High-speed monitoring of ethylene oxide at the sterilization unit

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ABSTRACT

A new application of Proton Transfer Reaction-Mass Spectrometry (PTR-MS) in the high-speed detection of ethylene oxide (EtO) is described. EtO, used to sterilize heat-sensitive medical products, is an aggressive mutagenic and carcinogenic agent. Therefore, precautions must be taken to protect personnel working at sterilization units. Using PTR-MS, the first high-speed measurements of EtO workload were conducted. Spatial and temporal EtO concentration patterns at sterilization units were determined. Online monitoring uncovered a leak in one sterilization chamber releasing EtO at concentrations up to 2 parts per million (ppmv) during the EtO desorption phase with the chamber door still closed.

We conclude that PTR-MS is able to determine EtO concentrations at a rate suitable for online surveillance of workload. Since single measurements cannot mirror temporal changes in concentration, high-speed measurement of EtO concentrations at sterilization units are recommend to guarantee safety and health of hospital personnel.

INTRODUCTION

EtO is broadly used to sterilize heat-sensitive medical equipment (LaMontagne and Kelsey, 1998). An estimated 75 000 health care employees in the United States alone are potentially exposed to EtO (Landrigan *et al.*, 1984). Among them, around 5000 workers possibly encounter EtO in its use as a sterilizing agent in the medical products manufacturing industry. A wide range of medical devices are sterilized using EtO (Centola *et al.*, 2001). However, a wide range of adverse effects elicited by acute and chronic exposure have been described (Preston, 1999, Shaham *et al.*, 2000, Their and Bolt, 2000). Although guidelines for occupational exposure limits exist, real-time monitoring of ambient air at sterilization units is not mandatory, even though the importance of continuous evaluation of ambient air has been highlighted (Rieder *et al.*, 2001b). Furthermore, Proton Transfer Reaction-Mass Spectrometry (PTR-MS) has recently been described as a valuable tool in the assessment of indoor air quality (Rieder *et al.*, 2001a).

Therefore, the aim of the present study was to perform high-speed monitoring of EtO at two sterilization units by PTR-MS to evaluate occupational exposure during sterilization.

METHODS

PTR-MS permits high-speed monitoring of volatile organic compounds (VOCs) with volume mixing ratios as low as a few pptv. Chemical ionization is thus applied based on proton-transfer reactions, with $[H_3O]^+$ as the primary reactant ion. $[H_3O]^+$ does not react with any of the natural components of air ($[O_2]$, $[N_2]$, [Xe], $[CO_2]$), as they have proton affinities lower than that of $[H_2O]$ molecules. Nevertheless, most of the VOCs have proton affinities greater than that of $[H_2O]$ and therefore proton transfer occurs at every collision with rate constants k within typical boundaries of 1.5×10^{-9} cm^3 s^{-1} $< k <$ 4×10^{-9} cm^3 s^{-1}. An additional advantage of using primary $[H_3O]^+$ ions is that many of their proton-transfer processes are non-

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dissociative, so that only one product ion species occurs for each neutral reactant. In cases where dissociation occurs, it frequently follows a straightforward pattern, e.g. ejection of an [H_2O] molecule from protonated alcohols (Lindinger *et al.*, 1998).

In PTR-MS concentration measurements, protonated EtO arises as a chemical species with masses of 45 atomic mass units (amu) and 46 amu (2.2% of the concentration at 45 amu, EtO with [^{13}C] isotopes). In addition to the concentrations at 45 and 46 amu, concentrations at 43 and 44 amu were measured to detect isotopes of chemical species other than EtO. A baseline concentration of 0.0088 ppmv was subtracted from all concentration measurements at 45 amu since this baseline might reflect chemical species other than EtO. In addition, high-speed measurements of all masses between 20 and 200 amu were performed during 7 working days to investigate possible fragmentation of larger chemical species. No such fragments interfering with mass 45 amu were detected.

EtO concentrations within and near sterilization chambers at the central sterilization unit (chamber L, chambers A and B) and at the ophthalmologic surgery unit (chamber C) of the Innsbruck University Hospital were investigated. The volumes of these chambers are 300 l (chamber L) and 180 l (chambers A–C).

A PTR-MS (Ionicon Analytics, Innsbruck, Austria) apparatus was positioned near the respective sterilization chambers. Air was collected through a Teflon® tube from within or near sterilization chambers. All EtO concentration measurements were conducted as high-speed measurements over several days, with the determination of EtO concentrations every 9 s.

The total room air volume of the central sterilization unit is 900 m^3. The full ventilation capacity is 8230 m^3/h, corresponding to a nine-fold air exchange per hour. The full ventilation capacity is used Mondays–Fridays 5:00 a.m. to 5:30 p.m. and Saturdays 5:45 p.m. to 12:30 p.m. During the night and on weekends, ventilation capacity is maintained at 50%.

Data Presentation

EtO concentrations are given either as maximum or as mean (SD) of concentrations during a time period. Units are given as parts per million (ppmv), corresponding to 1 part per 10^6.

RESULTS

The concentration of EtO directly after door-opening *within* the sterilization chambers varied between 0.19 and 31.46 ppmv (Table 1). The concentration of EtO in the chambers 9 h after door-opening was 0.100 ppmv (chamber L) and 0.091 ppmv (chamber A). The concentration of EtO in the large chamber (chamber L) 5 days after door opening was 0.035 ppmv.

The concentration of EtO in *room air* near the large chamber after door-opening showed a biexponential decay with two different time constants $\tau_1 = 0.50$ h (short-time behaviour 0–0.35 h after door-opening) and $\tau_2 = 10.1$ h (long-time behaviour 1–23.5 h after door-opening). During the 1-h phase after door-opening of the large sterilization chamber, EtO concentration in room air was 0.003 ± 0.002 ppmv.

During the sterilization phase (with chamber doors closed) none of the chambers released EtO. During the desorption phase (with chamber doors still closed) with a duration of 11.6 h one of the sterilization chambers (chamber B) released EtO at a maximum concentration of 1.95 ppmv and a mean concentration of 0.30 ± 0.195 ppmv near the chamber (Figure 1).

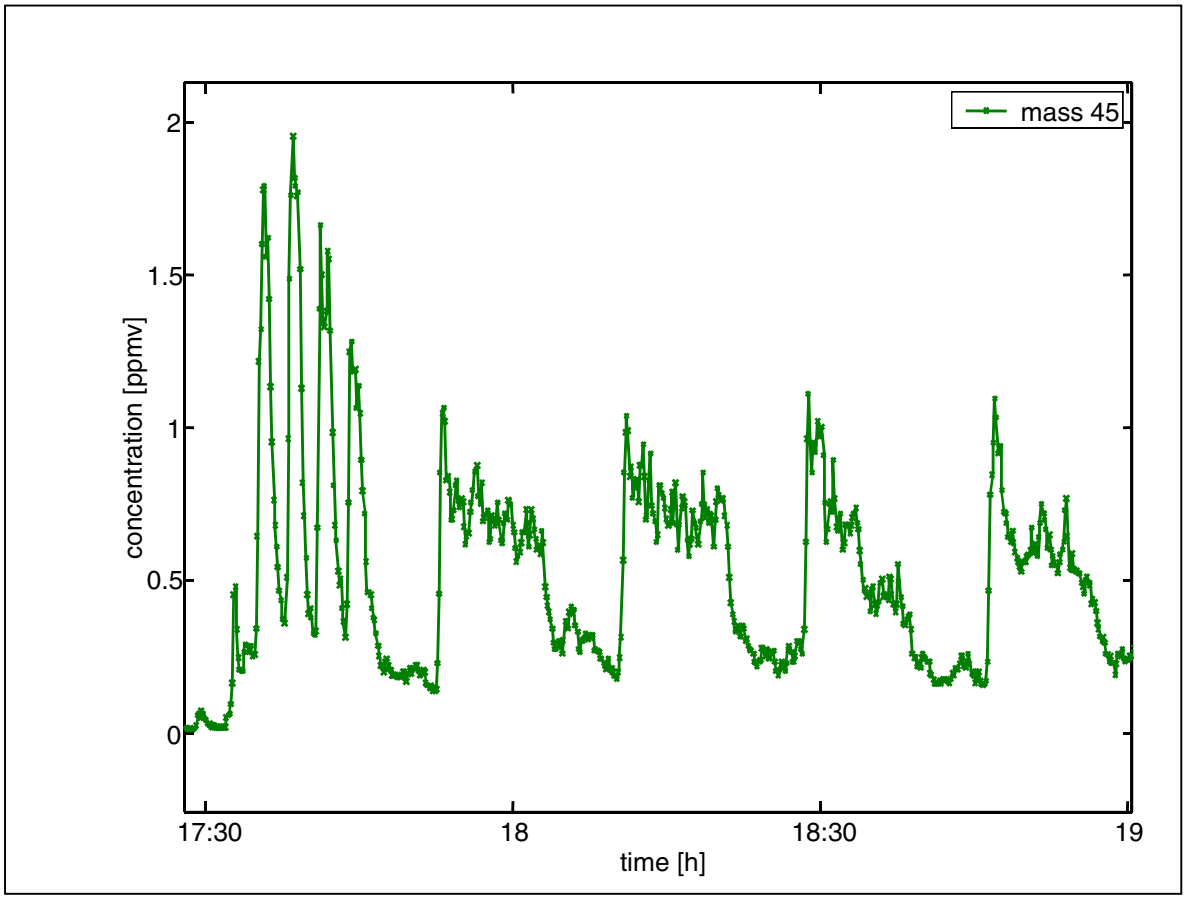

Figure 1 Concentration of ethylene oxide (EtO) near the defect sterilization chamber. During the sterilization phase, no EtO is released. During EtO desorption phase, EtO is released at a concentration of up to 2 ppmv outside the chamber although the door is closed.

DISCUSSION

In the present study, high-speed monitoring of EtO in ambient air at the sterilization unit was performed for the first time employing PTR-MS. Accurate determinations of EtO concentration patterns were obtained. It could be deducted from the measurements that chamber B (releasing EtO at concentrations of up to 2 ppmv) exhibited an EtO-leak effective during the desorption phase. This finding was verified by technicians inspecting the sterilization unit equipment.

Personnel at sterilization units are subject to a considerable health risk (Hogstedt *et al.*, 1986), which should be minimized as far as possible. LaMontagne estimated that one or more workers at 19% of EtO-using Massachusetts hospitals have experienced EtO-related health effects (LaMontagne and Kelsey, 1997). The National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) for EtO is 0.1 ppmv as an 8-h Time Weighted Average (TWA) with a 10-min ceiling limit of 5 ppmv (Landrigan *et al.*, 1984). Moreover, NIOSH has determined 800 ppmv as the EtO concentration immediately dangerous to life and health (IDLH) (NIOSH, 1986).

Workplace concentrations of EtO at medical sterilization sites have in the past been monitored with various methods, e.g., by using charcoal samplers and subsequent gas chromatographic analysis (Szopinski *et al.*, 1991).

The usual sampling techniques for ambient air give only a cumulative concentration value and no actual spatial or temporal profile of EtO concentrations. Being exposed, for example,

to 30 ppmv for 10 min during an 8-h day with otherwise relatively small concentrations would result in a TWA of 0.63 ppmv. Relating to our measurements, personnel working near the sterilization chamber during the desorption phase would have been exposed to 2 ppmv EtO in ambient air, which clearly exceeds thresholds, but this would have hardly been detected using cumulative measurements. Most importantly, real-time measurements could, in conjunction with the sterilization chamber's internal protocol, identify the timepoint of EtO leakage.

In full accordance with NIOSH, we therefore recommend high-speed measurement of EtO concentrations at sterilization units to guarantee safety and health of hospital personnel.

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