### PRELIMINARY SURVEY REPORT:

# CONTROL TECHNOLOGY FOR ETHYLENE OXIDE STERILIZATION IN HOSPITALS

AT

EUCLID GENERAL HOSPITAL EUCLID, OHIO

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PLANT SURVEYED:

Euclid General Hospital 101 East 185th Street Euclid, Ohio 44119

SIC CODE:

8062 (General Medical and Surgical

Hospitals)

SURVEY DATE:

August 1, 1984

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None

### 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 surverys 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 hr. 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. Euclid General 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 the category specifying: a sterilizer using a 12:88 EtO and Freon 12 mixture, extra evacuation phases at the end of the sterilizer cycle, vented evacuation drain controls, and local exhaust ventilation other than above the sterilizer door.

A survey was conducted in the CS Department on August 1, 1984. This report documents the information gathered and the preliminary evaluation of the department.

### HOSPITAL AND PROCESS DESCRIPTION

#### HOSPITAL DESCRIPTION

Euclid General Hospital is a not-for-profit, acute care facility with 345 beds. Services which the hospital provides include: general surgery, orthopedic surgery, neurosurgery, cardiovascular catheterization, and infant delivery. The hospital also provides an in-patient rehabilitation unit for patients recovering from severe physical trauma.

The original structure was constructed in the early 1950's, and occupied in the fall of 1952. Since then several additions have been made. The CS Department is located on the second floor of the south wing. The decontamination room is located in the old section of the building while the adjoining clean room is located in a section of the hospital built in 1977.

### CENTRAL SERVICE DEPARTMENT DESCRIPTION

Ethylene oxide gas sterilization operations for the hospital are conducted only in the Central Service Department. This department performs EtO sterilization for surgery, obstetrics, anesthesiology, respiratory therapy, the catheterization laboratory, x-ray, and emergency.

The CS Department employs 29 persons distributed over 3 shifts. On the day shift, only one person is assigned to operate the sterilizers and process loads in the sterilization room (known as the clean room). The others spend their time in the following areas: three or four are assigned to decontamination, five are in the preparation and packaging room, and three or four are in the linen room. Additionally, four employees work from 0900 to 1730 or from 1000 to 1830 in float assignments. The department director, assistant director, and secretary spend most of their time in offices or moving between the different areas of the department. During the evening shift, one person is assigned to each of the following areas: decontamination, preparation and packaging, linen, and operation of the sterilizers. The night shift employs one person in decontamination and one person in the linen room.

The layout of the CS Department is diagrammed in Figure 1. Of particular interest in this study is the clean room which serves three functions. One end of the room is used to store clean and sterile supplies. Another part of the room serves as a processing area where cart loads are prepared for sterilization and where sterile loads cool before storage or distribution. A third area of the room is occupied by a bank of sterilizers (two steam, and one EtO) and an aerator that are recessed along one wall.

The sterilizers may be accessed for maintenance through a small recess room located behind the sterilizers. This room is entered through a doorway off the hall and is locked to restrict access of unauthorized personnel. The backs of the sterilizers are open to the room, while the backside of the aerator is enclosed in a ventilated cabinet. Steam and water from the sterilizers are emptied into closed drains.

The EtO sterilizer is supplied with gas from a cylinder. The two cylinders are located in a vented, double-wall cabinet behind the aerator. They are

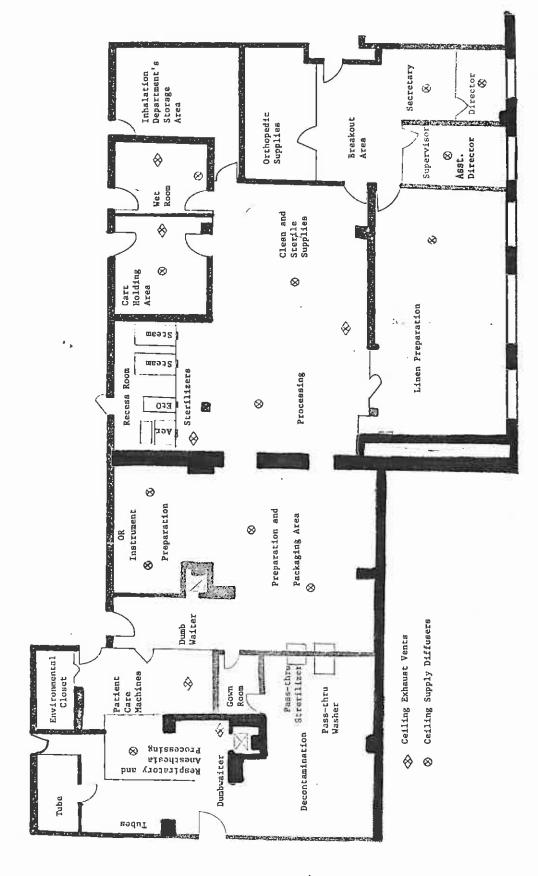


Figure 1. Central Service Department, Euclid General Hospital

connected to the sterilizer in a dual-load system through copper piping. This system automatically switches from an empty tank to a full one without requiring operator intervention.

#### 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 through a dumbwaiter. These items are washed and enter the preparation and packaging room by cart through the gown room or through a pass—through washer. 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 by three routes: by dumbwaiter, delivered to the door by the using department, or picked—up in the using department by CS personnel. The items are washed, dried, and either carted or carried through the gown room into the preparation and packaging room. The items may then be wrapped or heat—sealed in a peel—pak and carried to a table in front of the sterilizer bank. The sterilizer operator prepares the load for sterilization by arranging the items in wire baskets, placing a biological indicator in the load, and completing the necessary record forms. The wire baskets are placed on the sterilizer shelves, and the cycle is started at 0800 daily except Sunday.

The EtO gas sterilizer is a Sybron-Castle, Sentry Model 400, purchased in 1973. Its internal chamber size is 20-inches by 20-inches by 38-inches, a volume of approximately 9 cubic feet. The cycle is five and one-half hours duration, and consists of several phases: initial vacuum, humidification, and temperature adjustment to 140°F (about 30 minutes); EtO charging of the chamber and dwell period (about 4 hours); evacuation and pulse-purge (about 30 minutes).

At the end of the pulse-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 so that the door will swing open when the pressure is released. Next the aerator door is opened with a key, the door labeled with the times for the load, and the operator puts on protective cotton gloves. The sterilizer door is swung fully open, and the operator transfers the wire baskets one-by-one from the sterilizer to the aerator. The sterilizer door is closed, and the operator removes the biological indicator from the load. The aerator door is closed while the indicator is removed from the encasing syringe and placed in the incubator. The operator then reopens the aerator door and disposes the syringe in a waste container in the aerator. Tape labels of aeration times are placed on the appropriate shelves, and the door is closed.

The aerator is a Sybron-Castle Model 4041 with internal dimensions 2-feet by 4-feet by 5-feet, a volume of approximately 40 cubic feet. All items are aerated at  $135^{\circ}$ F for a minimum 12 hours. Items which will be placed in a patient's body are aerated for 30 hours.

The EtO sterilizer is supplied with gas from a compressed gas cylinder. If a cylinder empties during a cycle and an insufficient amount of EtO is supplied to the sterilizer, the dual-load system will switch to a full tank and continue the cycle uninterupted. At the time of the survey, the dual-load system was not working properly, and a cylinder emptying during a cycle would cause the cycle to abort. To avoid an aborted cycle, the sterilizer operator kept a count of how many loads had been processed from the cylinder before starting the load. About 26 to 32 loads can be processed on one cylinder. If a new cylinder is needed, the stock room brings one to the department, and a plumber from maintenance connects the new cylinder.

### POTENTIAL HAZARDS

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, and 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 effects 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.

### 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 three may be directly responsible for peak concentration levels on a daily basis.

### Uncontrolled Drain

During the evacuation phase of the sterilization cycle, it is estimated

that as much as 95 percent of the initial EtO gas charge may be removed through the vacuum pump and drain. Approximately 10 percent of this may be combined with water; however, this mixture easily separates releasing additional EtO gas. For sterilizers which evacuate to an uncontrolled drain, most of the EtO used in sterilization may be released to the workroom atmosphere thus providing peak concentrations during the evacuation phase.

### Opening of the Sterilizer Door

In many 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 is carried out when the door is opened and may diffuse throughout the room. This source of EtO may provide a peak exposure for the sterilizer operator, and may release a significant quantity of EtO into the workroom air as a back ground concentration.

### Transferring the Sterilized Load

It is estimated that five percent of the initial EtO charge remains on the sterile items and wrapping material and inside the package after the sterilization cycle is complete. These items are continuously releasing EtO gas; and, depending on the composition of the items and their packaging, can provide a significant EtO exposure source for the operator transferring the items to the aerator as well as contributing to the background levels of EtO in the workplace.

### SECONDARY EXPOSURE SOURCES

Other exposure sources may not be immediately identifiable, 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 gas or vapors.

#### 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.

### Replacement of EtO Gas Cylinders

Ethylene oxide gas is supplied to many sterilizers from pressurized gas cylinders. When replacing empty EtO cylinders, the worker may be exposed to EtO vapors from residual liquid or gaseous EtO in the supply lines. This may permit worker exposure to the EtO and may contribute to background EtO concentration levels. It is recognized that cylinder changes are not usually performed on a daily basis.

### Pressure Relief Valve

Another possible source of EtO is the sterilizer safety valve. If the sterilizer becomes overpressurized during the cycle, this emergency relief valve releases EtO gas. If not controlled or remotedly vented, this release may contribute a significant quantity of EtO to the workplace atmosphere.

#### 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-know 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, distance, and, to a lesser degree, by time.

The EtO sterilizer is recessed into a room and the drain and mechanical components of the sterilizer are separated from the clean room by a concrete wall. Only the door and control panal of the sterilizer are in the clean room. The recess room is under negative pressure with respect to the clean room and acts as an exhaust plenum for gases and vapors escaping at the drain and any release of EtO from the sterilizer safety valve. The recess room is locked and only persons authorized by the CS supervisor or maintenance may enter. There is no mechanism to alert workers when the sterilizer is in the exhaust phase and the room not must be entered.

Workers are also separated from the sterilizer by distance. The load processing work station is located at least 25 feet away from the sterilizer, and the operator assigned to that task is mobile, so that approximately 30 per cent of the work day is spent at that station. Only the sterilizer operator routinely moves into the sterilizer area and then only for two to three minutes at a time. Other workers in the department are stationed in rooms other than the clean room and have no contact with the sterilizer.

Workers on the evening and night shifts do not routinely process an EtO load. Department policy prohibits the processing of an EtO load on the night shift and on Sundays and holidays. These time constraints serve to isolate some of the workers from potential EtO exposure.

### Equipment Modification

In 1982, the department purchased an equipment modification to the sterilizer cycle from the manufacturer. The sterilizer cycle was modified to include a pulse-purge phase after the final evacuation of the chamber. The phase is designed to reduce the amount of EtO remaining in the chamber and the sterile load after the evacuation phase. This may greatly reduce the potential exposure of the operator during the transfer of the load to the aerator. A pulse of fresh, filtered air is injected into the chamber immediately followed by a purging of the chamber through a vacuum of approximately 5 inches water. Each pulse-purge takes about 1 minute. This process continues for approximately 30 minutes.

## Local Exhaust Ventilation

Local exhaust ventilation (LEV) controls EtO emissions at their source. This system includes exhaust hoods above the sterilizer, over the bank of sterilizers, at the drain, at the safety relief valve, around the aerator, and around the EtO cylinders.

Hospital maintenance designed and installed an exhaust hood over the EtO sterilizer in 1984. This hood is constructed of sheet metal and measures 5 1/2 inches by 36 1/2 inches by 8 inches. Exhaust is provided by a rectangular vent in the wall, located inside the hood and measuring 4 inches by 12 inches. The vent is connected to the dedicated system which exhausts the recess room. The hood is located about 17 inches above the sterilizer door. The hood is designed to capture EtO laden air rising as the sterilizer door is opened after the completion of the cycle.

Additional local exhaust is provided by a series of four, 7 by 17 inch louvered vents located about 27 inches above the tops of the sterilizers and aerator along the wall. These vents are passive and open to the recess room. Air flow from above the sterilizers and into the recess room is generated due to the negative pressure in the recess room. Vents are located over each of the sterilizers and the aerator. These vents serve to exhaust EtO and very hot air from the steam sterilizers into the recess room. Additional exhaust is supplied by a vent in the ceiling over the aerator measuring 8 inches by 14 inches. This exhaust is only operational when the aerator is operating. Local exhaust ventilation is also provided for the liquid/gas separator (purchased from Castle in 1982) at the attachment to the sterilizer drain.

When the sterilizer chamber is evacuated, a mixture of water and EtO passes through the vacuum pump and into the liquid/gas separator. There the water and gas separate due to centrifugal action, and the water is flushed down the drain. EtO gases are exhausted through a duct connected to the dedicated system exhausting the recess room.

The sterilizer safety relief valve is also exhausted through a duct connected to the same dedicated system.

The backside of the aerator located in the recess room is enclosed and vented to the dedicated exhaust system. This control provides exhaust for the EtO off-gasing from the sterilized goods in the aerator.

EtO supply cylinders are enclosed in a double-wall cabinet located behind the aerator in the recess room. The cabinet is vented to the dedicated system and is designed to exhaust any EtO which might escape during a cylinder change operation or in the event of a leaky cylinder connection. Supplied air is also provided for the cabinet to keep the cylinders cool in what may sometimes be a very hot environment.

### General Exhaust Ventilation

The CS Department has been remodeled during July and August this year. Most of the new ventilation is in the decontamination room which is on a recirculated air system and is under negative pressure with respect to the hallways and the clean room. Doors between the decontamination room and the preparation and packaging room are closed at all times.

The preparation and packaging room has four supply air diffusers. The only exhaust vent in this area is a slot hood over the pass-through washer. Air movement around the dutch door (a half door which is open to dispense sterile goods) indicates that area of the room is under slightly negative pressure.

The clean room has three supply air diffusers. Exhaust is provided by the louvered vents over the sterilizers and the local exhaust ventilation for the EtO sterilizer. The room is under slightly positive pressure. Air movement patterns defined using smoke tubes, indicated little air exchange through the two open doorways between the preparation/packaging room and the clean room. Lack of apparent air movement would not affect the diffusion of EtO from the sterilizer area to the prepartion/packaging room.

The linen preparation room was created during the remodeling by erecting a wall to separate the area from the clean room. The doors to this room are closed at all times. There is one supply air diffuser and one exhaust vent in the room. The exhaust vent provides a very strong negative pressure with respect to the clean room.

The recess room is exhausted by a dedicated system through two open duct vents located in the wall near the ceiling. This spring, the fan exhausting the room was replaced. Hospital records indicate the new fan increased the exhaust capacity by 75 percent.

The CS Department has a preventive maintenance contract with the sterilizer manufacturer with routine quarterly evaluations. The maintenance protocol specifies the evaluation of the EtO sterilizer and aerator for mechanical function and leak testing. The service person also inspects the sterilizer door gasket and replaces it as needed. The EtO cylinders, supply lines, drain pipes, and floor drain are regularly leak-tested. Any necessary repairs are made immediately. Hospital maintenance personnel also check for leaks or provide minor service as requested by the CS Director.

#### WORK PRACTICES

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

An important work practice which may limit the operator's exposure to EtO, is the immediate removal of the load from the sterilizer upon completion of the cycle. With the pulse-purge phase, the EtO in the chamber is theoretically at its lowest when the buzzer sounds at the end of the cycle. Any delay in opening the door and transferring the load allows the items to off-gas and EtO concentration levels to build up in the chamber.

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 Director provides an in-service program every 3 months using commercially available slides and tapes. The plumber assigned to change EtO cylinders for the department is also provided with instruction on EtO hazards and safe handling.

### PERSONAL PROTECTIVE EQUIPMENT

Employees are encouraged to wear protective cotton gloves when transferring items from the sterilizer to the aerator. After being worn for one transfer procedure, the gloves are also placed in the aerator with the load.

#### MONITORING

The CS monitoring program has three components: continuous monitoring with an alarm system, environmental area monitoring performed by a contractor, and medical monitoring.

In 1983, two monitoring sensors where installed in the department, one in the recess room between the sterilizer and the aerator and the other on the wall over the sterilizer. The sensors and alarm system are manufactured by Gas Tech (model 1565-6). The alarm station is mounted on a wall at the end of the bank of sterilizers, about 12 feet from the EtO unit. When EtO concentration levels reach 20 ppm an audible and visual alarm is triggered. If levels reach 50 ppm the audible alarm becomes continuous. Each of the sensors is on a separate alarm indicator so that the worker can identify which location has triggered the alarm. During the pulse-purge phase of the sterilizer cycle,

the sensor in the recess room is routinely triggered at the 20 ppm level. Workers have been instructed to evacuate the area and to notify maintenance if the sensors indicate 50 ppm in the work room.

Environmental area monitoring has been performed by Medical Instrumentation Systems - Hospital Shared Engineering Services, Inc. (MIS) four times since August 1981. Presently, MIS is scheduled to monitor the department every six months. MIS monitors using an infrared analyzer and makes air flow measurements. The most recent report indicates EtO levels are low. The measurements are not in a form which can be directly compared with the OSHA standard.

Upon employment, each person receives a blood work-up and physical evaluation. Employees in the CS Department are monitored through bi-annual blood tests. The purpose of these tests is to detect early warning signs of leukemia.

### 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. Without sampling results and ventilation measurements, no estimation of the effectiveness of these controls can be made at this time. The sterilizer modification to include a pulse-purge phase at the end of the cycle is an interesting control and is worth further evaluation.

Proper work practices for employees are clearly 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 Director provides education and training on proper work practices and the hazards of exposure to EtO.

The use of the continuous EtO monitor and alarm system can provide a valuable warning for the workers if a severe leak or emergency situation should arise. At the present time, the OSHA standard does not include a short term exposure limit (STEL). The agency is considering adding that provision to the standard sometime in the future. In that case the detection level of a sensor located over the sterilizer should correspond to the STEL, and would thus provide an immediate indication if the STEL for the sterilizer operator is exceeded.

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. It is recommended that initial personal sampling 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 in order 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 very sound program for EtO control. It is recommended that Euclid General Hospital be included in the Control Technology Assessment of Ethylene Oxide Sterilization in Hospitals, and that an in-depth survey be conducted in the Central Service Department.