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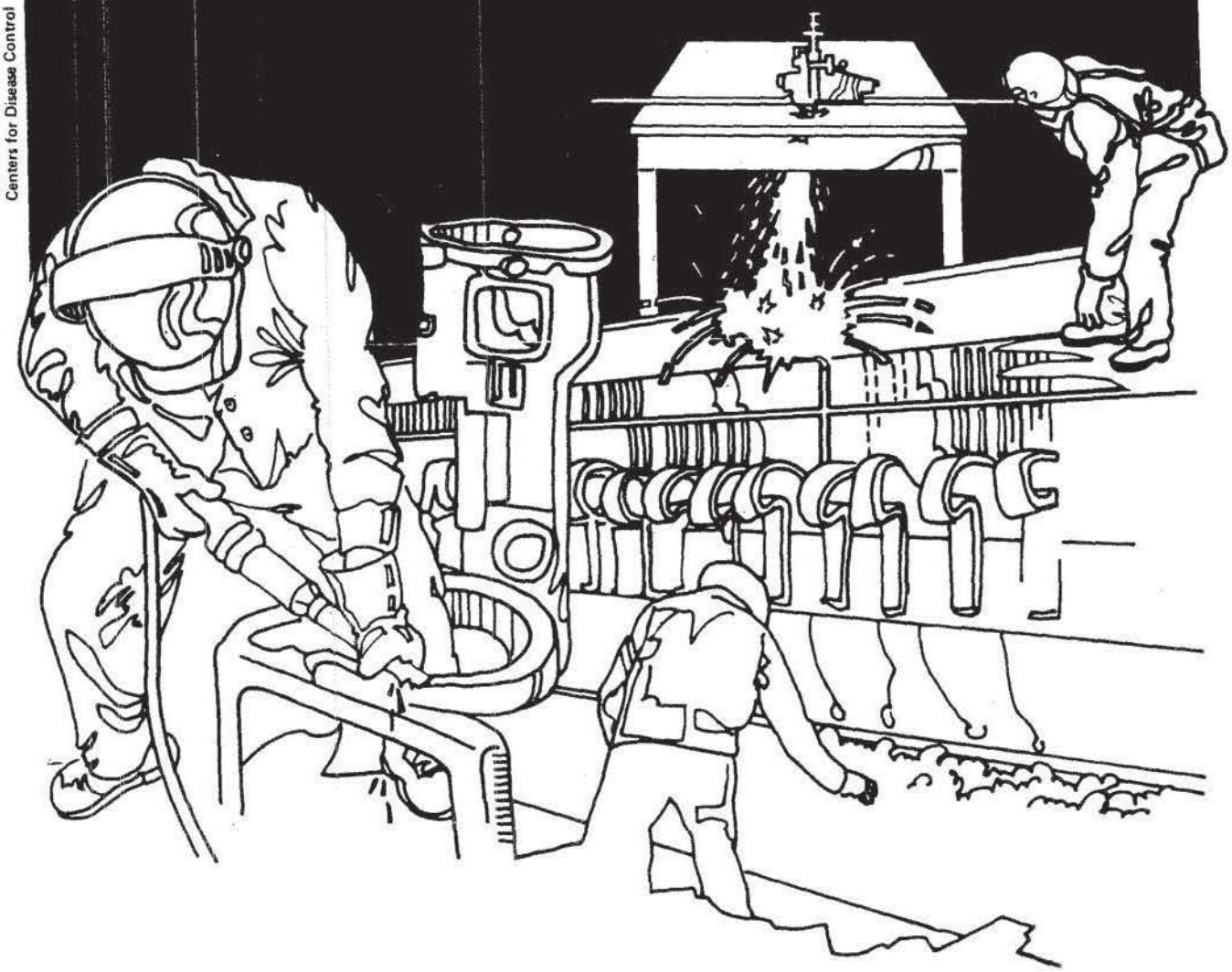

Health Hazard Evaluation Report

HETA 84-217-1884
CHILDREN'S HOSPITAL
NATIONAL MEDICAL CENTER
WASHINGTON, D.C.

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

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I. SUMMARY

On February 29, 1984, the National Institute for Occupational Safety and Health (NIOSH) received a request for a Health Hazard Evaluation from the Service Employees International Union, Local 722, representing the workers in the Sterile Processing and Distribution (SPD) unit of the Children's Hospital National Medical Center, Washington, D.C. Employees were concerned about their potential for exposure to ethylene oxide during its use as a sterilant.

An initial survey in March 1984 documented personal exposures for five SPD Technicians to EtO ranging from 2.0 to 4.6 ppm, and averaged 3.7 ppm for a full workshift. NIOSH recommends that exposure to EtO be controlled to less than 0.1 ppm for an 8-hour time-weighted average, and that exposure not exceed 5 ppm for more than ten minutes in a day. One 15-minute personal exposure of 25 ppm was measured. The OSHA PEL for EtO is 1 ppm for a 8-hour TWA. Numerous EtO emission sources were identified. Recommendations were made to reduce exposures.

A follow-up survey was conducted in December 1985 following installation of engineering controls on the sterilization equipment. These efforts reduced personal full-shift exposures for the SPD Technicians to an average of 0.40 ppm (range, 0.38 to 0.46 ppm). All six of the personal exposures exceeded the NIOSH REL of 0.1 ppm. A short-term exposure of 20 ppm was measured using an infrared direct-reading instrument. The same EtO emission sources were seen during this evaluation as were identified in the first survey, but the source strengths had diminished. It was recommended that the use of this sterilization equipment be discontinued.

Following repairs to the control system for the aeration chamber, hospital management requested a second follow-up evaluation. In May 1986 air sampling was conducted during a demonstration run of the sterilization equipment. During the demonstration, short-term air samples measured concentrations of EtO ranging from 0.3 to 0.4 ppm in worker areas beyond the control of local exhaust systems.

Children's Hospital had purchased new sterilization equipment at the time of this report. This equipment combines sterilization and aeration into one unit so that load transfer is not necessary. The unit is equipped with modern engineering controls.

In light of NIOSH's REL for ethylene oxide, it was determined that, although the final EtO concentrations measured were considerably lower than those found during the previous evaluations, these potential exposures on a daily basis presented an unnecessary and unacceptable risk for the workers in the SPD. It was recommended that the use of this sterilization and decontamination equipment be discontinued.

KEYWORDS: SIC 8069 (Specialty Hospitals, Except Psychiatric), ethylene oxide, sterilizer

II. INTRODUCTION

On February 29, 1984 the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation from the Services Employees International Union, Local 722, representing the employees at Children's Hospital National Medical Center (CHNMC) in Washington, D.C. The employees at CHNMC were concerned about their potential for exposure to ethylene oxide (EtO). EtO is used in the Sterile Processing and Distribution (SPD) department as a sterilant for heat sensitive items.

An initial evaluation of the decontamination/sterilization process was conducted in March 1984. Results and recommendations for this evaluation were reported to CHNMC and the requestors by letter in April, July, and October 1984. A first follow-up evaluation was conducted in December 1985 to determine whether engineering controls which were installed between the initial and follow-up evaluations were effective. The results and recommendations for this evaluation were reported by letter to CHNMC and the requestors in January and March 1986. A second follow-up was conducted in May 1986 at the request of CHNMC. The results and recommendations from this survey were reported by letter in July 1986. This report is a compilation of the reports of the three surveys conducted over the 26-month period.

III. BACKGROUND

Ethylene oxide decontamination/sterilization is conducted in the SPD department of the hospital. The layout of this area is in Figure 1. Decontamination in this report actually refers to a short sterilization cycle required for some items prior to handling, washing, and final sterilization. The ethylene oxide equipment is located in a mechanical room and is accessible and controlled from two sides. This equipment could be loaded from the Decontamination area side or the Clean Preparation and Packaging (sterile prep) area side. The accompanying ventilated aeration chamber is accessed only from the sterile prep side.

At the time of these evaluations, there were three Sterile Processing and Distribution Technicians (SPD Techs) who worked in decontamination, on three overlapping shifts, from 0700 to 2330. They processed items in the sterilizer about twice a week. These decontamination runs lasted about eight hours. Following an open aeration period in the Decontamination area, the decontaminated items were sent through a washer, removed on the sterile prep side, and then sterilized. There were ten SPD Techs working in the sterile prep area over two shifts; from 0700 to 1530, and 1500 to 2330. They process items in the sterilizer once a day, in the morning. These sterilization runs last about four hours. Occasionally, a second sterilization run would be completed on the second shift.

The sterilizer in use at CHNMC was an AMSCO Vacamatic II Floorloader, model M72FLS (S/N 750211-8). The chamber was six feet tall, 30 inches wide, and eight feet long. There were no emission control features installed with this unit. Figure 2 depicts a typical cycle for this kind of equipment. The first phase is for preevacuation and conditioning. During this phase the chamber is heated to 130-140°F and humidified (with steam) to 20-50% relative humidity. Next the chamber is charged with a mixture of EtO and dichlorodifluoromethane (12:88 mixture by weight) to expose the items for decontamination or sterilization. Following the exposure phase are two post-evacuation phases and two air flushes.

The potential for EtO emissions occurs during the post-exposure phases, barring leaks in the EtO charging system or faulty seals on the chamber doors. The typical means for evacuating the chamber is a water ring vacuum pump. Most of the EtO is vented through a stack to the outside, however a significant amount mixes with the water in the pump seal and is discharged down the drain. At the air break in the plumbing, a portion of the EtO diffuses away from the discharged water and can escape into the work area if it is not carried away by local ventilation.

A second source for EtO emissions is the gas which remains with the sterilized items following exposure. Unless the sterilizer is equipped to serve as an aeration chamber, the load must be removed and transferred for aeration. To do this the door to the sterilizer is opened and the load is manually moved to the aeration chamber.

Subsequent to sterilization runs, a 12-hour aeration period ensues, followed by a 48-hour quarantine period. The sterilized items are removed from the aeration chamber and stored in a designated quarantine cabinet (unventilated). Biological cultures sterilized with the load are inspected for growth before the load can be released from quarantine.

The SPD has its own heating, ventilation, and air-conditioning (HVAC) system. This system was designed to keep SPD negatively pressurized with respect to surrounding hospital areas.

IV. EVALUATION DESIGN AND METHODS

Personal exposure and general area air samples were collected to determine airborne concentrations of EtO. Air sampling and direct reading measurements were used to determine emission sources around the sterilization equipment.

Through the course of the project advances were made in the air sampling methodology for EtO. The method used during the initial evaluation was NIOSH method 1607.[1] This was a charcoal tube collection method and used two charcoal tubes connected in series.

The first tube contained 400 milligrams (mg) of activated coconut shell carbon and the second tube contained 200 mg. The air samples were collected at a flow rate of 20-50 milliliters per minute (ml/min). The samples were analyzed by a derivatization, gas chromatographic (GC) method. The EtO was desorbed using a benzene, carbon disulfide mixture (99:1). This was then derivatized to 2-bromoethanol by first adding hydrogen bromide, then sodium carbonate. This derivative was detected by electron capture. The analytical limit of detection (LOD) for this method was 0.1 microgram per sample (0.002 ppm for a 25 liter sample), and the limit of quantitation (LOQ) was 0.9ug/sample (0.018 ppm).

On subsequent evaluations NIOSH method 1607 was replaced with NIOSH method 1614.[1] The samples were collected on 150 mg of hydrogen bromide-coated petroleum charcoal. These samples were desorbed and reacted with 1 ml dimethylformamide (for 5 minutes), then analyzed by GC. The analyte, 2-bromoethylheptafluorobutyrate, was detected by electron capture. The analytical LODs and LOQs were different for the two follow-up surveys and are presented with the results.

A Foxboro® MIRAN 80 Ambient Air Analyzer was used for measuring peak worker breathing zone EtO exposure, general area EtO concentrations, and monitoring process equipment for EtO emissions. This is a portable, microprocessor-controlled infrared spectrometer. The instrument can continuously monitor the air and provide a printout of averaged data at a specified interval, or an instantaneous reading upon command.

V. EVALUATION CRITERIA

A. Environmental Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase

the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and Recommended Exposure Limits (RELs), 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs), and 3) the U.S. Department of Labor (OSHA) Permissible Exposure Limits (PELs). Often, the NIOSH RELs and ACGIH TLVs are lower than the corresponding OSHA PEL. Both NIOSH RELs and ACGIH TLVs usually are based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH RELs, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

B. Toxicological Effects of Exposure to Ethylene Oxide

Ethylene oxide is a major industrial chemical. It is used primarily as an intermediate in the production of other industrial chemicals such as ethylene glycol. Ethylene oxide is used also as a gas sterilant for heat-sensitive items in the health care industry and as a fumigant for such items as spices, books, and furniture.

Ethylene oxide is a highly exothermic reactant and potentially explosive substance. As a result, the handling, storage, and use of EtO presents potentially serious problems. EtO is a gas at room temperature and a liquid below 55°F. The liquid is relatively stable; however, vapor concentrations greater than 3% are highly flammable, and air mixtures of EtO will explode when exposed to heat or open flames.[2]

Acute Effects

The primary mode of exposure to ethylene oxide is through inhalation (breathing). Ethylene oxide is an irritant of the eyes,

respiratory tract, and skin. Early symptoms of EtO exposure include irritation of the eyes, nose, and throat and a peculiar taste. The delayed effects of exposure include headache, nausea, vomiting, pulmonary edema, bronchitis, drowsiness, weakness, and electrocardiograph abnormalities.[3] There have also been reports of cases of neurotoxicity induced by ethylene oxide exposure.[4,5,6]

Dermal (skin) contact with solutions of ethylene oxide as low as 1% can cause burns with edema (swelling) and erythema (redness). Although skin contact with undiluted EtO does not cause burns, it can cause frostbite as a result of rapid evaporation.[7] The severity of skin burns from solutions of ethylene oxide appear to be influenced by both the length of contact with the skin and the strength of the solutions, with solutions around 50% appearing to be the most hazardous.[2] Both the undiluted liquid and solutions of EtO may cause severe eye irritation or damage and there have been case reports of cataracts among workers exposed to high levels of EtO.[8,9]

Carcinogenic Effects

Ethylene oxide has been shown to be carcinogenic to animals. Two inhalation studies demonstrated carcinogenic responses in F344 rats. Results were similar in both studies and consisted of increased incidences of mononuclear cell leukemia, peritoneal mesotheliomas, and primary brain tumors.[10,11] Inhalation studies using $B6C3F_1$ mice were interpreted as clear evidence of carcinogenic activity. Dose-related increased incidences of benign or malignant neoplasms of the lung and benign neoplasms of the harderian gland were seen in both male and female $B6C3F_1$ mice following exposure to EtO vapor at 50 and 100 ppm. In female mice, EtO caused additional malignant neoplasms of the uterus, mammary gland, and the hematopoietic system (lymphoma).[12] There is also some limited evidence which suggests that workers exposed to ethylene oxide may experience an increased risk of leukemia as compared to unexposed workers.[13,14]

Mutagenic Effects

Ethylene oxide has been shown to cause changes in the genetic material of lower biological species including Salmonella[15] and fruit flies[16] as well as mammals, including rabbits[17] and monkeys.[18] These genetic changes have been shown to be heritable (passed from one generation to the next) in experiments with mice.[19] EtO has also been shown to have a dose-rate effect on genetic material.[20] Several studies have demonstrated that genetic changes can also occur among humans exposed to EtO. Workers

exposed to EtO have been found to have significantly increased numbers of chromosomal aberations and sister chromatid exchanges as compared to workers unexposed to EtO.[21,22]

Reproductive Effects

Animal experiments with ethylene oxide have indicated adverse reproductive effects from EtO exposure. A decrease in the number of pups born per litter was observed among female rats exposed to EtO prior to mating and during gestation (pregnancy)[23], and an increase in the number of malformed fetuses per litter was observed among female mice administered EtO intravenously during gestation.[24] Male monkeys exposed to ethylene oxide have been shown to have reductions in sperm count and sperm motility.[18] There is also some human evidence which suggests that women exposed to EtO during their pregnancies may experience increased rates of spontaneous abortions, although this information is not conclusive.[25]

C. Ethylene Oxide Exposure Criteria

NIOSH recommends that ethylene oxide be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to the lowest feasible level (LFL). In 1983, NIOSH recommended to OSHA that an 8-hour TWA be set lower than 0.1 ppm, because even at 0.1 ppm, according to available risk assessments, the risk of excess mortality is not completely eliminated. NIOSH also recommended 5 ppm as a ceiling concentration and that this ceiling not be achieved for more than 10 minutes in any work day.[26,27]

The OSHA PEL for EtO is 1 ppm for an 8-hr TWA exposure. The Standard also established an "action level" of 0.5 ppm as an 8-hour TWA concentration, above which employers must initiate certain compliance activities, such as periodic employee monitoring and medical surveillance. This standard is based on the animal and human data showing that exposure to EtO presents a carcinogenic, mutagenic, reproductive, neurologic, and sensitization hazard to workers. Included in the present OSHA standard are requirements for methods of controlling EtO, personal protective equipment, measurement of employee exposures, training, and medical surveillance of the exposed employees.[28]

During the rulemaking proceedings that led to the establishmnent of the 1 ppm OSHA PEL in June 1984, the issue of whether there was a need for a short-term exposure limit (STEL) for worker protection from EtO was raised. In January 1985, OSHA determined that adoption of a STEL for EtO was not warranted by the available health evidence. Resulting from litigation in 1986 (Public Citizen Health Group v. Tyson, U.S. Court of Appeals, District of Columbia

Circuit), the Court decided that the OSH Act compels OSHA to promulgate a short-term limit. In January 1988 OSHA proposed the adoption of an excursion limit (EL) of 5 ppm over a maximum 15 minute period (53 FR 1724, Jan. 21, 1988).

VI. RESULTS AND DISCUSSION

Initial Evaluation

The first NIOSH evaluation at Children's Hospital was conducted March 20, 1984. Full-shift worker exposures and general area concentrations of EtO were monitored, as well as short-term exposures during all phases of the EtO sterilization/decontamination process. These included; loading and unloading the sterilizer from both sides, loading and unloading the aeration chamber in Sterile Prep, open aeration in Decontamination, sterilizer evacuation at the end of exposure, and quarantine in Sterile Prep.

Results from the first evaluation are presented in Tables 1-4. Personal breathing zone results are in Table 1. The range of full-shift EtO exposures was 2.0 to 4.6 ppm for 5 samples. The average exposure was 3.7 ppm (SD $\pm$1.1). All personal exposures exceeded both the NIOSH REL (<0.1 ppm, 8-hr TWA) and the OSHA PEL (1.0 ppm, 8-hr TWA). One personal short-term exposure (15-minute) sample was collected during the transfer of items from the exposure chamber to the aeration chamber in Sterile Prep. This EtO exposure was 25.0 ppm, and exceeded the NIOSH REL for short-term exposure of 5 ppm for any 10-minute period in a day,and the proposed OSHA EL (5 ppm, 15-minute period). Only two SPD Techs handled the items exposed to EtO, one from Sterile Prep and one from Decontamination. Both workers had full-shift exposures of 4.6 ppm. All other exposures measured resulted from the workers performing their jobs in the Sterile Prep area.

Area sampling results are presented in Tables 2 and 3. Full-shift TWA area results ranged from 0.3 to 57 ppm (Table 2). Short-term area results ranged from 0.4 to 255 ppm (Table 3). These results showed that this system was fraught with EtO emission points. The greatest concentrations were found in the mechanical room, which contains the actual sterilization and aeration units, and mechanical accoutrements. The reason for the high concentration here is that the drain for the water-sealed pump discharge is in this room. Points of emissions into the worker areas were: the sterilizer doors, probably due to EtO escaping from the mechanical room around the doors, not faulty door seals; a faulty door seal on the aeration chamber; and the quarantine cabinet which is neither ventilated nor designed as a containment chamber. In the Decontaminaton Area, aeration of decontaminated items in the open room was practiced. One air sample collected in the corridor outside SPD measured 0.3 ppm EtO.

Table 4 presents direct reading instrument measurements of EtO. These measurements are supportive of the sorbent tube results.

Following this evaluation, recommendations were offered to reduce the exposures which were measured. The hospital administration had plans underway to install a local ventilation kit manufactured by AMSCO, the manufacturer of the sterilizer. This retro-fit kit included slot exhaust hoods above both sterilizer doors and a ventilated collar around the floor drain for the vacuum pump. We recommended that, in addition to installing the ventilation kit for the sterilizer: 1) the seal for the aeration chamber door should be replaced; 2) ventilation should be added to the quarantine cabinet; 3) open aeration in the Decontamination Area should be discontinued immediately; 4) the mechanical room should be off limits for all personnel during machine operation; 5) and instructions regarding sterilizer operating procedures and proper user work practices should be posted prominently, and all operators should be trained in these procedures and work practices.

First Follow-up Evaluation

On December 5, 1985, NIOSH investigators conducted a second evaluation to determine the effectiveness of equipment modifications in lowering worker exposure to EtO. At this time the AMSCO Enviro-Guard kit had been installed, and the NIOSH recommendations from the first evaluaiton had been complied with, except for ventilating the quarantine cabinet. Survey methods were similar to the initial evaluation, except that air samples were collected using the newer method (NIOSH Method 1614). The analytical LOD for the samples collected at this time was 1.8 ug/sample (0.04 ppm for a 25 liter sample, 0.5 ppm for a 2 liter sample), and the LOQ was 3.6 ug/sample (0.08 ppm and 1.0 ppm).

The air sample results collected during this survey are presented in Tables 5-7. Exposure to EtO for SPD Techs working in the Sterile Prep and Decontamination areas ranged from 0.38 to 0.46 ppm and averaged 0.40 ppm (SD $\pm$ 0.04) during first shift operations (Table 5). A short-term exposure (10 minutes duration) of 4.0 ppm was measured in the breathing zone of an SPD Tech while removing a decontaminated load from the sterilizer. On the third shift, two full-shift general area samples placed in worker areas measured 1 ppm EtO while a decontamination run was in progress (Table 6). On the first shift, during a sterilization run, full-shift area samples in worker areas measured concentrations ranging from 0.10 to 0.56 ppm. These samples indicated that any worker in the SPD areas monitored would have been exposed to EtO at concentrations greater than the NIOSH REL. EtO was detected at every potential emission point monitored during both sterilizer runs. One sample collected in the corridor outside the SPD measured 0.1 ppm EtO. This showed that those outside the sterilizer use areas still had a potential for exposure. Table 7 presents the

results of various short-term area samples collected during the first shift sterilizer run. The most remarkable result was the measurement of 85 ppm EtO outside the mechanical room door during the first exhaust phase of the decontamination run.

Following this second evaluation the NIOSH investigator determined that a health hazard still existed during the use of this sterilization equipment. It was recommended that use of the AMSCO Vacamatic II sterilizer should be discontinued until all control equipment installed on the sterilization unit, aeration chamber, and in the mechanical room was evaluated to determine whether performance was within design specifications. This equipment included the vacuum pump drain collar, slot hoods over the sterilizer doors, aeration chamber exhaust, the dedicated exhaust system for the mechanical room, and the restrictor valve between the exposure chamber and the evacuation pump. Also, work practices training should be reevaluated, and all trained workers should be monitored for a period of time by supervisory staff to ensure effectiveness of training.

Second Follow-up Evaluation

In April 1986, the management of Children's Hospital requested a second follow-up evaluation of the sterilization equipment. Upon inspection of the control systems following the first follow-up survey an exhaust fan belt for the aeration chamber was found to be so loose that it rendered the fan inoperable. On May 1, 1986, NIOSH investigaters conducted an evaluation during a demonstration run of the equipment, since normal operations had been discontinued at NIOSH's recommendation. The exposure chamber was empty during the demonstration. The purpose was to see if control systems were operating to prevent exposure to workers in surrounding areas. The integrity of the aeration chamber and potential exposures during transfer operations could not be evaluated.

Seventeen air samples were collected at six locations around the sterilizer before and during the demonstration run, using NIOSH Method 1614. The analytical LOD for these samples was 1.1 ug/sample (0.05 ppm for a 13 liter sample) and the LOQ was 2.2 ug/sample (0.10 ppm). Results for these samples are presented in Table 8.

There was no EtO detected prior to the demonstration run. A concentration of 0.66 ppm was found in the mechanical room during the demonstration. The concentrations found in areas around the system during the first exhaust phase (90 minute duration) ranged from 0.28 to 0.39 ppm. During the second exhaust phase (60 minute duration) the EtO concentrations were between the analytical LOD (0.09 ppm for a 7 liter sample) and LOQ (0.17 ppm), but were near 0.1 ppm.

Adjustments had apparently been made to lengthen the exhaust phases of the system. The exhaust phases lasted approximately 20 minutes during the first two evaluations and 60 to 90 minutes during ths evaluation. Engineering staff present during the air sampling period were not aware of any adjustments, but did not rule out the possibility. The most likely adjustment would have been to the restrictor valve between the chamber and the evacuation pump to allow for a slower discharge of the EtO from the chamber.

VII. CONCLUSION

It was determined that, although the EtO concentrations measured during the third survey were considerably lower than those found during the previous evaluations, these potential exposures on a daily basis presented an unnecessary and unacceptable risk for the workers in the SPD.

VIII. RECOMMENDATIONS

It was recommended that this equipment not be used for EtO sterilization and decontamination. Sterilization equipment with engineering controls which could limit exposure to EtO to below detectable concentrations was available. NIOSH has documented that exposures below 0.1 are achievable in several other health hazard evaluations.[29,30,31,32] It was suggested that it would be more beneficial to invest in new equipment than to spend further time and expense in trying to control the current system.

IX. EPILOGUE

Children's Hospital National Medical Center had purchased new sterilization equipment at the time of this report. The equipment has the capability to perform both sterilization and aeration processes. This feature eliminates the need to transfer sterilized items to a separate chamber for aeration and thus a significant source of EtO exposure. The unit is equipped with modern engineering control features.

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XII. DISTRIBUTION AND AVAILABILITY OF REPORT

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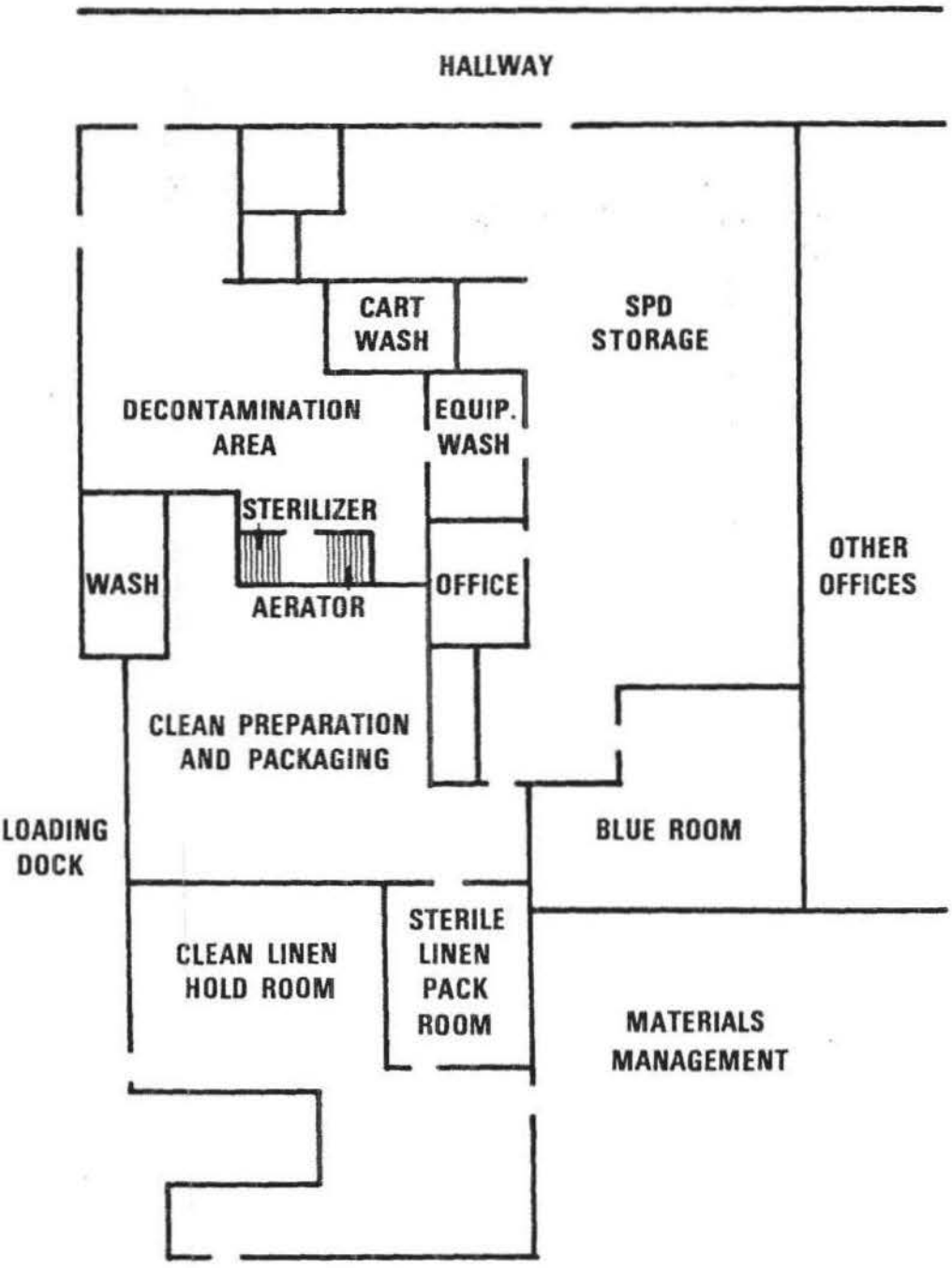
1. Children's Hospital National Medical Center, Washington, D.C.
2. Service Employees International Union, Washington, D.C.
3. OSHA, Region III

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.



STERILE PROCESSING AND DISTRIBUTION AREA FLOOR PLAN

Figure 1

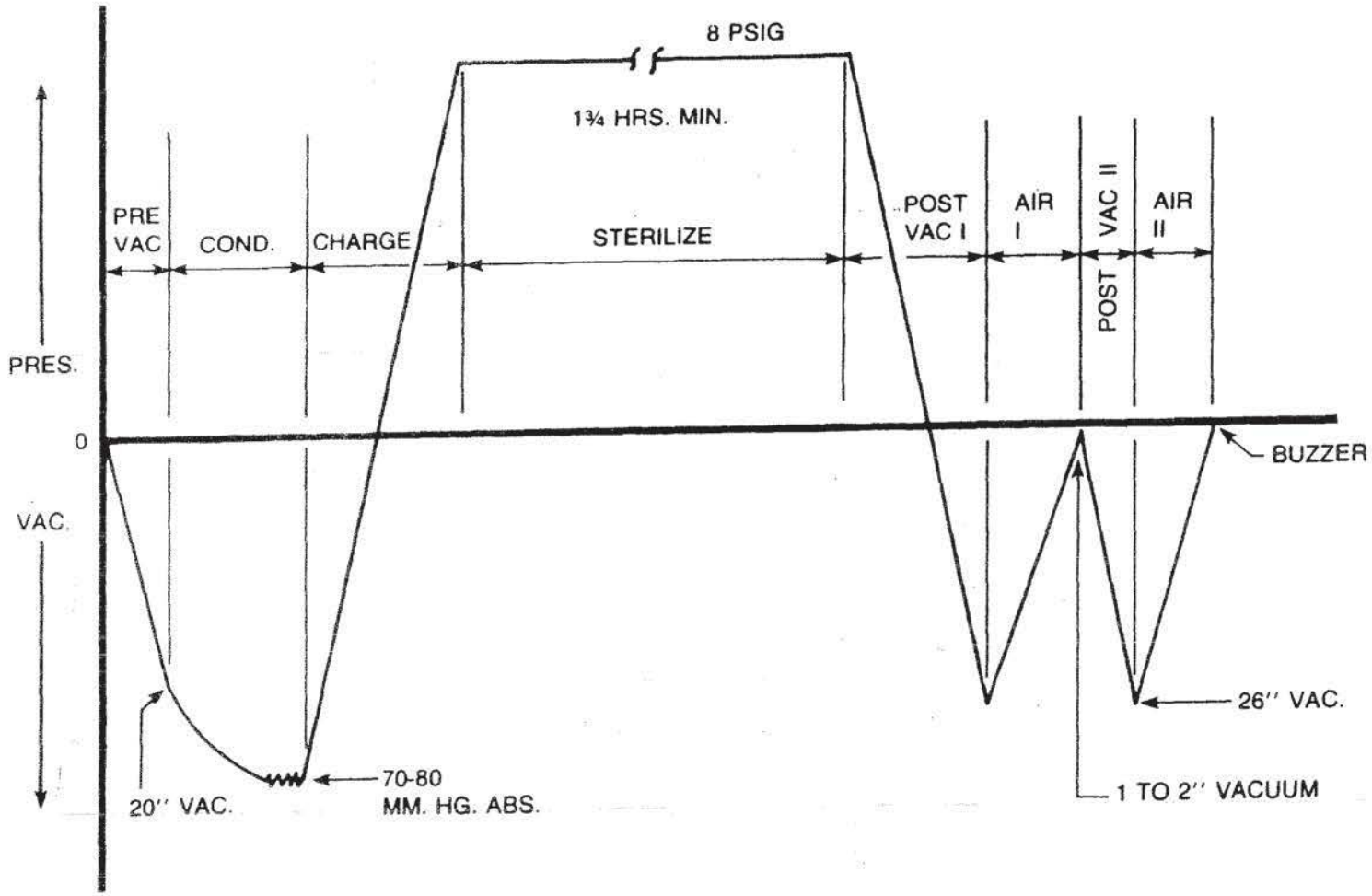


Figure 2 Sterilizer Typical Cycle

Table 1
Personal Ethylene Oxide Exposure Results
Children's Hospital National Medical Center
Washington, D.C.
March 20, 1984

HETA 84-217

Job	Sample Description #	Duration	Volume (liters)	Concentration, ppm Half-shift	TWA
SPD group leader	3	0718-1100	4.4	1.9	2.0
	31	1100-1522	4.2	2.1	
SPD technician	6	0720-1156	5.5	2.9	3.8
	33	1252-1522	3.0	5.4	
SPD technician	8	0722-1253	6.6	2.4	3.7
	27	1253-1522	2.9	6.7	
SPD technician	7	0728-1155	5.3	3.8	4.6
	35	1301-1510	2.6	6.3	
Decntamination group leader	2	0725-1207	5.6	3.6	4.6
	28	1208-1527	4.0	6.0	
				Ceiling (15-minute)	
SPD technician -during transfer of load from sterilizer to aerator	36	1340-1355	0.7	25.0	

Exposure Criteria: (ppm)		
	NIOSH	LFL*
	OSHA	1.0**

* Lowest Feasible Level, REL <0.1 ppm

** - The OSHA Standard consists of a Permissible Exposure Limit of 1.0 ppm determined as an 8-hour time weighted average (TWA) concentration and an "action level" of 0.5 ppm, as an 8-hour TWA. When employee exposures exceed the "action level", the employer must initiate certain compliance activities such as periodic employee exposure monitoring and medical surveillance.

Table 2
Full-Shift Area Ethylene Oxide Sample Results
Children's Hospital National Medical Center
Washington, D.C.
March 20, 1984

HETA 84-217

Area	Sample Description				
	#	Duration	Volume (liters)	Concentration, ppm Half-shift	TWA
Sterilizer door, sterile prep	1	0730-1203	5.5	3.2	3.8
	26	1204-1519	3.9	4.7	
Aerator	11	0733-1204	5.4	7.0	8.0
	30	1205-1519	3.9	9.4	
Tray preparation, sterile prep	9	0740-1108	4.2	3.1	2.2
	24	1108-1520	5.0	1.4	
Mechanical room, above drain	10	0745-1218	5.4	4.9	57
	20	1217-1524	3.7	132	
Decontamination, open aeration area	12	0745-1218	5.5	4.9	6.4
	21	1218-1524	3.7	8.5	
Sterilizer door, decontamination	13	0745-1221	5.5	2.7	11
	25	1221-1525	3.7	23	
Central supply storage area	15	0820-1158	4.4	0.2	0.3
	23	1158-1523	4.1	0.3	
Corridor, outside SPD/decontam	14	0830-1140	3.8	(0.02)*	0.3
	29	1142-1527	4.5	0.5	

* - This value was between the analytical LOD and LOQ. This is a trace value and is considered semi-quantitative.

Table 3

Short-term Area Ethylene Oxide Sample Results
Children's Hospital National Medical Center
Washington, D.C.
March 20, 1984

HETA 84-217

Area	Sample Description			
	#	Duration	Volume (liters)	Concentration (ppm)
Quarantine cabinet	17	0823-0949	4.3	19
SPD office	16	0830-0947	3.6	0.4
Aeration, decontamination	19	0957-1118	3.9	1.6
Mechanical room	18	0958-1119	3.9	0.7
Mechanical room during exhaust	34	1300-1326	1.3	255
Mechanical room during air flush	42	1328-1345	0.8	96
Decontamination, next to mechanical	40	1346-1401	0.7	7.1

Table 4
Direct Reading Measurements of EtO Concentrations
Children's Hospital National Medical Center
Washington, D.C.
March 20, 1984

HETA 84-217

Area/Location	Concentration (ppm)	Remarks
Decontamination		
Next to mechanical room door	40	During air flush prior to opening sterilizer door
SPD Tech breathing zone	18-24	During transfer from sterilizer to aeration area
Sterile Prep		
Over quarantine cabinet door	30	2 hours into quarantine period
	15	3 hours into quarantine period
	22	5 hours into quarantine period
Gap over sterilizer door	150	During 1st evacuation phase
	400	During 2nd evacuation phase
	70	During air flush
Front of sterilizer, breathing zone height	4	Prior to opening door
SPD Tech breathing zone	10-27	During transfer from sterilizer to aeration chamber
Aerator door	14	Top after 10 minutes
	8	Right side after 20 minutes
	8	Left side after 45 minutes
	4	Right side after 1 hour
6 feet in front of sterilizer	1	1 hour after unloading
10 feet in front of sterilizer	0.5	1 hour after unloading
15 feet in front of sterilizer	0.0	1 hour after unloading

Table 5

Personal Ethylene Oxide Exposure Results
Children's Hospital National Medical Center
Washington, D.C.
December 5, 1985

HETA 84-217

Area	Job	Sample Description			
		#	Duration	Volume (liters)	Concentration (ppm)
Sterile Prep	Group Leader	106	0720-1530	24.0	0.38
	SPD Tech	107	0725-1530	24.6	0.40
	SPD Tech	108	0727-1530	23.0	0.39
Decontamination	SPD Tech	205	0758-0909	7.1	0.52
	SPD Tech	119	0910-1552	19.6	0.45
	SPD Tech (combined)		0758-1552	26.7	0.46
Exposure Criteria: (ppm)				NIOSH	LFL*
				OSHA	1.0**

* - Lowest Feasible Level, REL <0.1 ppm

** - The OSHA Standard consists of a Permissible Exposure Limit of 1.0 ppm determined as an 8-hour time weighted average (TWA) concentration and an "action level" of 0.5 ppm, as an 8-hour TWA. When employee exposures exceed the "action level", the employer must initiate certain compliance activities such as periodic employee exposure monitoring and medical surveillance.

Table 6

Full-shift Area Ethylene Oxide Sample Results
Children's Hospital National Medical Center
Washington, D.C.
December 4-5, 1985

HETA 84-217

Area	Sample Description #	Duration	Volume (liters)	Concentration (ppm)
December 4, 1985, 3rd shift decontamination run				
Work table, decontamination side	001	2315-0744	25.7	0.98
Sterilizer door, decontam side	002	2315-0742	17.8	1.07
Sterilizer mechanical access room	003	2315-0748	22.3	19.0
Sterilizer door, sterile prep side	004	2319-0713	21.2	0.68
Near aeration chamber door	005	2320-0714	22.9	0.79
Central work table, sterile prep side	006	2320-0709	25.2	1.00
December 5, 1985, 1st shift sterilization run				
Work table, decontamination side	115	0744-1530	23.0	0.56
Sterilizer door, decontam side	114	0741-1535	22.1	0.63
Sterilizer mechanical access room	116	0747-1558	21.5	32.8
Sterilizer door, sterile prep side	104	0713-1555	7.0	0.78
Aeration chamber door, top	105	0714-1550	24.2	0.62
Central work table, sterile prep side	102	0711-1532	24.8	0.52

(continued)

Table 6 (continued)

Area	Sample Description			
	#	Duration	Volume (liters)	Concentration (ppm)
Far work table, sterile prep side	103	0712-1535	25.3	0.51
Sterile linen pack room	109	0730-1535	24.9	0.41
Sterile reserve room	110	0732-1544	26.2	0.19
SPD office	113	0736-1555	23.7	0.42
SPD storage area	112	0733-1545	23.5	0.15
Corridor, outside SPD supply area	117	0808-1535	23.8	0.10

Table 7

Short-term Area and Exposure Source Ethylene Oxide Sample Results
Children's Hospital National Medical Center
Washington, D.C.
December 5, 1985

HETA 84-217

Area	Sample Description #	Duration	Volume (liters)	Concentration (ppm)
End of decontamination cycle				
1st exhaust phase				
Sterilizer door, decontamination side	202	0806-0826	2.4	ND*
Sterilizer door, sterile prep side	201	0807-0832	2.8	1.92
Sterilizer mechanical access room door	203	0806-0808	<0.1	85
2nd exhaust phase				
Sterilizer door, decontamination side	208	0826-0844	1.2	1.76
Sterilizer door, sterile prep side	207	0832-0847	1.3	(1.41)**
-Decontam load transfer to aerator				
Sterilizer door, sterile prep side	212	0922-0928	0.5	ND
Decontam load removal for disposal				
On cart about 6 ft. from removed load	214	0932-0944	0.8	(1.65)

(continued)

Table 7 (continued)

Area	Sample Description #	Duration	Volume (liters)	Concentration (ppm)
During aeration of decontam load				
On aeration chamber door latch	215	1018-1305	15.9	0.45
On aeration chamber door hinge	216	1018-1305	15.9	0.70
End of sterilization cycle				
1st exhaust phase				
Sterilizer door, sterile prep side	217	1458-1518	1.9	2.23
Central work table, sterile prep side	220	1501-1517	1.6	2.17
2nd exhaust phase				
Sterilizer door, sterile prep side	223	1522-1533	1.2	(0.97)
Sterilizer door, decontam side	221	1520-1540	2.0	1.17
Central work table, sterile prep side	224	1522-1532	0.9	ND
Sterilized load transfer to aerator				
Sterilizer door, sterile prep side	301	1635-1641	0.7	ND
Aeration chamber door	302	1635-1642	0.8	ND

* - None Detected. The Limit of Detection for these samples was 1.8 micrograms per sample.

** - Values in parentheses are between the Limit of Detection (1.8 ug/sample) and the Limit of Quantitation (3.6 ug/sample) for the analytical method.

Table 8
Short-term Area and Exposure Source Ethylene Oxide Sample Results
Children's Hospital National Medical Center
Washington, D.C.
May 1, 1986

HETA 84-217

Area	Sample Description #	Duration	Volume (liters)	Concentration (ppm)
Prior to sterilizer operation				
Sterilizer door, sterile prep	01	1126-1150	3.67	ND*
Cart, sterile prep (6' from sterilizer)	03	1126-1150	3.50	ND
Sterilizer door, decontam	04	1128-1200	4.56	ND
Cart, decontam (6' from sterilizer)	05	1128-1159	4.41	ND
Near mechanical room door, decontam	02	1127-1156	4.35	ND
Inside mechanical room	06	1128-1159	4.05	ND
During demonstration				
Inside mechanical room	16	1154-1552	34.7	0.66
1st exhaust phase				
Sterilizer door, sterile prep	11	1257-1426	13.4	0.28
Cart, sterile prep	13	1257-1427	13.3	0.28
Sterilizer door, decontam	14	1255-1422	12.7	0.39
Cart, decontam	15	1255-1423	12.9	0.34
Near mechanical room door, decontam	12	1255-1421	12.9	0.37

(continued)

Table 8 (continued)

Area	Sample Description #	Duration	Volume (liters)	Concentration (ppm)
2nd exhaust phase				
Sterilizer door, sterile prep	21	1455-1547	7.8	(0.11)**
Cart, sterile prep (6' from sterilizer)	23	1455-1546	7.6	ND
Sterilizer door, decontam	24	1454-1544	7.2	(0.11)
Cart, decontam (6' from sterilizer)	25	1454-1543	7.0	(0.10)
Near mechanical room door	22	1454-1544	7.4	(0.13)

* - None Detected. The Limit of Detection for these samples was 1.1 micrograms per sample (ug/sample).

** - Values in parentheses are between the Limit of Detection (1.1 ug/sample) and the Limit of Quantitation (2.2 ug/sample) for the analytical method.

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