

## ABSTRACT

The uses of formaldehyde in a medical center, commercial availability, and possible health effects of exposure are discussed. The new OSHA standard and the need for this study are presented.

Formaldehyde usage is classified according to type, location, and amount of use. A sampling strategy was developed to determine possible exposures throughout the medical center. Available sampling methods and analytical procedures are listed and those chosen are discussed.

Sample results are presented by area according to type of use. A brief discussion of operations being carried out in each area and a summary of sampling results are given. Results of almost all formaldehyde sampling were below new OSHA standards. For those above prescribed OSHA levels, all follow-up samples were below the standard after implementing administrative controls. Recommendations are made to help with continued formaldehyde sampling at the medical center.

The medical center is currently in compliance with the new OSHA requirements. Reliable, efficient, and cost effective means of routine sampling needed to stay in compliance are discussed.

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## ACKNOWLEDGEMENTS

I want to thank Dr. David Fraser for advising me throughout my studies with his invaluable knowledge and experience. I also thank Dr. Wayne Thomann and all the good people in the Environmental Safety Department of the Duke University Medical Center for making this research possible. Thanks go to Dr. Jerry Tulis for his help and expertise and Carolyn Bishop for her guidance and patience with analysis at the OHSG Lab. I thank my former bosses, Dan Brower for giving me the chance to enter the field of industrial hygiene and Rich Familia for inspiring me to return to school for my Master's degree.

I especially appreciate the chance to study industrial hygiene at UNC and the financial assistance from the Occupational Health Traineeship which helped make it possible. Lastly, I would most like to thank my mom, family, friends, and Mr. Brian Daisy for the emotional and psychological support needed to complete my degree.

## I. INTRODUCTION

A. Formaldehyde is one of the most widely used chemicals in industrial and laboratory settings.<sup>1</sup> It is used as a preservative, a hardening and reducing agent, a corrosion inhibitor, and in the manufacturing of resins and other compounds. In industry, it can be used in the manufacturing of textiles, fertilizers, inks, glue, paper, wood, rubber, and pharmaceuticals. In health related occupations it is used by pathologists, autopsy technicians, morticians, anatomists, nurses, and surgeons for tissue preservation, sterilization, and decontamination. It has been estimated that up to one-third of all people occupationally exposed are in medical or other health related services.<sup>1</sup> Its wide and extensive use in the medical setting is due to its attributes as a fixative, preservative, disinfectant, and decontaminating agent.

B. Formaldehyde was first synthesized in 1859 by Alexander Butlerov. Nine years later A.W. Hoffman identified formaldehyde when he passed an air-methanol mixture over a hot platinum spiral. The commercial manufacturing of formaldehyde began in 1889 and had reached over five billion pounds per year by 1986.<sup>8</sup>

Formaldehyde is a colorless gas that is available commercially in saturated solutions of 37.0 to 40.0% of formaldehyde gas by weight in water. The solution is commonly called formalin and is considered 100.0% formalin, therefore one part formalin in nine parts of water is not a 4.0% solution but a 10.0% solution. Commercial formalin usually contains 10.0 to 15.0% methanol to increase shelf life and keep formaldehyde from combining with oxygen to produce formic acid.

C. Fixing fluids act as tissue preservatives, inhibiting autolytic changes and bacterial growth.<sup>2</sup> Fixatives help to harden tissue by either crosslinking or denaturing and precipitating protein in them. They also inactivate the enzymes of cells, thereby avoiding digestion of proteins and other macromolecular substances in the cell which would lead to postmortem degeneration of tissue.<sup>3</sup> Fixatives also kill bacteria and other disease causing organisms which might be present in the tissue.

A 10.0% buffered formalin solution is the most popular fixing agent in laboratories. Formalin's advantages include that it is relatively inexpensive, penetrates rapidly, does not overharden tissue, preserves fatty tissue, and permits the use of a wide assortment of staining methods.

For larger specimens, as in whole bodies, embalming prevents bacterial and enzymatic decomposition of tissues.



The fixative is distributed to all parts of the body via the circulatory system. The use of formaldehyde for embalming purposes increased dramatically when toxic metallic salts were banned in the late 1800's.<sup>4</sup> Embalming fluids typically contain 2.0% formalin, 2.0% phenol (to counteract the formaldehyde bleaching effect), 6.0% glycerin (to soften tissue and retard drying), 20.0% of 95.0% alcohol, and 70.0% water.

Formaldehyde has long been used as a disinfectant. The application of formaldehyde for inactivation of microorganisms was practiced before the turn of the century.<sup>5</sup> One of the first uses of formaldehyde vapor was to fumigate sick rooms.<sup>6</sup>

Formaldehyde is believed to inactivate bacteria, fungi, molds, and yeasts by combining with amino groups of proteins. In dilutions of 0.5 to 0.75%, formaldehyde kills aerobic bacteria in six to twelve hours and anaerobic bacteria in two to four days. It is used in place of heat sterilization in hemodialysis units to sterilize the dialysis machines. This is done by adding approximately 140.0 milliliters (ml's) of a 5.0% formalin solution to the machine through a suction line and letting it sit overnight. In some machines approximately 10.0 to 15.0 ml's of 37.0% formaldehyde is sucked in and left overnight.

Formaldehyde is also used to decontaminate biological safety cabinets, incubators, refrigerators, laboratory



rooms, or other enclosed spaces. It has become the chemical of choice for space disinfection.<sup>7</sup>

Formaldehyde can be generated from aqueous formalin solutions containing 37.0 to 40.0% formaldehyde by heating or vaporizing the solution or by mixing potassium permanganate to formalin in a 40:60% by weight volume ratio to cause an exothermic chemical reaction. Sodium dichromate, bleaching powder, potassium or sodium chlorate, or caustic soda can be used with appropriate ratios in place of potassium permanganate. The preferred method of generating formaldehyde gas is by heating paraformaldehyde, which is a solid polymer containing 91.0 to 99.0% formaldehyde. Heating is done in an electric frying pan or deep fat cooker at temperatures above 150.0 degrees centigrade in an atmosphere of 21.0 degrees centigrade or greater and a relative humidity of 60.0% or more.

For restricted laboratories where infectious agents are being used, decontamination must be done when that area is to become an unrestricted general use laboratory. In the case of biological safety cabinets, a routine performance certification may be necessary every six to twelve months. A decontamination of the cabinet must be done if infectious agents were used in order to enter the cabinet at minimal risk of infection. In the subject study, extensive formaldehyde sampling was done during the decontamination of biological safety cabinets and will be discussed in greater detail later.

Formalin is also used on a smaller scale for such operations as animal perfusions, northern blot gel preparation, pap smear samples, and blood sample tray preparation. In all these cases a 10.0% buffered formalin solution is used, either pre-made by the Pharmacy Department or diluted as needed prior to use.

## II. HEALTH EFFECTS

Various health effects of inhalation and dermal contact with formaldehyde have been reported. Formaldehyde is a primary irritant, it is toxic, and it is regarded as an occupational carcinogen. Responses have been produced upon ingestion, inhalation, and adsorption through the skin. Symptoms range from minor eye irritation to pulmonary edema and death upon ingestion.

A. Among the first symptoms seen are burning of the eyes (lacrimation) and irritation of the upper respiratory tract. Airborne concentrations as low as 0.1 parts per million (ppm) can cause eye, nose, and throat irritation.<sup>9</sup> Stephens used human subjects to determine an eye irritation threshold of 1.0 ppm for five minutes.<sup>10</sup> Morrill determined the threshold for eye irritation to be between 0.9 and 1.6 ppm and Bourne and Seferian reported eye irritations at concentration as low as 0.13 to 0.45 ppm.<sup>11</sup> This threshold limit may be impossible to determine quantitatively due to variation in individual responses, but most studies seem to support the lower ranges reported by Bourne and Seferian.

The inhalation of high concentrations of formaldehyde can be extremely dangerous. A concentration of 100.0 ppm is

immediately dangerous to life and health (IDLH) and is potentially fatal if exposure continues for thirty minutes or more.

B. It has been noted that dermal diseases and disorders account for over a third of all reportable occupational diseases, and are a serious problem in the United States workplace.<sup>12</sup> Formaldehyde is one of the most common causes of occupational skin disease.<sup>12</sup> The major effects of formaldehyde on the skin are the development of both irritant dermatitis and sensitization leading to allergic contact dermatitis. It may also cause urticaria (hives).<sup>13</sup>

Irritant dermatitis results from a direct injury to the skin and is more prone to occur or persist in atopic individuals, encompassing 20.0 to 30.0% of the general population.<sup>14</sup> Cases of primary skin irritation due to contact with formaldehyde have included erythema, inflammation of skin folds, decay of fingernails, and urticaria. Irritant reactions are more likely to occur under conditions of low humidity, repeated wetting and drying of the skin, temperature extremes, mechanical trauma, pre-existing skin disease, and concomitant exposure to other irritating substances. Repeated exposure to formaldehyde can cause development of hypersensitivity.<sup>15</sup>

According to Rostenberg, a 10.0% solution of formalin is a potential eczematous sensitizer.<sup>16</sup> Patch tests using 0.5%

formaldehyde showed positive responses in five nurses who had developed papules and vesicles on their fingers and faces after handling thermometers kept in a 10.0% formalin solution. Horsfall showed that 10.5 ppm of formaldehyde in air can produce skin effects in sensitive individuals.<sup>17</sup> Experiments by Jordan showed that the level of formaldehyde in liquid products must be reduced to 0.3% before the majority of sensitized individuals can tolerate them.<sup>18</sup> Once sensitized, a person may react to skin contact with any form of formaldehyde released from resins or other compounds.

C. Formaldehyde is readily absorbed in the respiratory system when inhaled because of its high solubility and reactivity. It is thought that the upper respiratory tract removes 95.0% of airborne formaldehyde and only 5.0% reaches the bronchioles.<sup>19</sup> This is supported by the fact that most of the effects of formaldehyde on the respiratory system are in the upper portion of the tract. Inhalation of formaldehyde has been shown to cause ciliostasis of the tracheal mucosa which could hinder the respiratory system's ability to deal with environmental insults. Interstitial inflammation of the lungs of various animals upon exposure to formaldehyde was shown by Coon.<sup>20</sup> Kane and Alarie have demonstrated a decrease in respiratory rates in mice, which is a characteristic of exposure to irritants.<sup>21</sup> It was

found by Amdur that guinea pigs exposed to 0.3 ppm to 50.0 ppm of formaldehyde had increased resistance to air flow and reduced compliance of the lungs.<sup>22</sup> Histopathologic changes were found in the nasal turbinates of rats exposed to formaldehyde concentrations from 2.0 to 15.0 ppm for thirty hours per week over an eighteen month period. Epithelial dysplasia and squamous metaplasia were found in many rats at all exposure levels. Inflammation of nasal mucous membranes was found in some exposed animals.<sup>23</sup>

D. Long term inhalation of formaldehyde gas is associated with nasal cancer in experimental animals.<sup>24</sup> Some studies in humans exposed to formaldehyde have demonstrated increased nasal and nasopharyngeal cancer.<sup>29</sup> In 1983 the American Conference of Governmental Industrial Hygienists (ACGIH) determined formaldehyde to be a suspect human carcinogen and in 1987 the Environmental Protection Agency (EPA) classified formaldehyde as a "B1 probable human carcinogen." This has led the Occupational Safety and Health Administration (OSHA) to regard formaldehyde as an occupational carcinogen.

Preliminary results were released in 1980 by the Chemical Industry Institute of Toxicology (CIIT) from a chronic toxicity and carcinogenicity study of inhaled formaldehyde in rats and mice.<sup>24</sup> These results showed that rats exposed to 15.0 ppm formaldehyde for six hours per day,



five days per week over eighteen months developed squamous cell carcinomas of the nasal cavities. The study was completed in 1981 and final results published in 1983 showed nasal cancers in rats exposed to 5.6 and 14.3 ppm, benign nasal tumors in rats exposed to 2.0 ppm, and nasal cancer in mice exposed to 14.3 ppm formaldehyde for six hours per day, five days per week for twenty-four months.<sup>25</sup>

In a separate study done by researchers at New York University, twenty-five out of one hundred rats developed squamous cell carcinomas of the nasal cavity after exposure to 14.0 ppm formaldehyde for six hours per day over 814 days, corroborating CIIT's finding that formaldehyde is an animal carcinogen.<sup>26</sup> Horton found no tumors of the lung after exposing mice to levels of formaldehyde ranging from 40.0 to 700.0 ppm for three hours per week for up to thirty-five weeks.<sup>27</sup>

Current epidemiologic studies provide little evidence of increased risk of nasal cancer from formaldehyde exposure but do indicate excesses of leukemia and cancers of the brain and mouth.<sup>28</sup> Further studies are underway although most epidemiologic studies are not yet completed. OSHA believes that overall cancer mortality is not an appropriate evaluation to determine causal relationships.<sup>29</sup>

Gofmekler observed an increase of pregnancy in rats by approximately 15.0%, a decrease in lung and liver weight in offspring, and increased weights of the thymus, heart,

kidneys, and adrenals upon exposing pregnant mice to 0.8 and 0.01 ppm formaldehyde. The most marked changes were in the kidney.<sup>30</sup> After review of a report by Olsen and Dossing and a report by Shumilina, OSHA stated that there appeared to be little, if any, risk of reproductive or teratogenic effects from the levels of exposure to formaldehyde typical of the occupational environment.<sup>31</sup>

Other biological effects have been noticed in animal research. Korean studies have indicated increased arthritis in rabbits upon intra-articular injections of formaldehyde.<sup>32</sup> In male mice chronic exposure to formaldehyde is associated with liver cytoplasmic vacuolar change and testicular degeneration.

E. Throughout the years both the increased use of formaldehyde and awareness of potential health effects have brought about changes in the standard for permissible exposure. The changes made in the OSHA standard reflect the experimental evidence showing formaldehyde first as a cytoplasmic poison causing irritation and dermal effects, later a systemic poison causing sensitization, and most recently a carcinogen causing nasal cancer in rats.

In 1943, Henderson and Haggard suggested an airborne exposure limit for formaldehyde of 20.0 ppm.<sup>33</sup> In 1946, the ACGIH set a 10.0 ppm threshold limit value (TLV) for formaldehyde which was lowered to 5.0 ppm in 1948. The

ACGIH later set a 5.0 ppm ceiling limit in 1963, not to be exceeded at any time. OSHA adopted a 3.0 ppm eight hour time weighted average (TWA) and a 5.0 ppm ceiling limit in 1971 based on 1967 American National Standards Institute (ANSI) standards. In 1973, the ACGIH lowered their recommended ceiling limit to 2.0 ppm and as early as 1983 recommended a 1.0 ppm eight hour TWA TLV.

F. The new OSHA formaldehyde standard which became effective February 2, 1988 is due in large part to the evidence of its carcinogenicity. The latest standard is 1.0 ppm eight hour TWA permissible exposure level (PEL), 2.0 ppm fifteen minute short term exposure level (STEL), and a 0.5 ppm eight hour TWA action level (AL).<sup>34</sup> The peak allowable exposure of 10.0 ppm for no more than thirty minutes was revoked.

The new standard carried with it a six month compliance period meaning that by August 2, 1988 exposure determination, medical surveillance, and emergency procedures must be completed. The deadline for laboratories was extended until September 2, 1988.<sup>34</sup>

### III. OBJECTIVES

This study was conducted to demonstrate how a modern medical center could meet the requirements for compliance of OSHA standards in a way that might serve as a model for other medical centers. An additional objective was to compare some of the formaldehyde sampling methods available and make recommendations for continued and routine sampling.

The first objective was to plan a comprehensive survey of formaldehyde users at the medical center. A complete and thorough survey is necessary before planning a sampling strategy.

#### IV. PERFORMING THE SURVEY

A. Because of formaldehyde's widespread and often sporadic use, developing a sampling strategy at a medical center can be difficult. There are many small unrelated departments using formalin in their own unique way. Accomplishing an adequate survey was critical in developing a good strategy.

The survey started by determining the distribution of formaldehyde within the medical center. By finding out from purchasing who is buying formaldehyde in any form, one can determine who is using it. In the case of this medical center, the Central Pharmacy Department makes up 10.0% buffered formalin from 37.0% formaldehyde and packages it in one gallon containers. A lot of one hundred to two hundred one gallon containers is periodically brought to the Materials Management Department where it is distributed to the departments that use it. Obtaining a list from Materials Management of departments that had checked out the formalin in the past six months helped identify users. An example of this list can be found in Appendix Number One. This list, along with information from purchasing as to persons buying 37.0% formaldehyde or paraformaldehyde, gave a starting point to help locate users of formaldehyde.

With this information, contact was made by phone with each person or department on each list. Information was gathered and recorded to further determine formaldehyde usage. Information included what formaldehyde was being used for, how much (quantity/time), how often, how long during the day, how it was used (laboratory conditions, hoods, personal protective equipment), what the current status was, who was responsible for use, location of use (building, laboratory number), and a contact name and phone numbers. An example of the table used to gather this information appears in Appendix Number Two.

It was determined from this information that formaldehyde use was widespread, sometimes heavy, but more often sporadic and minimal.

B. With the usage information in hand, a walk-through survey was conducted. Each area using formaldehyde was visited for inspection and to obtain further information from the employees and supervisor of that area. The number of people in that area and laboratory conditions were noted and possible sample scheduling or further contact was established.

Screening was then done in the heavy use areas by taking grab samples using National Draeger detection tubes.<sup>35</sup> The grab sample results gave an idea of exposure concentrations in these areas and helped determine how much further sampling was needed. These results are listed in Table 1.



Table 1  
 Draeger Tube Formaldehyde Grab Samples

<u>Area Sampled</u>	<u>Date</u>	<u>PPM</u>	<u># of Tubes</u>	<u>Activity</u>
South Path. Lab (M324)	6-6	<0.5	2	General
South Hist. Lab (M329)	6-6	~0.7	1	"
Autopsy Lab (M321)	6-6	<1.0	2	"
Autopsy Storage Room	6-6	1.0-1.4	1	"
Pharmacy Vault	6-6	<0.5	1	"
North Path. Lab (3544)	6-7	<0.5	3	"
Dial. West	6-7	<0.5	2	"
Dial. Mix Room	6-7	~1.5	1	Dilution
Dial. Main Room	6-7	~0.7	1	General
North Dial. (9224)	6-8	~1.0	1	"
South Hist. Lab (M329)	6-8	~1.0	1	"
Dial. Main Room	6-8	<0.2	2	"
Dial. Home Train Room	6-8	<0.2	1	"
South Hist. Lab	6-8	~0.5	2	Dumping
Jones Lab #249	6-16	0.0	1	BSC Decon.
Dial. Mix Room	6-20	0.5-1.0	3	Dilution
Dial. West	6-21	0.0-0.5	3	"
Dial. North	6-24	~1.0	1	"

Path. = Pathology

Hist. = Histology

Dial. = Dialysis

Care must be taken in using these results, as Balmat found that monitoring for formaldehyde with the Draeger tube can produce excessively high results.<sup>36</sup> Another study indicated the same problem at low and high levels of humidity and temperature.<sup>37</sup> However, to err on the high side is acceptable when using the tube as a screening device and the information obtained is still very useful in that context.

A master's report submitted to the faculty of the University of North Carolina by Jolley showed that the Draeger tube can also be used to measure peak exposures during formaldehyde use.<sup>38</sup> Jolley also used the Miran-1A Ambient Air Analyzer to measure peak exposures. The Miran can also be used as a pre-sample screening device in areas of high formaldehyde usage.

C. The first step in planning a strategy is knowing your resources. Becoming familiar with your work area, colleagues, and what is available to you is essential. The most critical issue is of course your budget, as most of your plans revolve around what can or cannot be afforded. Although a good study will have no financial boundaries, this is not always the case.

With the usage information and the screening results, where and when to sample was then determined. OSHA states that to protect the health of employees, exposure

measurements must be unbiased and representative of employee exposure.<sup>39</sup> A well designed sampling strategy showing that all employees are exposed below the PEL with a 95.0% certainty is sufficient evidence that the exposure limits are being met, provided approved analytical methods are used for measurements.<sup>39</sup>

There is no best measurement strategy for all situations. Some elements to consider when developing a strategy include the availability and cost of sampling equipment and analytical facilities, location and work operations of employees, intraday and interday variations in the process, number of samples needed, and precision and accuracy of sampling and analytical methods. Systematic changes in the exposure of an employee to formaldehyde can be caused by the employee changing patterns of movement in the workplace, closing or opening doors and windows, ventilation changes from season to season, changes in production processes or work habits of employees, and decreases in ventilation efficiency or failure of engineering controls.

It was decided for this study to immediately and periodically sample the heaviest users. Areas such as Autopsy, Surgical Pathology, and Dialysis were sampled much more frequently than others because of their heavy usage. The number of people exposed to formaldehyde in their work practices determined how many samples were taken in each

area. Smaller use areas that had similar work practices were included together. Worst case scenarios were then determined and sampled. Areas were broken down into heavy, moderate, and low use by frequency or volume of use (Table 2). Type of use was then described for each category. Table 2A shows how each area was classified as to type of use.

Area samples may not be representative of employee exposure. Personal samples better describe actual employee exposure and should be used to document them. However, area samples were taken in some cases to assess general room concentrations, to determine migration of formaldehyde into nearby areas, and in one specific area where formaldehyde exposure occurs but is used by more than one person. If there was an area where formaldehyde was used sporadically throughout the day by a number of employees entering and leaving that area, it was assumed that if the formaldehyde concentration was below the action level in that area and any one person working in that area would not be exposed over the action level.

OSHA states that if employees may be exposed above the action level, the employer must measure the exposure. In this study exposure was measured initially and if the exposure was above the action level, further sampling was done. If exposure was above the PEL, recommendations were made to lower exposure and subsequent sampling was done.

Table 2  
Formaldehyde Concentrations by Usage

<u>Area</u>	<u>Type of Use</u>	<u>Average PPM</u>
<u>Heavy Usage</u>		
Autopsy Lab	Tissue Preservation	0.12
Path./Hist. Lab	" "	0.29
Pharmacy	Dilution	0.10
Autopsy Lab	"	0.19
Dialysis	"	1.84
Bio. Safety Cabinet	Decontamination	0.23
Dialysis	Sterilization	<u>0.10</u>
		0.41 Avg.
<u>Moderate Usage</u>		
Dialysis	Sterilization	0.10
Dial. West/North	Dilution	0.0
Dept. of Medicine	Biopsies	0.13
Allergy. Pulm. Clinic	"	0.10
Inst. of All. Inf. Dis.	Preservation	<u>0.13</u>
		0.09 Avg.
<u>Low Usage</u>		
Neuropathology	Preservation	0.03
Heart, Lung, & Blood Inst.	"	0.0
Anat. Div. of OBGYN	Perfusion	0.03
Micro./Imm. Lab #316	Northern Blot Gel	0.03
"	Gel Transfer	0.21
RP #3 Lab #109	Blood Trays	0.0
"	Reading Trays	<u>0.0</u>
		0.04 Avg.

Table 2A  
Classification by Type of Use

<u>Tissue Preservation</u>		<u>Dilution</u>		<u>Sterilization/Decontamination</u>	
Autopsy Lab	8	Central Pharmacy	8	Bio. Safety Cabinet	6
Pathology Lab	7	Autopsy Lab	7	Dialysis Main	4
Histology Lab	4	Dialysis Main	5	Dialysis North	3
Dept. of Surgery Lab #125	3	Dial. North/West	3	Dialysis West	2
Neuropathology	3	Vivarium	2	Surgical Diag. Clinic	0.5
Vivarium	2	VA Pathology Lab	1	Surgical Out-Patient	0.5
Heart, Lung, Blood Inst.	2	Micro/Imm Dept (3)	1		
Delivery Room	1	<u>Perfusions</u>		<u>Northern Blot Gels</u>	
VA Pathology Lab	1			Micro/Imm Dept Lab #316	3
Hyperbaric Clin Program	1	Hyperbaric Clin Prog	2	" Lab #311	2
Rheum/Imm Lab #369 Carl	0.5	Dept. Med. Lab #350	2	" Lab #350	2
Div. Neurosurgery (Busse)	0.5	Div of Neurosurgery	1	" Lab #328	1
Emergency Department	0.5	Dept of Micro/Imm	1	Dept of Med/Neur. Div.	
Surgical Diag. Clinic	0.2	Anatomy Div of OB/GYN	1	RP #1	1
				" RP #3	1
Surgical Out-Patient Clin	0.2				
<u>Blood Tray Prep.</u>		<u>Biopsy Specimens</u>		<u>Pap Smears</u>	
Dept of Micro/Imm RP #3	3	Dept of Med Endoscopy	4	Allergy & Pulmonary Clin	2
VA Pathology Lab	1	Allgy & Pulm. Clinic	2	Emergency Dept.	1
		Surgical Diag. Clinic	1		
<u>Reagent Prep.</u>					
Chemistry lab #341	0.5	Use Scale*			

Low 1 ————— 10 Heavy  
Moderate

\* Compared within type of use



## V. SAMPLING AND ANALYSIS

A. Accurate and precise measurements of formaldehyde in the workplace is becoming more important as the health effects are better understood. Formaldehyde sampling methods are numerous, varied, and still being researched and refined. One of the earliest methods for collection and analysis of formaldehyde in air was published in 1943.<sup>40</sup> Growing concern of the potential adverse health effects associated with formaldehyde has generated renewed interest in sampling and analytical methods. Table 3 lists the methods available for formaldehyde sampling and analysis. Table 4 shows some operational parameters and Table 5 lists some advantages, disadvantages, and limitations.

The best known and most sensitive collection method is the impinger with solution. Many different solutions can be used in the impinger to collect formaldehyde vapor including Girard T Reagent, distilled water, 3.0% hydrogen peroxide in 0.025 N sodium hydroxide, and 2,4 dinitro-phenylhydrazine (DNPH) plus perchloric acid. The most common solution and the one suggested in the National Institute of Occupational Safety and Health (NIOSH) method 3500 is 1.0% sodium bisulfite.<sup>44</sup> This NIOSH method 3500 was originally adapted

TABLE 3. Methods Available for Formaldehyde Sampling and Analysis\*

<u>Method</u>	<u>Govt No.</u>	<u>Analytical Scheme</u>
Chromotropic Acid (CTA)	P&CAM 125	Collect in impinger with distilled water; add 1% chromotropic acid (CTA) followed by concentrated sulfuric acid; measure spectrophotometrically at 580 nm.
	P&CAM 235	Collect on alumina sorbent; desorb immediately into 1% solution of methanol in water; determine formaldehyde by CTA method.
Diffusive Monitors		Formaldehyde collected in sodium bisulfite solution in passive sampling badge; formaldehyde in solution determined by CTA method (Dupont).
		Formaldehyde collected on bisulfite-impregnated pad in passive sampling badge; formaldehyde-bisulfite adduct eluted with water; formaldehyde determined by CTA method (3M).
Pararosaniline (PR)		Formaldehyde collected in water in an impinger; mix with solution of tetrachloromercurate II plus sodium sulfate; add pararosaniline solution and measure spectrophotometrically at 560 nm.
		Formaldehyde collected in impinger with deionized water; add acidified pararosaniline followed by sodium sulfite; measure spectrophotometrically at 570 nm.
		Formaldehyde collected on 13 X molecular sieve, desorbed with deionized water; formaldehyde determined by PR method.
2,4 Dinitro- phenylhydrazine (DNPH)		Formaldehyde collected in bubblers containing DNPH in hydrochloric acid, which react to form insoluble precipitate; dissolve filtered precipitate in acetonitrile and measure, using high performance liquid chromatography with UV detection.
		Formaldehyde collected in impingers containing 2,4-DNPH plus perchloric acid (catalyst); measure hydrazone formed using HPLC with UV detection.

TABLE 3. (Continued)

<u>Method</u>	<u>Govt No.</u>	<u>Analytical Scheme</u>
2,4 Dinitro-phenylhydrazine (DNPH) (con't)		Collect formaldehyde on silica gel coated with DNPH; desorb with acetonitrile; measure with HPLC with UV detection.
		Formaldehyde collected on XAD-2 resin coated with 2,4 DNPH; hydrazone eluted with ethyl ether and measured using gas chromatography with flame ionization detection.
3-Methyl-2-benzothiazolone (MBTH)		Formaldehyde collected on filter paper, silica gel, or in impinger coated with/containing MBTH; add ferric chloride to form blue cationic dye; measure spectrophotometrically at 635 nm or 670 nm.
		Collect formaldehyde in bubbler containing MBTH; add ferric chloride and sulfamic acid to form blue cationic dye; measure spectrophotometrically at 620 nm.
Girard T Reagent	NIOSH 5327	Collect formaldehyde in impinger with Girard T reagent; measure formaldehyde-Girard T reagent derivative by polarography.
Hydrazine ( $H_2NNH_2$ )		Collect formaldehyde in bubbler using 10% methanol in water; react solution with hydrazine ( $H_2NNH_2$ ) to form formaldehyde-hydrazone; measure derivative by differential pulse polarography.
Oxidative Charcoal	NIOSH 318	Collect formaldehyde on charcoal impregnated with oxidizing agent; desorb in 0.1% hydrogen peroxide solution; measure formate ion by ion chromatography.
N-Benzylethanolamine (BAE)	NIOSH 354	Collect formaldehyde on charcoal impregnated with BAE; the benzloxazolidine formed is desorbed with isooctane and measured using capillary-column gas chromatography with flame ionization detection.
2-HMP	OSHA 52	Formaldehyde in air drawn through XAD-2 sorbent coated with 2-(hydroxymethyl) piperidine to form oxazolidine; oxazolidine desorbed with toluene and measured using packed column gas chromatograph with nitrogen-phosphorous flame ionization detector (NPD).

TABLE 3. (Concluded)

<u>Method</u>	<u>Govt No.</u>	<u>Analytical Scheme</u>
Basic Peroxide		Collect formaldehyde in impingers containing 3% hydrogen peroxide in 0.025 N sodium hydroxide; measure formate ion formed using ion chromatography.
5,5'-dithiobis (2-nitrobenzoic acid) DTNB		Collect formaldehyde in impingers containing 0.025 M pH 7 phosphate buffer plus $\sim 10^{-4}$ M EDTA; excess bisulfite is added to the collected samples to form the 1:1 formaldehyde bisulfite adduct; the excess bisulfite is reacted with DTNB to form a product measured spectrophotometrically at 412 nm; the amount of bisulfite what has reacted with the formaldehyde is then calculated by difference.

\*E. R. Kennedy, A. W. Teass, and Y. T. Gagnon, "Formaldehyde Analytical Chemistry and Toxicology," V. Turoski, Editor, Advances in Chemistry Series 210, 1985. Expanded by Neefus and Gutknecht, Research Triangle Institute, Research Triangle Park, N.C., 1988.

TABLE 4. Operational Parameters for Available Methods\*

Method	Sampler Type	Sample Rate (L/min)	Sample Volume (L)	Measure Limit (ug/samp)	Limit of Quantitation (ppm)
Chromotropic Acid	impinger	1.0	60	1.5	0.020
	sorbent tube, alumina	0.2	6	1.0	0.14
Diffusive monitors	badge	0.0017	0.8	0.25	0.25
	badge	0.0569	27	0.8	0.02
Pararosaniline	impinger	5.6	28	2.0	0.06
	bubbler	1.0	60	1.8	0.02
	molecular sieve sorbent tube	2.0	30	1.0	0.02
2,4-DNPH	bubbler	0.5-1.5	30	0.05	0.002
	impinger	0.5-1.5	31	0.25	0.007
	silica gel tube coated	0.20	20	2.5	0.11
	XAD-2 tube coated	0.20	5	0.64	0.11
MBTH	impinger	0.5	250	5.0	0.016
	bubbler	0.5	250	2.0	0.007
Girard T	bubbler	0.1-0.2	18	6.0	0.25
Hydrazine	bubbler	0.7-1.2	30	1.8	0.008
Oxidative charcoal	coated charcoal	0.2	100	3.0	0.02
BAE-coated tube	XAD-2 coated	0.08	38	2.0	0.04
2-HMP	XAD-2 coated	0.1	24	0.48	0.013
Basic Peroxide	impinger	0.5	30	2.0	0.05
DTNB	impinger	0.26-5	4	0.12	0.009

\*E. R. Kennedy, A. W. Teass, and Y. T. Gagnon, "Formaldehyde Analytical Chemistry and Toxicology," V. Turoski, Editor, Advances in Chemistry Series 210, 1985. Expanded by Neefus and Gutknecht, Research Triangle Institute, RTP, N.C., 1988.

TABLE 5. Advantages, Disadvantages, and Liabilities of Available Methods\*

Method	Govt No.	Advantages	Disadvantages	Limitations
Chromotropic Acid	P&CAM 125	Simple instrumentation; sensitive	Phenol, alcohols, olefins interfere; requires work with conc. sulfuric acid; absorbance of final solution increases with time	Impingers difficult to use
	P&CAM 235	Solid sorbent for collection; HCHO in methanol eluent stable for one month	CTA method; loss of HCHO on alumina sorbent after one hour	Desorption efficiency about 85%
Diffusive Monitors	Dupont	Easy to use; exposed badge can be stored two weeks; humidity has no effect.	CTA method	Response time about 3 seconds; should detect 15-30 minute peak exposure levels.
	3M	Easy to use	CTA method; badges unstable at high temperature	Sorbent must be kept moist--problems at low R.H.
Pararosaniline (PR)		Selectivity superior to CTA method, 2x detection limit over CTA	Small aldehydes, sulfite, SO <sub>2</sub> , cyanide, hydroxylamine interfere; PR tends to precipitate	Impingers difficult to use; 13x molecular sieve has 15 minute sampling limit at 80% R.H.
2,4 Dinitro-phenylhydrazine (DNPH)		Low detection limit (0.1ng); no other organic interference	Requires complex instrumentation (HPLC)	Must desorb within 1-2 days when collecting on silica gel coated with 2,4-DNPH

\*E. R. Kennedy, A. W. Teass, and Y. T. Gagnon, "Formaldehyde Analytical Chemistry and Toxicology," V. Turoski, Editor, Advances in Chemistry Series 210, 1985. Expanded by Neefus and Gutknecht, ATC, ATP, N.C., 1977



TABLE 5. (Continued)

<u>Method</u>	<u>Govt No.</u>	<u>Advantages</u>	<u>Disadvantages</u>	<u>Limitations</u>
3-Methyl-2-benzothiazolone (MBTH)		Samples stable for two weeks	Non-selective for aldehydes	Impingers difficult must measure developed color within one hour
Girard T Reagent	NIOSH S327	None	Complex instrumentation (polarograph) requires training in electrochemistry; polarography not very selective	Impingers difficult to use
Hydrazine ( $H_2NNH_2$ )		No phenol interference; relatively rapid procedure; no interference from acrolein, acetaldehyde and benzaldehyde	Complex instrumentation (pulse polarograph); electrochemistry lacks selectivity	Impingers difficult to use
Oxidative Charcoal	NIOSH 318	High sample capacity; exposed tube can be stored one month; solid sorbent easy to use	Formate, formic acid interfere; complex instrumentation (IC)	None
N-Benzylethanolamine (BAE)	NIOSH 354	14 day sample stability; solid sorbent easy to use; GC offers high selectivity	Complex instrumentation (GC)	Tube (BAE-coated chromosorb 102) capacity 150 $\mu$ g at 80% R.H.; compounds having equivalent GC retention times will interfere.
2-(hydroxymethyl) piperidine (HMP)	OSHA 52	Solid sorbent easy to use; GC offers high selectivity; samples stable 18 days	Complex instrumentation (GC); commercial tubes not available	Compounds containing nitrogen or phosphorous could interfere if GC retention time equivalent

TABLE 5. (Concluded)

<u>Method</u>	<u>Govt No.</u>	<u>Advantages</u>	<u>Disadvantages</u>	<u>Limitations</u>
Basic Peroxide		High sample capacity	Formate, formic acid interfere; complex instrumentation (IC)	Impingers difficult to use
5,5'-dithiobis (2-nitrobenzoic acid) DTNB		Simple instrumentation	Color-forming reaction must be timed exactly	Impingers difficult to use

from the Intersociety Committee and designated P + CAM 125.<sup>42</sup> This method is considered "active" because air is drawn through the impinger at a known flow rate by a calibrated sampling pump.

Alternatives to the impinger sampling method have been sought due to the awkwardness of wearing an impinger and the likelihood of liquid spillage or breakage of the glass impinger. There are also more interferences with the impinger method by such chemicals or air contaminants as phenols, alcohols, and olefins.

Another active method is drawing air at a known flow rate through a sorbent tube. Many different sorbents have been used, most coated or impregnated with specific compounds. Since charcoal alone as a sorbent was found to be ineffective due to low recovery, many different sorbents have been tried and are still being developed. Some of these sorbents include alumina, 13X activated molecular sieves, silica gel or XAD-2 resin coated with 2,4 DNPH, and XAD-2 coated with 2-(hydroxymethyl)piperidine. The sorbent suggested by NIOSH method 2502 (P+ CAM 354) is chromosorb 102 or XAD-2 coated with 2-(benzylamino)ethanol.<sup>43</sup> These tubes are available commercially as Supelco ORBO-22 sorbent tubes. A new tube has just been developed and tested and consists of silica gel impregnated with 20.0% sodium bisulfite.<sup>44</sup>

Another alternative to both impinger sampling and active sampling in general is known as passive or diffusive

monitoring. This method is by far the easiest and simplest to use but can have many limitations.

This method consists of using a passive sampling badge that does not draw air in actively but by diffusion. The badge is less cumbersome to wear for the employee and can be used in area sampling for longer periods of time over several work shifts if needed. It is lightweight, compact, and less restrictive. It is simply clipped to the employee's collar or set in an area where there is sufficient air movement. If the badge is put in an area without sufficient air movement or where the air is stagnant, diffusion may be inefficient causing inaccurate monitoring. Other limitations include extreme temperatures, extreme relative humidities, shelf life, post-use storage capabilities, and inability to use for short term fifteen minute exposures.

Different types of commercially available badges include the DuPont Series II type C-60, 3M 3720 and 3721, Kem Medical Vapor-trak, and the Air Quality Research PF-20. The DuPont C-60 badge contains a sodium bisulfite solution and the 3M, Kem Medical, and Air Quality Research badges all use a bisulfite impregnated pad. Each badge type has its own advantages and limitations and should be carefully reviewed before choosing a particular badge.

A wide variety of analytical methods are available for measurement of sampled formaldehyde. Table 3 shows the

corresponding analysis technique for each sampling methodology while Table 4 lists some operational parameters.

Because of formaldehyde's instability and reactivity, analytical methods do not involve direct measurement of the formaldehyde. A product of a reaction between formaldehyde and another chemical is measured instead.

The most common analytical procedures are the chromotropic acid (CTA) and pararosaniline methods. Both methods consist of a formation of colored products that can be measured using a spectrophotometer. The CTA method forms a purple monocationic chromogen upon addition of chromotropic acid and sulfuric acid to a two to four milliliter aliquot of the formaldehyde sample. The absorbance of the colored solution is read in a spectrophotometer at 580.0 nanometers and is proportional to the amount of formaldehyde in the solution. Impinger samples and all diffusive monitors are analyzed using the CTA method. Some sorbent tubes are analyzed in this way, such as an alumina sorbent and the new silica gel impregnated with 20.0% sodium bisulfite tube. The CTA method is described in the NIOSH 3500 method.<sup>41</sup>

Another analytical procedure is gas chromatography with a packed column and nitrogen-phosphorus flame ionization detector (FID). This procedure is used for the commercial XAD-2 tubes (Supelco ORBO-22) and is outlined by OSHA 52<sup>45</sup> and the NIOSH 2502<sup>43</sup> methods. Other analytical procedures

include liquid chromatography with ultra-violet detection, ion chromatography, and polarography.

B. Part of the sampling strategy is choosing the appropriate sampling equipment and means of analysis. Equipment was chosen based on accuracy, reproducibility, cost, availability, ease of use, and how quickly results could be obtained. Extensive literature research was conducted in order to learn more about each method's procedures, effectiveness, and limitations. Table 5 lists some of these limitations which should be considered before choosing which method to use.

Several different methods were used for comparison purposes and to establish a reliable, cost efficient means of sampling following this study. Two active methods were used, the impinger with 20.0 ml of 1.0% sodium bisulfite solution and a Supelco ORBO-22 sorbent tube. The impinger method was used for short term personal sampling, from fifteen minutes to one hour, and for long term (eight hour TWA) area samples. It was chosen because it is the most sensitive method, everything needed was readily available, and because analysis could be done immediately in-house using a spectrophotometer.

The Supelco ORBO-22 sorbent tube was used for long term personal and area sampling. It was chosen because it is less awkward for an employee to wear all day than the



impinger and because it was originally planned to be analyzed in-house, using an available gas chromatograph. It was later decided that in-house analysis would be too difficult and time consuming, therefore the tubes were sent to an accredited laboratory for analysis.

A third active method using 13X activated molecular sieves, suggested by Gold<sup>46</sup> and a master's report submitted to the faculty of the University of North Carolina by Hoffner,<sup>47</sup> was initially tried. Their work showed that the 13X molecular sieves could be used to efficiently collect formaldehyde. This method could be used at very little cost because the tubes could be prepared by the person doing the sampling and analysis could be done in-house using the spectrophotometer. This method was abandoned due to poor results and time restraints, but should still be considered in the future for formaldehyde sampling.

Six different kinds of passive monitors were used during this study. Monitors that were already in the Environmental Safety Department and those that were sent as free samples were used until a decision was made as to which fit our needs. The monitors used were the DuPont Series II type C-60, 3M 3720, 3M 3721, Kem Medical Vapor-trak, Air Quality Research PF-20, and the Bacharach Air-Scan. The DuPont C-60 and 3M 3721 could be analyzed in-house using the CTA method and the spectrophotometer. The 3M 3720, Kem Medical Vapor-trak, and Air Quality Research PF-20 were all sent back to

the manufacturer for analysis. The Bacharach monitor was analyzed immediately after use and gave results within eight to ten minutes by a staining method.

The Air Quality Research PF-20 and Bacharach Air-Scan monitors were both used only on two separate occasions. The PF-20's use was discontinued due to cost and turn around time for results. The Bacharach was no longer used because of cost, difficulty with analysis, and sample results.

The Kem Medical Vapor-trak was used throughout the study for fifteen minute short term sampling and long term personal and area sampling. The Vapor-trak is the only diffusive monitor recommended for short term sampling and was used with and later in place of the impinger.

Both the DuPont C-60 and the 3M 3720 were used initially for long term personal and area sampling. A field study done by Kennedy and Hull compared the two methods for performance and reliability.<sup>48</sup> The DuPont C-60 was eventually chosen over the 3M 3720 because both the monitors and the sample results could be obtained more quickly. The 3M 3720 and 3721 were later compared but were discarded because of poor results and slow delivery of the badges. Table 6 shows what methods were used for each situation.

Table 6  
Methods Used for Sampling

<u>Type of Sample</u>	<u>Sampling Methods Used</u>
Long Term Personal	ORBO-22 Sorbent Tube, DuPont C-60 Badge, Kem Medical Badge, 3M 3720/3721 Badge, Air Quality Research PF-20, Bacharach Air-Scan
Long Term Area	Impinger with 1.0% $\text{NaHSO}_3$ , ORBO-22 tube, 13X Molecular Sieves, DuPont C-60 Badge, 3M 3720/3721 Badge, Kem Medical Badge
Short Term Personal	Impinger with 1.0% $\text{NaHSO}_3$ , Kem Medical Badge
Instantaneous Grab	National Draeger Coloration Tube

## VI. RESULTS

A brief discussion is given for each area as to how formaldehyde is used, how often, how many people use it, and conditions or handling procedures that existed. Results are then listed for air sampling done in that area. Heavy use areas are discussed first, followed by moderate and finally low use areas. Table 2A shows the types of use and areas that use formaldehyde in that way. All employees were notified of the sampling results using the form found in Appendix Number 3.

A. The largest and most widespread use of formaldehyde was found to be for tissue preservation or fixation. It includes the heaviest users of formaldehyde in Autopsy and Surgical Pathology. In most cases a 10.0% formalin solution was used to preserve animal parts or human tissue for later examination and experimentation.

The Autopsy Laboratory can be one of the largest users of formalin at a medical center. Whenever an autopsy is performed, all tissue removed from the body is placed in a container with formalin for later gross examination. The brain is removed and stored in a ten quart pot with

formalin. Autopsies are performed on unpreserved bodies received directly from the hospital. The bodies are kept refrigerated if an autopsy cannot be performed immediately after death.

This medical center's Autopsy Lab has four technicians working in it. Two of the four assist in autopsies, one is responsible for formaldehyde dilution and occasional pot dumping, and the fourth is a "runner" who transports bodies and does general office work. Both area samples and personal samples on the technicians were collected.

Formaldehyde exposures can occur in three different ways. The first is when a technician is in the laboratory assisting with an autopsy. The technician is responsible for laying out instruments, preparing the body, filling pots and containers with formalin, and transferring the formalin containers between the autopsy table and storage. Autopsies are not done everyday and normally there are no more than one or two in a day. There may be occasions when more than two are done in a day, but it is a rare occurrence.

A second source of potential exposure in Autopsy is when formaldehyde is diluted to 10.0% formalin. This will be discussed in detail later with the other dilution procedures.

The third potential source of exposure in Autopsy is when pots containing brains in formalin are periodically dumped. Anywhere from ten to twenty pots are normally

dumped approximately every six to twelve weeks. The formalin in the pots is poured down a sink under the exhaust hood in the Autopsy Laboratory and normally takes approximately thirty minutes to complete. The brains are then put in a plastic bag and later burned in an incinerator. The technician wears gloves and an apron during the dumping procedure. All sample results <sup>work</sup> are well below the OSHA PEL and STEL. All areas where formaldehyde exposure can occur were well ventilated. Routine sampling is suggested due to the high formaldehyde use. These results are summarized in Table 7.

Another heavy user of formalin for preserving tissue is the Surgical Pathology Laboratory. This laboratory receives specimens from surgery or from areas doing biopsies in containers with 10.0% formalin. The containers are kept on a storage shelf in the laboratory for further examination.

There are two tissue specimen sectioning rooms where pathology residents examine and describe these specimens. Each of these rooms is small (approximately 7.5 feet by 7.5 feet) and has a cutting area with local exhaust ventilation where the resident works. The resident removes the specimens from the container, cuts and examines it while dictating, and places it in a small (approximately 1/2 inch x 1 1/2 inches) perforated plastic container called a "tim". The tims are then placed in a one gallon plastic container containing 10.0% formalin. The formalin is later poured



Table 7

## Autopsy Laboratory Sample Results

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
Autopsy	88-A09	6-28	Impinger	438	<det. limit	Lab area sample
"	88-A10	"	ORBO-22	438	0.22	"
"	88-A11	"	13X Sieve	438	0.002	"
"	88-A12	"	3M 3720	435	0.33	"
"	88-A13	"	DuP C-60	437	0.38	"
"	88-A14	"	Vapor-trak	436	0.15	"
"	88-67	9-1	Vapor-trak	33	<det. limit	Pot dump
"	88-69	9-1	"	15	"	Dumped small containers
"	88-71	9-20	"	30	0.04	Pot dump
"	88-35	8-8	DuP C-60	466	0.18	Tech. in lab
"	88-44	8-11	Vapor-trak	393	<det. limit	"
"	88-54	8-18	DuP C-60	452	0.13	"

off, replaced with water, and the tims are brought to the Histology Laboratory for processing and further examination. Normally two or three doctors worked in a room during an eight hour period, therefore area sampling was done in each room near the cutting area to determine exposure.

Although many people worked in the Pathology Laboratory, only one technician had the potential for exposure. The technician is responsible for checking in each specimen container (with opportunity to open it), keeping a five gallon jug of formalin filled in each sectioning room, setting up containers in sectioning rooms for residents to work with, pouring off the formalin in the container that residents place tims in, and transporting tims to Histology. Personal samples were taken of this technician on several different days. The results of these samples and of the area sections room samples are shown in Table 8. All samples results were well below the OSHA PEL, showing adequate local exhaust ventilation in the sections room and good work practices by the technician.

Smaller laboratories that are a part of the Surgical Pathology Department include Histology and Neuropathology. Formalin use in each of these laboratories is minimal. They each receive specimens for preparation and examination on a smaller scale than the Pathology laboratory.

The Histology Laboratory has two potential sources of exposure. Each operation is short term and has one

Table 8

## Pathology Laboratory Sample Results

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
Pathology	88-A25	7-28	Impinger	450	0.01	Sections room area sample
"	88-A26	"	ORBO-22	"	<det. limit	"
"	88-A27	"	3M 3720	"	0.14	"
"	88-A28	"	3M 3721	"	0.05	"
"	88-A35	8-18	ORBO-22	484	<det. limit	"
"	88-A36	"	DuP C-60	"	0.09	"
	88-A42	9-1	Vapor-trak	300	0.03	"
"	88-16	7-14	ORBO-22	505	<det. limit	Path. technician
"	88-17	"	3M 3720	500	"	"
"	88-18	"	AQRPF-20	501	"	"
"	88-49	8-16	ORBO-22	480	"	"
"	88-50	"	DuP C-60	"	0.09	"
"	88-62	8-30	Vapor-trak	"	0.03	"

technician responsible for it. The first procedure consists of loading specimens into tins and putting tins into a metal basket to be processed. Some specimens are taken out of pint containers with formalin, rinsed with water, and put in tins. Most of the tins are already filled with specimens and have been rinsed. This procedure is done at a sink in a back room of the Histology Laboratory. It normally takes ten to twenty minutes to complete and is done at the end of every working day. It used to be done on a larger scale three times a week after the first workshift but was discontinued midway through this study. Fifteen minute short term personal samples were taken during this procedure.

The second source of exposure was found to be during the dumping of formalin from one gallon jugs. Every Monday, Wednesday, and Friday three or four one gallon jugs are removed from the processor and dumped along with two one gallon water jugs and ten to fourteen one gallon jugs of alcohol. This is done in a sink in the corner of the main Histology Laboratory. The dumping takes fifteen to twenty minutes, including re-filling all formalin, alcohol, and water jugs. The technician wears rubber gloves and an apron while performing this operation.

The first fifteen minute short term personal sample taken was found to be above the OSHA STEL (88-48). A second sample was below the STEL but still above the action level

(88-65). During the dumping, the water tap was left running the entire time. A similar high result was found in the Dialysis unit (discussed later in Section C) when pouring formalin in a sink while tap water was running. It was therefore thought that the running water was creating turbulence and causing formaldehyde vapor to be brought up from the sink to the worker's breathing zone. Two subsequent samples were taken on separate occasions. The technician was asked to dump the formalin first without the tap water running. In both cases the exposure was greatly reduced, both being below the detection limit of the sampling device (88-73, 88-82).

In the Neuropathology Laboratory, there are three different people who can have minimal exposure to formaldehyde. One potential source of exposure is loading tins in a basket to be processed. All tins with specimens have been rinsed with water before arriving in the laboratory. The specimen containers are kept under an exhaust hood and any specimen removal or pouring off of formaldehyde from these containers is done at the sink in the laboratory.

Another source of exposure includes making up slides by putting one or two drops of 20.0% formaldehyde on them. These slides are made up almost every day but only a couple of times in a day. Exposure can also come from making up five gallons of 20.0% formaldehyde approximately once a

month or making four liters of Elvers fixative approximately every six to eight weeks. Elvers fixative includes formalin, glycerin, acetic acid, and alcohol.

Another procedure in the Neuropathology Department that is a potential source of exposure is brain cutting. Every Wednesday at four o'clock a doctor cuts and examines a number of brains while eight to twelve Pathology residents surrounding him make observations. Each brain takes approximately fifteen minutes to cut and normally one to four are processed. The brains have been sitting in 10.0% formalin for a period of time but are normally rinsed with water and placed in a container with water before cutting. This is done in a classroom on a cart with no local exhaust ventilation. The doctor wears gloves and an apron.

The sample results for both Histology and Neuropathology are summarized in Table 9. Except for the dumping procedure in the histology laboratory discussed earlier, all samples taken were below the OSHA PEL and STEL.

There are four areas that use formaldehyde for specimen preservation during biopsies. These are the Endoscopy Laboratory, the Allergy and Pulmonary Clinic, the Surgical Diagnostic Clinic, and the OBGYN Clinic. All four use formalin to preserve specimens as they are removed from a patient during a biopsy. A pint container of formalin is kept on hand and opened long enough to drop the specimen in. Biopsies are done on a particular day, but it is never known



Table 9

## Histology and Neuropathology Sample Results

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
Histology	88-14	7-12	Impinger	13	0.12	Tim loading
"	88-48	8-15	Vapor-trak	15	3.97	Dumping
"	88-65	8-31	"	"	0.65	"
"	88-73	9-21	"	"	<det. limit	"
"	88-82	10-12	"	"	"	"
Neuropath	88-83	10-12	"	60	0.02	Brain cutting
"	88-81	"	"	480	0.04	Tech. personal sample

whether a specimen will be taken until the biopsy is done. Generally two to six biopsies are done in a day, therefore the container could be opened six times during the course of a day for a total of less than thirty minutes.

Of the four units, the Endoscopy Laboratory has more opportunity to use the formalin. There is normally more than one nurse who assists in the biopsies, therefore area samples were taken near the formalin container to determine exposure. An area sample was set up in the proctoscopy room of the Surgical Diagnostic Clinic due to more than one person assisting on the biopsies. Personal samples were also taken in the Endoscopy Laboratory and the Allergy and Pulmonary Clinic when only one person assisted with biopsies. All results were below the OSHA PEL and are given in Table 10.

There are three areas that use formaldehyde to preserve specimens in after surgery. They are the Emergency Department, the Delivery Room, and the VA Medical Center Pathology Laboratory. Each uses formaldehyde very sporadically and has limited potential exposure.

In the Emergency Room, formalin is used to drop moles or lesions in that have been removed from a patient. The greatest use of formalin in the Emergency Room is for preserving aborted fetuses. The fetus is put in an appropriate container according to its size. The assisting nurse will fill the container with 10.0% formalin to be sent

Table 10

## Sample Results from Areas Performing Biopsies

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
Endoscopy Lab	88-A15	7-14	Impinger	497	<det. limit	Formalin container opened five times
"	88-A16	"	3M 3720	500	0.12	"
"	88-A17	"	DuP C-60	496	0.26	"
"	88-A18	"	ORBO-22	496	<det. limit	"
"	88-75	9-22	DuP C-60	450	0.26	Personal-container opened three times
All. + Pulm.	88-20	7-20	AQRPF-20	470	0.1	Personal-container opened one time
S.D.C.	88-A19	"	ORBO-22	480	<det. limit	Area-formalin not used
S.D.C.	88-A20	"	3M 3720	"	"	"
S.D.C.	88-A21	"	DuP C-60	"	"	"

All.+Pulm. = Allergy and Pulmonary Clinic

S.D.C. = Surgical Diagnostic Clinic

later to the Surgical Pathology Laboratory. This may be done once or twice a week as needed.

In the Delivery Room, specimens are put in containers with 10.0% formalin when doing bilateral tubal ligations or performing C-sections on patients. Each may be done two or three times in a day with the containers being opened for just a few seconds to drop specimens in. Both operations are emergency procedures, therefore use of formalin is unpredictable.

The VA Pathology Laboratory uses formalin even more sporadically, only once or twice in a day once a week. Specimens are put in containers with formalin and are brought to the medical center's Pathology Laboratory.

No samples were taken in any of these three laboratories due to the sporadic and unpredictable use. The potential exposure was assumed to be represented by other areas that use formaldehyde in a similar way more frequently.

Animal research is very prevalent in a medical research facility. Many different animals are used, including pigs, monkeys, dogs, rabbits, and mostly mice and rats. While the volume of formaldehyde used does not approach that used by the Autopsy or Pathology Laboratories, the number of laboratories conducting animal experimentation is greater and the use is more widespread. Nine different laboratories were found during this study that used some form of formaldehyde for animal research and experimentation.

There are five laboratories that use formalin during animal surgery to store specimens. There are generally one to four people performing surgery in each laboratory and it may be done anywhere from two or three times a week to once every two or three months. The containers are opened just long enough to introduce specimens in. In a one to two hour surgery the container might be opened for a total of ten to fifteen minutes.

The Institute of Allergy Infectious Diseases in the Department of Surgery does surgery one or two times in a week. It is done on a table by one of three people with no local exhaust ventilation. They also transfer these specimens from test tubes to tins approximately once a month. The transfer is done under a hood and ten to twenty tubes are typically used taking ten to fifteen minutes.

The Division of Neurosurgery, the Rheumatology and Immunology Research Laboratory, and the Vivarium all perform animal surgery under a hood once every two to three months. The Vivarium performs rat necropsies on a larger scale than the other two laboratories, but none of the three did any surgery during the time of this study so no sampling was done.

The Heart, Lung, and Blood Institute is the fifth laboratory using formaldehyde for animal research. One of two people periodically removed rat hearts from containers with formalin to cut them into smaller pieces and take

photographs. This was done every two to three weeks on a table and generally took three to six hours to complete, depending on the number of hearts. The hearts were rinsed with tap water at a sink after removing from the formalin and before cutting.

There are also four other laboratories and one mentioned previously that use some type of formaldehyde for animal perfusions. Two of these laboratories, the Hyperbaric Clinical Program and the Anatomy Division of the OBGYN Department, use liquid formalin for perfusion during animal surgery. Each one has the formalin run into a cavity inside the animal for ten to fifteen minutes during the surgery. One person is responsible for the surgery and it is done as needed on a workbench without local exhaust ventilation. It is normally months between perfusions and is very unpredictable.

The Division of Neurosurgery mentioned previously, the Division of Allergy Clinical Care of the Department of Medicine, and one laboratory of the Department of Microbiology and Immunology also do animal perfusions. Each of these three laboratories use paraformaldehyde when doing animal surgery once every two to three months. One person is responsible for heating and dissolving approximately ten grams of paraformaldehyde in fifty to one hundred milliliters of water or gluteraldehyde solution under a hood. The solution is then used for perfusion during



surgery or electromicroscopy of animals. This is also done under a hood. The fixative solution generally runs for ten to fifteen minutes during a one to two hour operation.

All nine laboratories use formaldehyde for tissue preservation or fixation during animal research sporadically, in small quantities, and the operators are generally well protected. Exposures to formaldehyde in any of these laboratories was believed to be minimal. Sampling could not be scheduled due to the unpredictable use, therefore sampling was sporadic and minimal. The results of sampling done in all of the nine laboratories are shown in Table 11.

B. Using formaldehyde for sterilization and decontamination in a hospital setting can be traced back one hundred years ago.<sup>5</sup> Along with heat sterilization, it is one of the most widely used means of inactivating microorganisms. The number of different areas that use formaldehyde for these purposes is not as great as the number that use it for tissue preservation and fixation, but the number of people in contact with formaldehyde in these areas and the potential exposures are greater.

The biggest user of formaldehyde for sterilization purposes is the Dialysis Laboratory. At the medical center there are two units, a Hemodialysis unit in the North Hospital with eight beds and a larger Dialysis Center off

Table 11  
Animal Research Sample Results

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
IAID	88-36	8-9	DuP C-60	180	0.13	Formalin for specimens
IAID	88-A29	"	ORBO-22	450	<det. limit	Lab area sample
IAID	88-A30	"	DuP C-60	"	"	"
HLBI	88-22	7-21	ORBO-22	444	<det. limit	Formalin for specimens
HLBI	8-23	"	DuP C-60	"	"	"
HLBI	88-27	7-29	3M 3721	405	"	"
ADOB	88-76	9-22	Vapor-trak	30	0.03	Formalin for perfusion

IAID = Institute of Allergy Infectious Disease

HLBI = Heart, Lung, and Blood Institute

ADOB = Anatomy Division of the OBGYN

campus with three sections and twenty-five beds. Both of these units use a 5.0% formalin solution to sterilize their dialysis machines.

In the North Hemodialysis Unit, six technicians are responsible for taking care of patients and the dialysis machines. Typically these patients are on the machines only during the first eight hour work shift, but occasionally there is a need for a patient to be on a machine for an extended period of time. There is a large room with five machines and three smaller rooms with one machine in each.

Each machine is sterilized with formalin solution at the end of each use. One person, usually the head nurse, is responsible for mixing up seven liters of a 5.0% formalin solution. This is done at a sink in a small room and generally takes five to ten minutes. This seven liter container is then used by any one of the six technicians to sterilize the dialysis machines. This is done by placing a vacuum line down into the container. The machine then sucks in approximately 150.0 milliliters of the formalin solution, taking about ten minutes to do so. The formalin is left in the machine overnight. One technician will then come in early the next day to set up the machines. The first thing the technician does is drain the formalin out of the machine. The formalin is emptied through a hose-line into a floor drain. Splattering may occur here, but the technician

is generally not near the machine. The draining process takes approximately ten minutes and the machine is then ready for use. All day personal samples and fifteen minute short term samples were taken in North Hemodialysis during dilution.

The Dialysis Center is composed of three separate areas, all in one building, approximately three miles from the North Hospital. All three areas receive patients daily for six to eight hours and no patients remain overnight. The three areas are the main room with seventeen dialysis machines, Dialysis West with five machines, and the home training room with three machines. The main room is the largest of the three sections (~30 feet by 40 feet) and typically has eight technicians assigned to it. All seventeen machines are sterilized daily with 5.0% formalin solution according to the procedure described for the North Hemodialysis Unit.

Dialysis West, with an area one-third the size of the main room, normally has two technicians operating the five machines. Four of the five machines are sterilized daily with 5.0% formalin and one machine is sterilized by sucking in approximately 1/4 cup of 40.0% formaldehyde solution. The same sterilization procedure is used for all five machines.

The home training room also has two technicians who operate three machines in an area the size of Dialysis West.

All three of these machines are sterilized using the same procedure but use 1/4 cup of 40.0% formaldehyde solution instead of the 5.0% formalin solution. Toward the end of this study, the home training room was not being used regularly but only for overflow from the main room.

One technician is responsible for sterilizing the R/O water system once a month. The technician pours one cup of 40.0% formaldehyde solution into the system where it is left for eight to ten hours. The formaldehyde is then drained out into a floor drain.

The other potential formaldehyde exposure is during the 5.0% formalin mixing done every day. A different technician each day is responsible for the dilution in the main room and one technician does the dilution in Dialysis West. The dilution and the fifteen minute short term samples taken during it will be discussed in greater detail later.

All twenty technicians in each of the four areas of Dialysis rotate between areas. The technicians have opportunity to work in either the North Hemodialysis Unit or in one of the three areas in the Dialysis Center. Long term personal and area samples were taken in each area along with the fifteen minute short term samples. The number of samples taken depended on the number of people working in the area. All long term personal and area samples taken were well below the OSHA PEL. The results are summarized in Table 12.

Table 12  
Dialysis Sample Results

Area	Sample #	Date	Method	Sample Time (mins.)	PPM	Comments
Main	88-A22	7-26	ORBO-22	450	<det. limit	Area sample
"	88-A23	"	3M 3721	453	0.03	"
"	88-A24	"	3M 3720	"	<det. limit	"
"	88-31	8-4	DuP C-60	428	0.15	Tech. sample
"	88-38	8-10	"	505	<det. limit	"
"	88-52	8-17	"	480	0.13	"
"	88-56	8-24	"	345	0.26	"
"	88-66	9-1	Vapor-trak	460	0.04	"
"	88-74	9-22	DuP C-60	450	0.21	"
North	88-26	7-27	"	463	0.13	"
"	88-47	8-15	"	452	0.17	"
"	88-63	8-31	Vapor-trak	320	<det. limit	"
West	88-32	8-4	3M 3721	420	"	"
"	88-33	"	3M 3720	420	"	"
"	88-39	8-10	DuP C-60	499	0.27	"
"	88-55	8-24	"	350	0.18	"

Main = Main Room of Dialysis Center

North = North Hospital Dialysis Unit

West = Dialysis West



Two other areas using 10.0% formalin solution for sterilization purposes are the Surgical Diagnostic Clinic and the Surgical Out-Patient Clinic. Each unit uses formalin to sterilize tools in once a week. Approximately 1/2 gallon of 40.0% formaldehyde solution is poured into a basin in a sink. The tools are soaked for approximately one hour. The formaldehyde is then poured down the drain and the tools are rinsed with water. The exposure was thought to be minimal, therefore, no samples were taken.

Formaldehyde is, in general, the chemical of choice for space disinfection.<sup>7</sup> Biological safety cabinets, incubators, refrigerators, laboratory rooms, building, or other enclosed spaces can be disinfected with formaldehyde. The opportunity to sample during decontamination of biological safety cabinets presented itself and will be discussed.

When biological safety cabinets are used in biomedical research, a routine performance certification is necessary when infectious agents have been used in the cabinet. Before certification can be done, a thorough decontamination of the cabinet must be achieved to allow the certifier to enter the cabinet without risk of infection. Decontamination is done with formaldehyde by heating paraformaldehyde inside the sealed cabinet to liberate formaldehyde gas. The gas is left in the cabinet for two to four hours or in some cases overnight. After this time a neutralizing agent, usually

ammonium carbonate, is heated and allowed to mix with the formaldehyde gas. The cabinet is then purged slowly and opened for the certification process. The certifier can then enter the confined space of the cabinet to wipe down the gas residue and to check the cabinet's filters for leaks.

Formaldehyde exposures were measured during the decontamination and certification process and at certain times when peak exposures were expected. Both personal and area long-term samples were taken along with fifteen minute short-term samples during purging. Personal samples were taken on the person performing the certification and his assistant. Area samples were taken in the laboratory area approximately three feet from the face of the cabinet to determine possible migration of formaldehyde vapor and to determine the potential exposure if a person worked in that area.

All but one of the long term personal and area samples taken were below the OSHA eight hour TWA PEL. Two personal samples were above the OSHA action level of 0.5 ppm (88-01, 88-45). Personal samples taken on two separate people working on the same cabinet showed slightly higher results for the person more involved with the decontamination.

One long term area sample was above the OSHA PEL of 1.0 ppm. It was taken in a laboratory where the formaldehyde gas was left in the cabinet overnight, showing a source of

potential exposure for someone working in that laboratory during that time. The area sample taken the next day after neutralization was considerably lower and below the OSHA PEL.

None of the fifteen minute samples were above the OSHA STEL of 2.0 ppm. One sample did approach the STEL (88-61) while others were high, showing that peak exposures did occur during the purging process. The weighing out and addition of paraformaldehyde to the heating devices could provide another source of peak exposures. No fifteen minute samples were taken during this procedure because the paraformaldehyde had already been pre-weighed earlier by the people doing the decontamination. A summary of results are shown in Table 13.

From these results it is concluded that as long as care is taken to properly seal the cabinet and the neutralization process is done, persons performing the decontamination and certification of biological safety cabinets have a low potential health risk from formaldehyde exposure. Recommendations include wearing gloves when wiping down the residue inside the cabinet to avoid skin contact, wearing a respirator when inside the cabinet during certification, and attaching a flexible hose to the cabinet exhaust vent connecting to local exhaust ventilation when purging the cabinet if the cabinet is not hard ducted.

Table 13

## Biological Safety Cabinet Decontamination Sample Results

Area	Sample #	Date	Method	Sample Time (mins.)	PPM	Comments
Jones Lab	88-A01	6-15	DuP C-60	985	1.15	Overnight decon-area
"	88-A02	"	3M 3720	1020	<det. limit	"
"	88-A04	6-16	Impinger	360	"	Area sample after neut.
"	88-A05	"	DuP C-60	360	0.16	"
"	88-A06	"	3M 3720	360	<det. limit	"
"	88-A07	"	Bacharach	360	"	"
"	88-A08	"	vapor-trak	290	0.02	"
"	88-01	6-15	DuP C-60	75	0.6	Personal during set-up
"	88-02	"	3M 3720	75	<det. limit	"
"	88-03	6-16	3M 3720	350	"	Personal after neutriliz.
"	88-04	"	Bacharach	340	>1.61	"
"	88-05	"	ORBO-22	350	0.07	"
Carl Lab	88-A31	8-10	DuP C-60	402	0.17	Area during decon.
"	88-A32	"	ORBO-22	407	<det. limit	"
"	88-40	"	DuP C-60	383	0.09	Personal-cert. asst.
"	88-41	"	"	"	0.21	Personal-decon. tech.
"	88-42	"	Vapor-trak	15	<det. limit	Paraform. addition
"	88-43	"	"	15	"	Cabinet purge
White	88-A33	8-11	ORBO-22	280	"	Area during decon.
"	88-A34	"	Vapor-trak	"	"	"
"	88-45	"	DuP C-60	250	0.60	Personal during decon.
C.M.	88-A37	8-24	DuP C-60	840	0.12	Overnight decon.-area
"	88-A38	8-25	"	395	0.47	Area during decon.-
"	88-A39	"	ORBO-22	405	<det. limit	no neutr.
"	88-58	"	DuP C-60	240	0.18	Personal during decon.
"	88-59	"	Vapor-trak	15	<det. limit	Personal during purge
Blue	88-A40	8-26	ORBO-22	250	<det. limit	Area during decon.
"	88-A41	"	Vapor-trak	"	0.07	"
"	88-60	"	"	250	0.06	Personal during decon.
"	88-61	"	"	15	1.53	During Purge
RP #3	88-A43	9-29	DuP C-60	270	0.17	Area during decon.
"	88-A44	"	Impinger	"	0.01	"
"	88-77	"	DuP C-60	280	0.33	Personal-decon. tech.
"	88-78	"	"	"	0.17	Personal-cert. asst.
"	88-79	"	Vapor-trak	15	0.68	Personal-cabinet pruge
"	88-80	"	Impinger	15	0.27	"

White = South Hospital White Zone

C.M. = Clinical Microbiology Lab

Blue = South Hospital Blue zone

RP #3 = Research Park Building Number 3

C. Different areas that dilute 37.0 to 40.0% formaldehyde solution to make different strength formalin solutions are included together because there are so many different areas and because the procedures are similar. The only major difference between each area is the volume of solution made.

The largest volume producer of formalin is the Pharmacy Department. One person from Pharmacy is responsible for periodically mixing sixty gallons of 10.0% formalin solution. This is done in a stainless steel vat in a building called the "vault" outside of the hospital. If the weather is good, mixing in the vat is done outside the vault. If the weather is bad, the vat is set just inside the door and all doors and vents in the vault are kept open during mixing. The operator wears gloves and an apron while performing the mixing.

The procedure starts with filling the vat with fifty gallons of distilled water. Nine hundred and seven grams of sodium acid phosphate (monobasic) is then added and the mixer is turned on until it dissolves. Two and one-half pounds of dibasic sodium phosphate is then added and mixed until it dissolves. Six gallons of 37.0% formaldehyde solution is then added and mixed well. Distilled water is added to bring the volume to sixty gallons and the entire solution is mixed well. With a rubber hose attached to the bottom of the vat, the mixture is pumped out of the vat into one gallon plastic containers. The containers are labeled



and stored in the vault for later delivery to the Materials Management Department. The one gallon containers are dispensed to various departments throughout the medical center. This operation takes place as needed, generally every three to five weeks. All sample results were well below the OSHA PEL and are listed in Table 14.

Another large volume producer of formalin is the Autopsy Laboratory. Sixty gallons of formalin is mixed as needed, generally every two to three weeks. The dilution is done in a small (approximately ten by ten feet) storage room adjacent to the Autopsy office and takes approximately fifteen minutes to complete. The room has its own ventilation and the technician wears gloves, an apron, and a half-mask respirator while performing the dilution. Three gallons of 37.0% formaldehyde are added to two separate thirty gallon containers, two cups of potassium acetate is added to one container, then each container is filled with water to thirty gallons using a hose. The formalin is taken from each container as needed out the bottom from a spout. All fifteen minute short term samples were well below the OSHA STEL and are listed in Table 14.

As previously mentioned, a daily dilution is done in each of three separate areas of the Dialysis Department. A single seven liter batch is mixed once a day both in the North Hospital Hemodialysis Unit and the Dialysis West Unit. In North it is done at a sink in a room approximately six by



Table 14

## Sample Results from Areas Doing Dilutions

Area	Sample #	Date	Method	Sample Time (mins.)	PPM	Comments
Pharmacy	88-11	7-12	Impinger	30	0.16	60 gal dilution in vault
"	88-12	"	DuP C-60	30	0.21	"
"	88-13	"	3M 3720	30	<det. limit	"
"	88-64	8-31	Vapor-trak	35	0.03	"
Autopsy	88-28	8-2	Impinger	15	0.56	60 gal. dilution
"	88-29	"	Vapor-trak	15	<det. limit	"
"	88-51	8-16	"	15	"	"
North	88-07	6-24	Impinger	9	"	7 liter dilution
Main	88-08	6-27	"	15	"	3-7 liter dilutions
"	88-21	7-20	Vapor-trak	15	4.11	3-3.5 l dilutions
"	88-25	7-21	"	15	12.42	"
"	88-53	8-17	"	12	<det. limit	2-9 l dilutions
"	88-57	8-24	"	15	"	3-9 l dilutions
"	88-68	9-1	"	10	"	2-3.5 l dilutions
M/1#316	88-37	8-9	"	15	"	65 ml dilution
M/1#328	88-70	9-19	"	53	0.03	gel prep-5 min dil

North = North Dialysis Unit

Main = Main Room of Dialysis Center

M/1 #316 = Microbiology and Immunology Lab #316

M/1 #328 = Microbiology and Immunology Lab #328

nine feet and takes approximately five to ten minutes. In Dialysis West, the dilution is done in the women's bathroom (approximately four by six feet) and takes five to ten minutes.

The main room of the Dialysis Center makes up a larger volume of formalin solution because of the greater number of machines. Generally two to four nine liter jugs of formalin are mixed at the sink in a thirteen by sixteen foot utility room behind the main room. The dilution takes approximately ten to twenty minutes and is done by a different person each day. There are two windows which some technicians preferred to have open. One technician chose to have a fan running behind them while the windows were open.

Result of formaldehyde sampling during dilution for these areas was typically well below the OSHA STEL. There were two samples taken during dilution on successive days that were above the STEL (88-21, 88-25). In each case, as in the formalin dumping operation done in the Histology Laboratory described earlier, formalin solution was poured down the sink while the tap water was running. The first day, the sample result was 4.11 ppm after pouring approximately one liter of formalin in the sink. The second day the sample result was 12.42 ppm after approximately three liters had been poured down the sink. Results of samples taken after asking the technician not to run the tap water while dumping formalin in the sink were all well below

the STEL. All results from Dialysis dilution can be found in Table 14.

The Vivarium has four different people who make a formaldehyde dilution in three separate areas. The formalin is used for specimen preservation after rat necropsies or animal surgeries as described earlier. A technician in the Vivarium Pathology Laboratory will make five gallons of 10.0% formalin solution every three to four months. This operation is done under a hood and takes approximately ten to fifteen minutes to complete. One gallon of a 2.0% formalin solution is made up from either a 37.0% formaldehyde solution or 10.0% formalin solution every two to three months in a separate laboratory. The dilution takes only five to ten minutes but every day ten test tubes are filled with ten milliliters of the 2.0% solution taking approximately fifteen minutes. In the second floor Autopsy/Necropsy room twenty liters of 10.0% formalin is made every six months. This takes approximately fifteen minutes but is done without a hood. None of these procedures described for the Vivarium were done during the time of this study, therefore no samples were taken. It was assumed the exposure was represented by the larger volume dilutions.

In the VA Hospital Pathology Laboratory, one of three or four people make up ten liters of 10.0% formalin solution every three or four months to use for specimen preservation.

This procedure takes five to ten minutes and is done under a hood. No sampling was done.

Remaining areas that did dilutions did so in very small quantities and only occasionally. Three separate laboratories in the Department of Microbiology and Immunology diluted 37.0% formaldehyde to 20.0% formalin for use in making Northern Blot gels. Each laboratory has two or three people that would make up thirty-two to fifty milliliters of the formalin solution for gels. The dilution is done at a laboratory workbench and takes just a few minutes to complete. Northern Blot preparation will be discussed in detail later in Section D.

D. There are a number of other uses of formaldehyde where in most cases the use was so infrequent, sporadic, and small that sampling could not be done. All these areas are included together as miscellaneous use.

Use of formaldehyde for making Northern Blot gels is widespread but typically minimal and very sporadic. Most laboratories stated that when doing northern blots, the gels can be made up two or three times a week for up to four or five weeks. But most said they could go for up to six months before they did any northern blots.

The northern blots technique is used to denature DNA. The gels are made up with 10.0 to 20.0% formalin and are used to transfer the DNA samples to the northern blots for

later study. All but one laboratory cut up the gel to be used in an enclosed machine the following day after preparation. Working with the gel typically took only ten to twenty minutes. One laboratory did the transfer by hand by placing the gel on blotter paper, placing the northern blot on top, and placing paper towels over both overnight to absorb the buffer and transfer the sample from gel to blot.

All but one laboratory did their own dilution of formaldehyde solutions as described earlier, with the one laboratory using Pharmacy-made 10.0% formalin. Making the formalin solution, pouring it into the gel, and working with the gel were the only potential sources of exposure. The Department of Microbiology and Immunology had six different laboratories that worked with northern blots. Each typically had four to six people that could do this type of work. The Department of Medicine has two separate laboratories, the Division of Neurology and the Division of Hematology, that uses northern blots. Two or three people can do this work in each of these two laboratories under a hood, but it only occurs approximately every six months.

Fifteen minute samples were taken during dilution in one laboratory and long term samples were taken in the one laboratory that did the transfer by hand. None of the other laboratories worked with northern blots during the course of this study. All sample results were well below the OSHA PEL and STEL and are listed in Table 15.

Table 15

Sample Results from Areas Preparing Northern Blot Gels

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
M/I #316	88-37	8-9	Vapor-trak	15	<det. limit	65 ml dilution
M/I #328	88-70	9-19	Vapor-trak	53	0.03	Gel Preparation
"	88-72	9-20	DuP C-60	440	0.21	Transfer

M/I #316 = Microbiology and Immunology Lab #316

M/I #328 = Microbiology and Immunology Lab #328



There are two areas that use 10.0% formalin solution to drop slides in after doing a pap smear. These two areas are the Allergy and Pulmonary Clinic and the Emergency Department. Each one drops slides in a small bottle containing forty to fifty milliliters of formalin. In the Allergy and Pulmonary Clinic, a doctor can do the pap smears in one of three rooms. The bottle is only open for a few seconds at a time. In the Emergency Room, there are two rooms where pap smears are done once or twice in a week by the physician on duty. In both areas, the pap smears are never scheduled so air sampling was difficult. Both areas received their bottles already filled with formalin from the Pathology Laboratory and returned the bottles to Pathology with the pap smear slides.

The VA Hospital Pathology Laboratory and one of the Microbiology and Immunology Laboratories use 37.0% formaldehyde solution on blood sample trays. Two or three drops of formaldehyde are put on each tray to sit overnight. The following day someone reads each tray under a microscope for a few minutes. Each laboratory has just one person assigned to do this procedure. The VA Pathology Laboratory does this very infrequently, normally does only four trays, and might not read each one the next day. The Microbiology and Immunology Laboratory does this procedure every two to three weeks and may have twenty or more trays at a time to do.

One of the Chemistry Department laboratories uses formaldehyde to prepare reagents. This is done every three or four months by using paraformaldehyde. Two grams of paraformaldehyde is dissolved in solution under a hood. No more than five minutes is spent on weighing and adding the paraformaldehyde to solution.

Sampling was done in the Microbiology and Immunology Laboratory in the Research Park building number three during both the formaldehyde addition to the trays and reading the trays the next day. Results were well below OSHA regulations and are listed in Table 16.

Formaldehyde may react with ionic chloride compounds in humid air to produce bis-chloromethyl ether (BCME) which has been shown to be a powerful carcinogen. OSHA has set an eight hour TWA PEL for BCME of one part per billion (ppb).<sup>49</sup>

Initial plans included taking air samples for BCME in areas where chloride compounds are used, as in the Dialysis Department where Clorox bleach is used to clean the dialysis machines and equipment. Due to time constraints and the fact that the sampling method is very different than that used for formaldehyde, it was decided that sampling could not be done during this study.

It was then decided that a memo would be sent to all areas storing formaldehyde with Clorox or any other chloride compound instructing them to separate each so there would be no chance of reaction. The decision was later made not to

Table 16

## Sample Results from Areas Preparing Blood Sample Trays

<u>Area</u>	<u>Sample #</u>	<u>Date</u>	<u>Method</u>	<u>Sample Time (mins.)</u>	<u>PPM</u>	<u>Comments</u>
Lab #109	88-30	8-3	Vapor-trak	8	<det. limit	16 trays done
"	88-34	8-4	"	340	"	"

Lab #109 = Research Park Building #3 Lab #109

send the memo after reviewing the results of two separate studies. Studies done by Kallos and Solomon<sup>50</sup> and by Tou and Kallos<sup>51</sup> both concluded that BCME does not form at the detection limit of 0.1 ppb after reacting formaldehyde vapor with hydrogen chloride at concentrations of 100.0 ppm of each or reacting aqueous hydrogen chloride with formaldehyde vapor in concentrations of 2000.0 ppm. They stated that occupational health problems would not be expected from hydrogen chloride and formaldehyde, since BCME is not formed even at concentrations of these reactants significantly above that which humans can tolerate.<sup>50</sup>

## VII. CONCLUSIONS

Formaldehyde is used extensively in a medical center environment. A comprehensive exposure survey was needed at the medical center because of formaldehyde's widespread use and to help comply with OSHA's new formaldehyde standard.

A complete survey of areas that use formaldehyde throughout the medical center was achieved. An account of type of use, frequency of use, work practices and conditions, and exposure population was made.

The fact that so many procedures are non-routine and infrequent makes sampling difficult in the time given for any one study, but would be possible with continuing and routine surveillance. Each type of formaldehyde use was represented by air sampling, if not each area. An attempt was made to sample as many areas as possible, with sampling being at least representative of areas that use formaldehyde in much the same way.

All long term samples taken were below the OSHA eight hour TWA PEL except for one area sample taken during the decontamination of a biological safety cabinet. Only two long term personal samples were above the OSHA action level, also during a decontamination procedure. All follow-up

samples after these three were well below the OSHA PEL. All but three fifteen minute short term samples were below the OSHA STEL. The three that were above the STEL were in two separate areas with very similar procedures. After changing the procedure for both, follow-up samples were well below the OSHA STEL.

It can be concluded from these results that exposure to formaldehyde vapor at the medical center was at an acceptable level and in compliance with OSHA. With the minimal usage in most areas, excellent work practices in every area, and adequate engineering controls in heavy use areas, it can be said that the potential health risk for formaldehyde at the medical center is very low. With continued monitoring of formaldehyde exposures and an increased awareness of the potential health risks through education, the medical center can remain in compliance with OSHA regulations and continue to provide safe working conditions for its employees.



### VIII. RECOMMENDATIONS

Other than specific recommendations made for individual areas, there are some general recommendations that apply to formaldehyde sampling done at the medical center.

The first and most important recommendation is to review the formalin distribution and formaldehyde purchasing records every six months to a year. This will help keep up with who is using formaldehyde and possibly uncover new areas that have started using it. From these records it will be possible to continue updating formaldehyde usage.

Sampling should be continued in the heavy use areas such as Autopsy, Surgical Pathology, and Dialysis. Routine monitoring should be scheduled to keep up with any changes that are made with regard to handling procedures, personnel changes, or working conditions.

With regard to sampling methods and analysis, a number of cost effective techniques should be pursued. Sample analysis should continue to be done in-house by use of the chromotropic acid/spectrophotometer method and by perfecting the use of the Environmental Safety Department gas chromatograph for sorbent tube analysis. The most inexpensive ways of formaldehyde sampling if in-house

spectrophotometer analysis is available are the 13X molecular sieves and the 3M 3721 diffusive monitor. Both of these sampling methods should be developed to provide the least expensive means of continued routine sampling. Finally, the Bacharach Air-Scan monitor should be looked at more closely to provide results that can be obtained almost immediately after sampling.

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APPENDIX

# APPENDIX NUMBER ONE

APRIL, 1988  
MATERIALS MANAGEMENT

DEPARTMENTAL USAGE BY ITEM FROM BILLING FILE  
(Includes Adjustments & Credits As Separate Entry)

ITEM #	DESCRIPTION	ISSUE UNITS	CHARGE CODE	DEPARTMENT NAME	PHONE	USAGE
			170-4562-77272	Home Health Care Pharmacy		6
			999-	Annual Physical Inventory Adjustment	681-3878	3
2051	FORMALIN - FORMALDEHYDE GL, 3.7%	1/GL	157-9260-73976	Surgical Pathology Lab /		220
			170-4450-77318	Pediatric Units Support Services / 15100		2
			303-6369-73312	National Heart, Lung and Blood Institute	681-5392	6
			830-2050-82050	Surgical Private Diagnostic Clinic		5
			998-	Cycle Counts-Overlay Orhand	681-3370	21
2052	KOLADEX	12/CS	170-1744-77420	OB/GYN Clinic		2
			170-1814-77188	Clinical Hematology Laboratory		3
			830-4170-84171	Medical Private Diagnostic Clinic		1
2054	BAG, BROWN PAPER 12LB SIZE 12	1/EA	157-9219-73949	Department of Medicine	684-5065	12
			170-1413-77894	Minot Rehabilitation		60
			170-1416-77897	CMSU-Combined Medical Specialities Unit		6
			170-1438-77322	Clinical Speciality Unit		10
			170-1466-77323	Prevost, Obstetrics and Gynecology		85
			170-1469-77326	Williams, Obstetrics & Gynecology		205
			170-1569-77279	OFC Pharmacy		520
			170-1738-77468	General Medical Clinic		275
			170-1746-77470	Oral Surgery Clinic		30
			170-1750-77474	General Surgical Clinic	684-6260	50
			170-2410-77831	Inpatient Unit, Eye Center		20
			170-4230-77413	Central Production, Dietetics		3500
			170-4450-77318	Pediatric Units Support Services / 15100		80
			170-4453-77216	Pediatric Units Support Services / 15300		10
			170-4460-77108	Surgical Units Support Services / 15100		132
			170-4501-77253	Sterile Processing		650
			170-4610-77280	Department of Anesthesia		100
			170-4713-77170	Emergency Department		127

## APPENDIX NUMBER TWO

DEPARTMENT NAME	PHONE	USAGE	USED FOR	HOW OFTEN	HOW LONG	PROTECTION (Hoods, PPE,)	CURRENT STATUS	COMMENTS
Allergy Clinical Care-Dept of Medicine	684-6266	1 gal/ year	Tissue preservation	Every-day	As needed	Gloves	Will look	Dr. Crapo-6266 350 Bell Bldg. 3 Labs from Chemistry storeroom diluted to 3% as needed.
Dept. of Medicine, Div. of Neurology	684-6274	1 gal/ month	Hyperdization of blots/10ml	"	couple mins.	Gloves	in Rpl-across from Jones	5963-M. Herbstreith-technician dilute 100% to 50% to make hyperdization solution.
Dept. of Medicine Div. of Hematology	684-3377	500ml/ year	Formald. gels for Northern blots		As needed	Under hood	has not used in 6 months will call	Dr. R. Bast - 3377 - Jones Bldg.
Microbiology, Immunology Research Lab	684-5569	500ml/ year	Formald. gels for Northern blots	once/ week	10-15 mins.	Gloves	will check	Dr. R. Corley - 5609-6016 ~10ml 40% formald. used. Jones Bldg. #316
Rheumatology, Immunology Research Lab	684-2746	1/2gal year	Six protein gels - ~20 ml	once/ week	couple mins/ sits covered overnight	Underhood	will ck. Carl bldg.	K. Culler - 2746,2226 - Laszlo Jakoi dilution to 2% - does 1/2.
Dept. of Pathology VA transplant Lab	684-6964	Gal/ year	fixing tissues dropped in container	twice/ week	couple mins/	Gloves	Bldg. 5 behind VA	Dr. A. Sanfilippo - 2482 Beth Barnhill 286-0411 Julie Fuller 286-6264 Dilute to 10% 5x at time

# APPENDIX NUMBER THREE

## EMPLOYEE NOTIFICATION

TO:

DEPARTMENT:

DATE:

FROM:

The following results are for air sampling done for the dates listed in the area or on the employee shown. After review, these results with the employee and getting both signatures, please send a copy back to this department while keeping the original for your files. If there are any questions please call the Environmental Safety Department.

EMPLOYEE/AREA SAMPLED	SAMPLE DATE	SUBSTANCE SAMPLED	PEL/STEL*	T.L.V.†	SAMPLE RESULT, TWA**
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METHOD:

COMMENTS:

\* PEL = PERMISSIBLE EXPOSURE LIMIT, STEL = SHORT TERM EXPOSURE LIMIT AS SET BY THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA).

† TLV = THRESHOLD LIMIT VALUE RECOMMENDED BY THE AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS (ACGIH)

\*\*T.W.A. = TIME WEIGHTED AVERAGE BASED ON AN 8 HOUR WORK SCHEDULE.

EMPLOYEE SIGNATURE \_\_\_\_\_

DATE \_\_\_\_\_

SUPERVISOR SIGNATURE \_\_\_\_\_

DATE \_\_\_\_\_