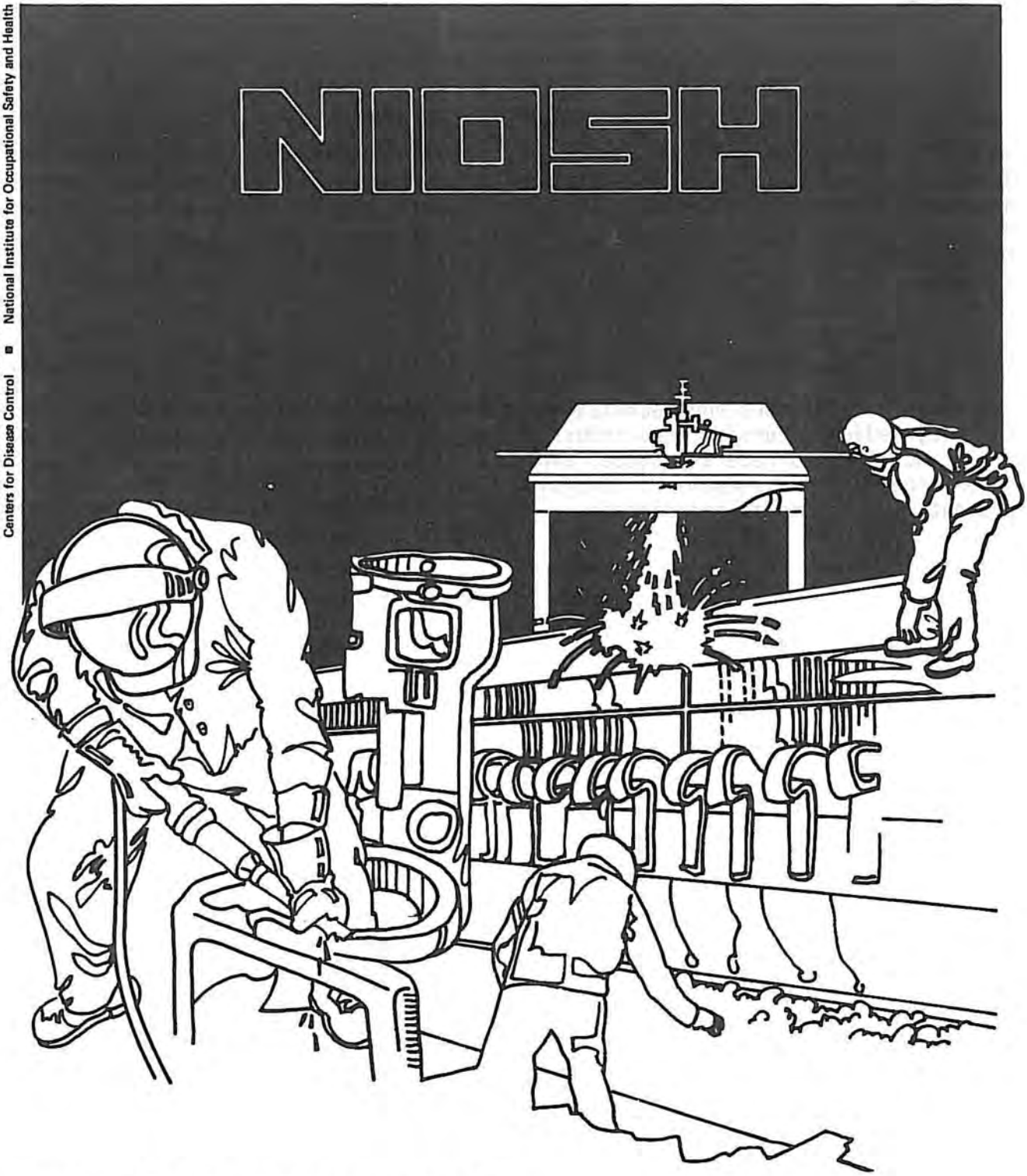
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health

NIOSH



Health Hazard Evaluation Report

HETA 82-303-1271
ST. FRANCIS HOSPITAL
HONOLULU, HAWAII

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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I. SUMMARY

In March 1982, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate formaldehyde exposures to hemodialysis technicians at St. Francis Hospital, Honolulu, Hawaii. Several employees were reported to have "respiratory ailments that are more severe than ordinary flu-type illnesses."

On July 28-30, 1982, NIOSH investigators conducted an environmental and medical survey of the St. Francis Hospital hemodialysis facilities at the hospital and at the Leeward satellite. Seventeen area air samples were collected for measurement of airborne formaldehyde concentration during sterilization of the artificial kidneys and of the dialysis consoles. Concentrations of airborne formaldehyde ranged from 0.04-1.28 parts of formaldehyde per million parts of contaminated air (ppm) based on one hour sampling periods. NIOSH recommends that airborne formaldehyde exposures be maintained to the lowest feasible limit because of its potential carcinogenicity. Earlier NIOSH recommendations based on irritancy recommended that formaldehye exposure be held below 0.5 ppm.

Medical evaluation consisted of a review of 20 questionnaires collected by the Hawaii Nurses Association and of private interviews with 22 workers at the various units. Of those interviewed, seven reported no problems with the formaldehyde, 12 had transient problems, mostly upper respiratory and eye irritation, and three had more prolonged respiratory symptoms suggestive of hypersensitivity and/or allergy. Five workers reported skin problems.

Exposures appeared to be transient, relating to sterilizing procedures on the dialyzer consoles, small spills when removing dialyzers from the Lixivitron® machines used for dialyzer sterilization, formaldehyde gas escaping from the drains, and inadvertant spills often due to removing the dialyzers from the Lixivitron® before the cycle reaches the very end. These exposures affected staff and patients in the general area of the Lixivitrons® in addition to the operators because the Lixivitrons® were located in patient areas without specific guarding or ventilation.

On the basis of the environmental and medical data, NIOSH concluded that a health hazard did exist to formaldehyde under the present operating procedures at the hemodialysis units at St. Francis Hospital, Honolulu, Hawaii. Recommendations to improve the situation are included in Section VIII of this report, the major one being to isolate the Lixivitron® machines from the patient area.

KEYWORDS: SIC 8081 (Outpatient Care Facility), SIC 8062 (General Medical and Surgical Hospital), dialysis unit, formaldehyde, artificial kidney sterilization, respiratory hypersensitivity, irritancy.

II. INTRODUCTION

In March 1982 the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation from a representative of the International Longshoremen's Workers Union, Local 142, on behalf of technicians employed at the St. Francis Hospital-Hemodialysis Center, Honolulu, Hawaii. NIOSH was requested to evaluate airborne formaldehyde concentrations during sterilization of the artificial kidneys (dialyzers) and dialysis consoles. Several employees were reported to have respiratory ailments similar to flu-type symptoms.

On July 28-30, 1982, NIOSH investigators conducted an environmental and medical survey of the St. Francis Hospital hemodialysis facilities at the hospital and at the Leeward satellite. The general findings of the investigation and recommendations for correction were presented to the hospital safety/security manager and to the doctor in charge of the dialysis facilities at a closing conference.

III. BACKGROUND

The St. Francis Hospital has operated a hemodialysis program since 1968. Approximately 138 patients are dialyzed three times per week at one of four units (self-care and limited care located on the hospital grounds, hemolysis center located in the hospital, or the Leeward satellite facility located in Waipahu). About 30 employees are estimated to be at risk of exposure to formaldehyde vapors at these facilities. There are also three smaller units on outer islands. These were not evaluated, but it was felt that problems, if present, would be similar to those units studied. Usually two sets of patients are cared for per day, six days a week.

Patients are connected to an artificial kidney (dialyzer) and dialysis console for three to five hours depending on the patient's diet, condition of the dialyzers being reused, and other medical factors. Once the patient is disconnected from the dialyzer, the nurse or technician connects the dialyzer to the sterilizing unit (Lixivitron®). The Lixivitron® system is designed to automatically clean, test, and disinfect up to four dialyzers simultaneously. The operator starts the cleaning operation which uses water, cleaning solution, and formaldehyde to automatically wash, rinse, clean, in-vitro leak and pressure drop test, and disinfect the dialyzers. Failure of a test halts the process. Once the cleaning operation is completed, the pertient data is printed out and the dialyzer is removed from the Lixivitron®; then the dialyzer and the printout are sealed in a plastic bag. The Lixivitron® is operated by trained personnel.

There are two Lixivitron® systems for the four areas studied. Neither of these systems are isolated from patients who are being dialyzed. One unit is located at the Leeward satellite facility and the other is located in the self-care unit. Dialysis staff from each of the three hospital units are responsible for sterilizing their patients' dialyzers.

Several types of dialysis consoles (AK-10, Travenol, and Milton-Roy Extracorpeal) are used in the dialysis units. All of the consoles are disinfected (bleach) daily and sterilized weekly. Two of the machines (Travenol and Extracorpeal) have a water tank which is sterilized weekly (batch machines). A cup of formalin solution is added to the water batch, circulated for a few minutes, and allowed to set overnight. The console unit is flushed prior to patient dialysis. The water tank has a plexiglass type lid to prevent odors from permeating the room.

The Hawaii Nurses Association Collective Bargaining Organization, the group representing the professional nurses at the hospital, had sent a questionnaire to 35 nurses at St. Francis dialysis facilities. Twenty (20) questionnaires were completed and were shared with NIOSH with personal identifiers removed. NIOSH's tabulation will be discussed along with the other findings in this study.

IV. HAZARD EVALUATION DESIGN

A. Environmental Criteria

Occupational exposure criteria have been developed to evaluate workers' exposure to chemical substances. Two sources of criteria were used to assess the workroom concentrations: (1) NIOSH Current Intelligence Bulletin No. 34,[1] and (2) the Hawaii-Division of Occupational Safety and Health Administration (DOSH) Standards. These values represent concentrations to which it is believed that nearly all workers may be exposed for up to an eight hour day, 40 hour work week throughout a working lifetime without experiencing adverse health effects. The NIOSH Criteria Document (77-126)[2] recommends a criteria of 0.5 ppm based on its irritative effects; however, the NIOSH Current Intelligence Bulletin No. 34 (April 14, 1981) recommends that occupational exposure be controlled to the lowest feasible limit because of its potential carcinogenicity.

Substance	Permissible Exposure Limit 8-hour Time-Weighted Average	Ceiling Value
Formaldehyde (NIOSH)	---	lowest feasible limit
Formaldehyde (Hawaii-DOSH)	3 ppm	10 ppm (30 min/8 hrs)

ppm = parts of a vapor or gas per million parts of air.

B. Toxicological Effects

Formaldehyde has a sharp odor which can be smelled at very low levels (less than one ppm). The first signs or symptoms noticed on exposure to formaldehyde at concentrations ranging from 0.1 to 5.0 ppm are burning of the eyes, tearing (lacrimation), and general irritation to the upper respiratory passages. Low levels of 0.3 to 2.7 ppm have been found to disturb sleep and to be irritating to a smaller number of people.[1] Higher exposures (10 to 20 ppm) may produce coughing, tightness in the chest, a sense of pressure in

the head, and palpitation of the heart.[3-5] Exposure of 50 to 1200 ppm and above can cause serious injury such as collection of fluid in the lungs (pulmonary edema), inflammation of the lungs (pneumonitis), or death.[2]

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 exposures.

Recent review[7] of airborne formaldehyde as a factor in indoor air pollution problems suggest a wide spread in individual responses to various formaldehyde levels. A small percentage of the population show a hypersensitivity to even low levels of formaldehyde which can include both upper and lower airway symptoms. The exact mechanisms of this "allergy" are unclear.

Formaldehyde has been shown in a study conducted by the Chemical Industry Institute of Toxicology[8] 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.[9] 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.[10]

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[11] 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 the recommendations.[12]

C. Material and Methods

1. Environmental

Seventeen area air samples were collected for formaldehyde from three hemodialysis rooms during either the sterilization of the dialyzers or the dialysis consoles. Air samples were collected using a sampling train (calibrated MSA vacuum pump and a one percent sodium bisulfite impinger solution) through which a known volume of air is passed. The impinger solutions were

subsequently analyzed by NIOSH Physical and Chemical Analytical Method No. 125. The analytical limit of detection is estimated to be 2 micrograms per sample.[13] Sampling locations are shown in Table I.

2. Medical

Besides tabulating the questionnaires supplied by the Hawaii Nurses Association, the NIOSH physician interviewed a sample of workers at each of the three Honolulu-based dialysis units and of those at the Leeward unit based on availability and job title. The technician who maintains the Lixivitron® machines under contract was also interviewed. One of four workers in the training unit was interviewed individually; 6 of 13 in the self-care unit; 7 of 17 in the limited care unit; 6 of 8 in the Leeward unit; and 1 of 14 in the hemodialysis center. Several other workers in the hemodialysis center were engaged in informal discussions. Interviewees included head nurses, other registered nurses, hemotech Is and IIs, and ward clerks.

V. RESULTS AND DISCUSSION

A. Environmental

Concentrations of airborne formaldehyde ranged from 0.04 to 1.28 ppm (Table I). Eight of the seventeen air samples were collected from the self-care unit for one hour periods. Formaldehyde concentrations ranged from 0.06 to 1.28 ppm. Formaldehyde odors were smelled during sterilization by the staff, the NIOSH representative, and one patient being dialyzed near the Lixivitron® system. The odors emanated from the drain line. Six of the seventeen air samples were collected from the Leeward satellite facility during dialyzer sterilization. Formaldehyde air concentrations ranged from 0.04 to 0.28 ppm based on one hour air samples. Formaldehyde odors emanated from the drain line and the gallon containers of formalin solution whose lids were not twisted on tightly. Three of seventeen air samples were collected for 20 minute periods during sterilization of the dialysis consoles in the limited care unit. Formaldehyde air concentrations ranged from 0.12 to 0.28 ppm.

Based on discussions with the employees and observations of employees' work practices, formaldehyde exposures appear to occur for the following reasons. (1) The Lixivitron® systems at the self-care center and the Leeward facility are not isolated from the patients being dialyzed and the dialysis staff, thus whenever there is an accidental spill, the formaldehyde vapors permeate the general room air. (2) The Lixivitron® system and the dialysis console drain lines connecting to the main drain lines are not air tight thus formaldehyde vapors escape to the room air during sterilization of the dialyzers and purging of the dialyzers prior to patient reuse. (3) The dialysis nurses and technicians who sterilize the dialyzer from their units rotate this duty. These individuals periodically get into a rush while managing patients and misread the Lixivitron® instrument panel thus disconnecting the dialyzers prior to the completion of the sterilization process. One incident occurred during the study in which the NIOSH industrial hygienist and the

technician were both splashed with formalin solution. A less than ideal machine design fosters removal of dialyzers before cycle completion. There is a visual countdown which reaches zero slightly before a control light indicates cycle completion. The countdown is much more prominent than the control light.

Although formaldehyde was detected during sterilization of the consoles, it is suspected that the exposures were instantaneous since the lids are maintained over the water batch tanks. Furthermore, it was reported that the general room ventilation system was left turned on through the weekend until Monday morning when the console units were drained and flushed. Doors to the room were also opened to help dissipate any formaldehyde vapors during this time.

B. Medical

Review of the Hawaii Nurses Association questionnaires, which covered units on both the main island and also the outer islands, showed that three out of the twenty responders had no personal problems with formaldehyde, but two expressed concern about long term health effects. Length of employment was two to twelve years. Fourteen reported irritative symptoms without lost work time or the necessity of visits to a physician. Of these five were moderately concerned and nine very concerned about long term health effects. Four responders mentioned serious health problems suggesting allergy and/or hypersensitivity. One, a short time employee, developed dermatitis in spite of the use of gloves. The other three had respiratory problems. One of the three had a history of allergies. The other two reported physician visits and sick leave. Several of the nurses mentioned a six unit facility as having very poor ventilation, but NIOSH investigators did not visit such a facility.

Of the 22 workers individually interviewed by the NIOSH physician, seven reported no current personal problems with the formaldehyde, although one indicated he/she had experienced headaches in the past. Of the 15 with "current" problems, 11 reported upper respiratory and eye irritation which cleared rapidly when exposure ceased, three reported dry skin, four reported headaches of variable duration, one reported repeated colds and bronchitis, and two reported upper respiratory irritation with congestion lasting at least until the next day along with problems of skin break-down on contact with formaldehyde. Two workers mentioned that they had gotten formaldehyde splashed in their eye while cleaning dialyzers. The use of a face shield while using the Lixivitron® was said to be inconvenient and so often omitted.

The fact that many workers experienced transient irritation from the formaldehyde is to be expected. It is of concern that eye protection is not routinely used as splashes from the Lixivitron® appear a constant danger. Two workers' symptoms strongly suggest a hypersensitivity to formaldehyde with prolonged respiratory symptoms and skin problems after exposure. One other worker's repeated colds and bronchitis may also represent a hypersensitivity.

VI. CONCLUSIONS

Although workroom air levels of formaldehyde were generally at low levels, there were instances where levels were undoubtedly higher for brief periods causing discomfort to both staff and patients. When working smoothly the Lixivitron® itself did not contribute to excessive formaldehyde exposure, but formaldehyde was able to escape from drain openings and from minor spills when dialyzers were removed from the Lixivitron®. In addition there was a constant danger of a splash or spill which would greatly increase exposure not only to the person operating the Lixivitron®, but also those in the immediate vicinity.

Cleaning the dialysis consoles also lead to brief increases in formaldehyde exposure, to a large extent controlled by having covers on the tanks. However formaldehyde was able to escape from drain openings. Also there was the possibility of spills, particularly on those units which drew their formaldehyde from an open cup during the sterilizing procedure.

Although most workers were only transiently affected by formaldehyde exposures, a few of the workers suffered prolonged adverse health effects after exposure suggesting a hypersensitivity and/or allergic basis for their complaints. It would be desirable for these individuals to work in areas where exposure is unlikely. Also the Nursing Association questionnaires suggest that there is considerable concern about formaldehyde which should be addressed.

VIII. RECOMMENDATIONS

1. The Lixivitron® system should be isolated from the patients in case of inadvertent spills or disconnecting dialyzers prior to the completion of the sterilization process.

2. Measures should be taken to prevent formaldehyde vapors from entering the room from the main drains serving the Lixivitron® systems and the dialysis consoles. This might be done using a continuous water flush or with tight seals for connecting line and venting to the outside.

3. Specific individuals should be assigned the responsibility for sterilizing the dialyzers as a primary duty to prevent inadvertent spills which occur because of misreading the instrument panel or because the staff gets rushed. This could be on a rotating basis. Employees should be instructed to use the proper protective equipment currently provided which consists of the following: face shield, apron, and gloves.

4. Formaldehyde air monitoring should be conducted subsequent to initiating any of the measures to reduce concentrations (recommendation #2) to determine whether airborne formaldehyde concentrations have been reduced.

5. In-service education on the use and effects of formaldehyde should be conducted periodically.

IX. REFERENCES

1. National Institute for Occupational Safety and Health. Formaldehyde: evidence of carcinogenicity. NIOSH Current Intelligence Bulletin 34. DHHS (NIOSH) Publication No. 81-111. April 15, 1981.

2. National Institute for Occupational Safety and Health. Criteria for a recommended standard...occupational exposure to formaldehyde. Cincinnati, Ohio: National Institute for Occupational Safety and Health. (DHEW publication no. (NIOSH) 77-126), 1977.

3. Committee on Toxicology: Formaldehyde--an assessment of its health effects. National Academy of Sciences, Washington, D.C., March 1980.

4. Loomis TA. Formaldehyde toxicity. Arch Pathol Lab Med. 1975;103: 321-324.

5. Kerfoot EJ, Mooney TF. Formaldehyde and paraformaldehyde study in funeral homes. Am Ind Hyg Assoc J, 1975;36:533-537.

6. Proctor NH, Hughes JP. Chemical hazards of the workplace. Philadelphia: J.B. Lippincott Company, 1978.

7. National Research Council, Indoor Pollutants. National Academy Press, Washington, D.C., 1981. pp 322-338.

8. Chemical Industry Institute of Toxicology. Statement concerning research findings, Docket No. 11109. CIIT, Research Triangle Park, North Carolina, October 8, 1979.

9. Nelson N. Written communication from New York University Medical Center, Institute of Environmental Medicine, to NIOSH, Rockville, Maryland, October 19, 1979.

10. International Agency for Research on Cancer. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans. Vol 29. Lyon: IARC, 1982:367-69.

11. Occupational Safety and Health Administration. OSHA safety and health standards. 29 CFR 1910.1000. Occupational Safety and Health Administration, revised 1980.

12. International Agency for Research on Cancer. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans. Vol 29. Lyon: IARC, 1982.

13. NIOSH Manual of Analytical Methods, DHEW publication no. (NIOSH) 77-157A.

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XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standard 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. International Longshoremen's Workers Union, Local 142.
2. International Longshoremen's Workers Union.
3. St. Francis Hospital.
4. Hawaii Nurses Association, Collective Bargaining Organization.
5. Hawaii Teamsters and Allied Workers Union, Local 996.
6. International Teamsters and Allied Workers Union.
7. U.S. Department of Labor/OSHA - Region IX.
8. NIOSH - Region IX.
9. Hawaii Department of Health.
10. 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

SUMMARY OF AREA AIR SAMPLES COLLECTED FOR FORMALDEHYDE VAPORS

St. Francis Hospital
Honolulu, Hawaii

July 29-31, 1982

DATE July	SAMPLE NUMBER	LOCATION	SAMPLE PERIOD	SAMPLE VOLUME (Liters)	FORMALDEHYDE CONCONTRATION (ppm)
29	F-1	Self Care/top of Travenol # 5841	1150-1255	65	0.06
29	F-2	Self Care/right side of Lixivitron® Odor of formalin from drains	1301-1402	61	0.31
29	F-3	Self Care/left side of Lixivitron® Odor of formalin from drains	1301-1402	61	1.28
29	F-4	Self Care/left side of Lixivitron® Formalin spill occured	1415-1523	68	0.48
29	F-5*	Self Care/right side of Lixivitron®	1415-1523	68	0.66
29	F-6*	Self Care/right side of Lixivitron®	1558-1608	70	0.12
29	F-7*	Self Care/left side of Lixivitron®	1558-1608	70	0.12
29	F-8	Self Care/right side of Lixivitron®	1608-1648	40	0.37
30	F-9	Leeward/left side of Lixivitron®	1103-1203	60	0.23
30	F-10	Leeward/right side of Lixivitron®	1104-1204	60	0.41
30	F-11	Leeward/Nurses' Station	1106-1206	60	0.07
30	F-12	Leeward/left side of Lixivitron®	1203-1303	60	0.28
30	F-13	Leeward/right side of Lixivitron®	1204-1304	59	0.32
30	F-14*	Leeward/Nurses' Station	1208-1304	56	0.04
31	F-15*	Limited Care/Nurses' Station	2227-2247	20	0.12
31	F-16	Limited Care/Middle of Larger Room	2227-2247	20	0.28
31	F-17*	Limited Care/Middle of Small Room	2227-2247	20	0.12
EVALUATON CRITERIA for irritative effects (NIOSH[3]) (Lowest feasible level recommended[1])					0.5

ppm = parts of a vapor or gas per million parts of air.
* = Samples leaked during shipment to laboratory.