



Scottish Health Technical Memorandum 2030

(Part 1 of 3)

Operational management

Washer-disinfectors

NHS in Scotland, HEEU, August 1999

Executive summary

SHTM 2030 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer-disinfectors (WDs) in use in the National Health Service for processing medical devices, laboratory ware and sanitary products.

No guidance is given on WDs intended for use in processing textiles or for dishwashers in general catering applications.

This part, 'Operational management', is intended as a guide for management, technical personnel with appropriate training and experience and also for users responsible for the day to day running of WDs. It will also be of interest to architects, planners, estates managers, supplies officers, and others.

Detailed information on the planning and design of a sterile services department including the provision of WDs is given in Scottish Hospital Planning Note 13, *Sterile services department*. Guidance for laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

Although this edition of SHTM 2030 reflects current WD technology it is recognised that considerable scope exists for improvements in the operational and management standards used with WDs.

NOTE: The term washer-disinfector is abbreviated to 'WD' throughout this publication.

The current British Standards for WDs, although only in force since 1993, are expected to be replaced by European Union (EU) Standards within the next two to three years. These Standards include consideration of the requirements arising as a result of European Union Directives on medical devices which affect WDs in two ways: firstly, some WDs will themselves be considered to be medical devices and therefore must meet the relevant requirements of the Medical Devices Directive; and secondly, the manufacturer of a medical device which is intended to be reprocessed is required to specify the method to be used for reprocessing which will include any necessary washing and disinfecting stage.

When practicable the information in this SHTM has been aligned with existing or anticipated standards and advice is offered when no standard has yet been formulated. The WDs described in this SHTM may not be suitable, without modification, for safely processing articles contaminated with either Hazard Group 4 pathogens or with agents which are unusually resistant to disinfection. HTM 2030 is superseded.

Contents

Executive summary

1.	Disinfection in healthcare: an overview	page 7
2.	Washer-disinfectors and the role of management	page 8
2.1	Introduction	
2.7	Legal framework for washing and disinfection	
2.12	Medicinal products	
2.16	Medical devices	
2.21	Published standards	
2.26	Washer-disinfectors as medical devices	
2.29	Water supply	
2.30	Safety	
2.35	Summary of management responsibilities	
3.	Statutory requirements	page 14
3.1	Introduction	
3.2	Health and safety	
3.5	Health and Safety at Work etc Act 1974	
3.6	Management of Health and Safety at Work Regulations 1992	
3.8	Workplace (Health and Safety and Welfare) Regulations 1992	
3.10	Provision and Use of Work Equipment Regulations 1998	
3.12	Pressure Systems and Gas Containers Regulations 1989	
3.14	Control of Substances Hazardous to Health Regulations 1999	
3.17	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985	
3.20	Manual Handling Operations Regulations 1992	
3.22	Personal Protective Equipment at Work Regulations 1992	
3.23	Consumer protection	
3.24	Consumer Protection Act 1987	
3.26	Electromagnetic Compatibility Regulations 1992	
4.	Personnel	page 19
4.1	Introduction	
4.2	Training	

- 4.6 Functional responsibility
- 4.11 Key personnel
 - 4.12 Management
 - 4.13 User
 - 4.17 Competent person
 - 4.21 Test person
 - 4.23 Maintenance person
 - 4.29 Microbiologist
 - 4.30 Control of infection officer
 - 4.31 Production manager
 - 4.32 Quality controller
 - 4.33 Laboratory safety officer
 - 4.34 Operator
 - 4.35 Manufacturer
 - 4.36 Contractor
 - 4.37 Purchaser

5. Operational management: an overview *page 25*

- 5.1 Introduction
- 5.6 Maintenance
- 5.8 Safety precautions
- 5.19 Equipment damage
- 5.24 Performance qualification
- 5.28 Loading
- 5.33 Documentation
- 5.37 Post-decontamination inspection and release for further processing

6. Maintenance *page 32*

- 6.1 Introduction
- 6.4 Planned maintenance (PM) programme
 - 6.4 Design of a PM programme
 - 6.9 Warranty period
 - 6.11 Review of a PM programme
 - 6.14 Routine housekeeping
 - 6.16 Overhauls
 - 6.19 Inspection of pressure vessels
- 6.25 Features requiring special attention
 - 6.25 Steam generators
 - 6.27 Stainless steel chambers
 - 6.28 Leak tightness of doors
 - 6.32 Door interlocks
 - 6.35 Chemical dosing systems
 - 6.36 Water sprays and jets

- 6.37 Ultrasonic transducers
- 6.40 Instruments
- 6.47 Water treatment plant
- 6.54 Ventilation plant
- 6.58 Returning a washer-disinfector to service
- 6.59 Trouble-shooting

7. Washer-disinfectors for human-waste containers

page 41

- 7.1 Introduction
- 7.5 Safety precautions
- 7.8 Load handling/presentation
- 7.11 Selection of cycle variables and chemical agents
- 7.15 Cycle monitoring
- 7.16 Product release

8. Washer-disinfectors for anaesthetic accessories

page 43

- 8.1 Introduction
- 8.6 Product compatibility
- 8.9 Load handling/presentation
- 8.13 Selection of cycle variables and chemical agents
- 8.18 Cycle monitoring
- 8.20 Product release

9. Washer-disinfectors for instruments and utensils

page 46

- 9.1 Introduction
- 9.3 Safety precautions
- 9.11 Product compatibility
- 9.13 Load handling/presentation
- 9.15 Selection of cycle variables and chemical agents
- 9.24 Cycle monitoring
- 9.29 Product release

10. Washer-disinfectors for thermo-labile endoscopes

page 50

- 10.1 Introduction
- 10.4 Product compatibility
- 10.5 Load handling/presentation
- 10.8 Selection of cycle variables
- 10.10 Cycle monitoring
- 10.12 Product release

11. Manually loaded ultrasonic washers *page 52*

- 11.1 Introduction
- 11.5 Safety precautions
- 11.10 Product compatibility
- 11.14 Load handling/presentation
- 11.19 Selection of cycle variables and chemical agents
- 11.21 Routine operation
- 11.25 Cycle monitoring
- 11.26 Product release

12. Liquid chemical disinfectors *page 55*

- 12.1 Introduction
- 12.3 Safety precautions
- 12.5 Product compatibility
- 12.7 Load handling/presentation
- 12.8 Selection of cycle variables and chemical agents
- 12.13 Cycle monitoring
- 12.18 Product release

13. Laboratory washer-disinfectors *page 58*

- 13.1 Introduction
- 13.3 Safety precautions
- 13.6 Product compatibility
- 13.7 Load handling/presentation
- 13.9 Selection of cycle variables and chemical agents
- 13.14 Cycle monitoring
- 13.16 Product release

Appendix 1: Glossary of terms *page 61*

Appendix 2: Abbreviations *page 65*

Appendix 3: Useful addresses *page 66*

References *page 68*

1. Disinfection in healthcare: an overview

- 1.1 Decontamination by washing and disinfection is a complex and subtle process. The testing, maintenance and reporting procedures described in this SHTM may seem excessive, but they are based upon good practice in both the UK and Europe, as formalised in European Standards designed to support the EC Directives.
- 1.2 The main purpose of washing and disinfection is to eliminate the hazard of contamination and infection.
- 1.3 Disinfection is the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.
- 1.4 The lethality of the process is less than that of sterilization but eliminates virtually all recognised pathogenic organisms, although not necessarily all microbial forms, for example bacterial endospores. Disinfection is adequate for the preparation of many items intended for use in patient care, but should not be used as a substitute for sterilization.
- 1.5 The hospital infection committee should prepare and implement a disinfection policy. This requires consultation between the microbiologist, infection control officer, engineer, pharmacist, supplies officer and representatives of medical, nursing and domestic staff.
- 1.6 The use of chemical disinfectants should be avoided when heat can be reasonably used as an alternative, for example in thermal disinfection or sterilization.

2. Washer-disinfectors and the role of management

Introduction

- 2.1 This part of SHTM 2030 covers the maintenance and operation of the various types of WDs used in hospitals, laboratories and other healthcare facilities.
- 2.2 Terminology used in washing and disinfection has long been inconsistent and this has often led to ambiguities. This SHTM introduces a set of terms which, it is hoped, will provide workers in this field with a standard vocabulary and will also be consistent with the EU Standards which are to be introduced in the near future. The glossary contains defined terms referred to in this part of SHTM 2030.
- 2.3 Full references for all the documents referred to in this part and also for selected documents providing additional information of which the reader should be aware are listed at the end of the publication.
- 2.4 The NHS is no longer protected by Crown immunity and is now subject to the full force of the law, notably in health and safety, medicinal products and consumer legislation. Tighter statutory control, brought in by new European Union Directives, will extend to almost every aspect of disinfection, and practices which were common a few years ago will no longer be acceptable.
- 2.5 The test, maintenance and reporting procedures described in this SHTM are based upon good practice in both the United Kingdom and the rest of Europe, as formalised in new European Standards designed to support the new EU Directives, and are designed to prevent the possibility of gross failure and serious incident.
- 2.6 Good staff morale is important. Anomalous behaviour which may foreshadow a malfunction of a WD is often first noticed by an alert operator or other relatively junior employee. It is vital that staff feel free to report such observations promptly, and that appropriate remedial action is taken. "Untiring vigilance" demands no less.

Legal framework for washing and disinfection

- 2.7 WDs are used in relation to both medical devices and medicinal products as well as for sanitary equipment, laboratory equipment and cutlery/crockery.
- 2.8 They may be used for reprocessing, within their intended use, medical devices, sanitary equipment, laboratory equipment, manufacturing

equipment and components (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery.

- 2.9 Users must be clear as to whether the load items they intend to process in a WD are classified as medicinal products or medical devices. While the practical requirements are very similar their implementation is covered by different legislation.
- 2.10 For the guidance given in this SHTM the various types of WDs are presumed to be used primarily as follows:
- a. for medicinal products – laboratory WDs;
 - b. for medical devices, WDs for human-waste containers, surgical instruments and utensils, for anaesthetic equipment, for heat labile medical equipment eg. endoscopes.
- 2.11 When a WD is purchased with the intention of processing both medicinal products and medical devices purchasers should ensure that the requirements for both types of product are met.

Medicinal products

- 2.12 The manufacture and supply of medicinal products are controlled by extensive legislation based on EU Directives for medicinal products. These are enacted in the UK by the Medicines Act and a number of Regulations.
- 2.13 The requirements for the manufacture and supply of medicinal products are set out in the 'Guide to good manufacturing practice for medicinal products' (GGMP) published in Part IV of the 'The rules governing medicinal products in the European Community'.
- 2.14 The GGMP contains guidance on cleaning of components and manufacturing equipment which has implications for the operation of WDs. When a WD is to be installed for processing containers, components or manufacturing equipment for use with medicinal products the GGMP should be consulted at an early stage.
- 2.15 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) when necessary.

Medical devices

- 2.16 This part refers to three EU Directives on the manufacture and supply of medical devices and in-vitro diagnostics:
- a. the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC) covers all powered implants or partial implants that are left in the human body. (Heart pacemakers are the most common example of powered implants.) The Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on

- 1 January 1993 as the Active Implantable Devices Regulations 1992 (see paragraph 4.29);
- b. the Medical Devices Directive (Council Directive 93/94/EEC) covers most other medical devices ranging from first aid bandages and tongue depressors through to hip prostheses and will therefore have a wide impact on disinfection. The Directive was adopted by the EU Council on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations;
 - c. the In-Vitro Diagnostic Medical Devices Directive will cover any medical device, reagent product, kit, instrument, apparatus or system which is intended to be used in vitro for the examination of substances derived from the human body. Some examples of in-vitro diagnostic devices are blood grouping reagents, pregnancy test kits, and hepatitis B test kits.
- 2.17 Whether, and if so in what circumstances, the Medical Devices Directive (93/42/EEC) applies to medical devices which are being reprocessed for further use – either within a particular healthcare facility or externally under a service contract – is a complex issue beyond the scope of this SHTM. Guidance is given in the MDA Directives Bulletin 18. If necessary advice should be sought from the Medical Devices Agency (MDA).
- 2.18 The relevant essential requirements of the Medical Devices Directive are:
- a. that devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Appendix 1, paragraph 8.1);
 - b. that devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (Appendix 1, paragraph 7.2).
- 2.19 There is no direct equivalent of the GGMP for medical devices. The same role is fulfilled by general quality system Standards (the BS EN ISO 9000 series), supplemented by Standards tailoring the requirements specified in the general Standards for medical devices (BS EN 46001 and BS EN 46002) and Standards providing guidance on compliance with these Standards (EN 724 and EN 50103).
- 2.20 These are mandated Standards and as such compliance with them affords the presumption of conformance with relevant essential requirements of the Directive.

Published Standards

- 2.21 British Standard 2745: 1993 specifies requirements for WDs for medical purposes. The standard is in three parts: Part 1: 'Specification for general requirements'; Part 2: 'Specification for washer-disinfectors for human-

waste containers' and Part 3: 'Specification for washer-disinfectors except those used for processing human-waste containers and laundry'.

- 2.22 There are no EU Standards, as yet, for WDs. CEN Technical Committee TC 102 is developing a series of mandated Standards relevant to the Medical Devices Directive for WDs. There are four parts with the working titles 'General requirements', 'Washer-disinfectors for human-waste containers', 'Washer-disinfectors for medical devices and surgical instruments' and 'Washer-disinfectors for thermo-labile medical devices (eg. endoscopes)'. IEC Technical Committee TC66 is developing Standards for 'Safety requirements for washer-disinfectors'.
- 2.23 When published compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.
- 2.24 This edition of SHTM 2030 has been written while the new Standards are in the course of development. The guidance given here is designed to be broadly consistent with the emerging Standards but SHTM 2030 should not be regarded as a substitute for the Standards themselves when ascertaining compliance with the EU Directives and the UK Regulations that implement them.
- 2.25 If the WD is purchased with the intention of processing both medical devices and components or equipment for use in the manufacture of medical products purchasers should ensure that the requirements for both types of load are met.

Washer-disinfectors as medical devices

- 2.26 The Medical Devices Directive (93/42/EEC) Annex IX, Classification Criteria, Rule 15 classifies as medical devices "all devices intended specifically to be used for disinfecting medical devices" and places them in Class IIa for conformity assessment purposes. It specifically excludes products that are intended to clean medical devices, other than contact lenses, by means of physical action.
- 2.27 WDs for cleaning and disinfecting medical devices are thus covered by the medical devices legislation and those supplied on or after 14 June 1998 will have to bear the CE marking in accordance with the provisions of the Medical Devices Directive. This will apply to many of the WDs described in this SHTM.
- 2.28 Detailed guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency.

Water supply

- 2.29 All organisations responsible for water supply have the statutory power to make and enforce bye-laws to prevent waste, excessive consumption, misuse or contamination of the water supply. The Model Water Bye-laws form the basis of such bye-laws. WDs must be designed, constructed, installed, operated and maintained in accordance with requirements of the relevant bye-laws.

Safety

- 2.30 Extensive guidance on the safe operation of various types of WDs is given within this SHTM (Chapters 5 to 11), while guidance on safety practice of testing WDs is given in SHTM 2030 Part 3, 'Validation and verification'.
- 2.31 Many of the chemical additives used in WDs and their associated ancillary equipment, eg. water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.
- 2.32 The 'Control of Substances Hazardous to Health (COSHH) Regulations' 1999 place an obligation upon management to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a special ventilation system.
- 2.33 Some of the substances that may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH 40 published annually by the Health and Safety Executive. These limits are a statutory maxima and should not be regarded as representing a safe working exposure. Employers have a legal obligation to ensure that exposure is reduced as far as reasonably practicable.
- 2.34 The WD, including any special ventilation equipment necessary for its safe operation, will be subject to the COSHH Regulations. These Regulations also include control of biological agents. This is of particular relevance to the operation of WDs which are commonly used to process items that may be heavily contaminated with pathogenic micro-organisms.

NOTE: Detailed guidance on ventilation systems is provided in SHTM 2025.

Summary of management responsibilities

- 2.35 SHTM 2030 will assist managers and other personnel to ensure that WDs are operated safely and effectively and in compliance with existing and anticipated legislation and standards. To this end, the major responsibilities of management can be summarised as follows:

- a. to ensure that washing and disinfection are carried out in compliance with the law and with the policy of the UK health departments;
- b. to ensure that all personnel connected with washing and disinfection, whether NHS employees or contract personnel, are suitably qualified and trained for their responsibilities;
- c. to ensure that purchased WDs conform to legal requirements, the minimum specifications set out in British and European Standards and any additional requirements of the UK health departments;
- d. to ensure that WDs are installed correctly and safely with regard to proper functioning, safety of personnel and environmental protection;
- e. to ensure that newly installed WDs are subject to a documented scheme of validation comprising installation checks and tests, commissioning tests and performance qualification tests before they are put into services;
- f. to ensure that WDs are subject to a documented scheme of periodic tests at yearly, quarterly, weekly and (in some cases) daily intervals;
- g. to ensure that WDs are subject to a documented scheme of preventative maintenance;
- h. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice;
- i. to ensure that procedures for dealing with malfunctions, accidents and dangerous occurrences are documented and adhered to.

3. Statutory Requirements

Introduction

- 3.1 So far as washing and disinfection are concerned, the chief areas of legislation with which managers should be familiar are health and safety, medicinal products and consumer protection including the medical devices regulations.

Health and safety

- 3.2 The largest body of law with which managers need to be familiar concerns health and safety, in particular the Health and Safety at Work etc Act 1974 (the HSW Act) and its various Regulations.
- 3.3 The HSW Act and its Regulations require employers to assess the risks to their employees. Attention is drawn to the following hazards which are implicit in the practice of washing and disinfection:
- a. the hazard of scalding from escaping steam or water vapour;
 - b. the high temperatures (up to 100°C) at which WDs are operated;
 - c. the toxic properties of chemicals used in certain WDs;
 - d. the infection hazard associated with the microbial pathogens that may be handled by personnel using certain laboratory WDs;
 - e. the hazard of infection to patients and staff by the inadvertent release of an infected load due to the failure of a disinfection and quality control process;
 - f. the hazards associated with the handling of heavy and hot loads while loading and unloading WDs;
 - g. the hazards associated with high pressure leaks from piping used for transfer of water or chemical agents.
- 3.4 The guidance given throughout this SHTM is designed to ensure that these hazards are minimised and that washing and disinfection procedures comply with the relevant legislation and established good practice.

Health and Safety at Work etc Act 1974

- 3.5 The HSW Act sets out the basic legal responsibilities of employers and employees with regard to health and safety at work.

Management of Health and Safety at Work Regulations 1992

- 3.6 The Management of Health and Safety at Work Regulations 1992 (SI 1992/2051) expand upon the principles of the HSW Act.
- 3.7 The core of the Regulations is a requirement of employers to make a systematic assessment of the risks to health and safety of their employees and others arising from work activities.

Workplace (Health and Safety and Welfare) Regulations 1992

- 3.8 The Workplace (Health and Safety and Welfare) Regulations 1992 (SI 1992/3004) are designed to ensure that workplaces meet the health, safety and welfare needs of each member of the workforce, including people with disabilities.
- 3.9 Most of the Regulations deal with the physical requirements of the workplace. Managers concerned with the operation of WDs should pay particular attention to the Regulations on maintenance, ventilation, temperature, lighting, cleanliness, room dimensions and space, floors, doors, and traffic routes.

Provision and Use of Work Equipment Regulations 1998

- 3.10 The Provision and Use of Work Equipment Regulations 1998 (PUWER) aim to ensure the provision of safe work equipment and its safe use.
- 3.11 PUWER 1998 replaces the existing Provision and Use of Work Equipment Regulations 1992 and applies to all equipment (including lifting equipment) used at work. PUWER 1992's requirements are carried forward in full but there are important new additions, including a requirement to inspect work equipment where significant risk could result from incorrect installation or relocation; deterioration, or as a result of exceptional circumstances; and to record the results of those inspections (Regulation 6).

Pressure Systems and Transportable Gas Containers Regulations 1989

- 3.12 These Regulations apply to steam and compressed air services supplying WDs and to those WDs with a pressurised chamber.
- 3.13 The Regulations define the duties of the competent person: a person or organisation responsible in law for advising on the scope of a written scheme of examination of a pressure system, drawing up the scheme, certifying the scheme as being suitable, and carrying out examination under the scheme.

Control of Substances Hazardous to Health Regulations 1999

- 3.14 The Control of Substances Hazardous to Health (COSHH) Regulations 1999 list a number of substances hazardous to health and specify a maximum exposure limit for inhalation, eg. glutaraldehyde.
- 3.15 The Health and Safety Executive (HSE) publishes an annually updated guidance note on current exposure limits – ‘Occupational Exposure Limits (EH40)’.

Until January 1998 an occupational exposure limit for glutaraldehyde had been in force. It has been cancelled and to replace it a Maximum exposure limit (MEL) has been set.

This is in the form of a concentration in air. It is illegal to expose people to concentrations of glutaraldehyde in air above this level.

Source: HSE Guidance EH40 Feb 1999.

- 3.16 Users of WDs should note that a “substance hazardous to health” may include a micro-organism which creates a hazard to the health of any person. Suitable precautions are required when handling items that may be contaminated with pathogenic micro-organisms.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985

- 3.17 Commonly known as RIDDOR, these Regulations impose duties on persons responsible for the activities of persons at work, and on self-employed persons, to report accidents resulting in death or major injury arising out of or in connection with work, and to report specified dangerous occurrences. They also require certain particulars of accidents at work to be reported both to the Department of Health and also to the Health and Safety Executive, and require records to be kept.
- 3.18 Some WDs may contain pressure vessels as defined under Part 1 of Schedule 1 (see paragraph 3.12).
- 3.19 Poisoning by chemical agents, eg. disinfectants, is a reportable disease listed under Schedule 2.

Manual Handling Operations Regulations 1992

- 3.20 These Regulations require employers to make an ergonomic assessment of all manual handling operations which involve a risk of injury and to reduce the risk as far as is reasonably practicable. Factors to be assessed include the nature of the task, the load, the working environment and individual capability. Reference should also be made to the ‘Lifting Operations and Lifting Equipment Regulations’ 1998

- 3.21 Managers should assess the risks associated with loading and unloading WDs, whether by loading trolleys or by hand. Top-loading WDs can be especially hazardous if lifting equipment is not available. The mass of the load is not the only source of risk; the temperature and other factors should be taken into account. Risks associated with maintenance and overhauling should also be assessed.

Personal Protective Equipment at Work Regulations 1992

- 3.22 Managers should assess whether the risks associated with washing and disinfection require the use of personal protective equipment (PPE). Some examples include heat-resistant gloves for use when hot loads are removed from WDs, protective gloves for use when loading contaminated material into WDs, eye or face protection when testing WDs containing pumped fluids and chemical agents, and foot protection for operators loading and unloading WDs.

Consumer protection

- 3.23 In recent years new legislation has been introduced affording protection to persons who may be harmed by unsafe goods supplied to them. In certain circumstances this may include products from WDs.

Consumer Protection Act 1987

- 3.24 Part 1 implements EU Council Directive 85/374/EEC (the Product Liability Directive) providing for compensation to be paid to persons injured by a defective product. Under the Act a product is defective “if the safety of the products is not such as persons generally are entitled to expect”, taking the circumstances into account. It is likely that civil action for damages could be taken against a hospital for supplying, for example, “disinfected” products that were not in fact disinfected and caused the infection of a patient.
- 3.25 The Active Implantable Medical Devices Regulations 1992 (SI 1992/3146) and the Medical Devices Regulations 1994 (SI 1994/301) are both issued under the Consumer Protection Act.

Electromagnetic Compatibility Regulations 1992

- 3.26 The Electromagnetic Compatibility Regulations (SI 1992/2372) (the EMC Regulations) impose requirements concerning the electromagnetic compatibility of most types of electrical and electronic apparatus which must be complied with when such apparatus is to be supplied or taken into service.

- 3.27 A WD (and any ancillary equipment) is a “relevant apparatus” within the terms of the Regulations, and will have to meet Standards for emission of and immunity to electromagnetic disturbance. Note that it is an offence not only to supply but also to “take into service” a WD that does not conform to the Regulations.
- 3.28 The Regulations do not apply to any WD supplied or taken into service in the EU before 28 October 1992. A WD supplied or taken into service in the UK on or before 31 December 1995 is not required to comply with the Regulations provided it complies with the requirements of the Wireless Telegraphy Acts listed in Schedule 1 of the Regulations.

NOTE: Detailed guidance on the application of the EMC Regulations in healthcare premises may be found in HTM 2014, *Abatement of electrical interference*.

4. Personnel

Introduction

- 4.1 This chapter introduces the personnel who share the responsibility for the safe and efficient operation of WDs. It gives guidance on qualifications and training and summarises areas of responsibility.

Training

- 4.2 It is essential that personnel at all levels should have a sound general knowledge of the principles, design and functions of WDs. They should be trained on those types and models of WD with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, safety of others and general safety. Training given to individuals should be recorded and reviewed regularly.
- 4.3 Users working in relative isolation should take care to ensure not only that they are trained in the use of WDs in their charge, but also that they are aware of the changing requirements of the law and good practice as outlined in this SHTM.
- 4.4 Further information is available from the Healthcare Engineering and Environment Unit and the Authorised Person (Sterilizers).
- 4.5 Detailed training on a particular model of WD is usually available from the manufacturer, either on site (such as during validation) or by courses at their premises.

Functional responsibility

- 4.6 There have been profound changes in the management philosophy of the NHS over recent years. With the wide range of circumstances in which a WD may be employed, from a busy sterile services department in a major general hospital to a small clinic, it is not possible to prescribe a universally applicable management structure for washing and disinfection.
- 4.7 The approach chosen for this SHTM is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual's role in connection with washing and disinfection but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with washing and disinfection and in some cases the same individual may take on more than one role.

- 4.8 In every case, however, it is possible to identify a user who is responsible for the day-to-day management of the WD. The philosophy of this SHTM is to invest the user with the responsibility for seeing that the WD is operated safely and efficiently.
- 4.9 In cases where steam is generated in a pressure vessel within the WD, the law requires that a competent person (pressure vessels), who is not the user, be designated to exercise certain responsibilities of inspection (see paragraph 4.17).
- 4.10 For small installations where the user is qualified to perform all required test and maintenance functions, no other personnel may be necessary. However, it is strongly recommended that in all cases the user receives professional advice from a microbiologist, and that maintenance be carried out by a suitable qualified person and a maintenance person with assistance from the microbiologist when microbiological testing is required.

Key personnel

- 4.11 The following personnel are referred to in this part of SHTM 2030. Further information including qualifications and areas of responsibility can be found in Part 1 of SHTM 2010.

Management

- 4.12 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the operation of the premises.
- 4.13 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small autonomous units the user may take on this function.

User

- 4.14 The user is defined as the person designated by management to be responsible for the management of a WD.
- 4.15 In a hospital the user could be a sterile services manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager; in primary care he/she could be a general practitioner, dentist or other health professional. When a WD is used to process equipment or containers for use in the preparation of medicinal products the user is normally the production manager in charge of the manufacturing process.
- 4.16 The principal responsibilities of the user are as follows:
- a. to certify that the WD is fit for use;
 - b. to hold all documentation relating to the WD;

- c. to ensure that the WD is subject to periodic testing and maintenance;
- d. to appoint operators where required and ensure that they are adequately trained;
- e. to maintain production records.

Competent Person (Pressure vessels)

- 4.17 The competent person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the 'Pressure Systems and Transportable Gas Containers Regulations 1989'. The shorter term "competent person" is used in this SHTM.
- 4.18 The following guidance on the qualifications for the competent person is based on the HSC Approved Code of Practice, Safety of Pressure Systems:
- a. where required to draw up or certify schemes of examination, the competent person should be qualified at least to technician engineer level, with adequate relevant experience and knowledge of the law, codes of practice, examination and inspection techniques and understanding of the effects of operation of the pressure vessel concerned. He or she must have established access to basic design and plant operation advice, materials engineering and non-destructive testing (NDT) facilities. The competent person must have sufficient organisation to ensure a reasonable data storage and retrieval system with ready access to relevant laws, technical standards and codes;
 - b. where required to carry out examinations, the competent person should have sufficient practical and theoretical knowledge and actual experience of the type of pressure vessel which is to be examined to enable defects or weaknesses to be detected and their importance in relation to the integrity and safety of the WD to be assessed.
- 4.19 The principal duties of the competent person under the Regulations are as follows (they need not all be exercised by the same individual):
- a. advising on the scope of the written scheme of examination;
 - b. drawing up the written scheme of examination or certifying the scheme as being suitable;
 - c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.
- 4.20 Most insurance companies maintain a technical division able to advise on appointing a competent person. Advice also may be obtained from Scottish Healthcare Supplies, Trinity Park House, Edinburgh.

Test Person (Washer-disinfectors)

- 4.21 The test person (washer-disinfectors) is defined as a person designated by management to carry out validation of washer-disinfectors and to provide advice on testing, maintenance and procedures. The shorter terms test person or TP are used in this SHTM. The test person should either:
- a. be a Test Person (Sterilizers) (see SHTM 2010 for a definition of this role);
 - b. be qualified to at least HNC level in engineering or relevant sciences and have at least two years experience in the validation of washer-disinfector processes; or
 - c. have at least five years experience in the testing of washer-disinfector processes.
- 4.22 The principal responsibilities of the TP are as follows:
- a. to advise on programmes of periodic testing and periodic maintenance of WDs;
 - b. to advise on operational procedures for routine production;
 - c. to conduct the validation test specified in SHTM 2030 Part 3, 'Validation and verification' and to prepare the validation report;
 - d. to conduct the periodic tests specified in SHTM 2030 Part 3, 'Validation and verification' and to prepare reports as required by the user;
 - e. to conduct any additional tests at the request of the user.

Maintenance Person (Washer-disinfectors)

- 4.23 The Maintenance Person (washer-disinfectors) is defined as a person designated by management to carry out maintenance duties on washer-disinfectors. The shorter terms maintenance person or MP are used in this SHTM.
- 4.24 The Maintenance Person should be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of washer-disinfector. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.

4.25 The principle responsibilities of the Maintenance Person are as follows:

- a. to carry out the maintenance tasks outlined in SHTM 2030 Part 1, 'Operational management';
- b. to carry out additional maintenance and repair work at the request of the user.

4.26 A Maintenance Person who has a minimum of 5 years experience in the maintenance of washer-disinfectors may, by agreement, perform the duties of the Test Person for the daily, weekly and quarterly tests described in SHTM 2030 Part 3, 'Validation and verification'.

Microbiologist

4.27 The microbiologist is defined as a person designated by management to be responsible for advising the user on microbiological aspects of disinfection.

4.28 The microbiologist should have a degree in microbiology and will normally be a member of the hospital staff.

4.29 The principle responsibilities of the microbiologist are as follows:

- a. to provide general and impartial advice on all matters concerned with washing and disinfection;
- b. to advise the user on the microbiological aspects of all disinfection procedures;
- c. to arrange for the culturing of biological indicators used in microbiological tests;
- d. to audit the documentation from all washer-disinfectors which have been tested by microbiological methods.

Control of Infection Officer

4.30 The Control of Infection Officer is defined as the person designated by management to be responsible for advising the user on all infection control aspects.

Production Manager

4.31 The Production Manager is defined as a person designated by management to be responsible for production of medicinal products and medical devices.

Quality Controller

4.32 The Quality Controller is defined as a person designated by management to be responsible for quality control of medicinal products and/or medical devices with the authority to establish, verify and implement all quality control and quality assurance procedures.

Laboratory Safety Officer

- 4.33 The Laboratory Safety Officer is defined as a person designated by management to be responsible for all aspects of laboratory safety in respect of equipment, maintenance, personnel and training relating to safety issues, and to ensure compliance with safety legislation and guidelines.

Operator

- 4.34 An operator is defined as any person with the authority to operate a WD. Their duties may include the noting of WD instrument readings, replenishment of consumable items, such as detergent, and simple housekeeping duties.

Manufacturer

- 4.35 The manufacturer is defined as a person or organisation responsible for the manufacture of a WD.

Contractor

- 4.36 The contractor is defined as a person or organisation designated by management to be responsible for the supply and installation of the WD, and for carrying out the installation checks and tests. The contractor is usually the manufacturer of the WD.

Purchaser

- 4.37 The purchaser is defined as the person or organisation who orders the WD and is responsible for paying for it.

Authorised Person (Sterilizers)

- 4.38 The Authorised Person (Sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness validation (see SHTM 2010 Part 1 for a full definition of the responsibilities of the Authorised Person (Sterilizers) with respect to sterilizers and the qualifications and experience required). AP(S) are also able to provide independent auditing and advice on washing/disinfection and WDs and to review and witness validation of these processes and machines.

Independent Advisor

- 4.39 The Independent Advisor is defined as a person who may or may not be registered as an AP(sterilizers), but can demonstrate to the satisfaction of management previous training and experience appropriate to carry out the designated tasks in respect of WDs as the AP(S) would carry out in respect of sterilizers. AP(S) is a suitable person to carry out the functions of an independent advisor.

5. Operational management: an overview

Introduction

- 5.1 It is important that all WDs are effective in achieving the performance required to produce clean and disinfected products, and that they are safe in operation.
- 5.2 Failure to achieve the required standard of cleanliness may also impair the capability of the process to achieve disinfection and/or subsequent sterilization.
- 5.3 The cleanliness and microbial safety of all products processed in a WD is ultimately dependent upon the care taken by the personnel responsible for its design, manufacture, installation, operation, test and maintenance.
- 5.4 Washing and disinfection may appear to be relatively simple processes, but considerable care is needed to consistently achieve satisfactory results. The quality and safety of the product obtained from a WD ultimately depends upon the vigilance of skilful personnel fully trained in the operation of WDs.
- 5.5 Responsibility for assurance on these points rests variously with the TP, the MP, the microbiologist, the control of infection officer, and the user.

Maintenance

- 5.6 Decontamination processes are among those processes which have to be validated before use. In consequence the performance of the process has to be routinely monitored (see SHTM 2030 Part 3, 'Validation and verification') and the equipment has to be maintained in good working order.
- 5.7 The maintenance of WDs should, therefore, meet the following requirements:
 - a. preventive maintenance should be planned and performed in accordance with documented procedures;
 - b. the procedure for each planned task, and the frequency at which it is carried out, should be specified and documented;
 - c. the WD should not be used to process contaminated loads until all maintenance tasks have been satisfactorily completed and recorded;
 - d. records of maintenance should be retained as specified in BS EN ISO 9001: 1994 or BS EN ISO 9002: 1994;

- e. the maintenance scheme, maintenance procedures and maintenance records should be reviewed periodically by a designated person who should be appropriately qualified and experienced.

Safety precautions

- 5.8 Whether products which have been processed in a WD are safe to handle and/or use, as appropriate, is ultimately dependent on the vigilance of all personnel responsible for its operation.
- 5.9 Effective decontamination necessitates, in many cases, complex operating cycles. Protection is provided, in the first instance, by fail-safe design principles some of which also serve to protect the product by indicating when an ineffective operating cycle has occurred.
- 5.10 However fool-proof the design, any safety device can be defeated ultimately, either wantonly or accidentally. To ensure that this does not occur requires the continuing vigilance of skilful personnel fully trained in the operation of WDs.
- 5.11 Some WDs are only intended to perform an initial step in the reprocessing of soiled re-usable items. Care should be taken to ensure that items which have been cleaned and disinfected in a WD are, when necessary, subjected to terminal sterilization prior to their use on patients.
- 5.12 To prevent the hazard of burning or scalding the door should be interlocked to prevent it being opened in mid-cycle. In the event of a fault there may be an escape of hot water vapour when the door is opened or hot water (up to 93°C) may be retained within the chamber and load.
- 5.13 Washing is a wet process and water dropping on to the floor can create a serious hazard of slipping and falling for personnel. Any leaks should receive urgent attention from maintenance staff and any spillages should be cleaned up as soon as possible.

Management should have a safety policy to deal with spillages which considers both the chemical and microbiological hazards that may be posed.

A copy of the documented procedures to deal with spillages should be available in the vicinity of each WD. The user, and all operators who may use the WD, should be trained in the implementation of these procedures.
- 5.14 Overloading load baskets, and/or load carriers, can cause a hazard and will also impair the efficacy of the disinfection process. Operators and maintenance personnel should ensure that the loading does not exceed the manufacturer's stated capacity for the loading accessories in use.

5.15 Detergents and other additives are, or may be, caustic and can cause adverse effects to exposed tissues; operators and maintenance personnel should wear protective gloves, a face shield and water-proof clothing whenever handling chemical additives or servicing the injection pumps or pipework. Contact with the eyes and skin or ingestion of chemical additives should be avoided.

5.16 Operators and maintenance personnel should read and follow the precautions and instructions given in the material safety data sheet and on the label prior to handling any chemical additive, refilling the container or servicing the injection pump and pipework.

All staff who may be exposed to contamination by any chemical additive should be trained in the action they should take to minimise harm to themselves and others in the vicinity. This will include: first aid; alerting emergency services if necessary; methods for cleaning and decontaminating the affected area; and the correct disposal of the materials used. There should be a written procedure detailing the actions to be taken in the event of spillages and contamination of personnel.

NOTE: The training should be part of a documented programme and should include periodic assessment and retraining.

5.17 Any equipment issued to operators should comply with the 'Provision and Use of Work Equipment Regulations (1998)'.

5.18 Operators and maintenance personnel should be issued with appropriate personal protective equipment (PPE) complying with the 'Personal Protective Equipment at Work Regulations (1992)'. In providing protection against, or minimising the risks from, hazards to health and safety priority should be given to engineering controls and safe systems of work; PPE should always be regarded as a last resort.

Equipment damage

5.19 The user should ensure that chemical additives used in the decontamination process are compatible with the materials of which the WD is constructed and also with the items to be processed.

5.20 Most WDs are made partly or wholly of stainless steel; the water supplied to the chamber, and the detergent and other chemical additives used, should have a low chloride content to minimise the risk of corrosion.

5.21 Lubricants for squeeze tubes on peristaltic pumps and other dispensing devices should be chosen and used in accordance with the manufacturer's instructions.

NOTE: In the absence of specific instructions silicone-based lubricants should always be used since petroleum-based lubricants can cause serious damage to many types of plastic tube.

- 5.22 Care should be taken to ensure that the walls of ultrasonic tanks are not scratched as this can cause serious cavitation erosion.
- 5.23 Operators should be instructed never to drop or rest load items directly on the bottom of an ultrasonic tank.

Performance qualification

- 5.24 New load items should not be processed until:
- performance qualification (PQ) tests as specified in SHTM 2030 Part 3, 'Validation and verification' have been conducted by the TP to the satisfaction of the user and the independent advisor; or
 - the user is satisfied that the new load item is represented by one of the existing loading conditions/process cycles for which a PQ report exists; or
 - the instructions from the manufacturer of the item are sufficiently detailed and specific that the appropriateness of the proposed treatment is readily apparent.
- 5.25 The user, in consultation with the manufacturer(s) of the load items, the Independent Advisor and the control of infection officer as necessary, should ensure that the load is suitable for the process to which it is to be exposed. This should include consideration of the compatibility of all process chemicals used.
- 5.26 The process selected will depend on the nature of the load and its ability to withstand the environmental conditions present during the operating cycle. The rates of change of cycle variables, such as temperature and pressure, may also need to be considered.
- 5.27 Before selecting a process it may be necessary to carry out preliminary tests on the product, or on a surrogate product, to determine both the levels and rates of change of the cycle variables necessary to achieve the required result and to determine which can be tolerated by the product without causing unacceptable changes in its performance.

Loading

- 5.28 The user should ensure that each load is presented to the process in accordance with documented procedures established and tested during PQ.

- 5.29 Overloaded baskets or load carriers will result in inefficient cleaning and disinfection.
- 5.30 Cannulated load items, which are intended to be connected to spigots on the load carrier to ensure flushing of the lumen, will not be adequately cleaned and disinfected if they are not properly connected.
- 5.31 Small and light items should be secured with a hold-down screen or by other means; if they are free to move around there is a serious risk of damage to the instruments. Small sharp instruments which have moved within the load may also represent a hazard to staff who have to subsequently handle the load.
- 5.32 Load carriers should only be used with the items for which they were intended.

Documentation

- 5.33 When the WD is used to process medical devices, other than sanitary appliances, intended for use on a patient without further processing, eg. sterilization, each production cycle should be fully documented. The user should ensure that the records are kept securely.

Cycles which were aborted, for whatever reason, should also be noted along with the remedial action taken.

NOTE: Further guidance is given in subsequent chapters on WDs for particular applications.

- 5.34 Operators should be encouraged to note and report any indication that the WD may not be working as expected.
- 5.35 A process log should be kept for those products, other than human-waste containers, which will be used without being subjected to further processing (eg. sterilization). This will include items such as anaesthetic accessories and some fibre-optic endoscopes.
- 5.36 If in doubt as to whether records are required, and if so which records are necessary, the user should consult the Independent Advisor.

Post-decontamination inspection and release for further processing

- 5.37 The user in consultation with the Independent Advisor should establish and document procedures to ensure that loads are not released for use or further processing, eg. sterilization, until the user is satisfied:

- a. that the disinfection stage of the process has been reproduced within the permitted tolerances established during commissioning and PQ; and
- b. that the cleaning stage of the process has been reproduced within the permitted tolerances established; and/or
- c. that visual inspection of the load shows that an acceptable standard of cleanliness has been obtained.

5.38 The procedures should ensure that:

- a. the load has been correctly positioned in the loading basket and/or on the load carrier;
- b. that the settings for the operating cycle are in accordance with the specification for that load type;
- c. that the instrument/indicator readings and/or chart record for the cycle conforms with the data established during validation within the permitted tolerances;
- d. that the decontaminated load shows no obvious defects – such as damage, residual soiling or staining – which may suggest a faulty operating cycle.

5.39 Whenever an operator has cause to suspect that the load may not have been properly disinfected the load must not be released. The user should be informed immediately.

5.40 A small percentage of load items which remain soiled after processing may not be sufficient cause to reject the entire load. The rejected items should be returned for reprocessing. However, the cause of the failure to clean all the items in the load should be investigated.

NOTE: This may be due to improper loading or items which were exceptionally heavily soiled or for which decontamination was unavoidably delayed.

5.41 Documented procedures for reprocessing rejected loads should be agreed between the user and the Independent Advisor. The method by which rejected loads are returned for reprocessing should be chosen to ensure that product flow in a controlled environment is not compromised.

5.42 For loads which are to be used in connection with the manufacture of medicinal products the quality controller will establish the procedures for product release.

5.43 After decontamination and before release of the product for use or further processing, as appropriate, the conditions for storage and handling should not compromise the cleanliness or freedom from microbial contamination of the product.

- 5.44 When a single-door WD is in use a system to clearly differentiate between processed and unprocessed loads may be required.

ARCHIVED (Oct 2001)

6. Maintenance

Introduction

- 6.1 Disinfection, and to a great extent, cleaning are processes whose efficacy cannot be verified retrospectively by inspection or testing of the product before use. For this reason decontamination processes (cleaning and disinfection and/or sterilization) have to be validated before use, the performance of the process routinely monitored, and the equipment maintained.
- 6.2 Means of ensuring that a WD is fit for its intended purpose will include the validation and testing programme specified in SHTM 2030 Part 3, 'Validation and verification', and also the programme of planned maintenance as described in this chapter.
- 6.3 The philosophy of maintenance and testing embodies two main principles to ensure that the required standards of performance and safety are met and maintained:
- a. all WDs are subject to a carefully planned programme of tests to monitor their performance;
 - b. all WDs are subjected to a planned programme of preventive maintenance.

Expertise on the maintenance of WDs is available at two levels, the MP/TP and the Independent Advisor.

Testing of WDs is dealt with in SHTM 2030 Part 3, 'Validation and verification'.

Planned maintenance (PM) programme

Design of a PM programme

- 6.4 The PM programme recommended by the manufacturer should be used when it is available. The maintenance programme may be modified subsequently to take account of equipment use, equipment history and local conditions after a suitable period of operational experience.

If no PM programme is available from the manufacturer a maintenance programme should be drawn up in consultation with the Independent Advisor and MP/TP.

- 6.5 A set of procedures should be developed for each model of WD, each containing full instructions for a particular maintenance task.

- 6.6 The frequency with which each task will need to be carried out will depend, in part, on the usage level for the WD and also on the quality of the water supplied to the WD. It may be necessary to adjust the programme so that work is carried out more frequently on WDs which are heavily used and/or are supplied with hard water.
- 6.7 It is important that maintenance is planned so that the WD is out of service as little as possible.
- 6.8 Systematic records should be kept of all maintenance work undertaken both to demonstrate that the work has been carried out and also to facilitate periodic review of the PM programme.

Maintenance and facilities management software packages (eg. WIMS) may be used to maintain a full technical and financial history of the equipment.

Warranty period

- 6.9 After the purchase of a new WD the manufacturer may carry out certain inspection and maintenance procedures under the terms of the warranty. This may not be a full PM programme. The user should ensure that the complete PM programme is carried out by the MP during the warranty period.
- 6.10 The user should also comply with any reasonable instructions from the manufacturer during the warranty period.

Review of a PM programme

- 6.11 The PM programme should be reviewed at least annually to ensure that the equipment is being fully maintained but without any unnecessary maintenance activity.
- 6.12 The review should aim to identify:
- a. the adequacy of maintenance records and compliance with the PM programme;
 - b. any emerging defects;
 - c. any changes required to the PM programme;
 - d. any changes required to any maintenance procedure;
 - e. any additional training required by maintenance personnel.
- 6.13 Proposed changes to the PM programme should be made in consultation with the WD manufacturer whenever possible.

Routine housekeeping

- 6.14 Certain maintenance tasks may be carried out by the user, or by the operator under the user's supervision, and should be recorded in the WD log.
- 6.15 Examples of such tasks include:
- checking that the rotating spray arms are free to rotate;
 - checking that nozzles are not blocked;
 - removal and cleaning of strainers and filters;
 - checking that the supply of chemical additives is sufficient for the day's use and replenishing if necessary;
 - cleaning the inside of the chamber;
 - cleaning the external surfaces of the WD and washing of loading side conveyors and trolleys;
 - for WDs with a built-in water softener, checking the level of salt in the regeneration tank and replenishing if necessary.

Overhauls

- 6.16 The user should arrange for each WD to receive periodic overhauls. For WDs which incorporate a pressure vessel this should be timed to precede the examination of the pressure vessel by the competent person and the yearly tests.
- 6.17 Improvements and modifications recommended by the WD manufacturer should be reviewed and considered for implementation before each overhaul.
- 6.18 The overhauls, and any necessary inspections, should be scheduled so that in any particular installation only one machine needs to be withdrawn from service at a time.

Inspection of pressure vessels

- 6.19 Under the 'Pressure Systems and Transportable Gas Containers Regulations 1989' all WDs which incorporate pressure vessels are subject to a periodic inspection by a competent person (see paragraph 3.13).
- 6.20 The Independent Advisor will advise on the application of the Regulations to any particular installation.

- 6.21 The competent person has five principal duties under the Regulations:
- advising on the scope of the written scheme of examination;
 - drawing up the written scheme of examination or certifying the scheme as being suitable;
 - carrying out examinations in accordance with the written scheme;
 - assessing the results of the examinations;
 - reviewing the written scheme of examination for its suitability.
- 6.22 The user should liaise closely with the competent person to ensure that the written scheme of examination is accommodated within the maintenance and testing programmes.
- 6.23 The competent person may require certain examinations to be carried out more frequently than recommended by the manufacturer.
- 6.24 Each written scheme of examination should specify detailed procedures for, and the frequency of, examination and should be regularly reviewed and updated.

Features requiring special attention

Steam generators

- 6.25 Steam generators, provided as an integral part of some WDs, are steam boilers and they should be subject to a written scheme of examination for pressure vessels.
- 6.26 Steam generators constructed from stainless steel will be subject to the risk of stress corrosion cracking. To minimize the risk the manufacturer's guidance on feedwater quality should be followed.

Stainless steel chambers

- 6.27 Stainless steel is used in the manufacture of many WD chambers. Over a wide range of specifications, stainless steels are susceptible to cracking from crevice corrosion and from stress corrosion initiated by chemical attack.

Leak tightness of doors

- 6.28 The door(s) of the WD are intended to prevent the escape of fluids into the surrounding environment, ie. to ensure freedom from aerosols which may be potentially infectious in the work place.
- 6.29 Damaged door seals are the major potential source of leaks and should receive careful attention as advised by the manufacturer.
- 6.30 The working life of door seals may be prolonged by regular cleaning.

- 6.31 Door seals should be renewed with spares provided, or approved, by the manufacturer at recommended intervals or when there is any sign of damage/deterioration.

Door interlocks

- 6.32 The interlocks on door(s) of the WD are intended to:
- a. prevent the operator gaining access to the load during processing;
 - b. prevent both the loading and unloading doors being open at the same time on “pass-through” WDs;
 - c. prevent the operator gaining direct access to a load that has not been satisfactorily processed.
- 6.33 Maintenance and inspection of door safety devices and door interlocks should be carried out in accordance with the WD manufacturer’s written instructions.
- 6.34 Security and settings of door safety switches and interlocks should be checked at least monthly. The setting should be within the limits specified by the manufacturer.

Chemical dosing systems

- 6.35 Admission of the correct amount of chemical additive at the right time in the operating cycle is essential to the correct functioning of a WD. The chemical additive dosing system should be subjected to regular (at least monthly) inspection, maintenance and test. This should include:
- a. visual inspection of all piping to ensure freedom from leaks;
 - b. visual inspection and/or testing to determine whether the delivery or pick-up piping is blocked by coagulated or hardened chemical additive (many of the chemical additives used are a viscous suspension) – and cleaning or replacing piping as necessary;
 - c. lubrication of the pinch tubing on peristaltic pumps in accordance with the manufacturer’s instructions;
 - d. verification that the volume dispensed is within the specified limits.

Water sprays and jets

- 6.36 The correct flow and distribution of water and aqueous solutions throughout the chamber and load are essential to the correct functioning of a WD. The spray system should be checked on a daily basis as part of the routine housekeeping tasks carried out by the user.

In addition maintenance staff should also check the system at least weekly; this should include:

- a. checking that the rotating spray arms, both installed within the chamber and located on load carriers, are free to rotate;
- b. checking that nozzles are not blocked – clean and/or replace if necessary;
- c. checking for wear in bearings of rotating parts – replace any worn parts as necessary;
- d. checking the mating of any necessary connection between the load carrier and the water supply in the chamber.

Ultrasonic transducers

- 6.37 Many ultrasonic cleaners are not fitted with means to provide continuous monitoring of performance. Transducers can fail or become detached from the ultrasonic tank without being noticed by the operator (other than by the deterioration in the cleaning performance).
- 6.38 Periodic functional testing of ultrasonic cleaners is described in SHTM 2030 Part 3, 'Validation and verification'.
- 6.39 The tank of the ultrasonic cleaner should be cleaned with a suitable neutral detergent and soft brush at least weekly.

Instruments

- 6.40 Each instrument fitted to WDs should be maintained and calibrated in accordance with the manufacturer's instructions. Any instrument which is reading incorrectly or inconsistently should be repaired by the manufacturer, or scrapped if it is not economical to repair.
- 6.41 Instruments which are consistent in their readings but are slightly inaccurate compared with a reference instrument should be checked for zero and span and then adjusted to work correctly at the value of interest, eg. at the normal working temperature.
- 6.42 An instrument case should never be left open and any broken glass should be replaced promptly.
- 6.43 Temperature measuring systems are subject to both inherent errors and to loss of calibration with use. Temperatures read from an indicator or recorder should be treated with caution and interpreted in the light of the established characteristics of the particular measuring system, the load and data from previous cycles.
- 6.44 Temperature recorders should be used to record the attainment of thermal disinfection conditions for all critical applications.

- 6.45 The absolute minimum intervention should be made to recording systems which are functioning correctly. Any adjustments should be strictly in accordance with the manufacturer's instructions.
- 6.46 Persons who change charts, print rolls and other consumables on recording instruments should be authorised to do so by the user. They should be fully trained and should be aware of the delicate nature of the instruments.

Water treatment plant

- 6.47 The correct functioning of water treatment plant incorporated in, or otherwise supplying, a WD is essential to maintaining the required cleaning performance.
- 6.48 The system should be inspected periodically to ensure that it is free from leaks.
- 6.49 The quality of water supplied should be verified by testing at weekly intervals for a period of three months following commissioning or major repair/overhaul of the water treatment system. At the discretion of the Independent Advisor and the microbiologist, the frequency of testing may be reduced to monthly intervals after three months of satisfactory weekly test results.
- 6.50 For water supplied from a de-ioniser or reverse osmosis plant this should include checking the pH and the conductivity to verify that these remain within specified limits.
- 6.51 When a water softener is used the water supply should be tested for hardness to ensure it remains below the specified maximum concentration of calcium salts.
- 6.52 Water intended for use as the final rinse water on items to be used invasively on patients or in the production of parenteral medicinal products should be tested for the presence of bacterial endotoxins.
- 6.53 Water intended for use as the final rinse water after a chemical disinfection process for load items which will not then be sterilized should be tested both for the presence of bacterial endotoxins and for total viable microbial count.

Ventilation plant

- 6.54 Correct operation of ventilation plant is essential to ensure:
- a. the safe operation of WDs which include a chemical disinfection stage;
 - b. the efficient operation of the drying stage (where this is included);
 - c. the maintenance of a comfortable working environment.

- 6.55 All ventilation systems associated with a WD should be inspected, serviced and maintained at least every six months. Guidance on maintenance is given in SHTM 2025.
- 6.56 WDs which include a chemical disinfection stage should have the associated ventilation system examined and tested annually.
- 6.57 Before undertaking maintenance work on the cabinet, or its associated ventilation system, it may need to be decontaminated and the advice of the designated safety officer should be sought. A permit-to-work system should be in operation.

Returning a washer-disinfector to service

- 6.58 Whenever any work has been carried out on a WD, whether or not this was part of the PM programme, the user should be satisfied that it is fit for use. Following major repairs, overhauls etc. which may affect the performance of the WD the user and Independent Advisor should draw up a schedule of checks and tests to be carried out before the WD is returned to service. This should include some or all of the recommissioning (yearly) tests specified in SHTM 2030 Part 3, 'Validation and verification'.

Trouble-shooting

- 6.59 A failure to clean all the items processed in a load through a WD is the most frequently observed fault. The most common causes of this type of failure, and thus those which should be considered first in any investigation, are:
- Incorrect loading:
 - items which are not correctly located in an appropriate load carrier will not be subjected to the intended washing process;
 - overloaded baskets and load carriers will allow some load items to shield others from spray jets etc;
 - hinged instruments which are not opened prior to washing will not be effectively cleaned.
 - Blocked spray jets, spray arms that are not free to rotate, or a blocked strainer in the chamber base.
 - Soiled instruments which have been stored for prolonged periods before decontamination – blood and protein will coagulate if stored for more than eight hours making this hard to remove.
 - Soiled instruments subjected to heat treatment before decontamination – this will lead to coagulation of blood and protein making this hard to remove.
 - Incorrect choice or quantity of detergent:

- (i) the detergent chosen must be compatible with the loads to be processed, the soil to be removed and the quality of water supplied;
 - (ii) malfunction of the dosing system may cause the wrong quantity of chemical additive to be used – too little will not provide the detergency required but too much may also impair cleaning by causing excessive foaming etc.
- f. Inappropriate water quality:
- (i) initial flush with water which is too hot will lead to coagulation of blood and protein making this hard to remove;
 - (ii) the hardness of water used during washing must be compatible with the detergent chosen;
 - (iii) hard water used in the final rinse will leave deposits on the surface of instruments.

7. Water disinfectors for human-waste containers

Introduction

- 7.1 This type of WD is used to empty, clean and disinfect human-waste containers (eg. bedpans, urine bottles, suction jars); both those which are not required to be sterile, eg. bedpans (but are required to be disinfected), as well as those which subsequently may be subjected to sterilization, eg. suction bottles.
- 7.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.
- 7.3 The key requirement for WDs of this type is the safe emptying of the human waste (faeces, urine, blood etc.) and the effective cleaning and disinfection of the items for re-use.
- 7.4 Two distinctly separate types of WD are used for this purpose: a flusher-disinfector in which cleaning is achieved by the physical action of jets of water and no detergent is used (although a de-scaling agent may be used); and a WD which incorporates a detergent washing stage.

Safety precautions

- 7.5 The area in which the WD is located should be provided with appropriate equipment to deal with spillage from the containers during transfer to the WD (see paragraph 5.13).
- 7.6 At the end of the operating cycle the washed and disinfected containers may be too hot to handle without protective gloves; containers may also retain significant volumes of hot water with the attendant risks of scalding. Operators should be trained in the use of the WD and should be provided with appropriate protective clothing.
- 7.7 Many of the chemical additives used as anti-scaling agents are toxic, irritant and corrosive. They are potentially hazardous and require careful handling and secure storage (see paragraphs 5.15 and 5.16).

Load handling/presentation

- 7.8 Load carriers are designed for particular types of containers; if it is intended to process a different container the manufacturer's advice on an appropriate load carrier should be sought.

- 7.9 The use of an inappropriate load carrier may prevent safe emptying of the container and may not permit effective cleaning and disinfection to take place.
- 7.10 Most WDs for human-waste containers are single-door machines; the area in which they are located should provide facilities for the segregation of containers awaiting processing and those that have been processed. These areas should be maintained in a good state of repair to facilitate the frequent cleaning which is required.

Selection of cycle variables and chemical agents

- 7.11 WDs which are connected to a hard water supply may need to include the use of a de-scaling agent to prevent the build-up of lime-scale on the containers being processed.

NOTE: A lime-scale deposit on the containers is not only unsightly but also makes the container more difficult to clean.

- 7.12 WDs for human-waste containers may be provided with a drying stage but this is rarely used for ward installations.
- 7.13 The operating cycle may combine the disinfection stage with the final rinse leaving the containers at high temperature at the end of the cycle. The operator should be provided with insulated gloves to allow safe removal of these hot items; being hot any residual moisture evaporates very quickly.
- 7.14 An option to use a cold final rinse, after disinfection, may be employed to facilitate the safe removal of the containers which will usually then require manual drying before use.

Cycle monitoring

- 7.15 The WD should be provided with either a temperature recorder to monitor and record the temperature attained during the disinfection stage or an indication from the automatic controller that the specified temperature was maintained for the specified time during the disinfection stage.

Product release

- 7.16 Before a product is released for re-use the operator should verify the successful completion of the disinfection stage and visually inspect each load item for cleanliness.

8. Washer-disinfectors for anaesthetic accessories

Introduction

- 8.1 This type of WD is used to process anaesthetic and respiratory accessories; both those which are not required to be sterile (but are required to be disinfected) as well as those which will be subject to further processing, eg. sterilization.
- 8.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.
- 8.3 The key requirement for WDs of this type is the circulation of water (and/or other aqueous solutions), used for washing, and hot air, used for drying, through the lumen of hollow items.
- 8.4 The facility to process anaesthetic accessories may be provided by a dedicated load carrier using a WD for instruments (see Chapter 9). A separate drying cabinet is often advantageous when a dedicated load carrier is used in a WD for instruments. Drying times for anaesthetic accessories are much greater than for instruments and the use of a separate drying cabinet improves the overall throughput of the WD.
- 8.5 WDs for anaesthetic accessories may incorporate a drying stage in the automatic process or there may be a separate drying cabinet.

Product compatibility

- 8.6 The instructions of the manufacturers of the anaesthetic accessories should be followed regarding the suitability of the various items for processing in a WD for anaesthetic accessories.
- 8.7 A neutral detergent or washing without a detergent may be necessary for some products, eg. laryngeal masks made of silicone rubber.
- 8.8 The maximum temperature attained during disinfection and drying may need to be controlled to minimise the oxidative degradation of rubber materials.

Load handling/presentation

- 8.9 The use of a load carrier specifically intended for anaesthetic accessories is essential.

- 8.10 Items with a lumen should be placed over, or connected to, the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumen during processing.
- 8.11 Items such as breathing bags and sets and self-inflating resuscitator sets (including valves) may need to be dismantled before being placed in an appropriate load carrier.
- 8.12 Other items such as Magill forceps and tubing clamps can be decontaminated in a WD for instruments (see Chapter 9).

Selection of cycle variables and chemical agents

- 8.13 An initial flush (pre-rinse) assists the removal of mucous, blood and other body fluids before washing commences. The water should be at a low temperature to avoid coagulation of proteinaceous material. Organic matter not loosened by the flushing stage may become coagulated during, and not be removed by, the wash cycle.
- 8.14 Anaesthetic accessories made from plastic may need to be washed, disinfected and dried at temperatures lower than those normally used for instruments and utensils.
- 8.15 The operating temperature for the drier is a balance between the speed of drying and the longevity of anaesthetic accessories made of rubber.
- 8.16 The importance of an effective drying stage cannot be over emphasised. Items which are left wet or damp will rapidly become re-colonised with micro-organisms.
- 8.17 The compatibility of all materials and items to be processed should be established by reference to the manufacturer's instructions, or when necessary by appropriate performance qualification testing.

Cycle monitoring

- 8.18 WDs used to disinfect anaesthetic accessories intended for re-use without further processing should be equipped with a temperature recorder, independent of the automatic controller, to monitor and record the temperature attained during the disinfection stage.
- 8.19 It is desirable that they should be equipped with means of monitoring, directly or indirectly, the flow of water during the flushing and washing stages and the flow of air during the drying stage.

Product release

- 8.20 Before anaesthetic accessories intended for re-use without further processing are released the recorded cycle variables should be checked to ensure that they are within acceptable limits for the process.
- 8.21 The load items should be inspected for cleanliness and dryness and to ensure that there are no signs of physical deterioration. For complex items, eg. valves, consideration should be given to function testing using a medical grade compressed air supply.
- 8.22 Items for use without further re-processing should be packaged to protect them from adventitious contamination.

9. Washer-disinfectors for instruments and utensils

Introduction

- 9.1 This type of WD is used to process surgical instruments, instrument trays and re-usable containers and hollowware.
- 9.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

Safety precautions

- 9.3 At the end of the operating cycle the washed and disinfected load may be too hot to handle without using protective gloves; bowls and receivers (particularly those made of polypropylene) may also retain significant volumes of hot water with the attendant risks of scalding. Operators should be trained in the use of the WD and provided with appropriate protective clothing (see paragraph 5.18).
- 9.4 Many of the chemical additives used are toxic, irritant and corrosive. They may be hazardous and will require careful handling and secure storage (see paragraphs 5.15 and 5.16).
- 9.5 A written procedure should be available for the filling or connection of all chemical additive containers. Staff whose duties include this task should receive formal training.
- 9.6 Adequate protective clothing, washing and eye washing facilities should be provided. Appropriate hazard labels should be displayed in the vicinity of use.
- 9.7 When the chemical additive(s) used has a volatile component the measurement of environmental concentrations may be necessary both during commissioning and as periodic routine checks.
- 9.8 During loading there should be minimal handling of contaminated instruments and equipment. Staff should be trained in the appropriate procedures and provided with suitable protective equipment including gloves and eye protection.

- 9.9 Before transferring instruments to the WD operators should carefully check the returned instrument trays for hazardous items, eg. scalpel handles with the blade left attached. When present, hazardous items should be carefully removed using, if necessary, handling equipment such as forceps or cheatais.
- 9.10 Operators should dispose of any sharps found into a sharps disposal container complying with BS 7320:1990.

Product compatibility

- 9.11 The compatibility of all materials and items to be processed should be established by reference to the manufacturers' instructions, or when necessary by appropriate performance qualification testing.
- 9.12 Factors to be considered in determining the compatibility of the load to the WD process include, but are not necessarily limited to:
- a. whether or not the load can be immersed in water;
 - b. the availability of an appropriate load carrier;
 - c. the maximum operating temperature (this will usually occur during the thermal disinfection or drying stages);
 - d. the internal pressure to which the lumen of a cannulated instrument may be subjected;
 - e. the mechanical damage which may occur from the impact of water jets or other items in the load;
 - f. the compatibility of chemical additives used – both with the instrument itself and in combination with other load items (when acidic chemical additives are used metal items of different composition in the same load may be subject to electrolytic corrosion).

Load handling/presentation

- 9.13 Load carriers specific to the type of load should be used to ensure that all surfaces to be cleaned and disinfected will be exposed to the action of the water jets, will not be dislodged by the water jets and will drain freely.
- 9.14 For single-door machines facilities to allow segregation of the handling equipment, eg. trolleys used for clean and dirty items, is required.

Selection of cycle variables and chemical agents

- 9.15 A flushing (pre-rinse) stage assists the removal of blood and other body fluids before washing commences. The water used for flushing should be at a low enough temperature to avoid coagulation of proteinaceous material.

Organic matter not loosened by the flushing stage may become coagulated during, and not be removed by, the wash cycle.

9.16 The choice of detergent will be based upon a number of factors. These include:

- a. the quality of water available;
- b. the nature of the soiling to be removed;
- c. the nature of the washing process.

Advice should be sought from both the WD and detergent manufacturers.

NOTE: For most applications mild alkaline detergents, up to pH 10.5, are preferred. The alkalinity contributes to the detergent action by the saponification and emulsification of fats and oils, by the peptidisation of proteins and by softening the water. The presence of alkaline builders also has a synergistic effect with surfactants present in the formulation.

9.17 A low foaming detergent will be required for most WDs since foaming will impair the wash action.

9.18 The use of enzymic detergents may be considered. These are most effective when used for soaking instruments since the contact time is of importance. Many enzymic cleaners are inactivated at the high temperatures used in wash cycles with non-enzymic detergent.

9.19 The quality of water used for the final rinse stage is important in ensuring freedom from scaling, process residuals etc.

9.20 The rinse stage may include a neutralising agent to counteract the detergent and/or minimise the effect of hard water which otherwise would cause "spotting" on the instruments.

9.21 The rinse may include an additive to facilitate free draining of water (rinse aid). Additives intended to lubricate hinged instruments (instrument milk) are also available. The use of these lubricants is generally contra-indicated. Instruments requiring lubrication may be identified on inspection after washing and disinfection and individually lubricated.

9.22 The final hot rinse may be combined with the disinfection stage.

9.23 Water purified by de-ionisation or reverse osmosis is preferred for the final rinse stage since this gives the lowest levels of process residuals and minimises the requirement for rinse additives.

Cycle monitoring

9.24 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.

- 9.25 The following variables may need to be monitored for each of the listed stages – together with the duration of each stage:
- a. Flushing stage:
 - (i) pump pressure or flow rate for water;
 - (ii) temperature of water.
 - b. Washing stage:
 - (i) pump pressure or flow rate for water and/or aqueous solutions;
 - (ii) temperature of water and/or aqueous solutions;
 - (iii) volume(s) of chemical additives injected.
 - c. Rinsing stage:
 - (i) pump pressure or flow rate for water and/or aqueous solutions;
 - (ii) temperature of water and/or aqueous solutions;
 - (iii) volume(s) of any chemical additives injected.
 - d. Disinfecting stage (moist heat):
 - (i) pump pressure or flow rate for water;
 - (ii) temperature of water.
- 9.26 WDs equipped to monitor all these variables have become commercially available only in the past two to three years.
- 9.27 As a minimum, WDs used to process surgical instruments should monitor the temperature during the disinfection stage and the time during which the temperature met or exceeded the specified minimum. There should also be means of ensuring an adequate flow of water within the chamber and load.
- 9.28 WDs that do not have independent monitoring of the time for which the specified temperature was maintained do not provide adequate assurance that the load was disinfected; a load that has not been disinfected may not be safe for staff to handle or for re-use.

Product release

- 9.29 Before a product is released for use or further processing it should be visually inspected for cleanliness and dryness. The attainment of the required temperature for the required time during the disinfection stage should be verified.

10. Washer-disinfectors for thermo-labile endoscopes

Introduction

- 10.1 This type of WD is used to process endoscopes which are thermo-labile and cannot withstand thermal disinfection. They are typically of the flexible fibre-optic or video-endoscope type.

NOTE: Rigid endoscopes capable of withstanding a thermal disinfection process may be decontaminated in WDs for instruments and utensils equipped with an appropriate load carrier designed to provide flushing of the lumen.

- 10.2 Disinfection is achieved by direct contact of the load with a chemical disinfectant solution at a specified concentration for a specified time either at a specified temperature or within a previously validated temperature range.
- 10.3 The disinfection facility may be provided as part of the automatic process or as a separate machine intended to disinfect items which have been cleaned. For this reason equipment for chemical disinfection is considered separately (see Chapter 12).

Product compatibility

- 10.4 Endoscopes may be harmed by some chemical additives or the use of an inappropriate operating cycle in the WD. The reprocessing instructions supplied by the manufacturer of the endoscope should be followed carefully.

Load handling/presentation

- 10.5 Few, if any, WDs for thermo-labile endoscopes are capable of cleaning the endoscope without any pre-treatment. As soon as the endoscope is removed from the patient, the channels should be flushed in accordance with the endoscope manufacturer's instructions. The outside of the instrument should then be wiped with a swab soaked in an aqueous solution of a suitable detergent.

Instrument/biopsy channels should be brushed through several times with a cleaning brush designed for the instrument in accordance with the endoscope manufacturer's instructions.

- 10.6 The use of a load carrier specifically intended for the endoscope(s) to be processed is essential.
- 10.7 The channels of the endoscope should be connected to the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumens during processing.

Selection of cycle variables

- 10.8 The cleaning stage should terminate with a rinse stage to remove any chemical agents used in cleaning which may be incompatible with the disinfectant to be subsequently used.
- 10.9 The automatic process should include means to ensure the removal of residual water which might dilute disinfectants.

Cycle monitoring

- 10.10 The WD should be equipped with means to provide independent monitoring of all critical cycle variables (see paragraph 9.25).
- 10.11 This should include means to verify that all channels to be irrigated with cleaning solution are not blocked.

Product release

- 10.12 Before a product is released for use or further processing it should be visually inspected for cleanliness and dryness. When the process includes a chemical disinfection stage the attainment of the required conditions should be verified (see Chapter 12).

11. Manually-loaded ultrasonic washers

Introduction

- 11.1 This type of washer is used to process metal instruments with complex interstices. It may be used as a pre-cleaning method before processing through a WD for instruments and utensils.
- 11.2 Ultrasonic cleaners work by subjecting the load to a high intensity of high frequency sound waves which causes cavitation at the surface of the instruments, loosening the soiling.
- 11.3 Ultrasonic cleaning is not a disinfection process and loads cleaned by ultrasonication must be subjected to a subsequent disinfection or sterilization process as appropriate.
- 11.4 The guidance offered in this chapter is, when relevant, equally applicable to ultrasonic cleaning processes included in a WD for instruments and utensils.

Safety precautions

- 11.5 Ultrasonic cleaners should only be operated in accordance with the manufacturers' instructions. They should only be operated when the lid is in place to avoid the dispersion of aerosols and to protect operators from the noise that may be generated.
- 11.6 Ear protection may be necessary for operators if the ultrasonic cleaner produces significant audible noise during operation.
- 11.7 Operators should be instructed not to put their hands, or any other parts of their body, into the ultrasonic tank while it is operating.
- 11.8 Items washed in an ultrasonic cleaner will only have been cleaned, not disinfected, and should therefore be handled with appropriate precautions.
- 11.9 Ultrasonic cleaners should never be operated with the tank empty since this can seriously damage the transducers.

Product compatibility

- 11.10 Ultrasonic cleaners are used to assist in cleaning jointed and serrated stainless steel instruments. Plastics and other similar materials which absorb the ultrasonic energy are not successfully cleaned by this method.

- 11.11 Cannulated instruments can be cleaned by ultrasonication but this is generally successful only when means are provided to ensure that the cannula is also flushed with cleaning solution during the process.
- 11.12 Cemented glass syringes and optical systems will be damaged if they are subjected repeatedly to ultrasonication.
- 11.13 The compatibility of all materials and items to be processed should be established by reference to the manufacturer's instructions, or by appropriate performance qualification testing when necessary.

Load handling/presentation

- 11.14 Instruments should be placed in the basket provided with the machine.
- 11.15 The cleaner should be located at a convenient height for loading and unloading. When heavy sets of instruments are to be processed the cleaner should be equipped with a mechanical lifting device.
- 11.16 Cannulated instruments should be connected to the appropriate nozzle on the load carrier to ensure that the cleaning solution can be pumped through the lumen during processing.
- 11.17 Hinged instruments should be opened before being placed in the cleaner.
- 11.18 Gross contamination, such as blood and other visible soil, should be rinsed off instruments before they are immersed in the ultrasonic tank.

Selection of cycle variables and chemical agents

- 11.19 The only variables selectable are the operating temperature (on some machines), the concentration of chemical additives and the exposure time.
- 11.20 The efficacy of ultrasonic cleaning is improved by the use of a low foaming surfactant or detergent. The choice of detergent and control of the in-use concentration of detergent have a significant effect on cleaning performance. Advice should be sought from both the WD and detergent manufacturers.

Routine operation

- 11.21 The tank should be filled with the volume of clean cold water recommended in the manufacturer's instructions and the required volume of detergent added. The ultrasonic cleaner should then be brought up to operating temperature (if it is of the thermostatically controlled type) and operated for a period of not less than five minutes to de-gas the solution.

- 11.22 After de-gassing, the instruments to be cleaned should be loaded into the ultrasonic cleaner using the basket provided and, when the lid is in place, the cleaner operated.
- 11.23 After the specified time the instrument basket should be removed, the instruments removed and either transferred to a WD for instruments and utensils or thoroughly rinsed in clean hot water (60°C or hotter) before drying prior to sterilization or chemical disinfection.
- 11.24 The tank should be emptied and refilled with clean solution when the solution has become visibly soiled or every four hours, whichever is the sooner. De-gassing is necessary after each fill, before instruments are processed.

Cycle monitoring

- 11.25 The user should carry out a daily test to verify the activity of the transducers (see SHTM 2030 Part 3, 'Validation and verification').

Product release

- 11.26 Before a product is released for use or further processing it should be visually inspected for cleanliness.

12. Liquid chemical disinfectors

Introduction

- 12.1 Machines for the automatic disinfection of items by liquid chemical disinfectants are intended for use only on items previously subjected to a cleaning process.
- 12.2 The guidance offered in this chapter is equally applicable when the disinfection process is included in a single machine with the cleaning process.

Safety precautions

- 12.3 Chemical disinfectants are potentially hazardous. Depending on the formulation they may cause irritation to the skin, eyes, respiratory tract and mucous membranes and may be volatile, flammable and corrosive. A risk assessment should be undertaken in accordance with the COSHH Regulations (see paragraph 3.14).
- 12.4 Staff training should include specific instruction on the procedures to be adopted in the event of equipment malfunction.

Product compatibility

- 12.5 The compatibility of all materials and items to be processed should be established by reference to the manufacturer's instructions, or when necessary by appropriate testing.
- 12.6 Factors to be considered in determining the compatibility of the load to the WD process include, but are not necessarily limited to:
- whether or not it can be immersed in aqueous solutions;
 - the availability of an appropriate load carrier providing the necessary connection to all channels which require disinfection;
 - the maximum operating temperature;
 - the internal pressure to which the channels may be subjected;
 - the compatibility with the chemical disinfectants used.

Load handling/presentation

12.7 Items to be processed should be:

- a. clean, to ensure that all internal channels are clear and that the activity of the disinfectant is not compromised by residual soiling;
- b. free from process residues from the cleaning process, eg. detergent, which may inactivate the disinfectant;
- c. dry or free from significant surface moisture which would cause dilution of the disinfectant solution;
- d. verified as undamaged, eg. by means of a leak test;
- e. dismantled to the extent necessary, eg. with valves opened or demounted as recommended by the manufacturer;
- f. protected with any necessary closure to prevent the ingress of aqueous solutions into the wrong part of the equipment, eg. videoscopes which are only immersible if the protective cap is in place;
- g. connected to the disinfectant so as to ensure the passage of disinfectant through all channels.

Selection of cycle variables and chemical agents

- 12.8 The activity of chemical disinfectants is time and temperature dependent. The temperature of the disinfectant solution should, therefore, be either thermostatically controlled or monitored during each cycle to ensure that it is within the temperature range validated during commissioning.
- 12.9 The exposure time should be controlled to ensure that the predetermined minimum exposure time has been attained.
- 12.10 As the various disinfectant formulations differ considerably in their properties, the choice of disinfectant should be made in consultation with the manufacturers of the equipment to be disinfected, the disinfector and the disinfectant. Guidance on the properties of commonly used disinfectants is given in 'Sterilization, disinfection and cleaning of medical equipment, guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Agency'.
- 12.11 The operating cycle must provide adequate rinsing after the chemical disinfection stage to ensure that residues of the disinfectant have been reduced to a level at which they do not present a hazard to patients.
- 12.12 The quality of the final rinse water, especially microbial quality, and the means of ensuring that quality are important characteristics of the process if recontamination of disinfected items is to be avoided. The manufacturer's instructions should be followed precisely.

Cycle monitoring

- 12.13 For disinfectant solutions which are formulated for multiple or prolonged use the date of preparation and/or activation and the number of operating cycles run should be recorded. Whenever practicable the concentration of disinfectants intended for re-use should be monitored on a daily basis.
- 12.14 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.
- 12.15 This should include means to verify that all channels to be irrigated with disinfectant solution are not blocked.
- 12.16 The disinfectant temperature and exposure time should be monitored for each cycle.
- 12.17 The means employed to maintain the quality of the final rinse water should be monitored in accordance with the manufacturer's instructions.

Product release

- 12.18 Before a product is released for use or further processing it should be verified that the chemical disinfection stage was within the limits previously determined during commissioning.

13. Laboratory washer-disinfectors

Introduction

- 13.1 This type of WD is used to process laboratory equipment and glassware and may also be used to process containers and equipment for use in the preparation of medicinal products.
- 13.2 Disinfection is achieved by direct contact of the load with water to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

Safety precautions

- 13.3 At the end of the operating cycle the load may be too hot to handle without protective gloves. Operators should be trained in the use of the WD and provided with appropriate protective clothing.
- 13.4 Many of the chemical agents used are toxic, irritant and corrosive. They are potentially hazardous and require careful handling and secure storage.
- 13.5 A written procedure should be available for the filling or connection of all chemical additive containers. Staff whose duties include this task should receive formal training.

Product compatibility

- 13.6 The compatibility of all materials and items to be processed should be established by reference to the manufacturers' instructions, or when necessary by appropriate performance qualification testing.

Load handling/presentation

- 13.7 Load carriers specific to the type of load should be used to ensure that all surfaces to be cleaned and disinfected will be exposed to the action of the water jets, will not be dislodged by the water jets and will drain freely.
- 13.8 For single-door machines facilities to allow segregation of the handling equipment, eg. trolleys used for clean and dirty items, is required.

Selection of cycle variables and chemical agents

- 13.9 A flushing (pre-rinse) stage assists the removal of gross soiling and proteinaceous material before washing commences. The water used for flushing should be at a low enough temperature to avoid coagulation of proteinaceous material.
- 13.10 The choice of detergent will be based upon a number of factors. These include:
- a. the quality of water available;
 - b. the nature of the load;
 - c. the nature of the soiling to be removed;
 - d. the nature of the washing process.

Advice should be sought from both the WD and detergent manufacturers.

NOTE: For some applications, particularly where detergent residues would be a significant problem for the intended use of the load, washing without detergent may be used.

- 13.11 The quality of water used for the final rinse stage is important in ensuring freedom from scaling, process residuals etc.
- 13.12 Water purified by de-ionisation, distillation or reverse osmosis is preferred for the final rinse stage since this gives the lowest levels of process residuals.
- 13.13 When the WD does not include a separate drying stage the use of a high temperature final rinse will facilitate the rapid natural drying of the load on removal from the WD.

Cycle monitoring

- 13.14 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.
- 13.15 The variables which may need to be monitored include those identified for WDs for instruments and utensils (paragraph 7.25).

Product release

- 13.16 Before a product is released for use or further processing it should be visually inspected for cleanliness. When disinfection is required the attainment of the required temperature for the required time during the disinfection stage should be verified.



- 13.17 For loads which are to be used in connection with the manufacture of medicinal products the quality controller will establish the procedures for product release.

ARCHIVED (Oct 2001)

Appendix 1: Glossary of terms

Automatic controller: Device that, in response to pre-determined cycle variables, operates the WD sequentially through the required stages of the cycle(s)/process.

Biological indicator: See EN 866-1:1997.

Calibration: The set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by Standards.

Calorifier: A closed vessel in which water is indirectly heated under a pressure greater than atmospheric.

Chamber: That part of the WD in which the load is processed.

NOTE: The chamber does not include steam generators, pipework and fittings from which it can be isolated.

Chemical disinfection: Disinfection achieved by the action of one or more chemicals; the primary purpose of which is to be microbicidal.

Continuous process machine: A machine which automatically transports the load through each stage of the operating cycle.

Chemical additive: A formulation of chemical compounds intended for use in a WD.

Cycle complete: Indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber.

Cycle variables: The physical and chemical properties (eg. times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of the washing and processes.

Decontamination: The combination of processes, including cleaning and disinfection and/or sterilization, used to render a re-usable item safe for further use.

Disinfection: the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

Disinfection temperature: The minimum temperature of the disinfection temperature band.

Disinfection temperature band: The range of temperatures, expressed as the disinfection temperature and the maximum allowable temperature which may prevail throughout the load during the disinfection time.

Disinfection time: The time period at which the cycle variable (eg. temperature of the load, disinfectant concentration in the chamber) is maintained at or above the value specified for disinfection.

NOTE: This includes detergents, surfactants, rinse aids, disinfectants, and enzymatic cleaners.

Door: Device provided as a means of closing and sealing the chamber.

Double-ended washer-disinfector: A WD incorporating separate doors for loading and unloading.

Fail safe: Attribute of WD design, component or its associated services that minimises a possible safety hazard.

Fault: Recognition by the automatic controller that the pre-set cycle variables for the WD cycle have not been attained.

Holding time: the time period for which the cycle variables are maintained at or above the value specified for disinfection.

Hysteresis: The lagging of effect behind cause.

Inoculated carrier: See EN 866-1.

Installation test: Series of checks and tests performed after installation of the WD in the place of use.

Load: A collective term used to describe all the goods equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle.

Loading door: Door in a double-ended WD through which the load is put into the WD prior to processing.

Loading height: The minimum height to which the underside of the load or load container has to be raised for it to enter the loading door.

Medical device: See EN 46001: 1997.

Monitoring: The measurement of physical variables, such as the function of the automatic controller to check the attainment, or otherwise, of the pre-set cycle variables essential to the efficacy of the operating cycle.

Operating cycle: The complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller.

Operating pressure: The gauge pressure at which the vessel is operated during normal use.

Override: The system by which the operating cycle can be interrupted or modified as necessary.

Safety hazard: Potential detrimental effect on persons arising from the load.

Steam generator: Vessel designed to contain water and a heating system (eg. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state.

Sterile: See BS EN 556.

Sterilization: Process used to render a product sterile.

Tank: A process vessel, integral to the WD, designed to hold solutions during processing.

Test organism: See EN 866-1: 1997.

Test soil: Substance used to test the washing efficacy of a WD.

Thermal disinfection: Disinfection achieved by the action of moist or dry heat.

Type test: Series of tests to establish the working data for a WD type.

Unloading door: Door in a double ended WD through which the load is removed after an operating cycle.

Usable space: Space inside the chamber which is not restricted by fixed parts and which is consequently available to accept the load.

Validation: See BS EN 554.

Viable micro-organism: Micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

Warning pipe: Overflow pipe so fitted that its outlet, whether inside or outside the building, is in a conspicuous position, where the discharge of water can be readily seen.

Washer-disinfector (WD): Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

NOTE: This type of machine does not include those designed specifically to wash linen or clothing.

Waste outlet: The point from which the chamber discharges the waste fluids.

Works test: Series of tests performed at the manufacturer's works to demonstrate compliance of each WD with its specification.

ARCHIVED (Oct 2001)

Appendix 2: Abbreviations

AP(S)	Authorised Person (Sterilizers)
BS	British Standard
°C	degrees Celsius
CE	Council of Europe
CEN	Committee European de Normalisation
COSHH	Control of Substances Hazardous to Health
DC	Direct Current
DI	De-Ionised (referring to water)
EEC	European Economic Community
EEF	Estates Environment Forum
EMC	Electro-Magnetic Compatibility
EN	European Norm
EU	Endotoxin Unit
GGMP	'Guide to Good Manufacturing Practice for Medicinal Products'(GGMP) published in Part IV of 'The Rules Governing Medicinal Products in the European Community'
HEEU	Healthcare Engineering and Environment Unit
HSE	Health and Safety Executive
HSW	Health and Safety at Work
MCA	Medicines Control Agency
MDA	Medical Devices Agency
MP	Maintenance Person (Sterilizers)
NDT	Non-destructive testing
NHS	National Health Service
OEL	Occupational Exposure Limit
PM	Planned maintenance
PQ	Performance qualification
PPE	Personal protective equipment
SHPN	Scottish Health Planning Note
SHTM	Scottish Health Technical Memorandum
TC	Technical Committee
TP	Test Person
WD	Washer-Disinfector
WIMS	Works Information and Management Systems

Appendix 3: Useful addresses

UK health agencies

NHS in Scotland
Healthcare Engineering and Environment Unit,
Graham Hills Building, 50 George Street
Glasgow G1 1QE
Tel 0141 548 3446

NHS Estates,
1 Trevelyan Square, Boar Lane,
Leeds LS1 6AE
Tel 0113 254 7000

Medical Devices Agency (MDA)
Hannibal House, Elephant and Castle,
London, SE1 6TQ
Tel 0171 972 8000

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
Edinburgh
0131 552 3255

Medicines Control Agency (MCA)
Market Towers, 1 Nine Elms Lane,
London SW8 5NQ
Tel 0171 273 3000

Scottish Executive Health Department
St Andrews House,
Edinburgh EH1 3DG
Tel 0131 556 8400

Health and Safety

Health and Safety Executive
375 West George Street
Glasgow
G2 4LW
0141 275 3000



Belford House
59 Belford Road
Edinburgh
EH4 3UE
0131 247 2000

Health and Safety Executive Information Line
0541 545 500

Standards organisations

British Standards Institution
British Standards House, 389 Chiswick High Road, London W4 4AL
Tel 0181 996 9000

European Committee for Standardisation rue de Stassart 36, B-1050
Brussels

Other organisations

Institute of Healthcare Engineering and Estates Management.
2 Abingdon House, Cumberland Business Centre.

References

NOTE:

Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	Title	Publisher	Date	Notes
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1968	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Medicines Act	HMSO	1988	
	Health and Safety at Work Act	HMSO	1974	
	Public Health (Scotland) Act	HMSO	1988	
	The Water (Scotland) Act	HMSO	1980	
SI 2179	Building Standards (Scotland) Regulations	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations	HMSO	1988	
SI 2372	Electromagnetic Compatibility Regulations	HMSO	1992	
SI 1380	Electromagnetic Compatibility (amendment) Regulations	HMSO	1994	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1994	
SI 2792	Health and Safety (Display Screen Equipment) Regulation	HMSO	1992	
SI 917	Health and Safety (First Aid) Regulations	HMSO	1981	

Publication ID	Title	Publisher	Date	Notes
SI 682	Health and Safety Information for Employees Regulations	HMSO	1989	
SI 341	Health and Safety (Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1994	
SI 2037	Lifting Operations and Lifting Equipment Regulations	HMSO	1998	
SI 2865	Management of Health and Safety at Work Regulations	HMSO	1992	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulation	HMSO	1994	
SI 2169	Medicines (Standard Provisions of Licences and Certificates) Amendment (No 3) Regulations	HMSO	1977 1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 2169	Pressure Systems and Transportable Gas Containers Regulations	HMSO	1989	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 201	Public supply contracts regulations	HMSO	1995	
SI 2023	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1985	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS EN ISO3746	Acoustics: determination of sound power levels of noise sources	BSI Standards	1996	
BS EN 1820	Anaesthetic reservoir bags	BSI Standards	1997	

Publication ID	Title	Publisher	Date	Notes
BS EN 1281	Anaesthetic and Respiratory equipment Part 1: Conical connectors	BSI Standards	1997	
BS EN 1282	Anaesthetic and respiratory equipment Part 1: Tracheostomy tubes: adult Part 2: Tracheostomy tubes: paediatric	BSI Standards	1997 1997	
BS EN 6001	Application of EN ISO 9001 to the manufacture of medical devices	BSI Standards	1997	
BS EN 6002	Application of EN ISO 9002 to the manufacture of medical devices	BSI Standards	1997	
BS EN 866	Biological systems for testing sterilizers and sterilisation processes Part 1: General requirements Part 2: For use in ethylene oxide sterilizers Part 3: For use in moist heat sterilizers	BSI Standards	1997 1998 1997	
BS 5304	Code of practice for safety of machinery	BSI Standards	1988	
BS EN 50081	Electromagnetic compatibility. Generic emission standard Part 1: Residential, commercial and light industry Part 2: In industrial environment	BSI Standards	1992 1994	
BS EN 50082	Electromagnetic compatibility. Generic immunity standard Part 1: Residential, commercial and light industry Part 2: In industrial environment	BSI Standards	1998 1995	
BS EN 55014	Electromagnetic compatibility . Requirements for household tools and appliances	BSI Standards	1997	
BS 5295	Environmental cleanliness in enclosed spaces	BSI Standards	1989	
BS 1427	Guide to field and on-site test methods for the analysis of waters	BSI Standards	1993	

Publication ID	Title	Publisher	Date	Notes
BS EN 50103	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical service	BSI Standards	1996	
BS EN 724	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices	BSI Standards	1995	
BS EN 60751	Industrial platinum resistance thermometer sensors	BSI Standards	1996	
BS 1139	Metal scaffolding Part 2: Couplers	BSI Standards		
BS 6734	Method for determination of antimicrobial efficacy disinfectants for veterinary and agricultural use	BSI Standards	1986	
BS 3928	Method for sodium flame test for air filters (other than air supply to IC engines and compressors)	BSI Standards	1969	
BS 5728	Measurement of flow of cold potable water in closed conduits Parts 2, 3, 5, 6, and 7	BSI Standards	1980 - 1987	
BS 5726	Microbiological safety cabinets Part 1: specification for design, construction and performance Part 2: Recommendations for information to be exchanged between purchaser, vendor and installer Part 3: Specification for performance after installation Part 4: Recommendations for selection, use and maintenance	BSI Standards	1992	
BS EN 2588	Portable sanitary pans for use in healthcare establishments Part 1: Specification for reusable bedpans Part 2: Specification for reusable pans for commode chairs	BSI Standards	1992 1992	

Publication ID	Title	Publisher	Date	Notes
EN 837	Pressure gauges Part 1: Bourdon tube Part 2: Pressure gauges. Selection and installation recommendations Part 3: Diaphragm and capsule pressure group. Dimension metrology	BSI Standards	1998 1998 1998	
BS EN ISO 9000	Quality management and quality assurance standards.	BSI Standards	1994	
BS EN ISO 9001	Quality systems. Model for quality assurance in design, development, production, installation and servicing.	BSI Standards	1994	
BS EN ISO 9002	Quality assurance. Model for quality assurance in production, installation and servicing	BSI Standards	1991	
BS 3693	Recommendations for design of scales and indexes on analogue indicating instruments	BSI Standards	1992	
BS 7671	Requirements for electrical installation. IEE Wiring Regulations Sixteenth Edition	BSI Standards	1992	
BS 7671	Requirements for electrical installation IEE Wiring Regulations 16 th Edition	BSI Standards	1992	
BS EN 61010	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements Part 2: Particular requirements for washer disinfectors and other equipment incorporating washing equipment for the treatment of medical materials and for laboratory processes	BSI Standards	1993	
BS EN 274	Sanitary tapware. Waste fittings for basins, bidets and baths. General technical specification.	BSI Standards	1993	
BS 4196	Sound power levels of noise sources	BSI Standards	1991	
BS 2621	Specification for glycerol	BSI Standards	1979	

Publication ID	Title	Publisher	Date	Notes
BS 3046	Specification for adhesives for hanging flexible wall-coverings	BSI Standards	1981	
BS 1704	Specification for solid-stem general purpose thermometers	BSI Standards	1985	
BS 5164	Specification for indirect-acting electrical indicating and recording instruments	BSI Standards	1975	
BS 5779	Specification for spray mixing taps	BSI Standards	1979	
BS 3218	Specification for test tubes and boiling tubes	BSI Standards	1982	
BS 5500	Specification for unfired fusion welded pressure vessel	BSI Standards	1997	
BS 6447	Specification for absolute and gauge pressure transmitters with electrical outputs	BSI Standards	1984	
BS 5898	Specification for principles of design and construction of volumetric glassware for laboratory use	BSI Standards	1980	
BS 1780	Specification for Bourdon tubes pressure and vacuum gauges	BSI Standards		
BS 853	Specification for vessels for use in heating systems	BSI Standards		
	Part 1: Calorifiers and storage vessels for central heating and hot water supply		1996	
	Part 2: Tubular heat exchangers for building and industrial services		1996	
	Part 3: Rubber hoses and hose assemblies. Wire braid and reinforced hydraulic type		1997	
BS 604	Specification for graduated glass measuring cylinders	BSI Standards	1982	
BS 6253	Specification for glass beakers for laboratory use	BSI Standards	1984	
BS 5040	Specification for plastic laboratory ware	BSI Standards	1976 - 1979	
BS 7320	Specification for sharps containers	BSI Standards	1990	
BS EN 60804	Specification for integrating-averaging sound level meters	BSI Standards	1994	

Publication ID	Title	Publisher	Date	Notes
BS 1752	Specification for laboratories sintered of fitted filters including porosity grading	BSI Standards	1983 (1994)	
BS 1449	Steel plate, sheet and strip Part 2: Specification for stainless heat resisting steel plate sheet and strip	BSI Standards	1983	
EN 285	Sterilisation. Steam sterilizers. Large sterilizer	BSI Standards	1997	
BS EN 554	Sterilization of medical devices. Validation of and routine control of sterilization by moist heat	BSI Standards	1994	
BS EN 556	Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile'	BSI Standards	1995	
BS EN 60584	Thermocouples – reference tables	BSI Standards	1996	
BS 5503	Vitreous china washdown WC pans Part 2: Materials, quality, performance and dimensions Part 3: Specification for pans with a horizontal outlet for use with 7.5l max flush capacity cisterns	BSI Standards	1977 1990	
BS EN ISO 3696	Water for analytical laboratory use. Specification and test methods	BSI Standards	1995	
BS EN ISO 5667	Water quality (All parts)	BSI Standards	1979 - 1998	
BS 6068	Water quality sampling Part 2: Sect 2.20 Methods for determination of cyanide by diffusion at pH6 Part 2: Sect.2.28 Method for determination of phosphorus: ammonium molybdate spectrometric method Part 2: Sect 2.37 Method of determination of chloride via a silver nitrate titration with chromate indicator (Mhor's method) Part 6: Sect. 6.5 Guidance on sampling drinking water used for food and beverage processing	BSI Standards	1986 1987 1990 1991	

Publication ID	Title	Publisher	Date	Notes
BS EN 25667	Water quality: guidance on sampling techniques and design of sampling programmes	BSI Standards	1993 & 1994	
BS EN 26461	Water quality detection and enumeration of the spores of sulfite-reducing anaerobes (Clostridia) Part 1: By enrichment in a liquid medium Part 2: By membrane filtration	BSI Standards	1993 1993	
BS 2745	Water disinfectors for medical purposes Part 1: Specifications for general requirements Part 2: Specification for human-waste container washer-disinfectors Part 3: Specification for washer-disinfectors except those used for processing human-waste containers and laundry	BSI Standards	1993 1993 1993	
EN (Draft)	Washer-disinfectors Part 1: (Draft) General requirements and tests Part 2: (Draft) Requirements and tests before washer-disinfectors for surgical instruments and trays, anaesthetic equipment, hollowware and glassware Part 3: (Draft) Requirements and tests for washer-disinfectors to human-waste containers Part 4: (Provisional) Requirements and tests for washer-disinfectors for thermolabile reusable instruments including endoscope	BSI Standards		
European Union (EC) Directives				
90/385/EEC	Active Implantable Medical Devices Directive Note: the Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992	Official Journal of the European Communities (OJEC)		

Publication ID	Title	Publisher	Date	Notes
91/356/EEC	Council Directive laying down the principle and guidelines of good manufacturing practice for medicinal products for human use	Official Journal of the European Communities (OJEC), L193, 17.7.91, p30		
93/42/EEC	Council Directive concerning medical devices	Official Journal of the European Communities (OJEC), L169, 12.7.93, p1		
80/778/EEC	Council Directive relating to the quality of water intended for human consumption	Official Journal of the European Communities (OJEC)		
93/94/EEC	Medical Devices Directive. Note: The Directive was adopted by the EC Council of Ministers on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations	Official Journal of the European Communities (OJEC), L319, 17.11.81, p19		
Scottish Health Technical Guidance				
SHTM 2007	Electrical Services Supply & Distribution			Issued in 4 parts
SHTM 2010	Sterilization	EEF	1999	Issued in 6 parts
SHTM 2011	Emergency electrical services	EEF	1999	Issued in 4 parts
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	EEF	1999	Issued in 2 parts
SHTM 2022	Medical gas pipeline systems Supplement 1: Dental compressed air and vacuum systems Supplement 2: Piped medical gases in ambulance vehicles	EEF	1999	Issued in 4 parts
SHTM 2025	Ventilation in healthcare premises	EEF	1999	Issued in 4 parts
SHTM 2027	Hot and cold water supply, storage and mains services	EEF	1999	Issued in 4 parts
SHTM 2031	Steam supply for sterilization	EEF	1999	Issued in 1 part

Publication ID	Title	Publisher	Date	Notes
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	EEF	1999	Issued in 6 parts
SHPN 15	Accommodation for pathology service	Scottish Office	1994	
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 26	Operating department	Scottish Office	1992	
SHPN 26 Supp.1	Operating department activity space data sheets	Scottish Office	1993	
SHPN 13	Sterile services department	Scottish Office	1994	
HBN 13 Supp 1	Oxide sterilization section			
	Scotconcode issued by HEEU	HEEU	1999	Version 3
NHS in Scotland Firecode				
HTM 82	Alarm and detection systems	EEF	1998	CD-ROM
Fire Practice Note 6	Arson prevention and control in NHS healthcare premises	EEF	1998	CD-ROM
Fire Practice Note 5	Commercial enterprises on hospital premises	EEF	1998	CD-ROM
Fire Practice Note 3	Escape bed lifts	EEF	1998	CD-ROM
HTM 84	Fire safety in NHS residential care properties	EEF	1998	CD-ROM
HTM 85	Fire precautions in existing hospitals	EEF	1998	CD-ROM
HTM 86	Fire risk assessment in hospitals	EEF	1998	CD-ROM
HTM 81	Fire precautions in new hospitals	EEF	1998	CD-ROM
HTM 83	Fire safety in healthcare premises: general fire precautions	EEF	1998	CD-ROM
Fire Practice Note 7	Fire precautions in patient hotels	EEF	1998	CD-ROM
Fire Practice Note 4	Hospital main kitchens	EEF	1998	CD-ROM
Fire Practice Note 10	Laboratories on hospital premises	EEF	1998	CD-ROM

Publication ID	Title	Publisher	Date	Notes
Health and Safety Publications				
(MDA SN 9619)	Compatibility of medical devices and their accessories and reprocessing units with cleaning, disinfecting and sterilizing agents. Medical Devices Agency	Dept. of Health	1996	
HTM 87	Textiles and furniture	EEF	1998	CD-ROM
(L5)	Control and substances hazardous to health and control of carcinogenic substances: Control of substances hazardous to health regulations 1999: approved code of practice. Health and Safety Executive	HSE Books	1999	3 rd Edition
(HC(79)3)	Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms	Dept of Health	1979	
(H(91)33)	Decontamination of equipment, linen or other surfaces contaminated with hepatitis B and/or human immunodeficiency viruses	Dept. of Health	1991	
(SAB(93)32)	Endoscope washer/disinfectors: recontamination of equipment	Dept of Health	1993	
	Microbiological safety cabinets: recommendations concerning their choice, installation, routine maintenance and use (Health Equipment Information No 86) Medical Devices Agency	Dept. of Health	1980	
	Scottish Infection Manual 1998 – guidance on core Standards for the Control of Infection in Hospitals, Healthcare premises and at the Community Interface	Scottish Office	1998	
	Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Directorate. Microbiology Advisory Committee	Dept. of Health	1993	
(L23)	Manual handling: Manual handling operations regulations 1992: guidance on regulations. Health and Safety Executive	HSE Books	1992	

Publication ID	Title	Publisher	Date	Notes
(EH40)	Occupational exposure limits. Health and Safety Executive	HSE Books		Issued annually
	Programmable electronic systems in safety related applications: an introductory guide. Health and Safety Executive	HSE Books	1987	
MDA DB 9501	Re-use of medical devices supplied for single use only	HMSO	1995	
	Safety in health service laboratories: safe working and the prevention of infection in clinical laboratories. Advisory Committee/Health and Safety Executive	HSE Books	1991	
(L22)	Safe working and the prevention of infection in the mortuary and post-mortem room. Health and Safety Executive			
	Work equipment. Provision and use of work equipment regulations 1998. Guidance on regulations. Health and Safety Executive	HSE Books	1998	
(L24)	Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992: approved code of practice and guidance. Health and Safety Commission	HSE Books	1992	
Miscellaneous References				
	Babb J R, Bradley C R, Barnes A R, <i>Question and Answer</i>	Journal of Hospital Infection	1992	Vol 20, p51-54
	Rollnick M, <i>How You Spend Your Pennies</i>	Health Estate Journal	1991	May, p12-15
	Dawson M, Novitsky T J, Gould M J. <i>Microbes, endotoxin and water</i>	Pharm Eng	1988	Mar/Apr vol 8, no2
	Twohy C W, Nierman ML, Duran A P <i>et al</i> , <i>Comparison of limulus amoebocyte lysates from different manufacturers</i>	Journal of Parent Science & Tech	1983	May/Jun vol 37, no3, p93-96
	<i>Bacterial endotoxin test</i> USP 8th Supp. Pharmacopoeial Convention		1993	Mar XXII NF XVII, p3349-3350

Publication ID	Title	Publisher	Date	Notes
	Chloride in waters, sewage and effluent. Methods for the examination of waters and associated materials	DOE/Nat. Water St. Committee	1981	
	Determination of pH in low ionic strength waters	DOE/Nat Water St Committee	1988	
	Determination of alkalinity and acidity in water	DOE/Nat Water St Committee	1981	
	Depryrogenation by dry heat. Technical report no 7. Parental Drug Association			Ch12, p101-108
	Dry heat destruction of lipo-polysaccharide. Applied Environmental Microbiology		1997	Vol 36 p715
	General principles of sampling and accuracy of results	DOE/Nat Water St Committee		
	Guidelines on the validation of the Limulus Amoebocyte Lysate test as an end product Endotoxin test for human and animal parenteral drugs, biological products and medical devices	US Food and Drug Administration	1987	
	Guide to contract procedures	NHS Estates	1998	
	International standards for drinking water	WHO	1971	
	Iron in raw and potable waters by spectrophotometry. Methods for the examination of waters and associated materials	DOE/Nat Water St. Committee	1977	
	Measurements of Electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters	DOE/Nat Water St Committee	1981	
	Model Engineering Specifications	NHS Estates, HMSO	1998	Issued in 4 volumes
	Model Water Bylaws: Dept. of the Environment	HMSO	1986	
	Ninhydrin test	Analytical Bio-chemistry	1993	Vol 211, p240-242

Publication ID	Title	Publisher	Date	Notes
	Phosphorus and silicon in waters, effluent and sludges	DOE/Nat Water St Committee	1992	
	Rules governing medicinal products in the European Community. Vol IV Good manufacturing practice for medicinal products. Commissions of the European Communities		1992	
	Scottish Capital Investment Manual	Scottish Office		
	Sterilization and disinfection of heat-labile equipment: report of a working Party on sterilization and disinfection of heat-labile equipment. Hospital Infection Research Laboratory		1986	
	Total hardness, calcium hardness and magnesium hardness in raw and potable waters	DOE/Nat Water St Committee	1981	
	Water Supply Bylaws Guide. Water Bylaws Advisory Service Water Research Centre		1989	2 nd Edition