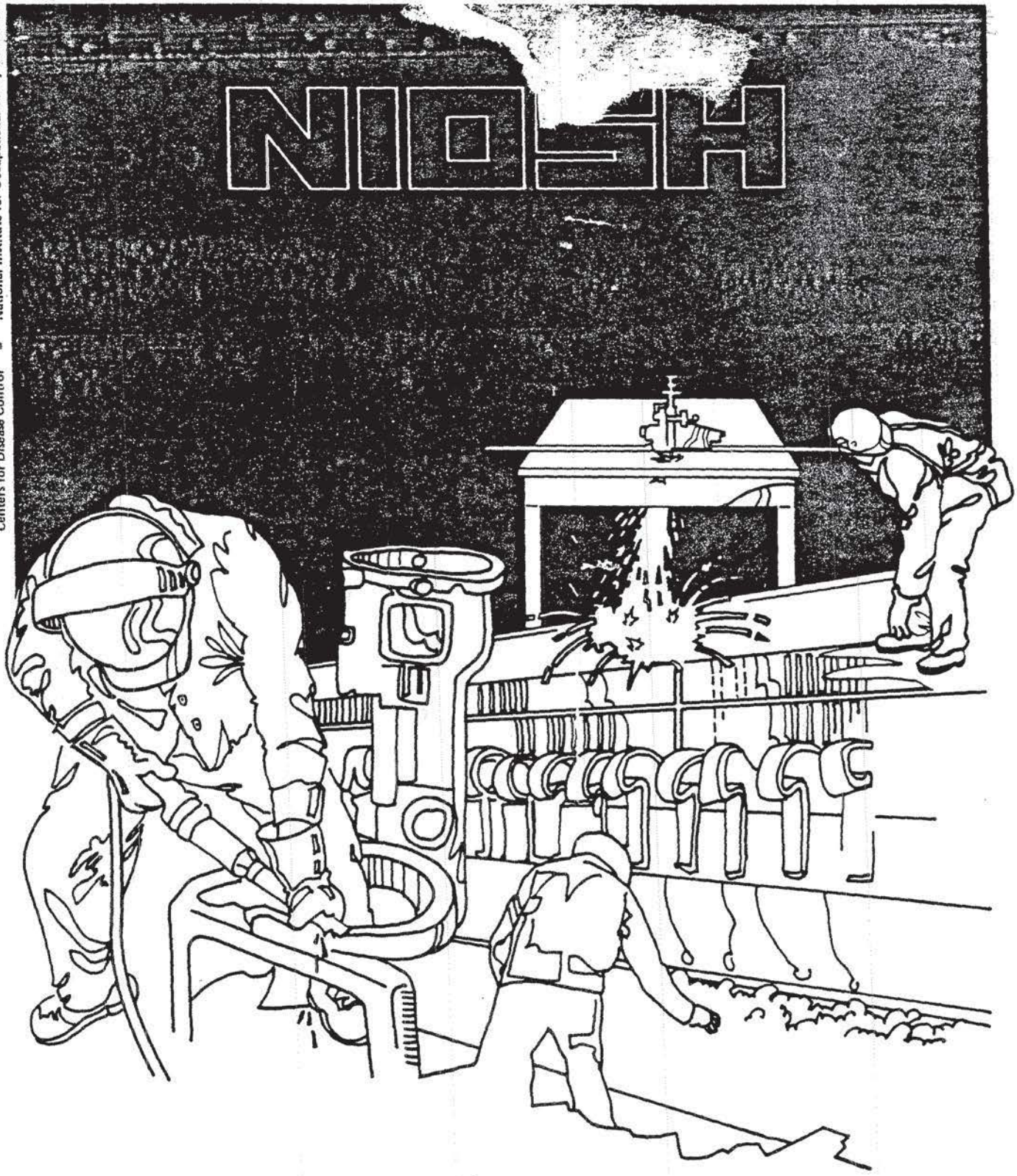
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

HETA 82-084-1147
AMERICAN MEDICAL SUPPLY D.B.A.
COMMUNITY DIALYSIS SERVICES OF DENVER
DENVER, 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.

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JULY 1982
AMERICAN MEDICAL SUPPLY D.B.A.
COMMUNITY DIALYSIS SERVICES OF DENVER
DENVER, COLORADO

NIOSH INVESTIGATOR:
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I. SUMMARY

In December 1981, the National Institute for Occupational Safety and Health (NIOSH) received a request from management at American Medical Supply D.B.A. Community Dialysis Services of Denver, Colorado, to evaluate a potential health hazard from exposures to formaldehyde during the sterilization of dialysis units and the reverse osmosis water treatment system.

On March 13-14, 1982, a NIOSH investigator conducted an environmental evaluation. Two breathing zone and eight general room air samples were collected in the dialysis clinic for formaldehyde analysis. The sampling times ranged from 20 minutes to 3 hours, 25 minutes, which was the time required for complete sterilization of the equipment and total time in which the worker was exposed. Formaldehyde concentrations ranged from nondetectable to 1.9 mg/M^3. Two of ten (20%) formaldehyde air samples (1.2 and 1.9 mg/M^3) met or exceeded the former NIOSH recommended criteria of 1.2 mg/M^3 for any 30 minute sampling period (based on the irritant properties of formaldehyde). These two samples were collected in the water sterilization room during the time formaldehyde was being flushed through the system. More recent evidence indicates that formaldehyde is a potential human carcinogen and NIOSH recommends that formaldehyde exposures be controlled to the lowest feasible level.

On the basis of environmental data, employee interviews, and personal observations, NIOSH concluded that a health hazard to formaldehyde existed at the time of this survey. Recommendations on preventing and correcting the formaldehyde hazard are included in this report.

KEYWORDS: SIC 8091 (Health and Allied Services, Not Elsewhere Classified), formaldehyde, dialysis units.

II. INTRODUCTION

In December 1981, the National Institute for Occupational Safety and Health (NIOSH) received a request from management at American Medical Supply D.B.A. Community Dialysis Services of Denver, Colorado, to evaluate a potential health hazard from formaldehyde during the sterilization of dialysis units and the reverse osmosis water treatment system.

On March 13-14, 1982, NIOSH conducted an environmental evaluation. Results of the environmental sampling were discussed with the requestor in April 1982.

III. BACKGROUND

The American Medical Supply D.B.A. Community Dialysis Services of Denver has 12 dialysis chairs for individual patient dialysis. Patients report to this clinic every other day for complete dialysis.

Approximately once a week these individual units, as well as the water treatment system, must be cleaned and sterilized. Formaldehyde is used to sterilize the reverse osmosis water treatment system. Purified water is used to prepare the dialysate. Formaldehyde is also used to sterilize the 12 individual patient dialysis units.

IV. ENVIRONMENTAL EVALUATION DESIGN AND METHODS

Two breathing zone and eight general room air samples were collected for formaldehyde on sorbent tubes containing Chromosorb 102 coated with N-benzylethanolamine using vacuum pumps operating at 50 cubic centimeters per minute and analyzed according to NIOSH P&CAM Method No. 354.

V. EVALUATION CRITERIA

A. Environmental

Three sources of criteria used to assess the workroom concentrations of the chemicals were (1) recommended Threshold Limit Values (TLVs) and their supporting documentation as set forth by the American Conference of Governmental Industrial Hygienists (ACGIH), 1981, (2) the NIOSH criteria for a recommended standards, and (3) the Occupational Safety and Health Administration (OSHA) standards (29 CFR 1910.1000), July 1980.

	Permissible Exposure Limits 8-Hour Time-Weighted Exposure Basis
Formaldehyde.....	* (NIOSH) (ACGIH) 4.5 mg/M^3 (OSHA)

mg/M^3 = milligrams of substance per cubic meter of air.
* = suspect carcinogen--no safe exposure level given.

Occupational health standards are established at levels designed to protect individuals occupationally exposed to toxic substances on an 8-hour per day, 40-hour per week basis over a normal working lifetime.

B. Toxicological

Formaldehyde[1] -- 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 cancers. 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 4.5 mg/M^3 was established based on the irritant effects of formaldehyde and not on the carcinogenic potential.

VI. ENVIRONMENTAL RESULTS

Two breathing zone and eight general room air samples were collected in the dialysis clinic for formaldehyde analysis. The sampling times ranged from 20 minutes to 3 hours, 25 minutes, which was the time required for complete sterilization of the equipment and total time in which the worker was exposed. Values for the formaldehyde samples ranged from nondetectable to 1.9 mg/M^3. (Refer to Table 1.) Two of ten (20%) formaldehyde air samples (1.2 and 1.9 mg/M^3) met or exceeded the former NIOSH recommended criteria of 1.2 mg/M^3 for any 30 minute sampling period (based on the irritant properties of formaldehyde). These two samples were collected in the water sterilization

room during the time formaldehyde was being flushed through the system. More recent evidence indicates that formaldehyde is a potential human carcinogen and NIOSH recommends that formaldehyde exposures be controlled to the lowest feasible level.

The worker performing the sterilization did have eye and nose irritation due to formaldehyde exposure.

VII. DISCUSSIONS AND CONCLUSIONS

Based on the environmental sampling, employee interviews, and personal observations, a hazardous situation existed during this evaluation to all workers being exposed to formaldehyde at the clinic. Acute formaldehyde exposures in excess of 1.2 mg/M^3 are sufficient to cause discomfort in any worker and pose a health hazard from the irritant properties, as well as the suspected carcinogenic potential, of formaldehyde.

VIII. RECOMMENDATIONS

1. Workers should be informed of the potential health effects from exposure to formaldehyde.

2. Ventilation should be installed that would prevent exposure to formaldehyde. A minimum of five air changes per hour in the work area would probably lower concentrations to an acceptable level.

3. When sterilizing the water system workers should not remain in the room.

IX. REFERENCES

1. Current Intelligence Bulletin 34: Formaldehyde: Evidence of Carcinogenicity. NIOSH Publication No. 81-111, April 15, 1981.

X. AUTHORSHIP AND ACKNOWLEDGMENTS

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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. American Medical Supply, D.B.A. Community Dialysis Services of Denver.
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 (BZ) and General Room Air Concentrations of Formaldehyde

American Medical Supply D.B.A.
Community Dialysis Services
Denver, Colorado

March 13-14, 1982

Sample Number	Location	Sampling Time	mg/M^3 Formaldehyde
1	Nurse's BZ	1:25 PM - 1:45 PM	*
2	General Room	1:25 PM - 1:45 PM	*
3	General Room	1:15 PM - 1:45 PM	1.2
4	General Room	1:15 PM - 1:45 PM	1.9
5	General Room	1:25 PM - 1:45 PM	*
6	Nurse's BZ	8:05 AM - 11:30 AM	*
7	General Room	8:30 AM - 11:30 AM	0.1
8	General Room	8:30 AM - 11:30 AM	*
9	General Room	8:30 AM - 11:30 AM	*
10	General Room	8:30 AM - 11:30 AM	0.3
EVALUATION CRITERIA			1.2**
LABORATORY LIMIT OF DETECTION mg/sample			0.00075

* = below laboratory limit of detection

** = 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.