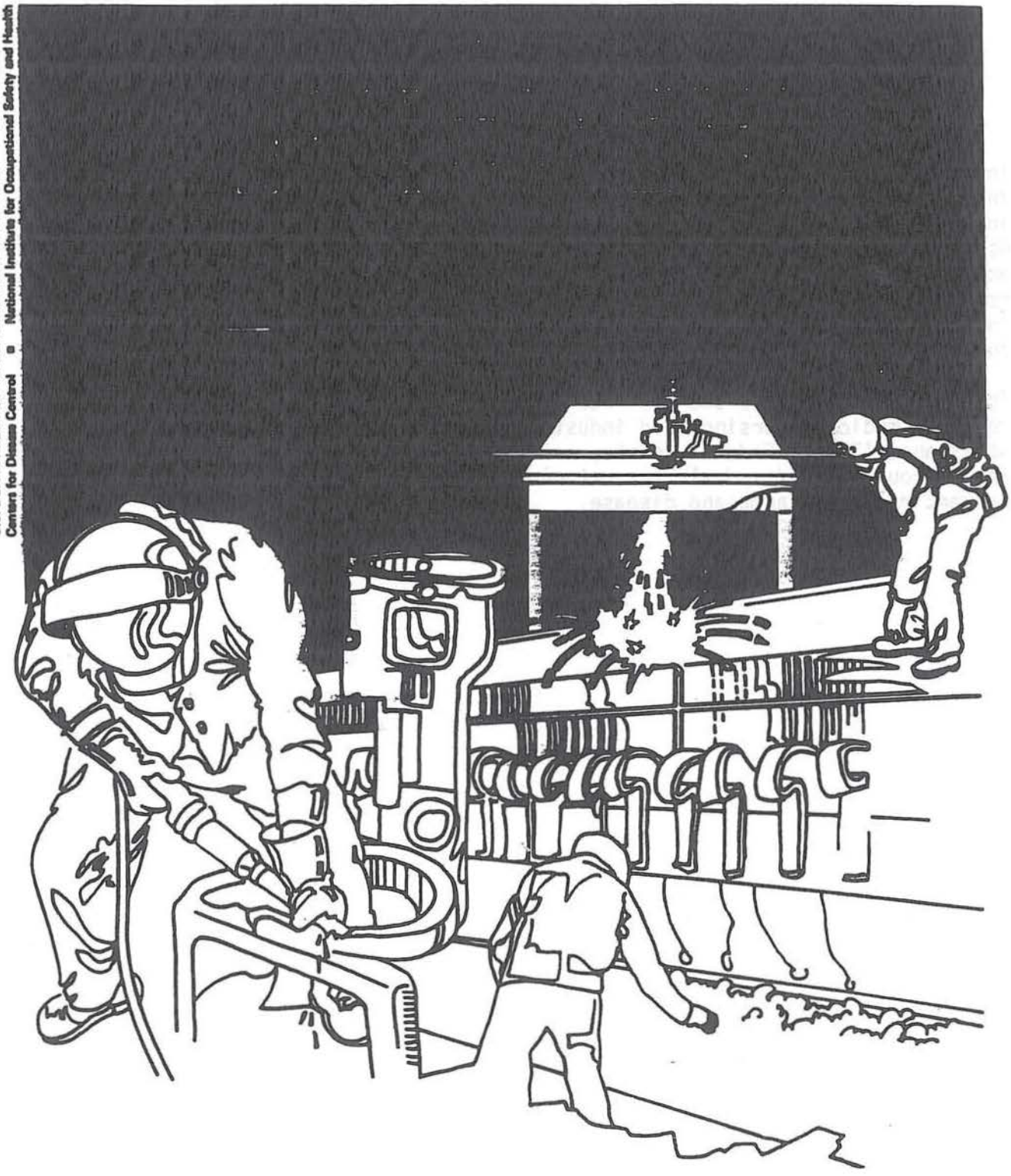
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

HETA 83-076-1414
SAINT JOSEPHS 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.

HETA 83-076-1414
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SAINT JOSEPHS HOSPITAL
DENVER, COLORADO

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I. SUMMARY

In December 1982, the National Institute for Occupational Health (NIOSH) received a request from Saint Josephs Hospital, Denver, Colorado, to evaluate exposures to xylene and formaldehyde. These chemicals are used in various laboratories at the hospital including the Reagent Preparation, Histology, Cytology, and Surgical Pathology Departments.

On March 22-23, 1983, NIOSH conducted an industrial hygiene and medical evaluation which consisted of air monitoring, a review of the exhaust and make-up air ventilation systems and personal interviews with the employees and management. Medical questionnaires were completed by all the employees involved in the study.

Twelve personal air samples were taken for xylene. The xylene concentrations ranged from less than 0.01 milligrams per cubic centimeter (mg/M^3) to 21.0 mg/M^3. The evaluation criteria for xylene is 435 mg/M^3. Seventeen air samples (eleven personal and six area samples) were taken for formaldehyde. The formaldehyde concentrations ranged from 0.01 to 1.9 mg/M^3. The present evaluation criteria for formaldehyde is based on NIOSH's Current Intelligence Bulletin No. 34 which recommends that exposures be limited to the lowest feasible level. This recommendation is based on the ability of formaldehyde to produce cancer in animals. Ventilation measurements indicated that a portion of the exhaust ventilation systems were ineffective in their ability to adequately reduce or eliminate the formaldehyde contaminant.

The medical questionnaires suggested symptoms resulting from chemical exposures in some of the employees. Health complaints consisted of burning eyes, nose, throat and skin irritation.

On the basis of the environmental and medical data obtained in this investigation, NIOSH determined that a health hazard did exist to those employees working with formaldehyde in both the Reagent Preparation and Surgical Pathology Departments, as well as during the disposal of tissue treated with formaldehyde. NIOSH also determined the exhaust ventilation systems in some of the departments were ineffective in reducing the exposures found. Certain work practices were also considered to be a major contributor to the formaldehyde overexposures. Recommendations on preventing and correcting formaldehyde exposures are included in this report.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals) formaldehyde, xylene, histology, cytology, surgical pathology, reagent preparation, tissue disposal; eye, noise, throat and skin irritation.

II. INTRODUCTION

In December, 1982, the National Institute for Occupational Health (NIOSH) received a request from St. Josephs Hospital, Denver, Colorado, to evaluate potential xylene and formaldehyde exposures in the Histology, Cytology, Surgical Pathology and the Reagent Preparation Departments.

On March 22-23, 1983, NIOSH conducted an environmental and medical survey to evaluate the potential exposures to xylene and formaldehyde. The disposal of waste tissue treated with formaldehyde was also evaluated during the study. Each of the exhaust ventilation systems, employees work practices and medical concerns were also evaluated.

A preliminary letter was sent to the requestor on July 15, 1983. Included in the letter were recommendations for engineering controls, personal protective clothing and proper work practices to reduce and/or eliminate the potential exposures as described in this report.

III. BACKGROUND

Since 1873 St. Josephs Hospital has been one of the largest hospitals in the Denver metropolitan area. Like other hospitals, St. Josephs uses both xylene and formaldehyde (formalin) in various departments and they are concerned about the adverse health effects associated with these chemicals.

Formalin is used in the Surgical Pathology, Histology and Morgue Departments and is primarily prepared in the Reagent Preparation Department. The normal formaldehyde concentrations used in these areas are 10 and 37 percent.

The following is a description of each of the departments surveyed including a discussion of the chemicals used, the existing exhaust ventilation systems, personal protective clothing and work practices evaluated by NIOSH:

A. Histology and Cytology

The Histology Department at St. Josephs is located in a room with approximately 900 square feet of working space. There are normally 3 to 4 employees working in this department on any given day. The chemicals evaluated in this room were xylene and formaldehyde which are used primarily in tissue fixing processes.

There are three laboratory hoods in this room and various procedures are performed in these including staining, chemical mixing, mold preparation and the removal/filling of chemicals used in the tissue processing machine.

The larger of the lab hoods in this department is a two compartment hood system which is used primarily for staining and other uses where a high efficiency exhaust system is required. This hood has two sash windows which allow the worker to adjust the individual window opening as needed. The most efficient position for these windows during a work procedure is with an opening between 8 and 10 inches. The second exhaust hood is equipped with a sink and this unit is located in the center of the lab. This hood is used primarily for washing equipment and changing solutions. The last exhaust hood is actually a storage compartment which contains a tissue processing machine. This compartment has two doors which are normally closed throughout the process and an exhaust duct located above the machine.

The Cytology Department is located next to the histology room and there are approximately 375 feet of working space in this department. Three employees normally work in this section; although additional staff members occasionally conduct research here. Xylene was the only chemical routinely used in this department. This department has one permanent overhead exhaust hood which is located along the north wall and one portable table-top (charcoal filter--type) exhaust box used for tissue staining. The average flow rate at the face of these hoods was 30 and 15 fpm respectively.

B. Reagent Preparation

The Reagent Preparation Department has approximately 350 square feet of operating space and during the NIOSH study there were two employees working in this department. Various chemicals are stored, mixed and distributed from this department and there was one laboratory exhaust hood in the room.

The exhaust system is a double fan type with one exhaust fan located within the hood and the other on the roof. This system requires that both fans be operating at the same time in order to obtain a face velocity of 175 to 200 fpm. With only one fan operating the face velocity drops below 75 fpm.

The only process evaluated in this department was the formalin mixing operation and this was performed outside the lab hood. This mixing process is normally performed by the employee and takes approximately 30 minutes to complete. This process was performed in the following manner:

1. Rinsing a 20 liter bottle with water
2. Filling bottles with deionized water to designated mark
3. Pouring 1 liter of formaldehyde into bottle and mixing
4. Pouring the final solution into 1 gallon bottles using funnel

Due to the amount of agitation occurring during the mixing process, it was felt by NIOSH that this means of preparing the formalin solution potentially subjected the employee to excessive formaldehyde exposures. NIOSH made various recommendations to improve this situation and once instituted reevaluated the new mixing process.

C. Surgical Pathology

Although there was only one surgical or gross pathology department at St. Josephs an additional pathology room was being constructed during the NIOSH study. Concerns by management regarding the potential exposures in this new pathology room were raised during the NIOSH study and these are discussed at the end of this subsection.

The surgical pathology room normally has 2 to 3 employees working in a space of approximately 125 square feet. The majority of the work performed here occurs in the morning between 9-11 a.m. and in mid afternoon between 2-4 p.m.

The majority of dissecting and preparing of specimens occurs at a work table which allows the pathologist to work on one side of the table while a technician prepares the dissected samples on the other side of the table. Other activities performed in this room which may potentially subject the employee to formaldehyde exposures include pouring or dumping formalin, looking for blocks submerged in formalin buckets and pinning out specimens for flooding with formalin.

There is one exhaust ventilation system in this room and it is located approximately three (3) feet from the main work table. The exhaust flow rate at the the face of the hood is approximately 10 to 40 fpm. During the dissection process it was also noted that the pathologist was required to dictate his procedures and findings into a recorder and frequently he would turn off the exhaust fan to avoid the noise which interferes with the recorder.

As mentioned earlier, St. Josephs recently constructed a new surgical pathology room to service OB/GYN. At the time of the NIOSH study this room was not yet operational, however, NIOSH did have an opportunity to evaluate the proposed work process and the exhaust ventilation system in this room. The work procedures were similar to those in the surgical pathology room evaluated by NIOSH. The face velocity with the new exhaust system was approximately 100 fpm which, given the distance from the work table, was considered insufficient to remove the contaminate from a worker's breathing zone.

D. Tissue Disposal

The tissue disposal operation takes place approximately every two weeks and normally requires one person approximately one half hour to complete. This process requires the operator to remove all waste tissue samples from the surgical pathology and morgue departments and dispose of the waste material. The final disposal process takes place in the morgue where the waste material is placed in large plastic bags and sent to a crematorium. There was no exhaust ventilation used during any phase of this process.

E. Miscellaneous

During each of the operations evaluated by NIOSH, the employees used laboratory coats or surgical clothing. Three different types of protective gloves, including latex, rubber and polyvinyl types were available to the employees. The only respiratory protection available was surgical masks.

IV. ENVIRONMENTAL DESIGN AND METHODS

A. Environmental

A total of twelve (12) personal samples were collected for xylene using a charcoal tube technique. Sampling pumps were used to draw the air through the tubes at 50 and 200 cubic centimeters per minute (cc/m). The samples were analyzed by gas chromatography using the modified NIOSH Method S-318.

A total of eleven (11) personal and six (6) general area type samples were collected for formaldehyde using the impinger technique. Sampling pumps were used to draw air through the impinger solution at one liter per minute (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 in the areas evaluated was interviewed, and a medical questionnaire was completed on 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 important to note, however, 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 primarily 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
Xylene.....	435 mg/M^3 (OSHA)
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

1. Xylene

Xylene has an irritant effect on the skin and mucous membranes and can have variable effects on the liver, kidneys, and gastrointestinal tract. Another major problem of xylene toxicity is its narcotic effect on workers, causing symptoms such as muscular weakness, lack of coordination, and mental confusion which may pose a risk to the worker and others. Current evidence indicates that xylene is not toxic to the blood and blood-forming organs.

2. Formaldehyde

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 4.5 mg/M^3 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 xylene and formaldehyde were evaluated. The following are the results of NIOSH's evaluation.

A. Environmental

Six personal samples were collected in the Histology Department and 6 personal samples in the Cytology Department for xylene. The sampling times ranged from six to eight hours. The results for the xylene sampling ranged from 0.01 to 0.13 mg/M^3 for the histology department and 0.02 to 0.21 mg/M^3 for the Cytology Department. All the samples were well below the current OSHA Standard of 435 mg/M^3 (refer to Table 1).

Seventeen air samples (eleven personal and six area samples) were taken for formaldehyde. The sampling period ranged from 7 to 390 minutes. The results obtained for the formaldehyde sampling ranged from less than analytical detection to 1.90 mg/M^3.

The higher results were found in the Reagent Preparation, Surgical Pathology and during the tissue disposal process (refer to Table 2). It was determined that a large contribution of the formaldehyde exposures in the Surgical Pathology area occurred during the disposal of

used formaldehyde. This procedure occurs at different times of the day and normally requires the employee to pour the solution into the sink. It was felt by the NIOSH investigators that this process agitates the solution greatly which increases the personal exposure to the employee. The exposures found in the mixing of the formalin solution in the Reagent Preparation department and during the disposal of waste tissue were determined to be primarily from improper work practices (refer to the Work Practices section).

All of the exhaust ventilation systems evaluated by NIOSH operated efficiently except in the Surgical Pathology department. The laboratory hoods in the Histology department had flow rates which averaged between 125 to 150 fpm across the face of the hoods when an 8-10 inch opening was used. With the sash openings greater than 10 inches the face velocity dropped significantly.

The local exhaust ventilation system in the Surgical Pathology department was considered to be ineffective in its ability to adequately remove the formaldehyde at the source (i.e., at the operators breathing zone during general formaldehyde use in this area). It was felt that this was due primarily to the inadequate flow rate of the system (10-40 fpm) and the extreme distance of the exhaust hood in relation to the main work area (approximately three feet). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends that laboratory hoods have a face velocity of 125-150 fpm during such operation.

The concerns described above would potentially apply to the procedures evaluated in the new OB/GYN surgical pathology section. It was determined that the exhaust system in the new department was pulling adequately (i.,e., averaging over 125-150 fpm face velocity). However, the distance between the face of the hood and the work area was approximately three feet from the main work area. Therefore, it is anticipated that this arrangement would have a minimal effect in removing the contaminant from the operators breathing zone.

B. Medical

Each of the employees were interviewed and requested to fill out a medical questionnaire. The results from the medical questionnaires suggest exposures to formaldehyde. This is based on health complaints which consisted of burning eyes, noise and throat and skin irritation during some periods of formalin use in both the reagent preparation and surgical pathology departments.

C. Work Practices

It was determined that improper work practices contributed to the workers over exposures during the preparation of the formalin solution in the Reagent Preparation department and during the disposal of tissue treated with formalin.

The improper work practice noted in the Reagent Preparation department consisted of the operator preparing the material while standing over the mixing process without using the exhaust ventilation system provided. After this concern was brought to his attention, a procedure was worked out which was thought to be compatible to the overall operation, and therefore, would potentially reduce the suspected high

exposures. The recommendations included the use of a carboy and a siphoning technique rather than a funnel and performing the mixing operation as close to the lab hood as possible. These procedures allowed for less agitation as well as the exhausting of fumes as they rose to the hood.

Based on NIOSH's recommendations it was determined that a second batch would be prepared to see if the changes would significantly reduce the suspected exposure. By reviewing Table 1 (Reagent Preparation section First Day versus Second Day), there was a significant reduction in exposure results (1.90 versus 0.21 mg/M^3 for personal samples and 0.35 versus 0.03 mg/M^3 for area samples) after NIOSH's recommendations were instituted.

The improper work practice noted in the disposal of waste treated with formaldehyde was due primarily to the operators not using the exhaust ventilation systems provided.

VII. CONCLUSIONS

Based on the environmental sampling data and the medical questionnaire results, a health hazard did exist to the employees who work in the Reagent Preparation and Surgical Pathology departments, as well as during the disposal of tissue treated with formalin. This conclusion is based on the allergenic and carcinogenic potential of formaldehyde.

It was also felt by NIOSH that a considerable reduction in the formaldehyde exposure could be maintained in the Reagent Preparation department as well as during the tissue disposal process by utilizing the exhaust ventilation systems in those areas where these operation are performed.

The exposures found in the Surgical Pathology department can be greatly reduced by improving the exhaust ventilation systems in this area and designing a system which will remove the contaminant away from the operators breathing zone. Finally, it was concluded that this may also be a problem in the new OB/GYN surgical pathology department.

VIII. RECOMMENDATIONS

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

2. Local exhaust ventilation should be improved in the Surgical Pathology department. This would prevent exposures to formaldehyde as described in the background section of this report. Based on the variety of activities performed in this department an alternative exhaust system should be considered. The best type of local exhaust ventilation for the various types of activities performed in this department is one which can be located as close to the source of exposure as possible. As a recommendation, it may be possible to use a flexible exhaust trunk type system which would be attached to a small hood. This type of system would then allow the hood to be moved from process to process as needed.

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. This is also true in other areas where continuous formaldehyde exposures are known to exist.

3. Once the exhaust ventilation system in the Surgical Pathology department has been improved, an environmental survey should be performed again in this area in order to determine the effectiveness of the new ventilation systems. An evaluation should also be performed in the OB/GYN Surgical Pathology department to fully determine the level of formaldehyde exposures in this area.

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 disposing of the formaldehyde treated tissue; that is, one which would include the use of an exhaust system in each of the departments where disposing of the waste material is performed.

6. Work practices should be reviewed periodically for each of those procedures performed where formaldehyde is used in order to assure that potential overexposures are not occurring. Concerns should be directed in the proper handling techniques, proper use of exhaust systems, personal protective equipment/clothing and good personal hygiene. For short term exposures where exhaust systems are not available, NIOSH/MSHA approved respirators should be used. New employees should be instructed on these concerns as soon as possible. Finally, when new processes are instituted where formaldehyde is used the entire process should be reviewed to eliminate potential overexposures.

IX. REFERENCES

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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. Saint Josephs 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 Xylene

Saint Josephs Hospital
Denver, Colorado
March, 1983

Job Description	Sampling Time (minutes)	mg/M^3 Xylene
Histologist	455	0.01
Histologist	510	0.02
Histologist	390	0.04
Histologist	490	0.01
Histologist	280	0.13
Histologist	405	0.02
Cytologist	357	0.31
Cytologist	330	0.19
Cytologist	330	0.02
Cytologist	370	0.01
Cytologist	380	21.0
Cytologist	390	0.04
EVALUATION CRITERIA:		435

LABORATORY LIMIT OF DETECTION: 0.01 mg/sample

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

TABLE 2

Breathing Zone and Area Air Concentration for Formaldehyde

St. Josephs Hospital
Denver, Colorado

March, 1983

Job/Area Description	Sampling Time (minutes)	mg/M^3 Formaldehyde
Histology Department		
Formalin Preparation-Personal	7	N.D.
Changing Formalin-Personal	75	0.10
Changing Formalin-Area	75	0.10
Surgical Pathology		
Pathologist-Personal	330	0.30
Pathologist-Personal	380	0.20
Pathologist-Personal	390	0.30
Pathologist-Personal	20	0.80
Technician-Personal	360	0.33
Technician-Personal	370	0.54
General Room Air Sample	330	0.30
General Room Air Sample	390	0.55
Reagent Preparation		
First Day		
Chemical Mixing-Personal	30	1.90
Chemical Mixing-Area	30	0.35
Second Day		
Chemical Mixing-Personal	30	0.21
Chemical Mixing-Area	30	0.03
Pathology/Morgue Waste Disposal		
Waste Disposal-Personal	20	0.82
Waste Disposal-Area	20	0.30

EVALUATION CRITERIA: L.F.L.*

LABORATORY LIMIT OF DETECTION: 0.25 ug/sample

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

* Formaldehyde has been shown to cause cancer in animals. Exposure should, therefore, be controlled at the lowest feasible level.