CONTROL TECHNOLOGY FEASIBILITY STUDY:

THE USE OF ENGINEERING CONTROLS IN HOSPITALS

PRELIMINARY SURVEY REPORT OF

St. Francis - St. George Hospital
Cincinnati, Ohio

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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. NIOSH was formally created by the Occupational Safety and Health Act of 1970. This legislation -- which also gave rise to the Occupational Safety and Health Administration (OSHA) in the Department of Labor -- called for a separate organization, NIOSH, to provide for research and education programs related to occupational safety and health. An important area of NIOSH research deals with methods for controlling occupational exposure to potential chemical and physical hazards.

Health care facilities, such as hospitals and medical clinics, can pose a number of health risks to employees. Seventy-five thousand[1] health care workers employed in sterilization areas are potentially exposed to ethylene oxide (EtO). An additional 25,000 other employees may be incidentally exposed to EtO due to improper engineering and administrative control.[1] These data serve well to emphasize the need to determine the level of exposure and evaluate the efficacy of the technologies and practices used to control exposures to such potentially harmful chemical agents. Good engineering controls and work practices should prevent health effects caused by acute exposures and significantly reduce risks associated with long-term exposures.

The objective of this control technology feasibility study is to obtain information on the techniques and procedures used for maintaining low concentrations of ethylene oxide in hospitals by use of practicable and commercially available control technology. The documented findings of the feasibility study will be the basis for a determination of need to perform an in-depth control technology assessment of one or more of these specific areas of interest. A subsequent in-depth study will result in a technical report designed to assist hospital personnel in their efforts to prevent employee exposures to occupational health hazards.

HAZARD DESCRIPTION AND EXPOSURE SOURCES

Ethylene oxide (EtO) presents hazards to exposed employees with both short- and long-term health effects. Evidence of these effects has been demonstrated in animal and human studies as well as epidemiologic investigations. Use of these agents is confined to a particular area of the hospital where several exposure sources may present a hazard.

ETHYLENE OXIDE

Ethylene oxide is a major industrial chemical, and while hospital sterilization procedures are estimated to use only about 0.02 percent of the annual United States production of EtO, NIOSH estimates that as many as 100,000 hospital personnel may be exposed.[2] Because of the large number of potentially exposed employees and the growing evidence of serious health effects, occupational health professionals and agencies are becoming increasingly concerned.

Ethylene oxide has several short-term effects. At concentrations as low as 200 parts per million (ppm), EtO exposures may cause irritation of the eyes, nose, and throat. Direct contact of EtO with the skin or eyes may result in burns and in allergic rash. With extended low level exposures and brief exposures to concentrations above 1,000 ppm, EtO can result in irritation of the lungs, coughing, chest pain, headaches, nausea, vomiting, drowsiness, weakness, and lack of coordination.[3]

In assessing the long-term effects of EtO exposure, animal, human, and epidemiologic studies are necessary. Animal studies have shown ethylene oxide to be a carcinogen in male and female rats (through inhalation exposure) and to produce malignant tumors in mice (by injection). The carcinogenicity of EtO in terms of human exposures is more difficult to define. Several epidemiologic studies have indicated an increased risk for cancer and leukemia, but the results can not be considered conclusive.[4]

Several in vitro tests including Salmonella typhimurium, Drosophila melanogaster, Escherichia coli, and in vivo tests such as micronucleus, dominant lethal, and the heritable translocation test have shown ethylene oxide to be mutagenic. Other long-term studies involving rabbits and monkeys show an increased frequency of sister chromatid exchanges and chromosomal aberrations. Two studies of workers exposed to EtO have also demonstrated an increased frequency of sister chromatid exchanges.[4]

Evidence of ethylene oxide induced reproductive effects is inconclusive. Rats treated with EtO have significantly reduced litter sizes, however, EtO inhalation by rats did not produce teratogenic effects. Intravenous injection of EtO in mice is teratogenic, but is not in rabbits similarly injected. Human studies have been limited. One study reported a reduced sperm count in exposed male workers, but the small sample size rendered the results inconclusive.[4]

Because ethylene oxide is explosive in the sterilization process, it is used in combination with Freon 12 (dichlorodifluoromethane) which renders it nonexplosive. The mixture is typically 12 percent EtO and 88 percent Freon by weight. Freon exposure may cause eye and skin irritation, and high exposures (2,300 ppm) in animals have been found to cause intoxication, weakness, dizziness, and loss of balance with convulsions. Excessive levels are expected to produce the same results in humans. Low level exposure to Freon causes irregular heartbeats and is considered to be the most significant effect.[5]

Since some of these effects have occurred at levels below the current Occupational Safety and Health Administration (OSHA) exposure standard of 50 ppm,[6] the American Conference of Governmental Industrial Hygienists (ACGIH) is recommending a reduction of the standard to an eight-hour time-weighted average (TWA) exposure of 1 ppm.[7] OSHA is presently considering that change.

Exposure to EtO is effectively limited to the area of the hospital where sterilization takes place. The highest exposure occurs when the sterilizer

door is opened after a cycle, when the concentration of EtO may reach 1,000 ppm for a short time. The gas discharge point, usually a floor drain beneath the sterilizer, can be another source of high EtO concentrations. Transferring materials from the sterilizer to the aerator is an important opportunity for exposure, especially since approximately 5 percent of the EtO in the sterilizer stays in the sterilized materials and packaging. Changing the EtO tank can also provide exposure to the worker both by inhalation and by skin contact.[3]

HOSPITAL DESCRIPTION

St. Francis - St. George is a two-year-old hospital located in Western Cincinnati, which was built to consolidate two older facilities. The 6-story hospital occupies about 300,000 square feet of area and employs approximately 1,200 persons.

The operation of interest, ethylene oxide gas sterilization, is conducted within the Supply, Processing, and Distribution (SPD) Department located on the first level. There are 41 persons employed in the sterilization area: Processing/Reprocessing.

GAS STERILIZATION

Sterilization is conducted to decontaminate medical supplies, surgical instruments, and other equipment. Most items are subjected to steam sterilization. However, heat sensitive items (e.g., telescopic instruments, plastic, and rubber goods) for which steam sterilization is impractical, are sterilized using EtO. This gas sterilant is capable of killing viable microorganisms, thus decreasing the incidence of bacterial infections.

The gas is supplied by two gas cylinders located on the Reprocessing side of SPD. A dual-load system is used where the second tank acts as a reserve gas supply when the first is empty. It is supplied premixed with a halocarbon, dichlorodifluoromethane (Freon 12) to render it nonexplosive.

The gas sterilizer, an American Sterilizer Company (AMSCO) Eagle Model 2025, has a chamber size of 20 x 20 x 38 inches. The unit is equipped with a microcomputer-programmed control feature that carries sequential instructions for each cycle. This feature is designed to assure sterilization cycle accuracy and alerts the operator in the event of a malfunction. An illuminated front control panel provides the following information for the operator.

1. Status of the sterilizer operation: conditioning, sterilization, exhausting, or complete, visual and/or audible alert in the event of an unlocked door, temperature drop, gas leak, or power failure.

2. Sterilizer TIME digital readout and countdown in hours and minutes.

3. CYCLE Selector: activates and visually displays the cycle for each load-type.

The sterilizer is equipped with AMSCO's "Envirogard" system for worker exposure protection. This system includes a post-sterilization purge cycle and a local exhaust ventilation system.

The sterilization process is conducted as follows: contaminated materials are plastic-bagged at the site of use and placed on metal carts in "soil rooms" on each of the five hospital floors. These items are delivered to the Reprocessing Area of SPD via a small elevator designed for this purpose. Heat-sensitive items are processed by hand or machine washing. Non-heat-sensitive items are initially decontaminated by steam sterilization. If items have been exposed to known contaminants, the items (heat sensitive or not) are first decontaminated using the EtO process.

Prior to sterilization, the materials are properly wrapped or packaged and labeled. Non-heat-sensitive items are terminally sterilized in steam sterilizers. Heat-sensitive items are loaded into wire baskets on the "dirty side" of the "pass-through" type EtO sterilizer and are gas sterilized.

The gas sterilization cycle lasts 6 hours, and includes vacuum, humidification, EtO charging, and exhaust phases. The post-sterilization cycle, a repeating 20-minute chamber air flush, follows the exhaust phase, and completes the process.

When the cycle is completed, the gas-sterilized materials are removed from the sterilizer and promptly placed in the adjacent aeration chamber for EtO out-gassing. The aeration time is 12 hours. Sterile items are subsequently stored or delivered as needed to surgery or other hospital departments.

Typically, the SPD Department runs three to four EtO sterilization cycles per day. During this period, approximately 17 employees are working in an area of potential EtO exposure.

ENGINEERING CONTROLS

The engineering controls for EtO were selected with the following criteria in mind. minimal personnel exposure to EtO, compliance with anticipated future regulatory standards, operational flexibility, and safety controls. The following technology was found to meet the above requirements.

1. Post-Sterilization Cycle

This is a terminal exhaust phase which includes two post-vacuums and a repeating 20-minute air flush. This exhaust is designed to reduce the residual EtO level in the chamber at the end of the programmed cycle, thus preventing build-up of EtO from load desorption due to delayed door opening.

2. Local Exhaust System

Local exhaust ventilation is provided to control EtO emissions at the two most critical points: above the sterilizer door and at the exit drain. A 1- x 20-inch slot hood is located above the door on each side of the sterilizer. Hot EtO-laden air from the chamber is drawn by a blower (located in an enclosure above the sterilizer) through two, two-inch flexible exhaust ducts to a dedicated exhaust vent to the outside of the building. The design airflow is approximately 125 cfm for each door.

The drain area beneath the sterilizer unit is locally exhausted via the same blower assembly. Ventilation is required here because when EtO gas is drawn by vacuum from the chamber at the end of the sterilization cycle, it is mixed with water, and discharged to the exit drain. Some of the gas escapes from the water at the drain airbreak and may diffuse into the environment. To control this emission, a liquid/gas separator is added to the drain connection. The blower then exhausts the separated drain gas through two-inch flexible ducting to the dedicated exhaust vent to the outside of the building.

3. Aeration

All gas-sterilized items are placed in a forced-draft, filtered warm air aeration cabinet (aerator) to protect employees from out-gassing of EtO-sterilized material. The operator loads the aerator (immediately after sterilization) with gas-sterilized materials, presses a power switch, sets a timer, and the aerator automatically times the aeration period, maintaining a constant cabinet temperature.

The aeration cabinet, 24 x 36 x 36 inches in size, is made of welded stainless steel with glass fiber insulation. It is connected to a dedicated exhaust duct to carry the effluent out of the work area. As an added precaution, the hospital has installed a canopy hood (1 by 3 feet) above the aerator door. The design airflow for this hood is approximately 700 cfm.

4 Ventilation of Gas Cylinder Area

Since leaks or gas cylinder changing operations can result in a significant EtO release, the gas cylinders are ventilated with a 1- x 3-foot canopy hood, which exhausts directly outside. The design airflow for this hood is 700 cfm.

5. General Dilution Ventilation

The Processing room, or "clean" side, where gas-sterilized goods are removed following sterilization, is ventilated with 100 percent fresh supply air, delivered through 6 ceiling supply air diffusers. This room is exhausted via two exhaust ducts located in the central ceiling area.

6. Safety Controls

Two sterilizer safety controls include a safety door lock and an alarm system. The cycle will not start until both doors are closed and locked.

The alarm system is activated in event of any cycle deviations that may jeopardize the sterilization process. For example, the sterilizer unit is programmed to automatically replace EtO gas absorbed by the load during a cycle. Should more than a normal replacement of gas occur, an audible alarm will alert the operator of a potential leak.

CONTROL MONITORING

Control monitoring consists of personnel exposure monitoring, equipment leak-testing, and monitoring of the local and general ventilation systems. These functions are performed semi-annually by AMSCO technical personnel. The hospital has both a monitoring and maintenance contract with AMSCO. Personal exposure monitoring is also done on a semi-annual basis by AMSCO.

CONCLUSIONS AND RECOMMENDATIONS

St. Francis - St. George hospital has instituted the most comprehensive control measures observed to date. The most effective control used is the local exhaust ventilation system. The slot hood above the sterilizer door is designed to capture EtO-contaminated air released when the door is opened at the end of the cycle. This system is also designed to control EtO released at the drain area. Additionally, canopy hoods have been installed above the aerator and gas cylinders -- a control not heretofore observed. It is highly recommended that St. Francis - St. George be included as an in-depth survey site.

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