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Safe use and handling of glutaraldehyde-based products in health care facilities

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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ST58 Safe use and handling of glutaraldehyde-based products in health care facilities

American National Standard

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Safe use and handling of glutaraldehyde-based products in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation
Approved 14 August 1996 by
American National Standards Institute, Inc.

Abstract:

This recommended practice provides guidelines for the safe use and handling of glutaraldehyde as a disinfectant and sterilant in health care facilities by defining facility design considerations, work practices, and engineering controls, including ventilation recommendations, that will help reduce personnel and patient exposure to glutaraldehyde.

Keywords:

Ceiling limit, chemical sterilants, disinfection, occupational exposure, OSHA, sterilization

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This recommended practice was developed by the Chemical sterilants Hospital Practices Working Group of the AAMI Sterilization Standards Committee. Committee approval of the recommended practice does not necessarily imply that all committee and working group members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies

Foreword

This recommended practice was developed by the Chemical sterilants Hospital Practices Working Group, under the auspices of the AAMI Sterilization Standards Committee. The objective of this recommended practice is to help promote the safe use and handling of glutaraldehyde as a disinfectant/sterilant in health care facilities by defining facility design considerations, work practices, and engineering controls, including ventilation recommendations, that will reduce personnel and patient exposure to glutaraldehyde.

This recommended practice reflects the conscientious efforts of concerned health care professionals, in cooperation with manufacturers of glutaraldehyde-based products, to develop recommendations for the optimum control of occupational exposure to glutaraldehyde. These recommendations might not be universally applicable to all circumstances. Also, these recommendations might not be immediately achievable in all situations. Therefore, the document should be used to guide knowledgeable personnel toward desirable performance objectives.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate that a course of action is permissible within the limits of the recommended practice; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

The provisions of this recommended practice should be reviewed by department managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with the appropriate hospital committees (e.g., safety, hazardous materials).

The concepts incorporated in this recommended practice should be considered flexible and dynamic. The

recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to: Technical Programs, AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Safe use and handling of glutaraldehyde-based products in health care facilities* (ANSI/AAMI ST58—1996), but it does provide important information about the development and intended use of the document.

Introduction: Need for the recommended practice

Glutaraldehyde-based products are effective sterilants and disinfectants that are used primarily for medical devices that cannot be steam-sterilized, particularly heat-sensitive, lensed instruments that are commonly subjected to high-level disinfection between patient uses. If used properly, glutaraldehyde-based products can be used without tissue irritation or other adverse health effects.[7] However, dermatologic and respiratory effects on overexposed personnel have been reported as well as eye irritation and, in some individuals, skin sensitization to glutaraldehyde; therefore, adequate precautions should be taken when using glutaral- dehyde-based products (Ballantyne 1995).

The occupational exposure limits discussed below were current at the time this document was published. However, it is essential that health care personnel keep informed of the status of federal, state, and local regulations applicable to glutaraldehyde, as well as with professional guidelines published by such organizations as the American Conference of Governmental Industrial Hygienists (ACGIH).[8]

For a number of years, most recently in 1995, ACGIH has recommended a ceiling threshold limit value (TLV-C) for glutaraldehyde of 0.2 parts per million volume (ppmv) (ACGIH 1995). Also in 1995, ACGIH issued a "Notice of Intended Changes" in which it was proposed that the TLV-C for glutaraldehyde be reduced from 0.2 ppmv to 0.05 ppmv. A threshold limit value is the airborne concentration of a substance to which "it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be affected more seriously by aggravation of a pre-existing condition, or by development of an occupational illness" (ACGIH 1995). A ceiling TLV is "the concentration that should not be exceeded during any part of the working exposure" (ACGIH 1995).

In 1989, based on the ACGIH recommendation at that time, OSHA adopted a TLV-C of 0.2 ppmv for glutaraldehyde as part of its Air Contaminants Standard (29 CFR 1910.1000). None of the exposure limits added to the Air Contaminants Standard in 1989 are currently in force due to legal challenges to procedural aspects of their adoption. However, federal OSHA can enforce these exposure limits, including the 0.2-ppmv TLV-C for glutaraldehyde, by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards. Additionally, as of 6 September 1993, 11 states with federally approved state OSHA programs had formally decided to continue to enforce the 0.2-ppmv TLV-C as originally promulgated in the Air Contaminants Standard.[9]

In October 1995, a major U.S. manufacturer of glutaraldehyde lowered its recommended airborne exposure limit for glutaraldehyde to a TLV-C of 0.1 ppmv.

This recommended practice sets forth guidelines for facility design, engineering controls, and work practices to assist health care personnel in minimizing occupational and patient exposure to glutaraldehyde. The provisions of this recommended practice should be reviewed by department managers and adapted to the needs of their

particular institutions. Written policies and procedures should be developed and implemented in consultation with the appropriate hospital committees (e.g., safety and hazardous materials).

Safe use and handling of glutaraldehyde-based products in health care facilities

1 Scope

1.1 General

This recommended practice provides guidelines for the safe use and handling of glutaraldehyde as a disinfectant and sterilant in health care facilities by defining facility design considerations, work practices, and engineering controls, including ventilation recommendations, that will help reduce personnel and patient exposure to glutaraldehyde.

NOTE—For the purposes of this recommended practice, "health care facilities" means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices. For convenience, the term "hospital" is sometimes used; in every instance, the term encompasses all other health care facilities.

1.2 Inclusions

This recommended practice specifically addresses

a) design considerations for areas in which glutaraldehyde disinfection and/or sterilization are performed;

b) proper work practices to help minimize occupational exposure to glutaraldehyde;

c) personnel qualifications, training, protective attire, and health considerations;

d) vapor monitoring.

Also included are definitions of terms, a bibliography, and annexes providing supplementary information on the properties of glutaraldehyde, current vapor monitoring technology, and federal and state-plan OSHA offices.

1.3 Exclusions

This recommended practice does not address the efficacy of glutaraldehyde for disinfection or sterilization, nor does it cover the safe use of liquid chemical sterilants other than glutaraldehyde. See AAMI (1990) for information on the safety and performance characteristics of chemical sterilants generally.

Glutaraldehyde is a major component of many sterilant/disinfectant products. Chemical and toxicological properties are unique for any given chemical, so the properties of glutaraldehyde discussed in this recommended practice should not be generalized to other components that a formulation might contain. The manufacturer of the sterilant/disinfectant product should be consulted for further details on the formulation and for a Material Safety Data Sheet (MSDS).

2 Definitions, symbols, and abbreviations

2.1 absorb: Take up or receive a vapor or liquid into a solid material.

2.2 adsorb: Collect (a gas, liquid, or dissolved substance) in condensed form on a surface.

2.3 air flow: Air movement as measured in volume of air per unit time (e.g., cubic feet per minute or liters per second).

2.4 air velocity: Air flow rate as measured by the average distance that air travels per unit time (e.g., feet per second).

2.5 automated glutaraldehyde processing equipment: Thermostatically controlled mechanical washer that eliminates manual cleaning and disinfection of medical devices.

2.6 ceiling value: Concentration of an airborne contaminant above which a person should not be exposed even momentarily. See also **threshold limit value-ceiling.**

2.7 employee breathing zone (EBZ): Sphere approximately 2 feet in diameter surrounding the head, according to the OSHA *Industrial Hygiene Technical Manual* (OSHA 1984).

NOTE—The term is commonly used by industrial hygienists and safety professionals to refer to the air around a worker's nose. Air samples collected from the shoulder or lapel are assumed to assess a worker's breathing zone exposure to air contaminants.

2.8 exhaust source: Motor and fan, or other means of providing air movement, placed upstream of all the sources of airborne pollutants to be expelled from the building.

NOTE—The exhaust source creates negative pressure, thereby drawing contaminated air into ducts or hoods and propelling it outdoors.

2.9 face velocity: Average rate-time of movement of air in feet per minute into a local exhaust ventilation system as measured at the opening of the hood.

2.10 head space: Space in a closed container above a solution.

2.11 high-level disinfection: Process designed to remove or destroy all fungi, vegetative bacteria (including *Mycobacterium tuberculosis*), viruses (including the human immunodeficiency virus [HIV]), and some bacterial spores.

2.12 industrial hygienist: Professional trained to anticipate, recognize, measure, evaluate, and control health hazards in the workplace.

2.13 local exhaust hood: System designed to capture contaminated air and conduct it into an exhaust duct.

NOTE—Also termed venting hood, pick-up hood, or pick-up duct.

2.14 personal protective equipment (PPE): According to OSHA, "specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment" (29 CFR 1910.1030).

2.15 ppmv: Parts per million volume. Concentrations of gas vapor in air are commonly measured in parts of gas vapor per million parts of air by volume: 1 ppmv equals 1 volume of gas vapor per 1,000,000 volumes of air.

2.16 sterilization: Process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

2.17 threshold limit value-ceiling (TLV-C): Concentration of an air contaminant to which "it is believed that nearly all workers may be repeatedly exposed day after day without adverse effect. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be affected more seriously by aggravation of a pre-existing condition, or by development of an occupational illness" (ACGIH 1995).

NOTE—For glutaraldehyde, the TLV is expressed as a ceiling value (TLV-C), which is "the concentration that should not be exceeded during any part of the working exposure" (ACGIH 1995).

2.18 venting: Collecting or capturing an air contaminant in order to discharge it via a pipe or duct to an area

where human exposure can be minimized.

3 Design considerations

3.1 General rationale

Traffic control; engineering controls (adequate ventilation); and proper equipment installation, operation, and maintenance can decrease unnecessary or inadvertent exposure of health care personnel, patients, or visitors to glutaraldehyde. This section provides guidelines for workplace design, traffic control, ventilation of areas in which glutaraldehyde sterilization or disinfection is performed, automated glutaraldehyde processing equipment, storage of unused glutaraldehyde solutions, and disposal of glutaraldehyde solutions and solution containers.

3.2 Containment areas

Designated areas for chemical sterilization and disinfection are strongly encouraged. Ideally, the space used for cleaning/decontamination should be separate from the space used for glutaraldehyde disinfection or sterilization of medical devices, and these spaces should be separate from patient procedure areas and personnel support areas. Policies and procedures should be standardized throughout the health care facility, with emphasis on necessary engineering controls and safe work practices.

Rationale: Glutaraldehyde-based products can be used in many areas of a health care facility (e.g., the operating room, endoscopic procedure area, respiratory therapy area, radiology department). Designating specific areas for the use of glutaraldehyde-based products helps minimize potential exposure to glutaraldehyde by ensuring that proper engineering controls are in place, that trained personnel are performing disinfection and sterilization, and that transport of glutaraldehyde solutions can be avoided (see 4.2.5). Separating the decontamination area from the preparation and disinfection/sterilization areas will limit the possibility of cross-contamination. Separating processing areas from patient procedure areas reduces the potential for cross-contamination and adverse health effects on patients with undetected respiratory ailments or asthmatic conditions. In addition, engineering controls such as local exhaust systems and increased ventilation might not be appropriate for patient procedure areas, because they can adversely affect negative-pressure air circulation systems.

3.3 Routing of traffic

Traffic in the processing area should be limited to trained personnel.

Rationale: Trained personnel will be aware of safe handling techniques and potential hazards and will be wearing appropriate protective attire.

3.4 Ventilation of areas/equipment in which glutaraldehyde is used

3.4.1 General

Proper ventilation can help ensure an irritation-free work environment. Glutaraldehyde odors can be detected at 0.04 ppmv and are the first indication that the ventilation might not be adequate. However, the characteristic sharp, pungent aldehyde odor of glutaraldehyde could be masked if a perfume is included in the formulation. Therefore, the ventilation system should be designed properly, and measures should be taken to ensure that it is operational at all times.

3.4.2 General room ventilation

Glutaraldehyde should be used in an area that is properly ventilated. Rooms in which glutaraldehyde disinfection/sterilization is performed should be large enough to ensure adequate dilution of vapor and should have a minimum air exchange rate of 10 air exchanges per hour. Ideally, local exhaust ventilation should be located at the level of the point of discharge of the glutaraldehyde vapor (see figure 1).

NOTE—Health care personnel should be observant of any sources of drafts that might be present (e.g., fans, open windows, air supply registers) and ensure that personnel in the area are not obstructing or interfering with

the proper function of the ventilation system.

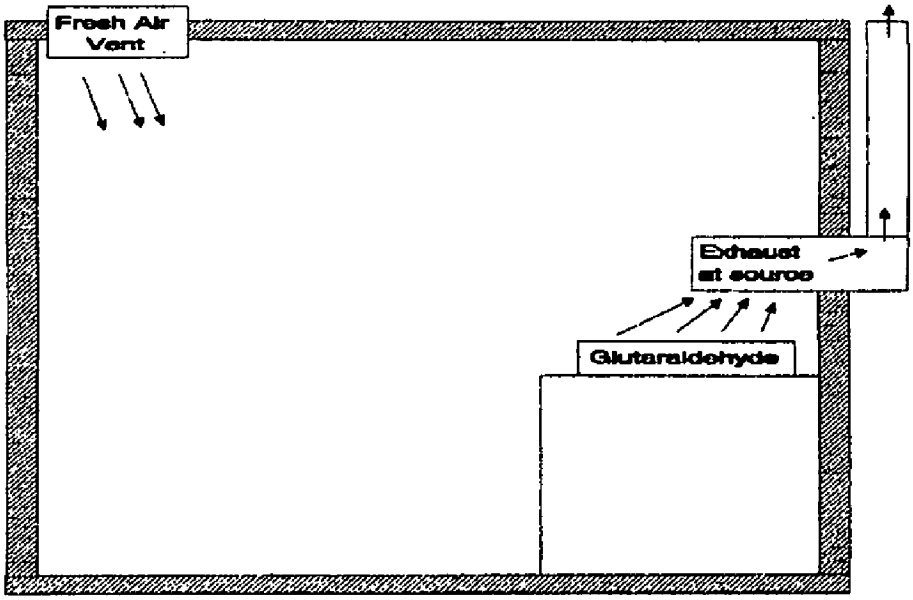

Figure 1—Recommended ventilation for glutaraldehyde.

Fresh air should enter on one side of the room. Local exhaust ventilation should be placed across the room from the fresh air return at the level of discharge of vapor. A minimum air exchange rate of 10 air exchanges per hour is recommended for areas in which glutaraldehyde is used. See 3.4.2.

Rationale: The appropriate air exchange rate for a particular area depends on a number of variables, including the volume of the room and asepsis considerations, as well as on the need to dilute chemical vapors. There are no national standards that specifically apply to ventilation of glutaraldehyde usage areas. The American Institute of Architects (AIA) does publish guidelines for general ventilation of areas in health care facilities, the most recent edition of which was approved in early 1996 (AIA 1996). These guidelines, while widely recognized in the health care community and referenced in the accreditation manual of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO 1996), are based mainly on considerations of odor control, asepsis, and personnel comfort. The committee judged that a general guideline should be provided here for general ventilation of glutaraldehyde usage locations and decided to recommend an air exchange rate of 10 air exchanges per hour. This air exchange rate is consistent with that generally recommended for dilution of vapors of another major chemical sterilant, ethylene oxide, with the AIA recommendations for sterilization areas, and with the MSDS for one commonly used glutaraldehyde-based product.

It should be noted that increasing the general room ventilation is usually not a cost-effective way to reduce hazardous vapor exposure levels due to the large amount of air that must be moved, heated, and cooled. Local exhaust ventilation located at the level of the point of discharge of the vapor prevents the vapor from escaping into the workplace and is the preferred method of reducing glutaraldehyde vapor concentrations. See also 3.4.3.

NOTE—The recommendations of this section do not negate negative and positive air-flow requirements.

3.4.3 Local exhaust ventilation

When general room ventilation is not adequate (as described in 3.4.2), a self-contained, free-standing system or a local exhaust hood should be installed for the containment of glutaraldehyde vapor. The purpose of the exhaust hood is to capture glutaraldehyde vapor during processing. The exhaust hood should be operating continuously. The local exhaust system should be designed to maintain adequate air movement to capture

glutaraldehyde vapor from the top of the container and thereby minimize personnel exposure. The American Industrial Hygiene Association (AIHA) recommends an average face velocity of 80 to 120 feet per minute (AIHA 1992). A ducted fume hood should be connected to a nonrecirculating exhaust system that goes to the outside atmosphere at a location away from people and air intake ducts. A ductless fume hood system delivers vapor to a filter system that chemically inactivates glutaraldehyde (figure 2). Clean filtered air is returned to the room. All fume hood systems should be monitored regularly for proper performance. The effectiveness of the filter bed on a ductless fume hood should be monitored, and the filters should be replaced regularly as needed.

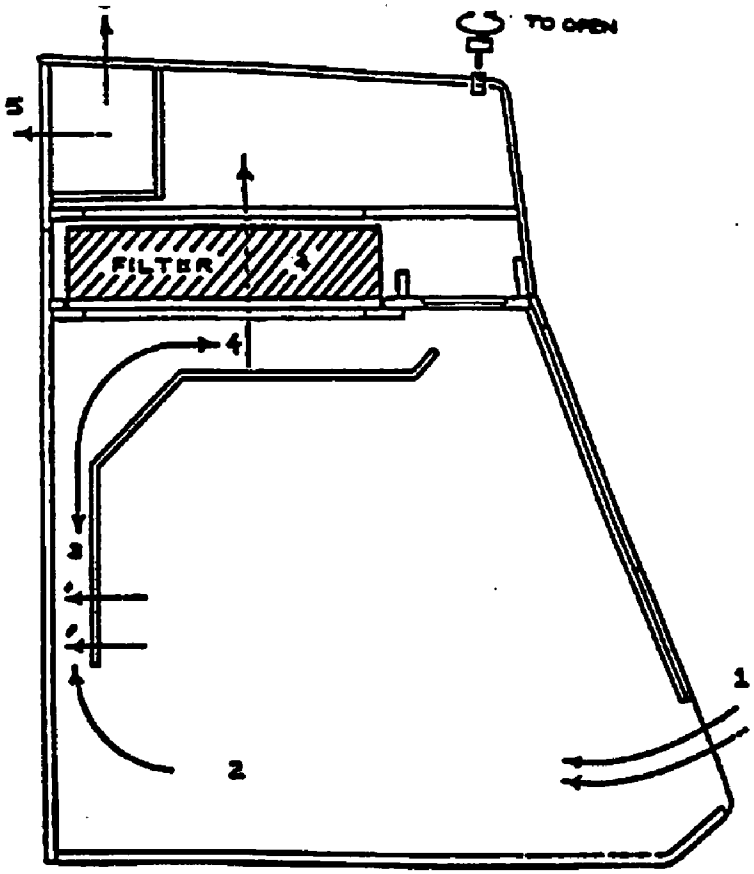

Figure 2—Schematic of a ductless fume hood showing the air-flow pattern.

As air is drawn into the hood from the room (1), a horizontal air stream (2) removes contaminants from the work surface to the rear (3) of the fume hood. The air is channeled up and into the filter bed (4). Clean filtered air is exhausted for recirculation (5).

Rationale: The major exposures to glutaraldehyde vapor occur when glutaraldehyde is poured into or out of a container system, when the container system is opened for use, when the solution is agitated during use, and when instruments are removed and rinsed. Local exhaust ventilation systems (including the exhaust hood, associated ductwork, and the exhaust fan) capture or control vapor at the source before the vapor can escape into the general work environment. The vapor is collected in a suitable hood and is either exhausted to the outside via a fan and duct system (ducted fume hood) or delivered to a filter system that captures or chemically inactivates the glutaraldehyde (ductless fume hood). Local exhaust ventilation is an accepted and effective industrial hygiene method to control the workplace hazards of airborne chemicals.

3.5 Automated glutaraldehyde processing equipment

3.5.1 Selection of equipment

Automated processing equipment using glutaraldehyde for high-level disinfection is designed to reduce

exposure to glutaraldehyde vapor. (The equipment manufacturer should provide exposure monitoring data verifying claims regarding glutaraldehyde vapor reduction.) Properly installed ventilation is still recommended, however, because glutaraldehyde vapor can escape into the work environment when the solution is activated and the equipment reservoir is filled. Proper ventilation is also required if it is necessary for the user to open the equipment mid-cycle or in case of equipment malfunction and troubleshooting.

Automated glutaraldehyde processing equipment can be semiautomatic or fully automatic. The current trend is toward fully automatic equipment because of the computer-generated documentation and greater ease in adapting the equipment for compliance with changing regulatory requirements.

Before automated processing equipment is installed, consideration should be given to space requirements, accessibility, safety features, mid-cycle inspection capability, any special plumbing requirements, filter requirements, the heating system, the capabilities of the cycle (e.g., prewashing, post-disinfection air- and alcohol-purge features), load capacity, capacity for accessory processing, and the means of changing and disposing of glutaraldehyde solutions.

Rationale: Although most types of automated processing equipment provide the same functions, the particular machine's specific capabilities, operational modes, safety features, and ability to meet the user's needs should be considered.

3.5.2 Installation

The equipment manufacturer's installation instructions should be followed. The equipment should not be operated until the equipment is properly installed/connected and its performance verified as per the manufacturer's instructions.

NOTE—The health care facility has the responsibility to ensure not only the correct functioning of automated processing equipment but also the safety of the work environment. Vapor monitoring should be conducted to ensure that the equipment minimizes employee exposure levels (see section 6).

Rationale: The equipment manufacturer is best able to advise the user regarding proper equipment installation. Verification of equipment performance before use is needed to ensure that the equipment can be operated safely and effectively and that vapor levels in the work environment are at or below the recommended TLV-C.

3.5.3 Equipment location

Selecting an appropriate location for the equipment should be a joint decision among the health care facility engineer, the department manager, the primary users of the equipment, the manufacturer's representative, and, as needed, an engineering or industrial hygiene consultant. The location of the equipment should take into account the manufacturer's instructions and any local codes. Equipment should be placed in a properly ventilated area.

Rationale: The health care facility is principally responsible for ensuring a safe work environment, but the manufacturer's advice will help ensure equipment effectiveness and ease of servicing. Industrial hygienists and certain engineering consultants have special expertise in the design of safe workplaces, and their advice also could be helpful.

3.5.4 Regulatory requirements

The health care facility must thoroughly investigate and comply with current federal, state, and local regulatory requirements and codes, including, but not limited to, electrical, fire prevention, safety, disposal, and ventilation codes. The health care facility must check with the local public owned treatment works (POTW) to determine whether the disposal of glutaraldehyde solutions into the sewer system is permitted.

Rationale: Compliance with federal, state, and local regulatory requirements is mandatory. Some local POTWs across the country prohibit the pouring of glutaraldehyde solutions into the sewage treatment system.

3.6 Storage of unused glutaraldehyde solutions

Unused glutaraldehyde solutions should be stored in tightly closed containers in a cool, secure, and properly marked location. Outdated glutaraldehyde solutions should be disposed of as per 3.7.1.

Rationale: Evaporation and exposure to high temperatures can result in polymerization of glutaraldehyde. Although the polymerization is not hazardous, it can negatively affect the biocidal efficacy of the product. Tightly closed containers in cool storage will prevent spills and contamination and enhance shelf life. Secure and properly marked storage locations will prevent accidental damage to the containers.

3.7 Disposal of glutaraldehyde solutions and solution containers

3.7.1 Glutaraldehyde solutions

Glutaraldehyde solutions should be disposed of in accordance with the manufacturer's instructions and federal, state, and local ordinances; it is especially important to consult with the local POTW for its requirements. If there are no disposal restrictions, solutions may be discarded, along with copious amounts of cold water, into a drain connected to a sanitary sewer. Glutaraldehyde solutions should not be discarded into septic systems.

Rationale: Five-day biological demand and aquatic metabolism studies indicate that glutaraldehyde degrades readily. Also, glutaraldehyde does not inhibit the growth of unacclimated sewage microorganisms at concentrations less than 5 milligrams/liter (mg/l) or 5 ppm.10

Due to dilution by other waste streams in a municipal sewage system and the fact that glutaraldehyde is deactivated by proteinaceous components of sewage effluent, some authorities have concluded that disposal of spent glutaraldehyde will have no adverse effects on the sewage treatment plant.11

Disposal of glutaraldehyde solutions (including neutralized solutions) into a septic system is not recommended because there is a greater likelihood that the glutaraldehyde could be entering the system at concentrations higher than 5 ppm. This is due to the fact that a septic system is not diluted by other waste streams. Concentrations of glutaraldehyde higher than 5 ppm inhibit the growth of microorganisms that are necessary for proper functioning of the septic system.

3.7.2 Glutaraldehyde solution containers

Empty containers should be disposed of in accordance with the disposal instructions given on the product label.

Rationale: Disposing of empty containers in an appropriate manner will prevent accidental chemical exposure or improper reuse of containers.

4 Work practices

4.1 General rationale

Procedures should be developed that will prevent contact with glutaraldehyde and reduce exposure to glutaraldehyde vapor to the lowest reasonably obtainable level below the TLV-C. This section provides processing recommendations and guidelines for dealing with spills.

4.2 Processing recommendations

4.2.1 Ventilation

Glutaraldehyde solutions should be prepared and used in a well-ventilated area (see section 3.4.1).

Rationale: Exposure to glutaraldehyde vapor, even at levels below the TLV-C, can cause symptoms such as headaches and/or irritation of eyes, nose, and throat. These symptoms should disappear when the individual leaves the area of glutaraldehyde usage. Exposure to glutaraldehyde vapor can also cause asthma-like symptoms in some individuals. See also 5.5.2 and 5.5.3.

4.2.2 Personal protective equipment

4.2.2.1 General

Personnel should wear appropriate personal protective equipment (PPE) designed to protect skin, eyes, and clothing from splashes when disinfecting/sterilizing instruments with glutaraldehyde solutions. The health care facility should develop a written program on the proper use of PPE. The health care facility must comply with OSHA's Medical and First Aid Standard (29 CFR 1910.151), which requires suitable facilities for eye washing. Personnel should also be familiar with the OSHA standards for employer/employee responsibilities for personal protective equipment (29 CFR 1910.132), eye and face protection (29 CFR 1910.133), respiratory protection (29 CFR 1910.134), and hand protection (29 CFR 1910.138).

On 6 April 1994, OSHA expanded the requirements of the Personal Protective Equipment Standard, which now specifies that an employer must conduct a hazard assessment to determine what hazards necessitate the use of personal protective equipment (29 CFR 1910.132[d]). The employer must verify that the required workplace hazard assessment has been performed through a written certification. The written certification must identify the workplace evaluated, the person certifying that the evaluation has been performed, and the date(s) of the hazard assessment; the document must be identified as a certification of hazard assessment.

The employer must provide specific training to each employee required to wear PPE. The employer must verify that each employee has received and understood the required training through a written certification that contains the name of each employee trained, indicates the date(s) of training, and identifies the subject of the certification.

4.2.2.2 Eye protection

Eyes must be protected against contact with the chemical solution, and vapor levels must be kept below the TLV-C to prevent eye irritation. Splashproof goggles or full face shields should always be worn when working with glutaraldehyde solutions. If any contact should inadvertently occur, the eyes should be flushed immediately with water; and washing should be continued for at least 15 minutes. Contact lenses, if worn, should not be removed. The employee should be seen immediately by an emergency room physician or eye care physician.

Suitable eyewash units must be available for immediate emergency use in all glutaraldehyde usage locations. The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI 1990). Among other things, ANSI Z358.1-1990 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units. Emergency eyewash units should be located within 10 seconds travel time and/or 100 feet travel distance of all glutaraldehyde usage locations. The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer's instructions. Before attempting to implement the ANSI standard, health care personnel should consult the standard itself to familiarize themselves with all of its provisions.

NOTE—See also 4.2.2.1 and 4.3.4.

Rationale: Glutaraldehyde in concentrations of 2% to 4% is classified as an eye irritant. Eye contact causes moderate to severe irritation, experienced as discomfort or pain, excessive blinking, and tear production, with marked redness and swelling of the conjunctiva. (See also 5.5.2.) Contact lenses should not be removed before eyewashing because, due to the cross-linking properties of glutaraldehyde, contact lenses could be bound to the cornea if in contact with glutaraldehyde; removal of contact lenses before treatment could cause injury to the eyes. Also, contacts left in place could protect the cornea. The availability of eyewash units for immediate emergency use is required by OSHA. Proper maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical and First Aid Standard (29 CFR 1910.151), and ANSI (1990).

4.2.2.3 Skin protection (liquid)

Skin should be protected from contact with the chemical solution. Gloves impervious to glutaraldehyde should always be worn if there is any possibility of contact with the solution. The forearms should be protected by elbow-length gloves or by protective sleeves made of a glutaraldehyde-impervious material. Nitrile and butyl rubber are the materials most impervious to glutaraldehyde. Gloves made of polyethylene and certain man-made copolymers give protection for several hours.

The permeability of gloves varies considerably, depending on the manufacturer, and this is especially true of latex gloves. Except in situations where only short-term, incidental contact is expected, latex gloves should not be used for skin protection against glutaraldehyde. If latex gloves are used, specific instructions should be provided regarding the length of time that they can safely be worn during contact with glutaraldehyde and whether they should be worn in single or double pairs. The recommendations of the glove manufacturer also should be consulted.

Polyvinyl chloride and neoprene gloves do not give adequate protection from glutaraldehyde and can actually absorb the chemical; therefore, the use of these types of gloves is not recommended.

Isolation gowns, lab coats, or aprons plus sleeve protectors that are made of appropriate protective materials will provide additional protection to skin and clothing. An example of a glutaraldehyde-impervious material used in the manufacture of protective clothing is polyethylene-coated, spun-bond polypropylene. It should be noted that "liquid-resistant" or "liquid-proof" clothing designed for protection against bloodborne pathogens might not be adequately protective against chemicals such as glutaraldehyde. Before purchasing PPE, the health care facility should obtain permeation data from the manufacturer, collected according to the ASTM F739-96 Permeation Protocol (ASTM 1996), that document that the material will provide acceptable protection against glutaraldehyde.

Protective clothing should be removed quickly if it becomes saturated, and it should be laundered before reuse. If any skin contact with glutaraldehyde should inadvertently occur, the skin should be washed thoroughly with soap and water and should be flushed with water for at least 15 minutes.

NOTE—See also 4.2.2.1.

Rationale: Brief contact with 2% to 4% glutaraldehyde can cause minor irritation to the skin; prolonged contact causes mild to moderate local redness and swelling. OSHA's expanded Personal Protective Equipment Standard (29 CFR 1910.132) requires that employers conduct a hazard assessment and "select, and have each affected employee use, the type of PPE that will protect the affected employee from the hazard identified in the hazard assessment" (see also 4.2.2.1). OSHA's new Hand Protection Standard (29 CFR 1910.138) states the following: "Before purchasing gloves, the employer should request documentation from the manufacturer that the gloves meet the appropriate test standard(s) for the hazard(s) anticipated." The referenced ASTM permeation protocol is the test method commonly used to evaluate the permeability of materials to various chemicals.

4.2.2.4 Respiratory protection

OSHA standards for respiratory protection and hazard communication (29 CFR 1910.134 and 29 CFR 1910.1200, respectively) require the use of appropriate respirators by all employees who could be overexposed to chemical vapor during routine or emergency work procedures. All personnel who might be required to wear respirators must be trained in the care and use of respirators. Routine respirator usage is not a substitute for appropriate engineering, administrative, and work practice controls. Regular respirator usage should only be a temporary measure until glutaraldehyde exposure is reduced by other means. HEPA respirators used to prevent transmission of tuberculosis and masks used to protect against bloodborne pathogens filter aerosol droplets, not chemical vapor. These types of respirators must not be used for glutaraldehyde protection.

The respirators used must be approved by the National Institute for Occupational Safety and Health (NIOSH) and must be appropriate for use with glutaraldehyde. NIOSH recommends the use of organic vapor cartridges with air-purifying respirators. Respirator selection must be based on the ambient exposure situation. Appropriate

engineering controls must be put into place in order to reduce exposure to glutaraldehyde vapor. If temporary respiratory protection is necessary, only a full-face, negative-pressure respirator or a self-contained breathing apparatus (SCBA) is acceptable (29 CFR 1910.134). Vapor monitoring will be helpful in determining those operations likely to cause an overexposure (see section 6).

Spill situations generally require a high level of respiratory protection. When the air concentration of glutaraldehyde vapor is unknown, the only acceptable respiratory protective equipment is a SCBA. However, if information is available about the amount and composition of glutaraldehyde spilled and the characteristics of the room ventilation, lower levels of respiratory protection could be adequate.

All personnel who might be required to wear a respirator for routine or emergency use must be included in a Respiratory Protection Program that meets the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134). An acceptable respirator program must include standard written operating procedures covering all aspects of the program (i.e., workplace surveillance; respirator selection; employee medical surveillance; procedures for periodic inspection, cleaning, and storage of respirators; employee training; qualitative or quantitative respirator fit testing; and program evaluation). Employee training, medical surveillance, and program evaluation should be repeated periodically (e.g., annually).

Rationale: OSHA's requirements for respirator use are very specific. OSHA does not allow permanent or continued use of respirators as a means of employee protection; for routine operations, respirators can only be used until engineering, administrative, and work-practice controls are adequate to prevent overexposures. See also “Introduction: Need for the recommended practice” and section 4.2.1.

4.2.3 Preparing activated solutions

Glutaraldehyde solutions should be prepared and activated according to the manufacturer's instructions. Personal protective equipment should be worn; and every effort should be made to minimize splashing, spilling, and personnel exposure. Preparation of activated solutions should only be performed in a properly ventilated area. The date of activation (mixing date) and the expiration date should be recorded on the activated solution container.

Rationale: The recommended ventilation, spill prevention procedures, and protective equipment are intended to protect the worker from the irritating effects of overexposure to glutaraldehyde. The activation and expiration dates should be recorded to ensure that the solution will not be used longer than its effective use life.

4.2.4 Pouring activated solution

The solution should be poured from the container to the disinfection/sterilization basin by a method that will prevent employee contact with the chemical solution and reduce exposure to glutaraldehyde vapor to the lowest reasonably obtainable level below the TLV-C. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods.

Rationale: Avoiding contact with glutaraldehyde-based products prevents skin irritation and damage or irritation to the eye and minimizes the potential for skin sensitization, which has been reported in a small proportion of users. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also 4.2.1 and 4.2.2.

4.2.5 Transporting solutions

Transport of glutaraldehyde solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport an activated solution to another area, that area should be properly ventilated, and a method of transportation should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface

area and thus increase the potential for vapor to rise to an air concentration above the TLV-C. Spills also increase the potential for skin and eye contact and irritation, as described in the rationale statements for 4.2.2.2 and 4.2.2.3.

4.2.6 Storing activated and unused solutions

Glutaraldehyde should be stored in a closed container or system in a well ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5][i]), with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of these containers should be as small as possible; the containers should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are placed into or taken out of the solution. Automated systems should be designed to prevent the escape of glutaraldehyde vapor and liquid.

Rationale: A closed system will minimize evaporation of the glutaraldehyde and subsequent personnel exposure to vapor.

4.2.7 Immersing items to be disinfected/sterilized

Personal protective equipment should be worn by the worker placing instruments/items into the activated solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry instruments/items in the activated solution, taking care to disturb and agitate the surface of the solution as little as possible.

When the solution must be manually irrigated or flushed through internal channels or lumens of an instrument, care should be taken to ensure that the employee is not splashed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The instruments/items should be allowed to soak for the amount of time designated by the manufacturer to achieve disinfection or sterilization. (See also the instrument manufacturer's instructions for additional recommendations on disinfection/sterilization.)

Rationale: These procedures will help prevent worker exposure to glutaraldehyde and help ensure the effectiveness of the disinfection/sterilization process.

4.2.8 Rinsing disinfected/sterile items

Personal protective equipment should be worn by the worker removing items from the activated solution; this activity should take place in a properly ventilated area.

Before the device is removed from the disinfecting/sterilizing solution, the solution should be removed from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Care should be taken to ensure that the employee is not splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to "squirt" from the channel opening.

The instruments/items should be gently removed from the solution and rinsed thoroughly in clean, potable water or (if the items are to be used in a sterile field) sterile distilled water. (Workers should rinse their gloved hands with water and then replace the cover on the solution container.) The external surfaces of the items and any removable parts should be rinsed with copious amounts of clean running water to remove all residual solution. For instruments with interior channels, each channel or the all-channel irrigator should be flushed several times with clean water until all residual solution is removed from the channels. The flushing procedure should be

repeated with air. (See also the instrument manufacturer's instructions.)

NOTE—If the instruments/items are not going to be used immediately and are to be stored, the flushing procedure should be repeated with a 70% alcohol flush, followed by air, to facilitate drying and to eliminate an environment conducive to bacterial growth.

Rinse water should be discarded promptly, not reused.

Rationale: Proper procedures for rinsing, flushing, drying, and storing instruments will help prevent worker exposure to glutaraldehyde and help ensure that residual glutaraldehyde is not introduced into patient tissue. See also Durante (1992).

4.3 Glutaraldehyde spills

4.3.1 Glutaraldehyde spill containment response team

Consistent with the JCAHO Hazardous Materials Plan, a glutaraldehyde spill containment "response team" should be created (JCAHO 1995). The response team should include a representative from the safety committee, a physician (ideally an occupational health physician), the unit supervisor, and any other personnel deemed appropriate. This response team should be responsible for developing and executing procedures for glutaraldehyde spills.

Rationale: To ensure rapid, efficient, and effective response to glutaraldehyde spills, it is important that specific individuals be assigned responsibility for developing and implementing procedures for handling the spills. The composition of the response team should reflect all expertise relevant to the control of glutaraldehyde spills and the resulting vapor.

4.3.2 Glutaraldehyde spill containment plan

A written plan for containment of glutaraldehyde spills should be prepared by the response team. The team should consider the concentration of glutaraldehyde in the solutions and the design of the facility (such as the type of ventilation, the air turnover rate, and the size and temperature of the room) before defining those spills that can be safely cleaned up by a health care worker. The procedures should specify (1) cleanup equipment, (2) placement of cleanup equipment for easy access, (3) a plan for alerting personnel, (4) recommendations for avoiding contact with the glutaraldehyde solution, and (5) evacuation of nonessential personnel, if necessary. The plan should include

a) the procedures for evacuating personnel in the event of a spill;

NOTE—All spills have the potential to cause the ambient concentration of glutaraldehyde to exceed the TLV-C.

b) the procedures for medically treating persons who might have come into contact with liquid glutaraldehyde or who are overcome by glutaraldehyde vapor;

c) the procedures for reporting an emergency to appropriate authorities (e.g., the safety officer or health and safety personnel);

NOTE—Glutaraldehyde spills need not be reported to regulatory authorities responsible for air quality (e.g., state health/environmental authorities such as a state Air Control Board, OSHA, or Environmental Protection Agency [EPA]). Glutaraldehyde does not have a reportable quantity (RQ) established by EPA under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA), nor is it on the toxic release inventory (TRI) list established under the Superfund Amendments and Reauthorization Act of 1986 (SARA), Title III. Glutaraldehyde concentrations of 1% or more are listed in some states' right-to-know regulations. Because glutaraldehyde contains no levels of listed substances that California has found to cause cancer, birth defects, or other reproductive harm, it is not listed under Proposition 65.

d) the procedures for material cleanup, which should specify ready access to equipment for the cleanup and the required personal protective equipment (see 4.3.3);

NOTE—An MSDS must be accessible to all personnel and appropriately filed to maintain OSHA compliance. If one is not currently on file, it can be obtained from the sterilant/disinfectant manufacturer or supplier.

e) a description of the employee training program and of the method used to verify competency;

f) the known rate of air exchanges;

g) the potential for the general ventilation system to carry glutaraldehyde vapor from the site of the spill to other areas in the hospital and a prescribed course of action to prevent the dispersal of glutaraldehyde in other areas;

h) the recommendations of the sterilant/disinfectant manufacturer for emergency procedures, as found in the MSDS or obtained by calling the manufacturer's emergency phone number;

i) a description of the respiratory protection program that outlines the safe use, location, storage, fit-testing, and periodic inspection of emergency-use respirators and the procedures to be used for medical assessment of staff required to use the apparatus;

NOTE—Personnel entering a spill area for corrective action might need to wear NIOSH/MSHA-approved respirators, depending on the ambient air concentration of glutaraldehyde vapor (see 4.2.2.4). Respirators and protective attire such as gloves and aprons must be readily accessible.

j) designation of the persons responsible for supervising the handling of glutaraldehyde spills.

Rationale: A well-designed plan of action, with which personnel are thoroughly familiar, will help reduce the potential adverse effects of a glutaraldehyde spill.

4.3.3 Suggested procedures for cleaning up glutaraldehyde spills

4.3.3.1 General

All spills, no matter how small, should be cleaned up immediately. The glutaraldehyde concentration, the volume of the spill, the temperature of the room and the solution, and the type of ventilation in the area of the spill will affect whether or not it can be cleaned up safely without the use of inactivating chemicals and respiratory equipment. The committee judged it safer not to use a volume measurement to differentiate between a drip, a splash, a small spill, and a large spill but instead to provide recommendations based on the assumption that anything larger than a drip or splash might need to be inactivated. It could be necessary to wear a respirator, depending on volume and ventilation. The use of a respirator is required for any spill with unknown vapor concentration (see 4.2.2.4).

4.3.3.2 Neutralizing chemicals

Several chemicals (e.g., sodium bisulfite, dibasic ammonium phosphate, household ammonia, ammonium carbonate powder) can be used to decrease the glutaraldehyde concentration in solutions and/or reduce ambient vapor levels in spill situations; there are also a number of commercially available products designed for this purpose. Such chemicals have varying degrees of activity; some are used to deal with the solution, some with vapor. Before using a glutaraldehyde-based product, health care personnel should be familiar with the manufacturer's specific recommendations, with supporting technical data, for chemicals to be used to clean up spills.

4.3.3.3 Drips and splashes

It is important that all spills, including drips and splashes, be cleaned up immediately. All necessary cleanup

equipment, including a mop and bucket, plastic dust pans, plastic trash bags, and sponges and towels, should be readily available. All necessary protective attire should be worn (see 4.2.2).

Drips and splashes can be wiped up quickly with a sponge, towel, or mop. Alternatively, the glutaraldehyde solution can be neutralized with an appropriate chemical agent (see 4.3.3.2) and then wiped up with a sponge, towel, or mop. The sponge, towel, or mop should be thoroughly rinsed with large amounts of water and the water discarded down the drain (see 3.7.1). After rinsing, reusable sponges, towels, or mop heads should be placed in the appropriate container to be laundered before reuse. After rinsing, disposable sponges, towels, or mop heads should be disposed of according to the procedures designated by the glutaraldehyde spill containment response team.

Rationale: The most important thing is to clean up the glutaraldehyde solution quickly to control vapor and prevent contact with skin or eyes. For small drips and splashes, it is not necessary to neutralize the glutaraldehyde, because the amount being rinsed down the drain will not exceed 5 ppm by the time it reaches a sewage treatment plant (see 3.7.1), nor is it likely to cause the room vapor to exceed the TLV-C. However, there is no harm in neutralizing the glutaraldehyde, regardless of the amount.

4.3.3.4 Large spills

Any glutaraldehyde spill larger than small drips or splashes can cause vapor levels to increase above the TLV-C. The spill should be cleaned up by a team equipped with the appropriate respiratory equipment for the ambient air concentration of glutaraldehyde vapor (see 4.2.2.4); the appropriate protective attire (including rubber boots or shoe protection); and the necessary cleanup tools: mop, sponges, towels, squeegee, plastic dust pan, plastic scoop, and a chemical for neutralizing the glutaraldehyde (see 4.3.3.2).

Large spills should be contained and neutralized or contained and collected for disposal. When spills are contained, it might be possible to neutralize the spilled solution with an appropriate chemical agent (see 4.3.3.2). Depending on the amount of solution and the environmental conditions, some heat and fumes could be liberated by the reaction. When large spills are collected using an absorbent, the absorbed medium can be disposed of/incinerated according to appropriate federal, state, and local regulations.

After the glutaraldehyde solution is collected and disposed of, the area where the glutaraldehyde solution was collected should be thoroughly rinsed. The cleanup tools should be rinsed with large amounts of water and the water discarded down the drain. Reusable cleanup tools, such as sponges, towels, or mop heads, should be placed in an appropriate container to be laundered before reuse. After rinsing, disposable sponges, towels, or mop heads should be disposed of according to the procedures designated by the glutaraldehyde spill containment response team.

Rationale: Immediate neutralization and cleanup of spills minimizes the potential for chemical exposure. Spills increase the surface area of the glutaraldehyde solution and, if left unattended, will increase the air concentration of glutaraldehyde. Larger spills present increased risk because the TLV-C could be exceeded; also, additional considerations are necessary for disposal of contaminated equipment and the neutralized solution. Proper respirators, protective clothing, and training are essential to preventing overexposure of workers and others in the area. See also 4.2.1 and 4.2.2.

4.3.4 First aid

Personnel who have come into contact with liquid glutaraldehyde should immediately remove contaminated clothing and shoes and thoroughly wash contaminated skin with flowing water. In the case of eye contact with liquid glutaraldehyde, the eyes should be flushed with copious amounts of water for at least 15 minutes. (As per 4.2.2.2, eye wash units should be available in all glutaraldehyde usage locations.) Contact lenses, if worn, should not be removed. Exposed personnel should be evaluated by a physician (ideally an occupational health physician or, in the case of eye contact, an eye care physician) immediately after the above emergency measures. Contaminated reusable clothing should be laundered before it is worn again, and rubber goods should be rinsed

thoroughly before use. Any heavily contaminated clothing, shoes, or equipment that cannot be thoroughly washed and decontaminated should be discarded.

As per 4.3.2 (b), written policies and procedures should be established for emergency medical care of glutaraldehyde-exposed personnel. Emergency room staff and others who will be responsible for the care of exposed personnel should have an established protocol designed specifically for the treatment of glutaraldehyde-exposed personnel.

Rationale: Exposure to glutaraldehyde concentrations less than 5% can cause moderate irritation to the eyes and moderate irritation to the skin. Flushing with water dilutes and removes the glutaraldehyde. For the rationale for the contact lens recommendation, see 4.2.2.2. Under occluded conditions (e.g., when the skin is covered by soaked clothing), the effects of glutaraldehyde are more severe, hence the recommendations concerning contaminated attire. Written policies and procedures and an established protocol will help assure emergency preparedness.

5 Personnel considerations

5.1 General rationale

This section provides guidelines for personnel qualifications, education, and training as well as personnel health considerations. It is important that liquid chemical disinfection and sterilization processing be supervised and performed by knowledgeable personnel if worker safety and the effectiveness of the disinfection/sterilization process are to be reliably ensured.

5.2 Qualifications

5.2.1 Supervisory personnel

All preparation and sterilization of items must be supervised by competent and qualified personnel. Personnel assigned to supervisory functions should be prepared for this responsibility by formal training, experience, and continuing education. Suggested minimum qualifications include

a) demonstration of current knowledge and adequate relevant experience in health care or hospital-related work (e.g., central service);

b) participation in the health care facility's formal orientation and training programs (e.g., educational seminars, personnel and materials management programs, and courses directly related to the position. Special emphasis should be placed on personnel safety; means of avoiding exposure to glutaraldehyde and other liquid chemical sterilants; safe use of liquid chemical sterilants, including applicable regulations and label directions; and decontamination, high-level disinfection, sterilization, and distribution of endoscopes and other medical devices);

c) participation in inservice programs designed specifically for the personnel performing the glutaraldehyde disinfection/sterilization process;

d) attendance at educational seminars and familiarity with the current literature on glutaraldehyde;

e) demonstration and improvement of expertise through teaching and through participation (as a member or resource person) in various committees within the health care facility, such as the standardization, nursing service, procedural, infection control, safety, hazardous materials, or pharmacy and therapeutics committees.

Rationale: Safe and effective chemical disinfection/sterilization should be supervised by knowledgeable personnel with broad-based hospital experience, especially in sterilization processing and infection control. These personnel must be thoroughly familiar with the potential hazards of exposure to glutaraldehyde and with techniques to reduce human exposure to glutaraldehyde.

5.2.2 Processing personnel

The responsibility for performing glutaraldehyde disinfection and sterilization processes must be assigned to qualified individuals with demonstrated competence in all aspects of disinfection/sterilization procedures and safety precautions.

Rationale: Safe handling and the use of appropriate practices will reduce occupational exposure to glutaraldehyde. Therefore, to ensure their safety and the safety of others, it is important that personnel engaged in processing activities receive special training and that their competency is verified.

5.3 Training and continuing education

Personnel engaged in chemical disinfection/sterilization processing must receive initial orientation and on-the-job training. This training program should cover the policies and procedures of the health care facility, safety precautions, appropriate PPE, and potential hazards. It is required by OSHA that personnel also receive training regarding OSHA's Hazard Communication Standard (29 CFR 1910.1200). In addition, personnel should seek formal and informal opportunities to enhance their knowledge (e.g., by attending seminars and keeping up with the literature). Records, including the names of employees in attendance, should be maintained for the orientation and training programs conducted. See also 5.5.1.

NOTE—The efficacy of glutaraldehyde disinfection/sterilization is not included within the scope of this document. It should be noted, however, that personnel training should cover the parameters of chemical disinfection/sterilization, basic microbiological principles, and infection control.

Rationale: Orientation, training, and continuing education decrease the possibility of errors during glutaraldehyde disinfection/sterilization processing and help ensure that personnel are conversant with the latest data and techniques. Knowledge of the health risks associated with exposure to glutaraldehyde will help ensure that potentially exposed personnel will adhere to established procedures.

5.4 Personal protective equipment

See 4.2.2.

5.5 Personnel health

5.5.1 Information concerning the potential hazards of exposure to glutaraldehyde

Personnel must be informed of the potential health effects of overexposure to glutaraldehyde and should be familiar with the information contained in the MSDS. The MSDS should be included in the safety manual and/or the safety section of the departmental policy and procedure manual.

Rationale: Information about potential health effects of overexposure to glutaraldehyde will encourage compliance with safety procedures. OSHA requires the MSDS to be available to each employee working with glutaraldehyde.

5.5.2 Short-term health effects

Glutaraldehyde is an irritant to the skin, eyes, and respiratory system. Skin contact can cause minor irritation with itching and slight local redness. Prolonged contact causes mild to moderate local redness and swelling. Glutaraldehyde is a skin sensitizer in a small percentage of exposed individuals. Glutaraldehyde in concentrations less than 10% is not known to be absorbed through the skin in harmful amounts. Glutaraldehyde is a protein cross-linking agent, and its reactivity with skin proteins is a major factor in limiting percutaneous absorption.

Glutaraldehyde in concentrations less than 5% is considered to be irritating to the eyes. Eye contact causes moderate to severe irritation, experienced as discomfort or pain, excessive blinking and tear production, with marked redness and swelling of the conjunctiva. Higher concentrations present a risk of serious damage to the

eyes, causing minor to moderate corneal injury that can persist and, if not adequately and promptly treated, could result in permanent impairment of vision.

If swallowed, glutaraldehyde in concentrations less than 5% can be mildly to moderately irritating to the mouth, throat, and stomach. There could be abdominal discomfort or pain, nausea, vomiting, diarrhea, dizziness, and weakness.

Nose and throat irritation and general tightness of the chest have been reported by workers exposed to glutaraldehyde vapor, even at concentrations below the current TLV-C of 0.2 ppmv. Inhalation of the vapor could cause asthma-like symptoms as well as aggravate pre-existing asthma and inflammatory or fibrotic pulmonary disease.12 Nosebleeds have also been reported in workers exposed to glutaraldehyde but are rare.

These symptoms are generally temporary and should subside when the individual leaves the area of glutaraldehyde exposure. Evidence indicates that skin and respiratory irritant effects are exacerbated with repeated exposure to glutaraldehyde.

The information in this section is based on Ballantyne (1995) and, in the case of the information on skin effects of prolonged contact with glutaraldehyde, Fowler (1989).

5.5.3 Long-term health effects

Respiratory irritation and skin sensitizing effects of glutaraldehyde have been confirmed (Beauchamp et al. 1993). There is no evidence of adverse reproductive health effects of exposure to glutaraldehyde, and a mortality study did not reveal any increased incidence of cancer deaths. Animal studies have shown no evidence of any target organ toxicity. Reports in the literature have implicated glutaraldehyde as a possible causal factor in occupational asthma (Chan-Yeung et al. 1993; Stenton et al. 1994).13

6 Vapor monitoring

6.1 General rationale

To ensure a safe work environment and to establish compliance with recommended limits and voluntary guidelines on occupational exposure to glutaraldehyde, several air sampling and monitoring techniques are currently in use. Information is available on the relative effectiveness of some of the methods and programs available for glutaraldehyde vapor monitoring in the hospital work environment (see annex B). The information contained in this section and in annex B should be used as a guideline. Monitoring technology continues to evolve, and it is incumbent on health care personnel to keep abreast of the latest developments.

NOTE—While health care facilities are not specifically required by law to monitor glutaraldehyde vapor concentration, OSHA can enforce the current TLV-C for glutaraldehyde by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards. Monitoring is necessary to demonstrate compliance with the TLV-C.

6.2 Instrumentation

6.2.1 Selection of monitoring methods

Some glutaraldehyde vapor monitoring methods must be performed or supervised by a technically qualified person trained in air-sampling strategies and monitoring techniques. Other monitoring methods are less complex and, with instructions from the manufacturer, can be used reliably by health care personnel to monitor the workplace. The monitoring method chosen will depend on the frequency of glutaraldehyde use, the level of monitoring needed, the availability of sampling and analytical instrumentation, and whether the health care facility chooses to initiate its own monitoring program or use an outside service. Another consideration is how monitoring data must be interpreted to assess worker safety. Because of these complexities, health care personnel should seek the advice of an industrial hygienist or other qualified professional when designing a monitoring program.

Rationale: Health care facilities vary in financial and technical resources and in the volume of glutaraldehyde disinfection/sterilization processing. Some glutaraldehyde monitoring techniques require a considerable amount of time, effort, cost, and data analysis. The relationship between the costs and benefits of sampling must be carefully considered without losing sight of the ultimate goal: a safe and healthful workplace for personnel.

6.2.2 Reliability and use of instrumentation

The instructions for use provided by the vapor monitoring equipment and sampling apparatus manufacturers must be followed. Data on the accuracy, reproducibility, and reliability of the instrumentation are also necessary. In particular, monitoring instrumentation and methods must be proven capable of accurately and reproducibly determining glutaraldehyde vapor concentrations in the range of (and below) the recommended limit on occupational exposure. When considering the use of any glutaraldehyde vapor monitoring equipment, the user should be aware that components and other characteristics of workplace air (e.g., inert diluents, water vapor, solvent vapor, and temperature variations) can interfere with the instrument's ability to accurately measure the glutaraldehyde vapor concentration.

Rationale: The manufacturer is the best source of information on the performance characteristics of monitoring equipment, and the manufacturer's instructions for use must be followed to ensure proper operation of the equipment and accurate results.

6.3 Procedures

6.3.1 Monitoring sites

Sampling should be conducted in all work areas where workers might be exposed to glutaraldehyde vapor. The glutaraldehyde use area should be monitored as well as the breathing zone of each employee directly involved with any decontamination or disinfection/sterilization process. Monitoring should be conducted during normal usage, when solution is being poured into/from immersion trays, or when solution is being agitated.

Rationale: Monitoring should yield a meaningful description of the glutaraldehyde concentration in the workplace and, hence, the potential for occupational exposure.

6.3.2 Frequency of monitoring

Monitoring also should be performed after initiating use of disinfection/sterilization processes or establishing a glutaraldehyde monitoring program. Monitoring also should be conducted whenever there is a major change in protocol, workplace ventilation systems, or case load, after major repairs to endoscope washers or other automated equipment, and after changes in work practices. The frequency of routine monitoring will depend on the amount of glutaraldehyde used by the health care facility, on the frequency of chemical sterilization processing, on other facility-specific factors, and on the recommendations of an industrial hygienist.

Rationale: Regular monitoring will help ensure that ambient glutaraldehyde concentrations are at or below the TLV-C and will help detect ventilation system inadequacies.

6.3.3 Ceiling exposures

Health care personnel should determine the workplace glutaraldehyde vapor concentration during all parts of the working exposure period, and this concentration should never exceed the TLV-C. Special attention should be given to short periods of time when airborne concentrations of glutaraldehyde vapor might be particularly high, for example, when the worker is pouring the spent solution down the drain or pouring fresh solution into the container or reservoir. To accurately assess a ceiling limit, exposure monitoring should be conducted for the shortest sampling time possible. OSHA states that "if instantaneous monitoring is not feasible, then the ceiling shall be assessed as a 15-minute time weighted average exposure which shall not be exceeded at any time over a working day." A 15-minute TWA sampling technique will usually understate exposure levels as they relate to a ceiling limit.

Rationale: See "Introduction: Need for the Recommended Practice," 4.2.1 and 5.5.

6.4 Record-keeping

If performed, employee breathing zone monitoring must be documented and records maintained in the department files or another designated location. This documentation should include the name and qualifications of the person or organization that conducted the monitoring, the date the survey was made, the sampling or analytical method used, the test protocol and instrumentation, workplace ventilation system characteristics at the time of sampling, the results (locations and measured glutaraldehyde concentrations), any personal protective equipment worn, and any recommendations for corrective actions. Employees must be notified of their personal monitoring results within 15 days of receipt of the results, and a copy of the monitoring records must be kept in each employee's file. In accordance with OSHA regulations, these records must be maintained by the health care facility for the duration of employment and for at least 30 years thereafter.[14] If employee breathing zone monitoring shows glutaraldehyde concentrations exceeding the recognized ceiling limit, corrective actions must be taken. It is recommended that the results of workplace monitoring be posted in an area that is readily accessible to employees.

Rationale: Good record-keeping enables the health care facility to establish a continuous history of the work environment. OSHA record-keeping requirements apply if monitoring is conducted.[15] When vapor monitoring results are posted, workers will know that potentially hazardous concentrations of glutaraldehyde might exist in the workplace, and the importance of good work practices will be reinforced. The importance of good work practices is also validated when vapor monitoring results verify that glutaraldehyde concentrations are below the recommended TLV-C. See also "Introduction: Need for the Recommended Practice."

Annex A
(informative)

Properties of glutaraldehyde

A.1 "Glutaraldehyde: factors important for microbicidal activity"[16]

Glutaraldehyde (1,5-pentanedial) is one of the most effective chemical microbicides known. Through a complex cross-linking mechanism, glutaraldehyde is potentially effective against a wide variety of microorganisms, including gram-positive bacteria, gram-negative bacteria, bacterial spores, sulfate-reducing bacteria, mycobacteria, fungi, algae, and viruses. This cross-linking mechanism is influenced by pH, time, concentration, and temperature. These factors also influence the interaction of glutaraldehyde with other components in the surrounding matrix. In addition, this same chemistry seems to be responsible for the ability of glutaraldehyde to react with and remove attached biofilms. Through an understanding of the factors that influence the efficacy of glutaraldehyde, conditions can be varied in such a way as to maximize the utility in the intended use.

A.1.1 Introduction

Glutaraldehyde has been in use for over 30 years in combating the growth of microorganisms. Its antimicrobial activity was first documented in 1957 in a patent assigned to the Union Carbide Corporation concerning the control of sulfate-reducing bacteria in water (Union Carbide 1957). Studies concerning organisms of medical interest ensued, and the material was quickly adopted as a sterilant for surgical instruments that could not tolerate the more traditional approach of steam treatment. In more recent years, glutaraldehyde has been used for control of microorganisms in such diverse environments as oil fields, industrial cooling towers, farm animal housing, and pharmaceutical clean rooms. In short, the properties of the biocide and its efficacy against a wide variety of microorganisms have been well-documented for many years. (For a review, see Gray 1980.)

A.1.2 Chemical and biological medium of action

The glutaraldehyde molecule is quite simple, consisting of a three-carbon aliphatic chain terminated by two aldehyde (CHO) groups: $OHC\text{-}CH_2\text{-}CH_2\text{-}CH_2\text{-}CHO$.

The terminal groups are chemically reactive and undergo the typical transformations characteristic of most aldehyde chemistry. The most important of these transformations, and the one on which virtually all industrially important glutaraldehyde chemistry is based, involves reaction of these aldehyde groups with primary amines.

A.1.3 Glutaraldehyde—the molecule

Structurally, glutaraldehyde or 1,5-pentanedial is a linear five-carbon dialdehyde shown in figure A.1 as structure I. For stability reasons, only aqueous solutions of glutaraldehyde are available for routine use. In water, glutaraldehyde exists in a very complex equilibrium mixture with the hydrated forms shown in structures II, III, and IV (Richards & Knowles 1968; Hardy et al. 1969, 1970; Korn et al. 1972; Whipple & Ruta 1974). Note that the cyclic hydrate (IV) exists in both a *cis* and a *trans* conformation. Thus, five distinctly different monomeric species of glutaraldehyde can undergo a reversible oligomerization reaction. The short oligomer chains can reach four to five residues in length and could contain some linear monomers. At four to five glutaraldehyde residues in length, these oligomers readily revert back to the reactive, monomeric form of glutaraldehyde under relatively mild conditions such as dilution coupled with slight warming or a slight increase in pH. If, however, these oligomers cross-link together or increase significantly in molecular weight, the nature of the resulting polymer becomes essentially irreversible.

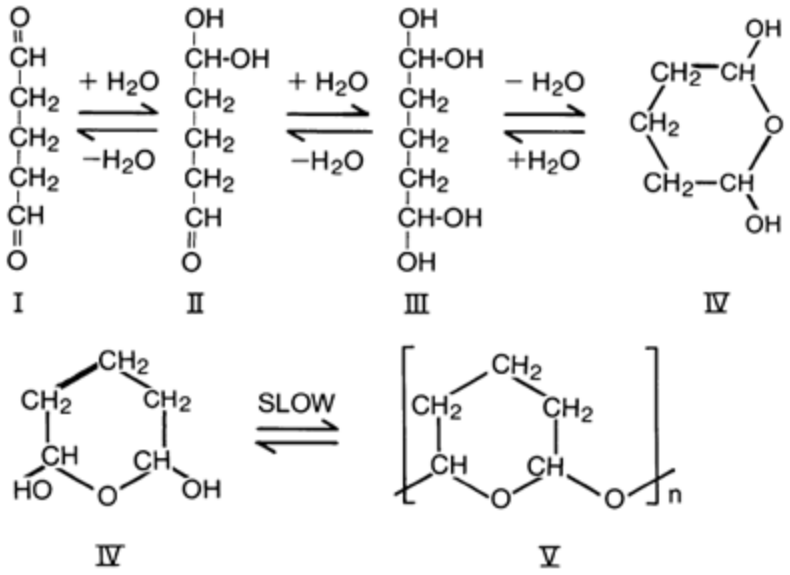

Figure A.1—Glutaraldehyde structural forms in water

Based on ^{1}H and ^{13}C nuclear magnetic resonance studies, the complex monomeric equilibrium has been shown to change with temperature and concentration (Hardy et al. 1969, 1970; Korn et al. 1972; Whipple & Ruta 1974). Surprisingly, pH variations over a range of 2 to 8.5 do not dramatically influence this equilibrium (King et al. 1974). This fact provides a key toward understanding the mechanism of action of glutaraldehyde, because the reactivity observed with glutaraldehyde is dramatically influenced by pH.

A.1.4 Chemical reactivity

With this fundamental information as background, a review of the chemical reactivity of glutaraldehyde will set the stage for a mechanistic understanding of the microbicidal properties of the compound. The key to the activity of glutaraldehyde is the fact that it is a reactive, difunctional reagent. As an aldehyde, glutaraldehyde can undergo the typical chemistry associated with aldehydes including oxidation, reduction, and condensation reactions. By and large, these reactions represent potential pathways for the loss of glutaraldehyde for productive chemical or antimicrobial purposes. As such, the potential for these reactions must be evaluated and controlled in order to effectively utilize glutaraldehyde.

The productive chemistry and antimicrobial activity of glutaraldehyde is based on the ability of aldehydes to

undergo alkylation reactions. Glutaraldehyde can alkylate sulfhydryl, carboxyl, and hydroxyl moieties. Although all of these functional groups can play some role in determining the activity of glutaraldehyde, nearly all the commercially significant reactions of glutaraldehyde can be predicted by just considering its reactivity with amino moieties.

Under typical use conditions, the reactivity of glutaraldehyde with amino groups is primarily with ammonia and primary amines; reaction with secondary amines, although slower, can also occur. Reactions with tertiary amines or quaternary ammonium salts have not been observed.

The bifunctional nature of the glutaraldehyde molecule has an important consequence: each end of the molecule can chemically react with a different amino group so that the glutaraldehyde can form a bridge, or cross-link, between these amino groups (Hughes & Thurman 1970).

All proteins are composed of amino acids, some of which contain free amino groups. In particular, lysine has a side chain that terminates in a primary amino group (Habeeb & Hiromoto 1968). Because glutaraldehyde readily reacts with such groups, proteins are efficiently cross-linked by the material (Cheung & Nimni 1982). The microbicidal properties of glutaraldehyde are thought to arise primarily from the reaction of glutaraldehyde with proteins on or near the surface of cells (Gorman & Scott 1978).

A variety of elegant mechanistic studies on the nature of the cross-linking reaction with glutaraldehyde have elucidated the molecular basis for this chemistry (Cater 1963, 1965; Bowes et al. 1965; Bowes & Cater 1965, 1966, 1968; Blass et al. 1974, 1976; Hardy et al. 1976a, 1976b, 1977). A number of aldehydes can cross-link amino groups and thus can act as tanning agents or as microbicides. A comparison of the ability of these aldehydes to cross-link collagen is given in figure A.2 (Bowes & Cater 1965). The aldehydes shown here range in chain length from one to six carbon atoms. All but the simplest member of the series, formaldehyde, are linear difunctional aldehydes. The first bar shown for each aldehyde is a comparison of their ability to introduce cross-links in collagen. At five carbons, this cross-linking reactivity is maximized, making glutaraldehyde the most effective cross-linking agent in the series.

While this fact alone helps to explain why the reactivity of glutaraldehyde is superior to that of the other aldehydes, the key actually lies in the observation that the cross-links introduced by glutaraldehyde are significantly more stable to hydrolysis both in boiling water and in mild acid (Bowes & Cater 1965; Blass et al. 1976). The observed difference in stability is consistent with the actual performance differences for these aldehydes in chemical and biological evaluations. This increased hydrolytic stability implies that the chemical nature of the glutaraldehyde-induced cross-links is different from the cross-links introduced by the other aldehydes (Harlan & Feairheller 1977).

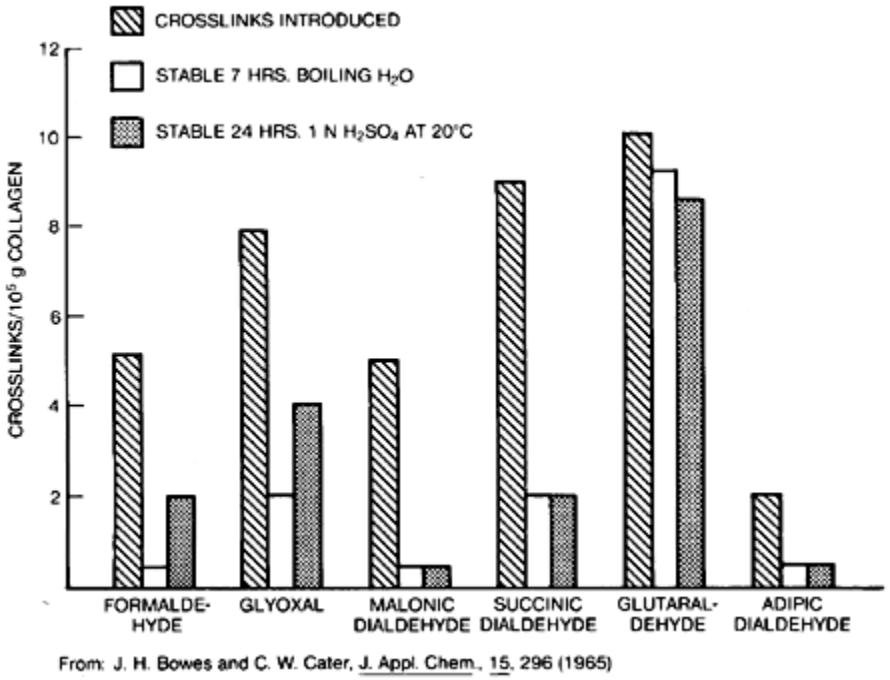

Figure A.2—Crosslinks with aldehydes
(From Bowes & Cater 1965)

Aldehydes are well-known to undergo reactions with amines to form imines or Schiff's bases. In fact, dialdehydes other than glutaraldehyde probably form just such cross-links as shown mechanistically in figure A.3. Such relatively simple cross-links would not be particularly stable to the hydrolytic conditions shown; therefore, the chemistry of glutaraldehyde-based cross-links must involve a different type of bonding.

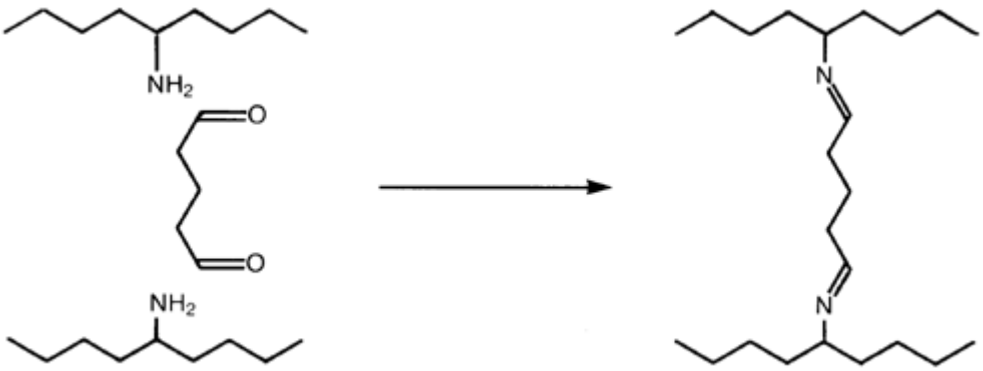

Figure A.3—Simple concept of glutaraldehyde-based cross links

Glutaraldehyde-based cross-links have been shown to be quite complex in nature (Cheung & Nimni 1982; Hardy et al. 1977). These cross-links typically contain two to three glutaraldehyde residues per cross-link (Bowes et al. 1965). At least 10 distinctly different molecular pathways for cross-linking have been observed with glutaraldehyde (Hardy et al. 1976a, 1976b, 1977). The significance of each of the pathways depends on the exact conditions present during the cross-linking reaction. To some degree, the simple imine type of cross-link shown in figure A.3 could play a role; however, the added hydrolytic stability of glutaraldehyde-based cross-links is due to a substantially different type of cross-link.

One possible cross-linking pathway is depicted in figure A.4 (Hardy et al. 1977). In this pathway, two molecules of glutaraldehyde react with two amino functions in a stepwise fashion to yield the skeleton of a bipyridyl cross-link. In fact, such systems can be readily oxidized to pyridyl components. Thus, the added stability of

cross-links introduced by glutaraldehyde might be due to their more stable pyridyl and bipyridyl character. Presumably, these extremely stable crosslinks serve as the basis for the superior chemical and biological performance typically observed with glutaraldehyde.

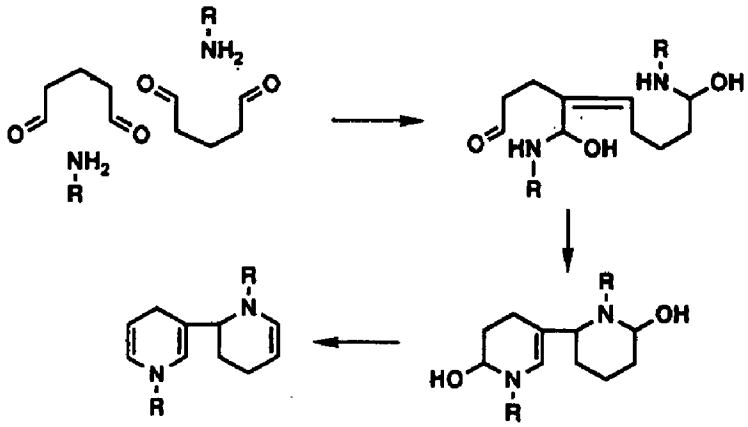

Figure A.4—Example of an actual glutaraldehyde-based crosslink

The exact structure of the cellular walls and membranes of microorganisms varies significantly from one type of organism to another. Regardless of the exact microorganism being considered, however, all contain amino acids and thus contain sites for potential reaction with glutaraldehyde. Organisms with different structural characteristics can differ in the accessibility of their amino residues; however, all contain some amino functionality and are thus susceptible to attack by glutaraldehyde. This fact accounts for the broad spectrum microbicidal action observed for glutaraldehyde.

A.1.5 Antimicrobial activity

A thorough knowledge of the mechanism of action of a reactive microbicide is extremely useful in order to optimize the factors that influence its reactivity. The factors that influence the activity of glutaraldehyde include pH, time, temperature, concentration, matrix, and nature of the use system. Of these factors, the influence of pH on microbicidal action is the most important for understanding the reactivity of glutaraldehyde.

Although moderate pH variations have little effect on the chemical nature of glutaraldehyde, the dramatic influence of pH on antimicrobial action has been well documented (Pepper & Lieberman 1962; Stonehill et al. 1963). Unfortunately, the discovery of the enhancement or potentiation of the microbicidal activity of glutaraldehyde under slightly basic conditions has caused considerable misunderstanding related to the actual utility of using glutaraldehyde as a microbicide. Hopefully, the following discussion will help clarify the confusion that has resulted from these reports.

If pH exerts an influence on microbicidal action but does not alter glutaraldehyde, then it must alter the microorganism in some manner (King et al. 1974; Munton & Russell 1970, 1972; McGucken & Woodside 1973; Gorman & Scott 1978; Beveridge et al. 1978). Amines, such as those found on the cellular surface, are influenced by pH in the classical acid-base sense. The pK for amines is typically around 9. That is, at a pH of 9 about 50% of the amino functions are protonated and the remaining 50% are not. These unprotonated or free amines serve as the reactive sites for glutaraldehyde attack. Therefore, as pH increases from acidic to basic, more reactive sites for glutaraldehyde attack are formed, and the cidal reaction with the cell occurs more rapidly.

At any given pH, a distribution of protonated and free amino moieties will exist on the microbial cell surfaces as shown in figure A.5. Under these conditions, glutaraldehyde rapidly forms complex cross links on the cell surface. This action is analogous to applying a molecular glue to the cell wall. The resulting cross linked microbe can no longer easily perform a large variety of essential cellular functions.

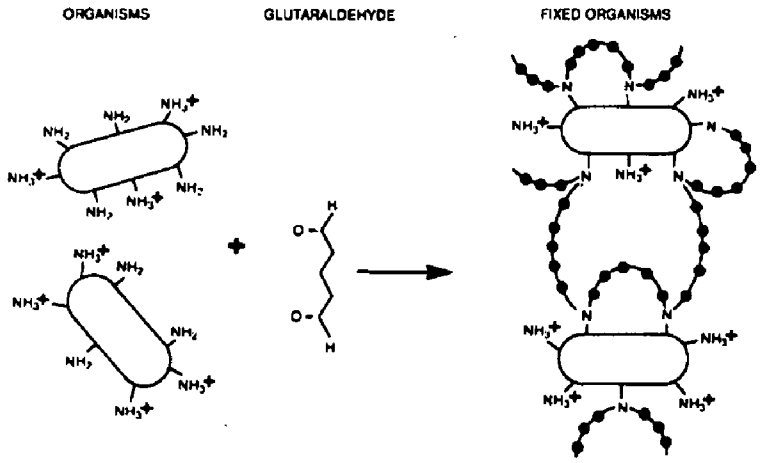

Figure A.5—Reaction of glutaraldehyde with microbial cells

The effect of pH on the rate of kill of *Escherichia coli*, a gram-negative bacterium associated with mammalian intestinal flora, is profiled in figure A.6.17 Due to the relatively rapid action of glutaraldehyde, these rate differences can be accurately determined only at relatively low concentrations and temperatures. As would be expected, the rate of action under basic conditions is faster because greater numbers of unprotonated (reactive) amino groups are present on the cell surface. As conditions become more acidic, a lag phase believed to be associated with cellular penetration can be seen. However, regardless of pH, microbial cells are killed.

The data in table A.1 demonstrate the first case, a short contact time experiment. This experiment was done to evaluate the performance of glutaraldehyde in the AOAC Use Dilution Method (AOAC 1975). The test involved the exposure of contaminated penicylinders to microbicide for 10 minutes. As can be seen, under these conditions glutaraldehyde definitely exhibited superior antimicrobial activity with increasing pH.

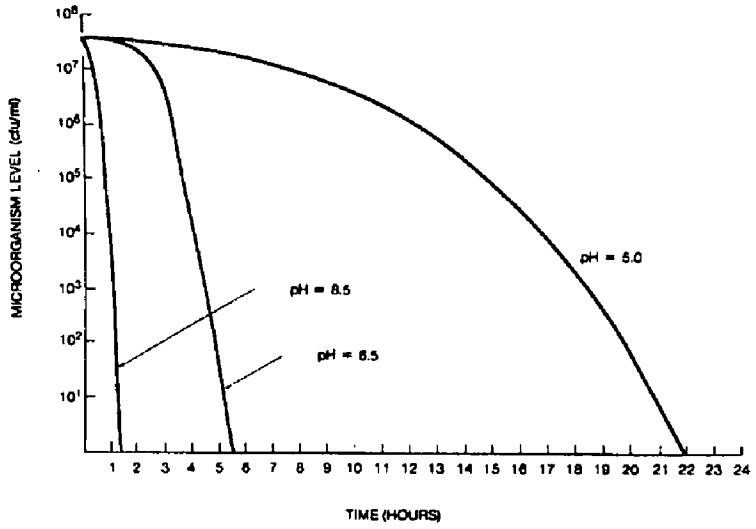

Figure A.6—Typical rate-of-kill curve for glutaraldehyde versus pH (glutaraldehyde concentration = 44 ppm; organism = *Escherichia coli*; temperature = 20° C)

Table A.1—Activity of glutaraldehyde as a function of pH

	pH level			
Glutaraldehyde concentration (%)	***5***	***6***	***7***	***8***
0	10^{+}	10^{+}	10^{+}	10^{+}
0.25	10^{+}	10^{+}	10^{-}	10^{-}
0.5	10^{+}	2^{+}	2^{+}	10^{-}
		8^{-}	8^{-}	
0.75	10^{+}	10^{-}	10^{-}	10^{-}

$^{+}$ indicates number of tubes showing growth

$^{-}$ indicates number of tubes showing no growth

The second case, long exposure time, is demonstrated in figure A.7. Here, *Pseudomonas aeruginosa* was exposed to buffered glutaraldehyde for 24 hours. No effect of pH on the minimum cidal level (50 ppm) was detected.

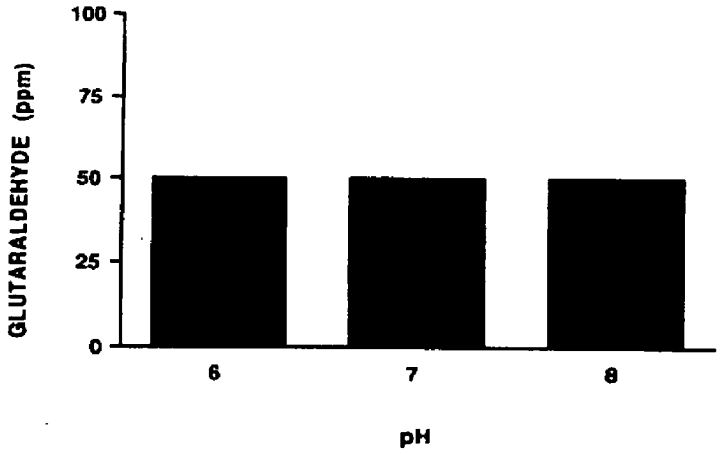

Figure A.7—Minimum cidal concentration of glutaraldehyde against *Pseudomonas aeruginosa* after 24 hours' contact

Depending on the intended application, speed of kill might be important. Thus, the nature of the intended application should be carefully considered when selecting laboratory evaluation techniques. If speed is critical, short contact time techniques such as the AOAC methods should be utilized. On the other hand, speed is not usually critical for many applications that are more preservative in nature. Under these circumstances, experiments that define the minimum effective dosage or minimum cidal concentration are generally preferred.

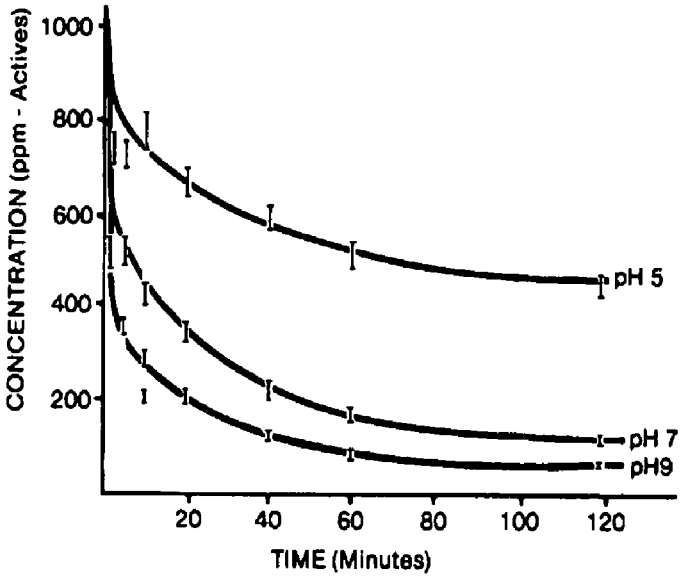

Figure A.8—Rate of loss of glutaraldehyde to nutrient broth

Another key factor that influences the activity of glutaraldehyde is the matrix or nature of the components found in the actual system where glutaraldehyde is to be used. A matrix can contain components that will interact with glutaraldehyde and thus will alter its performance. An example of the potential effect of the matrix is shown in figure A.8. This case involves the reaction of glutaraldehyde with nutrient broth, a common microbiological culture medium. Nutrient broth and most biological culture media contain amino functionalities that can react with glutaraldehyde. Under neutral to basic conditions (as present in most media), the amines in the formulation rapidly inactivated glutaraldehyde; however, the inactivation rate was slowed dramatically by reducing the pH to 5. Thus, glutaraldehyde cannot be fairly evaluated in most culture media. A more realistic indication of the antimicrobial efficacy of glutaraldehyde would be obtained by evaluating its performance in a sample taken directly from the actual system to be treated. Ideally, the test conditions should attempt to duplicate the anticipated conditions of use.

A.1.6 Activity against biofilms

The evaluation of antimicrobial compounds traditionally has relied on measurements of efficacy against free-floating (planktonic) microorganisms. However, attention in recent years has begun to shift to investigations of effects of microorganisms that adhere to surfaces and give rise to the type of deposits known as biofouling. These deposits contain not only colonies of microorganisms but also a combination of cellular byproducts, entrained debris, and inorganic materials. Biofilms can cause significant energy losses in water distribution systems as a result of increased fluid frictional resistance. In heat transfer equipment, biofilms can decrease heat transfer efficiency. Additionally, biological deposits are frequently associated with increased corrosion rates.

Mechanistically, microbiological fouling can be described as the transport of viable cells to a surface and subsequent attachment to the surface. Once attached to the surface, these cells must undergo active metabolism and growth in order to establish a biofilm. The organisms in the film can produce extracellular polymers that can serve to entrain other debris from the surrounding environment (Costerton et al. 1978). For these biofilms to become established, the fluid shear stress at the surface must be within a suitable range. The surface must be compatible with the microorganisms in the biofilm. In addition, a roughened surface can enhance the fouling potential by providing an attractive area for the anchoring of cells. The establishment of a biofilm also requires the absence of effective biofouling control techniques.

Flow rate can limit the formation or the thickness of a biofilm by two processes: a) hydrodynamic erosion

(Trulear & Characklis 1982; Powell & Slater 1982) or b) sloughing (Howell & Atkinson 1976). Hydrodynamic erosion is the natural process of abrading the film by having the water flow over its surface. The rate of hydrodynamic erosion increases with fluid velocity and with the thickness of the biofilm. Sloughing is a random process whereby portions of the film are simply lost from the surface. This is a process that appears to be based on transient film properties. The depletion of nutrients deep within the biofilm might be involved. Sloughing seems to be more pronounced in thicker, low bulk density biofilms.

Depending on the conditions present, the biofilm will develop at a rate that can generically be described by a sigmoidal rate curve (figure A.9). As the film initially begins to develop, the rate of biomass increase is very rapid. As the film approaches its natural equilibrium thickness, the rate of development becomes quite slow. An understanding of the specific development rate for a biofilm can be important when designing an adequate control program.

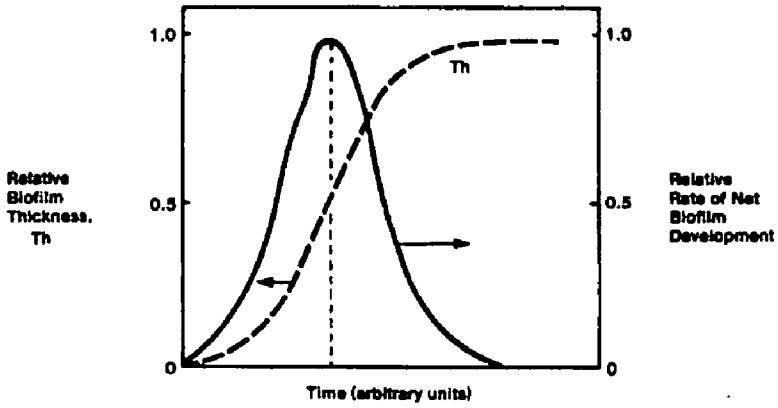

Figure A.9—Progression of net biofilm development is described by a sigmoidal-shaped curve; net biofilm development rate is the slope of the sigmoidal-shaped curve at any time

Glutaraldehyde has shown considerable utility in controlling microorganisms in water-handling systems where fouling and/or microbially influenced corrosion present problems. This utility has been demonstrated in both anaerobic, secondary oil recovery systems where corrosion-causing, sulfate-reducing (or sulfate-producing) bacteria cause problems; and in aerobic systems such as recirculating cooling water systems.

In water systems, the major problems associated with microorganisms are those that result from microbiological fouling. Thus, for a microbicide to be effective it must be capable of attacking the biofilm directly. The ability of glutaraldehyde to penetrate a biofilm and to kill sessile microorganisms was first documented by Costerton (Ruseska et al. 1982; Costerton & Lashen 1983). Field observations, however, suggested that more than just efficacy against organisms in the biofilm was involved.

In order to elucidate the factors that impact the performance of glutaraldehyde in more detail, a series of dynamic, laboratory-based experiments were conducted. The results of these experiments coupled with actual field observations suggest a mechanism of action that involves the dynamics of the system as well as the cidal activity of glutaraldehyde.

The factors that impacted the performance of glutaraldehyde against biofilms in variable dynamic environments were assessed using an annular reactor as a model system. By using established biofilms (3 days of uninterrupted growth), the impact of treatment with glutaraldehyde was evaluated. The treatments involved the addition of glutaraldehyde for 2 hours at a fixed level daily for 3 days.

Using the consumption of glucose by the organisms in the test system as a monitor of the viability of the microorganism in the biofilm,[18] the impact of the concentration of glutaraldehyde can be seen in figure A.10. At a concentration of 15 ppm, little impact was seen on the viability of the biofilm. At a level of 50 ppm, the antimicrobial activity of glutaraldehyde began to be detected. By the third day of this treatment level, a high

level of inactivation was evident. At higher treatment levels, nearly complete biofilm inactivation was observed as a result of the initial treatment.

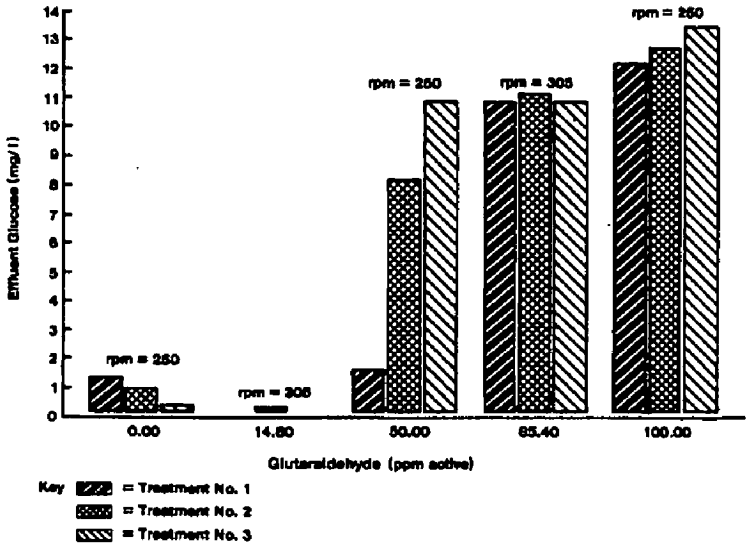

Figure A.10—Effluent glucose at 60 min. vs. glutaraldehyde treatment of biofilm in annular reactor

This measure of antimicrobial efficacy is consistent with values obtained in more conventional laboratory-based studies as well as those obtained against actual biofilms using an alternate reactor design; i.e., a Robbins Device (McCoy et al. 1981). However, it seems to oversimplify the actual mode of action of glutaraldehyde observed in field studies; therefore, additional studies were conducted. These studies were designed to probe the ability of glutaraldehyde not only to penetrate into and inhibit the organisms in a biofilm, but also to cause the film to be removed from the surface to which it is attached.

As previously discussed, biofilm development is limited by the flow rate of water over the film. The shear stress on the biofilm from flowing water can be simulated by controlling the rotational velocity of the annular reactor. As seen in figure A.11, rotational speed changes in the annular reactor simulate a wide range of fluid shear stresses. These shear stresses are similar to those seen in typical pipelines (see figure A.12).

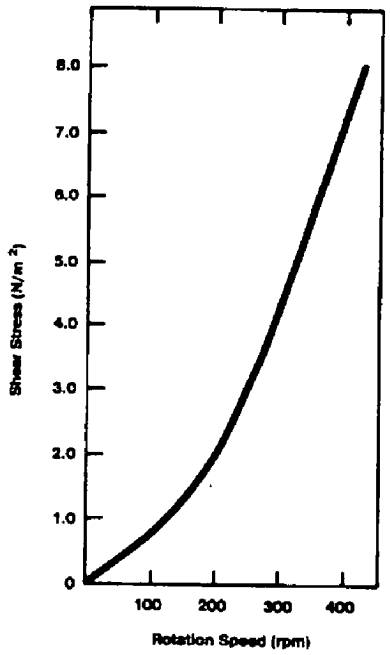

Figure A.11—Fluid shear stress as a function of rotational speed in the annular reactor

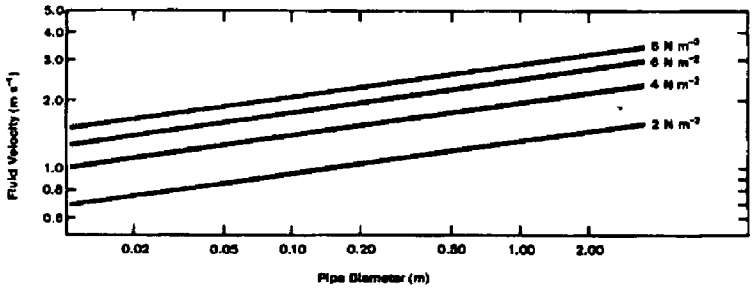

Figure A.12—The influence of fluid velocity and pipe diameter on fluid shear stress in a pipe

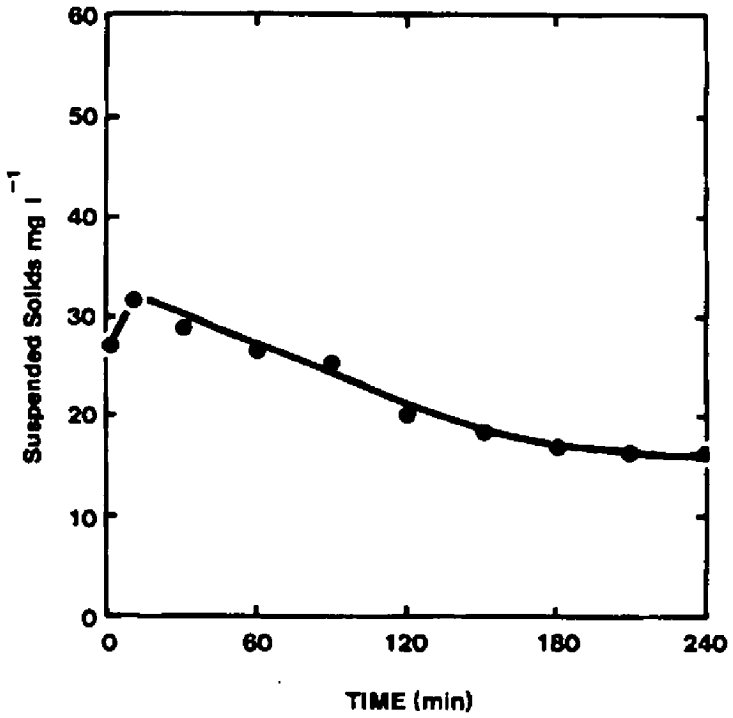

Figure A.13—Response of a biofouled annular reactor to glutaraldehyde addition (50 mg/l active) at t=0 (rpm=152)

The removal of biomass from the biofilm can be monitored by determining the level of suspended solids in the reactor effluent. In a mature biofilm, the rate of biomass removal is relatively constant. This removal is due primarily to the natural process of hydrodynamic erosion and is a function of the shear stress exerted (rpm) on the biofilm.

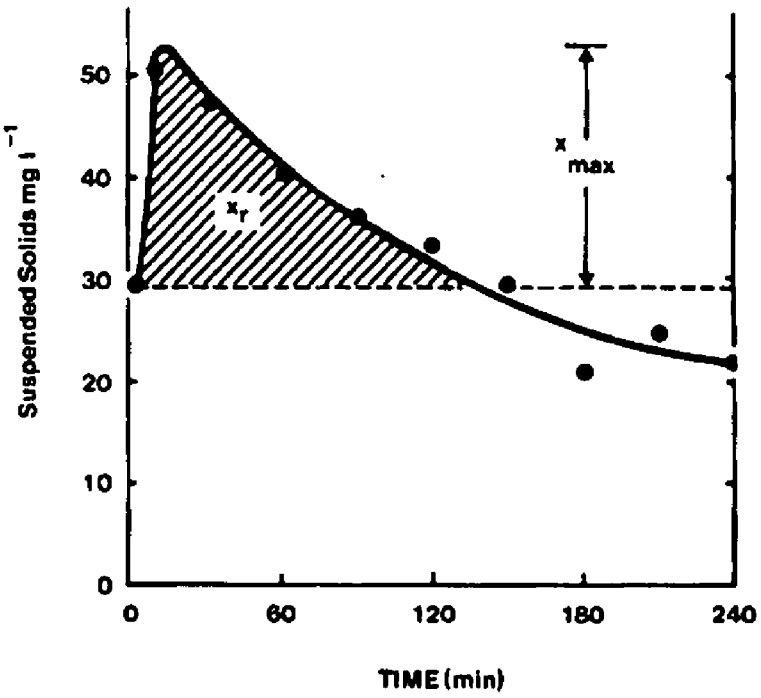

Figure A.14—Response of a biofouled annular reactor to glutaraldehyde addition (50 mg/l active) at t=0 (rpm=350)

Measurements of the impact of treatment on biomass removal are shown in figures A.13 and A.14. At a relatively low shear stress (152 rpm), a 2-hour slug treatment with glutaraldehyde caused a slight increase in the removal rate of biomass from the film. The impact of the same treatment at a higher shear stress (350 rpm) was significantly enhanced even though the initial level of biomass was essentially the same.

Attempts to quantify the amount of material removed were made by removing sample slides from the reactor before and after treatment. The value of such measurements, however, is limited because the removal process tends to disrupt the neighboring biofilm. Nevertheless, such measurements were made. While the data shown in table A.2 clearly demonstrate the removal of biomass from the film, the data are erratic from run to run. In addition to the inherent variability in such experiments, this case involved the use of an uncontrolled mixed culture.

As a result, the initial level of biomass present varied from experiment to experiment. Biomass removal, however, was seen as a result of treatment with glutaraldehyde regardless of the exact amount or character of the initial biofilm present.

Table A.2—Biofilm mass removed by treatment with glutaraldehyde (50 ppm active; 150 rpm)

Experiment number	*Initial mass (g/m^2)*	*Mass removed (g/m^2)*
1	0.40	0.18
2	0.48	0.32
3	4.01	0.57
4	4.49	1.42

Based on these observations, it can be stated that shear stress can alter the apparent antimicrobial efficacy of glutaraldehyde. While such laboratory experiments often yield somewhat erratic results, they can serve as useful probes if proper control experiments are conducted. Using this technique, the ability of glutaraldehyde to penetrate into an attached biofilm and to inhibit the microbial cells protected by the film can be seen. The actual mechanism of attack, however, seems to involve more than just killing or inhibiting cells in the biofilm. This additional control mechanism seems to accelerate the natural detachment rate of microorganisms from the biofilm. This mode of action can best be described as an enhanced erosion rate mechanism. Finally, these experiments point out that extremely low levels of glutaraldehyde have little, if any, impact on biofilms. Based on these experiments and field observations, the "no effect" level is on the order of 20 ppm.

The mechanism of action involved in enhancing the erosion rate is probably based on the same chemistry that is responsible for the antimicrobial activity of glutaraldehyde: the formation of cross links on the surface of cells in the biofilm. In the case of cellular detachment, however, complete reaction to the point of organism death does not seem to be required. We believe that partial fixative action on cells near the outer surface of the biofilm actually causes these cells to lose their adhesion to the film in such a way that they become more susceptible to hydrodynamic erosion. As these cells are swept from the surface, an irregular surface is formed. The polishing action of the flowing water on this irregular surface then enhances the observed activity by removing even cells that have not been significantly cross linked with glutaraldehyde.

This mechanism is consistent with observations that the action of glutaraldehyde is enhanced in areas where high flow rates are encountered. In areas of low or no flow, treatment with higher concentrations of glutaraldehyde and/or longer durations of treatment seems to be required for effectiveness.

A.1.7 Conclusions

Glutaraldehyde is an extremely effective microbicide that exerts its cidal activity by chemically reacting with amino groups on the external surface of cells. Its speed of action is influenced by many factors, the most important of which is pH. Presumably due to decreased protonation of cellular amines, the microbicide acts more rapidly at higher pH; however, with longer contact times, the effect of pH is less dramatic. The effectiveness of glutaraldehyde in the removal of biofilms has been demonstrated in laboratory assays and is dependent on glutaraldehyde concentration and fluid shear stress.

A.2 Factors influencing glutaraldehyde's microbicidal activity[19]

The factors that influence the activity of glutaraldehyde include pH, time, temperature, concentration, matrix, and the nature of the use system. Of these factors, the influence of pH on microbicidal action provides the key for understanding the reactivity of glutaraldehyde. The effect of pH on the reactivity of glutaraldehyde is discussed in detail in A.1.5.

Evaluation techniques that either enhance or minimize the effect of pH on rate of microbial kill can greatly alter the apparent microbicidal activity of glutaraldehyde. Some microbicidal tests are more concerned with speed of action. These involve very short contact times, often on the order of 10 minutes. After 10 minutes of contact,

glutaraldehyde would definitely appear to be more effective at a basic pH (excluding the effect of any added chemicals in the formulation). If a relatively long contact time were examined (e.g., 24 hours), little effect of pH would be seen because all the cells would have been killed by this time.

The rate of antimicrobial action of glutaraldehyde is also influenced by temperature. Chemical reactions are often enhanced by increasing temperature. Such is the case for the reaction of glutaraldehyde with microbial cells. Under basic conditions, kill rates increase slightly with increasing temperature; however, a dramatic rate enhancement is typically observed under acidic conditions. This effect is demonstrated in figure A.15 (Boucher 1974, 1975). In this case, an acidic 2% glutaraldehyde solution was evaluated as a sterilant. At 20° C [68° F], approximately 10 hours were required for sporicidal activity, whereas at 40° C [104° F], approximately 1 hour is required for the same activity. Thus, heat can be added to glutaraldehyde to increase the rate of activity.

In addition to pH and temperature, concentration, contact time, and an understanding of the matrix or nature of the components found in the actual system in which glutaraldehyde is to be used are important considerations in proper disinfection and sterilization techniques for an intended application. These factors are discussed in A.1.

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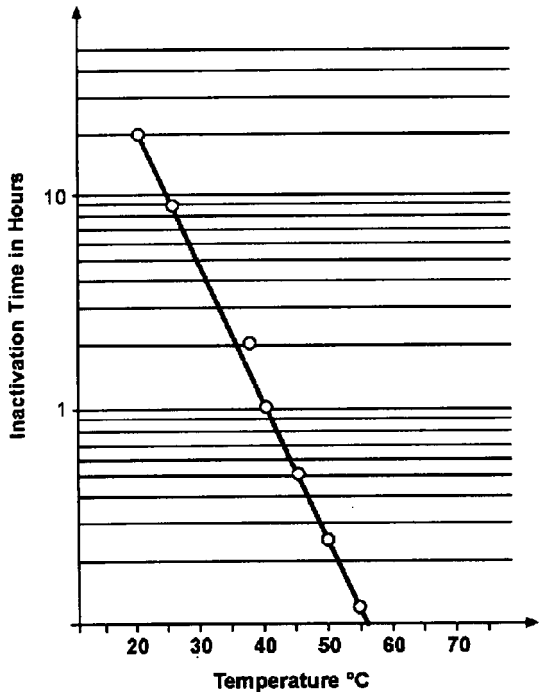

Figure A.15—Time required to inactivate *Bacillus subtilis* ATCC 6051 spores by acid potentiated 2% glutaraldehyde versus temperature

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Annex B
(informative)

Selecting airborne glutaraldehyde monitoring equipment or services for a facility that uses glutaraldehyde solutions

B.1 Introduction

This annex was developed to assist health care personnel to select equipment or services to measure airborne glutaraldehyde in the workplace and to assess worker exposure to airborne glutaraldehyde. This annex is intended to a) assist users in understanding the conceptual approaches that can be used to monitor airborne glutaraldehyde concentrations or worker exposure to glutaraldehyde; b) describe some of the glutaraldehyde exposure monitoring equipment and services currently available; and c) summarize certain advantages and disadvantages of the available equipment and services.

What is an "ideal" airborne glutaraldehyde monitor? Most experts would agree that an "ideal" glutaraldehyde monitor for glutaraldehyde exposure would meet the following specifications:

a) It would accurately measure airborne glutaraldehyde in the range of one-tenth to 10 times the TLV-C. (For instance, if the TLV-C is 0.2 ppmv, then this range would be 0.02 to 2.0 ppmv.)

b) It would be reliable.

c) It would be inexpensive.

d) It would be easy to use, requiring minimal technical ability on the part of the operator.

e) It would give an instantaneous reading.

f) It would be glutaraldehyde-specific.

The same experts who agree on specifications would also probably agree that such an ideal monitor does not, as of this writing, exist. However, the absence of such a monitor cannot be used as an excuse to avoid monitoring exposure levels. All managers of locations where glutaraldehyde is used have clearly defined responsibilities to monitor and minimize worker exposure to glutaraldehyde.

This annex is a general introduction to a complex subject. Before selecting a particular glutaraldehyde monitoring product or service, health care personnel should analyze the specific needs and resources of their institution and consult appropriate experts in chemical monitoring, industrial hygiene, and regulatory requirements.

B.2 Types of glutaraldehyde monitoring

Two general types of monitoring can be performed in facilities where glutaraldehyde is used: personnel

monitoring and area monitoring.

B.2.1 Personnel monitoring

Personnel monitoring is performed to determine the concentration of airborne contaminants in the employee breathing zone (EBZ); this measured concentration is assumed to be the amount actually inhaled by personnel. Personnel monitoring devices are generally worn by the worker for a certain length of time; the glutaraldehyde concentration in the EBZ is measured during the time the monitor is worn, and the results are expressed as a "time-weighted average" (TWA) concentration. Because glutaraldehyde has a ceiling exposure limit, the sampling time period should be as short as technically feasible, with a maximum sampling time of 15 minutes. To accurately measure exposure levels, a series of short samples should be taken during the entire work process.

The exposure limit for glutaraldehyde is a ceiling value that must not be exceeded, even for a brief period of time, at any time during the work shift. A 15-minute TWA measurement will usually understate exposure levels as they relate to a ceiling limit. Consequently, a measured 15-minute TWA concentration below 0.2 ppmv is not a guarantee that workers have not been overexposed at some time during the same period. Shorter sampling times might allow detection of brief, transient overexposures.

A significant disadvantage of most sampling devices is that the air concentration results cannot be acquired until some time after the sampling period. If a worker is exposed to a high concentration of glutaraldehyde vapor (e.g., because of a failure in the ventilation system or poor work practices), the worker has no way of knowing about the high glutaraldehyde concentration until after the results are received from the monitor analyst. In some cases, this delay could be several days or weeks after the sampling period.

Extensive laboratory analysis is not always needed, however. Recent advances in glutaraldehyde personnel monitoring devices, such as badges, allow some monitors to be analyzed by manufacturers or contract laboratories or even on-site in the health care facility. In addition, some monitoring equipment utilizes an electrochemical analyzer that measures the glutaraldehyde present in "snatch" samples that can be collected in the EBZ; the results are displayed shortly after the sample is taken. While such electrochemical analyzers do not meet the technical definition of a personnel monitor (a device that continuously measures samples in the employee breathing zone), they can be used to measure EBZ exposure levels if they are portable and can be held in the EBZ while work is being performed.

B.2.2 Area monitoring

Area monitoring is performed to determine the general (i.e., environmental) concentration of airborne contaminants in a prescribed space or area. There could be personnel in the area monitored, and the concentration of airborne contaminant that is measured might not be the concentration of contaminant actually inhaled by personnel if they are present. In addition, vapor levels under static exposure conditions (when solutions are not being agitated) tend to be much lower than actual use conditions.

Most area monitors are electronic devices or electronically controlled devices that measure, more or less instantaneously, the glutaraldehyde present at the sampling point of the device. Some active or passive sampling devices also can be used as area monitors. For example, if engineering controls (such as new ventilation equipment) have just been installed in an area where glutaraldehyde vapor had been escaping into the workplace, personnel monitoring devices can be used to measure ambient glutaraldehyde concentrations in the area while employees are not present. The monitor should be placed near an open tray or automatic washer in order to more closely represent actual use conditions. Even though such devices are used in this mode occasionally, their primary function is actual personnel monitoring.

B.3 Devices available for glutaraldehyde

monitoring

B.3.1 Characteristics and ratings of air monitoring

devices

Several types of devices are available for use in monitoring air concentrations of glutaraldehyde. For each type of device, the following characteristics are addressed:

a) *Principle of operation.* The manner in which the equipment detects or indicates glutaraldehyde concentration is briefly described.

b) *Portability.* A brief statement indicates whether the equipment can be routinely moved about the workplace.

c) *Ease of operation.* The ease with which the equipment can be used is characterized in two categories: "preparation and use" and "data collection." "Preparation and use" describes the complexities involved in preparing the equipment for use (e.g., calibration, special training requirements, sampler conditioning) and in actually using it. "Data collection" describes the complexities involved in determining the test results (ppm glutaraldehyde).

In these two categories, each type of equipment is rated as "simple," "moderate," or "difficult." *Simple:* The instructions provided by the equipment supplier are generally adequate for any use. *Moderate:* One or more aspects of the equipment require that the user receive inservice or other special training. *Difficult:* One or more aspects of the equipment require the skills of an individual with special expertise, such as a technician or industrial hygienist, who has been trained, or has the qualifications to be trained, in the proper use of the equipment.

As an example, some passive sampling devices (PSDs) require little or no preparation to use, and their actual use involves nothing more than clipping the device in place. Determining the results of such monitoring, however, sometimes requires relatively complex extraction and analysis techniques. Hence, this type of device would be rated "simple" in the category of "preparation and use" and "difficult" in the category of "data collection."

d) *Accuracy.* Accuracy (the difference between the measured concentration of glutaraldehyde vapor and the true glutaraldehyde vapor concentration) is likely to vary among device types within a given generic category of measuring devices. A perfectly accurate measurement device would be perfectly precise and perfectly reproducible.

e) *Glutaraldehyde specificity.* Some equipment will measure the presence of air components other than glutaraldehyde (i.e., it is not "specific" to glutaraldehyde). This annex addresses the impact of unrelated air components on the measuring device.

f) *Lower detectable limit for glutaraldehyde vapor.* The lower detectable limit is the lowest measurable concentration of glutaraldehyde claimed by the equipment manufacturer. The user should require the supplier to document claims regarding detection limits.

B.3.2 Active sampling devices

Principle of operation: In this technique, a small, portable, battery-powered suction pump (usually clipped to the worker's belt) is connected via plastic tubing to a glass tube or filter containing an adsorbant or reactive material. The pump draws a known volume of air through the glass tube or filter, and the contaminants (including glutaraldehyde) are adsorbed on to the surface of the material or chemically derivatized (i.e., converted to another stable chemical) by a reactive chemical on the filter. By clipping the glass tube or filter to the lapel of the worker's shirt or blouse, EBZ samples can be collected.

At the end of the sampling period, the tubes or filters are sealed and sent to a laboratory for analysis. At the laboratory, the adsorbant or reactive material is removed from the glass tubes or filters and treated with a solvent that desorbs the glutaraldehyde or derivatized glutaraldehyde. The solvent extract is then analyzed to

determine the overall amount of glutaraldehyde adsorbed or chemically derivatized during the sampling period. Knowing the duration of the sampling period, the volume of air drawn through the tube or filter, and the amount of glutaraldehyde adsorbed or derivaritized enables one to calculate a 15-minute TWA glutaraldehyde exposure.

The desorption process and analytical technique are moderately complex and should only be attempted by laboratories with experienced analytical chemists or technicians. Sample tubes or filters collected for analysis by a service laboratory might require special shipping procedures. The service laboratory should be consulted for proper packaging and shipping procedures.

Portability: Completely portable.

Ease of operation:

Preparation and use—Simple to moderate.

Data collection—Difficult.

Accuracy: Variable, depending mainly on the ability of the analyst and the accuracy of calibration.

Glutaraldehyde specificity: High concentrations of aldehydes and ketones are capable of interfering with the sampling of glutaraldehyde but can be separated out by proper analysis procedures.

Lower detectable limit for glutaraldehyde: The manufacturer should state the lower detectable limit.

Other comments: Portable pumps should have a feature that allows the user to detect whether or not the pump stopped functioning during the collection of the samples (as might occur, for instance, if the battery fails). Pumps must be calibrated before and after each use. (As batteries run down, air flow rate can change.) The pump supplier should be asked about the expected life of the pump and batteries; they all contain parts that eventually will wear out.

Blank and control samples also must be collected. The analytical laboratory should be consulted about the proper techniques for blank and control sampling.

Examples of active sampling methods include OSHA's Method Number 64 and NIOSH Method 2532.

B.3.3 Passive sampling devices

Principle of operation: Like active sampling devices, PSDs are clipped to the worker's lapel. Passive sampling devices rely upon the natural diffusion of glutaraldehyde into a sorbent of reactant material and, hence, do not require the use of a pump. These devices are normally worn throughout the full day or during short periods when the excursion level can be selected.

After the sampling has been completed, the PSD is either sealed and sent to a laboratory for analysis or, depending on the type of PSD, processed and read on site.

Blank and control samples must also be collected. The PSD manufacturer or the analytical laboratory should be consulted about the proper techniques for blank and control sampling.

Portability: Completely portable.

Ease of Operation:

Preparation and use—Simple.

Data collection—Moderate to difficult.

Accuracy: Variable.

Glutaraldehyde specificity: Refer to the manufacturer's literature.

Lower detectable limit for glutaraldehyde: The manufacturer should state the lower detectable limit.

Other comments: Some PSDs might be easier to analyze than active sampling devices. The absence of the portable pump is an obvious advantage (no battery, no pump calibration, and the PSDs are lighter).

Passive sampling devices could be suitable for area monitoring if the minimum air flow across the face of the PSD is attained as specified by the PSD manufacturer.

Some users have found considerable variability among types of PSDs.

B.3.4 Electrochemical analyzers

Principle of operation: A hand-held, direct-reading meter draws an air sample across a platinum fuel cell sensor, where the air vapor undergoes oxidation on the catalytic surface of the fuel sensor. This reaction produces an electrical response directly proportional to the ambient glutaraldehyde vapor concentration. Readings are immediate, and repetitive samples can be taken in seconds or minutes, depending on the level of the previous reading.

Portability: Completely portable.

Ease of operation:

Preparation and use—Moderate.

Data collection—Simple.

Accuracy: Variable, depending on the ability to eliminate interfering chemicals.

Glutaraldehyde specificity: Alcohols, aldehydes, and phenols can cause interference. Refer to the manufacturer's literature.

Lower detectable limit for glutaraldehyde: The manufacturer should state the lower detectable limit.

Other comments: Although electrochemical analyzers do not meet the technical definition of a personnel monitor, they can provide a rapid analysis of EBZ exposure levels at the time of sampling. Repetitive sampling over the course of the work process can pinpoint overexposure situations and help determine peak exposure levels; any reading above 0.2 ppmv does not meet the current TLV-C for glutaraldehyde.

Currently available electrochemical analyzers cannot be worn by the worker. To conduct sampling in the EBZ, the device must be held in the EBZ by the worker or a coworker. Some types of electrochemical analyzers must be reset by the worker after each measurement and then reactivated.

B.4 Questions that should be asked of monitoring device manufacturers

The prospective user should ask the manufacturer the following questions before a monitoring device is purchased:

a) What gases or contaminants will interfere with the performance of the device?

b) Can potential interferences be measured to obtain a true glutaraldehyde measurement?

c) Does the device require calibration? If so, how is the calibration performed? If a glutaraldehyde gas reference sample is required, the user should request a written statement from the gas supplier regarding the stability and availability of the gas mixture as well as any special handling instructions.

d) Is any special training required to use the device? If so, does the manufacturer provide this training?

e) What is the lowest concentration of glutaraldehyde that can be measured accurately by the device? At that level, what is its accuracy and repeatability?

f) What method is used to analyze samples (e.g., gas chromatography, high-performance liquid chromatography)?

g) How long does it take to receive the results of the sampling?

h) Is preventive maintenance of the device required? If so, who will perform the maintenance? Will it be necessary to return the device to the factory, or is field service available?

i) Are accessory devices available for use with the device (e.g., recorders and integrators)? Is the monitoring equipment "intrinsically safe" (i.e., explosion-proof)? If only intrinsically safe equipment is permitted in the facility, the manufacturer must certify that the equipment meets this requirement.

j) Has the device been field-tested by independent laboratories? (A copy of the protocol and the individual laboratory results should be supplied.)

k) Are other area health care facilities or organizations using this device? If so, which ones? (The user might wish to contact the health care facilities or companies and ask them if they are satisfied with the device.)

l) Are other monitoring services offered, such as a tracking system to provide at least an annual recapitulation of the results of periodic monitoring?

B.5 Contracted services

Many companies or organizations offer services that include glutaraldehyde monitoring. The breadth of additional services available varies significantly from contractor to contractor. Some will perform only personnel monitoring; others will conduct a complete survey of the health care facility to identify sources of glutaraldehyde vapor and will provide recommendations for possible solutions to identified problems. Some of the advantages of using contract services are as follows:

a) Reputable contractors are familiar with the causes of potential glutaraldehyde overexposure, thereby enabling them to save time at the outset in determining where the problems might be. Engineering or work-practice solutions can then be designed and implemented.

b) Contract services can be performed on a shared-services basis; that is, several health care facilities can jointly contract with the contractor. Discounts for services might be available under such circumstances.

c) The same contractor might be able to provide services meeting similar needs in other departments (e.g., monitoring waste anesthesia gases in the operating room).

A major consideration in relying solely on contract services is that some form of ongoing monitoring program must be implemented, especially if consultant or contract services are not ongoing. Contract services or other ongoing monitoring must take into account the amount of glutaraldehyde used, the location of the glutaraldehyde baths and equipment, the number of people normally present in the vicinity of glutaraldehyde processing activities, and other factors.

B.5.1 Finding contract service organizations

a) The local or state health department, occupational health consulting services, workmen's compensation or other insurance carriers, or universities can be approached to determine if they provide consultant services and, if not, to secure their recommendations.

b) Nearby health care facilities can be approached to learn their experiences with consultants and to get their recommendations.

c) Glutaraldehyde suppliers can usually provide suggestions.

d) Technical journals, such as the *American Industrial Hygiene Association Journal*, often contain consultant advertisements.

e) The American Industrial Hygiene Association can provide a list of consultants and accredited laboratories

in the region.

f) If a local consultant is not available, a cooperative effort (shared service) to bring in a reputable consultant can be considered.

B.5.2 Selection criteria

Once a list of possible service organizations is prepared, the following steps should be taken in selecting the one to hire:

a) References should be requested, preferably nearby clients with similar operations.

b) The consultant should describe the specific qualifications and years of technical experience of the individuals who perform the work. (Certified Industrial Hygienist or Professional Engineer are usually good credentials. Certified Safety Professional or Biomedical Equipment Technician could also be valid credentials, with appropriate experience.)

c) Those who perform the work should be interviewed and the following questions asked:
   1) How many glutaraldehyde facilities has the individual tested?
   2) Is the person familiar with the clinical use of glutaraldehyde? (Ask follow-up questions.)
   3) What kind of equipment will be used to perform the work? What interferences might affect the glutaraldehyde monitoring?
   4) What areas of the facility will be examined?

d) The contractor should be asked if blank or control samples are collected and submitted.

e) The contractor should specify who performs the analysis of the absorbent and describe the level of experience of this individual.

f) The general operation, the number and types of sterilization areas, the work practices, the number of employees per shift, and the facility layout should be discussed before monitoring. Agreement should be reached in advance about which activities will be monitored and what ancillary tests (e.g., verification tests) will be performed. Both personnel and area monitoring are desirable. It should be specified that all work shifts during which glutaraldehyde is used will be surveyed.

g) The contractor should be asked whether ventilation checks will be performed (e.g., local exhaust hoods, air exchange rate, location of building intake in relation to the building's exhaust points, positive/negative pressure areas).

h) The contractor should describe the report that will be issued upon completing the work and provide an example of the report format. The user and contractor should agree upon the date on which the report will be issued and who will receive a copy. The report should contain at least the following information:
   1) the date the monitoring was performed;
   2) a detailed description of the operations monitored;
   3) the names or identification numbers of the personnel monitored;
   4) the exact locations of the sampling devices (photographs or maps are very helpful);
   5) if applicable, the most recent date on which the monitoring devices were calibrated and the calibration technique used;
   6) the specific times that samples were collected, with notations concerning other pertinent activities (e.g., changing of the glutaraldehyde bath);
   7) the glutaraldehyde concentration in ppmv at each sample location (measured as a 15-minute TWA or a maximum concentration using a discrete monitor);
   8) a description of the sampling, calibration, and analytical procedures used;
   9) the name of the contractor's organization;
   10) the names and qualifications of the survey personnel who did the work at the facility;

11) a description of the personal protective equipment used;
12) the temperature and relative humidity of the area surveyed;
13) an authorized signature with a title.

l) The contractor's fee should be discussed.

j) The possibility of follow-up visits should be discussed. How many visits and when they will be scheduled should be determined.

k) Once the contractor has been selected, it is important to ensure that the contractor will provide ample advance notice before coming to the facility so that the appropriate supervisor can schedule time for the survey and so that actual normal operations (including glutaraldehyde disinfection/sterilization processes and disposal of "spent" solutions) will occur during the survey. A "simulated load" outside of the normal routine should not be surveyed.

Annex C
(informative)

OSHA area offices, regional offices, state-plan offices, and consultation project state directory

C.1 Federal OSHA area offices

Alabama
Birmingham—205/731-1534

Alaska
Anchorage—907/271-5152

Arizona
Phoenix—602/542-5795

Arkansas
Little Rock—501/682-4520

California
Long Beach—310/516-3734
Los Angeles—213/736-3041
Sacramento—916/263-2800
San Diego—619/237-7325
San Jose—408/452-7288

Colorado
Denver—303/844-3061

Connecticut
Hartford—203/240-3152

Florida
Jacksonville—904/232-2895
Plantation—305/424-0242
Tampa—813/626-1177

Georgia
Tucker—404/493-6644

Hawaii
Honolulu—808/541-2685

Idaho
Boise—208/334-1867

Illinois
Aurora—708/896-8700
Calumet City—708/891-3800
Des Plaines—708/803-4800
Peoria—309/671-7033

Indiana
Indianapolis—317/232-2693

Iowa
Des Moines—515/281-3606

Kansas
Wichita—316/269-6644

Kentucky
Frankfort—502/227-7024

Louisiana
Baton Rouge—504/389-0474

Maine
Augusta—207/622-8417

Maryland
Baltimore—410/333-4100

Massachusetts
Boston—617/565-7164
Braintree—617/565-6924
Concord—510/676-5333
Methuen—617/565-8110
Springfield—413/785-0123

Michigan
Lansing—517/377-1892

Minnesota
Minneapolis—612/348-1994

Mississippi
Jackson—601/965-4606

Missouri
Kansas City—816/426-2756
St. Louis—314/425-4249

Montana
Billings—406/657-6649

Nebraska
Omaha—402/221-3182

New Hampshire

Concord—603/225-1629

New Jersey
Avenel—908/750-3270
Hasbrouck Heights—201/288-1700

New Mexico
Albuquerque—505/766-3411

New York
Albany—518/464-4338
Bayside-Queens—718/279-9060
New York—212/264-9840
Syracuse—315/451-0808

North Carolina
Raleigh—919/733-7166

North Dakota
Bismarck—701/250-4521

Ohio
Cincinnati—513/841-4132
Cleveland—216/522-3818
Columbus—614/469-5582
Toledo—419/259-7542

Oklahoma
Oklahoma City—405/231-5351

Oregon
Portland—503/229-5910

Pennsylvania
Harrisburg—717/782-3902
Philadelphia—215/597-4956
Pittsburgh—412/644-2903
Wilkes-Barre—717/826-6538

Puerto Rico
Hato Rey—809/766-5457

Rhode Island
Providence—401/528-4669

South Carolina
Columbia—803/765-5904

Tennessee
Nashville—615/781-5423

Texas
Austin—512/482-5783
Corpus Christi-512/888-3257
Westbury—516/334-3344
Dallas—214/320-2400
Houston—713/750-1727

Lubbock—806/743-7681

Utah
Salt Lake City—801/530-6901

Washington
Bellevue—206/731-2131

West Virginia
Charleston—304/347-5937

Wisconsin
Appleton—414/734-4521
Madison—608/264-5388
Milwaukee—414/297-3315

C.2 Federal OSHA regional offices

Region I

CT, MA, ME, NH, RI, VT

133 Portland Street, 1st Floor
Boston, MA 02114
617/565-7164

Region II

NJ, NY, Puerto Rico, Virgin Islands

201 Varick Street, Room 670
New York, NY 10014
212/337-2378

Region III

DC, DE, MD, PA, VA, WV

Gateway Building, Suite 2100
3535 Market Street
Philadelphia, PA 19104
215/595-1201

Region IV

AL, FL, GA, KY, MS, NC, SC, TN

1375 Peachtree Street, NE
Suite 587
Atlanta, GA 30367
404/347-3573

Region V

IL, IN, MI, NW, OH, WI

230 South Dearborn Street
32nd Floor, Room 3244
Chicago, IL 60604
312/353-2220

Region VI

AR, LA, NM, OK, TX

525 Griffin Square Building
Room 602
Dallas, TX 75202
214/767-4731

Region VII

IA, KS, MO, NE

911 Walnut Street, Room 406
Kansas City, MO 64106
816/426-5861

Region VIII

CO, MT, ND, SD, UT, WY

Federal Building, Room 1576
1961 Stout Street
Denver, CO 80294
303/844-3061

Region IX

American Samoa, AZ, CA, Guam, HI, NV, Pacific Trust Territories

71 Stevenson Street, Suite 420
San Francisco, CA 94105
415/744-6670

Region X

AK, ID, OR, WA

1111 Third Avenue, Suite 715
Seattle, WA 98101-3212
206/553-5930

C.3 OSHA state-plan offices

Many states and territories operate their own safety and health programs under Section 18(b) of the Occupational Health and Safety Act. These approved state-plan OSHA programs have primary enforcement of OSHA regulations in their states, except for federal facilities such as military hospitals and Veterans Administration medical centers.

Alaska
Anchorage—907/271-5152

Arizona
Phoenix—602/542-5795

California
San Francisco—415/703-4590

Connecticut

Wethersfield—203/566-4550

Hawaii
Honolulu—808/586-8844

Indiana
Indianapolis—317/232-2378

Iowa
Des Moines—515/281-3447

Kentucky
Frankfort—502/564-3070

Maryland
Baltimore—410/333-4179

Michigan
Lansing—517/335-8022

Minnesota
St. Paul—612/296-2342

Nevada
Carson City—702/687-3032

New Mexico
Santa Fe—505/827-2850

New York
Albany—518/457-2741

North Carolina
Raleigh—919/733-0360

Oregon
Salem—503/378-3272

Puerto Rico
Hato Rey—809/766-5457

South Carolina
Columbia—803/734-9594

Tennessee
Nashville—615/741-2582

Utah
Salt Lake City—801/530-6901

Vermont
Montpelier—802/828-2288

Virgin Islands
St. Croix—809/773-1994

Virginia
Richmond—804/786-2377

Washington
Olympia—206/956-5488

Wyoming
Cheyenne—307/777-7786

C.4 OSHA consultation project state directory

Congress has authorized a joint federal-state activity whereby a visit from a state consultant who can give practical advice on job safety and health problems can be requested. While these consultants have received the same training as the federal inspection staff, the consultant cannot issue citations, propose penalties, or routinely provide information about workplace conditions to the federal inspection staff.

Alabama
205/348-7136

Alaska
907/269-4940

Arizona
602/542-5795

Arkansas
501/682-4520

California
415/703-4050

Colorado
303/491-6151

Connecticut
203/566-4550

DC
202/576-6651

Delaware
302/577-2879

Florida
904/488-3044

Georgia
404/894-3806

Hawaii
808/586-9100

Idaho
208/385-3283

Illinois
312/814-2337

Indiana
317/232-2688

Iowa
515/281-5352

Kansas
913/296-4386

Kentucky
502/564-6895

Maine
207/624-6460

Maryland
301/333-4218

Massachusetts
617/727-3463

Michigan 20
517/335-8250 

Michigan 21
517/322-1809 

Minnesota
612/297-2393

Mississippi
601/987-3981

Missouri
314/751-3403

Montana
406/444-6401

Nebraska
402/471-2239

Nevada
702/688-1474

New Hampshire
603/271-2024

New Jersey
609/292-0404

New Mexico
505/827-2877

New York
518/457-2481

North Carolina
919/733-2360

North Dakota

701/221-5188

Ohio
614/644-2631

Oklahoma
405/528-1500

Oregon
503/378-3272

Pennsylvania
800/382-1241

Rhode Island
401/277-2438

South Carolina
803/734-9599

South Dakota
605/688-4101

Tennessee
615/741-2793

Texas
512/440-3834

Utah
801/530-6855

Vermont
802/828-2765

Virginia
804/786-2376

Washington
206/442-5930

West Virginia
304/558-7890

Wisconsin[20]
414/521-5063 

Wisconsin[21]
608/266-0417 

Wyoming
307/777-7786

Annex D
(Informative)

Regulatory information

This annex provides information on the applicability of various regulatory requirements for potentially

hazardous substances.

Applicable requirements of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). Reportable Quantity (RQ) as per 40 CFR 302.4: none.

Requirements of the Superfund Amendments and Reauthorization Act of 1986 (SARA Title III). Threshold Planning Quantities (TPQs) and Reportable Quantities (RQs) for release as required in 40 CFR 355 (for SARA 302, 311, 312): none. SARA reportable release of toxic chemicals as per 40 CFR 372 (for SARA 313): none.

California Proposition 45. Glutaraldehyde contains no levels of listed substances that California has found to cause cancer, birth defects, or other reproductive harm, which would require a warning under the statute.

Massachusetts Right-to-Know Substance List (MSL) (105 CMR 670.000): 1%

Pennsylvania Right-to-Know: 1%

California SCAQMD 443.1 VOCs: ~~2% glutaraldehyde contains 31.06 grams (g) per liter (L) VOC; 1290.12 g/L of material less exempted compounds. 50% glutaraldehyde contains 566.82 g/L VOC; 1291.7 g/L of material less exempted compounds.~~ Not applicable.

Environmental Protection Agency (EPA) Hazard Categories: Immediate Health, Delayed Health.

Annex E

(Informative)

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OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Eye and face protection standard. *Code of Federal Regulations*, Title 29, Part 1910.133.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Respiratory protection standard. *Code of Federal Regulations*, Title 29, Part 1910.134.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Hand protection standard. *Code of Federal Regulations*, Title 29, Part 1910.138.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Medical and first aid standard. *Code of Federal Regulations*, Title 29, Part 1910.151.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Hazard communication standard. *Code of Federal Regulations*, Title 29, Part 1910.1200.

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Amendment 1 to ANSI/AAMI ST58:1996,
Safe use and handling of glutaraldehyde-based products in health care facilities

Introduction

Revise 3rd paragraph to read:

~~For a number of years, most recently in 1996~~ Currently, ACGIH ~~has recommended~~ recommends a ceiling threshold limit value (TLV-C) for glutaraldehyde of ~~0.2~~ 0.05 parts per million volume (ppmv)(ACGIH ~~1995~~ 2000). ~~Also in 1995, ACGIH issued a "Notice of Intended Changes" in which it was proposed that the TLV-C for glutaraldehyde be reduced from 0.2 ppmv to 0.05 ppmv.~~ A threshold limit value is the airborne concentration of a substance to which "it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be affected more seriously by aggravation of a pre-existing condition, or by development of an occupational illness" (ACGIH ~~1995~~ 2000). A ceiling TLV is "the concentration that should not be exceeded during any part of the working exposure" (ACGIH ~~1995~~ 2000).[2]

Revise 4th paragraph to read:

In 1989, based on the ACGIH recommendation at that time, the Occupational Safety and Health Administration (OSHA) adopted a TLV-C of 0.2 ppmv for glutaraldehyde as part of its Air Contaminants Standard (29 CFR 1910.1000). None of the exposure limits added to the Air Contaminants Standard in 1989 are currently in force due to legal challenges to procedural aspects of their adoption. However, federal OSHA can enforce ~~these~~ exposure limits, including the ~~0.2 ppmv~~ current ACGIH-recommended TLV-C for glutaraldehyde, by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards. Additionally~~, as of 6 September 1993, 11~~ states with federally approved state OSHA programs ~~had formally decided to continue~~ can opt to enforce ~~the 0.2 ppmv TLV-C as~~ exposure limits originally promulgated in the Air Contaminants Standard or recommended by ACGIH.[3]

Revise 5th paragraph to read:

~~In October 1995, a major U.S. manufacturer of glutaraldehyde lowered its recommended airborne exposure limit for glutaraldehyde to a TLV-C of 0.1 ppm~~. Certain Environmental Protection Agency (EPA) regulations also apply to glutaraldehyde. Users should contact the federal EPA office or their state EPA offices for information on EPA requirements.[4] Additional regulatory information can be obtained from the manufacturer's Material Safety Data Sheet.

Revise footnote 2 to read:

[2]~~Information on the current regulations of the Occupational Safety and Health Administration (OSHA) can be obtained from federal OSHA area and regional offices and from state-plan offices (see annex C).~~ Information on current ACGIH guidelines can be obtained by contacting the American Conference of Governmental Industrial Hygienists, Technical Affairs Office, Kemper Woods Center, 1330 Kemper Meadow Drive, Cincinnati, OH 45240, (513) 742-2020, http://www.acgih.org.

Delete footnote 3 and replace with:

[3]Information on current OSHA regulations can be obtained from federal OSHA area and regional offices and from state-plan offices (see annex C). OSHA's mail address and web site address are as follows: U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, NW, Washington, DC 20210, http://www.osha.gov.

Add new footnote 4:

[4]EPA's mail address and web site address are as follows: Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, http://epa.gov.

Subclause 1.3—Exclusions

Revise 1st paragraph, 2nd sentence:

See AAMI ~~(1990)~~ (2000) for information on the general safety and performance characteristics of chemical sterilants ~~generally~~.

Subclause 3.4.2—General room ventilation

Revise *Rationale* statement, 3rd and 4th sentences:

The American Institute of Architects (AIA) publishes guidelines for general ventilation of areas in health care facilities. The most recent edition was approved in ~~early 1996~~ 2001 (AIA ~~1996~~ 2001). These guidelines, while widely recognized in the health care community and referenced in the accreditation manual of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO ~~1996~~ 2001), are based mainly on considerations of odor control, asepsis, and personnel comfort.

Subclause 3.7.1—Glutaraldehyde solutions

Revise Footnote 4 to read:

[5]Bio-oxidation studies were conducted by Union Carbide Corporation according to *Standard Methods for the Examination of Water and Waste Water,* 4th ed., American Public Health Association, 1976, Parts 507 and 508. For additional information, see: ~~Union Carbide Corporation Bulletin BBTL 2050, "Deactivation and Disposal of Glutaraldehyde Solutions."~~ The Dow Chemical Company. *Deactivation and disposal of glutaraldehyde solutions.* Midland (Mich.): 2001.

Subclause 4.2.2.2—Eye protection

Revise 1st paragraph, 2nd sentence to read:

Splashproof goggles or both safety glasses with side shields and a wraparound full face shield should always be worn when working ~~with~~ around glutaraldehyde solutions.

Add to 1st paragraph of *Rationale* statement:

For eye protection, both safety glasses and face shields are needed, because many face shields alone do not offer total protection against eye contamination and their use should be considered an adjunct to safety glasses in order to protect facial skin.

Revise 2nd paragraph, 2nd and 3rd sentences:

The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI ~~1990~~ Z358.1—1998). Among other things ANSI Z358.1—~~1990~~1998 requires that . .

Subclause 4.3.1—Glutaraldehyde spill containment response team

Revise 1st paragraph, 1st sentence, to read:

~~Consistent with the JCAHO Hazardous Materials Plan,~~ A glutaraldehyde spill containment "response team" should be created ~~(JCAHO 1995)~~.

Subclause 4.3.3.2—Neutralizing chemicals

Revise title of Subclause to read:

Deactivating chemicals

Revise 1st sentence to read:

Several chemicals ~~(e.g., sodium bisulfite, dibasic ammonium phosphate, household ammonia, ammonium carbonate powder)~~ can be used to decrease the glutaraldehyde concentration in solutions and/or . . .

Subclause 5.5.2—Short-term health effects

Revise 4th paragraph, 1st sentence to read:

Nose and throat irritation and general tightness of the chest have been reported by workers exposed to glutaraldehyde vapor~~, even at concentrations below the current TLV-C of 0.2 ppmv~~.

Annex D—Regulatory information

Delete annex D.

Annex E—Bibliography

Change designation from "Annex E—Bibliography" to "Annex D—Bibliography."

Revise the following cited references as indicated:

AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS. *TLVs®: Threshold limit values for chemical substances and physical agents in the work environment and biological exposure indices with intended changes for ~~1995/1996~~ 2000/2001*. Cincinnati: ACGIH, ~~1995~~ 2000.

AMERICAN INSTITUTE OF ARCHITECTS ACADEMY OF ARCHITECTURE FOR HEALTHCARE. *Guidelines for design and construction of hospital and health care facilities, ~~1996-97~~*. Washington (D.C.): American Institute of Architects Press, ~~1996 (in press)~~ 2001.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Emergency eyewash and shower equipment.* ANSI Z358.1—~~1990~~1998. New York: ANSI, ~~1990~~ 1998.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Chemical sterilants and ~~sterilization methods~~ high-level disinfectants: A guide to selection and use.* AAMI TIR No. 7. Arlington (Vir.): AAMI, ~~1999~~ 2000. AAMI Technical Information Report.

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Add to For Further Reading:

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Developed by the
Association for the Advancement of Medical Instrumentation

Approved 31 October 2002 by
American National Standards Institute

Annotations from ST58.pdf

Page 3

Annotation 1; Label: AAMI; Date: 10/05/2000 8:30:15 AM
1 At the time this recommended practice was balloted, Dr. Chamberlain represented the Center for Devices and Radiological Health, U.S. Food and Drug Administration.

Annotation 2; Label: AAMI; Date: 10/05/2000 8:31:11 AM
2 At the time this recommended practice was balloted, Mr. Danielson represented HCA Wesley Medical Center, Wichita, Kansas.

Page 4

Annotation 1; Label: AAMI; Date: 10/05/2000 8:31:56 AM
3 At the time this recommended practice was balloted, Ms. Schultz represented AMSCO International.

Annotation 2; Label: AAMI; Date: 10/05/2000 8:32:53 AM
1 At the time this recommended practice was balloted, Dr. Chamberlain represented the Center for Devices and Radiological Health, U.S. Food and Drug Administration.

Annotation 3; Label: AAMI; Date: 10/05/2000 8:33:19 AM
5 At the time this recommended practice was ballotted, Dr. Glaser represented the United States Pharmacopeia.

Page 5

Annotation 1; Label: AAMI; Date: 10/05/2000 8:33:44 AM
6 At the time this recommended practice was balloted, Ms. Schultz represented AMSCO International.

Page 6

Annotation 1; Label: AAMI; Date: 10/05/2000 8:38:11 AM
7 Australia's PEC/3 Glutaraldehyde Assessment Report (1994) concludes that "glutaraldehyde can be used safely...if the proper control measures are in place. The main health effects of glutaraldehyde are irritation of the skin, eyes and respiratory system."

Annotation 2; Label: AAMI; Date: 10/05/2000 8:38:46 AM
8 Information on the current regulations of the Occupational Safety and Health Administration (OSHA) can be obtained from federal OSHA area and regional offices and from state-plan offices (see annex C). Information on current ACGIH guidelines can be obtained by contacting the American Conference of Governmental Industrial Hygienists, Technical Affairs Office, Kemper Woods Center, 1330 Kemper Meadow Drive, Cincinnati, OH 45240, (513) 742-2020, FAX (513) 742-3355.

Annotation 3; Label: AAMI; Date: 10/05/2000 8:39:19 AM
8 Information on the current regulations of the Occupational Safety and Health Administration (OSHA) can be obtained from federal OSHA area and regional offices and from state-plan offices (see annex C). Information on current ACGIH guidelines can be obtained by contacting the American Conference of Governmental Industrial Hygienists, Technical Affairs Office, Kemper Woods Center, 1330 Kemper Meadow Drive, Cincinnati, OH 45240, (513) 742-2020, FAX (513) 742-3355.

Page 13

Annotation 1; Label: AAMI; Date: 10/05/2000 8:56:58 AM
10 Bio-oxidation studies were conducted by Union Carbide Corporation according to Standard

Methods for the Examination of Water and Waste Water, 4th ed., American Public Health Association, 1976, Parts 507 and 508. For additional information, see Union Carbide Corporation Bulletin BBTL 2050, "Deactivation and Disposal of Glutaraldehyde Solutions."

Annotation 2; Label: AAMI; Date: 10/05/2000 8:57:14 AM
11 Australia's PEC/3 Glutaraldehyde Assessment Report (1994) estimated "that concentrations of glutaraldehyde in sewage treatment plants will remain below 200 mg/l. Such levels do not constitute a significant environmental hazard, and will be reduced further by biodegradation during sewage treatment."

Page 23

Annotation 1; Label: AAMI; Date: 10/05/2000 9:39:02 AM
12 Because of inadequate case reporting and the lack of an identified immune mechanism, glutaraldehyde is considered at this time to be a respiratory irritant, not a respiratory sensitizer. However, further studies are in progress on the respiratory effects of glutaraldehyde and their relationship to worker exposure.

Annotation 2; Label: AAMI; Date: 10/05/2000 9:44:24 AM
13 Ibid.

Page 25

Annotation 1; Label: AAMI; Date: 10/05/2000 9:47:04 AM
14 Access to Employee Exposure and Medical Records, 29 CFR 1910.20.

Annotation 2; Label: AAMI; Date: 10/05/2000 9:47:27 AM
15 Ibid.

Annotation 3; Label: AAMI; Date: 10/05/2000 9:48:01 AM
16 Adapted, with the permission of Union Carbide Corporation, from EAGAR, RG., Jr., LEDER, J., THEIS, AB. Glutaraldehyde: Factors important for microbicidal efficacy. Presented at the Third Conference on Progress in Chemical Disinfection, Binghamton, N.Y., April 3-5, 1986. Copyright 1986 Union Carbide Corporation.

Page 30

Annotation 1; Label: AAMI; Date: 10/05/2000 10:40:33 AM
17 Escherichia coli exhibits a broad range of tolerance to pH. Over the range shown, pH 5.0-8.5, no reduction in viability was seen in control experiments.

Page 33

Annotation 1; Label: AAMI; Date: 10/05/2000 10:48:55 AM
18 Because glucose is the only energy source available to the microorganisms in the test system, its consumption is an indication of microbial activity. Control experiments confirm its correlation with recoverable viable cells.

Page 38

Annotation 1; Label: AAMI; Date: 10/05/2000 10:52:16 AM
19 Abstracted, with permission from Union Carbide, from a presentation given at the NEFTA-GAZ Exhibition in Moscow, December, 1984, by R.G. Eager, Jr., PhD, and L. Marlin, PhD.

Page 55

Annotation 1; Label: AAMI; Date: 10/05/2000 10:56:30 AM
20 Safety

Annotation 2; Label: AAMI; Date: 10/05/2000 10:56:44 AM
21 Health

Page 56

Annotation 1; Label: AAMI; Date: 10/05/2000 10:57:54 AM
20 Safety

Annotation 2; Label: AAMI; Date: 10/05/2000 10:57:38 AM
21 Health

Page 57

Annotation 1; Label: AAMI; Date: 11/28/2000 3:56:47 PM
Errata issued February 1998 based on the following rationale: A recent review of the California law rule 443.1 determined that this rule does not apply to glutaraldehyde. Rule 443.1 applies to materials containing volatile organic compounds (VOCs) in any amount that are used as solvents or coatings. Glutaraldehyde is neither a solvent nor a coating. Therefore this rules is not applicable to glutaraldehyde.