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# TRAINING AND MEDICAL SURVEILLANCE UNDER OSHA'S ETO STANDARD

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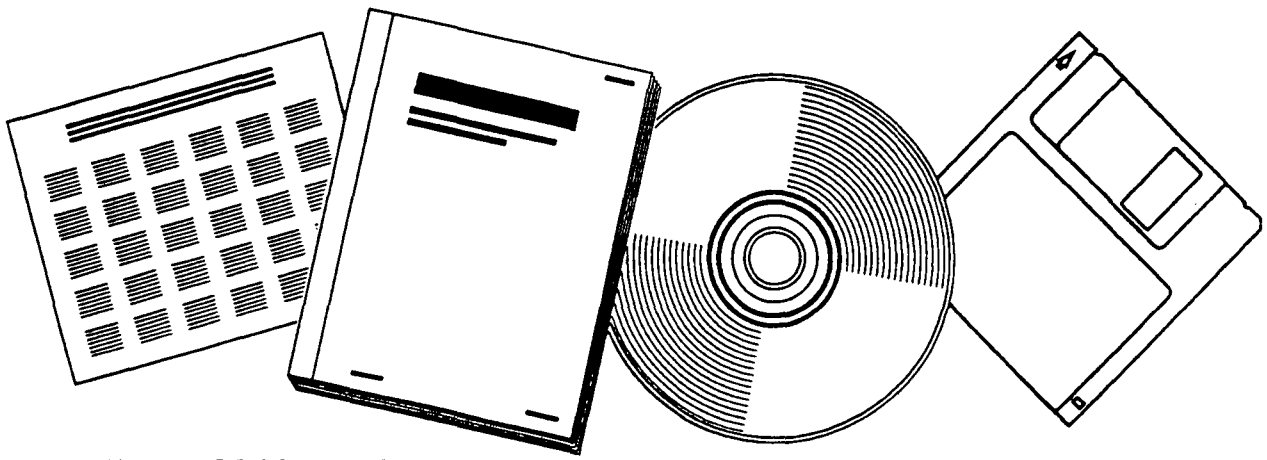

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16. Abstract (Limit: 200 words) The implementation of the exposure monitoring, training, and medical surveillance provision of OSHA's 1984 ethylene-oxide (75218) (EtO) standard in the hospital setting was evaluated. An attempt was made to identify strengths and weaknesses of medical surveillance, exposure monitoring, and training implementation in substance specific OSHA standards to provide for more effective practice, enforcement strategies, and policy making in these areas. The findings of the study indicated that by 1993, 98% of the hospitals using EtO had provided some form of training. By 1993, 95% of the hospitals had performed 8 hour personal monitoring, and 35% had exceeded the action level one or more times. Medical surveillance of EtO exposure was provided one or more times in 6% of the hospitals from 1985 through 1993. Reports of coverage of EtO medical surveillance issues in worker training were also strongly related with providing EtO medical surveillance, which supported the premise of OSHA that worker training is important in medical surveillance implementation. The presence of written detailed EtO medical surveillance policies was strongly and positively related to providing EtO medical surveillance.

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# Training and Medical Surveillance Under OSHA's EtO Standard
# Final Performance Summary Report on NIOSH 5 R03 OH03088-02

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## Training and Medical Surveillance Under the EtO Standard

### Importance to Occupational Safety and Health

This study examines the implementation of OSHA-mandated medical surveillance, exposure monitoring, and worker health & safety training. Historically, training and medical surveillance have been emphasized and studied less than other preventive measures, such as engineering controls, which focus more directly on the source of exposure. Training and medical surveillance are generally assumed to occur and to have some preventive impact; however, systematic evaluation of these areas is only recently becoming recognized as a research need. In addition, there has been little study of the implementation of exposure monitoring requirements by workers, supervisors, health & safety staff, and others in industry. This study aims to determine the extent and nature of exposure monitoring activities, the results obtained, and how exposure monitoring results are related to follow-up activities, such as training and medical surveillance. Systematic study will help to develop untapped preventive potential of exposure monitoring, training, and medical surveillance, fostering the development of a more integrated and balanced approach to hazard control at all levels.

The specific aims of this study are to critically evaluate the implementation of the exposure monitoring, training, and medical surveillance provisions of OSHA's 1984 Ethylene Oxide (EtO) Standard in the hospital setting. The broader goal of this research is to identify strengths and weaknesses of medical surveillance, exposure monitoring, and training implementation in substance-specific OSHA standards in order to provide for more effective practice, enforcement strategies, and policy-making in these areas. The functioning of OSHA's medical surveillance trigger scheme is being evaluated, most importantly to examine the relationships between exposure monitoring results and medical surveillance, and between training and medical surveillance.

### Objectives

The following three specific hypotheses, derived directly from the implementation strategies of exposure monitoring-driven substance-specific OSHA health standards are being tested: Hypothesis 1: Exceedance of trigger exposure levels is positively associated with implementation of EtO training; and Hypothesis 2: Exceedance of trigger exposure levels is positively associated with implementation of EtO medical surveillance. Two EtO exposure levels are specified to trigger training and medical surveillance requirements: the Action Level of 0.5 ppm Time-weighted Average (TWA) and the Excursion Limit of 5 ppm TWA per 15 period. We are asking to what extent employers are in compliance with these requirements and to what extent exposure monitoring specifically guides employers in the implementation of EtO training and medical surveillance. Hypothesis 3: The implementation of training is positively associated with the implementation of medical surveillance. As stated in current OSHA policy, part of the intent of training is to make workers aware of their rights under a standard, which in turn is presumed to make workers more likely to exercise those rights. We will test for an association which would be consistent with such a causal relationship between training and implementation of medical surveillance.

### Methodology

Our approach integrates theory and principles from occupational health, health education, and the social sciences with epidemiology and survey research methodology. All Massachusetts hospitals were surveyed by mail to identify EtO users. Of the 159 hospitals in the state, 92 responded as EtO users and 62 as non-users. The response rate for the mailed survey was 97% (154/159). EtO users were then administered a 15 minute standardized telephone interview (response rate = 92/92), followed by a standardized 1-2 hour on-site, face-to-face interview with the sterilization department supervisor (response rate = 90/92). Survey procedures are discussed in detail in LaMontagne et al (1996a). Strategies used to maximize participation rates and minimize information bias are discussed in depth in LaMontagne and Needleman (1996).

Brief questionnaires on the process and findings of EtO medical surveillance exams were mailed to providers wherever EtO medical surveillance was reportedly provided. The medical surveillance provider response rate was 65% (37/57 hospitals where surveillance provided).

**Significant Findings & Their Usefulness**

The findings of this study are detailed in LaMontagne et al (1996a & 1996b). The findings, as they relate to the three hypotheses specified in our grant proposal, are summarized below.

Hypothesis 1:

By 1993, 98% of EtO-using hospitals (90 of 92) in the study population had provided some form of EtO training (LaMontagne et al 1996b). By 1993, 95% of hospitals in the study had performed 8 hour personal monitoring, and 35% had exceeded the AL one or more times. Similarly, 87% of hospitals had performed 15 minute personal monitoring, and 29% had exceeded the EL one or more times. A formal analysis of the relationship between the implementation of EtO training and exceedance of trigger exposure levels was not warranted. We concluded from these data that EtO health & safety training implementation occurred independently of exceeding the formal OSHA training triggers of exceeding the AL or the EL. The EtO training that was offered is characterized in detail in LaMontagne et al (1996b).

Hypotheses 2 & 3:

Characterization of EtO Medical Surveillance Interventions

From 1985 to 1993, medical surveillance for EtO exposure was provided one or more times in 62% of EtO-using Massachusetts hospitals (LaMontagne et al 1996a). Sixty-five percent of EtO medical surveillance providers reported performance of all five medical surveillance procedures required by OSHA's EtO standard. Medical surveillance provider certification in occupational medicine or nursing, and a greater extent of coverage of written medical surveillance policies were related to higher likelihoods of fulfillment of OSHA required procedures (Relative Risks = 1.6 [$p = 0.04$ one-tailed] and 2.0 [$p = 0.01$], respectively). Twenty-seven percent of medical surveillance providers reported detection of EtO-related symptoms or conditions, ranging from mucous membrane irritation to peripheral neuropathy.

These findings reveal widespread implementation of OSHA-mandated EtO medical surveillance, with concomitant incomplete fulfillment of OSHA-specified procedures. This occurred despite concerted educational and outreach efforts by NIOSH, OSHA, EtO equipment manufacturers, professional associations, and others. This suggests a need for simpler and clearer medical surveillance requirements and improved communication efforts.

Determinants of Providing EtO Medical Surveillance:

Among OSHA's five specified triggers for providing EtO medical surveillance, only accidental worker exposures were related to providing surveillance ($RR = 2.56$, $p < 0.001$) (LaMontagne et al 1996b). Exceeding the Action Level for 30 or more days, one of OSHA's EtO triggers that is also used in a number of other standards, was not related to providing surveillance ($RR = 0.84$, $p = 0.714$). Reports of coverage of EtO medical surveillance issues in worker training were also strongly related with providing EtO medical surveillance ($RR = 3.68$, $p < 0.001$), supporting OSHA's premise that worker training plays an important role in medical surveillance implementation. Thirdly, the presence of detailed written EtO medical surveillance policies was positively related to providing EtO medical surveillance ($RR = 1.81$, $p < 0.001$). Each of these three variables also remained significantly related to providing medical surveillance in logistic regression analysis after adjustment for each other and for a wide variety of other covariates.

These findings have implications for improvement of OSHA medical surveillance implementation through revised trigger schemes, improved worker training efforts, and other measures. Findings are also relevant to the future development of medical surveillance and exposure monitoring policies in both substance-specific and generic contexts.

With respect to the usefulness of our findings to workplaces where EtO is used, we have attached a Summary Report that was sent to all study participants and supporters. The Summary Report includes detailed recommendations for improving EtO health & safety based on the findings of the study. It is written in relatively non-technical language with easy-to-read layout, explanation of how to use the report, and a detailed Table of Contents to make the Report as accessible and useful to the reader as possible.

## PRESENTATIONS, WRITINGS, AND PUBLICATIONS FROM "Training and Medical Surveillance Under the EtO Standard"

### Research Presentations

| | |
|---|---|
| November 1996 | Submitted: AMERICAN PUBLIC HEALTH ASSOCIATION ANNUAL MEETING, New York, NY. Submitted verbal presentation on "OSHA's 1984 Ethylene Oxide Standard: A Regulatory Success Story." (Abstract appended). |
| December 1995 | SOCIETY FOR OCCUPATIONAL & ENVIRONMENTAL HEALTH ANNUAL MEETING, Bethesda, MD: Occupational & Environmental Surveillance '95. Speaker on "Determinants of Providing Ethylene Oxide Medical Surveillance in Massachusetts Hospitals." |
| November 1995 | AMERICAN PUBLIC HEALTH ASSOCIATION ANNUAL MEETING, San Diego, CA. Session Presider for a four member panel on "Regulatory Approaches to Workplace Health & Safety" and Speaker on "Overcoming Practical Challenges in Intervention Research in Occupational Health & Safety." |
| October 1994 | AMERICAN PUBLIC HEALTH ASSOCIATION ANNUAL MEETING, Washington, DC. Speaker on "Exposure Monitoring, Training, and Medical Surveillance under OSHA's Ethylene Oxide Standard: Implications for Generic Standard-Setting Approaches." |
| October 1994 | NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY & HEALTH, Workshop on Intervention Research in Occupational Health & Safety. Invited Rapporteur for Breakout Session on Interventions for Healthcare Workers. |

### Unpublished Writings & Manuscripts

Doctoral Dissertation:

LaMontagne AD: Medical Surveillance for Ethylene Oxide Exposure in Massachusetts Hospitals, Doctoral Thesis, Occupational Health Program, Harvard School of Public Health, 1994.

LaMontagne AD and Kelsey KT (submitted): Evaluating OSHA's ethylene oxide standard: employer exposure monitoring activities in Massachusetts hospitals from 1985 to 1993. American J Public Health.

LaMontagne AD (1996): The Massachusetts Hospital EtO Health & Safety Study: A Summary Report for Study Participants and Supporters.

### Publications

LaMontagne AD and Needleman C (1996): Overcoming practical challenges in intervention research in occupational health & safety. American Journal of Industrial Medicine 29;4: 367-372.

LaMontagne AD, Mangione TW, Christiani DC, and Kelsey KT (1996a): Medical surveillance for ethylene oxide exposure: practices and clinical findings in Massachusetts hospitals. Journal of Occupational & Environmental Medicine 38;2:144-154.

LaMontagne AD, Rudd RE, Mangione TW, and Kelsey KT (1996b): Determinants of providing ethylene oxide medical surveillance in Massachusetts hospitals. Journal of Occupational & Environmental Medicine 38;2:155-168.

LaMontagne AD and Kelsey KT (1995): Medical surveillance under OSHA's ethylene oxide standard in hospitals: research findings and their implications for employee health practice. Journal of Hospital Occupational Health 15(1):1-9.

**Abstract submitted for Presentation at Annual Meeting of the American Public Health Association, November 1996:**

**OSHA'S 1984 ETHYLENE OXIDE STANDARD: A REGULATORY SUCCESS STORY,**

AD LaMontagne and KT Kelsey. The Occupational Safety and Health Administration (OSHA) promulgated a full health standard for ethylene oxide (EtO) in 1984 on the basis of its genotoxic and other hazards. We will present an overview of the successes as well as shortcomings of this standard as it has been applied in the healthcare industry, where the vast majority of potentially exposed workers are found. Based on an evaluation of the implementation of OSHA's EtO standard in Massachusetts hospitals conducted by the authors of this presentation as well as studies conducted by other investigators, we will describe the following successes of the standard: (i) most hospitals are aware of the standard and have implemented worker health & safety training, exposure monitoring, medical surveillance (where indicated), and other prevention and control measures; (ii) worker breathing zone EtO exposures have decreased logarithmically since promulgation of the standard; (iii) OSHA citation activity in hospitals is correlated with improved implementation of the EtO standard's exposure monitoring requirements; (iv) the EtO standard spurred the development of new engineering controls for EtO sterilizers that have been associated with decreased worker exposure levels; and (v) the costs of complying with OSHA's 1 ppm Permissible Exposure Limit have turned out to be only half of what was originally anticipated in OSHA's 1984 Regulatory Impact Analysis. On the other hand, (i) the training that is implemented is typically brief, infrequent, and passive in nature; (ii) accidental exposures that escape current exposure monitoring strategies continue to occur widely, and (iii) potential links between EtO exposure, allergic sensitization, and asthma suggest that efforts to further reduce exposures are warranted. Overall, the EtO standard provides an example of OSHA regulation resulting in increased hazard awareness, new control technologies, and reduced worker exposures. In marking OSHA's 25th anniversary, this case study illustrates the need for OSHA regulations as well as the net positive impacts they can have.

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