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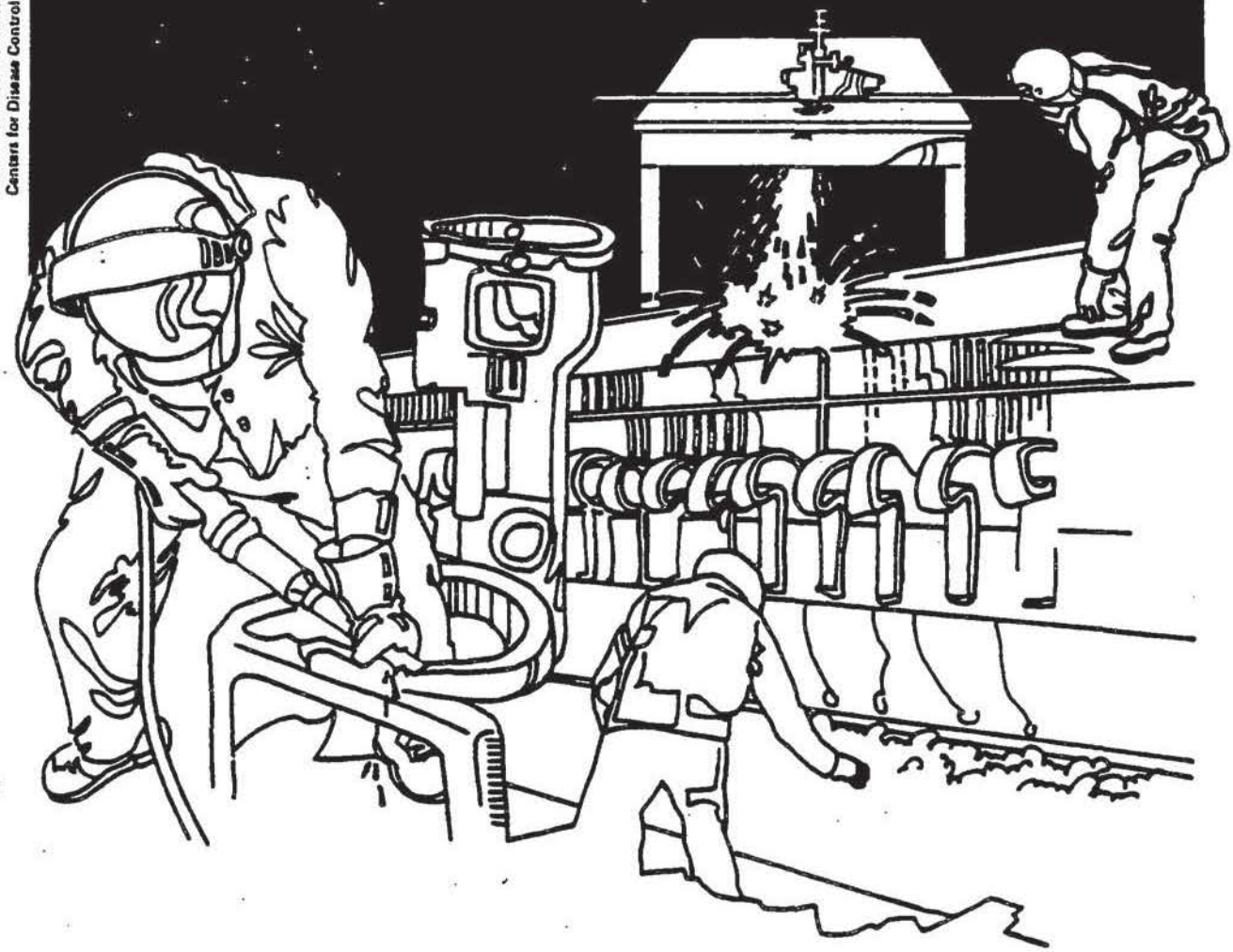

Health Hazard Evaluation Report

HETA 84-427-1613
PIKES PEAK DIALYSIS CENTER
COLORADO SPRINGS, COLORADO

PREFACE

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

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

HETA 84-427-1613
AUGUST 1985
PIKES PEAK DIALYSIS CENTER
COLORADO SPRINGS, COLORADO

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I. SUMMARY

In July 1984, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate potential occupational health exposures to formaldehyde at Pikes Peak Dialysis Center, Colorado Springs, Colorado.

On August 14 and 15, 1984 and February 22 and 23, 1985, NIOSH investigators conducted an industrial hygiene surveys to determine airborne concentrations of formaldehyde at the dialysis center. Operations evaluated included formalin mixing, attending patients, packing dialysis units, and sterilization dialysis units prior to reuse.

Formaldehyde levels measured at the dialysis center ranged from 0.28 to 1.0 mg/M^3 for personal samples and from non detectable (ND) to 0.75 mg/M^3 for the area samples. Each of these samples were below the current Occupational Safety and Health Administration (OSHA) Time Weighted Average (TWA) standard of 3.7 mg/M^3. Recent evidence, however, indicates that formaldehyde is a potential human carcinogen and NIOSH recommends that formaldehyde exposures be controlled to the lowest feasible level.

Health complaints described by a portion of the employees included sore throat, congestion, cough, occasional headaches, and general irritation of the eyes, nose, and throat. These complaints were described primarily by those employees who worked with formalin mixing, reuse/sterilization, and dialysis unit packing procedures. It was also determined that the exhaust ventilation system in the reuse/sterilization area was not operating efficiently.

On basis of the environmental and medical data collected, it was determined by NIOSH that a health hazard from formaldehyde existed during the survey periods. It was also concluded that the local exhaust ventilation system in the reuse/sterilization room did not adequately remove formaldehyde vapors from the source. Recommendations for reducing exposures are included in this report.

KEYWORDS: SIC 8081 (Health and Allied Services, Not Elsewhere Classified), formaldehyde, renal dialysis units, reuse/sterilization, formalin mixing and dialysis unit cleaning procedures.

II. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a request in August 1984 for a health hazard evaluation from a representative of the Pikes Peak Dialysis Center, Colorado Springs, Colorado. The request was to determine if there was a health hazard from formaldehyde used at the dialysis center. This included formalin mixing, normal activities of treating patients while on the dialysis unit, packing the units with formaldehyde on the weekends, and reuse/sterilization procedures. Several employees reported symptoms compatible to formaldehyde exposure, (e.g., eye, nose, and throat irritation; coughs, congestion, and headaches).

On August 14 and 15, 1984 and February 22 and 23, 1985, NIOSH investigators conducted environmental surveys at the Pikes Peak renal dialysis facility. Results from these surveys were given verbally to the requestor and the employees as they became available.

III. BACKGROUND

Pikes Peak Dialysis Center treats approximately 190 patients per week, or an average of 65 for 3 visits per week. The clinic is opened from Monday through Saturday and has approximately 20 employees. This includes a director/manager, technicians, nurses, dietitian, social worker, and clerical workers.

There are 16 dialysis locations including 13 consoles for normal care, one unit for isolation, one unit for back-up, and one location for self care. Currently the routine for attending to patients and the dialysis units is fairly consistent in terms of weekly activities. A description of these processes and the potential for formaldehyde exposures are described below.

1. Work Process

Patients are connected to an artificial kidney (dialyzer) and dialysis console for four hours per visit. Additional time per patient is based on the patient's diet, condition of the dialyzers being reused, and the general health of the patient. Once the patient is disconnected from the dialyzer, the nurse or technician connects the system for disinfection. All the consoles are disinfected (bleached) daily and sterilized weekly.

Once a dialyzer has been used it, as well as the other dialyzers used during that treatment period, are sent to reuse/sterilization for cleaning in a 4% formalin solution. Here one person will spend approximately 1 1/2 to 2 hours sterilizing all the dialyzers. This procedure takes place in a room approximately 9 X 18 feet and has two doors which are normally closed during sterilization procedures.

The last procedure which was thought to contribute to a potentially high formaldehyde exposure occurs on the weekends when the employees are required to pack and sterilize all the consoles. Normally 3 to 5 employees are in the room during this procedure although only 2 to 3 are required to perform the actual process. This process requires the

complete draining of each unit followed by filling and packing with a 10% formalin solution. This solution sets in the individual units for the entire weekend and is drained early Monday morning.

2. Ventilation

Besides the general room ventilation used in the building there is also a 1/2 inch slot-type local exhaust ventilation system located at the sterilization counter/sink. This sterilization counter is approximately four feet long by 20 inches deep and has four dialyzer holders (each holds two dialyzers at one time). Directly below these holders is a sink which collects and drains the formalin solution used in sterilization and waste materials from the dialyzers being flushed. The distance between each dialyzers drain port and the bottom of the sink is approximately 15 to 20 inches depending of the length of tubing coming off the dialyzer.

The slot exhaust is positioned along the back portion of the sink, directly below the dialyzer holders and is actually flush with the top of the sink. This system is designed to draw air across the front of the sink to the back and thus remove the formaldehyde contaminant from the workers breathing zone. The face velocity across the slot averaged between 30 to 40 feet per minute (fpm) and the capture velocity at the front of the sink, averaged between 5 to 10 fpm. This is inadequate and should to be redesigned.

3. Personal Protective Clothing

The employees on the main floor normally wear a lab coat or smock while attending to the patient during treatment. These employees also wear surgical gloves during weekend packing procedures.

The employees who performed the reuse/sterilization procedures wore surgical gloves, a NIOSH/MSHA approved formaldehyde type disposable respirator and goggles during the reuse process. Rubber aprons were an optional garment that could be worn by the employee while performing this activity.

IV. ENVIRONMENTAL DESIGN AND METHODS

A. Environmental

Seventeen air samples, ten (10) personal and seven (7) general area type samples were collected by drawing air through XAD-2 sorbent tubes to trap the formaldehyde vapors present. The sampling pumps drew air through the tubes at 80 cubic centimeters per minute for 20 to 360 minute periods. The samples were analyzed using gas chromatography according to NIOSH Method No. 250 with modifications. The samples were collected during formalin mixing, normal attendance to patients, dialysis unit packing, and dialysis reuse/sterilization.

B. Medical

Eight employees potentially exposed to formaldehyde solution were interviewed and a medical questionnaire was completed by each.

V. EVALUATION CRITERIA

A. Environmental

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

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

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8 to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures. At present neither OSHA or NIOSH have a standard or criteria for glutaraldehyde. The the current standard and criteria that has been established for formaldehyde is discussed in the following section.

B. Toxicological

Formaldehyde is a colorless, flammable gas with a strong, pungent odor. It can form explosive mixtures with air and oxygen. Formaldehyde is usually manufactured by reacting methanol vapor and air over a catalyst. Formaldehyde usually will contain small amounts of methanol and formic acid. Formaldehyde is sold mainly as an aqueous (waterbased) solution called formalin, which is about 50% formaldehyde by weight.

The first signs or symptoms from exposure to formaldehyde at concentrations ranging from 0.1 to 5.0 parts per million (ppm) are burning of the eyes, tearing, and general irritation of the upper respiratory passages. Exposures of 10-20 ppm produces coughing, tightening in the chest, a sense of pressure in head, and palpitation of the heart. Exposures at 50-100 ppm and above can cause pulmonary edema, pneumonitis, or death.

Formaldehyde is often used to sterilize hemodialysis machines. There have been cases of pulmonary distress associated with this procedure. Dermatitis from formaldehyde exposure is a well recognized problem. After several days of exposure, a worker may develop a sudden inflammatory reaction of the skin of the eyelids, face, neck, scrotum, and arms. Dermatitis may occur on fingers, back of hands, wrist, and forearms. Formaldehyde can also cause both dermal and respiratory allergic sensitization.

NIOSH recommends that formaldehyde be handled as a potential occupational carcinogen. These recommendations are based on a Chemical Industry Institute of Toxicology (CIIT) study in which laboratory rats and mice exposed to formaldehyde vapor developed nasal cancents. This is supported by a New York University study where rats exposed to a mixture of formaldehyde and hydrochloric acid vapors developed nasal cancers. Formaldehyde has also been shown to be a mutagen in several short-term laboratory studies.

Since formaldehyde has induced a rare form of nasal cancer in both rats and mice, NIOSH recommends that it be handled in the workplace as a possible occupational carcinogen. Exposure levels should be maintained as low as possible. The OSHA standard of TWA 3.7 mg/M^3 was established based on the irritant effects of formaldehyde and not on the carcinogenic potential.

VI. RESULTS AND DISCUSSION

Employee exposures to formaldehyde were evaluated. NIOSH's evaluation included air monitoring, medical evaluations (interviews and questionnaires), evaluation of the ventilation systems and the personal protective clothing used by the employees while working with formaldehyde. The following are the results of NIOSH's study:

A. Environmental

Seventeen samples (ten personal and seven area) were taken at Pikes Peak Dialysis Center. Sampling times ranged from 20 to 360 minutes. The results for the personal samples ranged from 0.30 to 1.0 mg/M^3.

Area air sample results ranged from non-detectable (ND) to 0.50 mg/M^3 (refer to Table 1).

Specifically, a personal sample taken during the formalin mixing process was 0.79 mg/M^3. Sample results in the reuse/sterilization area were 0.75 to 1.0 mg/M^3 and area samples taken here ranged from 0.42 to 0.75 mg/M^3.

The personal sampling results for the dialysis rinsing operation ranged from 0.32 to 0.90 mg/M^3. Sample results for nurse and technician exposure who work on the patient floor ranged from 0.14 to 0.50 mg/M^3. All other sampling results were non-detectable for the clerical/receptionist, nurses desk, and the director's office.

B. Medical

Eight employees were interviewed and requested to fill out a medical questionnaire. The medical evaluation indicated symptoms which may be attributable to formaldehyde exposures. Reported symptoms included eye, nose, and throat irritation; coughing and lung irritation; and chest tightness which normally occurred during or shortly after the work process.

C. Ventilation

Local exhaust ventilation was used in the reuse/sterilization room. As described in Section III (subpart 2) of this report, however, the flow rate obtained along the face of the hood was less than 40 fpm at the opening and less than ten fpm capture velocity. This is considered unacceptable and would do very little to reduce and/or eliminate the formaldehyde exposures found in this room during the reuse process.

E. Personal Protective Clothing

A variety of personal protective clothing was available to the employees while working with formaldehyde, including lab coats, protective goggles, aprons, respirators, and gloves. The only job which required use of this clothing was during the reuse procedures and this included respirators, goggles, and surgical (Latex) type gloves. Aprons were not required.

VII. CONCLUSIONS

In conclusion, based upon the current NIOSH criteria for formaldehyde; the toxicological effects of formaldehyde as well as the environmental air sampling and medical results obtained by NIOSH, a health hazard from formaldehyde did exist to the employees who work at the dialysis center.

VIII. RECOMMENDATIONS

In view of NIOSH's overall results, as well as personal communications with individuals who work at the center the following recommendations are made to ameliorate potential health hazards and to provide a better work environment for the employees covered by this report.

A. Environmental

1. Local exhaust ventilation should be improved in areas where formaldehyde will be used extensively. A capture velocity of at least 100 fpm is required in order to exhaust the formaldehyde vapors at the source of generation and away from the operators breathing zone. This exhaust system will also require appropriate make-up air for the system to work properly.

2. General room ventilation allowing for a minimum of five air changes per hour should be maintained in the general work areas. This would assist in lowering the formaldehyde levels found in all those areas tested.

3. After the exhaust systems have been remodeled, environmental air monitoring should be repeated to determine the effectiveness of the ventilation systems.

4. Wearing of personal protective clothing should be mandatory when handling formaldehyde and written instructions on the proper clothing and correct use is recommended.

   The protective clothing program should include the following:

   a. Respirators: These are necessary when the exposures to a chemical exceed known standards and/or criteria. However, respirators should not be considered a primary control and should only be used on a temporary basis in lieu of more permanent controls (e.g., engineering controls, substitution, etc.). Respirators can be used in a useful manner for such activities as non routine maintenance or repair activities and emergencies. In the case of formaldehyde, a NIOSH/MSHA approved formaldehyde vapor cartridge with a high efficiency pre-filter is best. However, if respirators are to be used, a complete training program on selection, maintenance and fit testing is required for adequate protection.

   b. Gloves: Each employee who works with formaldehyde should wear protective gloves for the extent of the work process if contact is possible. The ACGIH recommends that a variety of different materials be used when working with aldehydes. This includes butyl rubber (described as excellent), polyurethane, polyethylene, PVC and styrene butadiene rubber (as good to fair), and polyvinyl alcohol and Viton (as only exceptable).

c. Other Clothing: Additional personal protective equipment should include impervious aprons while working in the reuse/sterilization area. The material described above should also be considered when selecting appropriate aprons.

B. Medical

1. Avoid all skin and eye contact with formaldehyde. If eye contact occurs irrigate promptly with water and report to a physician. If skin contact occurs thorough washing is indicated.

2. Pre-placement and medical examinations for employees who will be expected to work with formaldehyde should be instituted. Questions should include concerns on skin sensitization, as well as eye and respiratory irritations. This is especially important for those working in reuse and the packing processes.

3. If adverse effects to workers from past or current exposures to formaldehyde are suspected, these employees should be evaluated medically. If confirmed (e.g., skin sensitization, asthma like symptoms, or other related health problems) the employee should not be required to work with the solution or they should be adequately protected from future exposures.

C. Other

1. Work practices in each of those areas where formaldehyde is used should be reviewed periodically in order to prevent over-exposures.

2. All containers and drains that receive formaldehyde solution should be adequately covered to reduce vapors from reaching the workers breathing zone.

3. The training and education of employees regarding safe work practices is essential to reducing and/or eliminating chemical exposures. Each employee should be instructed on the potential hazards associated with formaldehyde, proper use of personal protective clothing, work practices, and sanitation procedures. This would include signs and symptoms associated with formaldehyde as well as the avoidance of eating, drinking, or smoking while this chemical is being used.

4. Special emphasis should be placed on instructing new employees with annual reviews for all concerned employees.

5. Air monitoring should be performed periodically in each location where formaldehyde is used. This is especially important if there is any modification in the operation, that is, location or process changes and/or an increase in the use of formaldehyde. Good record keeping will allow easy identification of process change and employee exposures.

IX. REFERENCES

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NIOSH is thankful to the employees at Pikes Peak Dialysis Center for their cooperation and assistance with this Health Hazard Evaluation. The information gathered from this study will not only assist in maintaining the health and safety of those persons working here, but also other facilities that perform similar operations.

XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH, Publications Office, at the Cincinnati address.

Copies of this report have been sent to:

1. Pikes Peak Dialysis Center
2. U.S. Department of Labor/OSHA - Region VIII.
3. NIOSH - Region VIII.
4. Colorado Department of Health.
5. State Designated Agency.

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

TABLE 1

Breathing Zone and General Room Air
Formaldehyde Concentrations

Pikes Peak Dialysis Center
Colorado, Colorado

February, 1984

Job/Sample Description	Sampling Time (minutes)	mg/M^3 Formaldehyde
Formalin Mixing		
Personal sample	30	0.79
Reuse/Sterilization		
Personal sample	120	1.0
Personal sample	120	0.75
Area sample	120	0.42
Area sample	120	0.75
Dialysis Unit Packing		
Personal sample	20	0.32
Personal sample	20	0.90
Personal sample	20	0.42
Nurses/Technicians		
Personal sample	360	0.32
Personal sample	360	0.37
Personal sample	360	0.28
Personal sample	360	0.35
Dialysis Console Area		
Number 3	360	0.47
Number 4	360	0.50
Number 5	360	0.33
Other Areas		
Directors Office	360	ND
Reception/Clerical Office	360	ND
Nurses Desk	360	ND

EVALUATION CRITERIA — LFL**

LABORATORY LIMIT OF DETECTION mg/sample
0.002

ND = below laboratory limit of detection
mg/M^3 = milligrams per cubic meter of air per volume

** = Former NIOSH recommended level for any 30 minute sampling period. This level was based on formaldehyde's irritant effect (1976 NIOSH Criteria for Recommended Standard). Subsequently, it has been shown to cause cancer in animals. Exposures should be controlled at Lowest Feasible Level (LFL).

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