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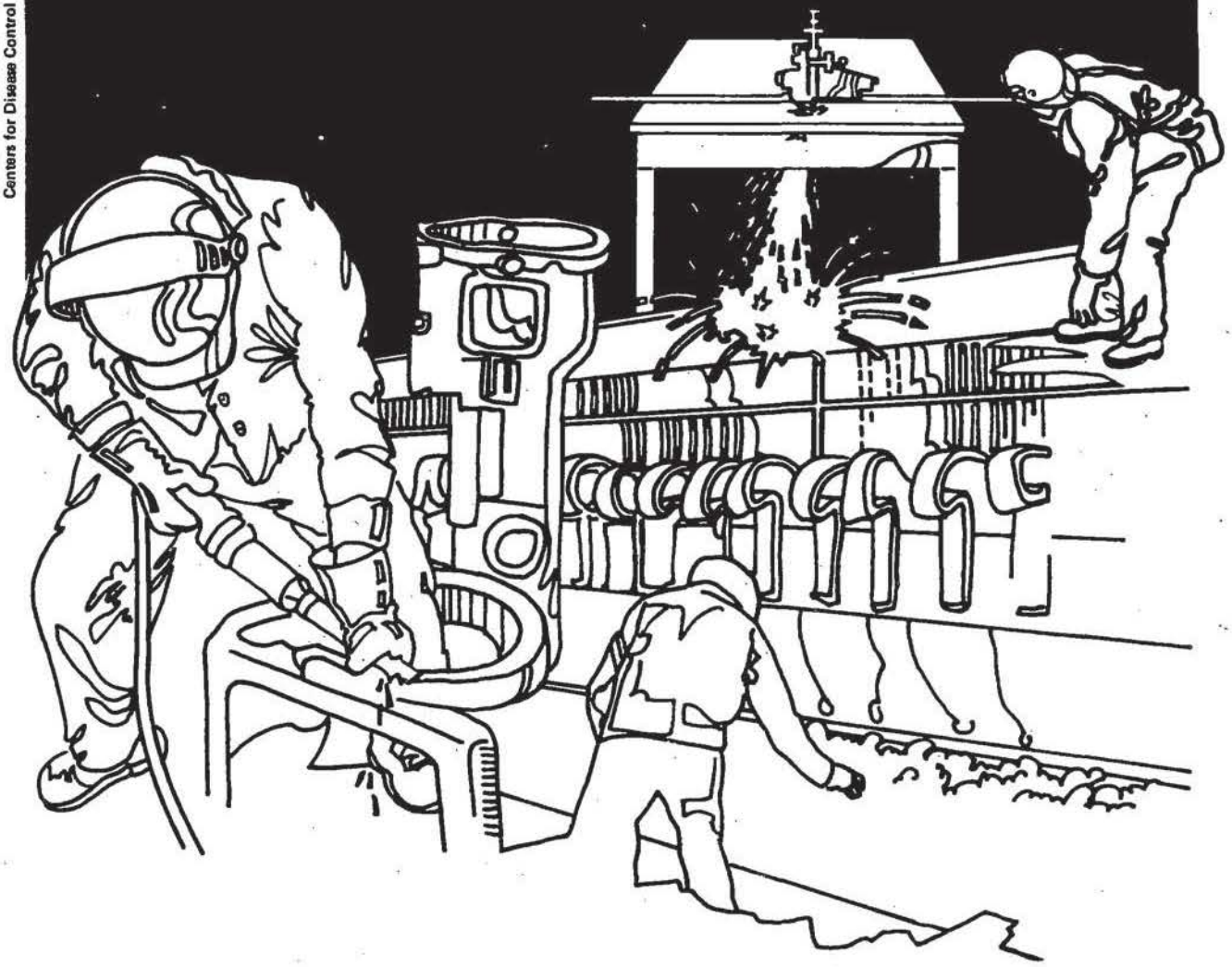

Health Hazard Evaluation Report

HETA 83-048-1347
NATIONAL JEWISH HOSPITAL
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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NATIONAL JEWISH HOSPITAL
DENVER, COLORADO

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I. SUMMARY

In December 1982, the National Institute for Occupational Safety and Health (NIOSH) was requested to evaluate exposures of research scientists to formaldehyde used during small animal research projects at National Jewish Hospital, Denver, Colorado.

In December 1982 and January 1983, a NIOSH investigator conducted an industrial hygiene survey to determine workers exposures to formaldehyde vapors generated during research studies.

A total of eleven air samples were taken, four personal and seven general area samples. The sampling times ranged from 90 to 240 minutes. The formaldehyde concentrations ranged from 0.18 mg/M^3 to 1.45 mg/M^3. One sample exceeded the former NIOSH exposure criteria of 1.2 mg/M^3. This recommended level was based on formaldehyde's irritant properties and not on its carcinogenic potential. The carcinogenic potential of formaldehyde is outlined in the NIOSH Current Intelligence Bulletin No. 34. NIOSH now recommends that formaldehyde be controlled at the Lowest Feasible Limit (LFL).

The results of the interviews with the exposed workers strongly suggest that formaldehyde exposures exist during the normal work day, i.e., burning eyes; nose, throat and lung irritation; as well as cough and chest tightness.

It was also determined that the exhaust ventilation systems in the laboratory were ineffective in their ability to adequately reduce the contaminant.

On the basis of the environmental sampling results and the medical questionnaire data, NIOSH concluded that a health hazard existed from formaldehyde exposures to the research personnel during the survey periods. Recommendations on preventing and/or eliminating the formaldehyde exposures are included in this report.

KEYWORDS: SIC 8221 (Colleges, Universities, and Professional Schools), formaldehyde, animal pulmonary research, lung fixation, formalin, bronchoalveolar lavage and histologic-morphometric analysis.

II. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a request in December 1982 from a representative of National Jewish Hospital, Denver, Colorado. The request was to determine if there was a health hazard to research scientists from formaldehyde vapors which are being generated during various phases of small animal research. Formaldehyde was the primary concern to the requestor; however, after the first NIOSH site visit it was determined that in one phase of the research (tissue slicing) the local exhaust ventilation system was inadequate.

The results of each evaluation were presented to the requestor and the employees when they became available. A letter with a complete copy of the results was also presented to all the concerned parties in March 1983.

III. BACKGROUND

National Jewish Hospital in Denver, Colorado, is a research hospital having a number of ongoing research projects which includes The Pulmonary Animal Research and Physiology Laboratory. Formaldehyde (formalin) is used extensively during these research studies and the main thrust of the animal research lab is small animal projects. The major area of research performed here concerns inflammation and airway disease of the lungs, and small animals are used during this research project.

The lab is approximately 900 square feet and is located in the basement of the hospital with multiple ancillary space in adjoining areas. A 30 liter formalin tank was present in the back corner of the room for lung fixation and was contained in a wooden enclosure. The tank itself is made of Plexiglass® and has a fluid tower to generate a set fixation pressure. This enclosure was not vented.

Normal activities of the lab include: (1) measurement of pulmonary function, (2) bronchoalveolar lavage, and (3) removal of lungs for fixation and histologic-morphometric analysis. The daily activities in the lab normal include two lungs being placed into the formalin tank. At an interval of one to two weeks, these lungs are removed, carried through the room in open containers and placed under a small metallic enclosure. Here the lungs are sectioned, placed into cassettes, and dropped into jars containing 10% buffered formalin. These cassettes, are subsequently removed, opened, and photographed in the open room. They are then transported in closed jars to a histology lab which is located in another building.

Maintenance is performed on the fixing tank by one to two people approximately once per month. This requires the tank to be drained by placing tubing from a sump pump in the tank to a nearby sink for draining. The tank is then flushed with tap water repeatedly and residual material manually removed. Finally, the tank is refilled from a 10 liter container of fresh formalin solution and this phase of the process takes only a few minutes to perform. Normally, all the tasks involving the tank are accomplished as rapidly as possible in order to minimize vapors released from the enclosure when the tank is open.

The lab has three different types of protective gloves available (latex, rubber, and polyvinyl types). Lab coats are also worn during the majority of activities performed in the lab and the only respiratory protection are surgical-type masks.

During the NIOSH survey periods, the only exhaust ventilation system used in the lab was a box-type compartment used for tissue slicing with an exhaust fan positioned behind an opening in the rear of the compartment.

IV. ENVIRONMENTAL DESIGN AND METHODS

A. ENVIRONMENTAL

Environmental samples were taken in each of the areas of concern.

A total of four (4) personal and seven (7) general area type samples were collected for formaldehyde using the impinger technique. The sampling pumps drew air through the impinger solution at one lpm. NIOSH Method No. P&CAM 125 was followed in the preparation of the impinger samples and analyzed using a Perkin-Elmer, Coleman spectrophotometer.

B. Medical

Each of the employees affected was interviewed and a medical questionaire was completed on each employee.

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.

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

mg/M^3 = milligrams of substance per cubic meter of air.
*LFL = suspect human carcinogen--exposures should be reduced to the Lowest Feasible Limit.

B. Toxicological

Formaldehyde has a sharp odor which can be smelled at very low levels (less than 1 ppm). The first signs or symptoms noticed on exposure to formaldehyde at concentrations ranging from 0.12 to 6.0 mg/M^3 are burning of the eyes, tearing (lacrimation), and general irritation to the upper respiratory passages. Low levels of 0.36 to 3.3 mg/M^3 have been found to disturb sleep and to be irritating to a smaller number of people.[1] Higher exposures (12.3 to 24.5 mg/M^3) may produce coughing, tightness in the chest, a sense of pressure in the head, and palpitation of the heart.[2--4] Exposures of 61.3 to 122.6 mg/M^3 and above can cause serious injury such as collection of fluid in the lungs (pulmonary edema), inflammation of the lungs (pneumonitis), or death.[5]

Dermatitis due to formaldehyde solutions or formaldehyde-containing resins is a well-recognized problem.[6] After a few days of exposure, a worker may develop a sudden inflammatory (eczematous) reaction of the skin of the eyelids, face, neck, scrotum, and flexor surfaces of the arms. An eczematous reaction also may appear on the fingers, back of the hands, wrists, forearms, and parts of the body that are exposed to the rubbing of clothing. Such rashes sometimes develop after years of asymptomatic exposure.

Formaldehyde has been shown in a study conducted by the Chemical Industry Institute of Toxicology[7] to induce squamous cell cancer of the nasal sinuses in both Fischer 344 rats and B6C3F1 mice. In a study by New York University, formaldehyde appears to have induced the same type of cancer in Sprague-Dawley rats.[8] Although humans and animals may differ in their susceptibility to specific chemical compounds, any substance that produces cancer in experimental animals, particularly in more than one species, should be considered a cancer risk to humans. Formaldehyde also has demonstrated mutagenic activity in several test systems.[9]

Based on these results, NIOSH recommends that formaldehyde be handled in the workplace as a potential occupational carcinogen.[1] Safe levels of exposure to carcinogens have not been demonstrated, but the probability of developing cancer should be reduced by decreasing exposure. An estimate of the extent of the cancer risk to workers exposed to various levels of formaldehyde at or below the current 3 ppm Occupational Safety and Health Administration (OSHA) standard[10] has not yet been determined. In the interim, NIOSH recommends that, as a prudent public health measure, engineering controls and stringent work practices be employed to reduce occupational exposure to the lowest feasible limit. The International Agency for Research on Cancer (IARC) concurs with these recommendations.[11]

VI. RESULTS AND DISCUSSION

Employee exposures to suspected airborne concentrations of formaldehyde were evaluated. The following are the results of NIOSH's evaluation.

A. Environmental

Four personal samples were collected on the employees working in the research lab and an additional seven samples were taken at various locations in the laboratory during the survey periods. The sampling times ranged from 90 to 240 minutes. The values for the formaldehyde samples ranged from 0.3 mg/M^3 to 1.45 mg/M^3. One of the formaldehyde samples exceeded the former NIOSH recommended criterion of 1.2 mg/M^3 (refer to Table 1). The 1.2 mg/M^3 NIOSH recommended level is, however, based on formaldehyde's irritant properties and not on its carcinogenic potential.

B. Ventilation

The one box/exhaust fan arrangement used for tissue slicing was pulling less than 30 feet per minute (fpm) at the source (i.e., at the point where the tissue is being sliced). It should be noted that as of NIOSH's last survey there was plans by the hospital to install a large fume hood in an adjoining room. It was told to the NIOSH investigator that this would be large enough to contain the tank, all materials, and working space for all procedures involving formalin fixed tissue.

C. Medical

Each of the employees were interviewed and requested to fill out a medical questionnaire. The results from the medical questionnaires strongly suggest excessive exposures to formaldehyde during the normal work day. That is, each person described symptoms of eye, nose, and throat irritation; coughing and lung irritation; and chest tightness which would occur at different times during the work day. One person also mentioned a problem of loose stools which occurred only while working for continous periods in the laboratory.

VII. CONCLUSIONS

Based on the environmental sampling and medical questionnaire results it is felt by NIOSH that a potential health hazard did exist to the employees who work in the small animal research laboratory evaluated at National Jewish Hospital. This conclusion is based on the allergenic and carcinogenic potential of formaldehyde.

VIII. RECOMMENDATIONS

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

2. Local exhaust ventilation should be installed, if it has not been already, that would prevent exposure to formaldehyde under each of the exposure conditions described in the background section of this report. Besides local exhaust ventilation a minimum of five air changes per hour should be obtained in the laboratory in order to assist in reducing background exposures.

3. Once the new exhaust ventilation system has been installed an environmental survey should be performed again in order to determine the effectiveness of the new ventilation systems.

4. Employees should continue to wear rubber gloves when working with formaldehyde to prevent skin absorption. This should also help in preventing the potential for formaldehyde dermatitis on hands and forearms.

5. A better system should be devised for cleaning the formaldehyde tank; that is, one that will minimize the operator°s contact to the solution and to the vapors during the maintenance operations. An example which might help reduce this exposure problem might be in the form of an internal wash with a drain which would allow, by way of a closed system, the waste material and solution to go into a container or drum.

IX. REFERENCES

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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. National Jewish Hospital
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 Area Air Concentrations for Formaldehyde

National Jewish Hospital
Denver, Colorado

Job/Area Description	Sampling Time (minutes)	mg/M^3 Formaldehyde
December 1982		
Tissue Slicing-Personal	180	0.46
Cutting Table	240	0.18
Fixing Tank	240	0.40
North Work Table	240	0.34
South Work Table	240	0.3
Tissue Slicing-Personal	180	1.45
January 1983		
Cleaning Fixing Tank-Personal	90	0.82
Cleaning Fixing Tank-Personal	90	0.83
South Work Table	90	0.70
Cutting Table	90	0.34
North Work Table	90	0.28
EVALUATION CRITERIA:		LFL*
LABORATORY LIMIT OF DETECTION: 0.25 ug/sample		

mg/M^3 = milligrams of substance per cubic meter of air
ug/sample = micrograms per sample

* LFL= Exposure should be controlled at the Lowest Feasible Level.

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