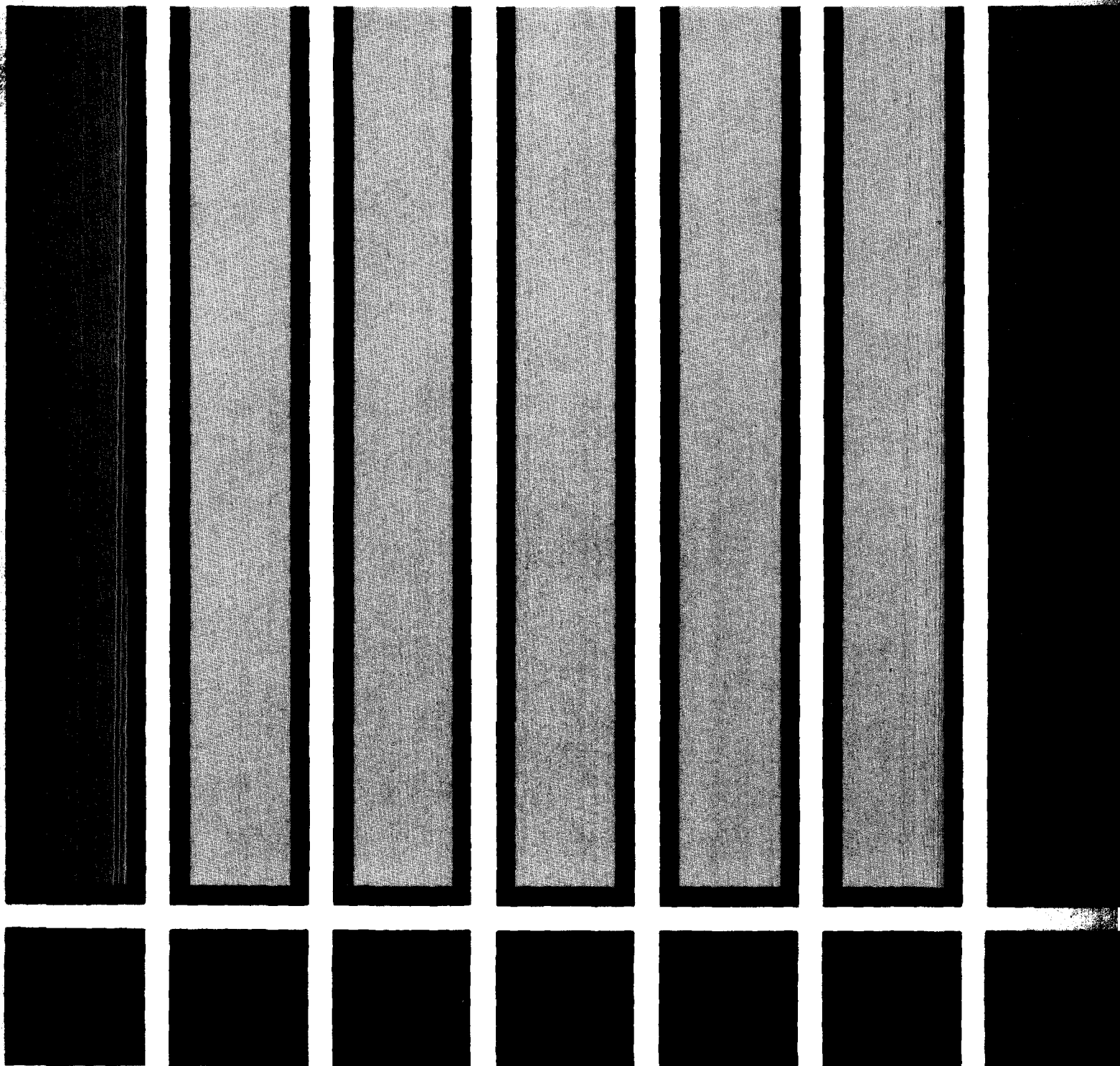


**NIOSH**

**criteria for a recommended standard . . . .**  
**occupational exposure to**  
**DIOXANE**



**U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**  
Public Health Service    Center for Disease Control  
National Institute for Occupational Safety and Health

**criteria for a recommended standard....**

**OCCUPATIONAL EXPOSURE  
TO  
DIOXANE**



**U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**  
Public Health Service  
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National Institute for Occupational Safety and Health  
**SEPTEMBER 1977**

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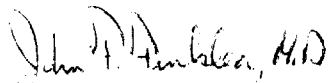
## PREFACE

The Occupational Safety and Health Act of 1970 emphasizes the need for standards to protect the health and safety of workers exposed to an ever-increasing number of potential hazards at their workplace. The National Institute for Occupational Safety and Health has projected a formal system of research, with priorities determined on the basis of specified indices, to provide relevant data from which valid criteria for effective standards can be derived. Recommended standards for occupational exposure, which are the result of this work, are based on the health effects of exposure. The Secretary of Labor will weigh these recommendations along with other considerations such as feasibility and means of implementation in developing regulatory standards.

It is intended to present successive reports as research and epidemiologic studies are completed and as sampling and analytical methods are developed. Criteria and standards will be reviewed periodically to ensure continuing protection of the worker.

I am pleased to acknowledge the contributions to this report on dioxane by members of my staff and the valuable, constructive comments by the Review Consultants on dioxane, by the ad hoc committees of the American Academy of Industrial Hygiene and the American Academy of Occupational Medicine, and by Robert B. O'Connor, M.D., NIOSH consultant in occupational medicine. The NIOSH recommendations for standards are not

necessarily a consensus of all the consultants and professional societies that reviewed this criteria document on dioxane. Lists of the NIOSH Review Committee members and of the Review Consultants appear on the following pages.



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The Division of Criteria Documentation and Standards Development, National Institute for Occupational Safety and Health, had primary responsibility for development of the criteria and recommended standard for dioxane. Leela I. Murthy, Ph.D., of this Division, had NIOSH program responsibility and served as criteria manager. Tabershaw-Cooper Associates Inc. developed the basic information for consideration by NIOSH staff and consultants under contract HSM-99-73-39.

The Division Review of this document was provided by Keith H. Jacobson, Ph.D. (Chairman), Douglas L. Smith, Ph.D., Frank L. Mitchell, D.O., and Clara H. Williams, Ph.D.

The views expressed and conclusions reached in this document, together with the recommendations for a standard, are those of NIOSH. These views and conclusions are not necessarily those of the consultants, other federal agencies, and professional societies, or of the contractor.

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CRITERIA DOCUMENT: RECOMMENDATIONS FOR AN OCCUPATIONAL  
EXPOSURE STANDARD FOR DIOXANE

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## I. RECOMMENDATIONS FOR A DIOXANE STANDARD

The National Institute for Occupational Safety and Health (NIOSH) recommends that worker exposure to dioxane (p-dioxane, 1,4-dioxane, diethylene dioxide, glycol ethylene ether) in the workplace be controlled by adherence to the following sections. The standard is designed to protect the health and provide for the safety of employees for up to a 10-hour workday, 40-hour workweek, during their working lifetime. Compliance with all sections of the standard should minimize adverse effects of exposure to dioxane on the health and safety of employees. The recommended environmental limit presented should be regarded as the upper limit of exposure, and every effort should be made to maintain exposure as low as is technically feasible. The standard is measurable by techniques that are valid and available to industry and government agencies. Sufficient technology exists to permit compliance with the recommended standard. The criteria and standard will be subject to review and revision as necessary.

Dioxane is a volatile liquid which can readily penetrate intact skin to cause systemic effects, which include adverse renal and hepatic changes. Exposure to dioxane may also cause cancer, a conclusion interpreted from experimental studies with animals, and much of the recommended standard is based on this conclusion. Because of the carcinogenic action of dioxane and its ability to penetrate the skin, occupational exposure to dioxane is defined as any work in workplaces where dioxane is handled, manufactured, or otherwise used, except where it is present as an unintentional contaminant in other chemical substances at less than 1% by weight or where it is only stored in leak-proof containers. The recommended exposure

limit, based on the belief that dioxane can be tumorigenic, is the lowest concentration reliably measureable by the sampling and analytical methods selected.

#### Section 1 - Environmental (Workplace Air)

##### (a) Concentration

Occupational exposure to dioxane shall be controlled so that employees are not exposed at airborne concentrations greater than 1 ppm (3.6 mg/cu m) based on a 30-minute sampling period.

##### (b) Sampling and Analysis

Procedures for sampling and analysis of workroom air shall be as provided in Appendices I and II or by any method shown to be at least equivalent in sensitivity, accuracy, and precision.

#### Section 2 - Medical

Medical surveillance shall be made available as outlined below to all workers subject to occupational exposure to dioxane.

##### (a) Preplacement examinations shall include at least:

(1) Comprehensive medical and work histories with special emphasis directed toward disorders of the upper respiratory system, and hepatic and renal functions.

(2) Physical examination giving particular attention to nares, and the hepatic and renal systems.

(3) Specific clinical tests to include at least liver and kidney function tests such as SGOT, SGPT, and a complete urinalysis.

(4) A judgment of worker's ability to use positive pressure respirators.

(b) Periodic examinations shall be made available at least annually. These examinations shall include at least:

(1) An interim medical and work history.

(2) A physical examination as outlined in (a)(2) and (3) above.

(c) Initial examinations shall be made available to all workers occupationally exposed to dioxane within six months after the promulgation of a standard based on these recommendations.

(d) Pertinent medical records shall be maintained for all employees exposed to dioxane in the workplace. Such records shall be kept for at least 30 years after termination of employment. These records shall be made available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employer, and of the employee or former employee.

### Section 3 - Labeling and Posting

All labels and warning signs shall be printed both in English and in the predominant language of non-English-reading employees. Employees unable to read the language used on labels and posted signs shall be appropriately informed of the location of hazardous areas and of the instructions on labels and signs.

#### (a) Labeling

The following warning label shall be affixed in a readily visible location on dioxane processing or other equipment and on dioxane storage tanks or containers:

DIOXANE

WARNING!

CANCER-SUSPECT AGENT

BREATHING VAPOR MAY BE HAZARDOUS TO HEALTH  
HARMFUL IF ABSORBED THROUGH SKIN OR IF INHALED

Avoid breathing vapor.  
Avoid contact with skin or eyes.  
Use only with adequate ventilation.  
Keep containers closed when not in use.  
Wash thoroughly after using.  
Extremely flammable.  
May explode.  
Keep away from heat, sparks,  
open flame and oxidizing materials.

First aid: In case of skin or eye contact, immediately flush eyes or skin with water for at least 15 minutes. Call a physician.

If swallowed, induce vomiting immediately if patient is conscious. Call a physician.

(b) Posting

Areas in which dioxane is present shall be posted with a sign reading:

DIOXANE

WARNING! CANCER-SUSPECT AGENT

HARMFUL IF ABSORBED THROUGH SKIN OR IF INHALED

Extremely flammable.

May explode.

Do not use near open flame or oxidizing materials.

Section 4 - Personal Protective Equipment and Protective Clothing

(a) Respiratory Protection

(1) Engineering controls shall be used if needed to maintain dioxane concentrations at or below the prescribed limit. Compliance with the permissible exposure limit may be achieved by the use of respirators only:

(A) During the time period necessary to install or test the required engineering controls;

(B) For nonroutine operations such as brief exposure at concentrations in excess of the environmental limit or for nonroutine maintenance or repair activities;

(C) During emergencies when air concentrations of dioxane may exceed the permissible limit.

(2) When respirators are permitted by paragraph (a) (1) of this section, they shall be selected and used pursuant to the following requirements:

(A) The employer shall ensure that no employee is being exposed to dioxane in excess of the environmental limit because of improper respirator selection, fit, use, or maintenance.

(B) The employer shall establish and enforce a respiratory protection program meeting the requirements of 29 CFR 1910.134.

(C) The employer shall provide respirators in accordance with Table I-1 and shall ensure that the employee uses the respirators in a proper manner when the concentration of airborne dioxane exceeds the recommended concentration limit.

(D) Respiratory protective devices described in Table I-1 shall be those approved by NIOSH or the Mining Enforcement and Safety Administration. The standard for approval is 30 CFR 11.

(E) The employer shall ensure that chemical cartridges and canisters are not used with dioxane except for evacuation or escape.

(F) The employer shall ensure that respirators are adequately cleaned, maintained, and stored, and that employees are instructed and drilled, at least annually, in the proper use and testing of respirators assigned to them.

(G) Respirators shall be easily accessible and employees shall be informed of their location.

TABLE I-1

RESPIRATOR SELECTION GUIDE FOR PROTECTION  
AGAINST DIOXANE

Concentrations of Dioxane	Respirator Type Approved under Provisions of 30 CFR 11
Greater than the recommended environmental limit (1 ppm) or entry into area of unknown concentration for emergency purposes	(1) Self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode (2) Combination Type C supplied-air respirator with full facepiece operated in pressure-demand mode with auxiliary self-contained air supply



(b) Protective Clothing

Protective clothing shall be worn in any operation in which the employee may come into direct contact with liquid dioxane. The clothing shall be impervious to penetration and resistant to degradation by dioxane. Neoprene-coated gloves, boots, overshoes, and bib-type aprons that cover boot tops shall be provided when necessary. Impervious supplied-air hoods or suits shall be worn when entering confined spaces, such as pits or tanks, unless known to be safe. In situations where heat stress is likely to occur, air-supplied suits, preferably cooled, are recommended. The employer shall ensure that all personal protective clothing is inspected regularly for defects and is maintained in a clean and satisfactory condition by the employee.

(c) Eye Protection

Eye protection shall be provided to, and worn by, each employee engaged in an operation in which dioxane, liquid or spray, may enter the eye. Chemical-type goggles, safety glasses with splash shields, or plastic face shields (8-inch minimum) made completely of dioxane-resistant material shall be used. Suitable eye protection shall be in accordance with 29 CFR 1910.133 and ANSI Z87.1-1968.

Section 5 - Informing Employees of Hazards from Dioxane Exposure

(a) All new and present employees working where occupational exposure to dioxane may occur shall be informed of the hazards, signs and symptoms of dioxane exposure, appropriate emergency procedures, and proper conditions and precautions concerning safe use and handling of dioxane.

(b) All employees occupationally exposed to dioxane shall be informed that dioxane has induced cancer in experimental animals after repeated oral ingestion and that, because of this finding, it is concluded that dioxane is a potential human carcinogen.

(c) Employers shall institute a continuing education program to ensure that all employees have current knowledge of job hazards and procedures for maintenance, cleanup, emergency, and evacuation. This program should include at least the following:

- Emergency procedures and drills.
- Instruction in handling spills and leaks.
- Decontamination procedures.
- Firefighting equipment location and use.
- First-aid procedures, equipment location, and use.
- Rescue procedures.
- Confined space entry procedures, if relevant.
- Inadequacy of odor as a means of detection.

The training program shall include a description of the general nature of the environmental and medical surveillance procedures and why it is advantageous for the worker to participate in these procedures.

Records of such training should be kept for at least 5 years. This training program shall be held at least annually, or whenever there is a process change, for all employees with occupational exposure to dioxane.

(d) Workers shall be informed that cancer has been induced in animals treated with dioxane at concentrations considerably higher than work environment exposures.

(e) Information as required shall be recorded on US Department of Labor Form OSHA-20, "Material Safety Data Sheet," or similar form approved by the Occupational Safety and Health Administration, US Department of Labor.

## Section 6 - Work Practices

### (a) Emergency Procedures

Procedures for emergencies, including fires, shall be established to meet foreseeable potential events. Necessary emergency equipment shall be kept in readily accessible locations. Where appropriate, respirators shall be available for use during evacuation.

### (b) Control of Airborne Dioxane

(1) Suitable engineering controls designed to limit exposure to dioxane to that prescribed in Section 1(a) shall be used. The use of completely enclosed processes is the recommended method for control of dioxane. Local exhaust ventilation may also be effective, used alone or in combination with process enclosure. When a local exhaust ventilation system is used, it shall be designed to prevent the accumulation or recirculation of dioxane in the workroom, to maintain dioxane concentrations below the limit of the recommended standard, and to remove dioxane from the breathing zones of employees. Exhaust systems discharging into outside air must conform with applicable local, state, and federal air pollution regulations. Ventilation systems shall be subjected to regular preventive maintenance and cleaning to ensure effectiveness, which shall be verified by periodic airflow measurements at least every 3 months. Measurements of system efficiency shall also be made immediately by personnel properly attired in any needed protective equipment and clothing when any change in production, process, or control might result in increased concentrations of airborne dioxane. Tempered makeup air shall be provided to work areas in which exhaust ventilation is operating.

(2) Forced-draft ventilation systems shall be equipped with remote manual controls and shall be designed to turn off automatically in the event of a fire in the work area.

(3) Exhaust vents to the outside shall be so located as to prevent the return of the exhausted air via air-intakes.

(4) Buildings in which dioxane is used and where it could form an explosive air-mixture shall be explosion-proof. Explosion vents are available and are effective on windows, roof and wall panels, and skylights as a safeguard against destruction of buildings and equipment in which flammable vapors may accumulate. Stair enclosures shall also be fire-resistant and shall have self-closing fire doors.

(c) General Work Practices

(1) Safety showers and eyewash fountains shall be installed in areas where dioxane is handled or used. The employer shall ensure that the equipment is in proper working order through regularly scheduled inspections performed by qualified maintenance personnel.

(2) Transportation and use of dioxane shall comply with all applicable local, state, and federal regulations.

(3) When dioxane containers are being moved, or when they are not in use and are disconnected, valve protection covers shall be in place. Containers shall be moved only with the proper equipment and shall be secured to prevent dropping or loss of control while moving.

(4) Process valves and pumps shall be readily accessible and shall not be located in pits or congested areas.

(5) Containers and systems shall be handled and opened with care. Approved protective clothing as specified in Section 4 shall be worn

while opening, connecting, and disconnecting dioxane containers and systems. Adequate ventilation shall be provided to prevent exposure to dioxane when opening containers and systems.

(6) Personnel shall work in teams when dioxane is first admitted to systems, while repairing leaks, or when entering a confined or enclosed space.

(7) Containers of dioxane shall be bonded and grounded to prevent ignition by static electrical discharge.

(8) Smoking shall not be permitted in work areas where there is dioxane.

(d) Work Areas

(1) Dioxane Hazard Areas

A hazard area is any space with physical characteristics and sources of dioxane that could result in air concentrations in excess of the recommended limit. Exits shall be plainly marked and shall open outward. Emergency exit doors shall be conveniently located and shall open into areas which will remain free of contamination in an emergency. At least two separate means of exit shall be provided from each room or building in which dioxane is stored, handled, or used in quantities that could create a hazard.

(2) Confined or Enclosed Spaces

Entry into confined spaces, such as tanks, pits, process vessels, tank cars, sewers, or tunnels where there may be limited egress, shall be controlled by a permit system. Permits shall be signed by an authorized employer representative certifying that proper preventive and protective measures have been followed.

Confined spaces which have contained dioxane shall be thoroughly ventilated to ensure an adequate supply of oxygen, tested for dioxane and other contaminants, and inspected for compliance with these requirements prior to each entry. Adequate ventilation shall be maintained while workers are in the confined space. Leakage of dioxane into the confined space while work is in progress shall be prevented by disconnecting and blanking the dioxane supply lines. Individuals entering confined spaces shall be furnished with appropriate personal protective equipment and clothing and connected by a lifeline harness tended by another worker outside the space, who shall also be equipped for entry with approved personal protective equipment and who has contact with a third party. Communication (visual, voice, signal line, telephone, radio, or other suitable means) shall be maintained by the standby person with the employee inside the confined or enclosed space.

(e) Storage

(1) Dioxane shall be stored in tightly closed containers in a well-ventilated area away from excessive heat and sunlight.

(2) Containers shall be stored in a safe manner to minimize the possibility of accidental breakage or spill.

(3) Storage containers shall be periodically inspected for leakage.

(4) Ventilation switches and emergency respiratory equipment shall be located outside storage areas in readily accessible locations which will be free of dioxane in an emergency.

(f) Cleanup of Spills and Waste Disposal

(1) If dioxane is spilled, the following steps shall be taken:

(A) Evacuate all nonessential personnel from the area.

(B) Adequately ventilate the area of the spill to prevent accumulation of the vapor.

(C) If in liquid form, collect for reclamation or absorb in vermiculite, dry sand, earth, or similar nonreactive material.

(2) Personnel entering the spill area shall be furnished with appropriate personal protective equipment and clothing. All other personnel shall be prohibited from the area.

(3) All wastes and residues containing dioxane shall be collected in dioxane-resistant containers and disposed of in a manner not hazardous to employees or to the general population. Dioxane wastes shall be appropriately marked. In selecting the method of waste disposal, applicable local, state, and federal regulations shall be followed.

Section 7 - Sanitation Practices

(a) Appropriate locker rooms shall be available for changing into required protective clothing in accordance with 29 CFR 1910.141(e), which requires separate storage for street clothes and protective clothing. Clothing contaminated with liquid dioxane shall be immediately removed and placed in a closed container in a well-ventilated area for later disposal or decontamination. Employers shall ensure that personnel who work with

dioxane shower before leaving the workplace at the end of a workday.

(b) Employers shall provide for decontamination of contaminated clothing, for example, by proper laundering. Commercial laundries, if used, shall be advised of dioxane hazards and of proper procedures for protection of laundry employees.

(c) Employers shall ensure that employees who handle dioxane wash their hands thoroughly with soap and water before eating, smoking, or using toilet facilities.

(d) The storage, preparation, dispensing, and consumption of food or beverages or smoking shall be prohibited in dioxane work areas.

#### Section 8 - Monitoring and Recordkeeping Requirements

##### (a) Personal Monitoring

A program of breathing zone or personal monitoring shall be instituted to identify and measure the exposure of all employees occupationally exposed to dioxane. This sampling and analysis shall be conducted at least every 3 months on at least 50% of the workers so that each worker's exposure is measured at least twice a year; this frequency and fraction of employees sampled may be different if so directed by a professional industrial hygienist. Sufficient numbers of samples shall be collected and analyzed to permit construction of valid estimates of the exposures of employees during each workshift; the number of samples and concentration determinations shall be based on such factors as mobility and job functions of workers in that operation. If monitoring of any employee shows exposure in excess of the recommended environmental limit, additional monitoring shall be promptly initiated. If confirmed, control procedures



shall be instituted as soon as possible; these may precede and obviate confirmatory monitoring if the employer desires. Affected employees shall be advised that exposures have been excessive and be notified of the control procedures being implemented. Monitoring of these employees' exposures shall be conducted at least as often as every 30 days and shall continue until two successive samplings at least a week apart confirm that exposure no longer exceeds the permissible limit. Normal monitoring may then be resumed.

(b) Recordkeeping

Environmental monitoring records shall be maintained for at least 30 years. These records shall include methods of sampling and analysis used, types of respiratory protection used, and concentrations found. Each employee shall be able to obtain information on his own environmental exposures. Environmental records shall be made available to designated representatives of the Secretary of Labor and of the Secretary of Health, Education, and Welfare.

Pertinent medical records shall be retained for 30 years after the last occupational exposure to dioxane. Records of environmental exposures applicable to an employee should be included in that employee's medical records. These medical records shall be made available to the designated medical representatives of the Secretary of Labor, of the Secretary of Health, Education, and Welfare, of the employer, and of the employee or former employee.

## II. INTRODUCTION

This report presents the criteria and the recommended standard based thereon which were prepared to meet the need for preventing occupational diseases arising from exposure to dioxane. The criteria document fulfills the responsibility of the Secretary of Health, Education, and Welfare under Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "...develop criteria dealing with toxic materials and harmful physical agents and substances which will describe...exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

The National Institute for Occupational Safety and Health, after a review of data and consultations with others, formalized a system for the development of criteria upon which standards can be established to protect the health and to provide for the safety of employees from exposure to hazardous chemical and physical agents. The criteria and recommended standard should enable management and labor to develop better engineering controls and more healthful work practices and simply complying with the recommended standard should not be the final goal.

These criteria for a standard for dioxane are part of a continuing series of criteria developed by NIOSH. The proposed standard applies only to the processing, manufacture, and use of dioxane as applicable under the Occupational Safety and Health Act of 1970. The standard was not designed for the population-at-large, and any extrapolation beyond occupational exposures is not warranted. It is intended to (1) protect workers against development of systemic effects and against local effects on the skin and

eyes, (2) be measurable by techniques that are valid, reproducible, and available to industry and governmental agencies, and (3) be attainable with existing technology.

Experimental toxicologic studies in mice, rats, and guinea pigs have indicated that dioxane can cause malignant tumors. These studies involved administration of the compound in drinking water. There is also equivocal evidence of carcinogenesis from dioxane when applied dermally, but this evidence has not been judged persuasive. While experimental inhalation studies and limited epidemiologic studies have not supported the implications that dioxane is carcinogenic, these studies have not been considered to be sufficient to negate the implications of the studies of dioxane administered at higher doses in the drinking water. Since a safe limit for this chemical substance, judged to be carcinogenic, is not known, a limit based on the sensitivity of the analytical and sampling methods has been recommended.

Concern for the carcinogenic and other toxic properties of dioxane by manufacturers may stimulate action to replace dioxane, for example, as a stabilizer for trichloroethane, by chemicals presumed or known to be much less toxic. Such manufacturers are urged to ensure that the substitutes are known, rather than presumed, to pose more acceptable toxicity properties.