determined as previously described.[4] Exposure variables were determined for 1985 through 1993 and 1990 through 1992. Detailed exposure data were obtained only for 1990 through 1992 because of expected limitations, such as lack of older records, manager turnover, and manager recall.[4] In addition, central sterile managers were asked if they had "an alarm which will sound when *EtO* is accidentally released" and were then asked about other types of alarms (e.g., for ventilation failures) to ensure valid responses.

OSHA inspection data. Searches of OSHA's Integrated Management Information System were requested from the Department of Labor under the Freedom of Information Act of 1986 for the following: (1) all OSHA inspections of Massachusetts hospitals (standard industrial classification code 8062) since Integrated Management Information System records have been kept (1980) through 1993 and (2) all OSHA inspections of Massachusetts hospitals where the EtO standard (1910.1047, promulgated in 1984) or the EtO permissible exposure limit (promulgated in 1971) was cited from 1980 through 1993.

Results

Initiation and Frequency of EtO-Monitoring Activities

Most hospitals reportedly performed 8-hour personal monitoring one or more times from the effective date of OSHA's EtO exposure–monitoring requirements in 1985 through 1993 (Table 1). However, the initial implementation of 8-hour or action-level monitoring typically occurred after 1985 (Figure 1A). By the end of 1985, only 43% of hospitals reported having performed action-level monitoring. More hospitals had never monitored for the excursion limit compared with the action level as of 1993 (Table 1). Initial monitoring, however, occurred closer to the required date for excursion-limit monitoring in 1988 than for initial action-level monitoring (Figure 1B). Nevertheless, only 48% of the 89 Massachusetts hospitals responding to the question on

initial excursion-limit monitoring had performed that monitoring by the end of 1988.

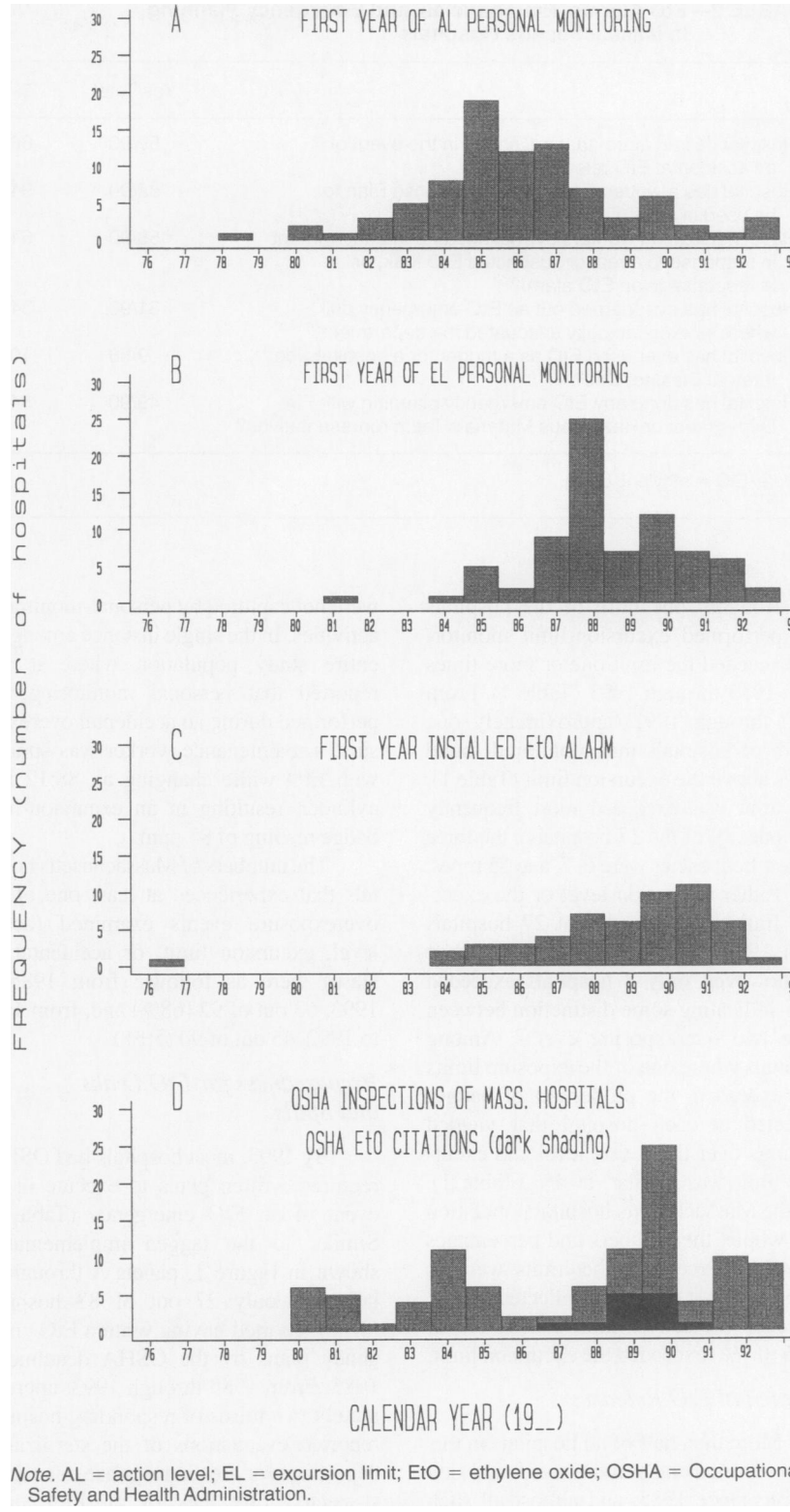
With respect to area monitoring activities, many hospitals responded to OSHA's emergency "alert" requirement by installing EtO alarms (Table 2). However, by the end of 1985, when the "alert" requirement became effective, only five hospitals reported having an EtO alarm (Figure 1C). The largest wave of EtO-alarm installations closely followed the 13 citations of Massachusetts hospitals for violations of the EtO standard from 1987 to 1991 (Figure 1D). These were the only citations of any part of the EtO standard or its preceding 50-ppm permissible exposure limit from 1980 through 1993. Of the 13 hospitals cited for EtO violations, 4 received citations of section h(2) of the EtO standard, which addresses the requirement for means to alert employees in EtO emergencies. Nine of the 13 hospitals were cited for action-level or excursion-limit personal-monitoring violations. In total, 10 of the 13 hospitals were cited for either personal-exposure monitoring or alert violations.

There was great variability in the levels at which EtO alarms were set to alert employees of emergency situations (Table 3). The median set level was 20 ppm, with a very wide range (Table 3). Alarm settings clustered around the action level, the permissible exposure limit, and the excursion limit (0.5, 1.0, and 5.0 ppm), as well as at 20 and 50 ppm. Managers at 16 of 59 hospitals (27%) did not know the set levels of their EtO alarms.

Several hospitals did not perform action-level or excursion-limit monitoring during 1990 through 1992 (Table 1). Among hospitals that did perform monitoring, the median number of action-level and excursion-limit badges collected (one badge per person for each time monitored) was similar, although the range was very wide (Table 1). Almost all personal monitoring was performed by means of passive dosimeters on a routine or ad hoc basis by the central sterile manager or employees.

Results of Employer Exposure Monitoring

Roughly one third of the hospitals that performed action-level monitoring exceeded the action level one or more times from 1985 through 1993 (Table 1). In 1990 through 1992, roughly one fourth of hospitals that monitored found levels above the action level (Table 1), indicating that overexposures were not restricted to the early years of the standard. The action level was usually exceeded only once (11 of the 17 hospitals that exceeded it from 1990 through 1992); the three highest frequencies were 6, 9, and 12 times. Roughly one tenth of hospitals exceeded the action level for 30 or more days one or more times (Table 1).



Note. AL = action level; EL = excursion limit; EtO = ethylene oxide; OSHA = Occupational Safety and Health Administration.

FIGURE 1—Initiation of EtO monitoring activities and OSHA inspections in Massachusetts hospitals, 1976 through 1993.

TABLE 2—EtO Alarms, Emergencies, and Emergency Planning in Massachusetts Hospitals

	Yes/Total	%
Hospital has an alarm that will sound in the event of an accidental EtO release?	59/90	66
Hospital has a written Emergency Response Plan to be used in case of EtO leaks or spills?	85/90	94
Have sterilization workers ever evacuated the department in response to a real or suspected EtO leak, or in response to an EtO alarm?	58/90	64
Hospital has ever carried out an EtO emergency drill where workers actually evacuated the department?	31/90	34
Hospital has ever used EtO as a trigger for a hospitalwide Internal Disaster Drill?	9/88	10
Hospital has done any EtO emergency planning with Fire Department or Hazardous Materials Team representatives?	49/90	54

Note. EtO = ethylene oxide.

TABLE 3—EtO Concentrations Required to Trigger EtO Alarms in Massachusetts Hospitals

Trigger Level, ppm EtO	Frequency, No. of Hospitals	%
0.5	4	9.3
1.0	5	11.6
2.0	1	2.3
5.0	6	13.9
7.5	1	2.3
10.0	1	2.3
20.0	7	16.3
25.0	3	7.0
40.0	1	2.3
50.0	11	25.6
75.0	1	2.3
100.0	1	2.3
250.0	1	2.3
Total	43	100.0

Roughly one third of the hospitals that performed excursion-limit monitoring exceeded the limit one or more times from 1985 through 1993 (Table 1). From 1990 through 1992, approximately one fourth of hospitals that monitored found levels above the excursion limit (Table 1). The limit was exceeded most frequently only once (9 of the 17 hospitals); the three highest frequencies were 6, 7, and 25 times.

Either the action level or the excursion limit was exceeded at 27 hospitals from 1990 through 1992. Among those 27, however, only 7 hospitals exceeded *both,* indicating some distinction between these two overexposure events. Among hospitals where one of the exposure limits was exceeded, the proportion of badges collected at each hospital that yielded readings over the action level and excursion limit was similar, at 4% (Table 1). For the Massachusetts hospital population as a whole, the numbers and percentages of badges exceeding the limits were as follows: 47 out of 10 981 collected (0.4%) exceeded the action limit, and 64 out of 8916 (0.7%) exceeded the excursion limit.

Accidental EtO Releases

More than half of all hospitals in this study reported one or more accidental EtO releases since 1985, and almost all such accidents resulted in worker exposures or likely worker exposures (Table 1). Often, more than one worker was exposed. Accidents were also reported by approximately one third of hospitals from 1990 through 1992, indicating that accidental overexposures continued to occur widely well after the initial years of the standard. Accidental overexposures, importantly, were not captured by personal-monitoring activities. In the single instance among the entire study population where it was reported that personal monitoring was performed during an accidental overexposure, a maintenance worker was sprayed with EtO while changing an 88:12 EtO cylinder, resulting in an excursion-limit badge reading of 85 ppm.

The numbers of Massachusetts hospitals that experienced at least one of the overexposure events examined (action level, excursion limit, or accidental release) were as follows: from 1985 to 1993, 63 out of 92 (68%) and, from 1990 to 1992, 45 out of 90 (50%).

Preparedness for EtO Leaks and Spills

By 1993, most hospitals had OSHA-required written plans to execute in the event of an EtO emergency (Table 2). Similar to the lagged implementation shown in Figure 1, panels A through C, however, only 27 out of 83 hospitals (32%) reported having written EtO emergency plans by the OSHA deadline in 1985. From 1985 through 1993, approximately two thirds of responding hospitals reported evacuations of the sterilization department or area in response to a real or suspected EtO leak or an EtO alarm (Table 2). In contrast, only about one third of hospitals carried out EtO emergency drills in which workers actually evacuated the department (Table 2). However, many hospitals were working to improve the handling of EtO emergencies, and several hospitals reported the use of an EtO emergency as a trigger for a hospitalwide disaster drill (Table 2). An additional 7 hospitals reported plans for such drills. Independent of EtO disaster drill activities, more than half of responding hospitals had done some EtO emergency planning with local fire departments or hazardous materials response teams (Table 2), and 6 hospitals reported their intention to do so.

Discussion

Implementation of Requirements

Our results indicate that most hospitals have implemented OSHA's EtO personal-monitoring requirements, but a substantial fraction had not fulfilled all initial monitoring requirements as of 1993. Where initial monitoring was performed, it typically occurred after required implementation dates despite widespread educational campaigns on EtO hazards and the EtO standard by the National Institute for Occupational Safety and Health (NIOSH), OSHA, EtO-equipment manufacturers, and others.[3,12,17] This implies a need for improved OSHA standard language, communication of standard requirements, and OSHA enforcement efforts.

Because EtO has poor warning properties and can lead to serious adverse health outcomes at exposures below its odor threshold, OSHA included a requirement for an alert in section h(1) of the EtO standard. A very delayed and incomplete implementation of the alert requirement was observed in this study. In the postsurvey EtO health and safety reviews provided to each hospital in the study,[3–6] we observed a widespread lack of understand-

ing of this requirement among managers. There has also been variable interpretation of the alert requirement by OSHA. Some OSHA officials have interpreted the requirement to mean that an EtO alarm is required, since this is the only reliable way to detect emergency situations before high worker exposures occur (correspondence between OSHA and the public on interpretations of specific requirements of the OSHA EtO Standard [29 CFR 1910.1047], available on request from Office of Health Compliance Assistance, 202-219-8036; see also reference 21). In other interpretations, however, OSHA correspondence has stated that "a sophisticated alarm system might be unnecessary for some facilities such as small hospitals with only one EtO sterilizer," in which case direct voice communication might be acceptable (clarification letter from OSHA to G.L. Notarianni, January 13, 1987, in publicly available correspondence between OSHA and the public on interpretations of the OSHA EtO Standard [29 CFR 1910.1047], available on request from Office of Health Compliance Assistance, 202-219-8036). However, voice "alert" can only possibly work in the event of a recognized leak. Yet unrecognized leaks can result in potentially high and prolonged exposures, as was prominently illustrated by a department of sterilization workers who experienced EtO-related flulike symptoms for 4 years until high EtO levels were discovered and controlled.[22] Although OSHA's intent was to provide a flexible, performance-based requirement for an alert, unclear language and inconsistent interpretation of the requirement by OSHA have contributed to employer confusion and have perhaps hindered the requirement's implementation. This occurred despite the publication of guidelines on the use of EtO alarms and other monitoring devices by NIOSH as part of its educational outreach efforts.[18,23]

Among hospitals that did install EtO alarms, there has been widespread confusion and controversy over the EtO concentration at which an EtO alarm should sound, as evidenced by the wide range of trigger concentrations observed in this study. Again, OSHA intended this requirement to be performance based, realizing that it was not feasible to specify an appropriate EtO alarm concentration for all settings. However, future standards and communication efforts—at a minimum—should carefully specify that time-weighted personal-monitoring exposure limits do not double as set levels for alarms. Much correspondence is on record for the EtO standard on this issue, where OSHA has had to clarify that EtO alarms are not required to be set at the action level, permissible exposure limit, or excursion limit (correspondence between OSHA and the public on interpretations of specific requirements of the OSHA EtO Standard [29 CFR 1910.1047], available on request from Office of Health Compliance Assistance, 202-219-8036; see also reference 21). In the absence of clarity on this issue, it has been reported that some EtO-alarm marketers and salespersons have interpreted the "alert" requirement in favor of their own interests, recommending sophisticated and expensive alarm systems that are sensitive to 1 ppm of EtO or lower in order to comply with the OSHA standard.[21] NIOSH's general recommendation for installing simple EtO alarms and setting them somewhere between 20 and 100 ppm[18] has not effectively reached central sterile managers and is not cited in OSHA responses to queries on this issue. In summary, needs for clarification and communication of requirements for an alert, coupled with observed deficits in planning and worker training for EtO emergencies, indicate clear opportunities for intervention.

Our data suggest that OSHA enforcement pressure stimulated many hospitals to install EtO alarms. The observation that most EtO citations included one or more personal- or area-exposure monitoring citations indicates that OSHA enforcement efforts are detecting exposure-monitoring problems at the hospitals that they do inspect. Significantly, however, OSHA enforcement efforts have not been sufficient to encourage full implementation of exposure-monitoring requirements since voluntary compliance has been incomplete and delayed at best.

Despite implementation problems, most hospitals that did perform EtO personal monitoring greatly exceeded OSHA's minimal requirements. Hospitals tended to monitor periodically, regardless of exposure-monitoring findings, as recommended by NIOSH.[18,23] This suggests hospital compliance with the spirit of personal-monitoring requirements over the letter of the law. It is unlikely, however, that very frequent personal monitoring (e.g., daily) provides markedly greater protection than monthly or quarterly periodic monitoring, particularly if personal monitoring is backed up by continuous area monitoring with an EtO alarm. This is a situation in which educational intervention could both improve health and safety and decrease compliance costs (i.e., decrease expensive personal monitoring and obtain a moderately priced EtO alarm). Significantly, however, our findings also indicate that hospitals should perform *more* excursion-limit personal monitoring during tasks that could involve accidental overexposures, such as during changing of EtO supply cylinders.

Findings of Employer Exposure Monitoring

Our data suggest a new low point in the steady decrease in 8-hour time-weighted average hospital EtO exposures that was described in a 1992 OSHA-commissioned evaluation of the EtO standard.[12] A 1986 study summarized the results of work-shift badges submitted for analysis to a particular badge manufacturer in 1985 and 1986, representing approximately 1000 hospitals: 18% of the badges exceeded the action level.[24] Similarly, an analysis of all work-shift EtO samples collected by OSHA inspectors from 1985 through 1992 showed that 7% of samples exceeded the permissible exposure limit.[12] Thus, our estimate that 0.4% of work-shift badges collected in Massachusetts hospitals from 1990 through 1992 exceeded the action level represents a sharp reduction in the frequency that the action level and permissible exposure limit have been exceeded from the mid-1980s to the early 1990s. We present these estimates for historical comparison, although they can be biased by high monitoring frequency at a minority of hospitals. (Thus, most results were presented on hospital-by-hospital basis.)

We also acknowledge that focusing on whether exposure limits have ever been exceeded in a given period can be biased by monitoring frequency; nevertheless, this is the approach OSHA currently uses to determine regulatory compliance. Rappaport has proposed a more scientific alternative, which accounts for monitoring frequency and focuses on the probability that a typical measurement would exceed an exposure limit.[25] This approach, however, has not been adopted by regulatory agencies.

Although EtO leaks and spills have been previously acknowledged as a potentially serious exposure problem,[12,17,18,23,26] we know of no previous estimates of the occurrence or prevalence of accidental EtO exposures. However, these may be the exposures of greatest concern for potential health effects because (1) accidental exposures occur widely and at

more hospitals than the exceeding of the action level or excursion limit; (2) they often involve more than one worker; (3) they could involve very high EtO-exposure levels relative to those detected by personal monitoring; and (4) they occur at relatively high dose rates (dose per unit of time). In animal experiments, EtO has been shown to cause more genetic damage when administered at high dose rates than when the same total EtO dose is administered over longer periods of time.[27] The excursion limit would reduce both high exposures and high dose-rate exposures if all exposures were captured by personal-monitoring activities. Our data indicate, however, that the excursion limit is not working as anticipated since accidents continue to occur and are not detected by excursion-limit monitoring (although some are detected by EtO alarms). This also suggests that anticipated mechanisms for documenting employee exposure for future medical follow-up, compensation claims, and epidemiologic study are failing to record important EtO-overexposure events. These observations indicate an urgent need for improved excursion-limit and alarm-monitoring practices as well as strategies to prevent accidental releases.

Conclusions

In summary, this statewide evaluation has shown widespread but incomplete implementation of OSHA's EtO-monitoring requirements. While personal-monitoring levels appear to be decreasing steadily, exposures exceeding the action level and exposure limit—as well as undocumented accidental exposures—continue to occur widely. Further OSHA enforcement activity and educational outreach by both OSHA and NIOSH would be likely to improve exposure-monitoring practices and reduce exposures. The need to reduce EtO exposures to the lowest level feasible[17,18,23] is underscored by reports of human genotoxicity and other molecular changes in workers exposed to EtO at levels below the permissible exposure limit and the action level[28–30] and EtO's recent reclassification as a known human carcinogen by the International Agency for Research on Cancer.[9] In addition, EtO's property as a potent allergic sensitizer[31] and the increasing reports of EtO-associated asthma in health care workers[32–34] also indicate a need to control the occurrence of high dose-rate EtO exposures in particular. Numerous opportunities for exposure-reduction interventions have been identified to support the achievement of this important goal. □

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