

PRELIMINARY SURVEY REPORT:
CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS
AT
WOOSTER COMMUNITY HOSPITAL
WOOSTER, OHIO

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HOSPITAL SURVEYED: Wooster Community Hospital
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Wooster, Ohio 44691

SIC CODE: 8062 (General Medical and Surgical
Hospitals)

SURVEY DATE: August 29, 1984

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INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) is the primary Federal agency engaged in occupational safety and health research. Located in the Department of Health and Human Services (formerly DHEW), it was established by the Occupational Safety and Health Act of 1970. This legislation mandated NIOSH to conduct a number of research and education programs separate from the standard setting and enforcement functions carried out by the Occupational Safety and Health Administration (OSHA) in the Department of Labor. An important area of NIOSH research deals with methods for controlling occupational exposure to potential chemical and physical hazards. The Engineering Control Technology Branch (ECTB) of the Division of Physical Sciences and Engineering has been given the lead within NIOSH to study the engineering aspects of health hazard prevention and control.

Since 1976, ECTB has conducted a number of assessments of health hazard control technology on the basis of industry, common industrial process, or specific control techniques. Examples of these completed studies include the foundry industry; various chemical manufacturing or processing operations; spray painting; and the recirculation of exhaust air. The objective of each of these studies has been to document and evaluate effective control techniques for potential health hazards in the industry or process of interest, and to create a more general awareness of the need for or availability of an effective system of hazard control measures.

These studies involve a number of steps or phases. Initially, a series of walk-through surveys is conducted to select plants or processes with effective and potentially transferable control concepts or techniques. Next, in-depth surveys are conducted to determine both the control parameters and the effectiveness of these controls. The reports from these in-depth surveys are then used as a basis for preparing technical reports and journal articles on effective hazard control measures. Ultimately, the information from these research activities builds the data base of publicly available information on hazard control techniques for use by health professionals who are responsible for preventing occupational illness and injury.

BACKGROUND FOR THIS STUDY

The present Control Technology Assessment of Ethylene Oxide Sterilization in Hospitals is the result of the research recommendations of the 1983 Feasibility Study of Engineering Controls in Hospitals. During the feasibility study, preliminary surveys were conducted at eight hospitals to assess the potential need for further research in the control of anesthetic gases, antineoplastic drug exposures, and ethylene oxide (EtO) sterilization operations. Based on the feasibility study, a need for the evaluation and documentation of effective engineering controls for EtO sterilization was identified.

The health effects of ethylene oxide have been under intense study for several years. EtO exposure may cause irritation of the eyes, nose, and throat. Dermal exposure to aqueous solutions of EtO may cause burns and allergic sensitization. Animal toxicity studies have shown EtO to be a mutagen and a

carcinogen. Studies of exposed workers have indicated increased mutagenic activity in human cells, an increase in the incidence of leukemia, and adverse reproductive effects. Many of these effects, both for exposed animals and humans, were observed at concentration levels lower than the former OSHA permissible exposure limit (PEL) of 50 parts EtO per million parts air (ppm), expressed as an 8-hour time-weighted average (TWA). As a result of these studies and the urgings of workers' groups, OSHA began the rulemaking process to issue a new standard in early 1983. On June 15, 1984 OSHA issued a new PEL of 1 ppm (8-hour TWA) for ethylene oxide based on its determination that EtO is a potential human carcinogen.

In response to the hospitals' need to control worker exposure to EtO to levels below 1 ppm, the Engineering Control Technology Branch of NIOSH is studying the control of EtO emissions from sterilizers in the hospital setting. The goals of this study are to evaluate and document effective engineering controls which select hospitals have implemented, and then to disseminate useful information and practicable recommendations on effective methods for controlling occupational ethylene oxide exposure.

BACKGROUND FOR THIS SURVEY

To identify hospitals which meet the design criteria of the study, ECTB has worked closely with the American Hospital Association and the Ohio Hospital Association, who have publicized and promoted the study to their member hospitals. Wooster Community Hospital expressed an interest in participating in the study and supplied information about the Central Service (CS) Department to NIOSH. Based on this information, it was determined that the hospital might fulfill the requirements of two categories: a sterilizer using 100% EtO with extra evacuation phases at the end of the sterilizer cycle and local exhaust ventilation above the sterilizer door, and a sterilizer using 100% EtO with in-chamber aeration.

A survey was conducted in the CS Department on August 29, 1984. This report documents the information gathered and the preliminary evaluation of the department.

HOSPITAL AND PROCESS DESCRIPTION

HOSPITAL DESCRIPTION

Wooster Community Hospital is a not-for-profit, acute care facility with 169 beds. Services which the hospital provides include: general surgery, eye surgery, obstetrics, neonatal care, urology, and an ambulatory care unit.

The original hospital structure was completed and occupied in 1950. The CS Department is located in the basement of a section of the hospital constructed in 1970.

CENTRAL SERVICE DEPARTMENT DESCRIPTION

Ethylene oxide gas sterilization operations for the hospital are conducted in the Central Service Department. The CS Department performs EtO sterilization for obstetrics, neonatal care, respiratory therapy, cystology laboratory, isolation cases, x-ray, and emergency.

The CS Department employs nine persons distributed over three shifts. The day shift employs four persons and a supervisor. Typically, one person works in the decontamination room and two others work in the sterilization and packing room (hereafter referred to as the clean room). Another person, the team leader, is assigned to operate the sterilizers and process the loads. This person is very mobile within the department and also picks up and delivers supplies to other departments in the hospital. The department supervisor spends most of her time in an office or moving between the different areas of the department. During the evening shift, three persons are in the department. One person is assigned to decontamination, one person works in the clean room, and the team leader operates the sterilizers. The night shift employs one person to work in both the clean room and the linen pack room.

The layout of the CS Department is diagrammed in Figure 1. Of particular interest in this study is the EtO sterilizer isolation room. This room was specially constructed to house the two EtO sterilizers and the two aerators. It is located behind the steam sterilizer recess room and is entered through the clean room. The clean room has three functional areas. One end of the room is used to store clean supplies and to wrap and package items for sterilization. Another part of the room serves as a processing area where loads are prepared for steam sterilization and where sterile loads cool before storage or distribution. A third area of the room is occupied by two steam sterilizers that are recessed along one wall.

The steam sterilizers may be accessed for maintenance through a small recess room located behind the sterilizers. This room is entered through a doorway from the EtO sterilizer room.

Sterile supplies and instruments are stored in two long, narrow rooms lined with shelves. Sterilizer cycle charts and records are stored in a small room off the clean room. A small quantity of the EtO cartridges used in the sterilizer are also stored in this room.

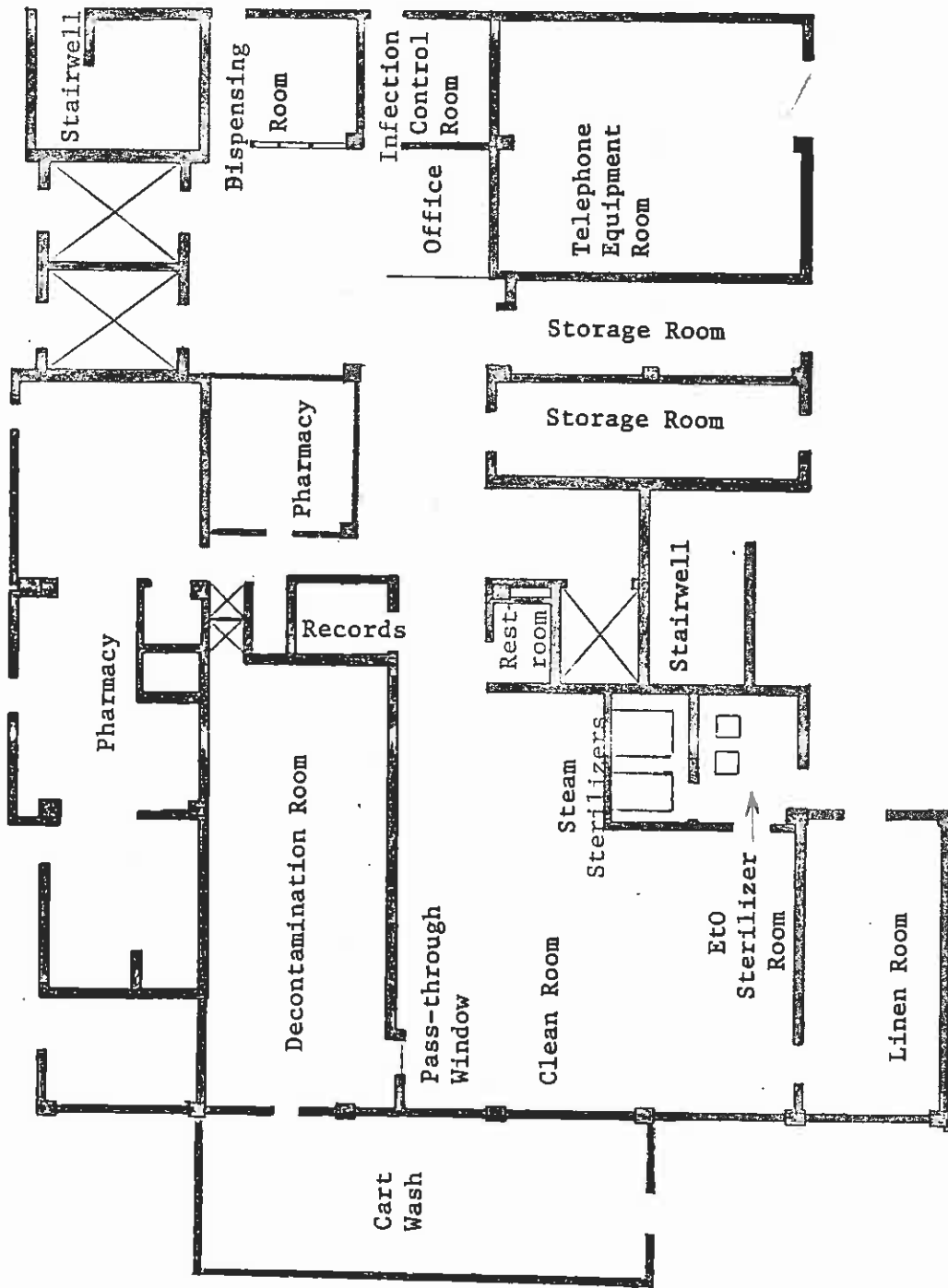


Figure 1. Central Service Department, Wooster Community Hospital.

PROCESS DESCRIPTION

The CS Department sterilizes medical supplies, surgical instruments and other equipment. Metal instruments and other items which can be steam sterilized are delivered to the decontamination room in covered or enclosed carts or via a "dirty trayveyor" (a vertical conveyor between floors used only for trays and small items). These items are washed and enter the preparation/packaging area of the clean room through a pass-through window between the rooms or through a pass-through washer/sterilizer. The items are dried, wrapped and packaged for terminal sterilization. Wrapped items are loaded onto carts in the processing area of the clean room and steam sterilized. The sterile items are either stored or delivered to the using department.

Heat- or moisture-sensitive items must be sterilized with EtO gas. These items arrive in decontamination in enclosed carts delivered to the door by the using department or via a "dirty trayveyor". The items are washed, dried, and passed into the preparation/packaging area of the clean room through the pass-through window. Very small items are hand cleaned and treated with ultrasonics before passing into the clean room. The items may then be wrapped or heat-sealed in a peel-pak and carried to a table near the EtO sterilizer room. The sterilizer operator prepares the load for sterilization by arranging the items in baskets, placing a biological indicator in the load, and completing the necessary record forms. The basket is placed in the sterilizer. Routine schedule requirements are two loads run in each of two sterilizers, one load during day shift and one load during evening shift.

The CS Department has two EtO gas sterilizers both manufactured by 3M Company. One sterilizer is a Steri-Vac model 400 purchased in 1975. The second sterilizer, a Steri-Vac model 400B purchased in 1983, was modified to include in-chamber aeration, thereby changing the model designation to a Steri-Vac 400C. Both sterilizers have an internal chamber volume of 4 cu.ft. and have warm (145°F) and cold (99°F) cycle options. A warm cycle runs about 2 hours and 30 minutes, while a cold cycle lasts about 5 hours and 30 minutes. The cycle consists of several phases: initial vacuum, preheat, humidification, EtO gas injection, dwell period, final vacuum, and a 15-minute fresh air purge. Both models have an additional fresh air purge which continues until the sterilizer door is opened. The model 400C also has a preprogrammed aeration cycle which the operator may elect to use on a particular load.

For loads which are to be aerated in the aerator, the sequence of events is as follows. At the end of the purge phase, a buzzer sounds alerting the operator that the cycle is complete and the door may be opened. The operator turns the door handle, presses and holds the "open door" switch for about 30 seconds until the door opens, and then pulls the door open about 1 inch so that the door catches on the latch above the door. The operator then leaves the room for 15 minutes to allow any residual EtO in the chamber to escape. At the end of the 15 minutes, the operator returns to the sterilizer and opens the door of the aerator located beneath the sterilizer. Next the sterilizer door is swung fully open, and the operator slides the basket out of the sterilizer and into the aerator. The empty EtO cartridge is removed from the sterilizer

chamber and put into the aerator. The operator then closes the aerator door and the sterilizer door.

Aeration times for the particular load are recorded in a log book in one corner of the room. The operator leaves and closes the door to the sterilizer room.

During the observed transfer operation, the operator also removed two sponges which were laying on the bottom of the sterilizer chamber. These sponges had been put in the sterilizer to aid the humidification phase which had not been working properly. The sponges were also placed in the aerator with the load.

The two aerators are manufactured by 3M Company, Steri-Vac models 33 and 33B with internal chamber volumes of 4 cubic feet. Normal aeration time for a load is 8 hours. Special items may require up to 24 hours aeration. Three of the four EtO loads each day are aerated in the two aerators. The evening load processed in the model 400C sterilizer uses the in-chamber aeration feature. Each aerator is located beneath an EtO sterilizer.

EtO is supplied to the sterilizer by a cartridge of 100% EtO inserted into a special slot in the sterilizer chamber. At the appropriate time in the cycle, the cartridge is punctured, filling the chamber with EtO gas. The department uses about 100 to 120 cartridges per month. The cartridges are brought to the department by maintenance personnel in lots of 10. Larger quantities of the cartridges are stored in a building separate from the hospital.

POTENTIAL HAZARDS, EXPOSURE GUIDELINES, AND EXPOSURE SOURCES

Workers exposed to EtO may experience both acute and long-term health effects. EtO is a central nervous system depressant, and in air can cause acute irritation to the eyes, upper respiratory tract, and skin at concentrations of several hundred to 1,000 ppm. Exposure to high concentrations may also cause headache, dizziness, nausea, and vomiting. Dilute (1 percent) aqueous solutions can cause blistering of human skin after prolonged contact, and allergic sensitization can also occur in some individuals.

NIOSH has conducted animal toxicity studies to determine the possible long-term health effects of EtO exposure. The results of the NIOSH studies support the conclusions of other researchers that EtO is a mutagen and a carcinogen in animals. The studies showed an increase in sister chromatid exchanges and in chromosomal aberrations, evidence of mutagenic activity. The studies also showed an increase in the frequency of leukemia, peritoneal mesotheliomas, and cerebral gliomas. Adverse reproductive effects were also observed.

The potential of EtO to cause mutagenic activity in humans has been examined by a number of investigators. The studies were conducted by examining blood lymphocyte cultures obtained from workers exposed to EtO in a variety of occupational settings. The results clearly demonstrate that EtO adversely affects human genetic material.

Epidemiologic studies of humans occupationally exposed to EtO, show an increase in the frequency of leukemia and other malignant tumors. Taken along with the results of the animal studies, EtO must be considered a potential human carcinogen.

In addition to the OSHA PEL of 1 ppm, the standard mentions an action level of 0.5 ppm, above which semi-annual monitoring is required. The American Conference of Governmental Industrial Hygienists has also adopted 1 ppm as an 8-hour time-weighted average Threshold Limit Value (TLV); however, they have allowed for an excursion limit such that short-term exposures should exceed 3 ppm no more than 30 minutes during a workshift and should never exceed 5 ppm. In its testimony to OSHA on the new standard, NIOSH recommended that a ceiling limit of 5 ppm not be achieved for more than 10 minutes in a workday, and that the 8-hour PEL be set lower than 0.1 ppm to reduce the risk of occupational mortality to the greatest extent possible.

PRIMARY EXPOSURE SOURCES

Hospital central service personnel may be exposed to EtO from several sources. Each source contributes to the ambient concentration of EtO but two may be directly responsible for most of the exposure on a daily basis.

Opening of the Sterilizer Door

In some situations, the most significant EtO emission source on a daily basis is the opening of the sterilizer door at the end of the sterilization cycle. In an uncontrolled system, warm, moist, EtO-laden air escapes from the sterilizer when the door is opened and may diffuse throughout the room. This source of EtO may release a significant quantity of EtO into the workroom air as a background concentration, and, depending on the work practices, may or may not provide a peak exposure for the sterilizer operator.

Transferring the Sterilized Load

Some of the EtO used in sterilization remains on the sterile items and wrapping material and inside the package after the sterilization cycle is complete. This EtO will be given off exponentially until equilibrium is reached with the surrounding air; and, depending on the composition of the items and their packaging, these off-gasing items can provide a significant EtO exposure source for the operator transferring the load to the aerator and contribute to the background levels of EtO in the workplace.

SECONDARY EXPOSURE SOURCES

Other exposure sources may not be as readily apparent, but may also provide important contributions to the background levels of EtO in the workroom air. Some of these sources may only intermittently release EtO.

Aeration

Post-sterilization aeration is essential for protection of the patients who will use the items and for controlling occupational exposure to EtO. While in

the aerator the sterile items continue to off-gas. If the aerator cabinet is not vented out of the building or to a dedicated exhaust, it can become a major contributor to the background EtO levels.

Maintenance

Sterilizer part failures, maintenance operations, and repair work can also result in significant exposures to personnel. Of particular concern are plastic and rubber components which will absorb EtO and may even react with the gas; these parts can deteriorate over time. Valves, connections, and the front door gasket are potential sources of leaks, and occasional exposure.

CONTROLS

PRINCIPLES OF CONTROL

Occupational exposures can be controlled by the application of a number of well-known principles, including engineering measures, work practices, personal protection, and monitoring. These principles may be applied at or near the hazard source, to the general workplace environment, or at the point of occupational exposure to individuals. Controls applied at the source of the hazard, including engineering measures (material substitution, process and equipment modification, isolation or automation, local ventilation) and work practices, are generally the preferred and most effective means of control in terms of both occupational and environmental concerns. Controls which may be applied to hazards that have escaped into the workplace environment include dilution ventilation, dust suppression, and housekeeping. Control measures may also be applied near individual workers, including the use of remote control rooms, isolation booths, supplied-air cabs, work practices, and personal protective equipment.

In general, a system comprised of more than one of the above control measures may be required to provide worker protection under normal operating conditions and also under conditions of process upset, failure and/or maintenance. Process and workplace monitoring, personal exposure monitoring, and medical monitoring may be used to provide feedback concerning the effectiveness of the controls in use. The maintenance of equipment and controls to insure proper operating conditions and the education of and the commitment from both workers and management concerning occupational health are also important ingredients of a complete, effective, and durable control system.

Not all principles apply to all situations, and their optimal application varies from case to case. The application of these principles are discussed below.

ENGINEERING CONTROLS

Isolation

Isolating workers from potential exposure sources can be a very effective method of control. Workers may be isolated by distance, physical barriers, and time. The CS Department workers are isolated from the sterilizer by a physical barrier.

The EtO sterilizers and aerators are isolated in a small room measuring 7 ft. by 11 ft. by 8 ft. The room was built in 1982. Doors into this room are closed at all times, and the door to the outside corridor is locked. Only the sterilizer operator enters the room routinely and then for less than 5 minutes at any one time. Maintenance personnel occasionally go through the room to enter the recess room for service of the steam sterilizers.

Local Exhaust Ventilation

Local exhaust ventilation (LEV) controls EtO emissions at their sources. Both sterilizers have local exhaust hoods over the doors. The Steri-Vac model 400 was retrofitted with an exhaust hood in 1983, designed and supplied by 3M Company. The hood sits on top of the sterilizer and measures 14.2 inches by 30 inches by 4.6 inches. The slot over the door measures 1 1/4 inches by 29 1/2 inches. Measurements made with a pocket anemometer indicate the hood face velocity is approximately 200 fpm.

The Steri-Vac model 400C has an exhaust hood built into the top panel of the sterilizer as a standard feature. The hood measures 27 1/4 inches by 30 inches by 4.6 inches. The slot over the door measures 1 1/4 inches by 29 1/2 inches. Measurements made with a pocket anemometer indicate the hood face velocity is approximately 200 fpm.

Both sterilizers have a flow indicator to visually alert the sterilizer operator if the local exhaust fan is not working, however, there is no audible alarm. The sterilizers and the aerators are vented into the same dedicated exhaust system. Local exhaust systems for both sterilizers also are part of the dedicated exhaust.

Cycle Features

Particular cycle features have been designed to protect the worker and the environment from EtO exposure. All 3M Company sterilizers operate at negative pressure throughout the cycle. This feature assures no leakage of gas from the chamber. The sterilizers are supplied with gas from small cartridges inserted into the chamber and automatically punctured during the cycle. These cartridges prevent the exposure opportunities which may occur during cylinder change operations for sterilizers using mixtures of EtO and halocarbons.

Perhaps the most significant cycle feature of the 3M Company sterilizer, is the continuous fresh air purge. In 1983, the department purchased this feature as a modification for the Steri-Vac model 400. The continuous purge is a standard feature for the Steri-Vac 400C. After the final vacuum of the sterilizer cycle, the chamber is purged with fresh air for 15 minutes. If the sterilizer door is not opened when the alarm sounds at the end of the 15 minutes, the vacuum pump continues to purge until the operator intervenes. The products in the sterilizer begin to off-gas EtO immediately following the completion of the final vacuum. The continuous purge prevents EtO from building up in the chamber should opening of the door be delayed.

In-Chamber Aeration

The Steri-Vac model 400C features in-chamber aeration as an option for the operator. Loads processed on the warm cycle may be left in the chamber after the final vacuum and through the air flush phases. Without operator intervention, the air flush phase continues with the temperature at 140°F for a minimum of 8 hours. In-chamber aeration allows the absorbed EtO in the products to off-gas completely before the operator comes in contact with the items.

General Exhaust Ventilation

The decontamination room is supplied by three air diffusers. A return exhaust grille is located in the ceiling over the pass-through washer. The decontamination room is under positive pressure with respect to the adjacent cart wash room and slightly positive pressure with respect to the clean room. Doors between the decontamination room and the cart wash room are closed at all times. A pass-through window between the decontamination room and the preparation/packaging area of the clean room is always open.

The clean room has four supply air diffusers. Exhaust is provided by three return exhaust grilles and a louvered vent over the steam sterilizer. The room is under positive pressure relative to the recess room for the steam sterilizers and the surrounding hallways. The clean room is also under positive pressure with respect to the EtO sterilizer room.

General ventilation for the EtO sterilizer room consists of one supply air diffuser and one exhaust grille to a dedicated exhaust system. Additional room exhaust is provided by the local exhaust hoods over the sterilizers' doors. The room is under negative pressure with respect to the clean room and is under positive pressure with respect to the steam sterilizer recess room and with respect to the surrounding hallways.

The recess room for the steam sterilizers is supplied with air through a louvered vent over a steam sterilizer. The room is exhausted by one grille in the duct for the EtO dedicated exhaust system.

Preventative Maintenance

The CS Department has a preventive maintenance contract with 3M Company for routine quarterly evaluations. The maintenance protocol specifies the evaluation of the EtO sterilizers and aerators for mechanical function and leak testing. The service person also inspects the sterilizer door gasket and replaces it as needed. Air lines and water lines are checked. Any necessary repairs are made immediately. Only 3M Company service personnel perform maintenance functions for these sterilizers.

WORK PRACTICES

Work practices may have an important effect on the potential exposure an employee may receive. Work practices for EtO handling and sterilizer operation are specified in a procedure/policy manual. Hazard information and sterilizer operation instructions are posted on the sterilizer door.

Employee education on the hazards of EtO exposure and its proper handling is an important part of the department's control program. New employees are given on the job training. The CS manager provides an in-service program every 3 months and taped seminars from the International Association of Central Service Managers.

MONITORING

The CS monitoring program is performed under contract by Medical Instrumentation Systems, MIS. Monitoring is done every 6 months and consists of area monitoring using a MIRAN IA infrared analyzer. Results indicate EtO concentrations in the sterilizer area during the transfer of the load to the aerator are 1 ppm or less.

RECOMMENDATIONS AND CONCLUSIONS

Findings of this preliminary survey indicate the Central Service Department has instituted engineering control technology for minimizing employee exposure to EtO and has developed a comprehensive program to protect its employees. Local exhaust ventilation has been provided in critical areas. Complete isolation of the sterilizer operation along with in-chamber aeration are potentially the most important controls. However, without sampling results and ventilation measurements, no estimation of the effectiveness of these controls can be made.

Proper work practices for employees are outlined in a procedure and policy manual, and, based on observation of the transfer of a load from the sterilizer to the aerator, the operator follows those procedures. The department supervisor provides education and training on proper work practices and the hazards of exposure to EtO.

Environmental monitoring of the department is an important part of the EtO control strategy and should be continued. However, to date there has been no personal sampling done to determine individual employee exposure. Initial personal sampling should be performed for the sterilizer operator over the full shift at least three times during a two week period to establish baseline exposure data. Thereafter, personal sampling should be performed at least every six months. Additional monitoring may be required to comply with the OSHA standard. Without this data it is impossible to judge the overall effectiveness of a control program.

Based on the preliminary survey, the CS Department appears to have a sound program for EtO control. Wooster Community Hospital is a candidate for an in-depth survey in NIOSH's study of control technology for ethylene oxide sterilization in hospitals.