

National Occupational Health and Safety Commission

SAFE USE OF ETHYLENE OXIDE IN STERILISATION/FUMIGATION PROCESSES

**National Code of Practice
for the Safe Use of Ethylene Oxide
in Sterilisation/Fumigation Processes
[NOHSC:2008(1992)]**

**Guidance Note
for the Safe Use of Ethylene Oxide in
Sterilisation/Fumigation Processes
[NOHSC:3016(1992)]**

APRIL 1992

**Australian Government Publishing Service
Canberra**

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ISBN 0 644 24525 5

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FOREWORD

The National Occupational Health and Safety Commission is a tripartite body established by the Commonwealth Government to develop, facilitate and implement a national occupational health and safety strategy.

This strategy includes standards development, the development of hazard-specific preventive strategies, research, training, information collection and dissemination, and the development of common approaches to occupational health and safety legislation.

The National Commission comprises representatives of the peak employee and employer bodies—the Australian Council of Trade Unions and the Confederation of Australian Industry—as well as the Commonwealth, State and Territory governments.

Consistent with the National Commission's philosophy of consultation, tripartite standing committees have been established to deal with issues relating to standards development, research and the mining industry. Expert groups may be established to provide advice to the standing committees on those issues with which the National Commission is concerned.

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PREFACE

In Australia ethylene oxide is widely used in sterilisation/fumigation processes. In hospitals and other facilities, ethylene oxide, because it is able to penetrate suitable wrapping material, has been usefully applied for sterilisation of equipment and supplies which are heat sensitive. Ethylene oxide is also used for pest control in some libraries, herbaria and museums.

Other chemicals have been tested for use in similar sterilisation/fumigation processes. Ethylene oxide has been shown to be superior in many situations.

In recent years, however, there has been concern about the health hazards of ethylene oxide. The recommended exposure standard for ethylene oxide has been reduced significantly during the past ten years. Concerns about its possible connection with adverse effects in reproduction and cancer were the main reasons for this re-evaluation.

In 1985 the National Health and Medical Research Council referred the issue of occupational exposure to ethylene oxide to the National Commission. Under the auspices of the National Commission's Standards Development Standing Committee, a State-based tripartite working party was convened in South Australia to develop a draft national code of practice for the safe use of ethylene oxide.

The *Draft National Code of Practice and Guidance Note for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* was released for public comment in February 1990. Comment was reviewed by an expert group in January 1991 and a revised guidance note and national code of practice were submitted to the National Commission in December 1991.

The National Commission, having considered the public comment on the draft national code of practice, now declares a final *National Code of Practice for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* [NOHSC:2008(1992)].

The National Commission recognises that situations can occur where, for occupational health and safety reasons, employees may be required to transfer from one work area to another. The issues of potential loss of income, income maintenance arrangements, job security and the application of legislation, such as workers' compensation Acts, are matters which need to be dealt with in the particular circumstances of the industry through normal industrial relations processes. They are not addressed in this document as they are considered to be outside its scope.

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IN STERILISATION/FUMIGATION
PROCESSES
[NOHSC:2008(1992)]**

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1. TITLE

1.1 This national code of practice may be cited as the *National Code of Practice for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* [NOHSC:2008(1992)].

2. PURPOSE

2.1 This national code of practice provides a basis for the reduction or elimination of risks arising out of the use and handling of ethylene oxide in sterilisation/fumigation processes in hospitals, museums, libraries and industry.

2.2 The National Commission's *National Model Regulations to Control Workplace Hazardous Substances* [NOHSC:1005(1991)]¹ and *National Code of Practice to Control Workplace Hazardous Substances* [NOHSC:2007(1991)]² provide a general framework for the control of all hazardous substances in the workplace. This *National Code of Practice for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* [NOHSC:2008(1992)] provides specific requirements for the use of ethylene oxide or its mixtures in the workplace. Consequently, this national code of practice should be used in conjunction with the two documents above and/or the regulations and codes of practice of relevant public authorities.

3. SCOPE AND APPLICATION

3.1 This national code of practice specifically addresses the hazards and risks of ethylene oxide sterilisation/fumigation and the procedures recommended for its safe handling and operation.

3.2 It is designed as an approved national code of practice consistent with the National Commission's *National Model Regulations to Control Workplace Hazardous Substances* [NOHSC:1005(1991)]¹ and *National Code of Practice to Control Workplace Hazardous Substances* [NOHSC:2007(1991)]².

3.3 This national code of practice does not deal with the manufacture of ethylene oxide or the use of ethylene oxide in the production of ethylene glycol, synthetic fibres, detergents or other substances.

3.4 The *National Model Regulations to Control Workplace Hazardous Substances* [NOHSC:1005(1991)]¹, the *National Code of Practice to Control Workplace Hazardous Substances* [NOHSC:2007(1991)]² and/or the regulations and codes of practice of relevant public authorities should be consulted for requirements regarding:

- (a) consultation;
- (b) provision of information — suppliers' duties;
- (c) provision of information — employers' duties;
- (d) induction and training;
- (e) assessment;
- (f) record keeping;
- (g) employees' duties; and
- (h) relevant public authorities and emergency services.

4. DEFINITIONS

4.1 In this national code of practice, unless the contrary appears:

`Biological monitoring' means the measurement and evaluation of hazardous substances or their metabolites in the body tissues, fluids or exhaled air of an exposed person.

`Employee' means an individual who works under a contract of employment, apprenticeship or traineeship.

`Employee representative' includes an employee member of a health and safety committee where established in the workplace, or a person elected to represent a group of employees on health and safety matters.

`Employer' means a corporation or an individual who employs persons under a contract of employment, apprenticeship or traineeship.

Note: The definition of employer includes the *self-employed* which means a person who works for gain, other than under a contract of employment, apprenticeship or traineeship, whether or not that person employs others.

`Exposure standard' means an airborne concentration of a particular substance in the worker's breathing zone, exposure to which, according to current knowledge, should not cause adverse health effects nor cause undue discomfort to nearly all workers. The exposure standard can be of three forms; peak, short term exposure limit (STEL) or time-weighted average (TWA).

`Health surveillance' means the monitoring of individuals for the purpose of identifying changes in health status due to occupational exposure to a hazardous substance. It includes biological monitoring (as defined) but not monitoring as defined elsewhere in this section.

`Material Safety Data Sheet (MSDS)' means a Material Safety Data Sheet which is in accordance with the National Occupational Health and Safety Commission's *Guidance Note for Completion of a Material Safety Data Sheet* [NOHSC:3001(1991)]³ (as amended from time to time).

`May' means that a requirement is optional.

`Monitoring' means to survey regularly all measures which are used to control hazardous substances in the workplace. This includes the monitoring of atmospheric contaminants, but does not include biological monitoring which is an element of health surveillance.

`Placard' means a placard which is in accordance with the National Occupational Health and Safety Commission's *Guidance Note for Placarding Stores for Dangerous Goods and Specified Hazardous Substances* [NOHSC:3009(1990)]⁴ (as amended from time to time).

`Practicable' means `practicable' in Victoria, Queensland, Western Australia and the Northern Territory, `reasonably practicable' in New South Wales, South Australia, the Australian Capital Territory and Commonwealth jurisdiction and `a reasonable precaution' in Tasmania.

`Regulated area' means an area containing ethylene oxide sterilisers, aerators, cylinders or piecework.

`Relevant public authorities' means those public authorities whose functional jurisdiction and responsibilities extend to occupational health and safety. It is expected that these will be defined on a State by State/Territory by Territory basis. A list of those authorities which might be expected to meet this definition is included at Appendix 4 of this national code of practice.

`Risk' means the likelihood that a substance will cause harm in the circumstance of its use.

`Shall' means that a requirement is mandatory.

`Should' means a recommendation.

5. RESPONSIBILITIES

EMPLOYERS

5.1 The prime responsibility for ensuring that ethylene oxide is used, handled, transported and disposed of safely and without risk to health rests with the employer.

5.2 It is the responsibility of management, in consultation with employees and/or health and safety professionals and/or relevant employee representatives, to develop and implement policy and programs which provide for:

- (a) close liaison between employees/employee representatives and supervisors/employers;
- (b) adequate training of all employees (including emergency/evacuation procedures);
- (c) adequate supervisory training;
- (d) distribution of appropriate information;
- (e) meeting statutory requirements;
- (f) introduction, maintenance and upgrading of standards;
- (g) updating of procedures; and
- (h) provision and maintenance of personal protective equipment.

EMPLOYEES

5.3 It is the responsibility of employees to:

- (a) comply with statutory requirements, regulations, instructions and procedures;
- (b) use the approved safety devices provided; and
- (c) cooperate with the employer in maintaining a healthy and safe workplace.

5.4 Employees should not cause or contribute to accidents or hazards which may endanger themselves or others. Employees should receive appropriate training in control measures and personal protective equipment and have the capacity (power) to carry out their responsibilities.

6. CONTROL

6.1 Information on employer responsibilities for the control of ethylene oxide is provided in a general way in the National Commission's *National Model Regulations to Control Workplace Hazardous Substances* [NOHSC: 1005(1991)]¹ and/or the regulations of relevant public authorities. Guidance on the forms of control is provided in the National Commission's *National Code of Practice to Control Workplace Hazardous Substances* [NOHSC: 2007(1991)]² and/or the codes of practice of relevant public authorities. Additionally, the following requirements are specific to the control of ethylene oxide or its mixtures.

ROLE OF EXPOSURE STANDARD

6.2 Employers shall ensure that exposure to ethylene oxide or its mixtures is kept as low as practicable and complies with the relevant exposure standard and general excursion limits for the exposure standard.

6.3 Ethylene oxide has been assigned a Category 2 carcinogen status by the National Commission, meaning it is a probable human carcinogen. It should be treated as carcinogenic to humans and should be used and handled with great caution. Exposure to ethylene oxide should be kept as low as practicable and under no circumstances shall it exceed the national exposure standard of 1 ppm TWA. Readers are referred to the National Commission's *Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment* [NOHSC:3008(1991)]⁵.

6.4 Compliance with this exposure standard should not preclude further efforts to reduce exposure. Exposure standards do not represent 'no effect' levels at which every worker can be guaranteed protection. Therefore, it is a good general policy to keep the exposure to any substance as low as practicable irrespective of whether present information indicates it is hazardous or not at a particular concentration, partly in case future experience shows that the substance represents a hazard which could have been prevented or limited by the application of simple control measures.

6.5 The absence of a relevant exposure standard for a *mixture containing ethylene oxide* shall not be considered an indication that exposure need not be controlled. Where there is no exposure standard, exposure shall be controlled to the lowest practicable level and this shall be assessed during the assessment process.

CONTROL HIERARCHY

Centralisation of Facilities

6.6 In addition to individual workplace controls, health authorities should seek to minimise the number of workers potentially exposed to ethylene oxide by centralising those

processes involving ethylene oxide. This would involve hospitals sending items to a central facility for sterilisation.

Elimination

6.7 Work activities involving the use of ethylene oxide that are not essential shall be eliminated wherever practicable.

Substitution

6.8 Substitution includes substituting a less hazardous substance, the same substance in a less hazardous form or the same substance in a less hazardous process. The possibility should be examined of substituting other methods of sterilisation, for example, steam, hydrogen peroxide or gamma radiation, and substitution through the use of disposable materials.

Isolation

6.9 Sterilising facilities should be limited in extent and centralised as much as possible. For example, in health care systems, health authorities should seek to minimise the number of workers potentially exposed to ethylene oxide by centralising the number of processes involving ethylene oxide, where practicable and in addition to individual workplace controls.

6.10 There should be physical isolation of the area in which ethylene oxide is used from other areas, for example, it should be located in a separate room. If this is not possible, the steriliser (and aerator) should be recessed in an equipment room so that the doors and the control panels are flush with the wall, and all of the mechanical components are behind the wall in the plant room. Often the ethylene oxide supply cylinders are also located in the plant room. When used in conjunction with local exhaust ventilation, this technique separates the workers from several potentially high ethylene oxide emission sources: the vacuum pump discharge line connection with the sewer drain, the overpressure relief valve and the ethylene oxide supply cylinders.

6.11 The steriliser should be located in an area which should have a minimum of 10 air changes per hour, and should also be under negative pressure with respect to adjoining rooms in order to prevent contamination of other areas. In addition, the plant room should also be under negative pressure with respect to the steriliser area.

6.12 The steriliser should not be located in areas where other hazardous conditions are present, for example, flammable liquids or gases and sources of ignition.

6.13 If a separate aeration cabinet or room is used, it shall be located as close as practicable to the sterilisation chamber and exhausted outside the building through dedicated local exhaust ventilation. The discharge should not be located near windows or air intakes.

Engineering Controls

Ventilation

6.14 In order to avoid high ethylene oxide concentrations, it is necessary to install properly designed local exhaust ventilation, for example, exhaust vents, canopy or hood-type vents, in locations such as:

- (a) above the steriliser door in order to capture escaping ethylene oxide vapours when the door is opened, and in case the chamber develops leaks around the door gaskets;
- (b) near pressure relief valves;
- (c) in the plant room near the cylinders attached to the steriliser, to remove ethylene oxide resulting from improper connection of hoses, faulty valves, as well as removing vapours present at the time cylinders are exchanged; and
- (d) near the exhaust vent of the aerator.

Exhaust ventilation equipment applied to processes should be of adequate design, material and airflow to remove and dispose of the ethylene oxide effectively, totally and safely.

Exhaust Gas Control

6.15 Exhaust gases from the steriliser should be scrubbed by passing them through a water spray. For large chambers, it is advisable to include two water spray operations. Alternatives to water sprays should be considered, for example, catalytic converters or incinerators.

6.16 Disposal of the exhausted mixture of ethylene oxide and water should occur only when this action is covered by a suitable trade waste agreement with the local authority. In these circumstances, very high ethylene oxide vapour concentrations are likely to occur at the open junction between the exhaust line and floor drain. A ventilated enclosure should be placed around the air gap between the sterilizer evacuation line and the drain. The enclosure should be baffled and ventilated to the exterior. The floor drain junction should be sealed, as should all other connections of the steriliser evacuation line and the drain line (except the openings into the ventilated enclosure). In addition, dedicated local exhaust ventilation to the outside should be provided. The vent should be sited at a suitable height well away from personnel likely to be in the vicinity.

6.17 Discharge points for all exhaust vents should be outside the building, via dedicated local exhaust ventilation, away from windows and personnel likely to be in the vicinity and no closer than a distance prescribed in environmental protection statutes or local government requirements for ventilation air intakes. Signposting for ethylene oxide exhaust vents should be placed near the vents on the outside or on the roof of a building as an indication for maintenance personnel. All venting duct work should be made of material impervious to ethylene oxide vapour, all joints within the duct work should be sealed.

Where flammable or explosive ethylene oxide mixtures are used, all fans and blowers should be explosion proof.

Adoption of Safe Work Practices

Design and Installation

6.18 A combined sterilisation/aeration facility should be used wherever possible, or preset minimum post-sterilisation times (for unit dose canister systems) to overcome the risk of exposure during transfer.

6.19 The design and installation of the sterilisation chamber and aeration cabinet shall comply with relevant legislation. It should also comply with Australian Standards AS 1210 *Unfired Pressure Vessels (known as the SA Unfired Pressure Vessels Code)*⁶, AS 1714 *Sterilizers — 12/88 Ethylene Oxide — Hospital Use*⁷ and AS 1862 *Aeration Cabinets (for Use with Ethylene Oxide Sterilizers)*⁸. Unit dose 100 per cent ethylene oxide canister systems are not yet included in these standards but should comply with the operator and environmental aspects of the standards.

For Ethylene Oxide Systems Supplied from Cylinders

6.20 All hoses or piecework shall be designed for the maximum operating pressure and be provided with:

- (a) safety relief valves on all liquid lines to prevent rupture; and
- (b) means of depressurising them.

All such safety valves and vents should be piped to the water scrubber or to a dedicated exhaust system.

6.21 The pressure regulator on the line should be set only marginally higher than the cabinet working pressure.

6.22 Valve systems should be fitted to prevent the flow back of gas during cylinder change over.

For Unit Dose Canister Systems

6.23 Only those sterilisers which require the canister to be inside the chamber with the door closed before the canister can be punctured should be used.

6.24 These sterilisers should incorporate measures to protect against the hazard of explosion. They should be either intrinsically safe, flame proof or fitted with an explosion disc. Any explosion disc should pose no risk to anyone operating or maintaining the machine.

- 6.25** The empty canister left when the sterilisation cycle has been completed should be aerated along with the load before non-incineration disposal.
- 6.26** Sterilisers using canisters should be located in separate, ventilated rooms or in laboratory hoods appropriate for controlling ethylene oxide exposure.
- 6.27** Sterilisation in these units is conducted at less than atmospheric pressure. The system should automatically sense pressure rises, for example, leakage of room air into the chamber, and act to reduce pressure in the sterilisation chamber. In the event that the pressure continues to rise, the system should abort its cycle, evacuate and purge the chamber with an alarm notification.
- 6.28** If insufficient gas is released from the canister when automatically punctured inside the chamber, the cycle should abort and an alarm should sound.
- 6.29** Failure of the compressed air supply may compromise the evacuation and aeration stages of the system and the system should abort and sound alarms if such a failure occurs.
- 6.30** Occlusion of bacterial filters used for air purges should cause the cycle to abort and an alarm to sound.
- 6.31** Any abort stage that occurs while there is, or the system controller expects there to be, ethylene oxide within the chamber shall cause the steriliser door to lock and an alarm to sound. The door lock shall only be accessed and by-passed by qualified service persons.
- 6.32** The discharge line of the steriliser is pressurised from the Venturi pump to the discharge point. Ethylene oxide could be forced out if there are any defects in the line. Periodic checks (weekly or prior to usage if used infrequently) should be made to ensure that there are no leaks in the discharge line. Alternatively, an extraction fan could be fitted in the duct line but outside the building, such that the line is maintained under negative pressure making all leaks inward.
- 6.33** Ethylene oxide in exhaust gases from a steriliser and aerator should be removed, by passing it through an appropriate emission control device before discharge to the open air. A water scrubber or catalytic converter could be used.
- 6.34** An easily read, clear, concise, step-by-step, written procedure for the addition of new cartridges and the removal of spent cartridges should be displayed on the steriliser door.

Regulated Work Areas

- 6.35** Areas containing ethylene oxide sterilisers, aerators, including aeration rooms, cylinders or piecework should be accessible only to authorised personnel and escorted visitors. A register of the names of authorised personnel should be maintained and displayed at the entrance.

- 6.36** The regulated area should not be used for:
- (a) the storage, preparation or consumption of food or drink;
 - (b) the storage of food or drink containers; or
 - (c) the storage or application of cosmetics.

6.37 Personal protective equipment should be stored immediately adjacent to the regulated area.

Storage of Cylinders

6.38 All cylinders, including those that are in use or are full or empty, should be isolated and chained in a secure, well-ventilated room or enclosure or located outside the building, protected from sunlight and excessive heat, and stored away from combustibles or possible ignition sources. The storage area should comply with Australian Standard AS 2030 *The Approval, Filling, Inspection, Testing and Maintenance of Cylinders for the Storage and Transport of Compressed Gases (known as the SA Gas Cylinders Code)*⁹.

6.39 Areas where cylinders are stored should be placarded in accordance with the National Commission's *Guidance Note for Placarding Stores for Dangerous Goods and Specified Hazardous Substances* [NOHSC:3009(1990)]⁴. Two examples of recommended placards are given in Figures 1 and 2 below.

Figure 1

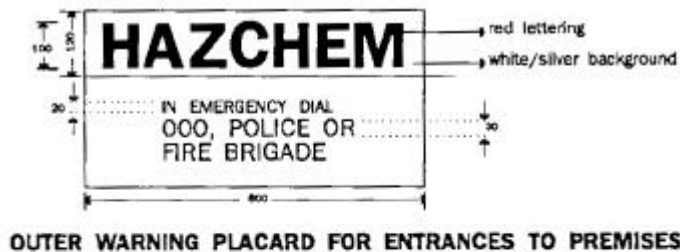
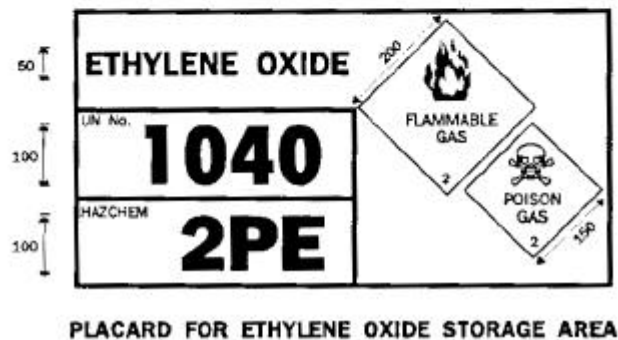


Figure 2



6.40 An easily read, clear, concise, step-by-step, written procedure for changing gas cylinders should be displayed at eye level above the cylinders in the cylinder storage area.

6.41 Gas cylinders in use should be installed on a weighing device to safeguard against slow leakage.

6.42 No acetylide forming metals, such as copper or copper alloys, should be allowed to be in contact with ethylene oxide because ethylene oxide may contain trace amounts of acetylene as an impurity. Such metal acetylides are explosive.

6.43 The gastight cylinder valve outlet cap should always be replaced and securely 'nipped up' to form a gastight seal. Any valve protection cap should be replaced whenever cylinders are not in use or are being transported.

6.44 All ignition sources, including static electricity, shall be controlled when 100 per cent ethylene oxide or any 'bottled' gas is in use.

Storage of Canisters

6.45 All bulk supplies of unit dose 100 per cent ethylene oxide canisters should be isolated and locked in a separate, secure, well-ventilated room or cupboard outside the steriliser area, protected from sunlight and excessive heat, and stored away from combustibles or possible ignition sources. Under no circumstances should full or spent canisters be disposed of by incineration.

6.46 No more than 10 full canisters shall be kept in the steriliser room inside a locked and ventilated cabinet or wire mesh enclosure.

Warning Signs

6.47 A sign should be posted at the entrance to each regulated area warning of the dangers within the area. The warning sign should contain information on:

- (a) danger and restricted entry;
- (b) the hazards of ethylene oxide; and
- (c) who to contact in an emergency.

Where specific protective clothing and respirators are required, this should be included on warning signs. No statement should appear on or near the warning sign which detracts from the effect of the warning.

6.48 A suggested sign is shown at Appendix 1. The lettering on signs should conform with Australian Standard AS 1319 *Safety Signs for the Occupational Environment*¹⁰.

Steriliser Cycle

6.49 The following should be observed in relation to sterilisers:

- (a) Records should be kept for both automatic and manual sterilisation. Systems for recording both temperature and pressure above and below atmospheric pressure should be provided to enable the operator to check that the cycle has proceeded satisfactorily.
- (b) The design of the door arrangement shall ensure that it cannot be opened under pressure, as required under Australian Standard AS 1714 *Sterilizers — 12/88 Ethylene Oxide — Hospital Use*⁷.

Exhaust Procedure

6.50 The following shall be observed in relation to exhaust procedures:

- (a) An adequate number of air purge cycles should be provided to reduce ethylene oxide vapour build-up in the closed chamber to an acceptable level and thereby reduce staff exposure to ethylene oxide vapour when the load is removed. The number of air purge cycles should be determined for the particular chamber and systems in use. Sterilisation chambers should be operated for a minimum of 10 air purge cycles or 60 minutes or in accordance with the manufacturer's recommendations before the load is removed. For fumigation chambers with combined aeration and ethylene oxide monitoring facilities, the ethylene oxide level should not be more than 0.5 ppm at the time of removal. ***It should be noted that this procedure only removes the bulk residual gas from within the load and chamber and does not remove gas residues from within the sterilised articles.***
- (b) An alarm should be installed to alert staff when the air purge cycles are complete.

6.51 To alert workers that a purge cycle is in progress, a warning light should be placed at each entrance to the room in which the steriliser/aerator is located, and a flashing or revolving light should be placed inside the room.

Placement of Load in, and Removal from, Steriliser

6.52 The following should be observed in relation to the placement of loads in, and removal from, sterilisers:

- (a) No damp or wet materials shall be sterilised.
- (b) Articles to be sterilised should be in containers or bags which have minimal resistance to gas transfer, for example, paper, linen and laminated bags in accordance with Australian Standard AS 1079 *Packaging of Items (Sterile) for Patient Care*¹¹. This allows shorter cycles and more effective gas exhausting at the completion of the sterilisation cycle.
- (c) The most likely times of employee exposure to high concentrations of ethylene oxide are during placement and removal of the load, especially for sterilisers without a built-in air wash cycle. The load shall be removed from the steriliser immediately at the end of the cycle and immediately transferred into the aerator. If transfer is not completed within a maximum of two minutes, a second air wash cycle is required. If this is not

done, the slow release of ethylene oxide from the sterilised materials will allow concentration levels to build up within the chamber again. After about an hour the levels can reach the same value as if no purge cycle had occurred. If it is not possible to remove the load immediately on completion of the cycle, then another air wash cycle should be activated either manually or automatically before removal of the load. See Paragraph 7 of Appendix C of Australian Standard AS 1714 *Sterilizers — 12/88 Ethylene Oxide — Hospital Use*⁷.

- (d) During the transfer, physical contact with the sterilised articles should be avoided. The operator should maintain the greatest practicable distance from the load (preferably an arm's length distance unless this poses an ergonomic risk). If handling is necessary, appropriate gloves shall be worn because diffusion of ethylene oxide from these articles into the air takes place immediately.
- (e) Materials should be transferred using only the metal baskets or carts provided.
- (f) Trolleys containing freshly sterilised articles should only be pulled and not pushed to allow air movement to take away ethylene oxide from the breathing zone.
- (g) Articles shall be placed into an aerator immediately after removal from a steriliser.

Aeration

6.53 The following should be observed in relation to aeration:

- (a) Increasing the number of evacuation air purge cycles is no substitute for aeration since the release of ethylene oxide from paper, cloth, plastics and similar materials takes many hours. It is important to have well-defined policies about the period for which sterilised articles shall be held in the aeration chamber or aeration rooms before release for distribution or handling.

In a properly ventilated, heated aeration cabinet (45-60°C), at least 12 hours aeration is recommended, including a positive biological test. ***Note that some items may not tolerate temperatures of 45°C and should be sterilised and aerated at lower temperatures, usually 37.8°C. Longer periods of sterilisation and aeration may be necessary if lower temperatures are used.*** Expert advice should be sought on this matter. The aeration cabinet should be fitted with its own operating cycle timer. It should be recognised that articles release ethylene oxide at different rates due to chemical make up, structure and packaging. Therefore articles may have different aeration times. Testing should be carried out to determine appropriate aeration periods, see Australian Standard AS 1862 *Aeration Cabinets (for Use with Ethylene Oxide)*⁸.

- (b) Aeration on open-shelf storage at room temperature is not acceptable in hospitals. In industry, dedicated ventilated (aeration) rooms are used for this purpose.
- (c) In a museum or library, there may be uncertainty about the number of air purges required as fumigated articles vary considerably in the rate at which they release ethylene oxide. The aeration cycle should therefore be continued until a satisfactory concentration of ethylene oxide inside the chamber is measured with an autosampler. The measurement should be taken after the cycle has ceased. If a satisfactory measurement is obtained, perform a further air purge cycle and remove the articles immediately the cycle ceases.

7. PERSONAL PROTECTIVE EQUIPMENT

7.1 In certain circumstances, personal protection of the individual may be required as a supplement to other preventive action. It should not be regarded as a substitute for control measures and must only be used in conjunction with measures such as process isolation, engineering control and safe work practices.

7.2 Employers should ensure that personal protective equipment is:

- (a) properly selected for the individual and task;
- (b) readily available;
- (c) clean and functional;
- (d) used; and
- (e) maintained by appropriately trained staff.

7.3 In respect of personal protective equipment, employers should ensure that employees are trained in its:

- (a) appropriate selection and fitting;
- (b) maintenance and storage; and
- (c) use.

SUITABLE PERSONAL PROTECTIVE EQUIPMENT

7.4 Suitable personal protective equipment is to be selected and used in compliance with relevant Australian Standards, in particular:

- (a) respiratory protection shall comply with Australian Standard AS 1716 *Respiratory Protective Devices*¹², and be chosen and used in accordance with Australian Standard AS 1715 *Selection, Use and Maintenance of Respiratory Protective Devices*¹³;
- (b) eye protection shall comply with Australian Standard AS 1337 *Eye Protectors for Industrial Applications*¹⁴, and selection and use of such devices with Australian Standard AS 1336 *Recommended Practices for Eye Protection in the Industrial Environment*¹⁵;
- (c) head protection shall comply with Australian Standard AS 1801 *Industrial Safety Helmets*¹⁶, and be used in accordance with Australian Standard AS 1800 *The Selection, Care and Use of Industrial Safety Helmets*¹⁷;
- (d) hand protection shall comply with Australian Standard AS 2161 *Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves)*¹⁸, where appropriate;
- (e) foot protection shall comply with Australian Standard AS 2210 *Safety Footwear*¹⁹; and
- (f) clothing for protection against chemicals shall comply with Australian Standard AS 3765 *Clothing for Protection Against Hazardous Chemicals*²⁰.

In some emergency situations, more specialised equipment may be required.

PROTECTION AGAINST ETHYLENE OXIDE

7.5 The following points should be considered in relation to ethylene oxide:

- (a) Splashes into the eye with liquid ethylene oxide may result in severe irritation and eye damage. Appropriate fully-enclosed chemical goggles or a face shield should be worn whenever there is danger of ethylene oxide coming into contact with the eyes, for example, in operations involving transportation and exchange of cylinders. Where there is an accidental spillage of ethylene oxide, full-face respirators are required to be used. In addition, if it is not practicable for cylinders to be stored in a dedicated exhausted enclosure, then full-face respirators need to be used when changing cylinders. They also need to be used when entering the plant room during the purge cycle.
- (b) Intermittent skin contact with liquid ethylene oxide may occur during exchange of cylinders or any maintenance work. Such skin contact may produce dermatitis at the site of contact. Great care shall be taken in choosing suitable protective clothing due to the extreme penetrating ability of ethylene oxide, and the consequent ineffectiveness of many types of conventional clothing materials designed to prevent skin contact. Suitable gloves made of butyl rubber are recommended. Refer to Australian Standard AS 2161 *Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves)*¹⁸ for further advice. Specific points include:
 - (i) gloves which become significantly contaminated with liquid ethylene oxide should be discarded,
 - (ii) clothing which becomes contaminated with liquid ethylene oxide should be removed immediately, fully aired and dried before laundering, and shoes and boots should be discarded,
 - (iii) splashes on the skin should be immediately washed with copious quantities of water for at least 15 minutes,
 - (iv) conscientious adherence to good personal hygiene practices and the wearing of appropriate gloves can eliminate most cases of skin contact with ethylene oxide, and
 - (v) following any work involving potential exposure to ethylene oxide, the hands should be thoroughly washed before eating, drinking, using toilet facilities or smoking.

RESPIRATORY PROTECTIVE EQUIPMENT

7.6 Respiratory protective equipment shall be used in accordance with the procedures and specifications outlined in Australian Standards AS 1716 *Respiratory Protective Devices*¹² and AS 1715 *Selection, Use and Maintenance of Respiratory Protective Devices*¹³.

- (a) Full-face, air-purifying-type respirators (filter types A2 or A3 — Organic Vapour — are suitable for concentrations up to 100 ppm. ***Note that the suitability of the filter for use with ethylene oxide should be confirmed***) are recommended for use with ethylene oxide, for example, when entering the plant room during the purge cycle or when entering an industrial aeration room. Filters should be discarded when the colour

of the indicator chemical changes to the end of life reference colour. A record of exposure times should be made. Filters should be sealed, in good condition and not more than six months old from when opened and re-sealed. Time recording is important due to the lack of odour warning properties for ethylene oxide. If there is doubt as to whether the filter is still viable, it should be discarded and replaced.

- (b) A positive-pressure or continuous-flow, air-supplied respirator with a full face-piece and suitable non-permeable head covering, conforming to Australian Standard AS 1716 *Respiratory Protective Devices*¹², shall be used for any accidental spillages during cylinder changeover, major leaks or maintenance work where prolonged exposure is likely.
- (c) In case of an emergency situation, for example, resulting from explosion or fire, a positive-pressure self-contained breathing apparatus should be readily accessible for rescue work.
- (d) Workers should be trained in the proper use of respirators and their limitations.
- (e) All respirators and replacement parts should be readily accessible and stored in a convenient, clean, sanitary, non-permeable location.

8. EMERGENCY PROCEDURES

8.1 In spite of the implementation of all practicable control measures, a leak, spill or uncontrolled release of ethylene oxide or mixtures containing ethylene oxide could still occur. Established emergency procedures, procedures for safe disposal of ethylene oxide or a mixture containing ethylene oxide and sufficient suitable personal protective equipment should be used, where appropriate, to enable the source of the release to be safely identified and repairs to be made. All persons not concerned with the emergency action should be excluded from the area of contamination.

8.2 An action plan should be developed to consider normal operating procedures, the personal protective equipment program, training, emergencies and other relevant issues.

ACTION PLAN CHECKLIST

8.3 It is recommended that the following topics be addressed by the action plan and the findings documented:

- (a) the location of the ethylene oxide;
- (b) possible sources of leaks, spills and contamination of ethylene oxide;
- (c) disposal routes;
- (d) a fire plan;
- (e) posting of ethylene oxide emergency instructions and procedures;
- (f) the location of eyewashes and showers for emergencies;
- (g) first aid and medical treatment;
- (h) a list of potentially useful resources;
- (i) protective clothing and respiratory protective equipment;
- (j) spill alarms and portable detectors;
- (k) procedures and responsibilities during actual emergencies;
- (l) training and drills;
- (m) a record of all incident reports;
- (n) an on-going personnel medical assessment table; and
- (o) complete documentation of all extreme exposures, that is, greater than 5 ppm.

9. FIRST AID

9.1 Ethylene oxide is listed in the National Health and Medical Research Council's Standard for the Uniform Scheduling of Drugs and Poisons²¹ as a Schedule 7 (Dangerous Poison) substance. This document is incorporated into State/Territory poisons Acts and contains first aid instructions for ethylene oxide.

EXCESSIVE EXPOSURE

9.2 If excessive exposure to ethylene oxide gas occurs, the effected employee and all other employees should immediately move, or be moved, away from the area of gas contamination and into fresh air. A physician should be consulted as soon as possible, regardless of the person's symptoms. While awaiting medical aid, the person should be kept quiet and warm. Symptoms may be delayed for up to six hours.

9.3 Excessive exposure to ethylene oxide by inhalation or skin contact must be reported to the supervisor as an incident. All complaints of *suspected* exposure to ethylene oxide also must be reported to the supervisor. All reports must be investigated immediately to determine the cause of the incident, and steps must be taken to prevent a recurrence.

SPLASHES OF LIQUID

9.4 If, for some reason, liquid ethylene oxide or its water solution is splashed onto the employee's face, the face and eyes should be immediately flushed with water for 15 minutes. In addition, for eye splashes, a physician must be seen urgently.

9.5 If ethylene oxide liquid or its solution is spilled on other parts of the body, all contaminated clothing should be removed immediately, and shoes and boots should be discarded. Quickly flush the skin with water for at least 15 minutes, and follow by washing with soap and water. Clothing shall be aired thoroughly and laundered before re-use.

SPECIFIC FIRST AID INSTRUCTIONS

9.6 The first aid instructions for ethylene oxide in the Standard for the Uniform Scheduling of Drugs and Poisons are:

| | |
|-------------|--|
| Poisoning: | If poisoning occurs, contact a doctor or Poisons Information Centre. |
| Inhalation: | Remove from contaminated area. Apply artificial respiration if not breathing. |
| Eye: | If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor. |

10. MAINTENANCE, EXAMINATION AND TESTING OF CONTROL MEASURES

10.1 The employer shall ensure that all control measures perform as originally intended and continue to prevent or adequately control exposure of employees to ethylene oxide or its mixtures.

10.2 A regular, ongoing maintenance program shall be implemented in order to detect and rectify leaks and faulty parts at an early stage, to avoid unnecessary exposure to, and excessive loss of, ethylene oxide. The maintenance program should be developed in consultation with employees and employee representatives.

10.3 Maintenance and sterilising department employees shall be trained and competent in the specific technical operation of the sterilisation equipment and procedures.

10.4 The maintenance program should contain the following:

- (a) A daily test/inspection of the following is required to maintain a safe work environment:
- (i) gas cylinder connections, where applicable,
 - (ii) the steriliser door gasket, for any signs of damage or build-up of foreign material,
 - (iii) the steriliser door gasket during the steriliser stage of a cycle, using an ethylene oxide gas monitor, and
 - (iv) the aeration cabinet door gasket during a cycle.

Any deficiencies should be reported and recorded.

The steriliser chamber, door and gasket should be cleaned daily. The inside door and chamber of the aerator should be wiped out daily with warm water and detergent.

- (b) For unit dose systems, the vent ducting is under positive pressure while ethylene oxide is removed from the machine, and requires periodic leak testing. Testing could be achieved by installing valves in appropriate places in the ducting so that it can be pressurised and the decay in pressure noted. Testing should occur on a weekly basis or as determined during the assessment process.

- (c) A weekly inspection program should:
- (i) ensure that air exchanges are adequate to cope with minor leakages which may occur from time to time,
 - (ii) allow the sites of leaks to be identified, and
 - (iii) allow any maintenance procedures to be undertaken.

Leak checks should include door gaskets and, where applicable, cylinders, the vacuum piping, gas lines in the storage area, hoses, valves, monitors, vents, etc. The system tested should be under full pressure and the test carried out with a suitable direct reading instrument. Leak testing on evacuated systems also should be performed. High pressure systems should be regularly pressure tested for leaks by doing a 'Drop Test' using nitrogen or some other inert gas.

Records of gas usage are not adequate as the sole indication of leaks as they do not reveal slow leaks from gaskets and gas lines.

- (d) Dust accumulating in the fine mesh filters around the control box in the aerator should be cleaned away monthly.
- (e) At periodic intervals (of at least once every 12 months), or as recommended by the manufacturer or as required by the relevant public authority, the following should take place:
 - (i) clean out any dust or grease from the top of the aerator,
 - (ii) ensure that the motor ventilation holes are free of dust,
 - (iii) check that plugs and thermocouple wires are secure, and
 - (iv) remove and replace the absolute filter on the floor inside the chamber.

Other recommendations are contained in Australian Standard AS 1714 *Sterilizers — 12/88 Ethylene Oxide — Hospital Use*⁷.

- (f) Piping connections shall be checked for leaks immediately after changing cylinders.
- (g) Up to date written reports of maintenance and inspections should be maintained including:
 - (i) the dates on which inspection and/or maintenance procedures were initiated and completed,
 - (ii) the components that were inspected and the extent of any maintenance procedures, including a list of replacement parts,
 - (iii) the dates on which leak tests took place, the points where leaks were detected and the dates when fixed,
 - (iv) the date, time, cylinder weight and installer of cylinders replaced, and
 - (v) the batch numbers of gas cylinders or canisters.

A copy of the maintenance report should be made available to the person in charge of the ethylene oxide sterilisation operation and the employee representative(s) for the designated area(s), and filed on site.

11. ATMOSPHERIC MONITORING

11.1 An atmospheric monitoring program for ethylene oxide is necessary in order to determine whether the control measures, precautions and work procedures as recommended in this national code of practice and the *Guidance Note for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* [NOHSC:3016(1992)] are being applied satisfactorily, and to ensure that the national exposure standard is not exceeded. The extent of such a program shall be determined in the assessment process. Employers are required to establish an appropriate atmospheric monitoring program in consultation with employees and employee representatives. This program should include static, personal and leak detection monitoring as required. Atmospheric monitoring is not an alternative to preventive or control measures: rather it is intended to be used as a regular performance indicator of the existing control measures and to ensure that employees are not exposed to a harmful work environment. Atmospheric monitoring will indicate the need for prompt remedial action if concentrations of ethylene oxide are assessed and found to exceed acceptable levels.

MONITORING STRATEGY

11.2 Workplace monitoring with sampling equipment, analytical resources and personnel, although costly, is essential and may be achieved with an appropriate sampling strategy as outlined below or as determined in the assessment process. Note that when setting the level of the alarm, one must consider the purpose of the alarm, whether there are people commonly in the area, the sensitivity of the instrument, and whether the instrument is specific to ethylene oxide or may respond to other substances.

11.3 To protect the health of employees, exposure measurement should be made from unbiased and representative samples of actual employee exposure. A proper sampling strategy usually encompasses selection of subjects for personal monitoring as well as selecting sampling times. It is important to ensure that an evaluation is made of maximum likely exposure. It should also address those issues such as sampling and analysis errors, statistical analysis of exposure data and the determination of the need for regular, ongoing exposure measurement. The details of a routine sampling strategy are very much dependent on the actual work situations.

11.4 Monitoring strategy is a complex subject and a complete discussion of the theory and characteristics is beyond the scope of this document. However, practical guidance is available in the United Kingdom Health and Safety Executive's guidance note *Monitoring Strategies for Toxic Substances*²² and the United States National Institute of Occupational Safety and Health's *Occupational Exposure Sampling Strategy Manual*²³.

Personal Sampling

11.5 A sampling procedure whereby air is sampled within the employee's breathing zone should be used to evaluate personal exposure to ethylene oxide. The exposure standard relates only to eight-hour TWA personal exposure. This standard should not be extrapolated to give indications associated with 'static sampling', 'area survey' or 'leak detection'.

Static Sampling

11.6 Static sampling is an air sampling procedure whereby fixed samplers are strategically located within a workplace. The assessment process may indicate that static sampling is an essential part of the monitoring strategy. This method is preferred when assessing the effectiveness of control measures or when determining sources of area contamination. However, because the airborne concentration of ethylene oxide may vary considerably at different times and from place to place, static samples are only of limited use in assessing actual personal exposures to ethylene oxide.

11.7 Static sampling should be performed by a monitoring device which collects air samples at the breathing zone height from a fixed point in the workplace. Alternatively, sophisticated multi-point remote monitoring instruments have recently become available commercially for bigger sterilisation installations where substantial quantities of ethylene oxide are used. This type of remote sampling system can be fitted with audible and visual alarms, together with a chart recorder.

Area Survey and Leak Detection

11.8 Portable, direct-reading instruments, for example, chemical detector tubes and portable infra-red analysers, should be made available for area survey, leak detection, and checking before each aerated load is withdrawn from the sterilisation/aeration chamber. In these cases, rapid measurement is highly desirable but accuracy of measurement is usually of secondary importance.

11.9 Some of these instruments are not specific for the measurement of ethylene oxide. For this reason, the limitations of these instruments, for example, interferences from other sources, need to be taken into consideration when they are used in the workplace.

11.10 Portable instruments should be calibrated regularly under controlled conditions. Chemical detector tubes can be used for area surveys. They are of little use for ongoing leak detection. It is important that these tubes are stored and used strictly in accordance with the manufacturer's instructions. Tubes should not be used after the expiry date of the batch. It is also a good practice to check one tube from each batch for efficiency.

MONITORING METHOD

Air Sampling Techniques

11.11 Practical guidance on air sampling techniques is available^{22,23,24}. There are two main types of sampling methods for the determination of TWA concentrations of ethylene

oxide in the workplace atmosphere:

- (a) active sampling — a method where an air moving device (usually a pump) draws a known volume of contaminated air through an ethylene oxide collection device, for example, a solid adsorbent tube; and
- (b) passive (diffusive) sampling — a method where the atmosphere is sampled by molecular diffusion, with ethylene oxide being adsorbed by a solid adsorbent within the sampler, which is usually a tube or a badge.

11.12 Many issues need to be considered when selecting sampling devices for a particular work situation. For example, a range of diffusive samplers is available commercially, but these samplers usually function well only under manufacturers' specified ranges of concentration, face velocity, sampling duration, temperature, humidity and pressure. It is therefore recommended that atmospheric monitoring be carried out or supervised by an appropriately qualified and experienced person.

Analytical Method

11.13 After sampling, ethylene oxide is usually removed from the solid adsorbent material and subsequently analysed by gas chromatography. Some other methods have also been reported²⁵.

11.14 Chemical analysis should be performed by a recognised laboratory with the appropriate skills and knowledge. Some manufacturers/suppliers of adsorbent tubes and badges also provide analytical services.

RECORD KEEPING

11.15 The following points should be considered in relation to record keeping:

- (a) Results of air monitoring should be recorded appropriately. Records should include the following information:
 - (i) when the monitoring was done and what the results were,
 - (ii) what monitoring procedures were adopted, including the duration,
 - (iii) the locations where samples were taken, and the specific operations in progress at the time and, in the case of personal samples, the names of workers concerned,
 - (iv) whether the results reflect normal operating conditions,
 - (v) how the results were interpreted,
 - (vi) the effectiveness of control, and
 - (vii) what preventive and remedial action was subsequently taken.

- (b) Results of workplace monitoring are confidential and should only be communicated to individual employees, employee representatives and relevant public authorities.
- (c) The overall air monitoring results should be available for inspection by personnel working in the areas where ethylene oxide may be present.
- (d) All air monitoring records should be kept and maintained by employers for a period of not less than 30 years.

11.16 A suitable register should be established and maintained by the employer to form a master reference for all information pertaining to matters such as installation, exposures, monitoring, health assessment, first aid, training, control measures, personal protective equipment, work practices, maintenance procedures and emergency procedures.

11.17 Advice on procedures for monitoring is given at Appendix 2.

12. HEALTH SURVEILLANCE

12.1 The purpose of health surveillance is to determine that the health of employees is not adversely affected while they are working with ethylene oxide.

HEALTH ASSESSMENT

General

12.2 In the case of *acute over-exposure*, a medical examination should be performed. Such medical examinations should take into consideration the effects referred to in Sections 2.6-2.8 of the National Commission's *Guidance Note for the Safe Use of Ethylene Oxide in Sterilisation/ Fumigation Processes* [NOHSC:3016(1992)].

12.3 In the case of *chronic exposure*, medical examinations cannot be used to predict chronic adverse effects as there is at present no medical or biological index of ethylene oxide exposure nor any validated medical test of sub-clinical effects. However, if there is reason to believe that effects referred to in Sections 2.9-2.10 of the National Commission's *Guidance Note for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* [NOHSC:3016(1992)] are occurring or have occurred, medical examinations to confirm or refute any such effects should be carried out in accordance with the National Commission's *National Model Regulations to Control Workplace Hazardous Substances* [NOHSC:1005(1991)]¹ and *National Code of Practice to Control Workplace Hazardous Substances* [NOHSC:2007(1991)]².

Pregnancy

12.4 Owing to the equivocal evidence that ethylene oxide may cause adverse effects in reproduction, any worker with ethylene oxide exposure who is planning pregnancy or is pregnant has the right to transfer to other suitable alternative duties for the duration of the pregnancy.

SAMPLE WARNING SIGN

A1.1 Regulated areas are areas containing ethylene oxide sterilisers, aerators, aeration rooms, cylinders and/or piecework, and should be physically isolated from other areas. For example, they could be located in a separate room.

A1.2 Warning signs, such as the following, should be posted at the entrance to the regulated area(s).

D A N G E R

**RESTRICTED ACCESS AREA
AUTHORISED PERSONNEL ONLY**

ETHYLENE OXIDE

**CANCER HAZARD AND REPRODUCTIVE HAZARD
FIRE AND EXPLOSION HAZARD**

This area must be kept locked at all times.

In case of emergency, contact: _____

METHODS FOR ATMOSPHERIC MONITORING

A2.1 Advice on suitable sampling techniques and methods of analysis for ethylene oxide may be found in the following publications:

- (a) Australian Standard AS 2986 *Workplace Atmospheres — Organic Vapours — Sampling by Solid Adsorption Techniques*²⁴;
- (b) the National Commission's *Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment* [NOHSC:1003(1991)]²⁶;
- (c) the United Kingdom Health and Safety Executive's *Monitoring Strategies for Toxic Substances*²²;
- (d) the United Kingdom Health and Safety Executive's *Ethylene Oxide in Air — Laboratory Method Using Adsorbent Tubes, Solvent Desorption and Gas Chromatography*²⁷;
- (e) the United States National Institute of Occupational Safety and Health's *Manual of Analytical Methods*²⁸;
- (f) the United States National Institute of Occupational Safety and Health's *Occupational Exposure Sampling Strategy Manual*²³; and
- (g) Esposito, G.G., Willies, K. and Bongiovanni, R., 'Determination of Ethylene Oxide in Air by Gas Chromatography' in *Analytical Chemistry*²⁵.

PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE OXIDE

Note: This appendix should not be used as a Material Safety Data Sheet because it does not contain all the information required and is not specific to the product in use.

A3.1 Ethylene oxide is a reactive and highly flammable chemical. Its main use in sterilisation and fumigation operations stems from the fact that it is a substance which penetrates plastics material. This property separates ethylene oxide from other gaseous fumigants, making it virtually essential in some sterilisation processes, as no suitable alternative substances exist.

IDENTITY

A3.2 Details relating to the identity of ethylene oxide are as follows:

| | | |
|------------------------------|--|-----------------|
| Name | Ethylene oxide | |
| CAS Number | 75-21-8 | |
| Synonyms | EtO; ETO; EO; Oxirane; 1,2 epoxyethane | |
| Molecular weight | 44.05 | |
| Chemical group | Epoxide. Ethylene oxide is the smallest of the epoxides. | |
| Chemical formula | C ₂ H ₄ O | |
| Structural formula | 0 | |
| | H ₂ C | CH ₂ |
| UN Number | 1040 | |
| Dangerous Goods Class | 2.1 (Flammable Gas) | |
| Subsidiary risk | 2.3 (Poison Gas) | |
| Poisons Schedule | Schedule 7 (Dangerous Poison) | |
| Conversion factors | 1 ppm = 1.80 mg/m ³ (25°C; 101.3 kPa) | |
| | 1 mg/m ³ = 0.56 ppm (25°C; 101.3 kPa) | |

PHYSICAL PROPERTIES

A3.3 Details relating to the physical properties of pure ethylene oxide are as follows:

| | |
|---|--|
| Physical state | Colourless gas at room temperature; liquid below 10.5°C. |
| Boiling point | 10.5°C |
| Freezing point | -113°C |
| Specific gravity | 0.87 |
| Vapour density | 1.52 (Air = 1) |
| Vapour pressure | 146 kPa at 20°C (1095 mm Hg) |
| Solubility | Ethylene oxide is miscible in water. On dissolving, ethylene oxide slowly reacts with water producing ethylene glycol. The gas mixes with most organic solvents, and is a powerful solvent for fats, oils, grease and rubber formulations. |
| Partition coefficient (logn octanol/water) | -0.30 |

FLAMMABILITY

A3.4 Liquids of ethylene oxide are highly flammable and vapours of ethylene oxide are subject to explosive decomposition. Ignition and decomposition can be initiated by many common sources of heat, and the pressure rise is sufficiently rapid and extensive to cause violent rupture of containers. Containers close to, or on, fire should be sprayed to keep cool. Flashbacks along vapour trails may also occur.

| | |
|-------------------------------------|---|
| Hazchem Code | 2PE |
| Flash point (open cup) | -18°C |
| Flammability limits | 3-100 per cent |
| Autoignition temperature | 429°C in presence of air, 560°C in absence of air. |

| | |
|---|---|
| Extinguishants (small fires) | Dry powder or carbon dioxide. |
| (large fires) | Water fog, dry powder or alcohol foam. AFFF-ATC foam should be applied if ethylene oxide has accumulated in a large pool. |
| Combustion products | Irritating gases produced. |
| Reactivity | Ethylene oxide is highly reactive. Avoid contact with acids, bases, metal oxides and metal chlorides. |
| Hazardous polymerisation | Highly exothermic polymerisation, leading to explosive decomposition, will occur at ambient temperatures. A slow polymerisation of ethylene oxide also occurs in storage in the presence of rust. |

ODOUR AND WARNING PROPERTIES

A3.5 THE SENSE OF SMELL MUST NOT BE USED TO WARN OF THE PRESENCE OF HARMFUL VAPOURS OF ETHYLENE OXIDE. The detection of ethylene oxide by sense of smell is unreliable, is subject to olfactory fatigue (sensory habituation) and does not occur until exposure is well past the concentrations considered hazardous.

| | |
|---|-------------------------|
| Odour | Sweet, ether-like odour |
| Odour threshold (perception) | 260 ppm |
| (recognition) | 500-700 ppm |

COMMON MIXTURES OF ETHYLENE OXIDE

A3.6 Ethylene oxide is normally mixed with either carbon dioxide or chlorofluorocarbons, such as Freon 12, to reduce the risk of explosion or fire.

A3.7 The ethylene oxide/Freon mixture most commonly used in hospitals is 12 per cent ethylene oxide and 88 per cent Freon. Industry commonly uses several mixtures, including 10 per cent ethylene oxide and 90 per cent carbon dioxide, and 90 per cent ethylene oxide and 10 per cent carbon dioxide.

A3.8 Common trade mixtures include:

- Sterigas 27 — 12 per cent ethylene oxide (by weight)/balance dichlorodifluoromethane;
- Fumigas 10 — 10 per cent ethylene oxide/90 per cent carbon dioxide; and
- Fumigas 90 — 90 per cent ethylene oxide/10 per cent carbon dioxide.

RELEVANT PUBLIC AUTHORITIES

A4.1 The following organisations are 'relevant public authorities' for the purpose of this national code of practice.

NEW SOUTH WALES

WorkCover Authority
400 Kent Street
SYDNEY NSW 2000
Telephone: (02) 370 5000

VICTORIA

Occupational Health and Safety Authority
Nauru House
80 Collins Street
MELBOURNE VIC 3000
Telephone: (03) 655 6444

QUEENSLAND

Division of Workplace Health and Safety
Department of Employment, Vocational Education,
Training and Industrial Relations
30 Makerston Street
BRISBANE QLD 4000
Telephone: (07) 227 4729

SOUTH AUSTRALIA

Occupational Health Division
Department of Labour
61 Hindmarsh Square
ADELAIDE SA 5000
Telephone: (08) 226 6510

WESTERN AUSTRALIA

Department of Occupational Health, Safety and Welfare
West Centre
1260 Hay Street
WEST PERTH WA 6005
Telephone: (09) 327 8777

TASMANIA

Department of Employment, Industrial
Relations and Training
81-89 Brisbane Street
HOBART TAS 7000
Telephone: (002) 30 7696

NORTHERN TERRITORY

Work Health Authority
Minerals House
66 The Esplanade
DARWIN NT 5790
Telephone: (089) 89 5010

AUSTRALIAN CAPITAL TERRITORY

As of June 1992

Occupational Health and Safety Unit
Chief Minister's Department
Level 1
North Building
London Circuit
CANBERRA ACT 2601
Telephone: (06) 275 8111

COMMONWEALTH EMPLOYEES

COMCARE Australia
ANZ Centre
12 Moore Street
CANBERRA ACT 2601
Telephone: (06) 275 0000

GENERAL

National Occupational Health and Safety Commission
(Worksafe Australia)
92 Parramatta Road
CAMPERDOWN NSW 2050
Telephone: (02) 565 9555

REFERENCED DOCUMENTS

1. National Occupational Health and Safety Commission, 'National Model Regulations to Control Workplace Hazardous Substances' [NOHSC:1005(1991)] in *Control of Workplace Hazardous Substances*, Australian Government Publishing Service, Canberra, 1991.
2. National Occupational Health and Safety Commission, 'National Code of Practice to Control Workplace Hazardous Substances' [NOHSC:2007(1991)] in *Control of Workplace Hazardous Substances*, Australian Government Publishing Service, Canberra, 1991.
3. National Occupational Health and Safety Commission, *Guidance Note for Completion of a Material Safety Data Sheet* [NOHSC:3001(1991)], 3rd Edition, Australian Government Publishing Service, Canberra, 1991.
4. National Occupational Health and Safety Commission, 'Guidance Note for Placarding Stores for Dangerous Goods and Specified Hazardous Substances' [NOHSC:3009(1990)] in *Storage of Chemicals*, Australian Government Publishing Service, Canberra, 1990.
5. National Occupational Health and Safety Commission, 'Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment' [NOHSC:3008(1991)] in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, 2nd Edition, Australian Government Publishing Service, Canberra, 1991.
6. Standards Australia, AS 1210 *Unfired Pressure Vessels (known as the SA Unfired Pressure Vessels Code)*, Sydney.
7. Standards Australia, AS 1714 *Sterilizers — 12/88 Ethylene Oxide — Hospital Use*, Sydney.
8. Standards Australia, AS 1862 *Aeration Cabinets (for Use with Ethylene Oxide Sterilizers)*, Sydney.
9. Standards Australia, AS 2030 *The Approval, Filling, Inspection, Testing and Maintenance of Cylinders for the Storage and Transport of Compressed Gases (known as the SA Gas Cylinders Code)*, Sydney.
10. Standards Australia, AS 1319 *Safety Signs for the Occupational Environment*, Sydney.
11. Standards Australia, AS 1079 *Packaging of Items (Sterile) for Patient Care*, Sydney.
12. Standards Australia, AS 1716 *Respiratory Protective Devices*, Sydney.
13. Standards Australia, AS 1715 *Selection, Use and Maintenance of Respiratory Protective Devices*, Sydney.

14. Standards Australia, AS 1337 *Eye Protectors for Industrial Applications*, Sydney.
15. Standards Australia, AS 1336 *Recommended Practices for Eye Protection in the Industrial Environment*, Sydney.
16. Standards Australia, AS 1801 *Industrial Safety Helmets*, Sydney.
17. Standards Australia, AS 1800 *The Selection, Care and Use of Industrial Safety Helmets*, Sydney.
18. Standards Australia, AS 2161 *Industrial Safety Gloves and Mittens (Excluding Electrical and Medical Gloves)*, Sydney.
19. Standards Australia, AS 2210 *Safety Footwear*, Sydney.
20. Standards Australia, AS 3765 *Clothing for Protection Against Hazardous Chemicals*, Sydney.
21. National Health and Medical Research Council, *Standard for the Uniform Scheduling of Drugs and Poisons*, Australian Government Publishing Service, Canberra, 1991.
22. Health and Safety Executive, *Monitoring Strategies for Toxic Substances*, Guidance Note (Environmental Hygiene) no. 42, Her Majesty's Stationery Office, London, 1989.
23. National Institute of Occupational Safety and Health, *Occupational Exposure Sampling Strategy Manual*, National Institute of Occupational Safety and Health, Cincinnati, Ohio, 1977.
24. Standards Australia, AS 2986 *Workplace Atmospheres — Organic Vapours — Sampling by Solid Adsorption Techniques*, Sydney.
25. Esposito, G.G., Willies, K. and Bongiovanni, R., 'Determination of Ethylene Oxide in Air by Gas Chromatography', *Analytical Chemistry*, vol. 56 no. 11, pp. 1950-1953, 1984.
26. National Occupational Health and Safety Commission, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment' [NOHSC:1003(1991)] in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, 2nd Edition, Australian Government Publishing Service, Canberra, 1991.
27. Health and Safety Executive, *Ethylene Oxide in Air — Laboratory Method Using Adsorbant Tubes, Solvent Desorption and Gas Chromatography*, Methods for the Determination of Hazardous Substances no. 26, Her Majesty's Stationery Office, London, 1987.
28. National Institute of Occupational Safety and Health, *Manual of Analytical Methods*, 3rd Edition, National Institute of Occupational Safety and Health, Cincinnati, Ohio, 1984.