HETA 92-124-2289

FEBRUARY 1993
MIDDLETOWN REGIONAL HOSPITAL
MIDDLETOWN, OHIO

NIOSH INVESTIGATORS:
Calvin K. Cook
Robert Malkin, DDS, Ph.D.
Leo M. Blade, CIH, MSEE

I. SUMMARY

On January 24, 1992, the National Institute for Occupational Safety and Health (NIOSH) received a request from a group of employees to conduct a Health Hazard Evaluation (HHE) at the pharmacy department of Middletown Regional Hospital, located in Middletown, Ohio. The request stated that a number of pharmacy workers suffered from eye irritation which they felt may have been related to exposure to ethylene oxide (EtO), a sterilizing agent used in the Central Supply Department (CSD), located adjacent to the pharmacy.

On April 14, 1992, a site visit was made by NIOSH investigators to conduct environmental monitoring in the general vicinity of the pharmacy area and CSD. This monitoring included full-shift personal breathing-zone and general-area air sampling for EtO during two sterilization and aeration cycles, and a series of real-time measurements for carbon dioxide (CO_2), respirable suspended dust (RSD), temperature, and relative humidity (RH).

Personal and area air monitoring conducted in the pharmacy and CSD revealed low concentrations of EtO. Ethylene oxide concentrations ranged from below the minimum detectable concentration (MDC) of 0.008 parts per million (ppm) to 0.02 ppm, well below the Occupational Safety and Health Administration (OSHA) standard of 1 ppm and the NIOSH recommended exposure limit (REL) of 0.10 ppm. Real-time measurements for CO_2, RSD, and temperature that were made in the pharmacy area were within their respective criteria. Relative humidity levels (28 to 33%) within the pharmacy were at the lower end of the American Society of Heating, Ventilating, and Air-Conditioning Engineers (ASHRAE) recommended range of 30 to 60%.

Employees reported symptoms of eye irritation including dry, itching and burning eyes. Symptoms temporarily decreased after humidity levels in the pharmacy were increased but they subsequently returned to previous levels.

Environmental monitoring revealed low relative humidity (RH) levels in the pharmacy area and only trace concentrations of ethylene oxide (EtO). The cause of the symptoms was not determined. Recommendations are made in the report to maintain humidity in the pharmacy at levels that satisfy the current the American Society of Heating, Ventilating, and Air-Conditioning (ASHRAE) criteria, and to provide proper maintenance of the heating, ventilating, and air-conditioning system.

KEYWORDS: SIC 8062, (general medical hospital) ethylene oxide, gas sterilization, indoor air quality, pharmacy, relative humidity, central supply.

II. INTRODUCTION

On January 24, 1992, the National Institute for Occupational Safety and Health (NIOSH) received a request for a Health Hazard Evaluation (HHE) from a group of employees of Middletown Regional Hospital, Middletown, Ohio to conduct a HHE in the pharmacy department. The request stated that a number of pharmacy workers suffered from eye irritation, which they felt may have been related to exposure to ethylene oxide (EtO), a sterilizing agent used in the hospital's Central Supply Department (CSD), located next to the pharmacy. On the afternoon of April 14, 1992, a site visit to the facility was made by NIOSH investigators. Both personal breathing-zone and general-area air monitoring were conducted to measure potential EtO concentrations in the pharmacy and CSD.

III. BACKGROUND

Since the construction of the Middletown Regional Hospital in 1978, both the pharmacy and CSD have been at their present locations on the lower level of the building. Both departments operate on 8-hour, three-shift work schedules. The 3000-square-foot pharmacy employs a staff of eleven workers including pharmacists and technicians. Located in a suite of rooms down a corridor from the pharmacy, the CSD employs a staff of about 20 workers classified as instrument technicians. On the afternoon of the NIOSH evaluation, three workers were present in both the pharmacy and CSD.

The CSD utilizes two sterilizer units. One is a large, "built-in" Amsco Model Eaglegard LV sterilizer (using 88% freon and 12% EtO), mounted in the wall between the "access room" and a room called the processing or set-up area. The unit's front panel (door and controls) is in the processing area, and the bulk of the unit sits in the access room. The other sterilizer is a smaller benchtop-style 3M Steri-Vac Gas Sterilizer model 400C (using 100% EtO), located in the instrument room. The CSD also was equipped with two separate aerators used to aerate sterilized products. The entire sterilizing process took approximately 10-14 hours to complete, which involved sterilizing products for 2½ to 4½ hours in a sterilizer unit, and then aerating for 8 to 10 hours. An Amsco model Envirogard III Gas Chromatograph is used by the CSD to continuously monitor EtO concentrations in areas surrounding the EtO sterilizers and the aerator units. Each month 22 loads of products are sterilized, utilizing an average of two gas cylinder tanks (size H, 140 pounds) of EtO per month. Preventive maintenance records show that each sterilizer unit is serviced bi-monthly.

The heating, ventilating, and air-conditioning (HVAC) needs of the pharmacy area are served by air handling unit (AHU) #1. This unit also serves the entire lower level of the hospital which includes the dietary services department, morgue, CSD, and central distribution department. The AHU was reportedly designed to provide a maximum supply air flow rate of 26,000 cubic feet per minute (CFM), consisting of a minimum of 38% outside air and a maximum of 62% recirculated air. The proportion of outside air in the supply-air is increased automatically by an "economizer" control, which modulates outside air, return air, and discharge (relief)

dampers. This control is useful whenever cool outside air is available and is helpful for handling the system's cooling needs. This HVAC system is a "variable-air-volume" (VAV) type; to achieve proper thermal control the supply-air volumetric flow rate to many of the spaces served is regulated by VAV terminals. Each VAV terminal has an internal damper which modulates the supply-air flow rate under the control of a thermostat in the occupied space served. The pharmacy, however, is one of several spaces served by this system that do not receive their supply-air through VAV terminals. Therefore their supply-air flow rate remains constant. Reportedly, the constant supply-air flow rate to the pharmacy is ample to effect 3 air changes per hour in the area.

The AHU contains a pre-filter (15-20% efficiency rating) and a bag filter (90-95% efficiency rating), a supply-air fan, cooling coils, a dry-steam humidifier, and heating coils. The dry-steam humidifier reportedly maintains relative humidities (RHs) in the occupied spaces of about 30% during the winter months and 50% during warmer transitional months. The system's supply-air flow rate is regulated by vanes on the supply-air fan, reducing flow as VAV terminals modulate supply-air flow rates lower, and controlling the static pressure in the supply-air ducts. The system contains a return-air fan, which has similar vanes to reduce the return-air flow rate in proportion to any reduction in the supply-air flow rate (to prevent the building from being placed under "negative pressure"--a condition which the static pressure in the building is less than that outside).

Supply-air is distributed from the AHU to the occupied areas of the lower level through a network of supply-air ducts leading to the VAV terminals and supply air diffusers. Return-air recirculates from the occupied spaces, through plenum ceiling slots, to plenums above the false ceilings. From there air enters one of a small number of return-air ducts and moves to the return-air fan. The return-air fan moves some of the air to the AHU, and some to the discharge duct. The return-air that enters the AHU is mixed with the outside air, and this "mixed air" enters the filter section of the AHU. It then enters the supply-air fan, which propels it through the conditioning sections (containing the cooling and heating coils and the humidifier) and out of the AHU into the supply-air duct network.

The access room in the CSD is served by a dedicated exhaust ventilation system which exhausts EtO-contaminated air directly to the outdoors. This system also provides exhaust ventilation to the processing area via "transfer-air" grilles in the wall between the two rooms. Most of the return-air ceiling slots in the processing area, and all of the slots in the adjacent instrument room, are blocked off. Apparently, the design purpose was to prevent recirculation of air from these rooms to AHU #1, with the dedicated exhaust system keeping the processing area under negative static pressure by removing air from the area at a rate greater than that at which it is supplied by the AHU. However, some air was believed to be recirculated to the AHU from the processing area because a few of the ceiling slots were partially open, and also because the room was not under negative static pressure compared to the adjacent sterile-storage room of the CSD (see subsequent discussion of ventilation-system evaluation).

The morgue, also located in the lower level but not adjacent to the pharmacy or CSD, has its own dedicated exhaust ventilation system which reportedly operates at all times to control potential airborne chemical and/or microbiological contaminants. Apparently, no air recirculates from the morgue back to AHU #1 because the exhaust system removes air from the area at a greater rate than the AHU supplies it, keeping the area under negative pressure (as explained in the subsequent discussion of the ventilation-system evaluation) compared with surrounding spaces -- including the space above its false ceiling (which connects, via an opening above the morgue's built-in refrigerator box, to the neighboring storage area).

IV. ENVIRONMENTAL EVALUATION AND METHODS

On April 14, 1992, NIOSH investigators performed an environmental evaluation of the pharmacy during the second shift that included a series of real-time measurements for CO_2 and respirable suspended dust (RSD) taken at various times and locations. Temperature and RH measurements also were taken to evaluate thermal comfort parameters within the pharmacy. To evaluate worker exposure to EtO, a total of eight full-shift air samples were collected during two sterilization/aeration cycles. In the pharmacy, a personal air sample for EtO was collected on a pharmacist, and three area air samples were collected at work stations. In the CSD, a personal air sample for EtO was collected on an instrument technician, and an area air sample was collected near each of two sterilizing units while they were in operation. To detect leaks around the door seals and drains of the Amsco sterilizer, a portable halogen leak detector was used to identify possible freon leaks. Since the 3M sterilizer was designed to use 100% EtO (no freon), the leak detector could not be used on that particular sterilizer unit.

An inspection of the HVAC system was conducted that focused on the amount of outside air supplied to the pharmacy and the general cleanliness and maintenance of the AHU serving the pharmacy. A visual inspection of the AHU serving the pharmacy was conducted to sight potential sources of contamination (e.g., biological growth, standing water, mangled fiber glass insulation, and overloaded particulate air filters) that may have adversely affected the pharmacy's air quality. Air movement in the pharmacy and central supply departments was determined qualitatively using ventilation smoke tubes. An inspection of the morgue was conducted in an effort to determine the potential for formaldehyde or other contaminants entering the pharmacy.

A. Ethylene Oxide

Air sampling and analysis were conducted in accordance with NIOSH Method 1614.[1] Air samples were collected on hydrogen bromide coated petroleum charcoal tubes using calibrated air sampling pumps operating at a flow rate of 80 milliliters per minute. Laboratory analysis included desorbing each charcoal tube sample with dimethylformamide and analysis using gas chromatography with electron capture

detection. The analytical method has a limit of detection (LOD) of 0.70 micrograms (μg) per sample, which equates to a minimum detectable concentration of 0.08 ppm, assuming an air sample volume of 24 liters.

B. Carbon Dioxide

Real-time CO_2 concentrations were determined using a Gastech Model RI-411A, Portable CO_2 Indicator. This portable, battery-operated instrument monitors CO_2 (range 0-4975 ppm) via non-dispersive infrared absorption with a sensitivity of 25 ppm. Instrument zeroing and calibration was performed prior to use with zero air and a known concentration of CO_2 span gas at 800 ppm.

C. Respirable Suspended Dust

Real-time respirable dust concentrations were measured using a GCA Environmental Instrument Model RAM-1 monitor. This portable, battery-operated instrument assesses changes in particle concentrations via an infrared detector, centered on a wavelength of 940 nanometers. Air is sampled (2 liters per minute) first through a cyclone preselector that restricts the penetration of particles greater than 9 micrometers (µm) in diameter. The air sample then passes through the detection cell. Operating on the 0 to 2000 micrograms per cubic meter ($\mu g/m^3$) range with a 32-second time constant yields an LOD of 1 $\mu g/m^3$.

D. Temperature and Relative Humidity

Real-time temperature and RH measurements were made using a Vista Scientific, Model 784, battery-operated psychrometer. Dry and wet bulb temperature readings were monitored and the corresponding RH calculated.

V. EVALUATION CRITERIA

A. Ethylene Oxide

Ethylene oxide (EtO) 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.

The primary mode of exposure to EtO 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 (fluid in the lungs), bronchitis, drowsiness, weakness, and electrocardiograph abnormalities.[2] There have also been reports of cases of neurotoxicity induced by ethylene oxide exposure.[3-5]

Based on animal experiments and limited human epidemiological data, NIOSH recommends that EtO be regarded as a potential occupational carcinogen and that exposure to EtO be controlled to less than 0.1 ppm determined as an 8-hour

time-weighted average (TWA) with a short-term exposure limit not to exceed 5 ppm for a maximum of 10 minutes per day. This recommendation is based on the available risk assessment data which show that even at an exposure level of 0.1 ppm, the risk of excess mortality is not completely eliminated.[6] Effective as of August 21, 1984, the standard of the Occupational Safety and Health Administration (OSHA) for occupational exposure to EtO was revised downward from 50 ppm to 1 ppm calculated as a TWA concentration for an 8-hour workshift. This downward revision in the standard was 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.[7]

B. Carbon Dioxide

Carbon dioxide is a normal constituent of exhaled breath and, if monitored, may be useful as a screening technique to evaluate whether adequate quantities of fresh air are being introduced into an occupied space. The ASHRAE Standard 62-1989, Ventilation for Acceptable Indoor Air Quality, recommends outdoor air supply rates of 20 cubic feet per minute per person (cfm/person) for pharmacies based on an estimated maximum occupancy of 20.[8]

Indoor CO_2 concentrations are normally higher than the generally constant ambient (outdoor) CO_2 concentration (range 300-350 ppm). When indoor CO_2 concentrations exceed 1000 ppm in areas where the only known source is exhaled breath, inadequate ventilation is suspected. Elevated CO_2 concentrations suggest that other indoor contaminants may also be increased.

C. Respirable Suspended Dust

Respirable particles smaller than 2.5 μm are associated with combustion source emissions. The greatest contributor to indoor respirable particulate is environmental tobacco smoke (ETS). In buildings where smoking is not allowed, respirable particulate levels are influenced by outdoor particle concentrations and by minor contributions from other indoor sources. In buildings with oil, gas, or kerosene heating systems, increased dust concentrations associated with the heating source may be important. Respirable particles, defined as particles smaller than 10 μm in diameter (PM^{10}), are a combined result of combustion, soil, dust, and mechanical source particle contributions. The larger particles are associated with outdoor particle concentrations, mechanical processes, and human activity. When indoor combustion sources are not present, indoor particle concentrations generally fall well below the Environmental Protection Agency (EPA) ambient PM^{10} standard of 150 micrograms per cubic meter of air ($\mu g/m^3$) averaged over a 24-hour period.[9]

D. Temperature and Relative Humidity

The perception of comfort is related to one's metabolic heat production, the transfer of heat to the environment, physiological adjustments, and body temperatures. Heat transfer from the body to the environment is influenced by factors such as temperature, humidity, air movement, personal activities, and clothing. ANSI/ASHRAE Standard 55-1981 specifies conditions in which 80% or more of the occupants would be expected to find the environment thermally comfortable.[10]

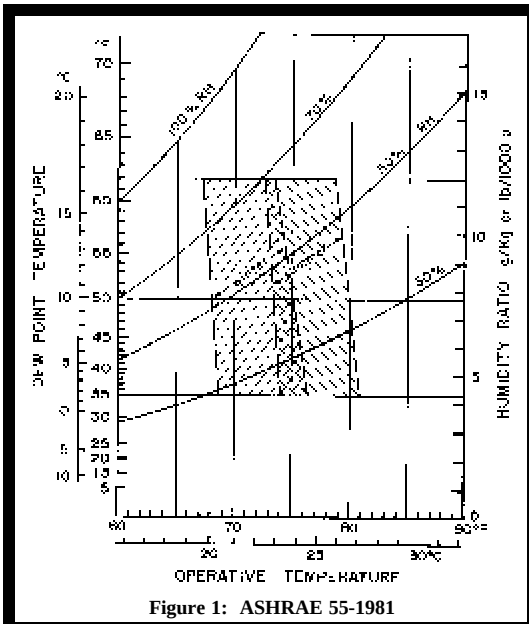

Figure 1: ASHRAE 55-1981

VI. RESULTS

A. Environmental

Personal and area air monitoring conducted in the pharmacy and CSD revealed non-detectable or low concentrations of EtO. Analytical results for all samples collected show EtO concentrations that ranged from below the MDC of 0.008 ppm (assuming a sampling volume of 24 liters) to 0.02 ppm , well below the OSHA standard of 1 ppm and the NIOSH REL of 0.10 ppm for up to an 8-hour TWA exposure. An inspection of the drain serving the EtO monitors found it to be properly ventilated as recommended by the Association for the Advancement of Medical Instrumentation (AAMI)[11]. Freon leaks were not detected by the portable halogen leak detector.

Real-time measurements for CO_2 taken within the pharmacy ranged from 425 to 650 ppm, outdoor measurements for CO_2 revealed a constant value of 400 ppm. All CO_2 measurements taken within the pharmacy were below the ASHRAE recommended guideline of 1000 ppm throughout the day of the evaluation.[8]

Temperatures measured within the pharmacy ranged from 68 to 73°F, slightly outside the thermal comfort range of 72 to 78°F (see Figure 1) recommended by ASHRAE. Relative humidity (RH) levels (28 to 33%) within the pharmacy were at the lower end of the ASHRAE recommended range of 30 to 60%. Outdoor temperatures ranged from 63 to 68°F, while RH ranged from 39 to 44%.

Measurements for RSD revealed values that ranged from 10 to 30 $\mu g/m^3$, below the Environmental Protection Agency 24-hour PM^{10} standard of 150 $\mu g/M^3$.

AHU #1 had an inadequately designed drain system in which the drain pipe was too high (located about two inches above the bottom of the condensate pan) to drain all water accumulated in the condensate pan. Approximately ½ inch of standing water was observed in the condensate pan. Water corrosion was present in the condensate pan, but there were no visual signs of biological growth. The particulate air filters appeared lightly soiled. No other sources of contamination were discovered.

The processing area that was supplied by the ventilation exhaust system, which also served the access room, was reported to be under negative pressure. However, ventilation smoke tube measurements showed the pressure within the processing area to be neutral compared to the sterile storage area. Air distribution in the pharmacy and CSD appeared adequate. An inspection of the morgue revealed that air within the morgue could possibly move to the pharmacy by way of the common ceiling plenum where there is an opening above the morgue's built-in refrigerator box, to the neighboring storage area. However, this appears unlikely since qualitative ventilation measurements showed that the morgue was under negative pressure due to the presence of the exhaust ventilation system, which reportedly ran at all times.

VII. MEDICAL EVALUATION-METHODS AND RESULTS

Seven individuals working in the pharmacy at the time of the NIOSH site visit, out of a total of 20 employees for all shifts, were interviewed during our site visit. Five employees reported symptoms relating to their eyes. Two reported "dry" eyes and three reported irritated or "burning" eyes.

During interviews, employees proposed etiologies for the symptoms. These included:

1. Exposure to EtO. As reported above, however, EtO exposures in the CSD and pharmacy were within OSHA workplace standards and NIOSH RELs.

2. Sensitivity to disinfectants and cleaners. NIOSH investigators reviewed available Material Safety Data Sheets (MSDS) for cleaners used in the hospital. The hospital has a cleaning contract and materials used include floor cleaners, sanitizers and waxes. Although these materials are irritative to the eye upon direct contact, they would not be expected to result in eye irritation when properly used for cleaning. One cleaner, however, did contain quaternary ammonium chlorides and polyethoxylated alkylphenol. If it is not adequately diluted, its vapor is capable of causing eye and mucous membrane irritation.

3. Odors from a diagnostic laboratory located above the pharmacy. The basement (where the pharmacy is located) is on a separate AHU than other floors in the hospital, so migration of vapors between floors in concentrations sufficient to cause symptoms would be unlikely.

4. Irritation from individual drugs stored in the pharmacy. Drugs are mixed in a horizontal flow hood to ensure sterility. Air enters through the bottom of the hood, passes through a series of filters and is blown over the preparation area directly at the employees mixing the drug. Since most pharmaceuticals mixed are powders, it is possible that some material may be picked up by the air flow and blown into the employee's eyes. No eye protection is used. The hood is in a separate room, however, it is unlikely that substantial amounts of material would be blown throughout the main pharmacy room. Oncology drugs are mixed on a different floor using a different hood with a vertical air flow.

5. Low humidity. NIOSH investigators frequently encounter reports of eye irritation in buildings that they evaluate. The humidity in the pharmacy (28-33%), as measured by the NIOSH investigators, was on the low end of the ASHRAE guidelines for comfort in office buildings. However, exposure to low humidity by itself is not known to cause a true dry eye, which is the evaporation of the innermost tear film[12,13]. In addition, controlled experiments subjecting people to low humidity have not resulted in either eye irritation or nasal mucosa irritation at humidity levels as low as 9%, although reported discomfort did increase. This increase was not significant and might have been due to electric shocks generated at the lower humidity[14].

The possibility of transmission of infectious diseases through the ventilation system from autopsies performed in the morgue, and possible exposure to formaldehyde used in the morgue was considered by NIOSH investigators. However, the morgue at Middletown Hospital was equipped with its own exhaust ventilation system which, if left on, should keep the area under negative pressure. The director of the morgue was interviewed by telephone and reported that the exhaust fan was left on at all times, and that the morgue only performed between 20 and 30 autopsies a year. Formaldehyde was used to store tissue samples, but the formaldehyde was poured directly out of the jar into the bottle where the tissue was to be stored and was used only during the autopsy. The number of autopsies performed at the hospital was insufficient to account for the almost constant reports of dry eyes.

VIII. DISCUSSION

The NIOSH evaluation revealed only trace concentrations of EtO and no apparent environmental sources for continual eye symptoms reported by the pharmacy workers. Recirculation of contaminated air from the morgue is apparently only possible if the exhaust system is not operating.

Following the NIOSH evaluation, hospital management was advised by NIOSH investigators to make additional RH measurements in the pharmacy and other areas of the hospital. The purpose of these measurements was to compare RH levels in the pharmacy to those measured in areas outside the pharmacy. These measurements revealed that RH levels in the pharmacy were lower than in all other areas of the hospital. Because the RH levels in the pharmacy were at the lower end of the ASHRAE guideline, a portable humidifier was first used to elevate RH levels in this area. RH in the pharmacy was later increased using the HVAC system's humidifier instead of the using a portable humidifier. Pharmacy employees reported that symptoms of eye irritation had subsided for approximately three months after the RH was increased. They originally attributed this to the increased humidity levels (that were not documented) in the pharmacy, but employees reported that symptoms subsequently returned to previous intensity.

Although there were no visual signs of biological growth present in the AHU, standing water in the condensate pan may promote biological growth, thus creating the potential for aerosolization of biological contaminants throughout the pharmacy and other areas of the hospital served by this AHU. The pharmacy reportedly was provided with 2.9 air changes per hour, however, the American Institute of Architects (AIA) recommends a provision of a minimum of 4 air changes per hour in pharmacies.[15]

IX. CONCLUSIONS

The results of this investigation indicated that EtO does not appear to be responsible for workers' health complaints. The cause of the employee symptoms was not determined. In a previous NIOSH investigation, perceived low humidity in indoor environments has been associated with dryness of the eyes, nose, and throat [16].

X. RECOMMENDATIONS

1. Relative humidity levels in the pharmacy should be maintained within the ASHRAE recommended guidelines of 30 to 60%. Increasing humidity levels must be done carefully to prevent other indoor environmental problems from developing (such as biological growth on ductwork), and should be done only if employees perceive the lower humidity

levels in the pharmacy are detracting from their comfort. Portable humidifying units may create bioaerosol problems if not properly maintained.

2. Redesign the drain system serving AHU #1 so the drain is located at the bottom of the condensate pan. This should allow water to drain properly from the pan. Failure to redesign the drain will continue to allow standing water to accumulate in the pan, which may result in the aerosolization of biological contaminants.

3. The exhaust flow rate in the access room should exceed the total supply flow rates to the processing area. This would serve to prevent EtO-latent air from escaping from the access room and entering the processing area because of the pressure difference of the two areas.

4. To help prevent future ventilation and air quality problems, a written HVAC maintenance program should be established and implemented that includes: (1) routine visual inspections of each AHU serving the hospital, (2) replacing particulate air filters on a regular basis, and (3) conducting HVAC performance tests. ASHRAE recommends testing, adjusting, and balancing HVAC systems every 3 to 5 years.

5. Employees should use eye protection when mixing pharmaceuticals in the horizontal flow hood.

6. Communication between management and employees should be increased to facilitate the exchange of concerns about environmental conditions in the work area. Management should be made aware of the concerns of the employees and should inform them of decisions made to address those concerns.

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XII. AUTHORSHIP AND ACKNOWLEDGEMENTS

Report Prepared by:

Calvin K. Cook
Industrial Hygienist
Industrial Hygiene Section

Robert Malkin, DDS, Ph.D.
Supervisory Epidemiologist
Medical Section

Leo M. Blade, CIH, MSEE
Industrial Hygiene Engineer
Industrial Hygiene Section

Originating Office: Hazard Evaluations and Technical Assistance Branch
Division of Surveillance, Hazard Evaluations and Field Studies

Report Formatted By:

Donna M. Humphries
Office Automation Assistant

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