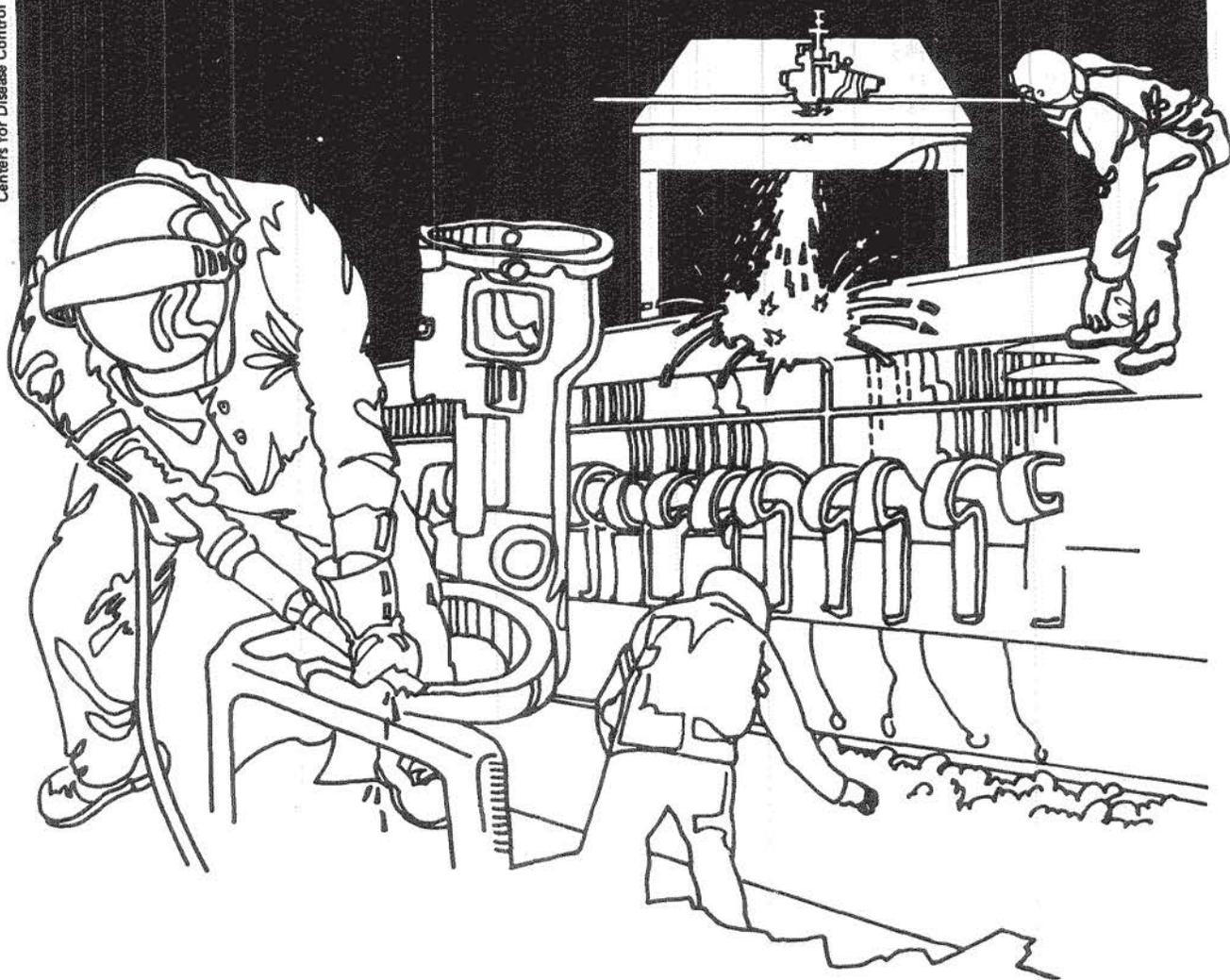


NIOSH



Health Hazard Evaluation Report

HETA 82-205-1314
NORTH CENTRAL
DIALYSIS CENTERS
CHICAGO, ILLINOIS

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.

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

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MAY 1983
NORTH CENTRAL DIALYSIS CENTERS
CHICAGO, ILLINOIS

NIOSH INVESTIGATOR
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I. SUMMARY

On April 12, 1982, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate occupational exposures at North Central Dialysis Centers, Chicago, Illinois. The requestor was concerned with exposure to formaldehyde during the cleaning and disinfecting of artificial kidney units at the company's three facilities.

In May 1982, NIOSH investigators conducted an initial survey followed by environmental surveys in June 1982. During these surveys, personal breathing zone and area air samples were collected for measurement of exposures to formaldehyde. After modifications to equipment and work practice changes were instituted, a follow-up environmental survey was conducted in December 1982, during which additional air samples for formaldehyde were collected.

Personal breathing zone air samples collected during the initial environmental surveys, showed that re-use technicians at two of the three facilities were exposed to time weighted average (TWA) concentrations of formaldehyde of 0.50 and 0.57 parts of contaminant per million parts of air (ppm). Recent evidence indicates that formaldehyde is a potential human carcinogen and NIOSH recommends that formaldehyde exposures be controlled to the lowest feasible level. The current Occupational Safety and Health Administration (OSHA) standard for occupational exposure to formaldehyde is 3 ppm. Personal breathing zone samples collected during the follow-up environmental surveys, showed that TWA concentrations of formaldehyde were below the limit of detection at all three facilities.

On the basis of the information obtained in this investigation, NIOSH has determined that a potential health hazard existed at North Central Dialysis Centers from occupational exposures to formaldehyde. However, these exposures were substantially reduced during the course of the evaluation. Based on evidence indicating that formaldehyde is a potential human carcinogen, further steps should be taken to ensure that exposures are maintained at the lowest feasible levels. Recommendations related to this evaluation are included in the full body of the report.

KEY WORDS: SIC 8081, Formaldehyde, Dialysis

II. INTRODUCTION

On April 12, 1982, a representative of the North Central Dialysis Centers requested a NIOSH health hazard evaluation. The requestor was concerned with employee exposure to formaldehyde during the cleaning and disinfecting of artificial kidney units used in hemodialysis treatments at the company's three facilities.

On May 11, 1982, NIOSH investigators conducted an initial survey during which background information on the process was obtained. Environmental surveys were conducted at the three facilities in June 1982, during which personal breathing zone and area air samples were collected to assess employee exposures to formaldehyde. In September 1982, an interim report was sent to the requestor which included the results of the environmental surveys and preliminary recommendations for reducing employee exposures. In December 1982, a follow-up environmental survey was conducted during which additional personal and area air samples for formaldehyde were collected to assess any changes in exposures.

III. BACKGROUND

North Central Dialysis Centers operate three facilities in the Chicago metropolitan area where patients undergo hemodialysis treatments. Following each treatment, the artificial kidney units require cleaning and disinfecting with a 3% formaldehyde solution. The following is a description of how the process occurs at each facility.

Facility 1, located at 55 East Washington Street, Chicago, Illinois, is the largest of the three facilities. At the time of the initial environmental survey, a machine (Lixivitron, United Medical Products) was utilized for automatic cleaning and disinfecting of the units. Use of the machine was discontinued prior to the follow-up environmental survey. A manual procedure was then utilized in which cleaning and disinfecting were carried out over a large shallow sink by a re-use technician. Following cleaning and volumetric testing, a vacuum aspirator connected to the sink faucet was used to draw a 3% formaldehyde solution into the kidney unit. The unit was then capped and placed on a cart for storage. A maintenance technician also spent time in the area. This employee was responsible for routine repairs of the dialysis units. Following each repair, a 3% formaldehyde solution was passed through the machine's network of tubing.

Facility 2, located at 2277 West Howard Street, Chicago, Illinois, has a smaller patient load and one employee serves as both the re-use and maintenance technician. Cleaning and disinfecting of the artificial kidneys at this facility were also carried out manually over a large shallow sink. At the time of the initial environmental survey, the fluid from the aspirator was channeled directly into the drain using a long section of tubing. During the follow-up environmental survey, the tube had been removed and the fluid from the aspirator flowed into the sink before reaching the drain.

Facility 3, located at 9730 South Western Avenue, Evergreen Park, Illinois had the smallest patient load. The cleaning and disinfecting process was conducted in a manner similar to the other facilities except that a shorter and deeper sink was utilized for cleaning.

Employees at all three facilities are required to wear rubber gloves and protective eyeglasses during the procedure. Respirators (designed for protection against dust, fumes, and mist) were made available but were not routinely used at the facilities. Local exhaust ventilation was not present in any of the three facilities; however, a window fan was present next to the operation at Facility 1.

IV. MATERIALS AND METHODS

The initial environmental survey was conducted at Facility 1 on May 25 and June 4, at Facility 2 on June 1, and Facility 3 on June 2, 1982. During these surveys, personal and area air samples were collected for measurement of employee exposures to formaldehyde. Samples were taken near the breathing zones of the employees and at other locations in the work area using battery-powered sampling pumps operating at approximately 50 cubic centimeters of air per minute (cc/min) attached via Tygon® tubing to solid sorbent tubes (Supelco Inc., XAD-2 Resin Formaldehyde Tubes). The samples were analyzed using gas chromatography in accordance with NIOSH Method No. P&CAM 354 (modified).¹ The duration, location, and other information pertinent to sample collection is presented in Table 1.

In order to determine if exposures had been effectively reduced by equipment changes and adherence to work practice recommendations provided in the interim report, follow-up environmental surveys were conducted on December 20, 22, and 23, 1982, at Facilities 1, 3, and 2, respectively. During these surveys, personal breathing zone and area air samples were collected and analyzed in the manner utilized in the previous surveys. Information pertinent to sample collection is presented in Table 2.

V. EVALUATION CRITERIA

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.

Formaldehyde is a colorless, flammable gas with a strong, pungent odor. It can form explosive mixtures with air and oxygen. Concentrations of 0.1 to 5 parts of formaldehyde per million parts of air (ppm) can cause eye, nose, and throat irritation. Higher exposures may produce coughing, tightening in the chest, decreased lung capacity, a sense of pressure in the head, and/or palpitation of the heart. Exposures at 50 to 100 ppm and above can cause serious injury, such as pulmonary edema (collection of fluid in the lungs) or pneumonitis (inflammation of the lungs). Formaldehyde has been shown to induce a rare form of nasal cancer in laboratory animals and to have mutagenic activity in several test systems. Although humans and animals may differ in their susceptibility to specific chemical compounds, any substance that produces cancer in experimental animals should be considered a cancer risk to man.²

The current Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for formaldehyde is 3.0 ppm as an eight-hour time weighted average (TWA). The NIOSH recommended standard

for occupational exposure to formaldehyde was 1.0 ppm based on any 30 minute sampling period. This recommendation was designed to prevent irritation effects. However, NIOSH recommended in a Current Intelligence Bulletin issued in April 1981, that formaldehyde be handled as a potential carcinogen. Safe levels of exposure to carcinogens have not been demonstrated, but the probability of developing cancer should be reduced by decreasing exposure. Therefore, it is recommended that as a prudent public health measure, engineering controls and stringent work practices be employed to reduce occupational exposure to the lowest feasible limit.²

VI. RESULTS

Complete results of the environmental samples are provided in Tables 1 and 2. Results of the samples collected during the initial environmental surveys indicated that detectable levels of formaldehyde were present during the cleaning and disinfecting process at Facilities 1 and 2. The concentration of formaldehyde in personal breathing zone air samples was 0.50 and 0.57 ppm for the re-use technicians, and 0.60 and 0.53 ppm in area air samples collected at the work areas, in Facilities 1 and 2, respectively. All personal and area samples collected at Facility 3 were below the level of analytical detection of 6 micrograms per sample (approximately 0.41 ppm based on a 12 liter air sample).

The results of the samples collected during the follow-up environmental surveys indicated a detectable level of formaldehyde in only one area sample collected in Facility 2; 0.84 ppm in a sample collected directly above the work area. All other personal breathing zone and area air samples were below the limit of detection of 5 micrograms per sample (approximately 0.34 ppm based on a 12 liter air sample).

During the initial environmental surveys, samples were collected for a duration longer than that required to actually perform the cleaning and disinfecting operations. Thus, short term exposures for the actual time of the operation would be expected to be greater, while 8-hour TWA's would be lower than the measured concentrations indicate. During the follow-up environmental surveys, the duration of sample collection was limited to the duration of the process.

VII. DISCUSSION

The results of the personal breathing zone samples indicate that employee exposures to airborne concentrations of formaldehyde were substantially reduced during the time between the initial and follow-up environmental surveys. Reasons for this reduction are most likely a result of more careful work practices (e.g. covering of fitting containers) and changes in equipment (e.g. elimination of automated process at Facility 1). However, although concentrations in all personal samples collected during the follow-up surveys were below the limit of analytical detection of 0.5 ug/sample, employees may have been

exposed to lower level concentrations of formaldehyde which may have been detectable by more sensitive sampling and analytical methods (e.g. P&CAM 125).³ Therefore, it would be prudent for the company to continue in its efforts to reduce all potential sources of formaldehyde exposure as much as possible. Three major areas where this effort should be directed are discussed below.

The open containers of the 3% formaldehyde solution used to hold the fittings for the dialysis units present a significant, but easily controlled, source of exposure. Since these containers are present in the work area at all times, they constantly provide a source for formaldehyde to evaporate into the workroom air. In order to reduce this source of exposure, the containers should be covered at all times except when in immediate use.

Another potential source of formaldehyde exposure occurs during the process of filling the dialysis units with the formaldehyde solution. Since the formaldehyde is drawn into the units by a vacuum aspirator, direct contact with the solution is minimized. However, careful work practices are still necessary in order to prevent overfilling of the dialysis units, which in-turn results in the excess formaldehyde entering the aspirator, mixing with water, and flowing into the sink. Despite the care taken to avoid excessive overfilling, some of the formaldehyde solution would be expected to enter the aspirator; therefore, the practice of maintaining a constant flow of water in the sink to further dilute and quickly wash any excess formaldehyde into the drain should be continued.

One additional area of formaldehyde exposure not reflected in the environmental sampling data is the procedure used for the preparation of the 3% formaldehyde solution. At Facility 1, automatic metering devices were used to prepare this solution. This greatly minimized any chance of exposure to the employees in the area. At Facilities 2 and 3, preparation of the solution was done manually by volumetric measurement. Although the time required for the mixing was relatively short, due to the higher concentration of the stock solution (37% formaldehyde) which is used in the dilution, there does exist a potential for a significant short-term exposure which should not be overlooked.

VIII. RECOMMENDATIONS

The following recommendations are made in order to further reduce potential employee exposures to formaldehyde:

1. Employees should be informed of the potential health effects from exposure to formaldehyde.
2. Employees should be initially trained, and thereafter periodically instructed, to ensure that proper work practices are used in order to reduce formaldehyde exposure to the lowest level possible.

3. In the rooms where formaldehyde is being used, ventilation should be maintained to provide at least 5 changes of air per hour .
4. When working with and mixing solutions of formaldehyde, employees should wear protective equipment, including rubber gloves, protective aprons, and eye protection.
5. Containers used to store the fittings for the artificial kidney units should be covered at all times. The containers used for this purpose should be of a design which will allow relative ease in opening and closing, while still maintaining an effective seal.
6. Automatic metering equipment should be used, when possible, for preparation of the 3% formaldehyde solutions. At the facilities where this equipment is not present, mixing should be conducted in a well ventilated area. As a further protective measure, appropriate respiratory protection should be utilized. The respirators currently in use, which are not effective in reducing formaldehyde exposures, should be replaced with NIOSH/MSHA approved respirators with chemical cartridges specifically approved for formaldehyde. The availability of these respirators would also provide the employees with a means of protection in the event that cleanup of a minor spill of formaldehyde becomes necessary.

IX. REFERENCES

1. NIOSH Manual of Analytical Methods, Volume 7, National Institute for Occupational Safety and Health, DHEW(NIOSH) Publication No. 82-100, August 1981.
2. NIOSH/OSHA Current Intelligence Bulletin 34, National Institute for Occupational Safety and Health/Occupational Safety and Health Administration, DHHS(NIOSH) Publication No. 81-111, December 23, 1980.
3. NIOSH Manual of Analytical Methods, Volume 1, National Institute for Occupational Safety and Health, DHEW(NIOSH) Publication No. 77-157, Second Edition, April 1977.

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XI. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination 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 Services (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 the following:

1. North Central Dialysis Centers
2. U.S. Department of Labor, OSHA - Region V
3. NIOSH Regional Offices/Divisions

For the purposes of informing the affected employees, copies of the report should be posted in a prominent place accessible to the employees, for a period of 30 calendar days.

TABLE 1
Results of Initial Environmental Surveys for Formaldehyde
at North Central Dialysis Centers
 Chicago, Illinois

Facility Number	Sample Date	Sample Type	Job Title/ Location	Sample Duration (minutes)	Formaldehyde Concentration (ppm)
1	6/4/82	Personal	Re-Use Tech.	213	0.50
1	6/4/82	Area	Above Machine	213	0.60
1	6/4/82	Personal	Maintenance Tech.	218	N.D.
2	6/1/82	Personal	Re-Use Tech.	217	0.57
2	6/1/82	Area	Above Work Area	245	0.53
2	6/1/82	Area	Above Desk	240	0.57
2	6/1/82	Personal	Re-Use Tech.	136	N.D.
3	6/2/82	Personal	Re-Use Tech.	98	N.D.
3	6/2/82	Area	Above Work Area	96	N.D.

N.D.- Below the level of analytical detection of 6.0 micrograms per sample.

TABLE 2
Results of Followup Environmental Surveys for Formaldehyde
at North Central Dialysis Centers
 Chicago, Illinois

Facility Number	Sample Date	Sample Type	Job Title/ Location	Sample Duration (minutes)	Formaldehyde Concentration (ppm)
1	12/20/82	Personal	Re-Use Tech.	155	N.D.
1	12/20/82	Area	Above Work Area	219	N.D.
1	12/20/82	Personal	Maintenance Tech.	223	N.D.
1	12/20/82	Areaonal	Center of Room	212	N.D.
3	12/22/82	Personal	Re-Use Tech.	105	N.D.
3	12/22/82	Area	Above Work Area	103	N.D.
3	12/22/82	Area	Center of Room	93	N.D.
2	12/23/82	Personal	Re-Use Tech.	121	0.84
2	12/23/82	Area	Above Work Area	120	N.D.
2	12/23/82	Area	Center of Room	118	N.D.

N.D.- Below the level of analytical detection of 5.0 micrograms per sample.

Results of the environmental samples collected during the environmental survey of May 25, 1982, are not included due to a high blank value (7ug) for this sample set.

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