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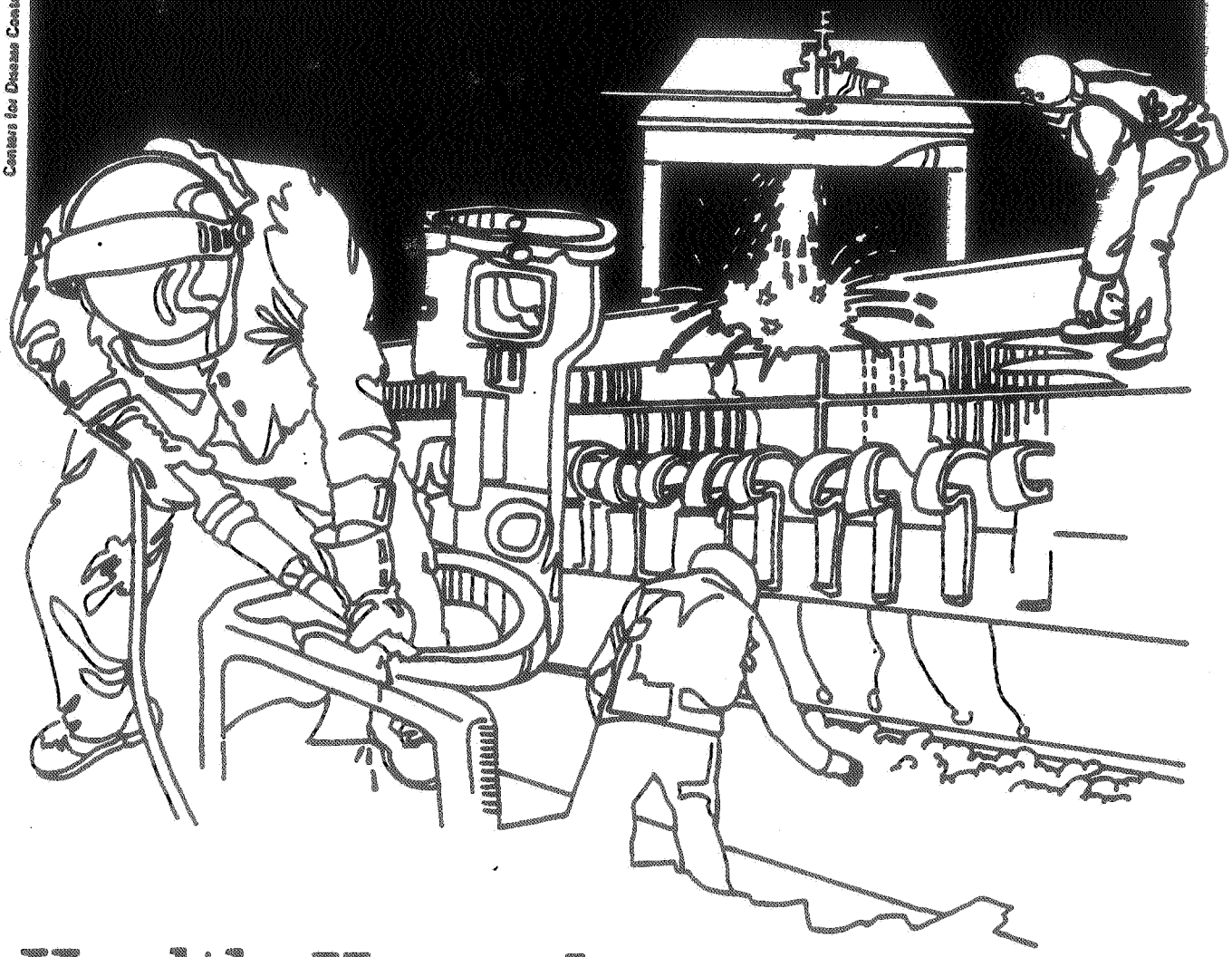

Health Hazard Evaluation Report

HETA 85-067-1614
HOSPITAL OF THE UNIVERSITY
OF PENNSYLVANIA
PHILADELPHIA, PENNSYLVANIA

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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HOSPITAL OF THE UNIVERSITY
OF PENNSYLVANIA
PHILADELPHIA, PENNSYLVANIA

NIOSH INVESTIGATORS:
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I. SUMMARY

On November 13, 1984, the National Institute for Occupational Safety and Health (NIOSH) received a request for a Health Hazard Evaluation from the Director of the Orthotic/Prosthetic Laboratory to reevaluate the environmental air quality in the laboratory. A previous NIOSH evaluation was done on May 8, 1981 for toluene and formaldehyde. Engineering control and stringent work practices recommendations were made. Although some renovations were made, the Director felt that they would not meet NIOSH recommended standards.

A NIOSH Industrial Hygienist visited the Lab on January 15, 1985 to determine what renovations were made and inventory the materials that were being used. On January 28, 1985, area environmental air samples were collected during the rigid foam mixing, pouring and grinding operations for monomeric MDI and total reactive isocyanate groups (TRIG). Area air samples were also collected for acetone, methyl ethyl ketone (MEK), formaldehyde, 1,1,1-trichloroethane, perchloroethylene, styrene and petroleum hydorcarbons.

Two of the three air samples for TRIG showed concentrations of 224 and 434 micrograms per cubic meter of air sampled (ug/m^3). (There is no standard or NIOSH recommended standard in the United States for TRIG: the British standard is 20 ug/m^3, time weighted average for a 10-hour workday and a 10-minute TWA of 70 ug/m^3). No detectable concentrations of MDI were found in any of the three area samples. Analysis of two area air samples for organic vapors showed the following: acetone - 0.3 milligram/cubic meter of air sampled (mg/m^3), MEK - 9.10 mg/m^3, formaldehyde - none detected, 1,1,1-trichloroethane - 0.91 mg/m^3, styrene - 7.05 mg/m^3, petroleum hydrocarbons - 3.79 mg/m^3. All of the above values did not exceed NIOSH recommended or Occupational Safety and Health Administration (OSHA) standards.

The results of this investigation indicated that laboratory personnel were exposed to isocyanates (although not to detectable levels of the monomer for MDI), during rigid foam mixing, pouring and grinding operations. Measures to improve working conditions are made in Section VIII of this report.

KEYWORDS: SIC 8922 (Noncommerical Educational, Scientific and Research Organizations, Orthotic/Prosthetic, Research), total isocyanates, MDI, polyurethane, organic solvents.

II. Introduction

On November 13, 1984, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Director of the Orthotic/Prosthetic laboratory requesting a reevaluation of the environmental air quality in the laboratory. A previous NIOSH evaluation was done on May 18, 1981 for toluene and formaldehyde. Engineering controls and stringent work practices recommendations were made. Although some renovations were made, the Director felt they would not meet NIOSH recommended standards and employees were still experiencing some ill effects.

A visit was made on January 15, 1985 to determine what renovations were made and to inventory the materials which were being used. It was determined that beside the organic solvents that were being used, the rigid foam casting operation would be evaluated as it contained diphenylmethane diisocyanate or 4,4'-methylene diphenylisocyante (MDI). On January 28, 1985, area environmental air samples were collected for organic solvents and MDI.

III. Background

The INA Orthotic/Prosthetic Research Laboratory is engaged in developing better orthopedic and prothetic devices for the patients of the University of Pennsylvania Hospital. Nylon hose is put on a previously plaster formed leg. A proper size sheet of polypropylene, polyethylene, acrylic or polyester resin is cut. The plastic is then put on a plate previously sprayed with a silicone parting agent. The sheets are then inserted into an oven with thermal rise exhaust, and heated at 300-425^{o}F depending on the plastic and the thickness of the sheet. The sheet of plastic is then removed from the oven and manually stretched tightly over the mold. The excess plastic is then cut off.

In the casting room, the two-component rigid foam is mixed and poured into the cast. After the resin polymerizes, the form is taken off and the grinding, sawing and sanding is done. Only general ventilation is utilized for mixing, pouring and polymerizing. The grinding, sawing and sanding operations have local exhaust ventilation to a collector, however, the air from the collector is recirculated into the room.

IV. Evaluation Design and Methods

Area environmental air sampling were performed on January 28, 1985, to characterize employee exposures to diphenylmethane diisocyanate (MDI) and total reactive isocyanate groups (TRIG) and organic solvents (1,1,1-trichloroethane, perchloroethylene, petroleum hydrocarbons, styrene, acetone and methyl ethyl ketone and formaldehyde). The sampling and analytical methods for these substances including collection device, flow rate, and referenced analytical procedures are presented in Table I.[1]

A synopsis of the newly developed NIOSH air sampling/analytical method for total reactive isocyanate groups is as follows:

A known volume of air is bubbled through a midget impinger containing a known quantity of a toluene solution of 1-(2-methoxyphenyl)-piperazine. An aliquot of the toluene solution is acetylated and then evaporated to dryness. The residue is dissolved in methanol and an aliquot is injected into a high-performance liquid chromatograph equipped with a UV detector capable of

detection at 254 nm. The change in concentration of 1-(2-methoxyphenyl)-piperazine is quantitated and the number of moles of reactive isocyanate groups present determined. The isocyanate groups are quantitated regardless of the size of the molecule to which they are attached.

V. Evaluation Criteria

As a guide to the evaluation of the hazard 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, pre-existing medical conditions, 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 not usually 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 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 contolling 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.

A. Isocyanates

All isocyanates contain the N-C-O group[2] which reacts readily with compounds containing reactive hydrogen atoms to form urethanes. The di- and poly-isocyanates contain, respectively, two and three or more of these

groups[2]. The chemical reactivity of the isocyanates makes them ideal for polymer formation. Hence, they are widely used in the manufacture of polyurethane foams, paints, adhesives, fibers, resins, and sealants[3].

The processes and operations in which diisocyanates are used will determine the severity of the hazard. Industrial processes involving evaporation from large surface areas may result in a greater potential vapor hazard than operations involving pouring-in-place of frothing techniques[4].

In general, the potential respiratory hazards encountered during the use of diisocyanates in the workplace are related to their vapor pressures. The lower-molecular-weight diisocyanates tend to be more readily volatilized into the workplace atmosphere than the high-molecular-weight diisocyanates. Although the vapor pressures of the higher-molecular-weight diisocyanates are relatively low, they may generate vapor concentrations sufficient to cause respiratory and mucous membrane irritation if they are handled in poorly ventilated areas. Also, the potential for skin irritation is generally higher for the lower-molecular-weight diisocyanates, and the severity of these irritant responses is reduced with increasing molecular weight[4].

Exposure to isocyanates can cause skin and mucous membrane irritation, nausea, vomiting and abdominal pain[5,6]. In high concentrations, isocyanates have a primary irritant effect on the respiratory tract. They can also act as respiratory sensitizers, producing asthma-like symptoms in sensitized individuals, even at very low concentrations.

Asthmatic attacks may occur immediately after exposure or at an interval of hours after cessation of exposure, presenting as nocturnal cough and breathlessness. Exposure to isocyanates may also result in chronic impairment of pulmonary function[4]. Isocyanate exposure during accidental spills is a major cause of sensitization, and there is evidence that massive exposures may produce effects on the central nervous system[4]. One recently completed animal study found dose-related statistically significant cancer excesses in mice and rats administered TDI by gavage (not the usual route of human exposure) in very high concentrations. The tumors were distant from the site of administration[7].

In the United States, federal Occupational Safety and Health Administration (OSHA) exposure standards for diisocyanates have been established only for toluene diisocyanate and methylene bisphenyl isocyanate. The current federal OSHA standard[8] and American Conference of Governmental Industrial Hygienists (ACGIH)[9] Threshold Limit Value (TLV) for MDI is a ceiling limit of 0.02 parts of MDI per million parts of air (ppm), (0.2 milligrams per cubic meter of air, (mg/m^3).

The current NIOSH recommended standard for occupational exposure to MDI is 0.05 mg/m^3 for up to a 10-hour workshift 40-hour workweek. The NIOSH recommended standard was based on three types of effects of exposure to MDI: direct irritation, sensitization, and chronic decrease in pulmonary function. This standard applies to diisocyanate monomers only, and not to higher polymers of these compounds[4]. Little is known about the toxicological effects of polymeric isocyanates. No long-term studies have been conducted on

polymeric isocyanates, and furthermore, their potential for inducing pulmonary hypersensitivity, as shown for monomeric isocyanates, has not been investigated(10). However, results of a recent NIOSH study revealed that work in an industrial setting where polymeric isocyanate exposures were documented was associated with small mean decreases in FEV_1 and FVC which were not observed in an unexposed group. Also, the change in FEV_1 over the shift correlated with personal airborne exposure to polymeric but not monomeric MDI(11).

On February 2, 1983, the United Kingdom Health and Safety Commission set a "common control limit" for workplace exposure to all isocyanates. This new control limit is an 8-hour TWA of 20 ug of isocyanate group per cubic meter of air, and a 10-minute TWA of 70 ug isocyanate group per cubic meter of air. This new control limit, in units of ug $(NCO)/m^3$, requires that the analytical methods be applicable to "total isocyanate", i.e., the sum of all isocyanate species, including monomers and prepolymers(12).

Solvent Criteria*	OSHA(8)	NIOSH	ACGIH(9)
1,1,1-Trichloroethane	1900	1900**	1900
Perchloroethylene	670	335	335
Petroleum Hydrocarbons	2000	350	1600
Styrene	430	-	215
Acetone	2400	-	1780
Methyl Ethyl Ketone	590	-	590
Formaldehyde	3.6	LFL	1.2

* Denotes - milligrams per cubic meter of air sampled.
** Denotes - 15 minute ceiling.

B. Solvents

1) 1,1,1-Trichloroethane(5)

Liquid and vapor are irritating to eyes on contact. This effect is usually noted first in acute exposure cases. Mild conjuctivitis may develop but recovery is usally rapid. Repeated skin contact may produce a dry, scaly, and fissured dermatitis, due to the solvent's defatting properties.

2) Perchloroethylene(5)

Acute exposure to perchloroethylene may cause central nervous system depression, hepatic injury, and anesthetic death. Cardiac arrhythmias and renal injury have been produced in animal experiments. Signs and symptoms of overexposure include malaise, dizziness, headache, increased perspiration, fatigue, staggering gait, and slowing of mental ability. These usually subside quickly upon removal into the open air.

3) Styrene(5)

Liquid and vapor are irritating to the eyes, nose throat, and skin. Liquids are low-grade cutaneous irritants and repeated contact may produce a dry, scaly, and fissured dermatitis.

4) Acetone, Methyl Ethyl Ketone[5]

These solvents may produce a dry, scaly, and fissured dermatitis after repeated exposure. High vapor concentrations may irritate the conjunctiva and mucous membranes of the nose and throat, producing eye and throat symptoms.

5) Formaldehyde[5,13,14]

Local - Formaldehyde gas may cause severe irritation to the mucous membranes of the respiratory tract and eyes. The aqueous solution splashed in the eyes may cause eye burns. Urticaria has been reported following inhalation of gas. Repeated exposure to formaldehyde may cause dermatitis from irritation or allergy.

Systemic - Systemic intoxication is unlikely to occur since intense irritation of upper respiratory passages compels workers to leave areas of exposure. If workers do inhale high concentrations of formaldehyde, coughing, difficulty in breathing and pulmonary edema may occur. Ingestion, although usually not occurring in industrial experience, may cause severe irritation of the mouth, throat, and stomach.

The National Institute for Occupational Safety and Health (NIOSH) recommends that formaldehyde be handled as a potential occupational carcinogen and that appropriate controls be used to reduce worker exposure. These recommendations are based primarily on a Chemical Industry Institute of Toxicology (CIIT) study in which laboratory rats and mice exposed to formaldehyde vapor developed nasal cancer, and are supported by a New York University study where rats exposed to a mixture of formaldehyde and hydrochloric acid vapors developed nasal cancer. Formaldehyde has also been shown to be a mutagen in several short-term laboratory studies.

VI. Results

It should be noted that during the May 8, 1981 NIOSH evaluation, the mixing and pouring of the rigid foam was done in a small alcove with a window fan. This is not a production operation and is only performed as needed.

Results of the general area air samples during the mixing, pouring, cutting, grinding and sanding operations to determine the employee potential exposures to total reactive isocyanate groups (TRIG) are presented in Table II. Two of the three general air samples had detectable (TRIG) 224 and 434 ug/m^3. No detectable levels were found in any of the three samples collected for monomeric MDI.

The analytical results for the total reactive isocyanate groups were originally reported in micromoles of NCO per sample. These values were converted to micrograms per cubic meter (as shown in Table II) using the molecular weight of 42 (N+C+O) for the NCO radical. These calculations were performed so that the resulting values could be compared with the United Kingdom's new standard for total isocyanate groups 20 ug/m^3 for an 8-hour TWA and a 10-minute TWA of 70 ug/m^3[12].

Atmospheric air samples were collected on the desks in the laboratory, where the employees may be exposed, for various organic solvents, Table III. All samples were well below their respective standards. Two samples collected for formaldehyde were below the laboratory limit of detection, 0.2 ug/sample.

VII. Discussions and Conclusions

There were three employees working in the Orthotic/Prosthetic Laboratory. Their work consists in making the mold of the limbs and then making the limbs from various plastics and adjusting them for the patient. Some of the work must be done at the patients' bedside. All operations are intermittant. During the atmospheric evaluation of May 8, 1981, the rigid foam operation location was performed in an alcove with window fan exhaust. This operation was moved into an adjacent room (casting area) and is done with only general air ventilation. However, the air from the collector which recirculated from the work area may contain unreacted diisocyanates. Other operations such as sawing, grinding and sanding have local exhaust air ventilation.

This operation could not be evaluated previously as they had no limbs that required rigid foam casting. The industrial hygienists requested that this operation be performed during this evaluation.

VIII. Recommendations

In view of the findings during this evaluation, the following recommendations are made:

1. A booth with one open side is needed, equipped with local exhaust to ventilate the mixing, pouring and setting rigid foam operation. The ventilation systems should be designed to prevent accumulation or recirculation of diisocyantes in the workplace environment and to effectively remove diisocyanates from the breathing zone of employees.

2. Until such a time as diisocyanates are effectively controlled, NIOSH(5) recommends a Type C supplied-air respirator with full facepiece operated in pressure-demand or other positive pressure demand or other positive pressure mode or with full facepiece, helmet, or hood operated in continuous-flow mode.

3. Supervisors and their employees should familiarize themselves with product manufacturers' recommendations regarding precautionary measures and specific directions before attempting to use any materials in the conduct of their work. Current Material Safety Data Sheets and all available information concerning products used, including health effects should be obtained and made available to all potentially exposed personnel. Furthermore, a continuing education program, conducted by a person or persons qualified by experience or special training, should be instituted to ensure that all employees have current knowledge and understanding of the job safety and health hazards,

proper work practices, and maintenance procedures. Materials should be labeled with information on proper use, personal protective devices needed, the description of adverse health effects.

4. The medical recommendations for employees exposed to isocyanates, as outlined in the NIOSH diisocyanate criteria document[5] should be followed. These recommendations include the need for pre-placement examinations and periodic medical surveillance:

a. Preplacement examination should include at least comprehensive medical and work histories, with special emphasis on pre-existing respiratory conditions such as asthma. A smoking history should also be compiled.

Physical examination giving particular attention to the respiratory tract and baseline measurements of forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV_1) should be done. The worker's ability to use negative and positive pressure respirators should be assessed.

b. Periodic examinations should be made available at least annually, or as determined by the responsible physician. These should include interim medical and work histories, and clinical examination giving particular attention to the respiratory tract and measurements of FEV_1 and FVC.

c. During examination, applicants or employees found to have medical conditions that could be directly or indirectly aggravated by exposure to diisocyanates, e.g.; respiratory allergy, chronic upper or lower respiratory irritation, chronic obstructive pulmonary disease, or evidence of sensitization to diisocyanates, should be counseled on their increased risk from working with these substances. Chronic bronchitis, emphysema, disabling pneumoconiosis, or cardiopulmonary disease with significantly impaired ventilatory capacity similarly suggest an increased risk from exposure to diisocyanate. If a history of allergy is elicited, applicants should be counseled that they may be at increased risk of adverse health effects from exposure to diisocyanates. Employees should also be advised that exposure to diisocyanates may result in delayed effects, such as coughing or difficulty in breathing during the night.

IX. Reference

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14. NIOSH Current Intelligence Bulletin 34, April 15, 1981.

X. Authorship and Acknowledgments

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XI. Distribution and Availability of Report

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Publications Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the Natonal Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. 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. Hospital of the University of Pennsylvania, INA Orthotic/Prosthetic Research Laboratory

2. Employee Representative

3. NIOSH, Region III

4. OSHA Region III

For the purpose of informing the three employees of the results of the survey, the employer shall promptly "post" for a period of 30 calendar days, the Determination Report in in a prominent place(s) near where employees work.

TABLE I

Air Sampling and Analysis Methodology
Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania
HETA 85-067

Substance	Collection Device	Flow Rate (liters per minute)	Analysis	References (1)
Methylene Bisphenyl Isocyanate (MDI)	Midget Impinger with 15 ml of 1 - (2-methoxyphenyl) - piperazine in toluene	1.0	High Performance Liquid Chromatography	NIOSH Method 5505 Total Isocyanates
Total Reactive Isocyante Groups (TRIG) (monomer & polymer)	"	"	"	"
Formaldehyde	ORBO 22	0.05	Gas Chromatography	NIOSH Method P&CAM 354 With Modifications*
Organic Solvents: 1,1,1-Trichloroethane	Charcoal Tube	0.2	Gas Chromatography Equipped with a Flame Ionization Detector	NIOSH Method P&CAM 127 With Modifications*
Perchloroethylene	"	"	"	-
Petroleum Hydrocarbon		"	"	-
Styrene	"	"	"	
Acetone	Ambersorb	"	Gas Chromatography	NIOSH Method S 3 With Modifications*
Methyl Ethyl Ketone	"	"		"

* The modifications included sample preparation, instrument condition settings, and/or column selection.

Table II
Results of Environmental Air Samples
For
Total Reactive Isocyanate Group

Hospital of the University of Pennsylvania
Philadelphia, Pennsylvnia
HETA 85-067

January 28, 1985

Sample Location (Casting Room)	Time	uMoles/Sample(1)	Total Reactive Isocyante Group (ug/m^3)(2)
General Air	08:45-15:00	0.2	N.D.(3)
Foaming Station	08:45-15:00	2.0	224
Foaming Station	08:45-09:14	0.3	434

Laboratory analytical limit of detection is 0.4 uMoles/sample.

1 & 2. The conversion from micromoles of NCO per sample to micrograms per cubic meter of air is made using the NCO radical and the molecular weight of 42 (N+C+O) and dividing by the air volume.

3. ug/m^3 = micrograms per cubic meter of air.

4. N.D. = nondetectable concentration.

Table III

Results of Environmental Air Samples
for
Organic Vapors*

Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania
HETA 85 067

January 28, 1985

Orthotic/Prosthetic Laboratory

Location	Time	1,1,1-Trichloroethane	Perchloro-ethane	Petroleum Hydrocarbons	Styrene	Acetone	MEK
Lab Desk	08:45-15:08	1.0	0.3	39.2	7.2	9.1	0.3
Lab Desk	08:45-15:08						
Laminating Area	08:45-15:08						

* Denotes - milligram of contaminant per cubic meter of air sampled.

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