HEALTH BUILDING NOTE 13
SUPPLEMENT 1

Sterile services department
Supplement 1: ethylene oxide sterilization section

1994

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Health Building Note 13

Supplement 1

Ethylene oxide sterilization section

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About this publication

The Health Building Note (HBN) series is intended to give advice on the briefing and design implications of Department of Health policy. These Notes are prepared in consultation with representatives of the National Health Service and appropriate professional bodies. Health Building Notes are aimed at multidisciplinary teams engaged in:

- designing new buildings;
- adapting or extending existing buildings.

Throughout the series, particular attention is paid to the relationship between the design of a given department and its subsequent management. Since this equation will have important implications for capital and running costs, alternative solutions are sometimes proposed. The intention is to give the reader informed guidance on which to base design decisions.

Building Note Supplements, such as this supplement to HBN 13 - 'Sterile services department', must be read together with the associated HBN.

Health Building Note 13 - Supplement 1

This supplement focuses on a dedicated ethylene oxide sterilization section integrated within a sterile services department. The accommodation provides for:

- packing products;
- pre- and post-sterilization processes;
- sterilization procedures;
- good manufacturing practice.

Contents

1.0 Scope of Supplement 1 to Health Building Note 13

Introduction

1.1 Health Building Note (HBN) 13, Supplement 1, is a guide to the planning and design of an ethylene oxide sterilization section in a sterile services department.

1.2 It is a supplement to HBN 13 - 'Sterile services department' 1992[1], which provides planning and design guidance for the accommodation requirements of a sterile services department providing sterilization and disinfection services to hospitals, the community and other clinical users. This supplement should be read in conjunction with HBN 13.

1.3 Supplement 1 focuses on the building and engineering service requirements in support of a validated and safe ethylene oxide sterilization service. A complex and specialist form of sterilization, the use of ethylene oxide should be limited to those departments which can fully justify its need; and where the necessary supporting protocols and test procedures can be provided.

1.4 Integral with the sterile services department the ethylene oxide sterilization section is expected to be supported, in a number of ways, by areas in the main department. However, there are certain restrictions - such as those associated with the ethylene oxide packing room being a clean room -which are critical in achieving satisfactory room relationships.

1.5 Ethylene oxide sterilization documents referred to by number, for example [6], are listed at the end of the supplement. Each repeated reference retains the same number.

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2.0 General service considerations

Introduction

2.1 Ethylene oxide is a hazardous material with respect to toxicity, flammability in air and explosive instability. It can, however, be handled with safety provided the necessary precautions are taken.

2.2 Ethylene oxide:

a. is flammable in concentrations greater than 3% (vol) in air;

b. has a boiling point of 10.5°C and vaporises rapidly at normal atmospheric pressure;

c. if inhaled, causes nausea, vomiting, irritation to the nose, loss of smell and progressively, stupor and coma;

d. produces serious burns in liquid and gas forms and is a possible carcinogenic hazard;

e. has a vapour density that is heavier than air and will accumulate at low levels, such as basements and drains.

2.3 As a sterilizing agent ethylene oxide is used either in its undiluted form, or mixed with inert gases such as carbon dioxide, nitrogen, or one of the non-flammable halogenated gases. The gas mixtures must not contain acetylene. For safety, pure gas sterilization is normally run at sub-atmospheric pressure. Sterilizers using gas mixtures are normally run at above atmosphere pressure.

2.4 Standards and guidance on aspects relevant to ethylene oxide sterilization can be found in the References section and Bibliography. Most guidance reference notes indicate the publication date. Users of such guidance must satisfy themselves that they are using the current issue.

2.5 Terminology and requirements given in this HBN are in accord with European and International standards mandated by the European Commission to support directives in the areas of health and safety, pressure systems, hazardous substances and medical devices. Relevant standards and regulations are listed in the references section and bibliography.

2.6 Considerable work is involved in the validation of an ethylene oxide sterilization system. This will include microbiological monitoring of the environment associated with the pre-sterilization stages of the process and physical monitoring of the environment in which product is stored after sterilization.

2.7 Project teams should consult the microbiologist, the local fire officer and the health and safety inspector early in the project's planning process.

General description

2.8 The majority of sterilizers will have chambers of 150-200 litres capacity. However, certain centres may be established to sterilize larger medical equipment where chambers of 200-400 litres wiII be used. The ethylene oxide supply for these larger sterilizers will normally be provided from cylinders containing a non-explosive gas mixture.

2.9 The installation, commissioning and the environment for both types of sterilizer require special consideration. Particular attention should be given to fire hazard, fire escape routes, and to the needs for environmental monitoring.

2.10 Large positive-pressure sterilizers are normally supplied from a cylinder manifold. In order to maintain the safety standards specified in this supplement, the cylinder manifold should be installed in a separate space.

2.11 An ethylene oxide sterilizer should be installed in a room separate from steam sterilizers, noting the following features:

a. large positive-pressure sterilizers will require external accommodation to house the cylinders connected to a manifold and to store one set of stand-by cylinders;

b. the sterilizer loading space should be ventilated and maintained under negative pressure with respect to, and be located separate from, the main sterile services department;

c. the sterilizer plant area should be maintained under negative pressure with respect to the loading area;

d. an exhaust hood located above the sterilizer door is required.

2.12 Since the concentration of ethylene oxide discharged from the sterilizer chamber may operate in the region of 1000 mg EO/litre and may be at a level that is unsafe to the operator, it is essential to reduce the concentration of ethylene oxide gas in the chamber before opening the sterilizer door.

2.13 Ethylene oxide sterilization is impaired if the product to be sterilized, and its immediate wrapping, is excessively dry. Product and materials should be packed and held, prior to sterilization, in an environment in which the relative humidity is maintained in the range 40-80% RH.

2.14 To achieve the necessary relative humidity, preconditioning is required. While this may be undertaken within the sterilizer chamber prior to the sterilization cycle, to do so will limit the use of the chamber for sterilization cycles. As an alternative, consideration should be given to providing a purpose-designed preconditioning room. However, where the volume of work does not justify such a provision, a specific preconditioning cabinet(s) may be provided.

2.15 Prior to ethylene oxide gas entering the sterilizer chamber the temperature and relative humidity within the product load should comply with the process specification. The temperature and relative humidity of the load may be required to be raised further in the conditioning phase of the sterilization cycle.

2.16 Following cycle completion, the product will need to be aerated in order to remove residues. This may be achieved within the sterilizer chamber, in an aeration cabinet or in a purpose-designed room. Such a room may be used exclusively for aeration or may also be used for the degassing and quarantine process. Associated extract systems should discharge to outside the building at a safe location.

2.17 The latter part of aeration is defined as degassing and is normally carried out in a separately designated degassing and quarantine room. The product must be held here for a period of at least seven days, during which degassing will continue. The room should be secure, and entirely separate from the processed goods store in the main department. Only after the results of biological test monitors show effective sterilization to have occurred **and** the level of residual ethylene oxide within the sterilized product has been verified as clinically acceptable, should the product be released to the processed goods store to await distribution to a user.

2.18 The sterilizer loading room, sterilizer plantroom and cylinder and manifold room should have, when in normal use, an environmental level of ethylene oxide gas consistently lower than that stipulated in the current edition of HSE Note EH40 'Occupational Exposure Limits'. [(2)]

2.19 The bioburden or microbiological contamination level of the product being presented for sterilization by ethylene oxide should be as low as can be practically achieved as the presence of organic matter impedes the sterilization process.

2.20 A physical cleaning process to remove completely all soil, blood and tissue debris is required prior to sterilization. Also, in the interests of good manufacturing practice, which requires that adventitious contamination be minimised by all practicable means, the environment provided in the ethylene oxide packing room should be controlled to standards as defined in BS5295:Part 1: 1989, Class L.[(3)]

2.21 Only cycles which have been validated should be used to process the product. Without the use of fully validated cycles quality would be impeded. It is recommended that all quality assurance aspects be designated to a responsible person.

2.22 The ethylene oxide sterilizer should be specified, Installed, commissioned and processes validated following the guidance in HTM 2010 - 'Sterilization'.[(4)]

2.23 The only definitive performance test for ethylene oxide sterilization is microbiological. The guidance given in HTM 2010 - 'Sterilization: Validation and verification'[(4c)] should be followed.

2.24 Since ethylene oxide is toxic and leaves residues, the aeration and degassing during quarantine of the product must be included as part of the validation process. Guidance on safety considerations and quantitative determination methods are highlighted in EN 30993-7: Biological evaluation of medical devices: Part 7: Ethylene Oxide Sterilization Residuals.[(5)]

Safety requirements

2.25 Due to the volatile nature of ethylene oxide gas, it must be handled with great care at all times. Project teams are reminded that operational safety requirements and the fire precautions required for an ethylene oxide sterilization section are, in many instances, similar and interdependent. The operational safety requirements detailed below should therefore be read in conjunction with the guidance given on fire precautions in paragraph 3.5:

a. operational procedures must be available and, where detailed processes are involved, work instructions should be on prominent display;

b. operational procedures should exclude the sterilization of products containing chlorine, that is, hypochlorite solutions;

c. there must be strict control to permit the access of only authorised personnel to the sterilizer loading room, plant room and the cylinder and manifold room;

d. consideration should be given to the safe discharge of gas from both the sterilizer and the ventilation system;

e. due to the disturbance of any fugitive ethylene oxide gas caused by air movement, suspended ceilings or raised floors where gas pockets can form should be avoided;

f. the ethylene oxide sterilization section should not be exposed to direct sunlight.

2.26 The following operational safety requirements are only specific to large positive-pressure sterilizers:

a. protectron goggles and respirators should be made available for use in an emergency, and for routine maintenance in all appropriate areas;

b. the temperature in the cylinder and manifold room should not be allowed to rise above that recommended by the cylinder or gas manufacturer;

c. the cylinder and manifold room should be provided with a safe method for purging the gas lines, either by nitrogen flushing or by operating a purge cycle, prior to a cylinder change;

d. an extract system is required to draw gas away from the operative in the area of cylinder change;

e. gas lines must be fitted with demountable filters in order to minimise the problems associated with the polymerisation of ethylene oxide;

f. the use of freons, as a carrier gas, is currently being phased out. Carbon dioxide gas is an alternative;

g. ethylene oxide gas detection apparatus must be installed.

Product

2.27 Prior to packaging, the product must be free from all organic contamination. Intricate medical equipment may therefore need to be dismantled prior to cleaning. Cleaning must be carried out in accordance with a cleaning protocol, which has been validated.

2.28 If the product to be sterilized contains pressure-sensitive electronic components which cannot be dismantled, for example a gas analyser, it may be necessary to have additional sterilization cycles that are pressure-related and compatible with the design of the product.

2.29 Items or components of the medical equipment (for example a gas analyser) prepared in the medical equipment section located in the main sterile services department and not requiring packaging, will gain access to the ethylene oxide sterilization section by direct entry to the sterilizer loading room. Use of the more conventional route, via the washing area and main packing room, is not suitable for this category of product. In this instance, the product will not pass through the ethylene oxide packing room.

2.30 Product should be packed in an environment controlled at a temperature and relative humidity commensurate with the condition set in the validation protocol

Service strategy considerations

2.31 The various service strategies for ethylene oxide sterilization currently in operation have developed in response to requests from the clinical users and the ability of the associated sterile services department to respond.

2.32 Any existing strategy should be reviewed critically prior to expanding the service. For this review, and also when the implementation of a new service is being proposed, the following aspects should be considered:

a. ethylene oxide sterilization should only be used to process product which is sensitive to, and may be damaged by, heat and moisture (having considered the suitability of steam at pressure and low temperature steam and formaldehyde);

b. ethylene oxide should not be used to reprocess "single use" items;

c. the need for an ethylene oxide service should be justified;

d. the possibility of buying in a service from another provider unit might be more economical;

e. the possibility of providing other users with a service should be investigated.

Recommended service strategy

2.33 The guidance given in this supplement is based on the following service strategy:

a. the ethylene oxide sterilization service forms part of the overall sterile services being provided;

b. the ethylene oxide sterilization section is integrated with the sterile services department;

c. a volume of work load is identified, having been assessed in response to clinical user requirements;

d. all processing aspects, with the corresponding equipment required, are identified;

e. protocols for processes are determined and validated in order to produce product complying with predetermined specifications;

f. a microbiological monitoring service is available;

g. operational and staff safety aspects are incorporated.

Sizing the section

2.34 The demand for this facility will depend on the need to process heat- and steam-sensitive items and specialised medical equipment. The sterile services policy and the subsequent work generated and operational policies to be implemented will influence the size of the section.

Workload and throughput calculation

2.35 The workload can be identified as the volume of assembled and packed product and, where appropriate, specific components of complex medical equipment.

2.36 Preconditioning and aeration may be undertaken either within the sterilizer chamber, specific cabinets or within purpose-designed rooms. If preconditioning is undertaken within the sterilizer chamber, this then becomes part of the conditioning stage of the sterilization cycle. When a preconditioning cabinet or room is chosen, the availability of the sterilizer chamber for "sterilization" cycles then increases. A similar option applies to where the aeration stage is undertaken, which may be within the sterilizer chamber, an aeration cabinet or within a purpose-designed room. Such issues should be examined very early in the planning stage in order to assess and size the facilities, for example accommodation and equipment requirements, as accurately as possible.

2.37 The throughput capacity of an ethylene oxide sterilizer will be influenced by variables such as the length of time required for the sterilization process and the hours that the department is operational. In most NHS situations only one sterilizer is likely to be required.

Basic sizing exercise

2.38 The workload and throughput calculations given for porous load sterilizers in Appendix 2 of HBN 13[1] are not applicable for ethylene oxide sterilizers, nor is the basic sizing exercise given in Appendix 3 of that document.

2.39 Once a service strategy has been identified, and the operational variables associated with the stages of the total process determined, the project team can then identify the activity spaces required for the ethylene oxide sterilization section, in response to local operational practices and need. Rooms required may include:

- a dedicated packing room, controlled to standards as defined in BS5295:1989:Part 1 Class L[3];
- a purpose-designed preconditioning room or a room with (a) preconditioning cabinet(s);

Figure 1 Activity spaces: showing rooms to be selected in support of decisions made on local operational practice

	Packing room	Precondition-ing room	Sterilizer loading room	Aeration room	Degassing/ quarantine room	Sterilizer plantroom	Cylinder and manifold room
Large positive-pressure sterilizer	√	√	√	√	√	√	√
Small transportable sterilizer (using canisters)	√	√	√	√	√	–	–
ADDITIONAL USE OF STERILIZER CHAMBER							
Preconditioning in large positive-pressure sterilizer	√	–	√	√	√	√	√
Preconditioning in small transportable sterilizer	√	–	√	√	√	–	–
Aeration in large positive-pressure sterilizer	√	√	√	–	√	√	√
Aeration in small transportable sterilizer	√	√	√	–	√	–	–

Key
√ denotes required
– denotes not required

- a sterilizer loading room;
- a purpose-designed aeration room or a room (maybe the sterilizer loading room or the degassing and quarantine room) with an aeration cabinet(s);
- a quarantine room where degassing will occur;
- a sterilizer plantroom;
- a cylinder and manifold room;
- a processing room.

2.40 See Figure 1 which illustrates the activity spaces from which a selection should be made in support of local operational practices and equipment.

2.41 The sterile services manager will be expected to identify standard unit batch loads comprising similar materials and of a size that fully utilises the usable sterilizer chamber volume.

2.42 The size of both the preconditioning and aeration rooms or number of cabinets required is dependent on:

a. the volume of product being processed and the size of the container used to move the product through both areas, and also the sterilizer;

b. the period of time required to precondition the product in order to raise the temperature and relative humidity to the sterilization cycle level;

c. the time required to allow the product to be aerated;

d. whether the aeration room will also hold the product, in quarantine, awaiting biological monitor clearance.

2.43 As ageneral guide, each unit batch load should be held in both the preconditioning and the aeration rooms for a period of approximately three times the duration of the sterilization cycle. In addition, product cannot be released until confirmation has been received that no growth has occurred on the biological monitors. Results of the biological monitor tests will take approximately seven days. Degassing and quarantine can share the same room. Regardless of where the degassing function is undertaken, there will always be a requirement to quarantine product batches.

2.44 A project team may, however, decide to provide a processing room where local operational practices and volume of workload are appropriate. The functions undertaken in the processing room include preconditioning, sterilizer loading and aeration. Using specific cabinets located in the processing room for both the preconditioning and aeration functions eliminates the need for purpose-designed rooms for these two functions.

2.45 See Figure 2 which illustrates the rooms required in support, as well as those not required, when a project team decides to provide a processing room.

Location of section

2.46 The total ethylene oxide sterilization process must be carried out in a secure and dedicated section. While the section will have a number of individual rooms, and be an integral part of the main department, the individual rooms will be separate from the main workrooms of the sterile services department. Access to the section will be restricted to authorised persons.

Figure 2 Processing room: showing rooms required in support

	Packing room	Precondition-ing room	Sterilizer loading room	Aeration room	Degassing/ quarantine room	Sterilizer plantroom	Cylinder and manifold room
Processing room with large positive-pressure sterilizer	√	–	–	–	√	√	√
Processing room with small transportable sterilizer (using canisters)	√	–	–	–	√	–	–

Note

The processing room embodies three principal functions:

- preconditioning;
- sterilizing;
- aeration.

Key

√ denotes required
– denotes not required

2.47 The ethylene oxide sterilization section is dependent on receiving functional support from a number of activity spaces provided in the sterile services department. The principle spaces giving support include the washing area, gowning room, packing room and the materials transfer room. The planning relationship of these spaces with the ethylene oxide packing room is critical.

2.48 The ethylene oxide packing room should be physically separate from the main packing room used to prepare product for steam sterilization. Physical separation does not preclude its location within the main packing room.

2.49 The entry of personnel and materials to the ethylene oxide packing room must be controlled. This can be achieved by using the sterile services department's gowning room for personnel and the materials transfer room for the supply of materials. Cleaned items, processed in the washing area, may be routed via the pass-through facility provided between the washing area and the main packing room.

2.50 The main packing room should not, however, become an extended traffic route for clean items and materials being taken to the ethylene oxide packing room. The design solution needs therefore to locate the ethylene oxide packing room in a position that will minimise, as far as possible, the distance each route takes within the main packing room.

Operational policies

2.51 Operational policies associated with the sterile services department may be extended, where appropriate, to cover the ethylene oxide sterilization section. In addition, operational policies specifically concerning the ethylene oxide sterilization section need to be determined and where detailed processes are involved, work instructions should be on prominent display.

2.52 Access to competent microbiology laboratory services is required in order to operate an ethylene oxide sterilization process. Therefore, the operational policies need to address arrangements for providing microbiological facilities and expertise. A microbiological laboratory, either on site or nearby, will be required to undertake the microbiological investigations which form part of the validation and routine control of ethylene oxide sterilization.

2.53 For sections operating large positive pressure sterilizers, protective goggles and a respirator is required in all areas other than the packing room, preconditioning room and aeration, degassing and quarantine room. As a member of staff may need to wear protective goggles and a respirator prior to entering the cylinder and manifold room, such safety items should be provided in a secure manner, at point of entry, outside this room.

3.0 General functional and design requirements

Introduction

3.1 This chapter provides guidance based on the service considerations outlined in Chapter 2. It includes topics which should be taken into account when designing an ethylene oxide sterilization section and should be read in conjunction with Chapter 3 in HBN 13.[1]

Workflow

3.2 The three classifications of goods received at the sterile services department for sterilization by ethylene oxide are soiled equipment, clean supply, and complex pieces or components of medical equipment which are inappropriate for porous load steam sterilization.

3.3 Figure 3 illustrates the workflows within the sterile services department that can be utilised by the ethylene oxide sterilization section for the following purposes:

a. soiled returns: washing area/packing room;

b. clean supply: materials store/materials transfer room/ packing room;

c. access route for specific medical equipment: medical equipment section/ethylene oxide sterilizer loading room;

d. processed product: processed goods store/despatch area;

staff movement: gowning room/packing room

3.4 Figure 4 illustrates the relationship of the activity spaces and workflows within the ethylene oxide sterilization section.

Fire precaution requirements

3.5 Ethylene oxide is highly flammable and forms explosive mixtures with air. For toxicity, flammability and explosive instability hazards, see paragraphs 2.1, 2.2 and the appropriate guidance documents listed in the References section and the Bibliography. It is, therefore, essential to comply with all the fire precautions as well as operational safety procedures (see paragraph 2.25). The major fire precautions requirements which concern building and engineering design are detailed below. These should be read in conjunction with appropriate DH Firecode documents.[6] Project teams are advised to consult the local fire officer at an early stage in the planning of an ethylene oxide sterilization section.

Location of the department/fire separation

3.6 As the ethylene oxide sterilization section and the sterile services department are classified as high fire risk and high fire load departments, the department's location within the hospital complex should be provided with either an open air space separation or structural fire separation from all high life risk departments.

The main objective of providing the fire separation is to eliminate the need to evacuate high life risk departments should a fire occur in the sterile services department/ ethylene oxide sterilization section. Also, the separation should enable the fire brigade to contain and extinguish the fire. The ethylene oxide sterilization section's fire separation must be imperforate, apart from the required access and fire exit doors, from all adjacent fire compartments above, below and on either side of the section.

Sub-compartmentation

3.7 The ethylene oxide sterilization section should, apart from the ethylene oxide packing room, form a 1 HFR sub-compartment within the sterile services department.

Fire hazard rooms: protection and containment

3.8 All rooms likely to be exposed to ethylene oxide gas must be considered as fire hazard rooms and be provided with a one-hour fire-resisting enclosure. This may be provided either to each individual room or where the layout is suitable to the rooms as a group.

3.9 In the ethylene oxide sterilization section the fire hazard rooms are:

a. sterilizer loading room;

b. sterilizer plantroom;

c. aeration room or room containing an aeration cabinet;

d. processing room.

3.10 Rooms not exposed to ethylene oxide gas are classified as non-hazard rooms, and these are:

a. packing room;

b. preconditioning room;

c. degassing and quarantine room, when separate from aeration.

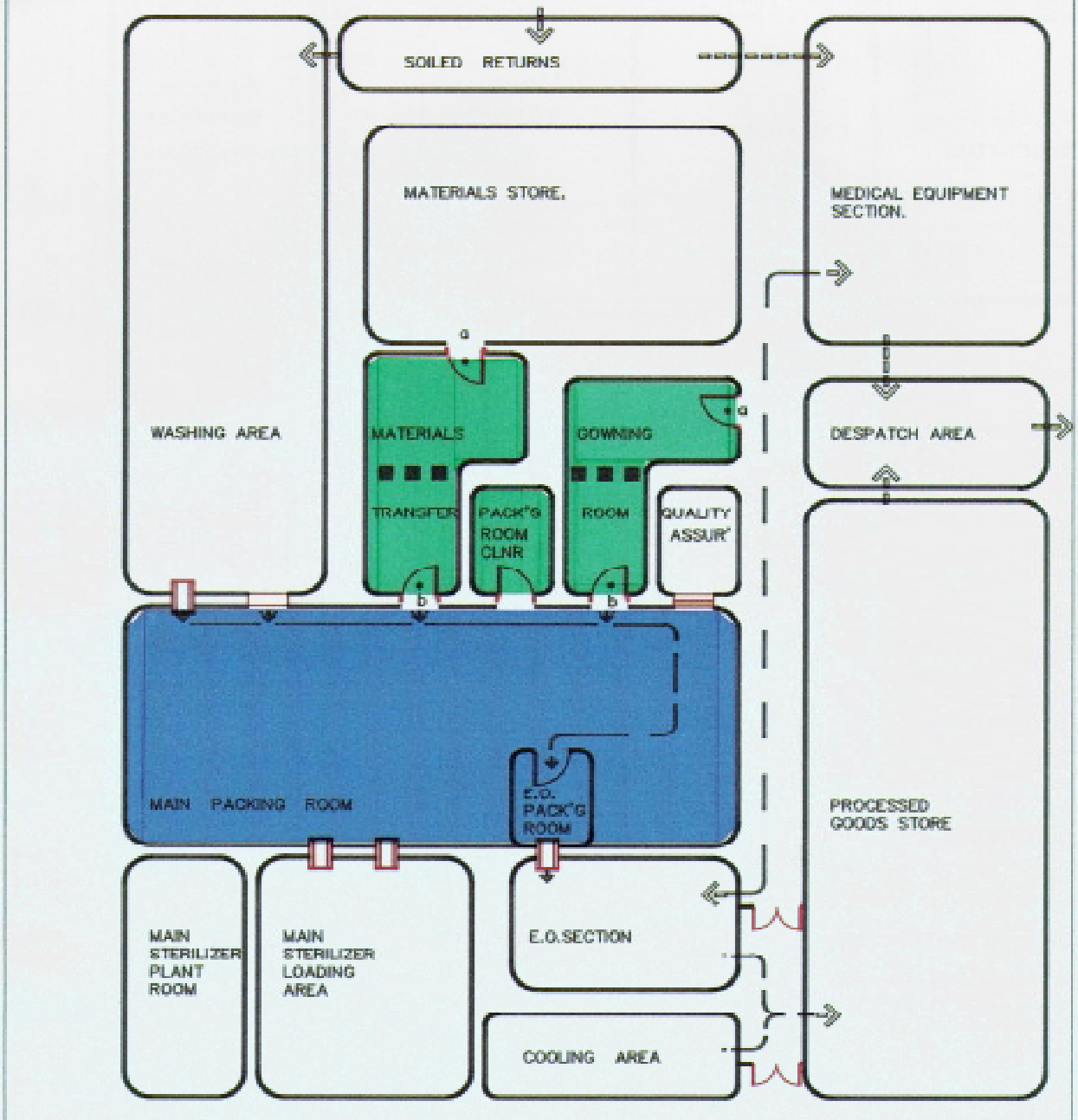

Figure 3 WORKFLOWS

A diagrammatic layout showing relationship of activity spaces & workflows within the sterile services department having an integrated ethylene oxide sterilization section.

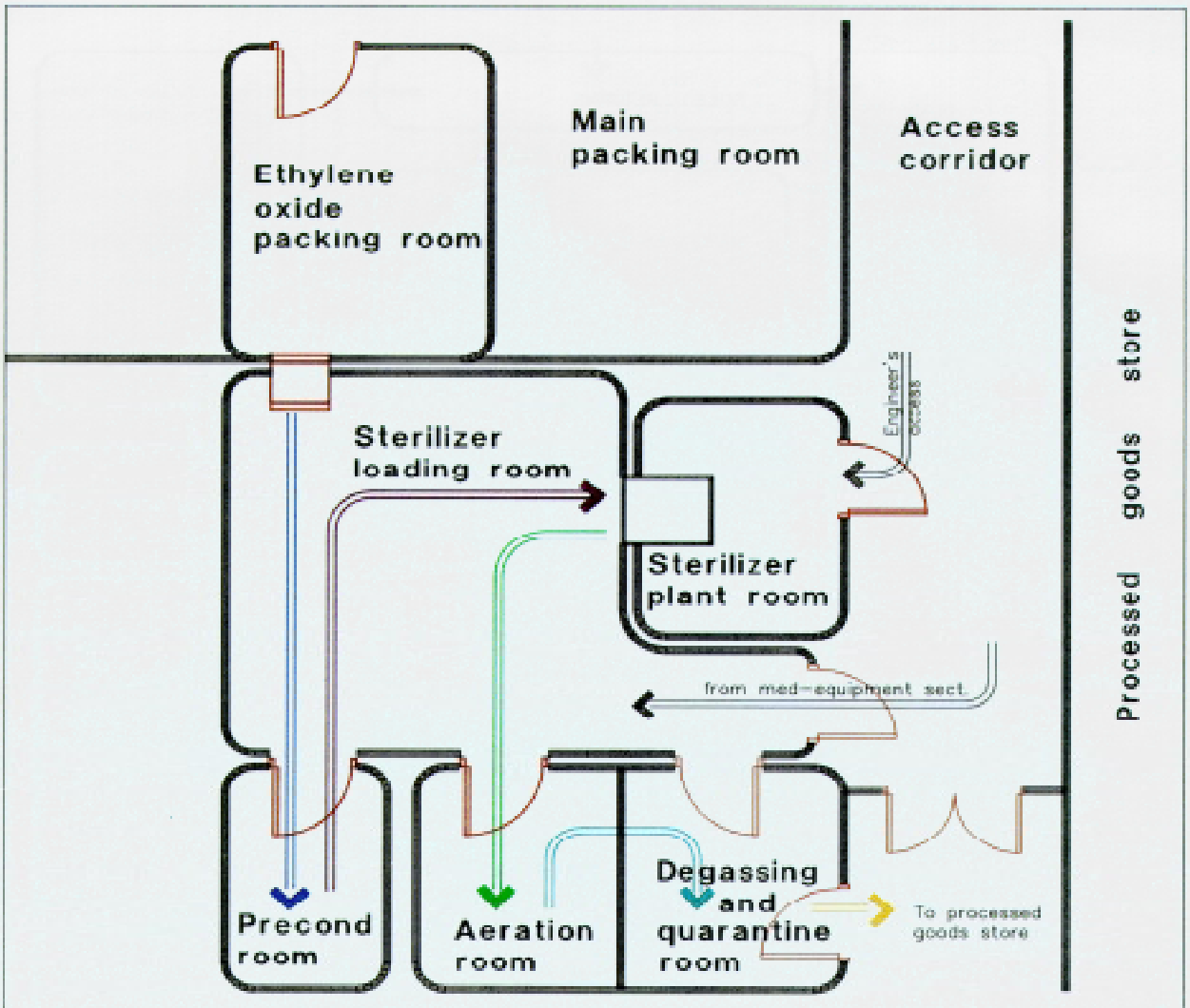

Figure 4 WORKFLOWS Diagrammatic layout of activity spaces & workflows within the ethylene oxide sterilization section.

Note: External cylinder & manifold room not shown in the above diagram.

Cylinder and manifold room

3.11 This is considered to be an explosion risk room. Therefore it must be located on an external wall and be provided with adequate explosion relief panels (see paragraphs 4.53 to 4.67). For information on the ventilation of this room, see paragraph 5.23.

Means of escape - travel distances

3.12 From any point within the ethylene oxide sterilization section sub-compartment:

a. the maximum travel distance to a fire exit door should not exceed:
   (i) 6 metres, where there is escape in one direction only; or
   (ii) 12 metres, where there is a means of escape in more than one direction; and
b. the minimum angle of divergence between alternative exit doors should be 45° (see HTM 81 [6a]).

Fire detection and alarm

3.13 An analogue/addressable automatic fire detection (see HTM 82[6b]) and alarm system must be provided, with appropriate zone indicator panels, as a separate zone within the whole hospital fire alarm system. This system must be entirely separate from the ethylene oxide gas detection, monitoring and alarm system.

3.14 The ventilation system to all fire hazard rooms must be dedicated and isolated from the whole hospital system. The safe discharge points for ethylene oxide gas should be agreed with the Health and Safety Executive as well as the Fire Authority - see Chapter 5, "Engineering services".

3.15 All furniture and fittings in fire hazard rooms should be non-combustible and non-absorbent.

3.16 All access doors/hatches to the fire hazard rooms should be 1 HFR self-closing doors. These doors may be fitted with auto-release stand-open detents, linked to the fire detection system if required, for the frequent movement of trolleys.

3.17 The storage of 100% ethylene oxide single-shot canisters within a fire hazard room, for example the sterilizer loading room or processing room, should be limited to a one-day use requirement. The canisters should be kept in an approved metal container.

3.18 Equipment in fire hazard rooms should be installed in accordance with the manufacturer's instructions.

Expansion and phasing

3.19 The need to expand this technically complex section, which lies within a main department should be avoided.

3.20 While estimated workloads should be reasonable to forecast, it is recognised that an increase in service demand may occur unexpectedly as a result of change in user need or as a result of some new development.

3.21 In most instances an increase in demand is unlikely to justify the purchase of an additional sterilizer. Such a solution should only be considered after the following alternatives have been examined:

a. improve current utilisation of sterilizer chamber;
b. extend the hours that the sterilizer is operational;
c. undertake preconditioning within a preconditioning cabinet or room, rather than in the sterilizer chamber;
d. increase the throughput of the aeration room by increasing the temperature and air supply to that room, to a limit avoiding product damage.

3.22 The guidance given on "Upgrading or adaptation of existing buildings" in HBN 13[1] should be considered.

Artificial lighting

3.23 Good lighting is essential within the packing, sterilizer loading and aeration/degassing/quarantine spaces.

3.24 The lighting level in the sterilizer plantroom and the cylinder and manifold room must be sufficiently effective to allow the maintenance engineer to undertake work without the use of any portable lamp.

Ventilation

3.25 A preconditioning cabinet or purpose-designed room and an aeration cabinet or purpose-designed room are known to emit radiant heat to the surrounding areas.

3.26 When the ethylene oxide packing room is located within, albeit physically separate from, the main packing room the air pressure in both packing rooms should be such that there is no pressure differential between them. The door to the ethylene oxide packing room should be kept closed, being opened only to allow entry to, and exit from, the room.

Maintenance/cleaning/finishes/floors/walls/ceilings

3.27 The guidance given in HBN 13 should be considered.

Door sets

3.28 Doors should be adequately sized to allow clear passage of trolleys. Where door closures are necessary, for example for the preconditioning, sterilizer loading and aeration rooms, automatic electrically operated hinged doors should be considered. Doors must be close-fitting with respect to the door frame.

4.0 Specific functional and design requirements

Introduction

4.1 This chapter describes in greater detail the individual spaces forming the ethylene oxide sterilization section located within a sterile services department. Each description includes relevant workflow patterns and room relationships. Details of activities, environmental conditions, and finishes are given on the activity data sheets listed in Chapter 7.

Ethylene oxide packing room

4.2 *Function*

a. inspect and assemble items;

b. pack items to be sterilized;

c. transfer product unit batch to the sterilizer loading area;

Location

a. a dedicated space within the main packing room;

b. adjacent to the ethylene oxide sterilizer loading area, with pass-through facility.

4.3 The ethylene oxide packing room should be physically separate from the main packing room. Where it is sited within the main packing room it should be bounded by walls, with an access door, and be a clearly identified individual space. The access door should be kept closed, being opened only to allow entry to, and exit from, the room. The partition walls between the ethylene oxide packing room and the main packing room may contain clear fixed light glazing to enable visual communication between the two areas and avoid a claustrophobic environment when the room is internal. It may also be useful to provide an observation window between the ethylene oxide packing room and the sterilizer loading room; however, this will need to maintain the 1 HFR integrity of this wall.

4.4 The design of the packing room should be in accordance with Class L in BS5295:1989:Part 1 'Environmental Cleanliness in Enclosed Spaces'[3] and with the document DH Manufacturer Registration Scheme, 'Guidance on Ethylene Oxide Sterilization 1990'.[7]

4.5 A workstation providing appropriate materials for the preparation of a unit batch is required.

4.6 Clean, dry items may come from the main washing area via the transfer hatch to the main packing room. From the main packing room, access to the ethylene oxide packing room can be direct using the access door. The route used within the main packing room should be kept to a minimum. Items will be inspected, assembled and packaged using appropriate materials.

4.7 Materials may come from the main materials store via the materials transfer room leading to the main packing room. From the main packing room access to the ethylene oxide packing room can be direct using the access door. Containers used to transport the materials should be returned, when emptied, to the main materials transfer room. The route used within the main packing room should be kept to a minimum.

4.8 The product, packaged and collected in a suitable container as a unit batch, will be transferred to the ethylene oxide sterilizing loading area via a double pass-through hatch. Emptied containers will be returned using the same hatch in reverse.

4.9 A recorder, with single chart thermohygrograph, is required to record the temperature and relative humidity of the packing room, and thereby facilitate its monitoring.

4.10 Staff working in the ethylene oxide packing room will follow the route and changing procedures detailed for all staff working in a clean room environment. As with supplies, staff may gain direct access from the main packing room with the route used being kept to a minimum.

Preconditioning room - purpose-designed

4.11 *Function*

- provide an environment at a predetermined temperature and relative humidity, in order to precondition product prior to sterilization;

Location

- direct access to the ethylene oxide sterilizer loading room.

4.12 This room requires a door in order to ensure that the product is secure and to assist in maintaining uniform conditions within the space. The length of time the door is left open should be controlled. Consideration should be given to providing a system to alert the operator that the

door has been left open. An audible and visual alarm activated after a predetermined delay is suggested.

4.13 A container holding a product unit batch will be received from the ethylene oxide packing room, via the sterilizer loading room.

4.14 The environmental conditions provided need to enable the equilibration of the unit batch load to the requirements detailed in the sterilization validation protocol determined locally.

4.15 The room should have assisted air circulation. Consideration should be given to the effect the product load will have on the air flow pattern within the room. Homogenous conditions of temperature and relative humidity throughout should be achieved.

4.16 A recorder, with single chart thermohygrograph, is required to record the temperature and relative humidity of the preconditioning room, and thereby facilitate its monitoring.

4.17 The preconditioning room should be easy to clean to minimise microbial contamination. In particular, care should be taken to avoid the growth of fungi. The room should be constructed from materials which will ensure a smooth surface finish and should be water resistant.

4.18 Each unit batch will be retained as a batch and should only be transferred to the sterilizer loading room when the sterilizer chamber is empty and free to receive the next load for processing.

4.19 A purpose-designed preconditioning room will not be required if the activity is undertaken using a preconditioning cabinet(s) or the sterilizing chamber. Preconditioning cabinets may be free-standing and may be located within the sterilizer loading room, processing room or within a specific room in which preconditioning cabinets are held.

Sterilizer loading room

4.20 *Function*

a. load and unload the ethylene oxide sterilizer;

b. test sterilization process and keep records;

c. provide safety equipment;

d. hold 100% ethylene oxide single-shot canisters, sufficient for one day's work (where appropriate);

Location

a. adjacent to the ethylene oxide packing room, with pass-through facility;

b. adjacent to the preconditioning room;

c. adjacent to the aeration room;

d. adjacent to the degassing and quarantine room;

e. adjacent to the sterilizer plantroom (where appropriate).

4.21 The functions carried out in the sterilizing loading area should reflect local operational policy and practice.

4.22 The sterilizer may be free-standing, or recessed with its own plantroom depending on the size, type and manufacturer of sterilizer selected.

4.23 Where it is decided to use a cabinet or cabinets, instead of purpose-designed rooms for preconditioning and aeration, the preconditioning cabinet(s) and/or the aeration cabinet(s) may be located within the sterilizer loading room or, alternatively, they may be located each within their own specific room.

4.24 Where a preconditioning cabinet and/or an aeration cabinet shares the same activity space as sterilizer loading, this space may then be known more appropriately as the processing room (see paragraph 4.68 below).

4.25 Items, or components, of medical equipment, for example a gas analyser, may be received directly into the sterilizer loading room having been prepared for processing in the medical equipment section located in the sterile services department. Such product should be processed further by following a predetermined protocol which has been validated.

4.26 A container holding a unit batch will be received from the packing room via a double pass-through hatch. A trolley to receive and transport the container further will be useful.

4.27 The container holding the unit batch, having been removed from either the preconditioning room or cabinet, will then be loaded into the sterilizer chamber. On cycle completion, including initial gas removal, the unit batch will be unloaded and transported directly to a purpose-designed aeration room or cabinet. Where an aeration cabinet is used it may be located within an aeration room or within the sterilizer loading room.

4.28 To preserve the safe environmental conditions required for this room, a hood should be mounted above the door of a sterilizer. The threshold level from sources such as fugitive gases following door opening or failure of the gas removal system, must not exceed that given in the current edition of HSE Note EH40 'Occupational Exposure Limits'.[2]

4.29 The sterilizer control system must be interlocked with the hood ventilation system to ensure that the maximum extract is achieved before the door starts to

open. The extract should be set to run either continuously or for a pre-set period. In either situation the flow rate should be increased to at least 0.3 m^3/s just prior to the chamber door opening (see paragraph 5.12 below).

4.30 End-of-cycle flushing should be included to reduce the concentration of ethylene oxide gas present in the free chamber space to a level that allows the chamber door to be opened with safety to the operative. While it is possible to aerate the sterilizer load within the sterilizer chamber, for operational considerations this should be supplemented by using a purpose-designed aeration room or cabinet.

4.31 For large sterilizers with an ethylene oxide supply from cylinders, it is recommended that a gas monitoring instrument be installed at a position which reflects personnel exposure, in order to alert operators should the level rise above the occupational exposure limits. The instrument should be suitable for measuring ethylene oxide concentrations in air with an accuracy of ± 10% at 8 parts per million. A multi-channel gas analyser with linked sensor probes located in other rooms namely the aeration, sterilizer plant, and cylinder and manifold rooms, should be considered.

4.32 Clear instructions on the use of the sterilizer, and emergency procedures, must be on prominent display. Access to this space should be restricted to personnel trained in the use of the sterilizer.

4.33 Where appropriate, secure storage for the 100% ethylene oxide single-shot canisters, sufficient for only one day's work, is required.

4.34 For large sterilizers with an ethylene oxide supply from cylinders, safety equipment, in the form of protective goggles and a respirator, should be held in this space.

4.35 Ventilation will be necessary and must take account of the heat emissions generated from the sterilizer, and other cabinets when located within this space. The air pressure of the sterilizer loading room should be negative with respect to all surrounding spaces, other than the sterilizer plant, aeration and quarantine rooms.

4.36 Operation of the multi-channel gas analyser should be such that in the event of a failure in the ventilation system, the sterilizer should shut down while the failure exists and it should not be possible to initiate a cycle. If the cycle is already in progress at a stage where ethylene oxide has been admitted to the chamber, access to the load should be prevented until the fault has been rectified.

Aeration, degassing and quarantine room(s)

4.37 *Function*

a. provide an environment at a predetermined temperature and relative humidity, in order to aerate product following sterilization;

b. hold product in quarantine until biological monitor clearance has been obtained;

Location

a. direct access to the ethylene oxide sterilizer loading room;

b. secure access to the main circulatory corridor to processed goods store.

4.38 Following sterilization and initial gas removal, a container holding a unit batch load will be transferred to one of the following situations where aeration can occur:

a. an aeration cabinet in the sterilizer loading room;

b. a purpose-designed aeration room;

c. an aeration cabinet in the degassing and quarantine room;

d. a combined aeration, degassing and quarantine room.

4.39 Choice will be determined according to local need and policy. However, as a rough guide, if throughput is such that a single batch of product cannot aerate and complete its period of quarantine before the next batch is ready to begin the process, then multiple aeration facilities (suitably-sized, purpose-designed room(s) or more than one aeration cabinet) are required.

4.40 In larger installations, the provision of two or more aeration cabinets in either the sterilizer loading room or the degassing and quarantine room is acceptable as an alternative to the need for a specific aeration room. Alternatively, where a combined aeration, degassing and quarantine room is provided, product batches must be arranged so that the newest are downstream of the airflow in the room. This option is least favoured because of the continual need to re-arrange all the batches each time a new one arrives or a released batch is removed to the processed goods store.

4.41 A crucial aspect of the aeration and degassing function is the safe discharge of the gas venting from the unit batch load. Differing types of packaged product will require differing aeration times and may take at least 15 hours. The aeration cabinet is probably more easily controlled and may therefore be the preferred choice. The control system of an aeration cabinet must be interlocked with the exhaust hood ventilation system to ensure that

the maximum extract is achieved when the sterilizer door opens and until the aeration cabinet door is closed. The extract should be set to run either continuously or for a pre-set period. In either situation the flow-rate should be increased to at least 0.3 m^3/s just prior to the sterilizer door and, where appropriate, the aeration cabinet door, opening.

4.42 A wire rack system is recommended, to aid free circulation of air, within an aeration and/or degassing and quarantine room(s).

4.43 Once packaged product has been sufficiently aerated, the unit batch must continue to be held for a period of quarantine to await clearance of the associated biological monitor tests. Following receipt of clearance, the product can then be transferred to the main processed goods store.

4.44 The air pressure of the aeration and/or degassing and quarantine room(s) should be negative with respect to all surrounding spaces except the sterilizer plant room. Environmental limits should conform with the guidance given in the current edition of HSE Note EH40 'Occupational Exposure Limits'.[2] A sensor probe, linked to the multi-channel gas analyser located in the sterilizer loading room, will monitor the concentration level of ethylene oxide gas present in the environment.

4.45 The room temperature should be maintained within a specified temperature band and should not normally exceed 55°C. A temperature recorder is required and its temperature sensor should be located at the coldest point and the recorder positioned outside the room, but remaining within the section.

4.46 Following validation of each unit batch, degassing should be carried out at the maximum temperature permissible, taking into account the accuracy of the control system.

4.47 Entry to/exit from the degassing and quarantine room to/from a linking circulation corridor located outside the section must be secure and used only by authorised personnel.

Sterilizer plantroom

4.48 *Function*

a. accommodate an ethylene oxide sterilizer;

b. maintenance and repair of sterilizer;

c. provide safety equipment;

Location

a. adjacent to the sterilizer loading room;

b. close to the manifold and cylinder room;

c. one wall or the roof should be external.

4.49 The sterilizer plantroom, containing the body of the ethylene oxide sterilizer, should have four walls. Adequate explosion relief should be provided through incorporating a blow-out panel in an external wall or the roof. A sterilizer plantroom is not required for a transportable sterilizer.

4.50 This space should be maintained at negative pressure with respect to all adjacent spaces and should have a minimum of 10 air changes per hour. The access door lock and ventilation system should be interlocked, to prevent access to the plant room unless the ventilation system is operative. A system must be fitted to provide an increase in air flow whenever the level of ethylene oxide gas exceeds the current long-term exposure limit (eight-hour time-weighted average reference period) which is currently 5 ppm. A sensor probe, linked to the multi-channel gas analyser located in the sterilizer loading room, will monitor the concentration level of ethylene oxide gas present in the environment.

4.51 Access to the sterilizer plantroom must be restricted to maintenance staff and personnel trained in the use of the sterilizer. Since the airborne concentration of ethylene oxide could exceed the levels given in the current HSE Note EH40 'Operational Exposure Limits',[2] protective goggles and a respirator should be available outside this space to allow a member of staff to put on prior to entering the plantroom.

4.52 Where ethylene oxide gas is discharged to the environment it should be at a safe level, with no possible risk of re-entering any building or air intakes, and away from pedestrian traffic. Where this is not possible, consideration should be given to reducing the discharge of ethylene oxide gas to the environment by fitting an incinerator, a catalytic converter or scrubber as follows:

a. using a method of incinerating or catalytically converting the gas and recycling the heat for use in both the preconditioning and aeration rooms;

b. using an ethylene oxide scrubber, which operates by discharging the ethylene oxide gas stream through a packed column of ceramic saddles against a counter-current of water. Ethylene oxide gas dissolves in the water and is then discharged to a sealed vented drain.

This equipment will normally be supplied by the sterilizer manufacturer. For additional information see HTM 2010 - 'Sterilization': Design considerations.[4b]

4.53 Safety equipment, in the form of protective goggles and a respirator, should be held readily available in this space.

4.54 A piped water supply should be sited adjacent to the area for use in the event of liquid ethylene oxide spillage.

Cylinder and manifold room

4.55 *Function*

a. accommodate ethylene oxide gas cylinders in a safe environment;

b. change cylinder and connect supply to manifold;

c. provide safety equipment;

Location

a. near the sterilizer plantroom.

4.56 The cylinder and manifold room should be secure, protected from the elements and separate from the sterilizer plantroom. Where a transportable sterilizer is used, this space will not be required.

4.57 This room should be used solely for the containment of ethylene oxide cylinders, manifolds, pipework and safety equipment.

4.58 Adequate explosion relief should be incorporated by providing a roof of lightweight, pliable material.

4.59 In order to minimise the risk in the event of an explosion, and to provide access in an emergency, the cylinder and manifold room must be located on an outside wall.

4.60 The space must be protected from possible accidental damage by road vehicles by providing a wall, crash barrier or bollards located approximately one metre from the main wall of the cylinder and manifold room.

4.61 A piped water supply should be sited adjacent to the area for use in the event of liquid ethylene oxide spillage.

4.62 Gas pipes from the manifold in the cylinder room to the sterilizer should be fitted with a non-return valve, constructed of stainless steel and lagged.

4.63 Valves should be fitted to allow the ethylene oxide to be turned on and off. Guidance for this is given in 'Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use' - IEC 101 0.[8]

4.64 Space needs to be provided to hold a set of replacement cylinders.

4.65 Pressure-relief valves must be fitted in any section of the pipework where the pressure can exceed the safe level, to act as a relief valve should the pressure in any of the cylinders rise to an unacceptable level, as recommended in BS6759:Part 2 - 'Safety Valves'.[9] Discharge of the gas should be in accordance with the details given in paragraph 4.52.

4.66 Purging the air out of the pipelines, either by using a cylinder containing nitrogen or by operating shortened cycles to remove the air will be required.

4.67 The maximum temperature in the cylinder store should be that recommended by the gas supplier/ manufacturer. Normally this should not exceed 38°C with a minimum of 10°C. Temperature-controlled water heating should be provided in the event of low temperature. A sensor probe, linked to the multi-channel gas analyser located in the sterilizer loading room, will monitor the concentration level of ethylene oxide gas present in the environment.

4.68 Safety equipment in the form of protective goggles, gloves and a respirator should be held both inside this space and also be available at point of entry, outside this room.

Processing room

4.69 *Function*

a. load and unload preconditioning cabinet(s);

b. load and unload ethylene oxide sterilizer;

c. hold one day's stock of single-shot canisters of 100% ethylene oxide (where appropriate);

d. test sterilization process and keep records;

e. load and unload aeration cabinet(s);

f. maintenance of sterilizer and cabinets;

g. provide safety equipment;

Location

a. adjacent to packing room, with pass-through facility;

b. adjacent to sterilizer plantroom (where appropriate);

c. adjacent to degassing and quarantine room.

4.70 In response to local operational practices and volume of product, project teams may elect to provide a processing room where a preconditioning cabinet, or cabinets, and an aeration cabinet, or cabinets, share an activity space with the sterilizer loading function.

4.71 The sterilizer may be recessed, located on a bench or mounted on a rack shared with the aeration cabinet.

4.72 A transportable or rack-mounted sterilizer eliminates the need for both the sterilizer plantroom and the cylinder and manifold room. Some large built-in sterilizers will require a sterilizer plantroom, others will not. Regardless of the size, type and manufacturer of sterilizer chosen, the need to provide a packing room and a quarantine room remains.

4.73 The volume of product to be sterilized daily generally influences the size and type of sterilizer selected.

4.74 A container holding a unit batch will be received from the packing room via a double pass-through hatch. A trolley to receive and transport the container within the processing room will be helpful.

4.75 Each unit batch will be retained as a batch and should only be transferred from the packing room when the preconditioning cabinet is free to receive it.

4.76 Each unit batch should only be unloaded from the preconditioning cabinet when the sterilizer chamber is empty and free to receive the next load for sterilization.

4.77 On cycle completion, including initial gas removal from the sterilizer chamber and flushing, the unit batch will be unloaded, transported directly to the aeration cabinet and loaded into it.

4.78 On completion of the aeration process the unit batch will be unloaded from the cabinet and transported directly to the degassing and quarantine room, to await clearance of the required biological monitor tests. Only on receipt of clearance can the product then be transferred to the main processed goods store.

4.79 The workflow pattern within the processing room should aid the separation of the three main activities being undertaken, providing a forward movement from preconditioning to sterilizer loading and then to aeration. Cross-routing and back-tracking of the workflow pattern should be avoided.

4.80 To preserve the safe environmental conditions required for this room, the guidance given in paragraphs 4.27, 4.28, 4.29 and 4.30 should be followed where a large sterilizer operating under positive pressure, using a mixture of ethylene oxide and inert gas, is selected.

4.81 Where a transportable sterilizer operating at negative pressure, using 100% ethylene oxide supplied from a single-shot canister is chosen, the guidance given in paragraphs 4.29 and 4.30 should be followed.

4.82 Where appropriate, secure storage for 100% ethylene oxide single-shot canisters, sufficient for one day's work, is required.

4.83 Clear instructions on the use of sterilizers and cabinets, and on all emergency procedures, must be on prominent display.

4.84 Access to the processing room should be restricted to personnel trained in the use of the equipment.

4.85 Safety equipment, in the form of protective goggles and a respirator, will not be required when a transportable sterilizer using single-shot canisters is selected.

4.86 The ventilation provided should take account of the heat emission generated from the sterilizer and the cabinets located in this space.

4.87 The air pressure of the processing room should be negative with respect to surrounding areas, other than the degassing and quarantine room and the sterilizer plantroom, where a plantroom is provided.

4.88 Further requirements for the processing room are given in BS5345.[11]

5.0 Engineering services

Introduction

5.1 This chapter complements the guidance contained in Chapter 6 of HBN 13 and seeks to avoid duplication by focusing on those aspects, mostly ventilation, associated with ethylene oxide. It should be read in conjunction with HTM 2010[4] and the other documents listed in the references section and bibliography.

5.2 The guidance applies to:

a. transportable sterilizers of 150-200 litre capacity designed to use 100% ethylene oxide single-shot canisters of nominal capacity 134 g;

b. larger sterilizers designed to use ethylene oxide pre-mixed in cylinders with inert gases, such as carbon dioxide (minimum 90% carbon dioxide) or nitrogen.

5.3 The guidance does not apply to sterilizers which use 100% ethylene oxide from tanks and cylinders.

5.4 This guidance reflects risk under single fault conditions in accordance with IEC 1010 - 'Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use', Part 1: "General Requirements" [8a] and Part 2: "Particular Requirements for Autoclaves and Sterilizers using Toxic Gas for the Treatment of Medical Materials, and for Laboratory Processes". [8b]

Ventilation

General

5.5 The following ventilation systems will be required:

a. mechanical ventilation for staff comfort;

b. mechanical ventilation for safety and process requirements;

c. local exhaust ventilation from sterilizer and aeration cabinet exhaust hoods to remove "fugitive" emissions to a safe location;

sterilizer chamber exhaust ventilation and/or drainage ventilation to atmosphere.

Packing room

5.6 The packing room mechanical ventilation system should be designed to ensure that, when the space is tested in accordance with Part 1 of BS5295[3] in the "unmanned condition", the particulate count and air pressure difference are to the standard specified for Class L environmental cleanliness. While the design may provide a supply only to this room and allow the air to pass to the main packing room and the sterilizer loading room, the air pressure in both packing rooms should be similar, see paragraph 3.26.

5.7 The temperature and relative humidity in the packing room should be selected with staff comfort in mind.

Preconditioning room/cabinet

5.8 The temperature and relative humidity in the preconditioning room/cabinet should be controlled and adjustable within ranges of 30-50°C and 40-80% RH respectively. To ensure uniformity between the load and room/cabinet, mechanical re-circulation of the air is required. The values chosen will normally be as close as possible to the temperature and relative humidity required at the end of the conditioning stage of the sterilization cycle.

Sterilization areas (loading, plant, aeration rooms)/ processing room

5.9 The sterilizer loading and plantroom ventilation system should provide a minimum of 10 air changes per hour and be fitted with a flow-measuring device in the supply and extract duct to activate an alarm when the flow drops below this level. If the supply and extract rate drops below 10 air changes per hour this device should also prevent the sterilizer door from being opened if a cycle is in operation and also prevent the start of a new operating cycle.

5.10 Figure 5 illustrates diagrammatically how the ventilation system relates to a transportable sterilizer installation using 100% ethylene oxide at a negative pressure. While the figure shows separate cabinets, the preconditioning and/or aeration stages may occur within the sterilizer or a purpose-designed room(s).

5.11 Similarly, Figure 6 Illustrates an installation using a large sterilizer and shows a separate room for each function. As an alternative to a purpose-designed aeration room, aeration may be carried out in cabinet(s) located within the sterilizer loading area. In the latter case, the exhaust ventilation may be as indicated in Figure 5.

5.12 The local exhaust ventilation (LEV) should provide a flow rate of at least 0.3 m^3/s from the hood located above the sterilizer door and 0.3 m^3/s from the hood

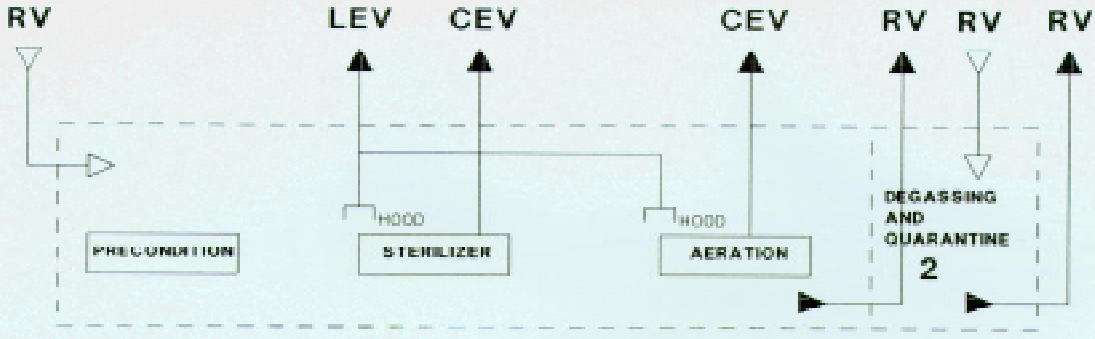

Figure 5 NOTIONAL VENTILATION FOR A SMALL TRANSPORTABLE STERILIZER

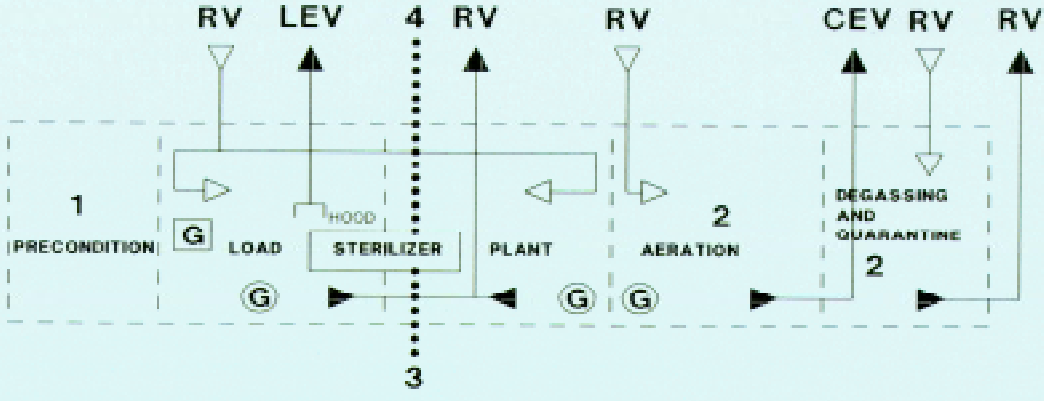

Figure 6 NOTIONAL VENTILATION FOR A LARGER POSITIVE PRESSURE STERILIZER

Key:

CEV	chamber exhaust ventilation
LEV	local exhaust ventilation
RV	room ventilation
▷	supply
▶	exhaust
Ⓖ	gas detector
G	gas monitor and alarm
1	temperature and humidity control
2	temperature and ventilation control
3	drain
4	drain ventilation

located above the door of the aeration cabinet. Where the hoods are combined, the combined flow rate should be at least 0.3 m^3/s. This system should also be fitted with a flow-measuring device in the extract duct. This device should be connected to the sterilizer and aeration cabinet to prevent the door(s) opening before the flow reaches 0.3 m^3/s. The system should remain energised for a pre-set period adjustable up to 30 minutes. If the flow drops below 0.3 m^3/s an alarm should sound. The method of interconnection between the sterilizer/aeration cabinet and the control device should be in accordance with the sterilizer/aeration cabinet manufacturer's recommendations.

5.13 The LEV control sequence should be as follows:

a. at the end of the sterilization or aeration cycle, prior to the sterilizer or aeration cabinet door opening, LEV is energised (free volt contact provided by sterilizer manufacturer);

b. when the flow reaches 0.3 m^3/s, the door open circuit is energised (free volt contact provided by ventilation contractor);

c. a timer range O-30 minutes is energised. This is connected to ensure that the LEV remains energised for a limited period from the start of door opening;

d. should the door be closed before the end of the limited period, the LEV remains energised for the remainder of the period;

e. the sequence should be repeated before the door is re-opened;

f. when the flow falls below 0.3 m^3/s an alarm should be energised.

5.14 The flow characteristics for each system or systems in combination must ensure that the long-term exposure limits set by the HSE in their annual publication EH40 - 'Occupation Exposure Limits'[2], is not exceeded. Air movement should be from the operator towards the sterilizer and/or aeration cabinet.

5.15 The room ventilation (RV), local exhaust ventilation (LEV) and chamber exhaust ventilation (CEV) systems should be physically separate, non-recirculating, and operate independently of each other.

5.16 The LEV and CEV ducting should operate at a negative pressure with respect to the areas through which they pass. This will normally require an extract fan to be located at the discharge end of the ductwork. This discharge should be located at least two metres above the building and positioned to ensure that there is no possible risk of the discharge re-entering any building through windows, air-conditioning intakes, etc.

5.17 The CEV on transportable sterilizers should be designed to remove ethylene oxide from the chamber during the gas removal stage and throughout aeration where this is included in the cycle.

5.18 The CEV for the aeration cabinet/room should be independent of other ventilation systems and be energised whenever an aeration cycle is in operation. If a room is used, the temperature and ventilation should be controlled within adjustable ranges, ambient temperature to 55°C and nominally zero to ten air changes per hour respectively.

5.19 Flow-measuring devices should be fitted in each extract duct (CEV, LEV, RV), and connected to prevent the sterilizer door from being opened while a cycle is in operation should a ventilation system fail. Similarly, devices should also be connected to prevent the aeration cabinet/room door from being opened. Where a room is provided, it must always be possible to open the door from within.

5.20 The sterilizer plantroom should be maintained at a negative pressure relative to all areas. The aeration room should be negative relative to the sterilizer loading room and the sterilizer loading room should be negative relative to other areas.

5.21 The design should ensure that the ventilation systems are in balance and maintain the pressure distribution illustrated in Figure 7.

5.22 The relationship between the volume of a room in which transportable sterilizers using single-shot canisters of 100% ethylene oxide are used, and the number of air changes required to reduce the concentration of ethylene oxide to 5 ppm when a standard 134 g canister is discharged into the room, is shown in Figure 8.

Cylinder and manifold room

5.23 Where a cylinder and manifold room is required on larger installations, it should be naturally ventilated and the design should ensure that it is normally subject to 10 air changes per hour. Local mechanical extract ventilation over the manifold should be provided and operate during cylinder change to control the level of ethylene oxide to the limits set by the HSE in the current edition of HSE Note EH40 'Occupational Exposure Limits'.[2]

5.24 The gas supply pipework connecting the manifold to the sterilizer should be seamless stainless steel and be fitted with a manual and automatic stop valve. The automatic valve should close whenever the gas or fire alarm system is activated.

Cold water services

5.25 Guidance is contained in HBN 13,[1] but it should be noted that a cold water outlet is required in the

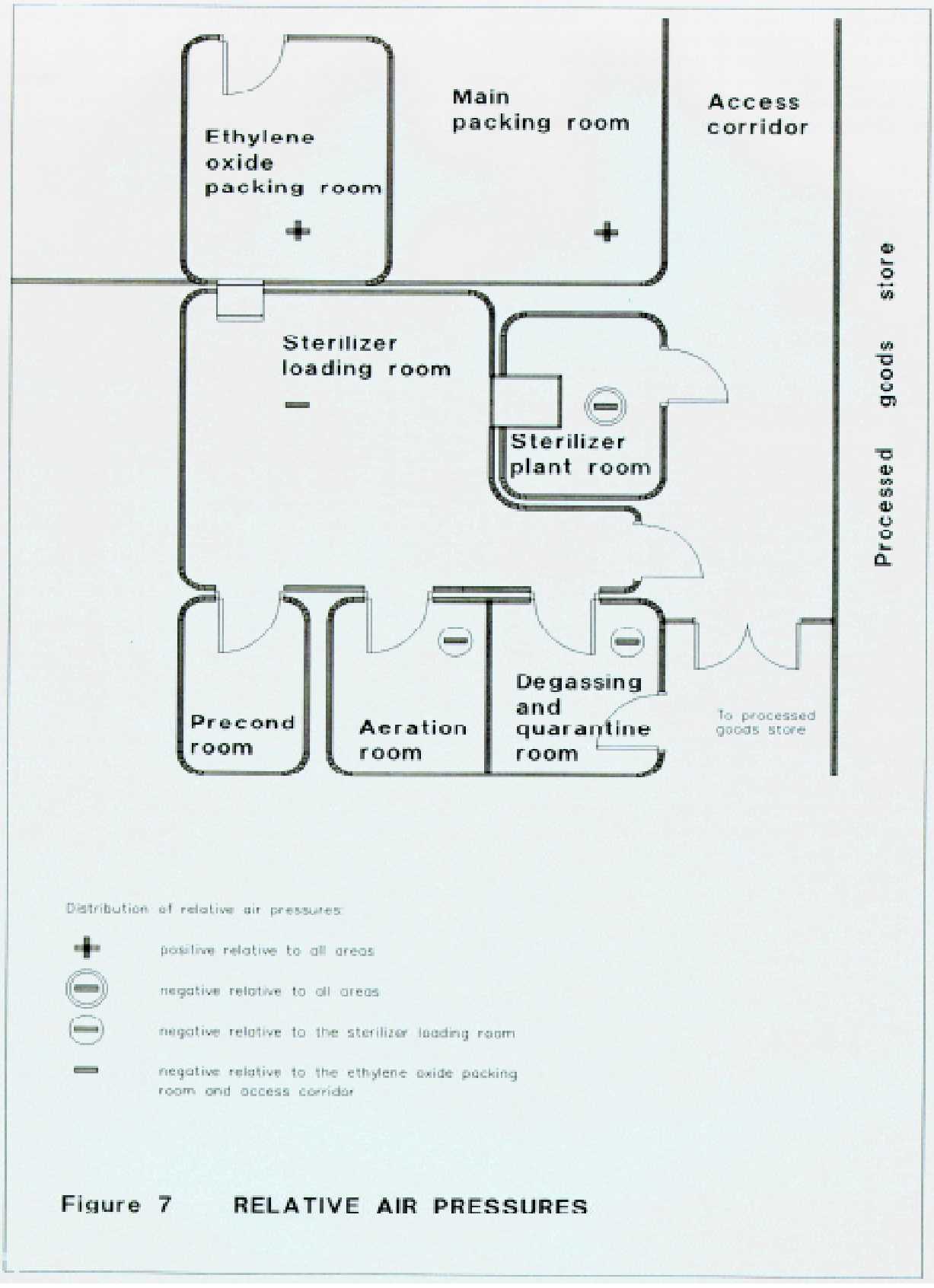

Figure 7 RELATIVE AIR PRESSURES

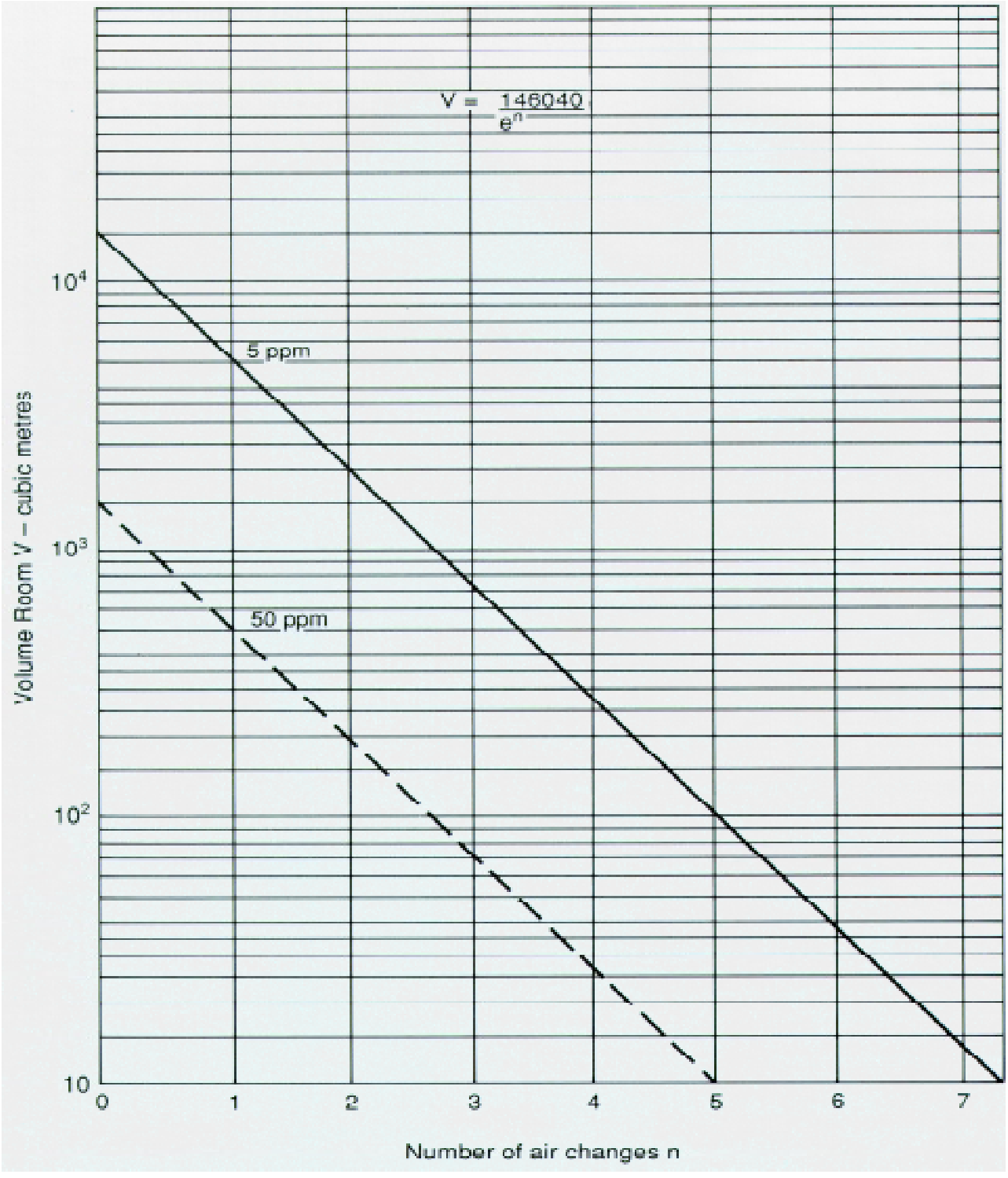

Figure 8 - Air changes required to reduce the concentration of ethylene oxide to 50 ppm and 5 ppm following the sudden release of 134 g of the gas into the workroom

proximity of the plantroom and the cylinder and manifold room. Precautrons should be taken to prevent freezing of any externally located supply.

Heating

5.26 Space heating guidance is contained in HBN 13.[1] The temperature in the cylinder and manifold room should be in accordance with the gas manufacturer's recommendations.

Ethylene oxide storage

5.27 Ethylene oxide should be stored as follows:

a. stock cylinders and canisters should be stored in main external store reserved for flammable Indus gases;

b. storage in the manifold room should be restricte one replacement set for the cylinder set in servi

c. canisters for immediate use may be held in a suitable cabinet in the sterilizer loading room or processing room.

5.28 All storage should be in accordance with the manufacturer's recommendations.

Compressed air

5.29 The quality and quantity of compressed air should be in accordance with the manufacturer's recommendations. For transportable sterilizers this will nominally be 2 l/ s at STP, supplied at 4 bar. See also HTM 2010 "Design considerations".[4b]

Electrical installation

5.30 The building electrical installation should be in accordance with BS7671 - 'Requirements for electrical installations', IEE Wiring Regulations 16th Edition.[10] Sterilizers should comply with IEC 1010 - 'Safety requirements for electrical equipment for measurement, control and laboratory use'.[8]

5.31 Electrical equipment should be mounted external to the ventilation ducts.

5.32 For the range of ethylene oxide sterilizers used in the NHS, interlocks between each ventilation system and the ethylene oxide sterilizer are sufficient to extensively reduce the risk of an explosive mixture occurring within the sterilizer loading and plantrooms and for this reason the need for the type of electrical protection defined in BS5345:Part 1,[11] Table 1 does not arise.

Environmental gas monitors

5.33 Ethylene oxide gas detection equipment is not required for installations where transportable sterilizers use single-shot gas canisters, see paragraph 2.25.

5.34 Ethylene oxide gas detectton equipment and alarms must be fitted in larger installations in the following locations, where appropriate:

a. sterilizer loading area;

b. sterilizer plantroom;

c. aeration room;

d. cylinder and manifold room.

5.35 Sensors should be located in positions which reflect personnel exposure and be connected to an Instrument located in the sterilizer loading room. In order to limit the number of Instruments required, a multi-channel scanning type is preferred, see paragraph 4.31.

5.36 The instrument should cause an alarm to sound and the local exhaust ventilation (LEV) system to be energised, should the level of ethylene oxide measured in the environment exceed a set level. This will normally be the maximum exposure limit (MEL) contained in the current edition of HSE publication EH40.[2] However, the gas sensor in the aeration room may need to be connected to a separate monitor so that the MEL can be set to a higher level in order to prevent alarms being activated due to instantaneous peaks occurring in this room.

Fire precautions

5.37 Fire precautions should be in accordance with the Firecode series of documents [6] and paragraph 3.5 of this supplement.

5.38 An automatic fire detection and alarm system should be provided in accordance with HTM 82[6b] and paragraphs 3.5-3.18 of this supplement.

5.39 A fire hydrant should be provided in accordance with HTM 81[6a] and its location agreed with the local fire authority.

Internal drainage

5.40 The drain from an ethylene oxide sterilizer should be independent from other drains and be connected to the main drain through a sealed trap. The connectron to the main drain should be vented to high level above the buildings, see paragraph 5.16. Similarly, other vents and drains must not be connected to the sterilizer vent pipe.

6.0 Cost information

Introduction

6.1 For all types of health buildings, it is important that building costs and revenue expenditure are kept as low as possible, consistent with acceptable standards. Within this general context, Health Building Notes provide a synopsis of accommodation for health buildings which the Department of Health, in association with NHS Estates and the National Health Service, recommends for the provision of a given service.

Works cost

6.2 To prepare an estimate of the works cost for a scheme, reference should be made to the Capricode Health Building Procedures Manual (Chapter 1, Stage 1, Annex 1(c)).[12] The total cost allowance for a scheme is derived by aggregating the cost of the functional units and Optional Accommodation and Services (OAS) as appropriate to the particular scheme.

6.3 The cost allowances cover the building and engineering requirements set out in this supplement. In costing the functional unit, it has been assumed that the ethylene oxide sterilization section will be located within the sterile services department where the common use of services will be available.

Functional unit

6.4 The functional unit for the ethylene oxide sterilization section is the sterilizer. Two sizes have been costed comprising either a large built-in unit using cylinders with a full complement of support rooms or, alternatively, a smaller transportable model which uses single-shot canisters. The activity spaces and areas used for costing the functional unit are listed in the schedule of accommodation at the end of this chapter.

Dimensions and areas

6.5 In determining spatial requirements, the essential factor is not the total area provided but the critical dimensions, that is, those dimensions critical to the efficient functioning of the activities which are to be carried out. To assist project teams in preparing detailed design solutions for the rooms and spaces, studies have been carried out to establish dimensional requirements in the form of critical dimensions. The result of these studies appear as ergonomic diagrams in HBN 40 - 'Common activity spaces'.[13]

6.6 For development planning and at the earliest stage of a design, it may be convenient for designers to have data available which will enable them to make an approximate assessment for the sizes involved. For this reason, the areas prepared for the purpose of establishing the cost allowances are Included at the end of this chapter.

6.7 It is emphasised that the areas published **do not** represent recommended sizes, nor are they to be regarded in any way as specific individual entitlements.

Circulation

6.8 Space for circulation, which includes allowances for planning provision, an engineering zone adjacent to the external walls, small vertical ducts and partitions, is shown in the schedule of accommodation and is included in the cost allowances.

Communications

6.9 Starr-cases, lifts and plantrooms, with the exception of an electrical switchcupboard, battery cupboard and a standard enclosure for medical gas isolation points, are not included in the cost allowances.

Engineering services

6.10 The following engineering services, as described in Chapter 5 and exemplified in the activity data, are included in the cost allowances. Primary engineering services are assumed to be conveniently available at the boundary of the department:

a. mechanical services

(i) heating;

(ii) ventilation: including dedicated ventilation plant and a share of the central refrigeration plant;

(iii) cold water;

(iv) fire main;

(v) compressed air;

(vi) automatic controls;

b. electrical services

(i) lighting system;

(ii) power system: socket-outlets, outlets for equipment, supplies for ventilation plant;

(iii) alarm system: fire, security, gas detection;

(iv) earth bonding of extraneous metalwork.

c. equipment (Group 1):

(i) sterilizer;

(ii)preconditioning cabinet;

(iii) aeration cabinet;

			Small sterilizer		Large sterilizer	
Para. no	Activity space	Space area m^2	Qty	Total area m^2	Qty	Total area m^2
4.02	Packing room	**11.0**	1	**11.0**	1	**11.0**
4.11	Preconditioning room	**3.5**	1	**3.5**	1	**3.5**
4.20	Sterilizer loading room		-	-	1	**13.0**
4.37	Aeration room		-	-	1	**3.5**
4.48	Plantroom		-	-	1	**8.5**
4.55	Cylinder and manifold room		-	-	1	**2.5**
4.69	Processing room	13.0	1	13.0		-
4.37	Degassing and quarantine room		1	**11.0**	1	8.0
	Net total			**38.5**		**50.0**
	ADD - planning provision		5%	**1.9**	5%	**2.5**
		Total		**40.4**		**52.5**
	ADD - engineering zone		3%	**1.2**	3%	**1.6**
	ADD - circulation		26%	**10.5**	26%	**13.7**
		Total		**52.1**		**67.7**
	Departmental areas			50.0 **m²**		**70.0** **m²**

Note

Local operational policy will determine the combination of rooms and cabinets selected for an ethylene oxide sterilization section. This combination may result in some of the activity spaces listed above not being required, principally through the use of cabinets, while other activity spaces may need to be larger in order to house the cabinets. It may therefore be necessary for project teams to adjust the activity space areas accordingly.

7.0 Activity Data

Introduction

7.1 The term "activity data" refers to an information system developed to help Project and Design teams by defining the users' needs more precisely. This information constitutes the computerised Activity DataBase. It comprises three types of information sheet: activity space data sheets (known as A-Sheets), their supporting activity data sheets (known as B-Sheets), and A-Sheet component listings (known as D-Sheets). The data is updated twice-yearly.

7.2 A-Sheets record in more detail than is described in this HBN each task or activity that is performed in a particular activity space (which may be a room, space or bay) together with details of the environmental conditions and the technical data necessary to enable the activities to be performed. Each A-Sheet also contains a list of the titles and code numbers of the relevant B-Sheets.

7.3 B-Sheets provide narrative text and graphics to scale relating to one activity. They show equipment fitted or supplied as part of the building, and the necessary engineering terminals. There are also "component B-Sheets" which show a range of particular components rather than an activity.

7.4 D-Sheets provide information about the total quantities of components (excluding those in Group 4) extracted from all the B-Sheets selected for inclusion in an individual A-Sheet.

7.5 Further information about the use and preparation of activity data can be found in the 'Guide to Activity Data Sheets and their use in health building schemes'. Potential users may obtain copies of the guide and an explanatory demonstration disk from NHS Estates, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE.

Activity data applicable to this HBN

7.6 The A-Sheets recommended for the activity spaces in this HBN are either new sheets, amended ones, or selected from existing sheets. A list of A-Sheet code numbers and titles is given in the following pages.

7.7 Further activity data sheets may be selected, or drawn up by project teams to their own requirements, for any services not described in the HBN or included in the list. Members of project teams are advised to contact NHS Estates for information and advice about the selection of activity data, at an early planning stage. However, in order to ensure consistent and economic provision, variations from the A-Sheets recommended for the spaces covered in this HBN should be considered only where it has been decided that the function of a space will substantially differ from that described.

List of activity data A-Sheets

7.8 **Note:** the activity data A-Sheets listed below may not carry a title identical to the activity spaces detailed in this HBN. Use of the appropriate A-Sheet code will, however, result in the correct activity space being accessed.

Activity space	A-Sheet code number	Paragraph no in HBN
Ethylene oxide packing room	R1006	4.2
Preconditioning room	R1007	4.11
Sterilizer loading room	R1009	4.20
Aeration room	R1018	4.37
Degassing and quarantine room	R1016	4.37
Sterilizer plantroom	K0309	4.48
Cylinder and manifold room	R1015	4.55
Processing room	R1017	4.69

Glossary of terms

The terminology used in DH 'Manufacturer Registration Scheme: Guidance on Ethylene Oxide Sterilization 1990'(7) has largely been adopted.

aeration: a part or parts of the sterilization process in which defined conditions are used, such that sterilant gas and its reaction products are desorbed from the load, and which may be performed within the equipment, in a separate room or enclosure, or by a combination of the two.

biological monitor: a preparation incorporating a specific number of viable bacterial spores of known resistance to the sterilization process.

commissioning: obtaining and documenting evidence that equipment installation follows design intentions, and that the equipment as installed will perform satisfactorily within predetermined limits (see also validation).

conditioning: treatment of product within the sterilization cycle, but prior to ethylene oxide admission, to attain a predetermined temperature and relative humidity throughout the load (see also preconditioning).

cycle completion: the point after completion of the sterilization cycle at which the load may be removed from the chamber.

degassing: the desorption of sterilant gas and its reaction products from the load by defined treatment outside the equipment after completion of the sterilization cycle.

flushing stage: the stage beginning at the end of the sterilant removal stage, when further sterilant is removed from the load and chamber by either:

a. multiple alternate admissions of filtered air or inert gas and evacuation of the chamber; or

b. continuous passage of filtered air or inert gas through the chamber.

preconditioning: treatment of the product prior to the sterilization cycle to attain both predetermined temperature and relative humidity throughout the load (see also conditioning).

preconditioning area: this may be a chamber or room in which preconditioning occurs. A room is defined as being an enclosed space capable of holding more product than can be accommodated in the sterilizer(s) at any one time. A chamber is an enclosed space which will accommodate only sufficient product to fill the sterilizer.

process: the stages to which the product is subjected to achieve sterilization from the point of receipt into, and despatch from, the sterile services department.

sterilization cycle: treatment in a sealed chamber comprising conditioning (if used), exposure to ethylene oxide, removal of ethylene oxide and flushing (if used).

sterilization load: the contents of a sterilizer chamber during one complete cycle. It may include more than one manufacturing batch or lot.

usable sterilizer chamber volume: the volume inside the sterilizer chamber which may be occupied by a full load.

validation: the exercise of carrying out a programme designed and documented to demonstrate that a process, operating within specified limits, will consistently produce product complying with predetermined specifications.

References

1 **Sterile Services Department (HBN 13).** NHS Estates, HMSO 1993. ISBN 011321412X.

2 **Occupational Exposure Limits (EH40).** Health and Safety Executive, 1993. (published annually)

3 **BS 5295:** Environmental cleanliness in enclosed spaces

Part 1:1989 Specification for clean rooms and clean air devices

4 **Sterilization (Health Technical Memorandum 2010):**

Management policy. NHS Estates, 1994.

Design considerations. NHS Estates (in preparation)

Validation and verification. NHS Estates, 1994.

Operational management. NHS Estates (in preparation)

5 **EN 30993** Biological evaluation of medical devices (European Standard)

Part 7 Ethylene oxide sterilization residuals. (Draft for comment 93/500349)

6 **Specific Firecode documents:**

6a **Fire precautions in new hospitals (HTM 81).** DHSS, HMSO 1987. ISBN 0113210825

Fire precautions in new hospitals (HTM 81) Supplement 1. NHS Estates, HMSO 1993. ISBN 0113214243

6b **Firecode: alarm and detection systems (HTM 82).** NHS Estates, HMSO 1989. ISBN 011321099X

7 **DH manufacturer registration scheme: guidance on ethylene oxide sterilization.** Department of Health, HMSO 1990. ISBN 0113212763

8 **IEC 1010** Safety requirements for electrical equipment for measurement, control and laboratory use. (International Electrotechnical Commission)

Part 1 General requirements

Part 2-042 Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes (in preparation).

9 **BS6759:** Safety valves

Part 2:1984 Specification for safety valves for compressed air or inert gases (AMD 5494, March 1987)

10 **BS7671:1992** Requirements for electrical installations. IEE Wiring Regulations. Sixteenth edition.

11 **BS5345:** Code of practice for selection, installation and maintenance of electrical apparatus for use in potentially explosive atmospheres (other than mining applications of explosive processing and manufacture)

Part 1:1989 General recommendations (AMD 7871, Sept 1993)

Part 2:1983 (1990) Classification of hazardous areas

12 **Capricode.** DHSS, HMSO 1986. ISBN 011761291X (currently under review)

13 **Common activity spaces (HBN 40):**

Vol 1 - Example layouts; common components. DHSS, HMSO 1986. ISBN 0113210477

Vol 2 - Corridors. DHSS, HMSO 1986. ISBN 0113210485

Vol 3 - Lifts and stairways. Department of Health, HMSO 1989. ISBN 011321197X

Vol 4 - Designing for disabled people. Department of Health, HMSO 1989. ISBN 0113211988

Bibliography

Emmerson, A M. **Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to Department of Health, Medical Devices Directorate.** Medical Devices Directorate, Department of Health, 1993.

EN 550 Sterilization of medical devices: validation and routine control of sterilization by ethylene oxide (European Standard) (Draft for Comment 91/57776).

Ethylene oxide: guidelines for bulk handling. Chemical Industries Assocration, 1992.

Ethylene oxide sterilizers: risk of environmental contamination (SIB(8)2). DHSS, 1983.

Glass, DC, Hall, AJ and Harrington, JM. **The control of substances hazardous to health: guidance for the initial assessment in hospitals.** Institute of Occupational Health, University of Birmingham, HMSO, 1989. ISBN 0113212623.

Guide to good manufacturing practice of National Health Services sterile services departments. Institute of Sterile Services Management, 1989.

Use and management of ethylene oxide sterilizers (SAB(90)63). Department of Health, 1993.

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