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Field Evaluation of Direct-Reading Continuous Ethylene Oxide Monitors

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Final Report



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I. INTRODUCTION

The Wilford Hall USAF Medical Center Central Processing Section (WHMC/SGLP) uses ethylene oxide (EtO) as a primary sterilizing agent. Because of their concern about the health effects of EtO, SGLP has searched for a continuous monitoring EtO system. In their search, they found two units (AMSCO's Envirogard III and Baseline Industries, Inc.'s Model 5500 Gas Analyzer), which were demonstrated during January and February 1989 for one week each in the sterilization area. To help determine if the continuous monitors were accurate, in January 1989 SGLP requested AF Occupational and Environmental Health Laboratory (AFOEHL) perform an evaluation of the two monitors.

A. Background: In September 1988 HQ USAF/SGPA requested HQ AFSC/SGPB task AFOEHL to evaluate AMSCO Envirogard III and other available instrumentation capable of warning central sterile supply (CSS) personnel of hazardous concentrations of EtO in the event of a sterilizer malfunction or a cylinder leak. In response to this tasking, AFOEHL contacted several instrumentation manufacturers including AMSCO and Baseline Industries, Inc. and obtained equipment specifications. A review of the specifications was made and an evaluation was completed.(1) However, this evaluation did not include actual field testing of the EtO monitors.

B. Objective: The objective of this evaluation was to conduct a field study to compare the performances of the two direct-reading continuous Eto monitors against the Occupational Safety and Health Administration's (OSHA) acceptable charcoal tube sampling method. In addition, the 3M EtO passive monitor sampling method was compared with the charcoal tube method and direct-reading instrumental method as well.

C. Survey Personnel:

Major Mohammad A. Hossain Capt David R. Carpenter MSgt Abel B. de la Rosa SSgt Pietro La Porta



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D. Personnel Contacted:

Colonel Darla Soeder, Head of Operating Room, WHMC Ms Josephine J. Anderson, Supervisor, Central Processing, WHMC Mr Hank Braly, Baseline Industries, Inc. Representative Mr Don Bebell, AMSCO Representative

II. METHOD AND RESULTS

A. Survey Procedure: Demonstrations of the two direct-reading continuous EtO monitors (Baseline Industries, Inc. and AMSCO) were arranged by SGLP. Both instruments were designed to continuously monitor EtO concentrations from four separate locations using a gas chromatography/photoionization detection (GC/PID) system and were capable of providing printout data showing date, time, preset alarm level, actual concentrations, and a time-weighted average (TWA). The demonstration for each instrument was held separately; however, the same sampling location was used for both monitors. Both instruments were temporarily installed for one week (AMSCO's Envirogard III in January and Baseline Industries Inc.'s Gas Analyzer in February) in the sterilization area. During the test only one sample point, in the mechanical room between the two EtO sterilizers, was continuously monitored by the instrument while simultaneous air sampling was conducted at the same location using charcoal tubes and 3M ethylene oxide monitors. For each instrument the test was conducted for only one day during the second shift. The charcoal tube sampling was accomplished by connecting two tubes in series in which the sampling rate was maintained at approximately 50 cubic centimeter per minute (cc/min). A record of the continuous monitor readings were obtained for the same time period as the air samples.

B. Analytical Methods: The samples collected during the test were analyzed by the Analytical Services Division of the AFOEHL. The charcoal tube samples were analyzed in accordance with the NIOSH Method 1607(2) and the 3M EtO monitors with the method developed by 3M Company, similar to NIOSH method 1614(3).

C. Results:

1. Since both instruments were demonstrated at different times, a direct comparison between the two continuous monitors was not possible. A comparison could be made between each instrument's response with the OSHA acceptable sampling method (charcoal tube) as well as the 3M EtO passive monitors performed during the test.

2. Figures I and II are graphs of the AMSCO and Baseline Industries, Inc. continuous monitor responses. These figures also show the corresponding time intervals during which we collected air samples. The Table summarizes the test results. For each air sample taken the corresponding average monitor response was calculated.

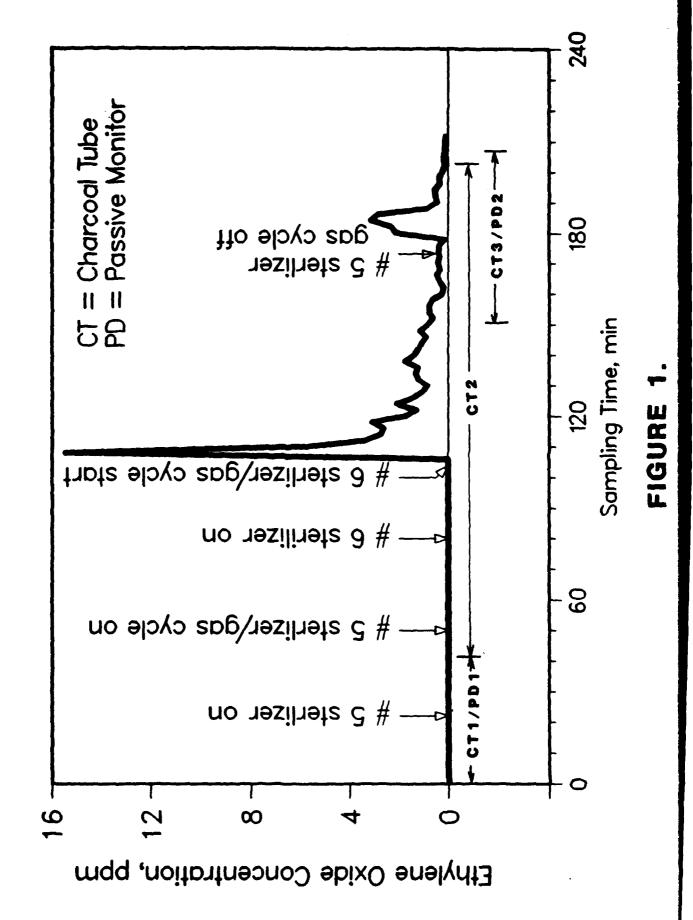
CONT III. CONCLUSIONS

A. Neither the Baseline Industries, Inc. nor the AMSCO continuous monitors corresponded to OSHA acceptable charcoal tube method of air sampling. Both instruments reported EtO concentrations much higher than those detected by the charcoal tubes. In only one instance did the continuous monitor, AMSCO, report a level less than the charcoal tube method. In this case, while the AMSCO monitor showed no response, the charcoal tube as well as the 3M EtO passive monitor reported a TWA concentration of 0.5 ppm.

B. The results indicated that any interferences with the detection system would be a positive error. Thus, the actual level of EtO would always be equal to or less than the continuous monitor reading.

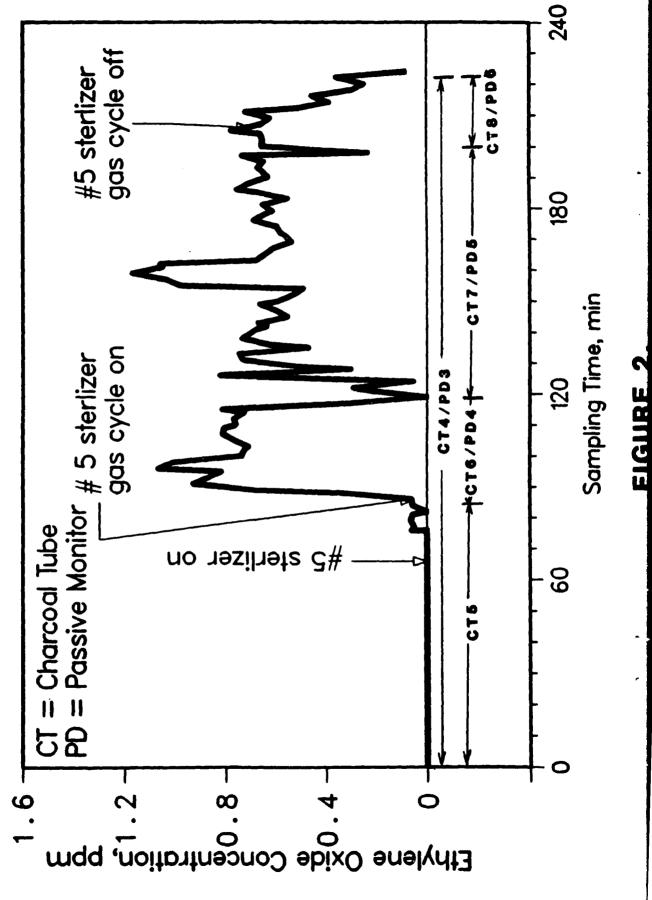
C. A good correlation between the 3M EtO passive monitor and charcoal tube sampling methods was established.

D. There is no way of knowing which method, the direct-reading continuous monitor or the charcoal tube/passive monitor, is more correct. However, the OSHA standard for EtO is based on measuring EtO by the charcoal tube method. Key words: Air Pollution, Trdustrial Medicina



AMSCO Ethylene Oxide Monitor Results

Baseline Industries, Ethylene Oxide Monitor Results



Comparison of Charcoal Tubes & 3M Passive Monitors Sampling Methods With Direct Reading Ethylene Oxide (EtO) Monitors

@EtO Monitors	*Charcoal Tubes	**3M Passive Monitors
A: ND	CT1: 0.5	PD1: 0.5
A: 0.93	CT2: ND (<0.013)	NS
A: 0.82	CT3: ND (<0.042)	PD2: ND (<0.041)
B: 0.571	CT4: ND (<0.017)	PD3: ND (<0.018)
B: 0.029	· · · · · · ·	NS
B: 0.656	CT6: ND (<0.122)	PD4: ND (<0.119)
B: 0.623	CT7: ND (<0.051)	PD5: ND (<0.049)
B: 0.480	CT8: ND (<0.167)	PD6: ND (<0.162)
Industries, Inc.	*Charcoal Tube **3M Passive Mo	
	A: 0.93 A: 0.82 B: 0.571 B: 0.029 B: 0.656 B: 0.623	A: 0.93 A: 0.82 B: 0.571 B: 0.029 B: 0.656 CT6: ND (<0.017) CT4: ND (<0.017) CT5: ND (<0.050) CT5: ND (<0.050) CT6: ND (<0.122) CT7: ND (<0.051) CT8: ND (<0.167) CT8: ND (<0.167)

Any direct reading method used for compliance monitoring would need to have the same response as the standard method.

IV. RECOMMENDATIONS

A. The continuous monitors should not be used for compliance monitoring. Personal exposure assessments should be made by using the OSHA acceptable sampling method described in 29 CFR 1910.1047, Ethylene Oxide(4).

B. Both continuous monitors responded by detecting EtO concentrations greater than the OSHA acceptable method. Either machine could be used as a screening or warning device.

C. If an organization is looking to use a direct-reading continuous Et0 monitor to warn personnel of a sterilizer malfunction or a cylinder leak, where high levels of Et0 is expected, a less sensitive low cost monitor should be considered.

References

- 1. AFOEHL/ECH letter to HQ AF/SGPA, 29 Nov 1988, Evaluation of Ethylene Oxide (EtO) Alarm Instrumentation.
- National Institute for Occupational Safety and Health: Ethylene Oxide, Method 1607. NIOSH Manual of Analytical Methods, Third Edition, DHHS (NIOSH) Publication No. 84-100 (1984).
- 3. National Institute for Occupational Safety and Health: Ethylene Oxide, Method 1614. August 1987 Supplement to the NIOSH Manual of Analytical Methods, Third Edition, DHHS (NIOSH) Publication No. 84-100 (1984).
- 4. U.S. Department of Labor, Occupational Safety and Health Administration: 29 CFR CFR Part 1910 Occupational Exposure to Ethylene Oxide. Fed. Reg. 49(122):25734 (June 22,1984).

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