STERILIZATION, DISINFECTION AND CLEANING OF MEDICAL EQUIPMENT:

guidance on DECONTAMINATION from the Microbiology Advisory Committee to Department of Health Medical Devices Directorate

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It is intended to form the first part of a three-part publication. All recipients of Part 1 will receive Parts 2 and 3 automatically, as soon as they have been printed, for insertion in this binder.

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Foreword

This document has been prepared and endorsed by the Microbiology Advisory Committee (MAC) to the Department of Health. This Committee was established to advise the Department on disinfection and sterilization practices for application in the Health Service. Whilst much information in this area has been published, the MAC recognises a need for a single document to outline recommendations from a number of sources. This document attempts to meet this need. A sub-committee on decontamination of the MAC was established to prepare this document, which has subsequently been endorsed by the full Committee. The membership of the MAC and the sub-committee on decontamination are listed in the acknowledgements.

This document is not a replacement for the many detailed publications which it cites and from which it draws its information.

Independently, representatives of a number of professional groups within the Health Service recognised the need for guidance on the detailed methods to be employed to decontaminate the increasingly complex items of medical equipment which are used. This arose from: the need to establish safe systems of work to protect personnel from infection; the implications of the Consumer Protection Act; and the establishment of quality systems for the maintenance of medical equipment. The Decontamination Working Group was formed to prepare such guidance. Members of the Decontamination Working Group are listed in the acknowledgements.

The MAC and the Decontamination Working Group agreed to cooperate in providing suitable guidance, and this publication is envisaged as the first of a series which will form a manual on decontamination.

This publication forms Part I of the manual and describes the general PRINCIPLES of the processes which are available for decontamination.

Subsequent parts of the manual will be:

Part II: containing PROTOCOLS for decontaminating using cleaning, disinfection and sterilization processes.

Part III: describing PROCEDURES for the decontamination of specific items of equipment.

These parts will be published at a later date.
All personnel advising on, or performing, decontamination procedures should be aware of the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations, which came into force in 1989.

These Regulations require all employees to assess the risks from exposure to hazardous substances and the precautions needed to prevent or adequately control exposure. There are also requirements for providing information, instruction and training and in some cases for monitoring exposure and for health surveillance. The Regulations are of particular significance to those who select decontamination procedures, as their decisions whether to use specific materials or about the necessary control measures can greatly influence the effect on those who carry out this work.

PART 1

PRINCIPLES

Contents of Part 1

Introduction to Part 1

The importance of hospital associated infection, both economically and with regard to patient morbidity, is recognized both nationally[1,2] and internationally[3], and the role of decontamination procedures as part of the essential control measures has been well accepted for many years[4,5]. The consequences of failed heat sterilization may not be obvious; but, when hospital associated cases of tetanus occur, the sterilization process is often the first object of investigation. However, in the case of disinfection, the consequences of failure are well documented, many authors having described common source outbreaks related to chemical disinfectant misuse[6,7,8,9].

Many changes in decontamination methods have occurred during the last 20 - 30 years; these include development of automatic high pressure autoclaves, and the use of low temperature steam with formaldehyde, or ethylene oxide sterilizers as well as the introduction of new or modified disinfectants. While for most of the decontamination methods available the engineering and microbiological testing methods are well understood, practice in some hospitals and health care settings has not always been ideal. As early as 1958 the Nuffield Provincial Hospitals Trust Report described inefficient performance in 9 of 25 autoclaves examine[10]. More recent work indicates that hospitals still experience problems with decontamination procedures, and certainly in General Practice there have been difficulties[11], although advice produced by the British Medical Association (BMA) should do much to improve this situation[12].

The need for scrupulous attention to decontamination procedures has been highlighted both for medical and dental professions and the lay public by the advent of HIV infection, although there are differing views, even within the professions, about the ways to prevent transmission of this virus by equipment[13].

Problems may arise in all areas of the decontamination process, from the choice of the appropriate method for a piece of equipment, through plant maintenance, engineering and microbiological monitoring, to post-decontamination storage and handling. Individuals from a wide variety of disciplines may be responsible for different aspects of decontamination processes. The manual addresses all aspects of decontamination and is in three parts; this Part provides the general principles of decontamination, illustrated by some examples of basic decontamination equipment; Part II contains protocols for methods of decontamination of different types of medical equipment; and Part III contains the procedures and usage of particular instruments and materials. The guidance in Part I of this document is particularly targeted to the needs of Infection Control Doctors, Infection Control Nurses and Sterile Services Managers; but it is hoped that it will be of assistance to other groups.

Misuse of terms is a particular problem which besets this subject, and for that reason a glossary of terms is included.

The choice of decontamination method may be related to the infection risk associated with the intended use of the equipment, classified in table 1.

Advice on decontamination is already available in a number of documents[14-22]. The aim of this publication is to bring this advice together in a format which can be updated and in a way which will provide easily accessible information to health-care workers so that they can provide the high standards of decontamination required by modern medical and surgical practice.

The choice of decontamination method will also depend on many other factors including the nature of the contamination, the time required for processing, the heat, pressure, moisture and chemical tolerance of the object, the availability of the processing equipment and the quality and risks associated with the decontamination method.

Unconventional Slow Viruses

Few methods of sterilization or disinfection are effective in inactivating certain unconventional slow viruses, such as the causative agents of Creutzfeldt Jakob Disease (CJD), Scrapie or Bovine Spongiform Encephalopathy (BSE). It should not be assumed that the methods outlined in this publication are effective against such agents. Guidance on methods suitable for decontamination of material contaminated with these unconventional slow viruses has been issued by the Department of Health and Social Security in DA(81)22[23] and amended in DA(84)16[24].

TABLE 1: Classification of infection risk associated with the decontamination of medical devices

Risk	Application	Recommendation
High	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area	Sterilization
Intermediate	Items in contact with intact skin, mucous membranes or body fluids, particularly after use on infected patients or prior to use on immuno-compromised patients	Sterilization or disinfection required. Cleaning may be acceptable in some agreed situations
Low	Items in contact with healthy skin or mucous membranes or not in contact with patient	Cleaning

(Modified table from reference 15).

References

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24. Department of Health and Social Security. DA(84)16, *'Management of Patients with Spongiform Encephalopathy (Creutzfeldt-Jakob Disease (CJD))',* 1984.

Glossary of Terms

CONTAMINATION — the soiling or pollution of inanimate objects or living material with harmful, potentially infectious or other unwanted material. In the clinical situation, this is most likely to be organic matter and micro-organisms but may also include other undesirable inorganic substances eg dust, soil, chemical residues, radioactive material, degradation products, packaging materials etc. Such contamination may have an adverse effect on the function of the inanimate object and may be transferred to a susceptible host during use or subsequent processing and storage.

The degree of risk to the host will depend on many factors, including the nature of the investigative or therapeutic procedure, the susceptibility of the host and the nature and extent of the contamination. The nature and extent of microbial contamination is referred to as the BIOBURDEN.

DECONTAMINATION — a process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response.

CLEANING — a process which physically removes contamination but does not necessarily destroy micro-organisms. The reduction of microbial contamination cannot be defined and will depend on many factors including the efficiency of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite of equipment decontamination to ensure effective disinfection or sterilization.

STERILIZATION — a process used to render the object free from viable micro-organisms, including bacterial spores and viruses.

DISINFECTION — a process, used to reduce the number of viable micro-organisms, which may not necessarily inactivate some viruses and bacterial spores. Disinfection may not necessarily achieve the same reduction in microbial contamination levels as sterilization.

DISINFECTANT — a chemical agent which under defined conditions is capable of disinfection.

SPORICIDE — a chemical agent which under defined conditions is capable of killing bacterial spores.

1 Sterilization by Steam

Keywords

Physical method

Moist heat

Sterilization process

Process

Steam under pressure attains a temperature higher than that of boiling water at atmospheric pressure. Viruses, together with vegetative bacteria, and their heat-resistant spore forms treated in steam pressure vessels are rendered non-infectious and non-viable.

The process of steam sterilization requires direct contact between pure dry saturated steam (i.e. at phase boundary conditions) and the material being sterilized at the required temperature for the required time in the absence of air.

The recommended combinations of time and temperature were published by the Medical Research Council Working Party in 1959. The lowest temperature recommended was 121°C for a hold-time of 15 minutes. Detailed specifications of each type of steam sterilizer and sterilization process are given in the relevant pan' of BS 3970 and Health Technical Memorandum HTM10 respectively (see Table 2, page 10). The higher temperature of 134°C for 3 minutes is preferred for items which will withstand this temperature and associated pressure.

In the simplest steam sterilization cycle, air is removed by displacement with steam. This limits the use of such machines to sterilization of unwrapped, nonporous items only.

Porous load sterilizers have an operating cycle which incorporates a vacuum-assisted air removal stage prior to steam admission for sterilization and can therefore be used for wrapped goods. An air detector is incorporated to monitor the adequacy of the air removal process.

Preferred Uses

The established method of choice for sterilization in health services is steam sterilization. It is commonly applied as a terminal sterilization process for previously cleaned items and bottled fluids. It also has practical use as a decontamination process to enable safe handling or disposal of contaminated items.

It may be applied to wrapped or unwrapped items, although care must be taken to use the type of sterilizer which has been designed and validated for the particular load. Appropriate care must be taken in loading the sterilizers to ensue optimal sterilizing conditions.

Exclusions

Items comprising any material which will *not* withstand exposure to temperatures of 121-138°C for the appropriate period at pressures greater than atmospheric, eg thermolabile plastics and fibreoptic endoscopes.

Not appropriate for waxes/oils, steam-impermeable powders and non-fluid items in sealed containers.

Steam sterilizers for unwrapped instruments and utensils are not suitable for porous loads and wrapped goods. The sterilization of equipment with a narrow lumen in sterilizers of this type requires careful consideration. Care is required to ensure that such equipment is positioned or supported to facilitate air removal. Guidance should be sought from the manufacturer of the equipment. See Department of Health, Safety Action Bulletins SAB(89)60 and SAB(89)73.

Equipment required

Steam sterilizers should comply with the requirements of British Standard BS 3970, Sterilizing and disinfecting equipment for medical products; Part 1, Specification for general requirements, 1990, plus the relevant part for a specific type of sterilizer, eg Part 4, 'Specification for transportable steam sterilizers for unwrapped instruments and utensils', or Part 3, 'Specification for sterilizers for wrapped goods and porous loads'.

The sterilizer may require a supply of piped steam or may generate steam by electrical heating from a water reservoir incorporated into the sterilizer (as is the case for most transportable sterilizers).

The equipment must perform an automatic cycle.

A door lock must prevent access whilst the vessel is under pressure.

Operating Procedure

The manufacturer's operating procedures should be followed precisely.

A typical operating cycle for the simplest steam sterilizer for unwrapped instruments and utensils is described as an example:

a) Sufficient water is added to the chamber or steam generator for a complete operating cycle.

b) The water is heated and steam generated to vent air from the chamber until the sterilizing temperature is attained.

c) The sterilization temperature is held within specified limits for not less than the minimum hold time.

d) Steam is exhausted from the chamber or condensed within the chamber.

e) At the completion of a satisfactory cycle, and when the autoclave is safe to open, 'Cycle Complete' shall be indicated and the door may be opened.

Monitoring

The following instruments and indicators must be located so as to be clearly read by the operator:

a) chamber-temperature indicating thermometer
b) a chamber-pressure indicating instrument
c) an operating cycle stage indicator
d) an operating cycle counter
e) a fault indicator
f) a 'cycle complete' indicator.

Every sterilizer must be subjected to functional performance tests. Attainment of specified sterilizing conditions is indicated by independent physical measurement of temperature and time, i.e. by thermometric measurements. There should be at least one thermocouple entry connection fitted to the sterilizer vessel. Performancetests should be undertaken with thermocouples as described in HTM10 and BS 3970. (See Table 2, page 10).

Biological indicators are *not* appropriate for this process. There may be a limited role for chemical indicators which provide visual indication that a particular time/temperature relationship has been achieved, but such indicators are not substitutes for the specified physical monitoring of sterilizer performance.

Sterilizers incorporating a vacuum-assisted air removal stage are fitted with an air detector to monitor the adequacy of the air removal process. In addition, performance testing using a Bowie-Dick test (or recognised alternative test pack) is required at the beginning of each working day.

Maintenance of Equipment

The sterilizer must be maintained according to the manufacturer's instructions. In addition, maintenance requirements together with routine and commissioning performance tests are described in HTM10 'Sterilizers'. (See Table 2, page 10). The retention of all records and results listed in HTM10 is essential to the conduct of preventative and remedial maintenance. Appropriate log books must be kept.

Advantage of the Process

Steam is a non-toxic, non-corrosive and highly effective sterilizing agent. The steam sterilization cycle is controlled by physical parameters and can therefore be utilised as a rapid and fully automatic process. The cycle is arrested and signalled as failed in the event of a machine/process failure.

Disadvantage of the Process

The quality of steam for sterilization is critical and for larger machines a limiting factor may be the requirement for mains steam and performance of the steam boiler. Such disadvantages have generally been overcome in sterilizers designed to BS 3970 (1990).

The operator must wear suitable protection to avoid direct contact with excessively hot loads. Pipes should be lagged.

Spectrum of Action

Steam sterilization is effective, with a significant safety factor, against all micro-organisms.

Safety Notes

There are potential hazards associated with high temperature steam under pressure. These have generally been overcome by modifications and developments in the design and operation of sterilizers. The sterilizer must be designed to 'fail safe', so that the failure of any component or its associated services must not create a safety hazard (ie to BS 3970 specification).

The safety of the sterilizer's pressure vessel must be certified on purchase and verified by regular insurance inspections.

For items infected with dangerous pathogens in Hazard Group 4 (ACDP, 1990), additional precautions are needed in the design of the sterilizer's drainage and ventilation systems to protect users and the environment.

Key References

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3. British Standards Institution, *Sterilizing and disinfecting equipment for medical products,*
BS 3970: Part 1, Specification for general requirements, 1990;
Part 3, Specification for sterilizers for wrapped goods and porous loads, 1990;

Part 4, Specification for transportable steam sterilizers for unwrapped instruments and utensils; 1990.

Other parts in preparation include:

Part 2, Specification for sterilizers for fluids in sealed rigid containers.

4. Department of Health, Safety Action Bulletin No 51, SAB(89)60, *Transportable sterilization and disinfection equipment: Guidance on purchase,* September 1989.

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Sterilization by Hot Air 2

Keywords

Physical method

Dry heat

Sterilization process

Process

Recommended time/temperature combinations for dry heat sterilization are 160°C for 2 hours, 170°C for 1 hour or 180°C for 30 minutes (European Pharmacopoeia and British Pharmacopoeia). The efficacy of dry heat sterilization also depends on the initial moisture of the microbial cells.

Compared with moist heat sterilization, dry heat sterilization is inefficient.

Preferred Uses

The main advantage of dry heat sterilization is its ability to treat solids, non-aqueous liquids, grease/ointments, closed containers and items which could be damaged by steam or moist heat.

Exclusions

This process is not to be used for aqueous fluids or materials that are denatured or damaged at 160°C (e.g. intravenous fluids, glycerol/water mixtures, rubber, plastics).

Equipment Required

This process requires a purpose built non-pressurisedchamber, insulated against heat loss, and containing perforated shelving to permit circulation of hot air. Temperatures of up to 180°C will be produced by an electrical heater controlled by an independent adjustable thermostat. Even temperature distribution throughout the chamber is achieved by forced air circulation using a fan unit. The door must be capable of being locked, preferably by an automatic timed interlock designed to prevent the door being opened whilst a cycle is in progress. An overheat cut-out should befitted, designed to operate at a temperature not exceeding 200°C. A thermocouple port will enable the load temperature to be monitored using a chart recorder and temperature gauge. If the electricity supply is interrupted before a cycle is completed the process times should automatically reset to zero and require manual reset.

Operating Procedure

The oven should be preheated to the sterilizing temperature before loading.

a) All items to be sterilized should be thoroughly cleaned and dried before the process is started.

b) The chamber should be loaded so as to permit free air circulation.

c) Heavy instruments should be supported in a metal cradle to facilitate heating by conduction.

d) Delicate instruments, such as eye instruments, should be supported to guard against physical damage.

e) All glass or all metal syringes should be assembled and hinged instruments closed.

f) Kraft paper bags or a simple layer of wrapping material can be used to pack individual items. Aluminium tubes, tins, or foil can be used.

9) Items are placed on the shelves in such a way that hot air can freely circulate throughout the chamber. The fan should ensure uniform heat distribution.

Monitoring

The duration of the sterilization cycle is governed mainly by the heat-up and holding times.

Sterilization time starts when the sterilizing temperature has been reached in the load. Temperatures can be checked by using multiple thermocouples placed in various load units throughout the chamber. The manufacturer should carry out the basic performance test on delivery and the user should carry out a production load test.

Biological indicators such as spores are not used routinely for this process. Chemical indicators may be used to demonstrate that the packages have been processed. Chemical indicators provide a visual indication that a particular time/temperature relationship has been achieved, but such indicators are not substitutes for the specified physical monitoring of sterilizer performance.

Maintenance of Equipment

The hot air oven must be maintained according to manufacturer's instructions. In addition, maintenance requirements and routine commissioning and performance tests are described in Health Technical Memorandum HTM10. All electrical installation must be checked routinely by qualified electricians. Door seals must be maintained routinely and all instrumentation and charts checked and calibrated.

Advantages of the Process

Dry heat is a useful method for sterilizing heat stable powders, waxes and non-aqueous liquids. Non-aqueous liquids include white soft paraffin, paraffin gauze dressings, eye ointment bases, oily injections, silicone lubricant and pure glycerol.

Dry heat is a suitable method of sterilization for non-stainless metals, hollow needles and all glass syringes.

Disadvantages of the Process

The heat-up time varies widely with load volume and the type of material and is slow. Powders and oils have very long penetration times because they are poor conductors of heat. This means that loads must contain similar types and quantities of material.

The sterilization time is long and additional time is required for the items to cool to room temperature prior to use. Items must be able to withstand at least 160°C for periods of 2 hours or more.

Spectrum of Action

All items must be completely clean and dry prior to sterilization. Under these conditions all micro-organisms will be killed.

Safety Notes

The manufacturer's operating instructions must be read before use.

Items should not be removed from the oven unless heat protective gloves are worn. The contents may be very hot. Items must be allowed to cool before use.

Key References

1. British Pharmacopoeia, 1988.
2. Department of Health and Social Security, Health Technical Memorandum 10, *Sterilizers,* 1980.
3. European Pharmacopoeia, 2nd ed, 1990.
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Sterilization by Ethylene Oxide 3

Keywords

Gaseous method

Ethylene oxide

Sterilization process

Process

Ethylene oxide is a highly penetrative, non-corrosive agent which has a broad-spectrum cidal action against vegetative bacteria, spores and viruses under optimal conditions of concentration, relative humidity temperature and exposure time.

Ethylene oxide sterilization is usually carried out within the temperature range 20°C to 60°C and with operating cycles from 2 to 24 hours. Ethylene oxide is commonly used under the following three conditions:-

a) at sub-atmospheric pressures using undiluted ethylene oxide, or ethylene oxide with an inert diluent gas

b) ethylene oxide with a diluent gas (such as fluorinated hydrocarbons or nitrogen) at a pressure of 2 bar

c) ethylene oxide with diluent gas (such as carbon dioxide) at pressure up to 6 bar

At ambient temperatures and pressure, ethylene oxide vaporizes rapidly and is flammable in mixtures containing more than 3% vapour in air. It is also toxic, irritant, mutagenic and potentially carcinogenic.

Preferred Uses

Sterilization by ethylene oxide is restricted to wrapped and unwrapped heat sensitive materials. It is predominantly an industrial process used, for example, for single use medical devices constructed of plastics. Ethylene oxide sterilization has limited Health Service application within regional units. Care must be taken because of the hazards associated with its use. These include toxicity, flammability and explosion risks as well as the effects on patients of residual ethylene oxide in the product sterilized.

Exclusions

This process should not be used where heat sterilization of the item is possible.

The process is an inappropriate method for soiled items. Organic debris, oil and serum exhibit a marked protective effect. The process is contra-indicated for ventilatory and respiratory equipment.

Plastic wrapping films (eg ethylcellulose, polyvinyl chloride, polyethylene, cellophane) have varying permeability to ethylene oxide. The preferred wrapping is spun-bonded polyolefin (Tyvek ®) or sterilization paper.

Equipment Required

Sterilizers using ethylene oxide, or ethylene oxide mixtures, should comply with the requirements BS 3970: Part **1** (Specification for General Requirements). A European Standard for ethylene oxide sterilizers is in the course of preparation.

There are two main types of ethylene oxide machine currently used in a limited number of British hospitals.

a) High pressure sterilizer using **a** mixture of inert gases such as carbon dioxide. This greatly reduces the risk of flammability but increases the risk of gas escape from the chamber, pipework and cylinders. The gas cylinder requires replacement after 1 — 4 cycles. Cycle time 1.5 — 2.5 hours.

b) A sub-atmospheric process with gas supplied from a single-shot canister which is inside the chamber and is punctured automatically during the cycle. Pure ethylene oxide is used to maintain an optimal concentration. The chamber capacity is relatively small (115 litres). Cycle time 3 — 5.5 hours.

The Department of Health (see SAB(90)63) and the Health and Safety Executive have strongly discouraged the use of simple non-humidified and non-controlled table-top machines.

Operating Procedures

During a typical ethylene oxide sterilization cycle, the following stages are performed:

a) Air is removed from the load by a vacuum pump.

b) The chamber and its contents are heated to the required temperature eg 37°C or 55°C.

c) Steam is introduced to humidify the chamber and load.

d) Gas is supplied from a cylinder or canister, whilst maintaining the conditions of pressure and temperature specified for the sterilization hold period.

e) Gas is removed by evacuation with the pump.

f) The chamber is flushed with filtered air for **a** specified period before the load can be removed.

g) Aeration before release of the sterilized item is essential; the length of time is dependent on the absorbency of the processed item, the temperature and the air exchange rate in the storage facilities.

Monitoring

Monitoring of humidity, pressure and temperature with time is required, also monitoring of the amount of ethlyene oxide used.

A performance test of the achievement of the physical parameters (humidity, pressure, temperature, ethylene oxide concentration), declared by the manufacturer as the 'sterilization cycle parameters', must be undertaken on an unloaded chamber. As the meeting of the specified physical parameters does not guarantee sterility, it is necessary for the efficacy of the process to be validated microbiologically by the user for each type of load and for there to be microbiological monitoring of each cycle using biological indicators. Guidance on validation and routine control is outlined in the Department of Health publication 'Guide on ethylene oxide sterilization'.

Maintenance of Equipment

Care must be taken both in maintenance of the ethylene oxide sterilizer and in the supply and storage of gas in containers or canisters.

All aspects of the use of the gaseous agents and the sterilizer must be in accordance with the revelant manufacturer's instructions.

Guidance regarding the installation, commissioning, validation and routine operation of ethylene oxide sterilizers is given in the Department of Health publication 'Guidance on ethylene oxide sterilization'. It is anticipated that Health Technical Memorandum HTM10 published by the Department of Health will be revised shortly to include guidance on ethylene oxide sterilization in hospitals. (See Table 2)

Advantage of the Process

Ethylene oxide is a highly effective sterilizing agent which has particularly wide industrial application for single-use medical devices. It may be used at temperatures and pressures which minimise damage to sensitive equipment.

Disadvantage of the Process

Potential problems from ethylene oxide residuals means that the aeration requirements give long turnaround times for processed items. The process is relatively expensive and the essential health and safety considerations for the sterilizer, gas storage and aeration mitigate against widespread use of this process in the health service.

The use of biological indicators means that considerable microbiological work is required to monitor the efficacy of the process.

Spectrum of Action

There is a broad-spectrum action against vegetative bacteria, bacterial spores, fungi, viruses and other living cells under optimal conditions of concentration, temperature, relative humidity and time.

Safety Notes

Precautions must be taken by personnel working with ethylene oxide to avoid the hazards of flammability and toxicity. The sterilizer room, aeration area and all gas cylinder storage areas should be ventilated adequately.

Because ethylene oxide is colourless and odourless at concentrations below 700 ppm, gas leaks and subsequent accidental exposure are likely to go unnoticed. Every area where any operator could be at risk should be monitored continuously by **a** gas level alarm.

The COSHH Regulations apply to sterilization by ethylene oxide which has been assigned a maximum exposure limit under the Regulations (See HSE Guidance Note EH40 — revised annually). For practical guidance on the application of the COSHH Regulations to the use of ethylene oxide in sterilization, consult the approved Code of Practice on COSHH in Fumigation Operations.

Key References

1. British Standards Institution. *Sterilizing and disinfecting equipment for medical products,* BS 3970: Part 1, Specification for general requirements, 1990.
2. Central Sterilizing Club Working Party Report. *Decontamination of heat-labile equipment,* 1986.
3. Department of Health, *DH Manufacturer registration scheme: Guidance on ethylene oxide sterilization,* 1990.
4. Department of Health, Safety Action Bulletin No 63, SAB(90)63, *Use and management of ethylene oxide sterilizers,* September 1990.
5. Department of Health and Social Security. Health Technical Memorandum 10, *Sterilizers,* 1980.
6. Health and Safety Executive, Guidance Note EH 40/91, *Occupational exposure limits,* 1991 (revised annually).
7. Health and Safety Executive, *Code of Practice 30, Control of Substances Hazardous to Health in fumigation operation, 1990.*

Sterilization by Low Temperature Steam and Formaldehyde 4

Keywords

Physico-chemical method
Moist heat and chemical
Sterilization process

Process

This combination of dry saturated steam and formaldehyde kills vegetative bacteria, bacterial spores and most viruses.

All objects exposed to this process are placed in the chamber of an automatically controlled sterilizer in such a way as to ensure the removal of air followed by exposure at sub-atmospheric pressure to the action of dry saturated steam at 73°C in which formaldehyde is entrained. All surfaces must be exposed to the action of this steam/formaldehyde mixture.

A variety of cycles are described in which there are variations in the combination of steam pulses, formaldehyde injection, holding stages, and the amounts of formaldehyde employed.

Preferred Uses

Items and materials, including appropriately wrapped goods, not damaged by this process but unsuitable for steam or dry heat sterilization. These include many materials and items of equipment with integral plastic components susceptible to damage by heat. Complex items including electromedical equipment may qualify for this process under these criteria.

Exclusions

Sealed, oily or greasy items, or those with retained air are unsuitable as are items likely to be damaged by exposure to these conditions of heat, moisture, chemical action and pressure variation.

All items where chemical reactions between the steam/chemical atmosphere and the material/object concerned may produce damage. The reversible absorption of formaldehyde by some fabrics and plastics must be considered; if elution is protracted and the amount absorbed is considered large, such items may remain for long periods unsuitable for patient usage.

All items contaminated with body fluids are excluded because hardened fixed protein deposits will be produced by this process. This includes 'ditty returns' from operating theatres, clinics, etc.

Patterns of loading must ensure both penetration and gas draining of items to prevent presence of condensed water and formaldehyde. Narrow bore tubing is prone to contain condensed water with trapped formaldehyde.

Equipment Required

This process requires a sterilizer which will deliver dry saturated steam at 73°C into which formaldehyde can be introduced during the course of **a** sterilizing cycle. The operation of this sterilizer must provide means to remove air, avoid excessive condensation, introduce formaldehyde throughout the load under controlled conditions while avoiding anomalous distribution, polymerisation, or the formation of formalin liquid, and finally to remove formaldehyde from the chamber and its load, so far as is practicable, finishing with a dry sterile formalin-free load. Removal of all traces of formaldehyde from some materials is not always possible.

Operating Procedure

The manufacturer's operating procedures should be followed.

The sterilizer is prepared and loaded and the cycle is initiated. The automatic control system will then follow the steps in the programme including the controlled entrainment of vapourised formalin in the steam supplied to the chamber or, in the event of a fault, will arrest the process and signal process failure.

A typical operating cycle involves the following events:

a) Air removal — air is evacuated by a pump with the assistance of pulses of steam admitted to the chamber to purge traces of air from the load. This provides a partial vacuum.

b) Formaldehyde introduction commences by evaporating liquid formalin in controlled amounts with the steam supply to the chamber. This may for example be done with a succession of steam pulses, Steam saturation at 73°C is maintained. Means to eliminate gradients of temperature humidity, and formaldehyde concentration must be provided.

Excessive condensation, and the formation of formalin liquid or formaldehyde polymer must be prevented.

c) Exhaust — this is done by ceasing to admit steam and formaldehyde and by pumping out the chamber vapour. A succession of pure steam pulses alternating with pumping will remove most of the formaldehyde from the load.

d) A vacuum is maintained for sufficient time to dry the load.

e) Filtered air is introduced, to restore atmospheric pressure and allow the door to be opened.

4 Sterilization by Low Temperature Steam and Formaldehyde (continued)

Monitoring

As this is a complex physico-chemical process, monitoring requires the recording of process time, temperature and steam pressure, the amounts of formaldehyde introduced into the chamber, and the duration of the various stages.

In addition to physical data, it is necessary for the process to be monitored microbiologically. Biological indicators are utilised to confirm the effectiveness of the process. These are standard test objects bearing a known number of the spores of a Bacillus stearothermophilus strain (eg: NCTC 10003), the performance and preparation of which comply with a specification, (European Standard, in preparation). The Line Pickerill helix is employed as a standard test carrier for these biological monitors.

Chemical indicator paper, which changes colour after exposure to the process, can be used to provide an indication that formaldehyde has been present and distributed evenly through the chamber.

All recording instruments must have sensors that are independent of those of the automatic process controller. These recordings, and the results of biological and chemical monitors, must be retained and where applicable compared with a master temperature record (MTR) produced at the time of commissioning the sterilizer. Deviations call for immediate investigation including technical and engineering review.

Leak rate and other routine tests are described in Health Technical Memorandum HTM10.

Maintenance

The sterilizer must be maintained according to the manufacturers instructions. In addition, maintenance requirements and routine commissioning and performance tests are described in HTM10 (See Table I, page 5). The retention of all records and results listed above is essential to the conduct of preventive and remedial maintenance. Appropriate log books must be kept.

Advantage of the Process

It offers the ability to provide suitable items and materials in a dry, packaged, sterile form. It is conducted under predetermined automatic control, generating appropriate records. The cycle is arrested and signalled as failed in the event of a machine/process failure.

Disadvantage of the Process

The process is complex and, because biological indicators are required for validation and monitoring of the cycle, there can be a delay in the release of articles for use.

Formaldehyde is a toxic, irritant sensitizing agent with an objectionable smell. It is suspected of being mutagenic.

Formaldehyde may be absorbed, and only slowly eluted, by some materials. This may slow down the recycling of resterilized items prepared in this way.

The equipment is expensive and complicated, needing regular skilled maintenance; it demands appropriate services including steam, electricity and drainage and may need to be insulated to contain heat and noise. A trained operator is required.

It is necessary to remove excess formalin from the atmosphere directly to the outside and at a point distant from access to ventilation systems.

If the machine is used for low temperature steam disinfection alone and for operation with formaldehyde, then it must be borne in mind that it is very difficult to be sure that the system is formaldehyde-free when employed for 'steam-only' operation: this might cause difficulties.

Spectrum of Action

Broad-spectrum action against vegetative bacteria, fungi, viruses and bacterial spores.

Safety Notes

There are several problems posed by the use of formaldehyde. Formaldehyde is irritant to the eyes, respiratory tract and skin. This has implications for both the user of the process and the recipient of processed items, where absorbed and subsequently slowly released formaldehydefrom residuals or formalin formed in moist sites within respiratory and other intricate equipment may be hazardous. Formaldehyde is toxic and suspected of being mutagenic. A COSHH assessment is needed for any work where formaldehyde is used. The current maximum exposure limit is 2ppm. (See HSE Guidance Note, EH40 — revised annually).

Adequate training in all aspects of the machine's use is essential (direct training by the manufacturer is recommended).

Key References

1. Alder, V.G., Brown, A.M. and Gillespie, W.A., *Disinfection of heat-sensitive material by low-temperature steam and formaldehyde, J. Clin Pathol.,* 1966, ***19,*** 83— 89.
2. Alder, V.G., *The formaldehyde/low temperate steam sterilizing procedure, J. Hosp. Infect.,* 1987, **9,** 194—200.
3. Department of Health and Social Security, Health Technical Memorandum 10, *Sterilizers,* 1980.
4. Departmental of Health and Social Security, Health Equipment Information, 88, 95/80, *Departmental advice on some aspects of disinfection and sterilization,* September 1980,26 — 28.
5. Gibson, G.L., *Processing heat-sensitive instruments and materials by low-temperature steam and formaldehyde,* J. Hosp. Infect., 1980, **1,** 95 — 101.
6. Health and Safety Executive, Guidance Note EH 40/91, *Occupational exposure limits,* 1991 (revised annually).
7. Line, S.J. and Pickerill, J.K., *Testing a steam-formaldehyde sterilizer for gas penetration efficiency, J. Clin. Pathol.,* 1973, **26,** 716 — 720.

TABLE 2: SUMMARY OF HOSPITAL STERILIZATION PROCESSES

TYPES OF STERILIZER	USE	MINIMUM TIME/TEMPERATURE FOR STERILIZATION	SUMMARY OF TESTS TO BE PERFORMED BY:			
			USER	MAINTENANCE ENGINEER	MAINTENANCE ENGINEER	MAINTENANCE ENGINEER
porous load steam sterilizer	wrapped instruments, dressings & utensils	134 — 138°C for 3 minutes	DAILY 1. warm up cycle 2. Bowie Dick test	WEEKLY 1. warm up cycle 2. leak rate test 3. air detector function test 4. visual check of temperature/pressure 5. Bowie Dick test	QUARTERLY weekly tests & validation/calibration of instrumentation (using thermocouples)	ANNUAL weekly tests validation/calibration of instrumentation (using thermocouples)
fluid-cycle steam sterilizer	fluids in sealed containers	121 — 124°C 15 minutes or 115°C for 30 mins	compare temperatures achieved with Master Temperature Record	visual check of temperature/pressure gauges	validation/calibration of instrumentation (using thermocouples)	validation/calibration of instrumentation (using thermocouples)
unwrapped instrument steam sterilizer	unwrapped instruments & utensils	134 — 138°C for 3 minutes	1. warm up cycle 2. visual check of temperature pressure	daily tests	validation/calibration of instrumentation (using thermocouples)	validation/calibration of instrumentation (using thermocouples)
hot air sterilizer	oils, powders & heat resistant instruments that may be damaged by steam	160°C for 2 hours	compare temperatures achieved with Master Temperature Recorder	visual check of temperature gauge	validation/calibration of instrumentation (using thermocouples)	validation/calibration of instrumentation (using thermocouples)
low temperature steam formaldehyde (LTSF) sterilizer	heat sensitive equipment	73°C for 3 hours	1. warm up cycle 2. leak rate test 3. spore test for each cycle 4. compare temperatures achieved with Master Temperature Record	1. warm up cycle 2. leak rate test 3. visual check of temperature/pressure gauges 4. local exhaust ventilation check	validation/calibration of instrumentation (using thermocouples)	validation/calibration of instrumentation (using thermocouples) test and examine local exhaust ventilation (at least every 14 months)
ethylene oxide sterilizer	heat sensitive equipment	varies with type of sterilizer	1. warm up cycle 2. spore test for each cycle	1. visual check of instrumentation 2. local exhaust ventilation check	validation/calibration of instrumentation (using thermocouples)	validation/calibration of instrumentation (using thermocouples) test and examine local exhaust ventilation (at least every 14 months)

Sterilization by Irradiation 5

Keywords

Physical method

Irradiation

Sterilization process

Process

Sterilization by irradiation can employ gamma rays or accelerated electrons. Irradiation has a broad spectrum of action.

The delivery of irradiation dose in excess of 25 kGray (2.5 Mrad) is accepted as providing adequate assurance of sterility.

Irradiation is widely used for the sterilization of single-use medical devices on an industrial scale.

Health Service personnel should be aware of the need to ensure that the storage and handling of single use products sterilized by irradiation does not compromise the integrity of the packaging. When packaging of any sterile product has been damaged, the sterility of the contents cannot be guaranteed.

Preferred Uses

Sterilization by ionizing radiation is an industrial process and is particularly suited to the sterilization of large batches of similar products.

Exclusions

Irradiation can cause serious physical deterioration of materials, particularly those subjected to a previous sterilization process. The effect of irradiation on materials requires detailed investigation and therefore irradiation is not suited for the resterilization of items within the Health Service.

Equipment Required

irradiation sterilization both by gamma irradiation and electron beam is a large-scale industrial process. A description of the equipment used is outside the scope of this document.

Operating Procedure

This is an industrial process and outside the scope of this manual.

Monitoring

The control of the irradiation plant must ensure that the sterilizing dose is delivered to all points within the product being exposed. This can be complex as the dose delivered to any particular product will depend on the composition and density of other materials within the irradiation chamber at the same time. The dose delivered at any point within a product container can be measured by the use of dosimeters. For detailed information on the validation and routine monitoring of sterilization by irradiation, see the UK Panel on Gamma and Electron Irradiation publication (1989).

Advantage of the Process

Irradiation is a reliable industrial-scale sterilization process for the sterilization of heat labile items.

Disadvantage of the Process

Irradiation can cause serious physical deterioration of materials. Furthermore, the validation of the process and the routine monitoring required for small batches of product, make it unsuited to health service use.

Key References

1. Department of Health, *Quality systems for sterile medical devices and surgical products,* 1990.
2. UK Panel on Gamma and Electron Irradiation, *Code of Practice for the validation and routine monitoring of sterilization by ionizing radiation. Radiat. Phys. and Chem.,* 1989, **33,** 245 — 249.

6 Disinfection with Low Temperature Steam

Keywords

Physical method
Moist Heat
Disinfection process

Process

This disinfection/pasteurization process kills most vegetative micro-organisms and viruses by exposure to moist heat.

Objects to be treated are placed in the chamber of an automatically controlled disinfector under conditions assuring the removal of air and subsequent exposure to steam on every surface and part of the object concerned.

Typical conditions are exposure to dry saturated steam at a temperature of 73°C for a period of not less than 10 minutes. The pressure is below atmospheric.

Preferred Uses

Items and materials not damaged by the conditions of the process are suitable, provided that air removal and subsequent steam penetration are assured.

Exclusions

Sealed, oily or greasy items, or those with retained air are unsuitable, as are those liable to damage by the conditions of heat, moisture and pressurevariation involved.

This process is unsuitable for items requiring sterilization and objects likely to be contaminated by bacterial spores or other agents of similar resistance to heat.

Equipment Required

This process requires a disinfector that complies with the requirements of British Standard BS 3970, Sterilizing and disinfecting equipment for medical products; 1990, Part 1, 'Specification for general requirements'and part 5, 'Specification for low temperature steam disinfection'. The disinfector will deliver dry saturated steam at the required temperature to all parts of the disinfection chamber with complete removal of air and without excessive condensation. The process is controlled automatically throughout, and the process parameters are recorded by sensors independent from those of the control system.

Operating Procedure

Operation involves the following order of events:

a) *Preparing the disinfector* — chamber surfaces should be at the temperature specified for operation to eliminate cold spots that occur where there are masses of metal such as the chamber head-ring. If necessary, this may be achieved by running a cycle with the chamber empty prior to use.

b) *Loading* — standard containers and chamber shelving are specified to facilitate the operation of the disinfector by ensuring the **access** of steam to all items.

c) *Air Removal* — air is evacuated by a pump with the assistance of pulses of steam admitted to the chamber to purge traces of air from the load. This provides a partial vacuum.

d) *Holding stage* — steam is admitted so that the conditions of temperature and pressure specified for the load are produced and monitored for the appropriate time.

e) *Exhaust* — steam admission ceases and the chamber is evacuated by the pump, so that a pre-set vacuum is produced and maintained for a specified time to dry the load. Heated filtered gas may be introduced to assist drying.

f) *Air admission* — at the end of the drying period, air is admitted to the chamber, to restore atmospheric pressure; this allows the door to be opened. This air is admitted through a filter to prevent the reintroduction of micro-organisms.

The automatic control system once started will execute the programme steps or, in the event of a fault, will arrest the process and signal process failure.

Monitoring

As this is a physical process depending on the condensation of dry saturated steam, it may be monitored satisfactorily by registering the pressure, temperature and time of the process during the holding stage. These must be recorded by instruments attached to sensors functioning independently of those of the automatic control system. A simulator is not essential.

All recordings should be retained and checked against a master temperature record (MTR) established on commissioning the disinfector. This is part of correct management, and essential for proper maintenance. Deviations call for immediate investigation including technical and engineering review.

Defined procedures (e.g. daily leak tests and load tests) must be carried out routinely as prescribed in Health Technical Memorandum HTM10.

Maintenance

The disinfector must be maintained according to manufacturer's instructions. Maintenance is specified in HTM10. The records of routine tests for air leaks, of test loads, those of routine cycles, and the appropriate log books recording preventive and remedial maintenance, together with the master temperature record are all essential to the conduct of proper maintenance.

Advantage of the Process

This is a physical process under automatic control capable of reproducible and recordable performance to specified parameters. Machine and processing faults are automatically detected and signalled and the process is stopped and aborted. The process has a broad-spectrum of disinfection action, is non-toxic and non-corrosive; equipment is simple to operate and safe to use on a wide range of materials not excluded by the criteria given above. It yields a pre-packaged product in a dry state in a short time.

Disadvantage of the Process

It must be carried out by a trained operator, and there is a range of exclusions. The capital cost of the equipment is considerable, and it needs regular and skilled maintenance. The equipment is fixed and requires considerable amounts of steam power and water as well as insulation to contain noise and heat.

Spectrum of Action

This process kills vegetative micro-organisms and some heat-sensitive viruses. It disinfects but does not sterilize.

Safety Notes

Low Temperature Steam disinfectors and components such as chambers, electrical fittings, pipework and instruments are covered by current British Standards. Purchasers must ascertain BS specifications are complied with. Operators must be given appropriate courses of instruction and training. Declared machine faults and recorded deviations require immediate investigation and correction by skilled engineers including the manufacturer, if necessary. Manufacturer's instructions must be followed.

Key References

1. British Standards Institution, *Sterilizing and disinfecting equipment for medical products,* BS 3970, Part 1, Specification for general requirements 1990; Part 5, Specification for Low Temperature Steam Disinfector, 1990.
2. Department of Health and Social Security, Health Technical Memorandum 10, *Sterilizers,* 1980.
3. Departmental of Health and Social Security, Health Equipment Information, 88, 95/80, *Departmental advice on some aspects of disinfection and sterilization,* September 1980,26 — 28.

7 Disinfection with Boiling Water

Keywords

Physical method

Moist heat

Disinfection process

Process

Boiling water is an efficient disinfection process which kills susceptible micro-organisms. This is not a sterilizing process.

Exposure to soft water boiling at 100°C at normal atmospheric pressure for 5 minutes or more forms the disinfection cycle.

Prior to disinfection all articles must be thoroughly cleaned. Items should be totally immersed in boiling water in a safe manner. Care should be taken to ensure that air is not trapped in tubing.

Preferred Uses

This process can only be used for clean items that can withstand immersion in water at temperatures of 100°C for more than 5 minutes. The item must be robust enough not to be damaged by repeated agitation. Suitable items include metal instruments such as specula, proctoscopes and sigmoidoscopes.

Exclusions

This process is not to be used if a better method is available. Heat labile items which are damaged by hot water at 100°C must not be processed. Hollow or porous items where hot water will not penetrate the lumen, and tubes longer than 1 metre cannot be disinfected in this way.

This process is not suitable for items requiring sterilization.

Equipment required

This process requires a purpose built instrument/holloware boiler equipped with a thermostatic, over-temperature cut out and a timed lid interlock. Items for disinfection are placed on a perforated tray equipped with a raising/lowering lever. The equipment is designed to minimise scaling and for ease of emptying/refilling.

Operating procedure

A typical operating cycle involves the following events:

a) Fill the water boiler with water of suitable quality (distilled or de-ionised) and bring the water to the boil.

b) Open the lid of water boiler and raise perforated tray with lever.

c) Placeclean disassembled instruments on tray in single layer and lower perforated tray into water. Close hinged lid.

d) When water boils, set time lock for five minutes. Do not interrupt cycle by adding more items once cycle has started.

e) When the cycle is finished-reverse procedure. Remove instruments and store dry.

f) Empty boiler at end of session and leave empty.

Monitoring

It is not possible to monitor this process satisfactorily. A temperature gauge should be fitted. The time lock is set for five minutes to prevent cycle disruption.

No chemical or bacterial indicators can be used.

Maintenance of Equipment

The boiler must be maintained according to the manufacturer's instructions. All electrical installations must be checked routinely by trained electricians. The boiler should be emptied and cleaned daily and de-scaled when necessary. Two percent sodium carbonate added to the water slows down scaling. Use distilled or de-ionised water.

Advantage of the Process

Boiling water has a broad disinfecting effect and is non-toxic.

The process is inexpensive.

Disadvantage of the Process

There is no independent method of checking efficacy and no means of indicating a failed process. The process requires careful attention to detail. The boiler requires regular cleaning to prevent build-up of scale.

Following disinfection the articles are wet, unfit for storage and may become readily recontaminated. Items must be allowed to cool before use.

Boiling water in an open vessel is potentially hazardous.

Spectrum of Action

Boiling water inactivates most non-sporing micro-organisms, fungi, viruses and some heat-sensitive spores.

Safety Notes

All staff must be trained adequately before using the equipment. Boiling water in a open vessel presents a scalding hazard when loading. The presence of water and electrical equipment is a potential hazard.

Key References

1. Department of Health and Social Security, Health Equipment Information, *88, 95/80, Departmental advice on some aspects of disinfection sterilization,* September 1980.
2. Lowbury, E.J.L., et al, *Control of Hospital Infection,* 1981.
3. Maurer, I.M., *Hospitalhygiene,* 3rd ed., 1985.
4. Russell, A.D., et al, *Principles of Disinfection, Preservation and Sterilization,* 2nd ed, 1992.

Disinfection with Washer/disinfectors 8

Keywords

Physical method

Moist heat

Disinfection process

Process

Washer disinfectors use a combination of physical cleaning and thermal microbicidal action to achieve disinfection of contaminated re-usable items. This can either be as a process prior to re-use or make items safe to handle before further reprocessing.

Preferred Uses

This process can be used only for items that will withstand wet heat at temperatures of about 80°C for repeated exposures. The items must be sufficiently robust to withstand powerful water jets and alkaline detergents. For devices such as anaesthetic tubing and masks this process can be sufficient to allow re-use. For surgical instruments, this process should be an initial decontamination to remove gross soil (ideally total soil) and to make the instruments safe for handling.

Exclusions

This process must not be used for items intended for single use only. Also excluded are hollow or porous items where the hot water will not adequately penetrate any internal lumen; some machines may have special adaptors to enable hollow and lumen items to be satisfactorily processed.

This process does not sterilize but items may be sterilized subsequently by an appropriate process.

Equipment required

A purpose built instrument washer/disinfector should have a thermostatically linked cycle and safety interlocks to prevent opening during cycle. Internal racks in the machine to take required instruments should not to impede water spray. Suitable detergents and rinse aids will be released into the machine from an automatic dispenser or reservoir during the washing cycle.

A soft water supply or other water treatments, as indicated by the manufacture, will be required.

Operating Procedure

A typical operating cycle will comprise;

a) A series of cool or warm washes with detergent to remove soil at below protein coagulation temperatures.

b) A series of rinses to remove residual detergent.

c) A phase of the cycle that achieves a temperature of at least 71°C for three minutes, 80°C for at least one minute or 90°C for one second in all parts of the load (usually in the final rinse).

d) A heat-assisted drying cycle.

Monitoring

The machine must be commissioned with temperature measurements in a "worst case" load, such that the most inaccessible portions reach at least 71°C for at least three minutes. The chamber cycle parameters should be noted and rechecked routinely and monitoring should occur such that any gross failure in water supply or electrical power results in clear indication of a failed cycle. It should not be possible to remove the load in the normal manner if this occurs. Cleaning efficacy should be determined using a standard 'soil' test.

Maintenance

The washer/disinfector should be maintained according to the manufacturers instructions. Each load should be checked after washing to ensure routine cleansing is adequate. Routine thermometric checks should be performed.

Advantages of the Process

The process is safe for the operator. In addition, there is good disinfection of items by cleaning and heat; minimal handling of contaminated instruments by staff; it results in clean items. The process combines cleaning and disinfection.

Disadvantages

The equipment has a high initial cost and requires adequately trained staff to operate and load the machine correctly. Planned preventative maintenance costs may be high and will include routine thermometric monitoring. The process may need artificially softened water. The detergents used may require use of barrier skin protection for the staff handling them.

Spectrum of Action

Disinfection with washer/disinfectors will inactivate all micro-organisms except bacterial spores and some heat-resistant viruses.

Safety Notes

Detergents may be irritant when allowed contact with the skin or mucous membranes. A risk assessment, under the Control of Substances Hazardous to Health (COSHH) Regulations, will have to be undertaken before a procedure can be used.

Key References

1. British Standards Institution, Washer-disinfectors for medical purposes, BS 2745.
Part 1, Specification for general requirements, (draft);

Part 2, Specification for human-waste container washer-disinfectors, (draft);
Part 3, Specification for washer-disinfectors except those used for processing human-waste containers and laundry, (draft).

2 Central Sterilising Club, Working party report 1: *Washer/Disinfection machines,* 1986.
3. Lowbury, E.J.L., *et al, Control of Hospital Infection,* 1981.

Decontamination By Manual Cleaning/Washing 9

Keywords

Physical method

Physical removal

Cleaning process

Process

Manual cleaning by washing is a soil-removing process requiring energy which results in the physical removal of a high proportion of micro-organisms without necessarily achieving microbial destruction. Cleaning is a necessary prerequisite of equipment decontamination to ensure effective disinfection or sterilization.

Preferred uses

Wide application in the decontamation of environmental (walls, floors, furniture and fittings) and equipment surfaces including items in contact with healthy skin.

Exclusions

Cleaning is not acceptable as the sole or terminal process for invasive equipment in direct contact with the patient for which disinfection or sterilization is required.

The process must not be used for items intended for single-use only.

Manual cleaning of items should only be undertaken when other mechanical methods are inappropriate or unavailable.

Equipment Required

Immersion

A sink or receptacle which will hold sufficient volume of water/detergent to ensure that the item of equipment to be cleaned, can be fully immersed.

Wiping

A receptacle to contain water/detergent mixture and cleaning cloths.

Additionally, both methods require a receptacle for clean rinse water, drainage surface and clean, absorbent, non-shedding drying cloths.

Monitoring

Due to the lack of control methods available to test the efficiency of manual cleaning, the user should be aware of the following factors that may affect this:

a) Water temperature;

b) Detergent concentration;

c) Nature and method of soil removal;

d) Accessibility of fluid to the item.

Maintenance of Equipment

All sinks, receptacles and surfaces (including water supply and drains) should be regularly inspected for breaks/damage.

Advantages of the Process

The process is relatively cheap and safe for the operator. It does not require expensive processing equipment.

Disadvantages

Manual processes require a high level of operative training and are time consuming. There are risks associated with the handling of contaminated items.

Spectrum of Action

The process is broad spectrum in action. An important, limiting factor is accessibility of the micro-organisms to the soil removing process. Cleaning will reduce the bioburden.

Safety Notes

Care should be taken in the direct handling of intricate or sharp-edged items to avoid injury. A waterproof protective apron or gown and robust rubber gloves should be worn. Eye protection may be required if splashing is likely to occur. A risk assessment, under the Control of Substances Hazardous to Health (COSHH) Regulations, will have to be undertaken before a procedure can be used.

Use with Other Processes

The process may be combined with chemical disinfection.

Key References

1. Collins, B.J., (1988), *The Hospital Environment: How clean should it be ? J. Hosp. Infect.,* **11,** (Supplement A), 53 — 56.

2. The Control of Substances Hazardous to Health Regulations, 1988.

Keywords
Chemical method
Chemical disinfectants
Disinfection process

Process

A chemical disinfectant is a compound or mixture which, under defined conditions, is capable of destroying micro-organisms by chemical or physico-chemical means. It is usually in the form of a liquid, sometimes as a solid to be dissolved in a liquid, and occasionally a gas. Disinfectants can be supplied ready to use or may need accurate dilution to an appropriate in-use strength. Individual disinfectants vary in their properties, making the precise choice of a disinfectant important if a specific task is to be achieved in a particular set of circumstances.

The process of disinfection is the application of a chosen disinfectant, at a specific concentration to an item that is capable of being rendered safe for a particular task. There must be good contact between disinfectant and item to be disinfected for a predetermined minimum time. Some disinfectants contain surfactants and may be used for combined cleaning and disinfecting but most items require thorough cleaning before immersion in a disinfectant.

If a toxic disinfectant is used all irritant residues should be removed before the item is re-used. Care should be taken when rinsing to ensure that items are not (unacceptably) recontaminated during this procedure.

Preferred uses

Chemical disinfection can be used, in a variety of forms, where a reduction in the level of a particular microbe, or microbes, is required to achieve safety. Disinfection must always beconsidered with a particular aim in mind and not as a routine 'housekeeping' procedure. It is not a substitute for sterilization and is not as effective as heat disinfection. It must not be used where these methods, or the use of single-use items, would be more appropriate. The selection of the disinfectant used is governed by the type and amount of soiling.

Equipment Required: Manual Process

A sterilizable dedicated receptacle with lid to hold sufficient disinfectant such that items can be fully immersed and a timer or stop clock. Facilities or receptables are also required for cleaning items with detergent prior to immersion in disinfectant, for rinsing in sterile water to remove toxic disinfectant residues and for drying processed items before use.

Equipment Required: Automated Process

Automated chemical washer disinfectors are available for some heat sensitive items, e.g. flexible fibre optic endoscopes and accessories. These can be sequentially programmed to clean, chemically disinfect, rinse and dry all accessible external surfaces, channels and other internal surfaces. These reduce staff exposure to the disinfectant and can be programmed to comply with the disinfectant contact times indicated in local or national policy. Machines should be compatible with the instruments processed and either self-disinfecting or accessible for decontamination so that they do not become **a** source of infection.

Available Products

Disinfectants are best classified generically, with characteristics being similar within any one class of compounds. Concise information on the properties of available chemical disinfectants can be found in the PHLS publication 'Chemical disinfection in hospitals'. The difference between disinfectant types ranges from products capable of killing bacterial spores to products with severely limited microbicidal spectra.

Monitoring

It is not possible to monitor routinely the efficiency of chemical disinfection. Its efficiency depends on choice of disinfectant and the way it is used. Thus correct selection of chemical disinfectants depends on knowledge of their properties and successful use is achieved by ensuring that the user is adequately trained.

Advantage of Process

Chemical disinfection has its primary use in removing infection risk from equipment that would be damaged by the temperatures used in the more readily available forms of sterilization or by more efficient forms of disinfection involving heat. It allows relatively convenient and rapid decontamination without high financial outlay on equip ment. It is usually an inherently mobile decontamination method and can readily be used outside as well as within hospitals.

Disadvantage of Process

Disinfection, by definition, does not guarantee a sterile product; as such it cannot be used for invasive items which are required to be free of all microbial contamination. Chemical disinfectants can be toxic, flammable, corrosive or have other material incompatibilities.

Even if a particular disinfectant has been shown in laboratory tests to be capable of killing a specific pathogen, this does not mean that it will, in all circumstances, eliminate that pathogen. Factors other than innate microbial resistance can lead to practical failures of disinfection. These include:

a) Inactivation of the disinfectant by chemical or physico-chemical reactions. A wide variety of substances (eg blood and other body fluids, incompatibly charged detergents, wood, cork, plastics, rubbers and some inorganic chemicals) can neutralise disinfectants. Which disinfectant is neutralised by which substances will vary with disinfectant type. It is important to consider which substances will be present in what quantities when choosing a disinfectant.

b) Physical protection of micro-organisms can occur within organic material. A layer of blood or other organic substance will hamper penetration of any disinfectant. If the disinfectant cannot reach its target micro-organisms, it cannot kill them. Some disinfectants will coagulate proteins and will thus hamper their own penetration.

c) Disinfectants can decay and lose efficacy. This may happen only when a disinfectant is diluted ready for use, both in its diluted and concentrated form, or not at all. Decay will be more rapid at elevated temperatures. Presence of impurities can initiate and accelerate decay.

d) All disinfectants take time to work. The time required comes from a combination of the speed of action and concentration of the disinfectant, the amount of neutralisation and the protection of target organisms by extraneous matter.

Spectrum of Action

Most disinfectants are capable of eliminating Gram-positive and Gram-negativevegetative bacteria and enveloped viruses (sometimes referred to as 'lipophilic' or 'hydrophobic' viruses). Sequentially less easily eliminated targets are: non-enveloped viruses (sometimes called 'hydrophilic' viruses), mycobacteria (particularly the slower growing 'atypical' mycobacteria), protozoa1 cysts and bacterial spores.

Safety Notes

Chemical disinfectants are often toxic when allowed contact with skin and mucous **membrane or** by vapour inhalation. They can also be corrosive and flammable. A risk assessment, under the Control of Substances Hazardous to Health (COSHH) Regulations, will have to be undertaken before a procedure can be used.

Use with Other Processes

Chemical disinfectantscan be used in combination with other methods of killing or removing micro-organisms such as heat and cleaning. These can be sufficiently synergistic to achieve sterilization (as in low temperature steam and formaldehyde) or may just increase the degree of microbial elimination, as in the use of hypochlorite in washing processes. In the latter example, the temperature of the water in the washing process is insufficient alone to cause microbial death but greatly increases the efficiency of chemical disinfection. This is therefore additive to physical removal of contamination in the washing process.

Physical cleaning prior to chemical disinfection should be done where practicable as this:

1) lowers the microbial challenge to the disinfectant;
2) removes barriers to disinfectant penetration;
3) removes substances that may inactivate the disinfectant. Care must be taken that cleaning solutions and materials do not themselves inactivate the disinfectant or react dangerously.

Key References

1. Ayliffe, G.A.J., *et* al, *Chemical Disinfection in Hospitals,* 1984.
2. The Control of Substances Hazardous to Health Regulations, 1988.
3. Russell, A.D., *et* al, *Principles of Disinfection, Preservation and Sterilization,* 2nd ed, 1992.

11. Disinfection with Formaldehyde

Keywords

Gaseous method
Formaldehyde gas
Disinfection process

Process

Formaldehyde gas under optimal conditions of concentration, exposure time and relative humidity is a broad-spectrum anti-microbial agent.

At atmospheric pressure and temperatures up to 50°C, the gas has limited sporicidal action and is a disinfecting agent only. This process is quite distinct from the combined physico-chemical process of steam at sub-atmospheric pressure with formaldehyde (LTSF).

The formaldehyde cabinet comprises a large air-tight cabinet and a control console which automatically dispenses and circulates gaseous formaldehyde at temperatures up to 50°C and ambient pressure. Following an appropriate exposure time for disinfection, ammonia gas is released to neutralize residual formaldehyde. Finally the cabinet and its contents are flushed through with fresh air.

Formaldehyde is a hazardous substance; it is a flammable and explosive gas, toxic and irritant to eyes, respiratory tract and skin. Such properties require careful control and monitoring of the process and consideration of possible adverse effects to staff, equipment and patients.

Preferred Uses

Terminal disinfection processing of large thermolabile items, particularly intricate electrical equipment that cannot withstand heat or moisture. Suitable items include suction pumps and baby incubators. Previous application for the disinfection of ventilators has generally been superseded by the provision of bacterial filters and autoclavable circuitry.

Exclusions

This process is not to be used where heat disinfection or sterilization of the item is possible or where contact between any component material and the gases (formaldehyde/ammonia) may result in any adverse effect to the equipment or user. If in doubt, consult the manufacturer of equipment to be processed or the Department of Health for advice.

Paper, rubber and some plastic materials are excluded from this process because formaldehyde residue may persist or be trapped within the product.

The process requires pre-cleaning of accessible surfaces wherever possible and is not appropriate for grossly soiled items. The potential hazard and expense of the process requires careful consideration of its place as a disinfection process.

Equipment required

A purpose built automatic machine is required. The ad hoc use of a 'box' with manual application of formaldehyde releasing agents, (e.g. tablets) is unsafe for product and operator and should not be used under any circumstances.

There are two main types of formaldehyde cabinet currently used in the UK:

a) A unit which can accommodate 2 — 5 large items e.g. baby incubators and ventilators in addition to a number of small items such as respiratory circuits and Ambu bags. Options of short cycle (3.5h) or long cycle (10 h) are available.

b) A machine which is of much smaller capacity accommodating only a single large item. Cycle time 3 hours.

Operating Procedure

Manufacturer's instructions should be followed.

A typical operation will comprise the following stages:

a) The items to be terminally disinfected are first dismantled and cleaned by washing wherever possible. Heat-resistant items such as sterilizable circuitry are removed for heat sterilization.

b) The reassembled cleaned items are placed in the formaldehyde cabinet for the terminal disinfection process. Electrical power points will be available to enable items of equipment to be operating throughout the cycle, thus promoting increased penetration of gas to less accessible surfaces. The disinfection unit may be fitted with couplings so that corrugated tubing, Ambu bags and similar devices can be flushed with formaldehyde.

c) A measured volume of gaseous formaldehyde is generated within the cabinet from aqueous solution by an automatic process, under controlled conditions of temperature and relative humidity. Formaldehyde gas is pumped intermittently through the cabinet during the exposure hold time.

d) After the appropriate disinfection time, the cabinet is flushed with air followed by ammonia to neutralize residual formaldehyde.

e) The final stage consists of repeated air flushing, after which the cycle ends, the door can be opened and the equipment removed and stored for additional aeration prior to clinical use.

Monitoring

Indication is given on the machine of the stage of the cycle, temperature, relative humidity and the addition of formaldehyde/ammonia. There is limited process control available for directly monitoring the item to be processed. Formaldehyde-sensitive indicator paper may be used to indicate that the gas has reached a particular part in the load but will not confirm 'disinfection'. Biological indicators for this process are available but require careful evaluation.

Both types of machine have 'abort' systems which prevent accidental exposure to formaldehyde as a consequence of a failed cycle and both have safety interlocks.

Maintenance of Equipment

Manufacturer's instructions are to be followed. Regular maintenance by trained personnel is essential.

Advantage of the Process

An automatic process which can be incorporated into the practical organisation of a medical equipment decontamination unit (SDU or other), with the formaldehyde cabinet providing the link between the dirty/dismantling activities and the clean/testing activities.

The items being disinfected may be operated at the same time, permitting confirmation of adequate functioning of the machine.

Disadvantage of the Process

The equipment is expensive to purchase, operate and maintain. Concern remains about the monitoring of the process.

If the item being processed fails to operate at any point in the cycle, the penetration or removal of the gases will be compromised.

Formaldehyde is toxic, irritant and has an objectionable smell. It may be absorbed and only slowly eluted by some materials and consequently formaldehyde residuals may be hazardous within respiratory and other intricate equipment.

Spectrum of Action

Formaldehyde inactivates all types of micro-organism, including bacterial spores and viruses. The action is influenced by formaldehyde concentration, temperature, available water content in the micro-organisms and/or process and the duration of exposure.

In typical cycles at atmospheric pressure and temperatures up to 50°C, the process will kill vegetative organisms. The effect of this process on hepatitis B and HIV viruses requires further evaluation, but formaldehyde is generally regarded as an effective virucidal agent.

Safety Notes

The manufacturer's instructions must be followed. Adequate training in all aspects of the machine's use is essential (direct training by the manufacturer is recommended).

Formaldehyde has a strong smell and is irritant to the eyes, respiratory tract and skin. This has implications both for the user of the process and the recipient of processed items, where absorbed and subsequently slowly released formaldehyde from trapped residuals, or formalin formed in moist sites within respiratory and other intricate equipment, may be hazardous (Note: SIB(8)3). Formaldehyde is toxic and is suspected of being mutagenic. A COSHH assessment is needed for any work involving the use of formaldehyde as a disinfectant. The current maximum exposure limit is 2ppm (See HSE Guidance Note, EH40).

Key References

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2. Department of Health and Social Security' Health Equipment Information, 88, 95/80, *Departmental advice on some aspects of disinfection and sterilization,* September 1980,26 — 28.
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5. Roncorni, A. J., Casewell, M. W., and Phillips, I., *The disinfection of clinically contaminated Matburn suction pumps and baby incubators in an 'Aseptor' forma/in cabinet. J. Hosp. Infect.,* 1980, **1,** 251 — 260.
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12 Disposal by Incineration

Keywords

Physical method

Dry heat

Sterilization process

Process

Incineration by burning is a highly effective sterilization process operating under carefully controlled conditions.

It is applicable to all micro-organisms and to most materials.

Items to be incinerated should be fed automatically into the incinerator chamber. Immediate and complete combustion must occur in existing furnaces with a secondary combustion zone exit gas temperature in excess of 850°C.

This should be raised to in excess of 1000°C if cytotoxic drugs are in the waste stream.

Preferred Uses

This is the preferred disposal route for clinical wastes including all combustable material of an infectious nature (ie both clinical and laboratory waste).

Exclusion

The process should not generally be used for metal instruments orequipment; however, used hypodermic needles can be dealt with in this process.

Re-usable linen should not be incinerated, as reliable decontamination processes are available in laundries.

Problems may occur with some plastics which may clog the perforated trays in the incinerator.

PVC and other chlorinated plastics may give problems with toxic emissions to the environment.

Large volumes of fluids (eg drainage bag fluid) should not be dealt with in this manner.

Equipment Required

Clinical waste incinerators should comply with BS 3316: 1987 or any subsequent standard to ensure complete combustion of waste to acceptable environmental standards.

The design of incinerators should take into account the health and safety of those operating and maintaining the plant. In particular, safe access for operation, maintenance and upgrading operations should be considered before installation.

The design of the plant should ensure that where a malfunction of an item creates a hazard then the plant reverts to a fail safe condition. Automatic shut down should be incorporated where a significant risk condition arises.

The majority of incinerator plants in the NHS operate at less than 1 tonne/hr of waste. Many operate at less than 350 kg/hr and may only burn 1 yellow bag at a time (average weight 2 kg each 90 secs ie 80 kg/hr.)

Where possible, automatic mechanicalcharging of incinerators should be provided eg conveyor belt or weighed hopper input. These should be fitted when more than 50 kg/hr are processed.

Clinical waste incinerators need to be licensed by the Local Waste Disposal Authority and authorised by the Local Authority or Her Majesty's Inspectorate of Pollution.

Operating Procedure

Incinerators should be operated at high enough temperatures in both primary and secondary chambers to ensure full combustion and sterility. (See PG5/1(91),1991.)

The secondary chamber temperature should be maintained at all times during the burn to ensure correct temperatures in the primary chamber and appropriate emission control.

Particular attention should be paid to correct loading. Excessive loading can lead to incomplete combustion and incomplete sterilization.

When the plant is not fired up general cleaning and planned preventative maintenance should be performed.

All ash, residues etc. must be cleared out when required and discarded according to local written policy.

Once the incinerator is fired up it must be comfirmed that immediate combustion of clinical waste occurs at the time of introduction (by visual inspection).

Dark smoke must not occur for more than five minutes in an eight hr period and for not more than two minutes continuous.

The emission of blacksmoke must not occur.

Particulate matter must be less than 500mg/m^3.

Note: For new, replacement or upgraded plants new regulations will be introduced and enforced within the next four years (see Ref 4).

All emissions to be colourless and free from visible smoke and odourless at the site boundary.

Emission levels to be lowered and strictly adhered to.

Particulate matter should be less than 100mg/m^3 at the site boundary.

Monitoring

Procedures should be introduced to sample routinely, measure and monitor the efficient functioning of the plant in order to maintain all emissions below the new standard requirements. Temperatures should be monitored continuously.

Maintenance of Equipment

The incineration plant must be operated by trained personnel and supervised by a designated officer.

Procedures must be laid down for the routine emptying and cleaning of the furnace. Appropriate measures need to be taken to dispose of residues and ash which can now be handled safely.

Routine chimney maintenance is required.

Planned preventative maintenance is necessary to ensure the safe operation of incinerators and to ensure a sterile end product. Permit-to-work systems should be set up for plant maintenance and breakdown.

Clinical Waste

Clinical waste should be separated into yellow bags and taken to the incinerator as soon as practicable.

Clinical waste should be collected, transported and stored in a dedicated trolley or container; the contents can then be tipped automatically into the feeding mechanism of the incinerator. If the bags have to be picked up this should be done by the neck of the sack.

Basic protective equipment e.g. gloves/overalls should be provided to all personnel carrying and loading clinical waste for transport.

The waste disposal policy should outline clear procedures for action in the case of spillages or accidents.

Washing and sanitary facilities should be provided in close proximity to the incinerator for use by staff employed in that area.

Note: The waste disposal policy should identify plans for both the storage and the disposal of waste when the incinerator is not operational.

Advantage of the Process

All infectious clinical waste including human tissue is destroyed.

Operating temperatures exceeding 850°C will cause total and immediate destruction of all micro-organisms including unconventional slow viruses and other unconventional agents.

Potentially dangerous and infectious materials, such as hypodermic needles and other sharps, are destroyed thus negating the need for final disposal in a deep landfill.

Heat recovery systems are an option.

Disadvantage of the Process

Capital and revenue costs are high and will increase with the implementation of new stringent regulations.

On-site facilities are expensive but if contracting out is the agreed option, authorities must take into account the costs of safe storage, safe transport and containment.

Improperly discarded instruments and equipment will be inadvertently destroyed.

N.B. There are many variables in the process which may affect the sterilization performance of an incinerator and appropriate monitoring is essential.

Key References

1. Blenkharn, J.I. and Oakland, D. , *Emission of viable bacteria with the exhaust flue gases from hospital incinerators. J Hosp. Infect., 1989,* **14,** 73 — 78.
2. British Standards Institution, *Incinerators;* BS 3316: Part 4,
   Code of practice for the design, specification, installation and commissioning of incineration plant for the destruction of hospital waste, 1987.
3. British Standards Institution, *Specification for Sharps Containers,* BS 7320, 1990.
4. Department of the Environment *Secretary of State's guidance on Clinical Waste incineration* processes under 1 tonne/hour PG5/1(91), 1991.
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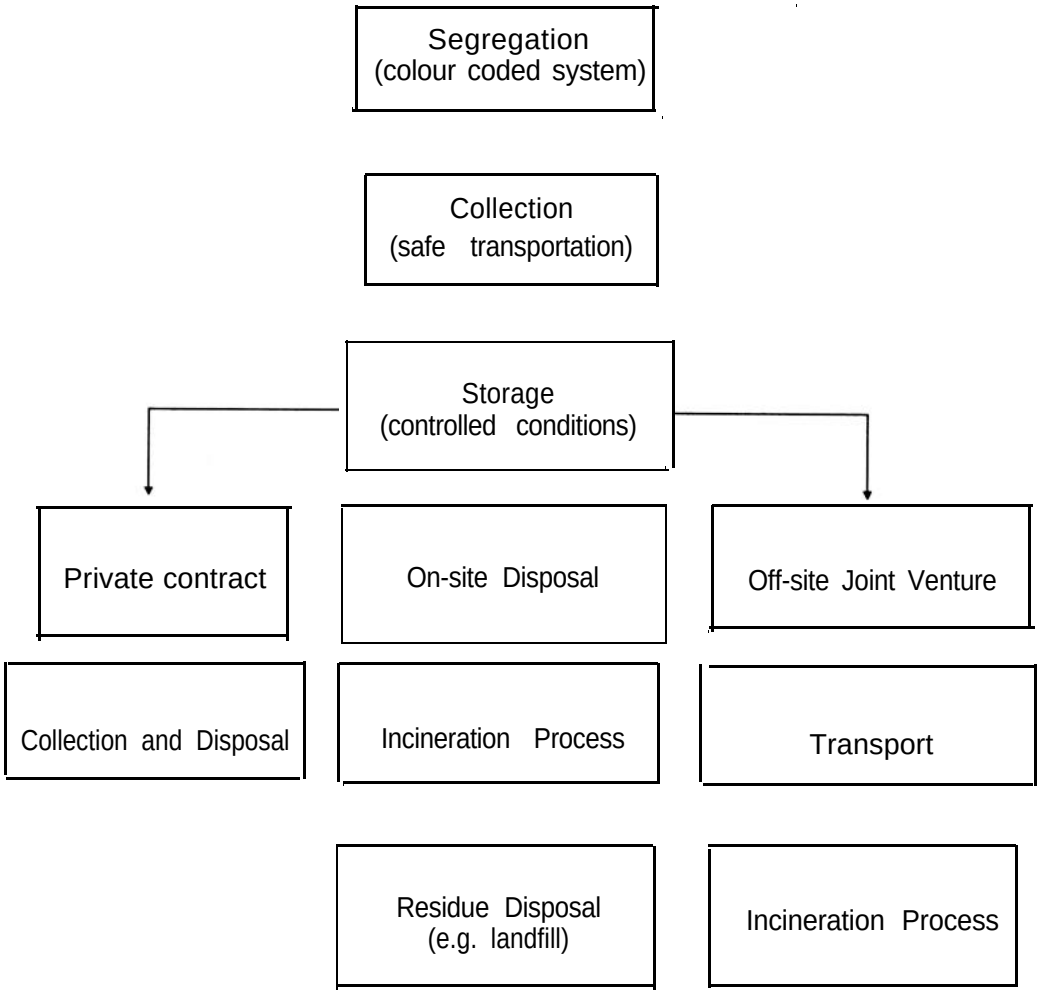
6. Health and Safety Executive (Health Service Advisory Committee), The *safe disposal of clinical waste,* 1982.
7. McPherson,. R, *Disposal of clinical waste — practical implication of the 'Green' Bill for the NHS, Inst. Sterile Supply Manag. J.,* July/August 1990, 16 — 19.

TABLE 3 Waste Management flow chart



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