

HETA 86-226-1769
JANUARY 1987
MONTGOMERY HOSPITAL
NORRISTOWN, PENNSYLVANIA

NIOSH INVESTIGATOR:
Michael S. Crandall, CIH

I. SUMMARY

On February 27, 1986, the National Institute for Occupational Safety and Health (NIOSH) received a request for a Health Hazard Evaluation from Montgomery Hospital, Norristown, Pennsylvania. NIOSH was requested to evaluate worker exposures to glutaraldehyde when used as a disinfecting agent for respiratory therapy equipment, bronchoscopes, physical therapy whirlpool tubs, surgical instruments, and anesthesia equipment parts.

On September 16-17, 1986, an environmental evaluation was conducted in the Respiratory Care, Pulmonary Diagnostics, and Physical Medicine areas where the glutaraldehyde was being used. Five personal breathing zone air samples and nine area air samples were collected to determine potential glutaraldehyde exposures. Sampling times ranged from seven to thirty minutes. A medical questionnaire was used to determine the prevalence of acute symptoms possibly attributed to exposure to glutaraldehyde.

Personal exposure concentrations of glutaraldehyde ranged from none detected (ND) to 1.6 mg/m³. Two of the five personal exposures exceeded the American Conference of Governmental Industrial Hygienists' (ACGIH) Ceiling-TLV of 0.7 mg/m³. One other exposure was 0.6 mg/m³. At present there is neither a NIOSH recommended exposure limit nor an OSHA permissible exposure limit for glutaraldehyde. Area air samples measured glutaraldehyde concentrations ranging from ND to 1.0 mg/m³. Inadequate general ventilation, the absence of local exhaust ventilation, and varying work practices were all factors contributing to the relatively high exposures.

The symptom questionnaire was completed by 44 workers who used glutaraldehyde at least once a week. Twenty-eight (64%) workers reported eye irritation while using the glutaraldehyde solution, 28 (64%) reported nose irritation, 18 (41%) throat irritation, 14 (32%) skin irritation, 7 (16%) sore throat, and 12 (27%) headache. The higher prevalences of symptoms occurred in the Respiratory Care/Pulmonary Diagnostics and Physical Medicine groups.

On the bases of the environmental sampling and symptom questionnaire results, it was concluded that a health hazard did exist from glutaraldehyde exposure for nurses and technicians who perform disinfecting and sterilizing procedures. Recommendations for reducing exposure are included in Section VIII of this report.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals); glutaraldehyde, disinfecting, sterilizing; eye, skin, and respiratory irritation.

II. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation in February 1986 from a representative of Montgomery Hospital, Norristown, Pennsylvania. Concern for employees using a solution containing glutaraldehyde (CIDEX 7) for disinfecting and/or cold sterilizing health care equipment and instruments prompted the request.

An initial environmental evaluation was conducted on April 29-30, 1986. Air sampling for glutaraldehyde vapor was conducted in six use areas of the hospital; Respiratory Care, Pulmonary Diagnostics, Physical Medicine, Operating Room, Anesthesia, and an outpatient clinic. There were analytical problems with the air sampling method used (NIOSH method 2531) during this survey; therefore, the evaluation was rescheduled. A second evaluation was conducted on September 16-17, 1986 using two air sampling methods, NIOSH methods 2531 and 2532. This evaluation included only the first three areas mentioned above. Once again the analysis of the samples collected using method 2531 failed due to technical problems. The samples collected using NIOSH method 2532 were successfully analyzed. These results were verbally reported to the hospital when they were received in November 1986.

III. BACKGROUND

Montgomery Hospital is a public hospital serving Montgomery County Pennsylvania. The hospital employs 1200-1300 workers and has 250 physicians on staff. Glutaraldehyde is used extensively for disinfection and/or cold sterilization of respiratory therapy equipment, pulmonary diagnostic equipment, physical therapy equipment (whirlpool tubs), and to a lesser extent surgical instruments. Glutaraldehyde has been used here for the past 10 years.

CIDEX 7, a 2% glutaraldehyde solution, is effective for 28 days, once activated, and can be used for disinfection and sterilization. For disinfection against vegetative organisms, and pathogenic fungi and viruses, it is recommended that items be soaked for at least a 10-minute period. To sterilize against resistant pathogenic spores, the minimum soaking time is 10 hours.

A. Respiratory Care

In the Respiratory Care area the activated glutaraldehyde solution was kept in a covered 10-gallon plastic bucket, which contained a perforated inner basket. Items to be disinfected, generally parts from respiratory ventilators, are first washed with a detergent, then placed in the perforated basket and immersed for at least 20 minutes. Once removed, the items are rinsed and placed in a drying cabinet. This procedure could be repeated four or more times per work shift. Gloves were available and sometimes worn when removing and rinsing the disinfected items.

B. Pulmonary Diagnostics

In the Pulmonary Diagnostics area the glutaraldehyde solution (about 2 gallons) was kept in a deep, covered plastic pan. This was used to disinfect diagnostic equipment such as, fiber optic bronchoscopes. These are soaked for 10 minutes, then rinsed. The frequency of this operation is variable, but can take place four times per work shift. The CIDEX 7 is changed every 14 days here.

C. Physical Medicine

In the whirlpool room of the Physical Medicine department, glutaraldehyde is used to disinfect whirlpool tubs after each day's use. Monthly, the tubs are all disinfected whether they have been used or not. Historically, the method used to perform this task was to spray the glutaraldehyde solution onto the tub surface and pump shafts at the end of the day and let it stay overnight. In the morning they are rinsed before use. The method used at the time of the follow-up evaluation was to spray the solution onto a gauze pad, and then wipe down the tub surface. The pump shafts are still sprayed.

D. Other Areas

The operating rooms, anesthesia equipment area, and the outpatient clinic were not monitored for glutaraldehyde exposure during the follow-up evaluation. The staff in these areas reported that there was no CIDEX 7 being used at the time of the survey.

In the operating rooms, urologic and arthroscopic surgical equipment are soaked for the prescribed amount of time immediately prior to surgery, then rinsed and used when needed. Anesthesia equipment parts are disinfected as needed in an area of that department. In the outpatient clinic, the glutaraldehyde is used to sterilize gynecological examination instruments.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

Fourteen air samples were collected on September 16-17, 1986 using a solid sorbent (5% dinitrophenylhydrazine hydrochloride coated on XAD-2) to trap the glutaraldehyde vapor. Four personal and ten general area samples were collected by drawing air through glass tubes containing 150 milligrams (mg) of the solid sorbent at a flowrate of 0.8-1.0 liters per minute (lpm) using calibrated sampling pumps. Sampling times varied from less than 10 to 40 minutes.

Each sample was desorbed with 3.0 milliliters of acetonitrile and then analyzed by high pressure liquid chromatography (HPLC) equipped with a UV detector (365 nonometers). The limit of detection (LOD) for this method was 2.0 micrograms per sample (ug/sample) and the limit of quantitation (LOQ) was 6.0 ug/sample (NIOSH method 2532).¹

B. Medical

A brief medical questionnaire was completed by 44 hospital employees who worked with glutaraldehyde. The questionnaire was self-administered, and inquired about smoking habits, allergies, and whether or not the worker experienced eye, nose, throat, or skin irritation, sore throat, or headache when using the glutaraldehyde solution CIDEX 7.

V. EVALUATION CRITERIA

A. Environmental Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLVs are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLVs usually are based on more recent information than are the OSHA permissible exposure limits (PELs). The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH recommended exposure limits (RELs), by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

At present neither OSHA nor NIOSH have established exposure criteria for glutaraldehyde. The ACGIH has established a TLV of (C) 0.2 parts per million (ppm) which is equal to (C) 0.7 mg/M³. The designation C refers to a ceiling concentration that should not be exceeded even instantaneously.²

B. Chemistry/Toxicology of Glutaraldehyde

The use of glutaraldehyde has expanded over the last twenty years and it is now used in a variety of different fields. It was originally developed as a quick acting sporicidal agent without the undesirable properties of formaldehyde. Today, glutaraldehyde is used primarily for disinfection or sterilization of medical, dental and hospital equipment.

In a recent NIOSH-National Occupational Exposure Survey (NOES 1981-82) it was determined that glutaraldehyde is being used not only in a variety of areas in the medical industry (e.g., inhalation therapy, dental, urology, gastrointestinal, ambulatory services, electron microscopy and cytochemistry) but also in photography, shoe repair, dyes and tanning operations. The survey estimated that approximately 14,000 workers are potentially exposed to glutaraldehyde in the industries described.

Since 1982, glutaraldehyde has been marketed as a replacement for formaldehyde in dialysis reuse processes and it was estimated at the time that approximately 1 percent of hemodialysis operations in the United States have now begun to use glutaraldehyde for this procedure. The following information is an accumulation of studies and articles written on the chemistry and toxicology of glutaraldehyde.

1. Chemistry^{3,4,5,6}

Products containing glutaraldehyde are most frequently available as 2%, 10%, 25% and 50% aqueous solutions, which have no flash points and are non flammable. In general, glutaraldehyde is a saturated dialdehyde with the following formula: $\text{CHO-CH}_2\text{-CH}_2\text{-CH}_2\text{-CHO}$. Its molecular weight is 100.13. In contrast to formaldehyde, which is a simple aldehyde, glutaraldehyde has two active carbonyl groups. Under proper conditions these two groups, either singly or together, undergo most of the typical aldehyde reactions to form acetals, cyanohydrins, oximes, and hydrazones. Through the crosslinking reaction, the carbonyl groups react with protein.

As a raw material, glutaraldehyde is synthesized and commercially available as an acidic aqueous solution. Aqueous solutions of glutaraldehyde are mildly acid in reaction and at an acid pH of approximately 3-4, glutaraldehyde solutions are stable for a period of many months. In this acid state they are not sporicidal. When rendered alkaline, however, the glutaraldehyde gradually undergoes polymerization. Above a pH of 9, the polymerization proceeds comparatively rapidly and eventually loses activity. In the pH range of 7.5 to 8.5 the polymerization reaction is slowed down considerably, so that full antimicrobial activity (i.e., sporicidal, bactericidal, viricidal, and fungicidal) is maintained for at least two weeks (14 days).

Most glutaraldehyde used in hospitals is a 2.0% concentration which has a two-component system that must be mixed together, or activated, prior to use for disinfection or sterilization. The activated solution that contains 2.0% glutaraldehyde is buffered to an alkaline pH of 7.5-8.5 as described above. To buffer this concentration of glutaraldehyde to the required alkaline range, the addition of 0.3 percent of sodium bicarbonate is necessary. Although other alkalinating agents may be employed, the alkali metal bicarbonates, such as sodium bicarbonate, have given best results.

To provide greater utility to the activated or buffered glutaraldehyde solution, it has been convenient to add, in addition to the alkaline buffer, surfactants to promote the wetting and rinsing of surfaces, sodium nitrite as a

corrosion inhibitor, a peppermint oil odorant, and yellow and blue FD and D dyes, indicating that activation through mixing the two components has been completed. Before the addition of the buffer-dye combination, the unactivated glutaraldehyde solution is colorless; after the addition, the solution turns a characteristic fluorescent green. It should be noted that there are approximately eight different brands of this type of

material on the market today and each of these may have slightly different chemical ingredients as well as percent concentrations.

The majority of the 2% water solution available is used primarily as a cold disinfectant and sterilizer for hospital medical and dental work. In addition to the 2% solutions the most frequently used are the 25 and 90% solutions which are used as intermediates and fixatives for tissues, and for crosslinking polyhydroxy materials and proteins.

2. Toxicology

The majority of research articles available on glutaraldehyde today concern its ability to disinfect and/or sterilize against spores, bacteria, virus and fungus. There have been no epidemiological research studies reported in the literature to date and there have been only a limited number of human toxicological findings which have been reported recently on glutaraldehyde. The following is an accumulation of the more important information on animal, as well as the human toxicity studies currently available.

a. Dermatologic Effects

The Environmental Protection Agency in 1969, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) established that glutaraldehyde was considered to be a moderate skin irritant based on information collected during animal studies at that time.⁷

In one study aqueous solutions of 2 percent activated glutaraldehyde produced faint yellow staining of the skin and hair on rabbits after the first application. The staining became more intense and turned to a golden brown over the six week period of application. Discoloration persisted up to 35 days after application ceased. A mild "rash" appeared during the early stages but disappeared despite continued application of the solution. In the same study a 25 percent solution of glutaraldehyde produced a severe erythematous reaction with edema after one to two daily applications with necrosis and eschar formation in seven to ten days.

Activated glutaraldehyde retains the skin sensitizing properties of pure glutaraldehyde.⁸ One study reported that allergic contact dermatitis was found in radiologists and X-ray technicians from the handling of X-ray solutions containing glutaraldehyde. The authors concluded that all persons with hand dermatitis who handle X-ray films should have a patch test with one percent aqueous solution of glutaraldehyde.⁹

b. Respiratory Tract Effects

Glutaraldehyde has a pungent odor, an odor recognition threshold of 0.04 ppm by volume in air and an irritation response level of 0.3 ppm.⁶

In one study, activated glutaraldehyde versus pure glutaraldehyde increased the irritant effects to the upper respiratory tract of workers. Another study indicated that the vapor from pure glutaraldehyde was noticeable and considered irritating by some persons. The authors, therefore, concluded that glutaraldehyde should be kept covered whenever possible and used in a well-ventilated area in such a manner so as to prevent prolonged breathing of the vapor.¹⁰

c. Eye Effects

Studies on the effects of glutaraldehyde on the eyes of rabbits produced severe corneal opacity and irritation of the iris and conjunctiva. These reactions were not reversed during a seven-day observation period. In rinsed eyes, there was similar irritation of the conjunctiva which remained during the seven-day observation period. The cornea and iris showed less irritation, which was partially reduced during the seven-day observation period.¹¹

d. Mutagenic and Teratogenic Effects

In the most recent publication of the Registry of Toxic Effects of Chemical Substances (RTECS), 1983-84 three studies were cited in which glutaraldehyde was evaluated for possible mutagenic and teratogenic effects in animals. The study on mutagenic research on chickens showed that glutaraldehyde at 8% did not produce DNA damage.

The second study referenced stated that glutaraldehyde did not produce teratogenic effects. The study did illustrate, however, that glutaraldehyde administered to mice at 50 gm/kg produced central nervous system, musculoskeletal and craniofacial damage (including nose and tongue). It was also determined in this study that glutaraldehyde at 8 gm/kg produced fetotoxicity (i.e., stunted fetus).

The third study showed that glutaraldehyde acts as an antimetabolic and fixative substance to the eggs of a non-mammalian test species (Pleurodele) when they were treated with a .050 M solution.

e. Other Research

The results of two studies demonstrated an increased irritation from glutaraldehyde when the dialdehyde is activated. In one study mice were exposed at 8 and 33 ppm (33 and 133 mg/m³) of alkalinized glutaraldehyde for 24 hours. The animals reacted with distinctly nervous behavior, panting and washing of the face and limbs, with symptoms disappearing after a few hours. Half of each group were sacrificed immediately postexposure, and the rest one day later. Lungs and kidneys showed no histopathologic damage, but the livers of the mice exposed at 33 ppm showed definite signs of toxic hepatitis, possibly still reversible, since it was present to a somewhat lesser degree in the animals autopsied one day postexposure.⁶

In a second study, simulating a complete cold-sterilizing procedure lasting twelve minutes, the integrated sample of activated, 2% aqueous solution resulted in 0.38 ppm (1.33 mg/m³) of glutaraldehyde measured at the operator's breathing zone. Although some irritation had been felt throughout this procedure, it was not until the end of the operation, when the equipment being sterilized was air-hose dried, that severe eye, plus nose and throat irritation were felt by the operator and the investigators, who also experienced sudden headache.⁶

A NIOSH investigation concluded that a health hazard existed at a hospital where glutaraldehyde was used in small animal research studies, and as a sterilant and disinfectant of respiratory therapy equipment. Glutaraldehyde concentrations in 8 personal breathing zone samples ranged from none detected to 1.5 mg/m³. Six of these exceeded the ACGIH TLV of 0.7 mg/m³. Medical questionnaires revealed that 9 of 11 exposed workers reported irritative symptoms compatible with exposure to glutaraldehyde. Eye and throat irritation were the most prevalent symptoms.¹³

In summary, the current literature illustrates that glutaraldehyde is a relatively strong irritant to the nose and a severe irritant to the eye. It can produce staining and may be slightly irritating to the skin. It also may cause skin sensitization (allergic contact dermatitis) from occasional or incidental occupational exposures. Furthermore, it appears that the relatively strong irritant effect of pure glutaraldehyde on the eyes, nasal passages, upper respiratory tract and skin are slightly enhanced when the dialdehyde is activated. Finally, recent information suggests that glutaraldehyde is not mutagenic or teratogenic, but is fetotoxic.

VI. RESULTS AND DISCUSSION

A. Environmental

Environmental air sampling results are presented in Table 1. The breathing zone sample results, which represent as closely as possible the actual worker inhalation exposure, ranged from none detected (ND) to 1.6 milligrams per cubic meter (mg/m³). Two of these results were greater than the 0.7 mg/m³ ceiling evaluation criterion, and a third value was 0.6 mg/m³, averaged over a fifteen minute exposure period.

Three of the personal samples were collected in the Respiratory Care area while the worker was removing parts from the glutaraldehyde solution, rinsing them, and placing them in the drier. The sink where the items are rinsed is in a corner, with overhanging cabinets that make the space somewhat confined. This, and the lack of exhaust ventilation, lead to the significant exposures found while performing this task.

One of the breathing zone samples was collected in the Pulmonary Diagnostics room. The technician was performing a typical disinfection of a bronchoscope, lasting about 5 minutes. There was no glutaraldehyde detected on the sample.

The highest worker exposure measured, 1.6 mg/m³, was during the disinfection of the whirlpool bath tubs in the Physical Medicine department. On September 17 the therapist performed the monthly disinfection of all ten tubs. This operation lasted 20 minutes.

General area air sample results indicate that co-workers, if in the vicinity where the glutaraldehyde solution is being used, may also experience the typical acute irritation symptoms. Glutaraldehyde concentrations ranged from none detected to 1.0 mg/m³ in areas where the CIDEX 7 was being used. The NIOSH investigator experienced symptoms in every instance while monitoring the collection of personal samples. The symptoms included eye, nose, and throat irritation, and cough.

B. Medical

Forty-four employees, from five work areas, filled out a self-administered medical questionnaire. Results from these are presented in Table 2. The results showed that 28 of the 44 (64%) experienced eye irritation, 28 (64%) nose irritation, 18 (41%) throat irritation, 14 (32%) skin irritation, 7 (16%) sore throat, and 12 (27%) headache when using the glutaraldehyde solution. The prevalence rates were higher for these irritation symptoms in the Respiratory Care and Pulmonary Diagnostics, and Physical Medicine departments.

VII. CONCLUSIONS

The environmental monitoring documented overexposure to glutaraldehyde as it is commonly used in the Respiratory Care and Physical Medicine departments at Montgomery Hospital. The medical data indicate that a majority of the workers in these areas experience acute irritative symptoms typically associated with overexposure to glutaraldehyde. It is therefore concluded that a health hazard exists in these areas. A potential health hazard exists in other use areas based upon the high prevalence of irritation symptoms reported while using CIDEX 7.

VIII. RECOMMENDATIONS

The following recommendations are made to help reduce exposures to glutaraldehyde during the use of CIDEX at the Montgomery Hospital. These recommendations are based upon the results of the health hazard evaluation, observations made during the evaluation, and discussions with hospital staff.

A. Environmental

1. If possible, substitution of materials which are less hazardous is an excellent way to avoid exposures to the employees and should be investigated for the operations evaluated in this study.
2. If a substitute material is not available, a work station should be constructed, with local exhaust ventilation, in the Respiratory Care area to be used for equipment and instrument disinfection with the glutaraldehyde solution. A design suggestion would be a laboratory hood large enough to contain the CIDEX immersion system and an equipment washing and rinsing sink. Ideally, the CIDEX bucket would be sunken into the counter top for easy access. The design should require a face velocity at the hood opening of at least 100 feet per minute, with the airflow directed toward the back of the hood away from the operator's breathing zone. This system will require an appropriate amount of filtered and tempered replacement air in order to work properly. This system should be designed and installed by professionals with laboratory ventilation experience.
3. In the whirlpool room in the Physical Medicine department, a dilution ventilation system should be installed which will exhaust contaminated air at a sufficient rate to reduce worker exposures to glutaraldehyde to 0.1 mg/m³ or less. This system will require approximately an equal amount of filtered and tempered, fresh replacement air for proper operation. This air should be evenly distributed throughout the area. This system should keep the area under a slight negative pressure while in operation. Ideally, it should be controlled by a switch and a timing device, so that the worker disinfecting whirlpool tubs can activate the system, have it operate during the task and for an hour past the task completion, then shut down automatically.
4. Once the exhaust systems have been installed, an environmental air monitoring survey should be performed again in these areas to determine the effectiveness of the ventilation systems.

5. In order to decrease exposure to glutaraldehyde during the whirlpool disinfection task, a long handled applicator is recommended. Instead of spraying the solution onto the applicator, it would be better to dip it into a container of the liquid. The use of this type of system would keep the worker away from the confining tub, and eliminate the aerosol created by spraying the CIDEX. The pump shafts would still have to be sprayed.
6. Personal protective clothing should be mandatory when handling glutaraldehyde and a written program on proper use and correct clothing is recommended. This should include the following:
 - a. Respirators are necessary when the exposures to a chemical exceed known standards and/or criteria. However, respirators should not be considered a primary control and should only be used in lieu of more permanent controls (e.g., engineering controls, substitution, etc.). Respirators can be used in a useful manner for such activities as non routine maintenance or repair activities and emergencies. In the case of glutaraldehyde a NIOSH/MSHA approved organic vapor cartridge with a high efficiency pre-filter should be used. However, if respirators are to be used, a complete training program on selection, maintenance and fit testing is required for adequate protection.
 - b. Each employee who works with glutaraldehyde should wear protective gloves for the extent of the work process. The ACGIH recommends that a variety of different materials be used when working with aldehydes. This includes butyl rubber (described as excellent); polyurethane, polyethylene, PVC and styrene butadiene rubber (good to fair) and polyvinyl alcohol and Viton (only acceptable).
 - c. Other personal protective equipment should include lab coats, protective goggles and impervious aprons. The material described above should also be considered when selecting and appropriate aprons.

B. Medical

1. Eye contact with glutaraldehyde should, after prompt irrigation with water, be reported to a physician. Skin contact should be avoided and the skin promptly washed if contact is made.
2. Preplacement or initial medical questionnaires and examinations for employees who will be expected to work with glutaraldehyde should include questions on skin sensitization, eye and respiratory irritations.
3. If adverse effects to workers from past or current exposures to glutaraldehyde are suspected these employees should be evaluated medically. If confirmed (e.g., skin sensitization, asthma like symptoms or other related health problems) the employee should not be required to work with the solution or should be adequately protected from future exposures to glutaraldehyde as described above.

C. Other

1. Work practices in each of those areas where glutaraldehyde is used should be reviewed periodically in order to assure that potential overexposures are not occurring. Emphasis on the avoidance of exposures in confined spaces as described earlier in this report should be of primary concern.
2. The training and education of employees regarding safe work practices is essential to reducing and/or eliminating chemical exposures. Therefore, each employee should be instructed on the potential hazards associated with glutaraldehyde, proper use of personal protective clothing, work practices,

avoidance of confined space exposures and health and sanitation concerns. This would include signs and symptoms associated with glutaraldehyde as well the avoidance of eating, drinking or smoking while this chemical is being used.

3. An educational program to instruct new employees on the hazards of glutaraldehyde should be implemented, as well as an annual review for all concerned employees should be implemented if it has not been already.
4. Air monitoring (NIOSH Method 2531 or 2532) in all locations should be performed periodically and records kept of the results. This is especially important if there is any modification in the operation; that is, location or process changes and/or an increase in the use of glutaraldehyde.

IX. REFERENCES

1. National Institute for Occupational Safety and Health. NIOSH manual of analytical methods. 3rd ed. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1984. (DHHS (NIOSH) publication no. 84-100).
2. ACGIH, Threshold Limit Values (TLV) for Chemical Substances in the Work Environment, 1984-85.
3. Stonehill, A.A., et.al., "Buffered Glutaraldehyde - A New Chemical Sterilizing Solution," A.J.H.P. 20: 458-465 (September) 1963.
4. Miner, N.A., et. al., "Antimicrobial and Other Properties of a New Stabilized Alkaline Glutaraldehyde Disinfectant/Sterilizer," A.J.H.P. 34: 376-382 (April) 1977.
5. Borick, P.M.: Chemical Sterilizers (Chemosterilizers), In Advances in Applied Microbiology, Academic Press, New York, NY, 1968, pp. 291-312.
6. Glutaraldehyde - Documentation of the Threshold Limit Values - Fourth Edition, ACGIH, 1983, pp. 204-205.
7. Anon: Regulations for the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, section 362.116, 7 CFR part 362, Federal Register 34: 6106-6112 (April 4) 1969.
8. Jordan, W.P., et. al.: "Contact Dermatitis from Glutaraldehyde," Arch. Derm. 105: 94 (1972).
9. Fisher, A.A., "Reaction to Glutaraldehyde," with particular reference to radiologists and x-ray technicians, CUTIB Vol. 28, 2, pp. 113-114 and 119-122, 1981.
10. "Human Sensory Irritation Threshold of Glutaraldehyde Vapor - Report to Dr. N.A. Miner," Arbrook, Inc., Arlington, TX (February 19, 1976)
11. Anon: Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, part 162, Federal Register 40: 28279 (July 3) 1975.
12. NIOSH: Registry of Toxic Substances 1983-84 Cumulative Supplement V.1, p. 966.
13. Pryor, P.D., "National Jewish Hospital, Denver, Colorado" HETA 83-074-1525, NIOSH, November 1984.

X. AUTHORSHIP AND ACKNOWLEDGEMENTS

Report Prepared by: Michael Crandall, M.S., C.I.H
Industrial Hygiene Engineer
Industrial Hygiene Section

Originating Office: Hazard Evaluations and Technical
Assistance Branch
Division of Surveillance, Hazard
Evaluations, and Field Studies

Report Typed By: Linda Moris
Clerk-Typist
Industrial Hygiene Section

X. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Publications Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. Montgomery Hospital
2. Employee Representatives
3. OSHA, Region V

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

TABLE 1
 GLUTARALDEHYDE SAMPLING RESULTS
 MONTGOMERY HOSPITAL
 NORRISTOWN, PENNSYLVANIA
 SEPTEMBER, 16-17, 1986
 HETA 86-226

Job/Area Description	Sample Type	Sample Duration	Volume (liters)	Glutaraldehyde mg/m ³
<u>September 16, 1986</u>				
<u>Respiratory Care</u>				
Supervisor	BZ*	1446-1451 1508-1518	15	0.6
Counter, 3' from CIDEX bucket	GA*	1442-1521	39	(0.1)**
Next to sink, after rinse	GA	1517-1546	29	0.4
<u>Physical Medicine</u>				
On sink, inside whirlpool room	GA	1552-1620	28	0.7
Hallway, outside whirlpool room	GA	1553-1620	27	ND***
<u>September 17, 1986</u>				
<u>Respiratory Care</u>				
Supervisor	BZ	0832-0848	16	0.8
Counter, 3' from CIDEX bucket	GA	0830-0905	28	0.3
Next to sink, during and after rinse	GA	0830-0905	28	1.0

Criteria ACGIH (C)+ 0.7

Limit of detection - 2.0 ug/sample
 Limit of quantitation - 6.0 ug/sample

(continued)

TABLE 1 (continued)

Job/Area Description	Sample Type	Sample Duration	Volume (liters)	Glutaraldehyde mg/m ³
<u>September 17, 1986</u>				
<u>Respiratory Care</u>				
Technician	BZ	1007-1014	7	(0.4)
Counter, 3' from CIDEX bucket	GA	1007-1037	24	(0.02)
Next to sink, during and after rinse	GA	1007-1037	24	ND
<u>Pulmonary Diagnostic</u>				
Technician	BZ	1427-1432	5	ND
<u>Physical Medicine</u>				
Therapist	BZ	1510-1530	20	1.6
On sink, inside whirlpool room	GA	1510-1545	28	0.4
		Criteria	ACGIH	(C) ⁺ 0.7

Limit of detection - 2.0 ug/sample

Limit of quantitation - 6.0 ug/sample

* BZ - Sample collected in the workers breathing zone

GA - General area sample

** Values in parentheses are between the analytical LOD and LOQ

*** ND - None detected (below the analytical LOD)

+ The exposure criteria is designated as a ceiling concentration that should not be exceeded, even instantaneously

TABLE 2
SYMPTOM QUESTIONNAIRE RESULTS
MONTGOMERY HOSPITAL
NORRISTOWN, PENNSYLVANIA
HETA 86-226

Department	n	Symptoms							
		Smoke Cigarettes	Allergy/ Asthma	Iritation		Sore Throat	Skin	Throat	Headache
				Eye	Nose				
Respiratory Care and Pulmonary Diagnostics	9	1 (11%)	3 (33%)	8 (89%)	8 (89%)	6 (67%)	5 (55%)	4 (44%)	5 (55%)
Physical Medicine	4	1 (25%)	1 (25%)	3 (75%)	4 (100%)	3 (75%)	2 (50%)	0	0
Anesthesiology	7	2 (28%)	2 (28%)	4 (57%)	5 (71%)	3 (43%)	3 (43%)	1 (14%)	2 (28%)
Operating Room	23	10 (43%)	6 (26%)	13 (56%)	11 (48%)	6 (26%)	4 (17%)	2 (9%)	5 (22%)
Outpatient Clinic	1	0	0	0	0	0	0	0	0
Totals	44	14 (32%)	12 (27%)	28 (64%)	28 (64%)	18 (41%)	14 (32%)	7 (16%)	12 (27%)

n - number of workers