

VICTORIAN ADVISORY COMMITTEE ON INFECTION
CONTROL

REVIEW SUB-COMMITTEE REPORT

1998

INFECTION CONTROL

TASKFORCE

GLUTARALDEHYDE

RECOMMENDATION

NUMBER 11

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1. INTRODUCTION

In 1998, the Infection Control Taskforce survey identified poor adherence to practice guidelines and safety procedures when glutaraldehyde was used for ‘high level’ disinfection. In particular, the survey found instances of inappropriate use, poor work practices, and inappropriate engineering, including ventilation and monitoring controls. The issues surrounding glutaraldehyde were considered by the Infection Control Taskforce and several strategies were recommended and endorsed by the Minister for Health and the Department of Human Services. In response to these findings, the Taskforce recommended that *Hospital and Metropolitan Network infection control plans should identify a strategy to immediately meet glutaraldehyde safety standards, and a strategy for phasing out the use of glutaraldehyde use for high level disinfection purposes other than in a self-contained closed system by 30 June 2001.*¹

Following publication of the Infection Control Taskforce recommendations for glutaraldehyde safety standards and the development of strategies for phasing out the use of open systems, the Department was approached by the Gastroenterology Nurses Society of Australia (GENSA) [now known as the *Gastroenterology Nurses College of Australia (GENCA)*] and by the Director of the Gastroenterology Unit at Monash Medical Centre, Southern Health, with concerns regarding glutaraldehyde use.

The Department sought an evidence-based review, from the Centre for Clinical Effectiveness (CCE), Monash Medical Centre (MMC),² on the relative safety and effectiveness of both manual (open soaking) and closed systems. Following the final CCE report, the Department sought advice from the Standing Committee on Infection Control (SCIC) [now the *Victorian Advisory Committee on Infection Control – VACIC*] on the merits of revisiting the original 1998 Taskforce recommendations. The Standing Committee on Infection Control was requested to provide expert advice on the safety and effectiveness of both manual and automated methods, and on standards and protocols that should be observed in the disinfection of endoscopes. In February 2000, a Subcommittee was established to undertake the review with representation from the Department of Human Services (Acute/Public Health Divisions), professional organizations and later, the Victorian WorkCover Authority.

In undertaking the review process the sub-committee found that concerns associated with the use of glutaraldehyde included:

- Occupational health and safety requirements including the elimination and substitution of glutaraldehyde and adherence to the DHS Infection Control Task Force 1998 recommendation to phase out the use of glutaraldehyde in open systems
- The use of disinfection rather than sterilisation for items entering a sterile body site; and
- The absence of educational requirements and practice standards for health care workers.

RECOMMENDATIONS

The Subcommittee identified seven key recommendations for implementation:

Recommendation 1

Where practicable, the phasing out of glutaraldehyde use for high-level disinfection purposes other than in a self-contained, closed system be implemented by December 2001. The exceptions are transoesophageal endoscopes (TOE), ultrasound and foetal monitoring probes and those endoscopes that cannot withstand submersion or pressure gradients. Further, that the use of alternative technologies and chemical disinfection agents, to glutaraldehyde, be investigated and implemented where practicable in both open and closed systems.

Recommendation 2

All health services and hospitals must meet infection control, engineering, occupational health and safety requirements to ensure the safety of patients and staff regardless of the technology or chemical disinfection agent in use by December 2001.

Recommendation 3

Glutaraldehyde is a high level disinfectant and, as such, must not be used for any medical instruments introduced into sterile tissue sites in accordance with *AS 4187– 1998*.³

Recommendation 4

All health services and hospitals must comply with the Occupational Health and Safety (Hazardous Substances) Regulations 1999. Further, the Department of Human Services *Guidelines for the Use of Glutaraldehyde in the Health Industry*⁴ must be complied with by December 2001 as recommended by the Department of Human Services Infection Control Task Force 1998.¹ Further, the subcommittee recommends the guidelines be reviewed as a matter of urgency to provide accurate and up-to-date information for users.

Recommendation 5

That all health services and hospitals should establish formal policies and procedures for the use of, and access to, glutaraldehyde and all other chemical disinfection agents and alternative technologies by February 2002.

Recommendation 6

A competency based education and training program should be developed and undertaken by all health care workers working with glutaraldehyde⁴ in particular but should also include all other chemical disinfection agents and systems in use.

Recommendation 7

All health services and hospitals should establish a patient and equipment tracking system for all reusable medical equipment processed by chemical disinfection by July 2002.

2. CENTRE FOR CLINICAL EFFECTIVENESS INFECTION CONTROL EVIDENCE BASED LITERATURE REVIEW FINDINGS

The review of evidence is inconclusive and does not appear to favour either automated or manual systems for the use of glutaraldehyde. On examination of the 1999 literature review undertaken by the Centre for Clinical Effectiveness² the Subcommittee identified that:

- Automated machines do not perform better than manual disinfection processes in the decontamination of endoscopes.
- There is no ideal method or chemical currently available for high level disinfection.
- The use of glutaraldehyde in appropriately ventilated areas, subject to strict compliance with relevant occupation safety and infection control standards/guidelines^{3,4,5,6} can be considered an acceptable process.
- Whether glutaraldehyde is used in a well-ventilated open system or in a closed system, there are common requirements to protect patients from infection. These include scrupulous cleaning of the instrument and equipment prior to disinfection, constant monitoring of concentrations, protocols for the entire process, staff education and certification, and validation of disinfection processes.
- The establishment of, and adherence to, protocols and practice standards are important factors contributing to staff and patient safety as is the disinfection process.
- The local exhaust ventilation system (LEV) (“fume cabinet”) design must incorporate mechanisms that prevent or restrict the generation or emission of vapours, aerosols or splashes. Engineering design must comply with the Australian Standard 2243.8-1992.⁷ To minimise exposure, consideration of the high relative density of glutaraldehyde vapour is essential.

These findings would also suggest that the use of closed systems, alternative technologies and chemical disinfection agents would not compromise effective infection control. However, in considering the 1996/97 infection control survey findings (inappropriate use, poor work practices, and inappropriate engineering, including ventilation and monitoring controls), the committee concluded that safer alternatives/technologies should be used where practicable.

3. GLUTARALDEHYDE AND DISINFECTION

Findings

Glutaraldehyde is a high-level chemical disinfectant and must not be used as a substitute for sterilization.

The use of glutaraldehyde for disinfection of endoscopes is discussed in Section Ten (p.58-60) and Appendix C (p.71-74) of Australian Standard AS4187-1998: *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*³ Of particular note is the distinction made between items to be inserted into sterile body tissue sites (p.71) and those for use in non-sterile sites. The former items must be sterile rather than disinfected. In New South Wales, this principle has been embodied in legislation through the *Medical Practice Act 1992*, the *Nurses Act 1991* and other regulations for health care professionals. Western Australia has followed this lead.

Glutaraldehyde is inactivated in the presence of organic matter therefore endoscopes must have their channels thoroughly cleaned before being submersed. Failure to thoroughly clean medical equipment prior to its processing, remains a vital concern whether an automated system is in place or not.

The Subcommittee concluded that:

- Transoesophageal endoscopes (TOE), ultrasound/foetal monitoring probes and some endoscopes cannot withstand pressure gradients or submersion due to their design and pose a particular concern for their disinfection. Careful consideration should be given to the use of these items.
- Evidence based practice does not support the continued use of glutaraldehyde for the disinfection of items inserted into sterile body tissue sites (critical items).
- Infection control literature indicates that glutaraldehyde is an effective chemical disinfectant where high-level disinfection is required for instruments inserted into non-sterile body tissue sites however alternative technologies and chemical disinfection agents are available.
- Alternatives to glutaraldehyde should be introduced for disinfection of semi-critical equipment. (Appendix 1 Summary of products reviewed, environmental controls and applications).

Recommendations

- In evaluating the need for the continued use of glutaraldehyde or the introduction of alternative technologies, consideration should be given to the type of service provision and level of activity undertaken by the health service or hospital.
- Health services and hospitals should ensure that input and assessment by infection control and sterilization services managers is obtained prior to the purchase of new equipment and technology.
- Use of automated systems shall be in strict accordance with the disinfectant solution and automated system manufacturer's instructions.
- A risk assessment must be undertaken by all health services or hospitals prior to any purchase decision and the introduction of either manual/automated systems or alternative chemical disinfection agents.

- Health services and hospitals should restrict the use of glutaraldehyde in open systems to transoesophageal endoscopes (TOE), ultrasound and foetal monitoring probes and some endoscopes (or to emergency use where the alternative technology fails and patient care may otherwise be compromised). However, available alternative chemical disinfection agents and technologies should be considered and used where practicable (Appendix 1).
- In accordance with AS 4187-98³ the subcommittee recommends that all health services and hospitals including endoscopy units establish protocols that:
 - Eliminate the use of chemical disinfection processes for critical items, and
 - Minimise the use of glutaraldehyde chemical disinfection for semi-critical items.

Recommendation 1

Where practicable, the phasing out of glutaraldehyde use for high level disinfection purposes other than in a self-contained, closed system be implemented by December 2001. The exceptions are transoesophageal endoscopes (TOE), ultrasound and foetal monitoring probes and those endoscopes that cannot withstand immersion or pressure gradients. Further, that the use of alternatives to glutaraldehyde be investigated and be implemented where practicable in both open and closed systems.

Recommendation 2

All public acute care hospitals must meet infection control, engineering and occupational health and safety requirements to ensure the safety of patients and staff regardless of the technology or chemical agent in use by December 2001.

Recommendation 3

Glutaraldehyde is a high-level disinfectant and, as such, must not be used for any medical instruments introduced into sterile tissue sites in accordance with AS 4187 – 1998.³

4. OCCUPATIONAL HEALTH AND SAFETY

It is important to note that the use of any chemical agent or cleaning product for cleaning or disinfection will have occupational health and safety implications.

Whilst glutaraldehyde can be used safely in an appropriately built and maintained exhaust fume cabinet, many hospitals were identified in the 1996/1997 Infection Control Survey¹ as failing to comply with recommendations for safe handling of glutaraldehyde.

Findings

The occupational health and safety (OHS) issues associated with glutaraldehyde are significant and well documented both locally and internationally. At a local level, concerns by healthcare workers and union bodies about health associated risks and sensitivities have predominated in the nursing profession. The National Occupational Health and Safety Commission (NOHSC)⁸ and the National Industrial Chemicals Notification and Assessment Scheme (1994) Priority Existing Chemical No. 3 Glutaraldehyde (NICNAS)⁹ has declared glutaraldehyde a Priority Existing Chemical and in its report recommends a hierarchy of control measures for controlling its associated risks. The higher order controls-elimination and substitution-are consistent with the Subcommittee's recommendations.

DHS guidelines on safe use also recommend a hierarchal approach to controlling risks. The Victorian Occupational Health and Safety (Hazardous Substances) Regulations 1999¹⁰ requires by law, that the hierarchy of controls be implemented as far as practicable (Table 1). This essentially means that where there is a substitute lower risk chemical or system, this chemical or system is required where practicable to be implemented. WorkSafe has indicated that the availability of substitute chemicals and systems and their current use in hospitals provides indication of practicability.

Table 1 Occupational Health and Safety (Hazardous Substances) Regulations 1999-Hierarchy of Controls¹⁰

- | |
|---|
| <ul style="list-style-type: none">▪ Elimination▪ Substitute with less hazardous substances▪ Isolate or enclose the process▪ Apply engineering controls, including local exhaust ventilation, to contain or minimise exposure (Appendix Two)▪ Adopt safe work practices that minimise exposure including job rotation▪ Provide, and ensure the maintenance and use of, appropriate and adequate personal protective equipment |
|---|

There are a number of bodies of work in Australia that describe recommended practices for the use of glutaraldehyde.^{3, 4, 5, 6, 10, 11} A review of available documents revealed that no one document adequately addresses:

- All aspects required for infection control principles and practice, and
- Safe and effective use of glutaraldehyde and other chemical disinfectants. (Appendix Two)

Material safety data sheets (MSDS) should form part of the risk assessment process undertaken by health services and hospitals and should be available where chemical agents are in use. They contain information

on the properties and uses of the chemical agent, health hazards, precautions for use and safe handling information.

Recommendations

All health services and hospitals using glutaraldehyde must follow the hierarchy of controls outlined in the Occupational Health and Safety (Hazardous Substances) Regulations 1999¹⁰ together with the DHS *Guidelines for the Use of Glutaraldehyde in the Health Industry* (1996),⁴ that provide practical guidelines for implementing the regulations. Further the sub-committee recommends these guidelines be reviewed by the Department to remove ambiguities and provide clarity for users.

In addition, the Subcommittee concluded that a number of areas in the document are open to interpretation. It is felt that words such as ‘should’, ‘can’ and ‘may do’ do not provide clear instruction and are left open to the discretion of the user or organisation to interpret.

In general, the Sub-committee felt the Guidelines⁴ are poorly adhered to and that implementation of the Guidelines must be mandatory for all health services or hospitals using glutaraldehyde.

Recommendation 4

All Health Services and hospitals must comply with the Occupational Health and Safety (Hazardous Substances) Regulations 1999.¹⁰ Further, the Department of Human Services Guidelines for the Use of Glutaraldehyde in the Health Industry⁴ must be complied with by December 2001 as recommended by the Department of Human Services Infection Control Task Force 1998.¹ Further, the subcommittee recommends the guidelines be reviewed as a matter of urgency to provide accurate and up-to-date information for users.

(Appendix 3)

5. ALTERNATIVE TECHNOLOGIES AND NEW CHEMICAL AGENTS

5.1 AUTOMATED GLUTARALDEHYDE TECHNOLOGIES

Findings

The 1998 Infection Control Taskforce¹ made reference to the adoption of self-contained units for glutaraldehyde use, but the omission of an accurate description of what constitutes a self-contained unit has resulted in a wide interpretation by health services and hospitals. The VACIC Sub-committee defined a closed system as one that uses automated technology for the glutaraldehyde disinfection process and rinsing cycle.

There was unanimous support for the use of automated systems. However, there have been a number of published papers referring to problems with some automated systems including the absence of mechanical alarm monitoring design features (alarm mechanisms to detect that glutaraldehyde is not passing through all channels), with resultant contamination and cycle failures.¹² Thorough investigation of the features of these systems is required prior to purchase to ensure they provide safe and effective disinfection of the endoscope.¹³

Table 2 and Table 3¹⁴ provide some examples for consideration and potential errors that may occur during the day-to-day use of both automated and non-automated systems for high-level chemical disinfection of medical equipment.

Table 2 Considerations for the use of automated endoscopic reprocessing systems (AERS)¹⁴

- | |
|--|
| <ul style="list-style-type: none">▪ Compatibilities between the endoscope and a specific system▪ Compatibilities between the endoscope, specific system and chemical disinfectant solution▪ Conflicting recommendations between manufacturers of endoscopes and AERS▪ Potential for contamination of AERS▪ Use of an AERS to process an endoscope that should not be processed in an AERS▪ Design feature facilitating the formation of biofilms which may be impossible to eradicate thus repeatedly contaminating the endoscopes rather than disinfecting them▪ The type of procedure to be performed▪ The ability to, and contingency for, the provision of services if an automated system failure occurs |
|--|

Table 3 Potential for the inappropriate use of non-automated glutaraldehyde systems

- | |
|---|
| <ul style="list-style-type: none">▪ Inadequate submersion of the endoscope (i.e. insufficient disinfectant solution used, incorrect submersion technique)▪ Incorrect activation of the disinfectant solution▪ Failure to follow the manufacturer's instructions for use of disinfectant solution▪ Incorrect dilution/concentration▪ Glutaraldehyde temperature below 20° C▪ Incorrect containment of solution▪ Inadequate submersion times▪ Inadequate rinsing of endoscope▪ Inadequate protection and engineering controls exposing health workers to fumes (vapours) and aerosols |
|---|

5.2 ORTHO-PHTHALALDEHYDE (OPA)

A review of the efficiency and occupational health and safety aspects of ortho-phthalaldehyde (OPA) was undertaken by Dr Margaret M Peel¹⁵ using available literature and the Therapeutic Goods Administration submission documentation supplied by Johnson & Johnson Medical Australia.¹⁶

Findings

- OPA does not require activation before use and has little odour. Although OPA can stain skin, clothing and proteins on instruments and other environmental surfaces, the stains are removable. The stain can be seen as beneficial by highlighting inadequate cleaning procedures as the chemical clings to organic matter.
- Personal Protective clothing and equipment should be worn when working with OPA.
- OPA tends to be more stable than glutaraldehyde as it shows no tendency to polymerise at inappropriate pH levels.
- Activated glutaraldehyde may be used for a period of 14 to 28 days whereas OPA can only be used for 14 days. However, glutaraldehyde becomes more dilute over this period whereas OPA does not sustain significant dilution.
- OPA is less irritating and has been reported as having only mild irritation compared with glutaraldehyde. OPA has not been implicated in the development of contact dermatitis.
- The cost of OPA is expected to be higher but this may be offset by its advantages over glutaraldehyde.
- OPA is rapidly effective against mycobacteria. However, Dr Peel found that its effectiveness against mycobacterium avium complex should be further investigated. Mycobacterium avium complex is more resistant to glutaraldehyde than Mycobacterium tuberculosis and is relevant for HIV- infected patients undergoing bronchoscopy.
- OPA is not as effective against sporing bacteria as glutaraldehyde.

Recommendations

Dr Peel has recommended that OPA is a suitable alternative to glutaraldehyde for high-level disinfection of endoscopes (excluding bronchoscopes).

- The subcommittee has accepted the recommendation of Dr Peel that OPA is an acceptable replacement for glutaraldehyde for endoscopes (except bronchoscopes) as it provides a safe level of chemical disinfection and satisfies occupational health and safety aspects for the use of chemical disinfectants.
- Health services and hospitals should carefully assess all aspects of chemical disinfection use in assessing a change to OPA.
- Occupational health and safety aspects of OPA and the information contained in the material safety data sheet must be considered. OPA may cause mild skin and eye irritation. Personal protective clothing and

equipment must include gloves, goggles and appropriate body protection. The level of clothing and equipment required will depend on the results of the risk assessment undertaken.

5.3 GLUTARALDEHYDE USER STATIONS (GUS)

Glutaraldehyde user stations (GUS) are designed to minimise the volume of glutaraldehyde or other chemical disinfectants used. The design reduces the exposed surface area of the chemical used and efficiently neutralises any generated vapours. They are designed for particular endoscopes, particularly those that cannot be submersed. The GUS design also provides floor or wall mounted models (for use in less spacious units).

Findings

Information on the GUS system was received from Mr M Wilson Dalcross Pty. Ltd.¹⁷ as part of the Subcommittee's investigations into alternative technologies. The GUS system may be used with either glutaraldehyde or OPA and the company claims that:

- This technology minimises the volume of chemical disinfectant used, reducing the exposed surface area and efficiently neutralises fumes.
- As a wall-mounted model, less space is required for the disinfection process. This is particularly useful in situations where the installation of a LEV ('fume cabinet') with access to external air-conditioning duct systems is not possible.
- The GUS system is suitable for endoscopes that are unable to be fully submersed.
- Different models are available for the various types of endoscopes.
- Nozzles that prevent aerosol production are used for filling the GUS system's canisters.
- The GUS system meets the maximum concentration levels of WorkSafe Australia.

Recommendations

- Following a review of the GUS system, the Subcommittee is in agreement that this system may be useful in situations where infrequent endoscopic procedures are performed and space is limited.
- That the system may be used for non-submersible endoscopes and those endoscopes that cannot withstand pressure gradients due to their design properties, thereby all health services and hospitals will reduce occupational health and safety hazards for patients and staff.
- As with any chemical system, care must be taken to reduce the possibility of leakage and potential exposure to staff.

Recommendation 5

That all health services and hospitals should establish formal policies and procedures for the use of, and access to, glutaraldehyde and all other chemical disinfection agents and alternative technologies by February 2002.

6. EDUCATION

Findings

- Education of all staff (medical, nursing and others) is seen as an essential element to ensure that the knowledge and skills necessary to minimise infection and OHS risks for both patients and staff. Education should be competency-based using the following to form the basis of this education program:
 - Australian Nursing Council Incorporated (ANCI)¹⁸ competency statements
 - Gastroenterology Nurses College of Australia (GENCA)/Gastroenterology Society of Australia (GESA) Guidelines⁵
 - Australian College of Operating Room Nurses Limited (ACORN Ltd) Policy Statements and Guidelines⁶

Queensland Health is taking the lead in establishing a working group with representation from all states, professional and academic groups/associations to develop national guidelines and minimum competencies for staff routinely working in endoscopy fields. The Victorian Department of Human Services, Public Health Division is currently representing Victoria as a member of the working group.

Recommendations

That:

- The VACIC seek a suitably qualified professional to develop competency based education for Victorian health services and hospitals in conjunction with the national guidelines currently in development with VACIC representation and the *Guidelines for the Use of Glutaraldehyde in the Health Industry*.⁴
- Such competency based education shall incorporate the promotion of the hierarchy of controls approach to the use of hazardous substances, including the phasing out of open systems of glutaraldehyde for high-level disinfection where practicable.
- Random audits of this education and training program and its participants be conducted.

Recommendation 6

A competency based education and training program should be developed and undertaken by all health care workers working with glutaraldehyde¹ in particular but should also include all other chemical disinfection agents and systems in use.

7. PRODUCT IDENTIFICATION AND TRACEABILITY

Findings

Many health services and hospitals currently use a combination of AS 4187-98, GENCA and ACORN guidelines^{3, 5, 6} and the manufacturer's recommendations, in developing product identification and traceability policies and protocols. It is apparent that uniform minimum practice standards for the documentation of chemical disinfection/sterilisation processes are not in use in Victorian health services and hospitals.

The development of a generic tool that would meet the requirements of all health services and hospitals was not supported, however, the Sub-committee agrees that the development of, and inclusion of a sterilizing and endoscope disinfection recall and tracking component should be introduced. Two documentation systems should be in place, (1) endoscope history and (2) patient record documentation.

Recommendations

The Sub-committee has recommended minimum documentation criteria for the following areas in both manual and automated high-level disinfection/sterilant systems:

Manual systems

- Temperature of solution*
- Concentration levels*
- Each endoscope should be identifiable with a unique identification (ID) code (flexible endoscope serial number)
- Name of staff member responsible for cleaning
- Name of staff member responsible for submersion and disinfection
- Name of staff member responsible for removal from glutaraldehyde and rinsing
- Patient name and unit record (UR) number
- Leak testing should be performed routinely, and documented each time the endoscope is used together with the name of the staff member responsible.
- Documentation of the batch number of the high-level chemical disinfectant or sterilant being used

Automated systems

- Temperature of solution*
- Concentration levels*
- Each endoscope should be identifiable with a unique identification (ID) code (flexible endoscope serial number)
- Name of staff member responsible for cleaning
- Name of staff member responsible for submersion and disinfection
- Name of staff member responsible for removal from glutaraldehyde and checking process parameters
- Patient name and unit record (UR) number
- The printout from automated systems shall be kept as a permanent record of the cycle
- Leak testing should be performed routinely, and documented each time the endoscope is used together with the name of the staff member responsible.
- Documentation of the batch number of the high-level chemical disinfectant or sterilant being used

Note: applicable only if glutaraldehyde is in use

Recommendation 7

All health services and hospitals should establish a patient and equipment tracking system for all reusable medical equipment processed by chemical disinfection by July 2002.

8. GLOSSARY OF TERMS / TECHNOLOGIES

<i>Biofilm</i>	A layer of material on the surface of an instrument or device which contains biological materials and, in which micro-organisms may be embedded.
<i>Chemical disinfection</i>	The inactivation of non-spore-forming organisms by use of chemicals.
<i>Closed system – single and multiple use of glutaraldehyde</i>	<p>Closed systems are fully sealed and self-contained units that enable the operator to disinfect the endoscope by connecting the endoscope to its channel attachments without coming into contact with the glutaraldehyde disinfectant solution.</p> <p>Operator contact with the disinfectant solution occurs only when the bulk solution containers are replaced or the disinfectant solution is decanted into the closed system.</p> <p>Closed systems may have:</p> <ul style="list-style-type: none">• a detergent and disinfecting cycle, or• just a disinfecting cycle, and• may or may not recycle the glutaraldehyde disinfectant solution.
<i>Critical equipment</i>	<p>Those items that are introduced directly into the bloodstream or into normally sterile tissue sites within the body.</p> <p>For example: surgical instruments including laparoscopy instruments, cardiac catheters.</p>
<i>Disinfection</i>	The inactivation of non-spore-forming organisms using either heat and water (thermal) or by chemical means.
<i>Material Safety Data Sheet (MSDS)</i>	A document that describes the properties and uses of a substance, that is, identity, chemical and physical properties, health hazard information, precautions for use and safe handling information. (NOHSC)
<i>Non-critical equipment</i>	<p>Those items that either do not generally come into contact with the patient or only come into contact with intact skin.</p> <p>For example: blood pressure cuffs and tourniquets.</p>
<i>Open system</i>	A system whereby endoscopes are submerged or partly submerged in a chemical disinfectant solution that is not sealed or enclosed <i>and</i>

may or may not reuse the chemical disinfectant solution.

Semi-critical equipment

Those items that come into contact with intact and non-intact mucous membranes and do not generally penetrate body surfaces.

For example: non-invasive flexible fibre-optic endoscopes, endotracheal and other anaesthetic equipment.

Sterile

A state of being free from viable micro-organisms.

Sterilization

A validated process used to render a product free of all forms of viable micro-organisms.

Traceability system

A method of identification to enable tracing of a sterilized or disinfected item from sterilizer/disinfector cycle to patient use. It allows for identification of process problems and recall of items released for patient use.

Validation

A documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications.

REFERENCES

- 1 Victorian Government Department of Humans Services, Infection Control in Victorian Public Hospitals, May 1998, Victoria.
- 2 Evidenced Based Literature Review for Automated versus Manual Systems for Glutaraldehyde Use, 1999, Centre for Clinical Effectiveness Monash Medical Centre, Southern Health, Victoria.
- 3 Australian Standard AS 4187 – 1998 Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities, Sydney, New South Wales.
- 4 Department of Human Services Victoria Guidelines for the Use of Glutaraldehyde in the Health Industry (1996) Victoria.
- 5 Gastroenterological Society of Australia & Gastroenterological Nurses Society of Australia (GESA & GENSA): Infection Control in Endoscopy Guidelines 2000 Sydney, New South Wales.
- 6 Australian College of Operating Room Nurses Limited : Standards, Guidelines and Policy Statements 2000 Adelaide, South Australia.
- 7 Australian Standard AS 2243.8 – 1992 Safety in Laboratories Fume Cupboards Part 8, Sydney, New South Wales.
- 8 The National Occupational Health and Safety Commission (NOHSC) Canberra, Australian Capital Territory.
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- 10 Occupational Health and Safety (Hazardous Substances) Regulations 1999 Victoria.
- 11 Infection Control in the Health Care Setting – 1996, National Health and Medical Research Council (NHMRC) Canberra, Australian Capital Territory.
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- 13 Ayliffe GAJ, Babb JR, Taylor L, Hospital-acquired Infection Principles and prevention, 3rd Edition, Butterworth Heinemann, Oxford, United Kingdom.
- 14 Dr Denis Spellman : Endoscopic Automated Reprocessing Systems – Outbreaks and Pseudo-outbreaks; Victorian Infection Control Nurses Association (VICNA) Conference 1999 Melbourne Victoria.
- 15 Dr MM Peel, Ortho-phthalaldehyde (Cidex OPA) as High-level Disinfectant for Endoscopes, January 2001 Victoria.
- 16 Therapeutic Goods Administration Submission, Johnson & Johnson Medical (Australia) 2000 Sydney New South Wales.
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18 Australian Nursing Council Incorporated (ANCI) Competency Statements, Canberra, Australian Capital Territory.

APPENDIX TWO: SAFE AND EFFECTIVE PRACTICES FOR GLUTARALDEHYDE REQUIREMENTS

- Professional organizations/departments/legislation that have relevant Standards, Policies, Guidelines and legislation were consulted as part of this review. Each standards, policy, guidelines or piece of legislation was reviewed individually to see whether it met both occupational health and safety and infection control requirements and was graded accordingly. The Subcommittee concluded that no one document meets all of these requirements for the use of chemical disinfection agents.
- The table below lists these with an assessment of the occupational health and safety and infection control elements/requirements.

Standards, Policies, Guidelines and Legislation	Occupational Health and Safety Requirements		Infection Control Requirements	
	Safety	Education	Practices	Education
Guidelines for the Use of Glutaraldehyde in the Health Industry; Department of Human Services 1996	2	1	0	0
Occupational Health and Safety (Hazardous Substances) Regulations 1999 Worksafe / WorkCover Victoria	3	3	0	0
Standards, Policies and Guidelines; Australian College of Operating Room Nurses Limited (ACORN) 2000	1	0	1	1
Infection Control in Endoscopy Guidelines Gastroenterology Nurses Society (now College) of Australia [GEN{C}SA} 2000	1	1	2	1
Infection Control in the Health Care Setting National Health and Medical Research Council of Australia 1996	0	0	0	0
AS 4187 – 1998. Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities; Standards Australia 1998	1	1	1*	2

Legend:

- | | |
|--|--|
| 0 Does not meet guidelines/standards/legislation | 3 Meets guidelines/standards/legislation |
| 1 Partially meet guidelines/standards/legislation with major modifications | 4 Exceeds guidelines/standards/legislation |

2 Meets guidelines/standards/legislation with minor modifications

* Standard under review

APPENDIX 3: HAZARDOUS SUBSTANCES REQUIREMENTS

The following is a summary of the Occupational Health and Safety (Hazardous Substances) Regulations 1999 requirements.

What is a hazardous substance?

The National Occupational Health and Safety Commission has defined a hazardous substance as meeting the following criteria:

- Hazardous substances are chemicals that can harm your health.
- They may be solids, liquids or gases, pure substances or mixtures.
- For the purposes of the regulations, they are defined as those:
 - on *The List of Designated Hazardous Substances* or which
 - meet *The Approved Criteria for Classifying Hazardous Substances*

What are the key duties of employers?

The Occupational Health and Safety (Hazardous Substances) Regulations 1999 require employers (occupiers) to:

- obtain a copy of the current manufacturer's or importer's MSDS for all hazardous substances supplied to the workplace and ensure that workers have access to them
- ensure all containers of hazardous substances supplied are labelled with the manufacturer's or importer's label
- ensure decanted or transferred hazardous substances are labelled as required
- ensure hazardous substances in systems/paperwork are identified
- set up a hazardous substances register
- assess risks to health if hazardous substances are used and record the risk assessment result and justify the conclusion
- eliminate or reduce risks associated with the use of hazardous substances as far as practicable in accordance with a hierarchy of control measures
- carry out atmospheric monitoring and health surveillance in certain circumstances
- provide employees with information, instruction, training and supervision
- consult with health and safety representatives under certain circumstances
- undertake additional duties if scheduled carcinogens are used

Table 2 *Examples of Guidelines for the Use of Glutaraldehyde in the Health Industry* ⁴
content open to
Interpretation change title to reflect ambiguities & non adherence

Section	Content
7.	<u>Risk assessment</u> Many departments do not have training instruction in place
8.1, 9.5	<u>Risk control</u> Many positions in endoscopy units do not provide task/duty/activities rotation
9.3	<u>Engineering controls</u> Not all departments have glutaraldehyde positions close to sinks, some departments have glutaraldehyde in patient areas.
9.3.4	<u>Air recirculation systems with carbon filters</u> There are departments that use this system on a regular basis for all cases.
9.8.6	<u>Personal protective equipment</u> Respirators are not available in every department
9.9	<u>Training and education</u> Written policy not in place in many departments