Scottish Health Technical Memorandum 2030

(Part 3 of 3)

Validation and verification

Washer-disinfectors

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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 NHSScotland 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 is intended as a guide for 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* and Health Building Note 13 Supplement 1 *'Ethylene oxide sterilization'* section. Guidance for Laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

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

The current British Standards for WDs, although only in force since 1993, are expected to be replaced by European 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 are of concern for 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 where 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.

Contents

1. General

Introduction

1.1 This part of SHTM 2030 covers the validation and periodic testing of the various types of washer-disinfectors (WDs) used in hospitals, laboratories and other healthcare facilities.

1.2 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 the field with a vocabulary that will be consistent with the European Union (EU) standards that are to be introduced in the near future. The glossary provides a definition of terms referred to in this part of SHTM 2030.

1.3 References for all the documents referred to in this part and other selected documents that provide additional information of which the reader should be aware are contained at the end of this part.

Legal framework for washing and disinfection

1.4 WDs are used in relation to both medical devices and medicinal products as well as for sanitary equipment, laboratory equipment and cutlery/crockery.

1.5 WDs may be used for reprocessing medical devices, sanitary equipment, laboratory equipment, manufacturing equipment (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery, within their intended use.

1.6 WDs may also be used as part of the manufacturing process for medical devices, medicinal products, in-vitro diagnostics or laboratory products in processing ‘single-use’ products or components such as bottles and vials.

Medicinal products

1.7 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.

1.8 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 Volume IV of ‘The rules governing medicinal products in the European Community’.

1.9 The GGMP contains guidance on cleaning of components and manufacturing equipment which have implications for the design, installation and 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.

1.10 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

1.11 SHTM 2030 Part 2, 'Operational management', refers to the three European Directives on the manufacture and supply of medical devices and in-vitro diagnostics.

1.12 Whether, and if so in what circumstances, the Medical Devices Directive 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. If necessary, further guidance is given in the MDA Directives Bulletin 18.

1.13 The essential requirements of the Medical Devices Directive require inter alia:

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 (Annex I, 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 (Annex I, paragraph 7.2).

1.14 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), standards providing guidance on compliance with these standards (BS EN 724 and BS EN 50103) and the Institute of Sterile Services Management (ISSM) guidance document 'Standards & Practice'.

1.15 Other than the ISSM guidance these are mandated Standards and as such compliance with them affords the presumption of conformance with the relevant essential requirements of the Directive.

Published Standards

1.16 British Standard 2745: 1993 specifies requirements for WDs for medical purposes. The Standard is in 3 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'.

1.17 There are no European Standards, as yet, for WDs. CEN Technical Committee TC102 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 (for example endoscopes)'.

1.18 IEC Technical Committee TC66 is developing Standards for 'Safety requirements for washer-disinfectors'.

1.19 When published, compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.

1.20 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.

1.21 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.

Key personnel

1.22 The following personnel are referred to in this part of SHTM 2030.

Management

1.23 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.

1.24 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

1.25 The user is defined as the person designated by management to be

responsible for the management of a WD.

1.26 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.

1.27 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)

1.28 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 Safety Regulations 2000. The shorter term “competent person” is used in this SHTM.

1.29 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.

1.30 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.

1.31 Most insurance companies maintain a technical division able to advise on appointing a competent person. Advice may also be obtained from Scottish Healthcare Supplies, Trinity Park House, Edinburgh.

Test Person (Washer-disinfectors)

1.32 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. 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.

1.33 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)

1.34 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.

1.35 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.

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

a. to carry out the maintenance tasks outlined in SHTM 2030 Part 2, 'Operational management';

b. to carry out additional maintenance and repair work at the request of the user.

1.37 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, quarterly and yearly tests described in this SHTM 2030.

Microbiologist

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

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

1.40 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

1.41 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

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

Quality Controller

1.43 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

1.44 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

1.45 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

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

Contractor

1.47 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

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

Independent Advisor

1.49 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.

Water supply

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

Safety

1.51 Guidance on the safe operation of the various types of WD is given in SHTM 2030 Part 2; 'Operational management'. As far as testing is concerned, normal safety precautions are adequate except in the case of WDs using liquid chemical germicides. In this case users are recommended to operate a permit-to-work system to ensure that such WDs are declared safe to work on, and that personnel working on them have documented authority to do so.

Chemical additives

1.52 Many of the chemical additives used in WDs and their associated ancillary equipment, for example water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.

1.53 The 'Control of Substances Hazardous to Health (COSHH) Regulations 1999' place upon management an obligation to ensure that suitable measures are adopted 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.

1.54 Some of the substances which may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH40 published annually by the Health and Safety Executive. These limits are statutory maxima but 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.

1.55 The WD, including any special ventilation equipment necessary for its safe operation, will be subject to the COSHH Regulations. These Regulations introduced controls on biological agents which are of relevance to purchasers of WDs. Detailed guidance on ventilation systems is provided in SHTM 2025.

Infectious materials

1.56 All WDs have the potential to process infectious materials. The user should therefore ensure that personnel working on WDs wear appropriate protective clothing and are fully informed of any hazards that may be present. In case of doubt the microbiologist should be consulted.

2. Testing of washer-disinfectors

Introduction

2.1 WDs are used to carry out the processes of cleaning and disinfection consecutively.

2.2 In some instances a visual inspection for residual contamination may be considered sufficient for monitoring the adequacy of the cleaning process before use. However, this is not true in all cases; for example, visual inspection will not detect soiling on the internal surfaces of instruments with lumens and will not detect low, but potentially significant, concentrations of soiling (for example proteins) or residual chemical additives from the WD remaining on load items.

2.3 There is no simple method to verify by inspection or test the efficacy of the disinfection process on a product prior to use.

2.4 In consequence, cleaning and disinfection processes have to be validated before use, the performance of the process monitored during routine use, the calibration of controls and instrumentation verified, and the equipment subjected to a suitable maintenance programme.

2.5 The control protocols described in this part of SHTM 2030 provide the means for ensuring that the WD is fit for its intended purpose and includes tests and checks carried out during manufacture, after delivery, during validation and periodically thereafter. Tests are also required before a WD is returned to service after repairs that affect one or more components which influence the attainment of critical process control variables or after modification.

2.6 The control protocol is based on four key aspects to ensure that the required standards of performance and safety are met and sustained:

a. all WDs are subjected to a planned programme of tests to validate their performance, that is, to provide experimental evidence that, when operated under the specified conditions, the WD will reliably produce cleaned and disinfected items to the standard required;

b. all WDs are subjected to a planned programme of tests to monitor their performance;

c. all WDs are operated in accordance with an agreed procedure by staff trained in the use of the WD;

d. all WDs are subjected to a planned programme of preventative maintenance irrespective of whether a preventive maintenance scheme is operated on the premises.

2.7 Expertise on all aspects of the operation and testing of WDs should be available on three levels; the Independent Advisor, Test Person (WD), and Maintenance Person (WD).

2.8 The scheduled test programmes include simple tasks to be undertaken by the user as well as more complex tests undertaken by the MP/TP.

2.9 Schedules for pre-delivery works tests (when necessary), installation checks, validation tests and periodic tests are presented in Chapters 3, 4, 5 and 6 of this document, and discussed below. When appropriate, the schedules refer to detailed test procedures described in later chapters.

2.10 Maintenance of WDs is dealt with in SHTM 2030 Part 2; 'Operational management'.

Responsibilities

2.11 WDs should be subjected to a planned programme of testing both before delivery and on-site. The on-site testing should be carried out using the procedures described in this SHTM and should include installation qualification, operational qualification and process qualification. The purchaser, manufacturer and contractor have distinct responsibilities.

Management

2.12 Management should nominate, when necessary, an Independent Advisor to provide advice on validation and a MP/TP to carry out the checks and tests required.

2.13 The Independent Advisor should review the results of pre-delivery works tests carried out by the manufacturer, and review the test instruments provided by either or both the contractor (see paragraph 1.37) and the MP/TP to ensure that their accuracy, calibration and condition meet the standards for test instruments described in Chapter 8.

2.14 The MP/TP should witness the installation checks and tests carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory and arrange for test loads to be supplied as required.

2.15. The TP should carry out the initial operational qualification and performance qualification tests.

Manufacturer

2.16 The manufacturer should ensure that the WD is designed, manufactured and tested within a quality system complying with the requirements of BS EN ISO 9001 or BS EN ISO 9002.

2.17 The manufacturer should carry out pre-delivery works testing. The extent of testing will depend on whether the product is in serial production or a 'one off' and, for machines in serial production, whether the manufacturer has obtained a certificate of compliance to a relevant British or European Standard by means of a type test for the particular type and size of WD.

Contractor

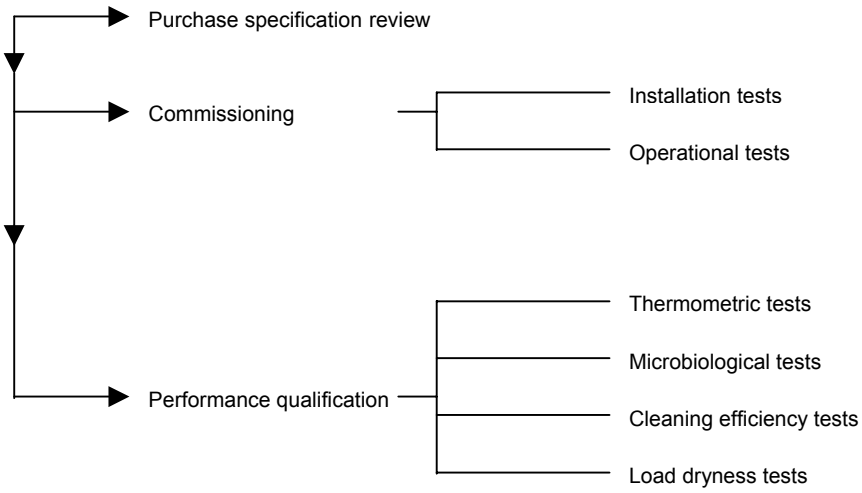
2.18 The contractor, who may also be the manufacturer, should complete the installation checks and tests specified in Chapter 4 to the satisfaction of the MP/TP before the WD can be accepted for use in accordance with the contract.

2.19 The contractor should provide the test instruments and equipment (but, unless otherwise specified in the contract, should not be expected to provide the test loads). The test instruments provided should meet the standards for test instruments described in Chapter 8.

Validation

2.20 Validation is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a pre-determined specification. Validation is a total process beginning with a review of the specification against which the equipment is purchased. This is to ensure that it will meet the user's specified production needs including installation qualification, operational qualification and performance qualification. Installation qualification and operational qualification are sometimes referred to jointly as 'commissioning'.

Figure 1: The validation process



Works tests

2.21 Before delivery of the WD, the manufacturer should subject the machine to a programme of factory tests. The extent of these tests will depend on whether the WD is in serial production or is a unique design (a 'one-off'). For machines in serial production the works tests are intended to verify that, in respect of various critical attributes, the WD performs in conformity with the results obtained from type testing. It is rarely necessary to attend the factory to witness works tests but the manufacturer should make the results of these tests available on or before delivery of the WD.

2.22 For 'one-off' designs a more extensive programme of works tests, similar to the programme of type tests for machines in serial production, is required and the purchaser may wish to arrange for their representative (either the Independent Advisor or MP/TP) to attend the factory to witness these tests before accepting delivery of the WD.

2.23 The schedule for type test and works tests is set out in Chapter 3.

Commissioning

2.24 Commissioning is defined as the process of obtaining and documenting evidence that the equipment has been provided and installed within the agreed purchase specification, and that it functions within pre-determined limits when operated in accordance with the manufacturer's instructions.

2.25 Commissioning consists of a series of installation tests to be carried out by the contractor and operational tests to be carried out by the MP/TP.

Pre-Installation checks

2.26 The contractor should verify that the site services are adequate for the operation and performance of the WD before it is delivered.

2.27 The contractor should verify the condition of the water supply and set chemical dosing levels as appropriate.

Installation tests

2.28 The contractor should carry out the required installation checks on delivery of the WD to ensure that the WD has been supplied and installed correctly and is safe to operate.

2.29 Ventilation systems should be checked by the contractor responsible for their installation.

2.30 When these checks have been completed and found satisfactory the contractor should carry out the installation tests necessary to demonstrate that the WD is working satisfactorily. The contractor is not required to carry out any thermometric tests unless these were specified in the purchase contract. Any assistance required from the purchaser should be agreed as part of the purchase contract.

2.31 If any modification, maintenance or repair work is carried out on the steam, water, compressed air ventilation or drainage systems after the installation tests have been completed, the relevant installation tests should be repeated before the operational tests are undertaken.

2.32 The schedule for installation checks and tests is set out in Chapter 4.

Operational tests

2.33 When the WD has been installed and accepted the MP/TP should carry out a sequence of operational performance tests to evaluate the basic performance and safety of the WD. Some of these tests are identical to those specified as installation tests and need not be repeated if operational testing follows within ten working days of the completion of the installation tests.

2.34 For operational tests see Chapter 5.

Performance qualification

2.35 Performance qualification is defined as the process of obtaining documented evidence that the equipment, as commissioned, will produce an acceptable product when operated in accordance with the specification.

2.36 Performance qualification consists of tests designed to show that:

a. soil removal and cleaning have been effective throughout the load and the WD chamber, and the products are of the required standard of cleanliness, free from process residues (when applicable);

b. disinfection conditions have been attained throughout the load and the WD chamber, and to the required standard for the type of load being processed. A thermometric test is sufficient for WDs employing a thermal disinfection process. Additional microbiological tests will be required for WDs that use chemical disinfectants and may be necessary for WDs where the nature of the load or loading conditions do not permit thermometric monitoring which accurately reflects the conditions pertaining in the load.

2.37 In principle, it might be argued that a performance qualification test is required for each loading condition that a WD is required to process. In practice, it is possible to identify reference loads and reference loading conditions which present an equal or greater challenge to the process than the loads which may be encountered in normal use.

Documentation

2.38 Accurate and efficient record keeping is an essential part of the management of a WD. The extent and nature of the records that are necessary varies with the type of WD and the use to which it is put. Guidance is given in SHTM 2030 Part 2, ‘Operational management’.

Summary sheets

2.39 On completion of the validation process the MP/TP should immediately prepare a summary report containing the results of the commissioning and performance qualification tests and essential working data.

2.40 The summary report should be signed by the MP/TP and countersigned by the user to certify that the WD is fit for use.

2.41 Summary reports should be securely retained by the user and be available for ready reference.

Validation report

2.42 Within one month of the completion of the validation process the MP/TP should prepare a full validation report which should include:

a. all the data supplied by the contractor, collected during the installation checks and tests, with written confirmation that they meet the manufacturer's specification;

b. written confirmation that the calibrations of all measuring instruments fitted to the WD have been verified;

c. all the data collected during the commissioning tests, with written confirmation that they meet the specified requirements;

d. data showing the correlation between the performance of the measuring instruments fitted to the WD and the test instruments used;

e. reports containing all the data collected during the performance qualification tests with written confirmation from the MP/TP and the user of the loading conditions and types of load (including when necessary reference to specific individual items) which may be satisfactorily processed in the WD.

2.43 When data is in the form of electronic data files, the report should include copies of disks or tapes containing the data in a format agreed with the user and a printout of the directory of each, annotated to show where the data for each test is to be found.

2.44 The MP/TP should certify that all necessary tests have been carried out and that the results are satisfactory.

2.45 The records of any microbiological tests should be signed by the microbiologist.

2.46 The Independent Advisor should review and countersign the completed validation report.

2.47 The validation report should be retained by the user. Copies may be retained as necessary by the MP/TP, the Independent Advisor, the Microbiologist, Estates Dept. and, where applicable, the Quality Controller.

Periodic tests

2.48 After validation and when the WD is passed into service, it should be subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals, refer to (Table 5).

2.49 The user, Microbiologist and the MP/TP are responsible for the periodic tests.

2.50 The daily, weekly and quarterly test schedules provide evidence that the WD continues to operate within the limits established during commissioning.

2.51 The yearly test schedule is a revalidation procedure and provides a more comprehensive test programme than the other periodic tests; it serves to demonstrate that data collected during commissioning and the performance qualification remain valid.

Revalidation

2.52 In addition to annual revalidation (Table 5), further revalidation is required in the following circumstances:

a. when the WD is to be returned to service after repair or component replacement of part of the systems which affect satisfactory attainment of the pre-set variables of the operating cycle;

b. when the pre-set values of the cycle variables have been modified;

c. when the software in a programmable electronic system (PES), used for control of the process, has been modified;

d. whenever the user or Independent Advisor advises that revalidation is necessary;

e. whenever it is required by an authorised inspectorate or licensing authority.

2.53 The full revalidation procedure is identical to that specified for the yearly test. See Chapter 7.

2.54 It will not always be necessary to carry out a full revalidation and the advice of the Independent Advisor, Microbiologist or the Control of Infection Officer should be sought on which tests are required following any particular event.

Repeat validation

2.55 Revalidation and periodic tests are designed to establish the continued conformance of the equipment and its performance with data established during the original validation study.

2.56 There are occasions when it may be necessary to repeat the full set of tests carried out during the initial validation in order to obtain a new set of data.

2.57 Repeat validation will be necessary:

a. when the WD is modified to such an extent that it must be presumed that the original data is no longer valid;

b. when a WD, other than a table top machine, has been moved and installed at a new site;

c. when the WD has been dismantled or extensively overhauled;

d. whenever the user or Independent Advisor advises that repeat validation is necessary;

e. whenever it is required by an authorised inspectorate or licensing authority;

f. whenever revalidation fails to confirm compliance with the original data and no cause for the discrepancy can be found.

2.58 It will not always be necessary to carry out a full repeat validation and the advice of the Independent Advisor should be sought as to which tests are required following any particular event.

Types of test

2.59 The tests should fall into the following categories:

a. **Automatic control tests** which are designed to verify the correct functioning of the operating cycle from the readings obtained from the instruments fitted to the WD;

b. **Thermometric tests** which are designed to provide assurance that the temperature requirements for disinfection are met by using accurate measuring equipment, independent of the instruments fitted to the WD to monitor the temperatures attained within the chamber and reference loads;

c. **Microbiological tests** which are designed to show that disinfection conditions are attained when thermometric methods alone are inadequate for this purpose;

d. **Cleaning efficacy tests** which are designed to show, by monitoring the removal of a test soil, that the process will effectively clean products of the type to be processed.

2.60 Other performance tests specific to certain types of WD are designed to provide assurance that the WD will perform correctly under the anticipated conditions of use.

Procedure on failure of a test

2.61 There should be no difficulty in ensuring that a correctly installed and maintained WD will comply with both the validation tests and periodic tests described.

2.62 Failure of a test generally indicates that a WD is not working to specification and it should be withdrawn from service and the failure investigated.

2.63 In practice, the action to be taken is a matter of judgement and will depend on the nature of the failure and the use to which the WD is being put. It may be acceptable for the WD to continue operating under carefully defined restrictions until the cause of the failure can be established and rectified.

2.64 The Independent Advisor and the user should agree the course of action to be taken.

2.65 The user has the ultimate responsibility for certifying that the WD is fit for use.

Inter-relationship of test programmes

2.66 The tests described in this part of SHTM 2030 are intended for use in type tests, works tests, commissioning (installation and operational tests), and performance qualification (thermometric tests, microbiological tests, cleaning efficacy tests and load dryness tests), and routine periodic tests.

2.67 The inter-relationship of the various test programmes, the place where they would usually be conducted and the responsibility for conducting the tests are shown in Figure 2.

2.68 The circumstances under which each of the test schedules should be applied is given in Table 1: ‘Summary of manufacturer's test programmes for WDs'.

2.69 The programmes of tests should be applied to all WDs where relevant. Details are given under the test schedules for particular types of WD.

Figure 2: Inter-relation of test programmes

Location	Serial Production	'One-off' WD Production	Responsibility
Factory	Type Test ➜ Works Test	Type Test	Manufacturer

Location	Tests	Responsibility
On-site	INSTALLATION	Manufacturer/TP(s)
	OPERATIONAL	Manufacturer/TP(s)
	PERFORMANCE QUALIFICATION	User/MP(s)/TP(s)
	PERIODIC ROUTINE TEST	TP(s)
	ANNUAL REVALIDATION TESTS	User/MP(s)/TP(s)

3. Schedule of type tests and works tests

Introduction

3.1 The manufacturer carries out type tests on representative samples of WDs in serial production to demonstrate compliance of the WD design with its specification and/or published Standards as appropriate.

3.2 The manufacturer carries out works tests on each WD before it leaves the manufacturing site to ensure that each WD meets specification.

3.3 For WDs in serial production the programme of tests required for the works test is usually a reduced set of the tests in the schedule for type testing.

3.4 For WDs of 'one-off' design the schedule of works tests would necessarily be the same as the schedule for type testing.

3.5 Type tests, and more rarely works tests on one-off designs, may be carried out or witnessed by a third party to allow certification of the product to a relevant standard e.g. BS 2745 Part 2 or Part 3. The product certification scheme run by BSI leads to the award of the 'kitemark' for certified products. A similar scheme is operated through CEN for products complying with European Standards and compliant products may carry the CEN 'keymark'. Those clinical WDs which are classified as medical devices and are supplied on, or after, 14 June 1998 will be required to bear the CEN marking.

3.6 The manufacturer should make available to the purchaser the results of type tests and works tests on or before delivery of the WD.

3.7 It will rarely be necessary for the purchaser, or their representative, to visit the manufacturer's works to witness works testing except, perhaps, in the case of 'one-off' machines. The advice of the Independent Advisor should be sought.

3.8 A summary of the tests which should be included in a programme of type tests and works tests is shown in Table 1.

Table 1: Summary of manufacturer's test programmes for WDs

	Type Test	Works Test
1. Cleaning efficacy		
Chamber	✓	
Load	✓	
Load carrier	✓	
2. Thermometric		
Thermal disinfection	✓	✓
Temperature control	✓	✓
Over-temperature cut-outs	✓	✓
Chemical disinfection	✓	✓
Thermal insulation	✓	
3. Microbiological		
Disinfection	✓	
4. Load dryness	✓	✓
5. Fluid emission		
Chamber leak proof	✓	✓
Door seal	✓	✓
Vapour emission	✓	✓
6. Sound power	✓	
7. Electromagnetic interference	✓	
8. Doors & interlocks		
Cycle start	✓	✓
Loading/unloading	✓	✓
With services	✓	
On fault condition	✓	✓
9. Process residuals	✓	
10. Chemical dosing		
Accuracy and repeatability	✓	✓
Low level indicator	✓	✓
11. Water quality		
Rinse water	✓	
In relation to performance testing	✓	
Water volume	✓	
12. Air quality	✓	
13. Pipework		
Dead volume	✓	
Free draining	✓	
Overflow	✓	✓
Venting system	✓	
14. Instrumentation		
Legibility	✓	
Calibration	✓	✓
15. Load carriers		
Fitting	✓	✓
Stability	✓	✓
Alignment	✓	✓
Force to move	✓	✓
Effect in cycle	✓	
16. Operating cycle		
Spray system	✓	✓
Reproducibility	✓	✓
Fault indication	✓	✓

4. Schedule of installation tests

Introduction

4.1 On delivery of the WD the contractor should carry out the installation checks included in the contract and as set out in this chapter to establish that:

a. the WD has been provided and installed correctly;

b. the WD is safe to operate;

c. the WD does not interfere with other equipment;

d. all connected services are satisfactory and do not prevent attainment of the designed cleaning and disinfection performance of the WD.

4.2 The contractor responsible for installing the WD should carry out installation checks on services and other ancillary equipment. These checks should be completed and all services and ancillary equipment found to be satisfactory before carrying out installation checks on the WD itself.

4.3 The contractor responsible for installing the WD should carry out any additional checks specified by the manufacturer.

4.4 The MP/TP should carry out any checks specified in this chapter which were not included in the purchase contract for the WD.

4.5 As a safety precaution, checks on chemical dosing systems (for chemical additives such as detergents, disinfectants etc.) should be carried out using water. Checks on fume extract systems designed to eliminate personnel exposure to hazardous chemicals (for example gluteraldehyde) should be carried out using a non-hazardous substitute or a smoke test.

Checks on ancillary equipment

4.6 Ancillary equipment should, whenever practicable, be installed and commissioned before validation of the WD begins.

4.7 When the checks on ancillary equipment require the WD to be in operation, the MP/TP should carry them out in co-operation with the contractor for the WD.

4.8 The contractor for the WD is not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.

Engineering services

4.9 Check that the following requirements are met:

a. the engineering services have been installed correctly, they are adequate to meet the demands of the WD, they do not leak and all necessary isolating valves/switches and test points have been installed;

b. drains remove effluent effectively when all plant in the vicinity, including the WD, is connected and operating;

c. the water treatment plant (if fitted) operates correctly and the quality of water supplied for each stage of the process is in accordance with the specification;

d. the provision for storage, handling and connection to the WD for all process chemicals, meets the requirements for safe handling of potentially hazardous chemicals;

e. the exhaust ventilation and/or condenser unit fitted to the WD is adequate to remove the hot, humid air evolved from the washing, thermal disinfection and drying and unloading processes;

f. for WDs employing volatile process chemicals, the exhaust ventilation maintains the environmental concentration below any limit specified for occupational exposure and that the discharge is to a safe place.

NOTE: The maximum permitted concentration and the method of detection and analysis will depend on the chemical being used.

Additional checks for WDs using a chemical disinfectant

4.10 WDs using chemical disinfectants require further tests to the ventilation and safety systems because of the possible emission of toxic gases or vapours.

4.11 For WDs using a chemical disinfectant, check that the ventilation system within the loading (or unloading) area of the WD, the plant room (if applicable) and the storage area for the disinfectant meet the specified requirements. Particular attention should be paid to the following:

a. the installation meets the manufacturer's specifications;

b. air flow is from the operator towards the WD and air does not flow from the plant room (if applicable) or disinfectant storage area into the loading (or unloading) area;

c. exhaust systems are non-recirculating and their discharges comply with relevant safety Regulations.

4.12 Check that local exhaust ventilation incorporated in the WD or installed as a dedicated accessory meets the specified requirements. Particular attention should be paid to the following:

a. air flow is from the operator towards the WD;

b. the rate of flow complies with the specified requirements;

c. The exhaust discharge complies with safety Regulations.

4.13 When the disinfectant solution is intended to be discharged to drain ensure that the drainage system is trapped, sealed and vented to a safe position. The drainage system should be checked to ensure that it is not possible for toxic materials to be vented into any other part of the building.

Checks on the WD

Preliminary checks

4.14 Check that the electrical equipment on the WD is correctly connected to the electrical service. Carry out the following electrical tests:

a. insulation resistance;

b. phase sequence (for 3 phase installations);

c. polarity;

d. bonding and earth continuity;

e. emergency stop.

4.15 After the WD has been installed, check that the following requirements are met:

a. the manufacturer has supplied all the documents specified in the contract;

b. the WD has been supplied and installed in accordance with the contract;

c. calibration verification certificates for the measuring instruments and controller(s) on the WD have been supplied;

d. no defects are apparent from a visual inspection of the WD;

e. all supports, bases and fixings are secure and without imposed strain from service connections;

f. thermal insulation is in good condition and securely attached;

g. security and settings of door safety switches are in compliance with data

supplied by the manufacturer;

h. keys, codes or tools required to operate locked controls and control over-rides have been supplied, operate correctly and only operate the control for which it is intended;

i. loading conveyors and trolleys, load carriers and load baskets are effective and safe in use.

Functional checks

4.16 During an operating cycle, with an empty chamber, check that the following requirements are met (several cycles may be necessary to complete all the checks):

a. the selection of automatic or manual control is by key, code or tool. The selection of one control mode inactivates the other control modes;

b. under automatic control, water, steam, compressed air or chemical additives cannot be admitted into the chamber, and the operating cycle cannot start until the door is closed;

c. under manual control, the operator can advance the cycle only sequentially through each stage. Any stages designed to remove chemical additives from the chamber and load cannot be circumvented;

d. throughout the cycle, the indicated and recorded values of cycle variables are within the limits specified by the manufacturer;

e. throughout the cycle, there are no leaks of water, steam aerosols, toxics chemicals or effluent;

f. there is no evidence of interference to or from other equipment connected to the same services;

g. there is no evidence of electromagnetic interference to or from other equipment;

h. operation and reading of all instruments appear to be satisfactory;

i. the temperature of surfaces routinely handled by the operator does not exceed those specified in SHTM 2030 Part 2, ‘Design considerations’;

j. the effluent temperature does not exceed that specified in SHTM 2030 Part 1, ‘Design considerations’.

4.17 At the end of the cycle check that the following requirements are met:

a. the door opening system cannot be opened until the cycle has been completed, that is, the automatic controller has operated in accordance with its specification;

b. for systems incorporating one or more cycle stages at pressures 200 mbar above or below atmospheric pressure:

(i) the door opening system cannot be operated until the chamber has been vented to atmosphere and the chamber pressure is within 200 mbar of atmospheric pressure;

(ii) the door retaining parts cannot be released until the seal between the door and chamber has been broken, and the chamber is effectively vented to atmospheric pressure.

Response to external faults

4.18 It is necessary to check that the WD reacts correctly and safely when exposed to a number of external fault conditions; that is, a safety hazard is not created and a false indication of satisfactory completion of a cycle is not obtained.

4.19 During an operating cycle, check the response of the WD to the following simulated faults (as appropriate to the type of WD):

a. operation of the emergency stop button;

b. power failure;

c. failure of the disinfection process;

d. failure of extract ventilation (chemical disinfection).

TABLE 2

Machines being put into service for the first time
TESTING SCHEDULE

Type of WD	Pre Installation Checks			Installation Checks						Commissioning Tests			
						Drainage							Water System
Para Ref.		(9.37)	(9.49)	(9.54)	(9.55)	(11.4)	(9.17)				(11.4)	(9.95)	
	Design Specification. Use and services	Water Quality (Hardness)	Water Supply Temperature	Water Supply Pressure	Verification of WD instrument calibration	Automatic Control Test	Blocked Drain Protection	Estimation of dead volume of Drainage pipework	Efficacy of Drainage Discharge	Safety Checks	Automatic Control Test (each cycle)	Verification of WD instrument calibration	Chemical Purity
Human Waste	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Surgical Instruments	U/M/A	U/A/C	U/A/C	U/A/C/	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Holloware	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Anaesthetic Accessories	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Endoscopes	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Laboratory	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Utensils & Crockery	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP

A = Independent advisor
TP(s) = Test Person
MP(s) = Maintenance Person
U = User
M = Microbiologist or Control of Infection Officer
C = Contractor / Supplier / Manufacturer

TABLE 2 (continued)

TESTING SCHEDULE

Type of WD	Commissioning Tests								
	Doors and Interlocks				Chemical Dosing				
Para Ref	(9.69)	(9.73)	(9.76)	(9.8)	(9.88)	(9.9)	(18.9)	(18.3)	(17.3)
	Cycle Start	In Cycle	Double ended WD	Fault indication	Reproducibility of Volume	Low Level Detection	Channel Patency	Self Disinfection	Ultrasonic Activity
Human Waste	TP/C	TP/C	TP/C	TP/C	C	TP/C			
Surgical Instruments	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U		TP/C
Holloware	TP/C	TP/C	TP/C	TP/C	C	TP/C			
Anaesthetic Accessories	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U		
Endoscopes	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U	TP/C	
Laboratory	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U		
Utensils and Crockery	TP/C	TP/C	TP/C	TP/C	C	TP/C			

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TABLE 2 (Continued)

TESTING SCHEDULE

Type of WD	Commissioning Tests								
		Cleaning Efficacy Test (6.23)							
Para Ref.	(9.115)					(9.101)	(9.108)	(10.3)	(9.113)
	Test for air quality	Test Soil (6.28)	Reference Load	General Instruments	Endoscopic/ MAT instruments	Load carrier temperature test	Over temperature protection test (if fitted)	Thermometric test for thermal disinfection	Load dryness test
Human Waste		U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Surgical Instruments	U/M/C	U/M/C	U/M/C	U/M/C	U/M/C	TP/C	TP/C	TP/C	TP/C/U
Holloware	U/M/C	U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Anaesthetic Accessories	U/M/C	U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Endoscopes	U/M/C	U/M/C	U/M/C	U/M/C	U/M/C				TP/C/U
Laboratory	U/M/C	U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Utensils and Crockery		U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U

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5. Schedule of operational tests

Introduction

5.1 To demonstrate compliance with specifications the contractor should carry out installation checks and tests before operational tests are carried out (see Chapter 4); these may be repeated by the MP/TP if required.

5.2 Operational tests and performance qualification (see Chapters 5 and 6) tests are carried out by the MP/TP.

5.3 Unless otherwise specified in Chapter 8 the tests should be carried out with the WD at normal working temperature, which may require a 'warm-up' run to be carried out before commencement of testing.

5.4 A number of the tests required can be carried out concurrently on the same operating cycle and this is also indicated in Chapter 8.

5.5 The calibration of test equipment should be checked before and after use as described in Chapter 8.

5.6 In principle, performance qualification tests should be carried out after operational tests have been completed. However, for WDs employing a thermal disinfection stage, the performance qualification tests may be performed while the temperature sensors used in the commissioning tests are still in place.

5.7 Although dishwashers generally are excluded from this SHTM, there may be instances where, due to local needs, dishwashers should be tested to verify compliance with current disinfection standards (especially in the case of patients who are immunologically compromised).

5.8 The responsibility for microbiological tests rests with the user, microbiologist and control of infection officer. The scope and contents of any tests will be incorporated in local protocols agreed between the above persons and will take account of local circumstances.

5.9 During the commission of WDs for endoscopes, the Occupational Health Officer should carry out tests on and around the machine for traces of disinfectant vapour, particularly in the vicinity of the door or lid when opening at the end of a process. The frequency of testing will be determined by the local Occupational Health Officer.

6. Schedule of performance qualification tests

Introduction

6.1 Performance qualification (PQ) is the procedure for obtaining documented evidence that the WD, as commissioned, will produce cleaned and/or disinfected goods of the standard required when operated in accordance with the operational instructions.

6.2 PQ tests are performed as part of the initial validation procedure, as part of any repeat validation procedure and whenever the user, acting on the advice of the Independent Advisor, judges that new loading or operating conditions require a new PQ test.

6.3 Circumstances that may lead to new PQ tests would include changes to the quality of the water supply, changes to the chemical additives used in the cleaning and disinfection process, changes to the loading system or the requirement to process a new type of product.

6.4 Performance qualification should not be undertaken on any WD until the requirements of the installation and operational tests specified in Chapters 4 and 5 have been met.

6.5 Soil removal efficacy tests are required for all WDs as part of the performance qualification (see Para 6.24).

6.6 Performance qualification tests are carried out by the MP/TP.

6.7 Tests should be carried out with the WD at normal working temperature which may require a ‘warm-up’ run to be carried out before commencement of the tests.

6.8 Test data obtained from the PQ tests should be recorded in a written PQ report which clearly identifies the loading conditions, the operating cycles, the chemical additives and the water quality used at each stage of the cycle.

6.9 The user should employ the PQ report to confirm the suitability of the process for loads which are to be processed. It should be used by the MP/TP and Independent Advisor as the basis for comparison with subsequent performance requalification tests.

6.10 Performance requalification (PRQ) is the process of confirming that the WD continues to meet the performance standards established during PQ and that the working data established during PQ tests remain valid.

6.11 Performance requalification is carried out annually as part of the yearly test schedule, as part of any revalidation or repeat validation study, or whenever the user requests such confirmation.

6.12 Before undertaking performance requalification tests the MP/TP should confirm, either by testing or by reference to current test records, that the WD meets the requirements of the installation and operational tests.

Loading conditions

6.13 A **loading condition** is a specified combination of the nature and number of load items, the items of chamber furniture, and their distribution within the chamber. For example, a load placed on the topmost level of a four level load carrier constitutes a different loading condition from the same load placed on the lowest level.

6.14 In principle, validation is not complete until a PQ test has been performed for each loading condition that the WD is expected to process.

6.15 In practice, the loading conditions specified in the tests to be carried out during commissioning are designed to represent the nature of production loads and to present a greater challenge to the process than production loads. In these cases further PQ tests will not be required; the data obtained from the commissioning tests will be sufficient.

6.16 PQ tests are required under the following conditions:

a. when the proposed production loading condition presents a greater challenge to the process than that presented by the commissioning tests; for example, WDs for surgical instruments will require PQ tests if the mass of metal instruments to be processed exceeds that of the standard test load or if it is intended to process instruments with narrow lumens;

b. when the nature of the load is not represented by the commissioning tests; for example, WDs for surgical instruments will require PQ tests if it is intended to process instruments with narrow lumens such as endoscopes.

6.17 When PQ tests are required it is often possible to select a production load that is known to be a greater challenge to the process than any of the others. This **reference load** can then serve as a ‘worst case’ and allow one PQ test to be valid for a range of less demanding conditions.

Surrogate devices

6.18 Many of the devices that constitute the most difficult loads to process in a WD, which therefore require PQ, are difficult to monitor either thermometrically or microbiologically, are in short supply and are extremely expensive; examples include fibre-optic endoscopes, videoscopes, etc.

6.19 A **surrogate device** is a test piece designed and constructed to emulate the characteristics of a device to facilitate appropriate monitoring of the cleaning and disinfecting processes.

6.20 An example of a surrogate device might be a rigid endoscope emulated by a similar length of stainless steel tube of appropriate diameter and bore. The surrogate device can be constructed to incorporate the appropriate temperature sensors so that it may be separated into sections to facilitate the evaluation of residual test soil or survivors from a microbial challenge.

6.21 The surrogate device should have similar geometry and thermal mass and, as far as may be practicable, should be constructed of the same materials and the same surface finishes as the device it is designed to emulate. There are several devices available for assessing the efficacy of WD processes, and these can be used in conjunction with the reference loads as part of the testing procedures. Their suitability to a particular process should be verified before use. Advice should be sought from the Independent Advisor.

6.22 When an instrument presents particular problems in validation the manufacturer of the instrument should be requested to provide details of the method by which they recommend that PQ studies should be performed.

Cleaning efficacy tests

Native soiling

6.23 Cleaning efficacy tests are intended to demonstrate the ability of the WD to remove or reduce to acceptable levels, soiling and contamination which occurs during normal use of re-usable items.

6.24 Naturally occurring contamination shows considerable variation both in the nature and proportion of constituents and also in the extent of soiling which may occur during use.

NOTE: These tests should be carried out by the user in conjunction with the Microbiologist.

6.25 Test methods based on the detection of naturally occurring soiling are difficult to standardise and show poor reproducibility due to:

a. the variation in the composition of the soiling which may affect the ease with which soiling is removed;

b. the changes in sensitivity of detection which may occur due to variation in composition of the soiling;

c. the variation in the extent of soiling.

6.26 A number of methods exist for estimating (both qualitatively and quantitatively) the residual levels of some important soils or components of soils. These include detection of blood (Hydrogen peroxide test, Kastle-Meyer test), protein (Ninhydrin test, Biuret test) or bacterial endotoxins (LAL test).

6.27 Common practice in the past has been to rely solely upon visual inspection to detect unacceptable levels of residual soiling. This method has poor sensitivity, is very subjective and can be greatly influenced by a number of factors including the intensity and nature of the illumination in the inspection area.

Test soils

6.28 Artificial test soils are designed to simulate the nature of native soiling and to be equally, or more difficult to remove.

6.29 By incorporating appropriate marker substances, they can provide improved sensitivity of detection.

6.30 Test soils can be used to give a quantified loading level, quantified detection and hence a quantified estimate of the soil removal which has occurred.

6.31 Test soils avoid any hazard which may be associated with native soiling (for example blood borne viruses) which may be of particular concern with the more extensive handling necessary for test work.

6.32 Worldwide, many different test soils have been specified for testing WDs but they generally fail to meet the key criteria necessary for a test soil.

NOTE: These tests should be specified by the Independent Advisor.

Standard test soils

6.33 Current proposals for the European standard for WDs are to specify a test method for the validation of test soils. This would allow acceptance of the use of any test soil which meets the defined criteria and is validated as equivalent to a particular native soil, or soils.

6.34 Test soils are specified in BS 2745.

NOTE: These tests should be specified by the Independent Advisor.

Process residues

6.35 The nature of process residues and the level of such residues that may be of concern depend on the chemical additives and quality of water used during the process and the intended use of the washed and disinfected product.

6.36 The water used for the process may give rise to a number of chemical residues on processed items. The most obvious of these is the presence of limescale from the use of hard water.

6.37 The water used for the process may give rise also to contaminants of microbial origin. Bacterial endotoxins, primarily derived from the cell wall of Gram negative bacteria, may give rise to adverse (pyrogenic) reactions when introduced into the mammalian body. Items not autoclaved and intended for surgically invasive use or for the preparation or administration of parenteral fluids should be free from, or have acceptably low levels of, bacterial endotoxins.

NOTE: These tests should be carried out by the user in conjunction with the Microbiologist.

6.38 The chemical additives used during the process (detergents, rinse aids etc.) may not be completely removed by the rinsing process. The residual level which may be tolerated will depend upon the nature of the chemical and the intended use of the product. The supplier of any chemical agent used should provide data on the chemical composition of the chemical agent and the biocompatibility of the components of the chemical agent. The supplier should also provide details of the method of detection, which may be used to determine whether processed items are free from residuals at the specified levels.

Disinfection

Thermometric tests

6.39 Thermometric tests are required for both thermal disinfection processes and chemical disinfection processes.

6.40 For thermal disinfection processes the time temperature relationships which are generally regarded as acceptable are shown in Table 3.

Table 3: Thermal disinfection temperature bands

Disinfection temperature (°C)[a]	Minimum exposure time (minutes)	Maximum allowable temperature (°C)
65	10	70
73	3	78
80	2	85
90	1[b]	95
93[c]	10	98

Note:

a. The disinfection temperature is measured at the surface to be disinfected.

b. The exposure time of 1 second (as specified in BS 2745 Part 1) is too short for reliable measurement and a minimum time of 1 minute should be used.

c. This time/temperature relationship is only used for items known to be contaminated with large amounts of pathogenic organisms, for example in laboratories.

Microbiological tests

6.41 A microbiological PQ test is required, in addition to the thermometric test, for WDs in which disinfection is carried out using a chemical germicidal agent (see Chapter 10).

6.42 Normally, microbiological testing is not required for thermal disinfection processes. If particular circumstances make such testing necessary or desirable the advice of the microbiologist should be sought. Direct evaluation of microbial efficacy within the WD is difficult. Whenever practicable, microbiological testing should be carried out by:

a. undertaking a laboratory investigation of the inactivation characteristics of the micro-organisms of interest (that is, by determination of the D value and Z value over the range 65ºC to 95ºC);

b. calculating from these data the exposure conditions necessary to give the required assurance of disinfection;

c. determining attainment of the required exposure conditions in the WD by physical measurement (temperature, time etc.).

NOTE: Advice of the microbiologist should be sought for these tests.

Load dryness tests

6.43 The presence of residual water on cleaned and disinfected items is undesirable since it may interfere with the correct functioning of the item, promote re-contamination and microbial growth, or prevent attainment of sterilizing conditions. In many cases these data will already be available from the published literature.

6.44 The ability of the WD to dry the load may be evaluated either visually, when appropriate, or by drying to constant weight and determining the mass of residual water present at the end of the WD process cycle.

PQ report

6.45 All the data collected during PQ tests should be filed in a PQ report, a copy of which should be kept with the plant history file.

6.46 The PQ report should contain or refer to the complete specification for the washing/disinfection process. The specification should be sufficiently detailed to allow the loading condition and the operating cycle (including the type and volume of all chemical additives and the water quality) to be replicated on any future occasion.

6.47 The report should include the following:

a. a specification of the loading condition defined by the nature and number of the load items, items of chamber furniture and their distribution within the chamber; photographs taken of the load are valuable for future reference and can minimise the need for extensive descriptive text;

b. a specification of the operating cycle, defined by the settings for the cycle variables; for microprocessor based control systems a copy of the program held independently on electro-magnetic storage media is suitable also;

c. a specification of the service supply, defined by reference to the nature and volume of all chemical additives and the quality of the water service(s);

d. a specification of any pre-test operation of the WD, for example a warm-up cycle;

e. a specification of any pre-treatment of the test load, for example manual cleaning, ultrasonic cleaning etc;

f. all the indicated, recorded and measured data from the test; these should be annotated with the target values and permitted tolerances of elapsed time and other cycle variables at all significant points of the operating cycle, for example at the beginning and end of each stage or sub-stage;

g. for WDs equipped with process recording, the original of the process record derived from the test should also form part of the record.

Master process record

6.48 A master process record (MPR) is a record of the values and permitted tolerances of cycle variables for a correctly functioning operational cycle against which test and production cycles can be checked.

6.49 It is derived from the process records obtained during a PQ test, or during commissioning when no PQ test was required.

6.50 The MPR may be a 1:1 copy of the process record from a chart recorder, a template derived from the process record or data stored in a computer system and compared automatically with the data from each production run.

6.51 An MPR is intended to facilitate production control on WDs when the attainment of the validated standards of cleanliness and disinfection are critical to the safe subsequent use of the product.

6.52 When a number of different processes and different loading conditions are to be used for production it will be necessary to prepare an MPR for each operational condition.

Tests for performance requalification

6.53 Performance requalification (PRQ) tests are performed once a year to ensure that the established criteria for cleaning and disinfection are still being met. The PRQ tests should follow the yearly schedule of tests and checks listed in Chapter 7.

6.54 For a given operating cycle it is necessary to perform the PRQ tests only for those reference loads for which a PQ test was performed and reported.

6.55 The need for additional PQ tests in the light of changes in the nature of loads being processed should be agreed between the user and the TP.

6.56 The procedure for the PRQ test is essentially the same as that used for the corresponding PQ test. The operating cycle and the loading conditions used should be identical with those used previously for the PQ test.

6.57 The PRQ test should be considered satisfactory if the values of the measured variables are within the tolerances stated in the PQ report.

6.58 The results of the PRQ tests should be linked with the relevant PQ report and retained securely.

6.59 The PRQ test should meet the specified requirements without difficulty for a WD which has passed the yearly test programme. If the PRQ test is not satisfactory the advice of the Independent Advisor and/or the WD manufacturer should be sought.

TABLE 4

Tests carried out following commissioning and at any time a machine is subjected to change or major service

TESTING SCHEDULE

Type of WD	Performance Qualification					
	Installation Checks	Cleaning Efficacy Test		Operational Tests		
Para Ref.	(10.3)	(6.35)	(9.113)	(7.8)	(11.4)	(9.95)
	Thermometric Test	Process Residues	Load dryness test	Safety Checks	Automatic Control Test (each cycle)	Verification of WD Instrument Calibration
Human Waste	MP/TP		U/M	MP/TP	MP/TP	MP/TP
Surgical Instruments	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Holloware	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Anaesthetic Accessories	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Endoscopes	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Laboratory	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Utensils & Crockery	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP

A = Independent Advisor
TP(S) = Test Person
MP(S) = Maintenance Person
U = User
M = Microbiologist or Control of Infection Officer

7. Schedule of periodic tests

Introduction

7.1 Periodic tests are carried out at daily, weekly, quarterly and yearly intervals. They are the shared responsibility of the MP/TP, microbiologist and the user.

7.2 The yearly test schedule is identical to that required for revalidation. It contains the tests required for re-commissioning and for re-qualification of the performance of the WD.

7.3 Tests should only be undertaken after completion of the planned maintenance tasks described in SHTM 2030 Part 2; 'Operational management'.

7.4 Unless otherwise specified in Chapter 9 the tests should be carried out with the WD at normal working temperature, which may require a 'warm-up' run to be carried out before commencement of testing.

7.5 A number of the tests required can be carried out concurrently on the same operating cycle and this is also indicated in Chapter 9.

7.6 The results of periodic tests, whether carried out by the MP/TP, microbiologist or the user, should be filed securely, for example in the plant history file.

7.7 Although dishwashers generally are excluded from this SHTM, there may be instances where due to local needs, dishwashers should be tested to verify compliance with current disinfection standards (especially in the case of patients who are immunologically compromised).

Weekly safety tests

7.8 The user should examine the door seals as a safety check before starting the sequence of weekly tests.

7.9 For WDs which include a pressure vessel or pressure system (for example steam or compressed air), make any check required by the competent person in connection with the written scheme of examination for the pressure vessel.

Yearly safety tests

7.10 In order to ensure the continued safe functioning of the WD the MP/TP should conduct a series of safety tests before starting the yearly tests.

7.11 The Independent Advisor should draw up a documented programme of the yearly safety tests necessary for a particular installation.

7.12 The original installation checks and tests may be used as a basis for the yearly safety test paying particular attention to those factors which affect safety and especially to those which may have changed since the previous annual safety test (or installation test).

7.13 The adequacy and safe connection of all engineering services should be verified.

7.14 The responsibility for microbiological tests rests with the user, microbiologist and control of infection officer. The scope and contents of any tests will be incorporated in local protocols agreed between the above persons and will take account of local circumstances.

7.15 During the commission of WDs for endoscopes, the Occupational Health Officer should carry out tests on and around the machine for traces of disinfectant vapour, particularly in the vicinity of the door or lid when opening at the end of a process. The frequency of testing will be determined by the local Occupational Health Officer.

TABLE 5

SCHEDULE OF PERIODIC TESTS

Type of WD	Daily Test				Weekly Test			Quarterly Tests								
Para Ref.	(11.4)	(9.101)				(13.5)	(6.27)		(7.8)		(10.3)	(9.31)	(9.69)	(9.73)	(9.76)	(9.80)
	Automatic Control Test (Roate cycles)	Check Spray Arm for Rotation & Blockages	Remove & Clean Strainers /Filters	Check Spray Nozzles for Blockage	Carry out Daily Test	Monitor final rinse water quality	Cleaning Efficacy	Carry out Daily and Weekly Tests	Safety Checks	Basic Function of Engineering Services	Thermo-metric Tests for Disinfection	Water system Chemical Purity	Doors & Interlocks			
													Cycle start	In Cycle	Double ended WD	Fault indication
Human Waste	U	IF FITTED	U	U	U/MP		U/M	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP	MP/TP	MP/TP	MP/TP
Surgical Instruments	U	U	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Holloware	U	U	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP	MP/TP	MP/TP	MP/TP
Anaesthetic Accessories	U	IF FITTED	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Endoscopes	U	IF FITTED	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Laboratory	U	U	U	U	U/MP		U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Utensils & Crockery	U	U	U	U	U	U/MP	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP

A = Independent Advisor
TP(S) = Test Person
MP(S) = Maintenance Person
U = User
M = Microbiologist or Control of Infection Officer

TABLE 5

SCHEDULE OF PERIODIC TESTS

Type of WD	Yearly and Revaliation										(Weekly, Quarterly, Yearly) Cleaning Efficacy Test	
Para Ref.		(11.4)	(8.29)	(9.88)	(9.90)	(18.9)	(18.3)	(17.3)	(9.101)	(9.108)		
	Carry out Daily, Weekly and Quarterly Tests	Automatic Control Test (each cycle)	Verification of WD instrument calibration	Chemical Dosing		Channel Patency	Self Disinfection	Ultrasonic Activity	Load carrier temperature test	Over temperature protection test (if fitted)	Reference Load	Endoscopic /MAT instruments
				Reprod-ucibility	Low Level Detection							
Human Waste	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP				MP/TP	MP/TP IF FITTED	U/M	U/M
Surgical Instruments	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP/U	MP/TP	MP/TP IF FITTED	U/M	U/M
Holloware	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP				MP/TP	MP/TP IF FITTED	U/M	U/M
Anaesthetic Accessories	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP			MP/TP	MP/TP IF FITTED	U/M	U/M
Endoscopes	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP		U/M	U/M
Laboratory	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP			MP/TP	MP/TP IF FITTED	U/M	U/M
Utensils and Crockery	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP				MP/TP	MP/TP IF FITTED	U/M	U/M

A = Independent Advisor
TP(S) = Test Person
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U = User
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Schedule of typical periodic tests

Daily Test (where applicable)
- automatic control test
- check spray arm for rotation (if fitted)
- check spray nozzles for blockage
- remove and clean strainers/filters

Weekly Test (where applicable)
- carry out daily test
- cleaning efficacy

Quarterly Tests (where applicable)
- daily and weekly tests
- safety checks
- basic function of engineering services
- thermometric tests for disinfection
- chemical purity (water system)
- doors and interlocks (start, in cycle etc)

Yearly Tests and Revalidation (where applicable)
- daily, weekly and quarterly tests
- automatic control test (each cycle)
- verification of WD instrument calibration
- water system purity
- chemical dosing (reproducibility/low level detection)
- channel patency
- self disinfection
- ultrasonic activity
- load carrier temperature
- over temperature protection
- cleaning efficacy (consult Microbiologist/Independent Advisor)

The precise schedule of periodic tests should be agreed with the independent advisor, microbiologist and the control of infection officer, recognising the manufacturer's recommendations.

8. Test equipment and materials

Introduction

8.1 This chapter reviews the major items of portable test equipment necessary to carry out the test procedures described in this SHTM.

8.2 Instrumentation technology continues to advance rapidly making it increasingly difficult and undesirable to provide detailed specifications for the equipment to be used in testing WDs. There is a trend towards computer controlled data loggers with software which enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated and/or graphed data. Although these new systems may offer advantages, the traditional instruments, such as chart recorders, remain the accepted standard.

8.3 The objectives of this chapter are both to ensure that traditional measurement methods are supported adequately and to define clearly the essential requirements that apply to the test equipment whether it is a traditional system or the latest technology.

8.4 When it is proposed to use measurement and/or recording techniques that are not covered in this SHTM the advice of the Independent Advisor should be sought.

8.5 It has been assumed also that there will be ready access to standard laboratory equipment and supplies.

Calibration and sources of error

8.6 The integrity of the measuring system is essential in order to obtain meaningful results. Significant errors can arise through improper use of calibration instruments and it is therefore important that staff are trained and skilled in their use. Two types of errors exist: Intrinsic and Introduced. Intrinsic errors relate mainly to the instruments best capability and usually cannot be improved upon without modification. Introduced errors may be very small or great, depending upon the skill used in the process.

Careful attention to detail including the location of the test instruments, effective maintenance and the skill of personnel trained in the application, handling and use of the instruments are required to eliminate or minimize errors. Systematic errors can be reduced by careful calibration.

8.7 Instruments should be subjected to a planned maintenance and calibration programme in accordance with the instrument manufacturer's recommendations. The drift status of instruments should be monitored to ensure that they remain within their intrinsic specification. Each instrument

should be labeled with a unique reference number, a calibration date, date due and a reference to a UKAS/NAMAS laboratory reference from which its current calibration status may be traced. If being transported, a suitable protective carrying case should be used.

8.8 The calibration of all test instruments should be verified at a frequency defined by the stability of the equipment. In the first instance the period should be at least yearly. Calibration should be carried out against reference instruments with a valid certificate of calibration provided within a NAMAS or ISO/EN17025 scheme of accreditation. A written procedure that describes the calibration method should be prepared and made available for the Independent Advisor to review. A history record should be kept for each instrument.

8.9 All test instruments should be located in a position protected from draughts and not subjected to rapid temperature variations. Test instruments should be allowed a period of time to stabilize within the environment of the test site prior to use. The instrument manufacturer's instructions should be followed.

Recorders

8.10 Test recorders are required to measure temperature in all types of WD and may also be required for the measurement of pressure, flow rates and humidity. They should be designed for use with the appropriate sensors, independent of those fitted to the WD. Most of the tests described in this SHTM may be conducted with a single recorder combining both temperature and pressure functions showing both records on the same chart or printout. For WDs incorporating humidity control or humidity monitoring of a hot air drying stage, the measurement of humidity is desirable but not essential.

8.11 Analogue recorders should comply with the display requirements of BS 3693. Recorders using a potentiometric system should comply with BS 5164.

8.12 Digital recorders (data loggers) have many advantages over traditional pen recorders. Data may be presented graphically or as a listing of numerical values or as a combination of both. In many cases parts of the operating cycle can be expanded and replotted for closer examination.

8.13 Digital recorders should have the facility to copy data onto tape or disk which can then be removed for secure storage. Software used with digital recorders should be developed under a quality system (such as BS EN ISO 9001).

8.14 The accuracies quoted by recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. Temperature measurement errors due to ambient temperature changes should not exceed 0.04°C per °C rise.

Temperature measurement

Temperature sensors

8.15 Temperature sensors should be used to sense the temperature in locations specified in the tests described in this SHTM. The sensors should be either platinum resistance elements complying with BS EN 60751 or thermocouples complying with BS EN 60584.

8.16 The performance characteristics of the temperature sensor should not be adversely affected by the environment in which it is placed, e.g. pressure, hot detergent solution etc.

8.17 In order to avoid undue disturbance of the system being measured, the major diameter of the temperature sensors and their connecting leads which will be located within the WD should not exceed 2 mm.

Thermometric recording instrument(s)

8.18 One or more thermometric recording instruments should be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described in this SHTM. They may also be used to verify the readings obtained from instruments fitted to the WD.

8.19 The recording instrument(s) should record the temperature from a minimum of eight temperature sensors. The channels may be multiplexed or independent of one another. The data recording rate for each channel should not exceed 1.0 s. All data sampled should be used for the interpretation of results.

8.20 The scale range should include the expected maximum and minimum values of the cycle variables throughout the operating cycle with sufficient allowance for any deviations resulting from a malfunctioning WD. This should normally include at least the range 10°C to 110°C. Instruments determined as suitable for testing sterilizers according to SHTM 2010 will normally be suitable for most systems except tunnel washers.

8.21 In some WDs the air temperature close to the heater bank during the drying stage may considerably exceed the upper limit of the air drying temperature.

8.22 The most critical stage of the WD operating cycle is the disinfection stage. It is during this period that the values of the cycle variables are at their most critical and the recorder should be capable of measuring them to sufficient accuracy to confirm that the disinfection conditions have been attained. The criteria are as follows:

a. For digital recorders, the sampling interval should be short enough for the holding time to contain at least five independent measurements in each recording channel;

b. The response time of the recorder should be short enough to enable the output to follow significant fluctuations in the cycle variables and to ensure that successive measurements are independent of each other. It should not be longer than the sampling interval;

c. The recorder must be accurate enough to show clearly whether the measured temperatures are within the disinfection temperature band. The intrinsic repeatability of the recorder should be ± 0.25°C or better and the uncertainty of measurement of the complete measurement system including sensors should be no more than ± 0.5°C taking all component errors into consideration. The additional error due to changes in environmental temperature should not exceed 0.04°C per °C;

d. For analogue instruments the minor mark interval should not exceed 0.5°C and the chart speed should be not less than 10 mm per minute/600 mm per hour. The resolution should be not less than 0.5°C. Digital instruments should register and record in increments of not more than 0.1°C.

NOTE: For the shortest holding time recommended (1 second at 90°C) this would correspond to a sampling interval of 0.2 second. However it is suggested that the minimum exposure time set should be not less than 12 seconds for which a sampling interval of 1 second is then appropriate. For pen recorders the chart speed should be fast enough to allow fluctuations on that scale to be clearly resolved. The duration of the holding time should be measurable to within ± 10%.

Use of sensors

8.23 WDs conforming to BS 2745 are equipped with thermocouple entry glands.

8.24 In older machines, having no dedicated entry port, sensors can be introduced through a door seal, with care. If possible, sensors should be distributed across the point of entry so that the integrity of the seal is not compromised, i.e. it is not good practice to introduce 8 thermocouples into a chamber via a door seal all at the one point since this will invariably compromise the seal.

8.25 Many of the tests require a sensor to be placed at the reference point specified by the manufacturer as representative of the conditions prevailing throughout the chamber and load. This will usually be in the drain or sump of the chamber and will often be adjacent to the sensor used for the automatic controller.

8.26 The sensors may often be placed in positions where they are submerged for most of the cycle. Under these conditions water may migrate along the wire between the cores and the outer insulation sheath. To prevent damage to the recorder the outer sheath should either be punctured or stripped back a few centimetres from the end connected to the recorder to allow droplets of water to fall clear of the recorder.

8.27 Sensors used to monitor the temperature of load items and the chamber walls should be held securely in good thermal contact with the region to be monitored using high temperature masking tape or autoclave indicator tape.

Calibration

8.28 Calibration should be carried out in accordance with the instrument manufacturer's instructions by a validated method using a working or reference standard which is traceable to a UKAS/NAMAS laboratory reference.

8.29 It is normal practice to use a recorder which is routinely calibrated against an independent thermometer prior to measurement work on the WD being carried out. The independent thermometer is usually placed in a heat source or bath as are the recorder sensors. A comparison calibration is then carried out. The heat source should be of a design that meets the recommendation of publication EA-10.13 Feb 2000 'Guidelines on the calibration of temperature block calibrators'. Procedures used when applying comparison calibrations should also be in accordance with these guidelines. Comparison calibration is carried out before and after each series of tests on a WD. The heat source should be of a design that meets the recommendation of publication EA-10.13 Feb 2000 'Guidelines on the calibration of temperature block calibrators'. Procedures used when applying comparison calibrations should also be in accordance with these guidelines, and at a temperature within the disinfection temperature band.

8.30 Adjustment may be carried out to the recorder prior to testing to ensure the best results are obtainable. Following any adjustment, the temperature measured by all temperature sensors when immersed in a temperature source at a temperature within the disinfection temperature band should not differ by more than ±0.25 Deg ºC.

8.31 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ± 0.1°C and within the disinfection temperature band should not differ by more than 0.5°C after calibration and adjustment.

Self contained systems

8.32 Temperature measuring systems involving the use of leads from the sensing point within the load to an external measuring instrument are difficult or impractical to use within several designs of WD, for example continuous process machines consisting of several interconnecting cabins which are separated by intermediate doors during processing.

8.33 Single channel data loggers should only be used as a complementary test and trend of the full process. Full temperature mapping by traditional means remains the standard.

8.34 A number of different designs of small self-contained single channel data loggers for the measurement of temperature are commercially available. They are independently powered, may be programmed to take readings at the required rate for the required duration and are downloaded onto a personal computer on completion of the data logging period. Those housed in protective cases rated at IP68 are suitable for inclusion in washing machines.

8.35 Care needs to be taken in selecting units which are capable of withstanding the high temperature which may be found during the thermal disinfection stage (90°C) and drying stage (105°C) of the cycle since many of these devices are powered by batteries which will not withstand temperatures above approximately 75°C.

8.36 Data loggers with an external probe may be housed in an insulated waterproof container through which the lead to the sensor passes by means of a leak tight gland. A 25 mm thick layer of mineral wool insulation on all surfaces of a data logger contained within a 1000 ml screw top polypropylene jar has proved suitable. The waterproof container should protect the device from elevated temperatures.

8.37 The accuracy obtainable from these units is rarely to the standard specified for conventional temperature recorders but the limit of error should not exceed ± 0.8°C when tested over the range 0°C to 100°C at an ambient temperature of 20°C ± 3°C. Rapidly changing environmental temperatures, which can cause thermoelectric currents to alter measurement stability, are the most likely reasons for the greatest errors. The additional error due to changes in environmental temperature should not exceed 0.04°C per minute. Instruments should register and record in increments of not more than 1°C.

8.38 The device should be capable of recording the sensed temperature at least every 1 second and should be capable of storing not less than 1800 records.

8.39 For continuous process WDs, not less than three such devices will be needed together with a conventional temperature recorder.

Pressure measurement

8.40 Pressure may be required to be measured over the range from atmospheric to 10 bar (for example for the water supply pressure). Differential pressure of 1 –100 hectoPascals may be required to be measured (for example for the determination of the pressure drop across filters).

Transducers

8.41 Transducers for use with pressure recorders should conform with BS 6447, be suitable for the purpose and be of an accuracy equal to, or better than, the gauges specified below. The natural frequency of the sensor and connected tubing should be not less than 10Hz and the time constant for rising pressure (0–63%) should be not greater than 0.04 seconds.

Gauges

8.42 Pressure gauges are required when the pressure recorder is unsuitable or for verifying the calibration of pressure instruments fitted to the WD.

8.43 Three pressure gauge ranges will normally cover the whole pressure range for all WDs.

8.44 Pressure gauges should be temperature compensated and except for the differential pressure gauge be Bourdon-tube gauges conforming to BS EN 837 of nominal size 150 mm and accuracy class 0.25 (that is, the air should not exceed 0.25% FSD).

8.45 Gauges should be tested yearly by a recognised testing laboratory as described in BS EN 837-1, 1998.

8.46 The measurement of differential pressure across air filters may be made with an inclined water manometer.

8.47 The recorder for pressure measurement should have an overall limit of error no more than 1% of the maximum specified operating pressure.

Flow measurement

Water

8.48 The volume of water used for each stage of the operating cycle may be measured using a water meter complying with BS 5728.

8.49 The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 16 bar.

NOTE: When the meter is connected in the pipe there will be a noticeable pressure drop across the meter. Although this should be less than 1 bar it may interfere with the normal operation of the WD and therefore should not be used during tests for other characteristics than the volume of water used.

8.50 The meter should have a minimum scale division of 0.1 litres or less and be designed to measure flow rates over the range 1 litre per minute to 25 litres per minute.

8.51 A single jet turbine system is sufficiently accurate for the purpose. Other systems such as multi-jet turbine or semi-positive displacement systems complying with BS 5728 Class D, may also be used.

Chemical additives

8.52 The volume of chemical additive used for each stage of the operating cycle may be measured using a flow meter. There are a number of commercially available flow sensors designed to monitor flows in the range 0 to 2 litres/minute which are suitable for interfacing to a recorder or datalogger.

8.53 The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 10 bar.

8.54 The system should have an accuracy of ± 2.5% of full scale deflections or better.

8.55 The calibration of the meter should be verified by determining the indicated volume flowing, using a graduated measuring cylinder.

Gas monitoring equipment

8.56 A gas monitoring instrument is required for tests on WDs using chemical additives which have a significant vapour pressure and are a potential risk.

8.57 The nature of the instrument will depend on the substance to be monitored. In case of doubt, advice should be sought from the manufacturer of the chemical additive or the Independent advisor.

8.58 The scale range of the measuring instrument should include the appropriate short term exposure limit or occupational exposure limit and extend to at least ten times that exposure limit.

Aerosol generator

8.59 An aerosol generator is required for tests on WDs incorporating air filters intended to deliver air free from micro-organisms.

8.60 The device should be capable of generating a polydisperse aerosol with

particles having the size distribution shown in Table 6.

Particle counting photometer

8.61 A particle counter is required for tests on WDs incorporating air filters intended to deliver air free from micro-organisms. The device should be suitable for estimation for comparison of mass concentration of airborne particles as defined in Table 6.

8.62 It should have an accuracy of better than ± 5% over the range of a five-expandable, six-decade resolution (that is 0.01% to 100% of the test cloud) as specified in Appendix C of BS 5295: Part 1.

8.63 The photometer should have a minimum threshold sensitivity of 0.0001 $\mu g l^{-1}$ and should be capable of measuring aerosol concentration in the range 80-120 $\mu g l^{-1}$.

8.64 The sampling flow rate should be 0.40 ± 0.05 $l s^{-1}$ and sampling should be via a suitable probe.

Table 6: Particle size distribution for aerosol generator

Particle size µm	Fraction % by mass
<0.5	>20
<0.7	>50
<1.0	>75

Source: BS 5295: Part 1

9. Testing methods

Introduction

9.1 This chapter discusses general principles and methods that are used in the tests described in this SHTM.

Terminology

9.2 For the purposes of this SHTM the following definitions have been adopted.

Cycle variables

9.3 The **cycle variables** are the physical and chemical properties such as time, temperature, pressure, flow rate, concentration and chemical composition that influence the efficacy of the cleaning and disinfection processes. Many of the tests described in this SHTM require the values of cycle variables to be determined experimentally and then compared with specified or standard values.

9.4 An **indicated value** is that shown by a visual display fitted to the WD.

9.5 A **recorded value** is that shown on the output of a recording instrument fitted permanently to the WD.

9.6 A **measured value** is that shown on a test instrument, for example a temperature recorder attached to the WD for test purposes.

9.7 A **noted value** is that written down following personal observation of an indicated, recorded or measured value.

Disinfection conditions

9.8 Most operating cycles have a stage in which the load is exposed to the disinfection conditions for a specified length of time. This period is known as the **holding time**.

9.9 The **disinfection conditions** are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

9.10 The holding time is preceded by a period in which the disinfection conditions are present in the chamber but have yet to be attained throughout the load. This is known as the **equilibration time**.

9.11 Together the equilibration time and the holding time constitute the **plateau period**. The plateau period can always be determined from the indicated or recorded temperature in the chamber during each cycle. The equilibration

and holding times cannot be ascertained unless the temperature in that part of the load which is slowest to reach temperature is also being measured.

9.12 For thermal (moist heat) disinfection, the disinfection conditions are specified by a **disinfection temperature band**, defined by a minimum acceptable temperature, known as the **disinfection temperature**, and a **maximum allowable temperature**.

9.13 The higher the disinfection temperature the shorter the holding time which will be required to achieve the same level of disinfection (see Table 3).

9.14 For liquid chemical disinfection, the disinfection conditions are specified by a **disinfection temperature band** and a **disinfectant contact concentration range**. The disinfection temperature band is defined by a minimum acceptable temperature, known as the disinfection temperature and a maximum allowable temperature. The disinfectant contact concentration is specified by the minimum acceptable concentration in contact with the load to be disinfected and the maximum allowable concentration.

9.15 For those WDs in which the chemical disinfection stage is thermostatically controlled at elevated temperature, the duration of the exposure to chemical germicide may be determined thermometrically. In most cases, investigation of the performance of chemical disinfection processes can only be carried out successfully using microbiological test methods in conjunction with physical testing.

9.16 The disinfection temperature band may also be quoted for liquid chemical disinfection/sterilization processes but is not a complete specification of the disinfection conditions since the efficacy of such processes depends also on the concentration of the chemical agent.

Blocked drain protection (Commissioning Test)

Introduction

9.17 In the event that the drain from the chamber of the WD become blocked, continued operation of the WD must not allow water and suspended soil to be discharged either during the operating cycle or, for cabinet type WDs with sealed door(s), by sudden discharge when the door is opened at the end of the cycle.

9.18 The purpose of blocked drain protection is to prevent spillage and minimise the risk of cross-infection.

9.19 In the test, the drain is deliberately blocked and successive operating cycles are run until the water level is above the level of the door seal. The test is intended for use both as a type test (and as such is a requirement of BS 2745: Part 2 1993) and as an installation test.

9.20 The manufacturer should be consulted to detail a suitable test method.

Estimation of dead volume of pipework (Manufacturers Type Test)

Introduction

9.21 Residual water that does not drain from the internal pipework of the WD may provide an environment for microbial growth; these micro-organisms may then be available to re-contaminate the disinfected load.

9.22 The test is intended primarily as a Type test but may also be of value as an operational test or when investigating microbial contamination occurring in a WD.

Equipment

9.23 Volumetric measuring vessels of appropriate size are necessary.

Method

9.24 The pipework of the WD which is known to be dry (either following dismantling and re-assembly or purging with dry compressed air for not less than 30 minutes) is flushed with a known volume of water (simulating the flow that would occur in normal use).

9.25 The volume of water flushed through the system should be twice that determined as the volume used per operating cycle. The volume of water discharged is measured and the dead volume, estimated as the volume retained, calculated from the difference between the two values.

9.26 When the WD has two or more pipework systems which are entirely separate (for example for flushing water, wash water, rinse water, chemical disinfectant solution) each system may be tested separately.

Results

9.27 The volume of retained water should be less than 1% of the volume of water used.

For WDs with chemical disinfection systems, the retained volume in the pipework providing the final rinse volume should be, as nearly as possible, zero.

Water system

Introduction

9.28 A continuous supply of water of the specified chemical and microbiological quality is essential to the correct functioning of all WDs. Water which is too hard or has too high a concentration of dissolved solids may impair the activity of detergents (or require the use of increased quantities of chemical additives) and cause deposits, scaling or corrosion of items being processed.

9.29 Water containing high numbers of micro-organisms may recontaminate disinfected items. For all these tests the water should be sampled from the water supply pipe to each WD. Additional samples may need to be taken from any water treatment plant when trying to identify the cause of a non-conformity.

9.30 Testing of water should be carried out by the microbiologist. The following is a typical example of sampling and testing method.

Water samples

9.31 Water samples should be obtained from draw-off points installed at convenient locations within the system.

9.32 The sampling procedure should be suitable for all the physical, chemical, and biological determinands of interest. It may be used for water samples throughout the water distribution system.

9.33 The sampling containers used should be specific for the determinants of interest. This should include, as appropriate:

a. 330 ml sterile single use plastic containers containing sodium thiosulphate for testing of microbiological quality of water (total coliform, faecal coliforms, and total viable count at 37^{o}C);

b. 250 ml sterile, pyrogen free, single use containers (for determination of bacterial endotoxin levels and/or total viable count);

c. 1 litre acid washed, borosilicate bottles, (for determination of cations);

d. 1 litre polypropylene bottles, (for determination of anions, total dissolved solids);

e. 100 ml high density polyethylene bottles (for determination of pH, conductivity).

9.34 The first 50 ml of sample taken at each sampling point should be run to waste.

9.35 All samples should be taken in duplicate.

9.36 Samples should be tested within four hours of collection or stored at 2°C to

5°C and tested within 48 hours of collection.

Water quality tests

9.37 The following sections describe analytical methods which may be used to determine the various biological, physical and chemical properties of water samples for the various qualities of feedwater to the WD.

9.38 The methods of analysis required to detect chemical contaminants at low concentrations with a high level of accuracy require the use of a laboratory with appropriate expertise, facilities and experience. Other tests can be carried out on-site or with very simple laboratory facilities; these lack the precision and sensitivity of the laboratory tests but are sufficient for most purposes.

NOTE: Advice on the testing of sterile water for final rinsing, should be sought from the microbiologist.

9.39 This SHTM contains detailed procedures for tests which may be carried out on-site or with very simple laboratory equipment at, or shortly after, the time of sampling.

9.40 The precision, accuracy, sensitivity and limits of detection of these methods are usually inferior to those of laboratory methods. They are useful, however, in that they provide evidence of any gross failure and the results are available straightaway making them of diagnostic value during a fault finding exercise. They are generally economical compared with more sophisticated laboratory analysis and can be carried out by non-specialist personnel after thorough, but limited, training. The results should not however be used as evidence in cases of dispute.

Choice of method

9.41 For any given determinant there will usually be several methods which are suitable and cover the range of concentrations of interest. The methods given below are intended to be representative of those which may be suitable. They are chosen as examples of tests which may conveniently be carried out on site.

9.42 A number of test systems are available commercially. Before adopting one of these methods care should be taken to ensure that the test(s) provides results of sufficient accuracy and sensitivity.

9.43 It is not necessary to use experienced chemical analysts to undertake the on-site analysis of water samples described. It is, however, essential that personnel receive appropriate training before attempting to carry out this work.

9.44 It is apparent that many contaminants will be detected by two or more of the determinations normally carried out for laboratory analysis. For example, an

increase in one or other of the ionic species present will cause an increase in electrical conductivity and an increase in the evaporative residue as well as showing an increase in the concentration of that particular ion.

9.45 Further guidance on appropriate test methods may be obtained from BS 1427: 1993.

9.46 Tests suitable for use on-site fall into three main categories:

a. **instrumental tests** using portable instruments designed for on-site use for example portable pH meters, ion selective electrodes etc.;

b. **spectrophotometric tests** based on measurement of the absorbance of a coloured reaction product; measurement may be visual or photometric and may be against a precalibrated coloured disc or against standard reference solutions;

c. **titrimetric tests** these may be carried out using standard laboratory equipment or with commercially available apparatus designed for field use; the latter is usually much simpler to use.

9.47 For all the instrumental methods described there is commercially available equipment specifically intended for field use. All the variables for which instrumental methods are described are temperature dependent. The equipment used should be temperature compensated. Also the equipment should be allowed sufficient time on site, before it is put into use, to equilibrate to the local ambient temperature.

9.48 Commercially available test kits based on visual or photometric comparison with coloured discs have become an accepted standard for on site analysis. Manufacturers usually supply a complete test system, including kits of reagents. To ensure compatibility, and maintenance of the manufacturers claimed sensitivity and accuracy for the method, the kit specified by the manufacturer should not be substituted.

Water supply temperature

Introduction

9.49 The water supplied to the various stages of the WD operating cycle should be at an appropriate temperature. If the temperature of the water supplied to the flushing stage is too high (> 45°C) there is a risk of coagulating proteinaceous soiling and inhibiting the cleaning process. If the temperature of water supplied to the washing, rinsing and disinfection stages is too low the WD cycle may be greatly extended, with a significant reduction in throughput, while the water is heated to the required temperature within the WD. Water supplied in the temperature range 25°C to 40°C presents a serious risk of microbial contamination of the system.

Equipment

9.50 An indicating or recording thermometer is necessary.

Method

9.51 The temperature of the water supply should be measured from a sampling point as close to the WD as possible. Place the temperature sensor in the middle of the flowing stream as close as practicable to the sampling point. Allow the water to flow for at least a minute before the temperature is read.

Alternative method (for periodic testing)

9.52 When it is not convenient, or practicable, to run the water to waste from a sampling point close to the WD the water temperature may be estimated by measurement of the temperature of the outer surface of the supply pipe. When it is intended to use this method the correlation between the temperature of the water flowing out of the pipe and the surface temperature of the pipe at a particular point should be established during installation testing. The surface temperature should be measured using a sensor designed for the purpose and the manufacturer's instructions for ensuring good thermal contact with the surface should be followed. The temperature should be noted or recorded during a normal operating cycle not less than 30 seconds after the start of water flow through the pipe to the WD.

Results

9.53 The noted value should be within the temperature range specified for the installation.

Water supply pressure

Introduction

9.54 If the pressure of the water supply to the WD is below the minimum pressure specified by the manufacturer, the performance and productivity of the WD will be affected adversely.

9.55 If the pressure of the water supply to the WD is above the maximum pressure specified by the manufacturer, the capacity of overflow devices may be inadequate, the designed performance characteristics of valves etc. may be exceeded and in extreme cases there may be the risk of damage to components of the WD or to products being processed. (For example many flexible endoscopes are likely to be damaged if subjected to internal pressures greater than 35 kPa.)

9.56 The test should be carried out as an installation and/or operational test. The test should be repeated when any change is made to the water services supplying the WD (including the connection or removal of other machines).

Equipment

9.57 Pressure indicator or recorder 0–10 bar is necessary.

Method

9.58 The pressure sensor should be connected to each of the water supply pipes to the WD, as close to the WD as may be practicable, on the supply side of the WD isolating valve for that supply. The static pressure when the valve is closed and the pressure indicated throughout a normal operating cycle should be recorded or observed and noted. When the water service also supplies other equipment on the same supply line, the test should be run both with the other equipment operating throughout the test (or their operation simulated by an appropriate discharge to waste) and with no other equipment operating.

Results

9.59 The water pressure should remain within the supply pressure limits specified by the WD manufacturer.

Overflow test

Introduction

9.60 For WDs which incorporate one or more water storage tanks within the WD the capacity of the overflow(s) to discharge all excess water, as intended, without spillage into the WD or working area should be verified.

Method a: Type test or Works test

9.61 The WD should be connected to all necessary services and the water supply pressure adjusted to not less than 6 bar under the conditions of flow which prevail with the supply valve(s) fully open.

9.62 Fully open the supply valve(s).

9.63 Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 minutes.

Method b: Installation test

9.64 The WD should be connected to all necessary services.

9.65 Fully open the supply valve(s).

9.66 Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 minutes.

Results

9.67 The WD and installation should be regarded as satisfactory when equilibrium conditions have been attained within the tank(s) without discharge of water other than by the intended (piped) overflow.

Volume of water used per stage

9.68 During type testing, the manufacturer should be required to determine the volume of water used during each stage of the cycle. These data are used in calculations of the service requirement (see SHTM 2030 Part 1; 'Design considerations'). The volume of water used for each stage of the cycle should be within ± 5% of the volume specified by the manufacturer.

Doors and door interlocks

Cycle start interlock

Introduction

9.69 The interlock should prevent a cycle being started with the door open.

Method

9.70 Testing should be carried out as follows. The doors should be left open and unlocked. All services should be connected. An attempt should be made to initiate an operating cycle.

9.71 The doors should then be closed and locked and a further attempt made to initiate an operating cycle.

Results

9.72 It should not be possible to initiate a cycle with the door(s) left open. With the door(s) closed it should be possible to initiate an operating cycle.

In-cycle interlock

Introduction

9.73 An interlock is required to ensure that the door(s) cannot be deliberately or inadvertently opened while the WD is in operation.

> **NOTE:** When practicable, the interlocks should be visually inspected to verify engagement before attempting to open the door.

Method

9.74 The door(s) should be closed and locked and the operating cycle started. While the operating cycle is in progress an attempt should be made to unlock each of the doors.

Results

9.75 In these circumstances it should not be possible to unlock any of the doors.

Double-ended WDs

Method

9.76 Both during and between cycles, attempts should be made to open either or both the loading door and unloading door of the double ended WD.

Results

9.77 It should not be possible to open the unloading door after initiation of a cycle until a cycle has been completed satisfactorily.

9.78 It should not be possible for both doors to be opened at the same time.

9.79 It should not be possible to open the loading door until a cycle has been satisfactorily completed and the unloading door has been opened and closed.

Failed cycle interlock

Introduction

9.80 The interlock should prevent an operator from removing a load in the normal manner at the end of a cycle which failed.

Method

9.81 During an operating cycle one, or more, of the services to the WD should be interrupted sufficiently to cause a cycle failure.

Results

9.82 A 'fault' should be indicated. It should not be possible to open the unloading door (if fitted); it should only be possible to open the loading and/or unloading door by means of a special key, code or tool.

Fault indication on sensor failure

Introduction

9.83 A failure of any sensor used as part of the control system of the WD should cause a fault to be indicated by the automatic controller.

Method

9.84 Each sensor providing information to the automatic controller is disabled in turn to establish that a fault is indicated.

9.85 Testing of each sensor should be carried out as follows. An operating cycle should be started. During, or before, the stage of the cycle at which the sensor is intended to provide data used to determine the control of the cycle the sensor should be disabled.

9.86 Each sensor should be tested in both 'open circuit' and 'short circuit' failure modes.

Result

9.87 A fault should be indicated during or at the end of the cycle. It should not be possible to open the door on a single-ended WD or the unloading door of a double-ended WD.

Chemical dosing

Reproducibility of volume admitted

Introduction

9.88 The test is intended to verify the setting for the dispensed volume of chemical additive(s) and to ensure that it is reproducible within defined limits. The test should be carried out for each chemical dosing system on the WD.

Equipment

9.89 A flow meter of appropriate range may be used.

A measuring cylinder to BS 604: 1982 (1993) is necessary [or BS 5404: Part 2: 1977 (1994) when compatibility with the chemical additive to be measured has been established].The size of measuring cylinder should be appropriate to the volume of chemical additive to be dispensed.

Method

9.90 Testing should be carried out as follows:

a. Disconnect the supply line to the chamber as close as possible to its discharge point into the chamber or water circulation system;

b. Actuate the dosing system and collect the discharged volume of the chemical solution in the measuring cylinder;

c. Repeat the test three more times. Record the volume dispensed on each test.

Results

9.91 The mean collected volume from the final three tests should be within ± 10% of the nominal dispensed volume.

Care is required since many of the concentrates used are irritant or corrosive. Water may not be an acceptable substitute because, for many dosing systems, differences in viscosity can affect the dispensed volume.

Indication of insufficient chemical additives

Introduction

9.92 The use of the correct volume of chemical additive(s) is necessary for the correct functioning of the WD. The WD should be equipped with means to ensure that a cycle is not initiated when there is insufficient chemical additive remaining in the reservoir to complete a cycle.

9.93 The test should be carried out for each chemical dosing system on the WD.

Method

9.94 A low level of additives is placed in the dispenser reservoir and repeated cycles are run. Care is required since many of the concentrates used are irritant or corrosive. Water may not be an acceptable substitute because, for many dosing systems, differences in viscosity can affect the dispensed volume.

9.95 Fill an otherwise empty container with sufficient chemical for more than 2 but less than 4 operational cycles. Run the WD on 3 consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or weight).

Results

9.96 The WD should indicate at the beginning of the third or fourth cycle that there is insufficient chemical remaining to complete a cycle.

Instrumentation fitted to WD

Verification of calibration

9.97 Specifications for instruments fitted permanently to WDs are given in the relevant British Standards and will be included in the forthcoming European Standards; they are discussed in SHTM 2030 Part 2; 'Design Considerations'.

9.98 The calibration of instrumentation fitted to the WD should be verified by comparison with calibrated test instruments during steady state conditions e.g. the temperature during the disinfection hold period. A reference channel should be identified on the recording equipment and placed in the same position as the indicating sensor to ensure that the measurement probe is in the same position as the indicating probe.

9.99 This may be carried out concurrently with other testing, for example during the automatic control test during quarterly periodic testing.

Load carriers

Introduction

9.100 Load carriers come in a variety of forms including trolleys, carriages and baskets. Their correct functioning is essential to the successful outcome of a WD operating cycle. It is important that they cannot easily be misaligned, that they function correctly and that, when applicable, they make good connection with service supply points in the chamber and with load items (when necessary).

Method

9.101 The alignment of load carriers, their connection to water, air or chemical additive supply in the chamber (when applicable) and their connection to load items e.g. cannulated instruments (when applicable) should be verified by visual observation.

9.102 Load carriers with rotary spray arms should be checked to ensure that the spray arms are free to rotate, both when the load carrier is empty and when fully loaded.

Thermometric tests

9.103 Thermometric tests are carried out to verify the attainment of the specified conditions throughout the chamber and load during the operating cycle. Continuous process WDs and multi-chamber WDs in which the use of recorders with fixed sensors is impractical should be tested using single channel data loggers that can be processed through the WD. The use of biological indicators as a substitute for thermometric testing is not acceptable.

Load carrier temperature (Validation Tests, Yearly Tests & Re-validation)

Equipment and materials

9.104 A temperature recorder complying with the requirements specified in Chapter 8 and having not fewer than six sensors is necessary.

> **NOTE:** Three independent data loggers and a temperature recorder having at least one sensor may be used as an alternative.

Method

9.105 Temperature sensors should be located at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature and one on each door of cabinet washer.

9.106 The temperature attained should be measured throughout three operating cycles (3 tests for validation, 1 test for yearly), the first of which should be at least 60 minutes since the machine was last used (a ‘cold start’) and the final three with not more than a 15 minute interval between cycles (a ‘hot start’). The WD should be operated empty except for chamber furniture (for example load carriers).

9.107 The load carrier should be replaced between cycles with a load carrier at ambient temperature.

9.108 Multi-chamber WDs may be tested with each chamber tested consecutively using independent data loggers to record the temperature of the load carrier. A temperature recorder with fixed sensors may be used to record the temperature adjacent to the reference sensor.

9.109 This test may be run simultaneously with the chamber wall temperature test.

NOTE: When the length of cycle and/or the number of data-loggers available precludes re-use of the data-loggers with not more than 15 minutes between cycles the WD should be kept in continuous operation so that when the second and subsequent tests are initiated not more than 15 minutes has elapsed since the first chamber completed a cycle.

Results

9.110 The results should be the following:

a. The temperatures recorded on the surface of the load carrier should be within the range 0°C to 5°C of the disinfection temperature throughout the holding period for the disinfection stage;

b. The temperatures recorded on the surface of the load carrier should be within ± 5°C of the set temperature for the relevant stage throughout the holding period for each of the other stages;

c. The temperature indicated/recorded by the WD instruments should be within ± 2°C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage;

d. The temperature profile obtained for the operating cycle should be consistent within ± 2°C for the last three test cycles.

Over-temperature protection

Introduction

9.111 The WD is fitted with over-temperature protection (i.e. 5°C above the operating temperature) to ensure that, in the event of the automatic control failing to control the temperature in the WD, the temperature will not rise to a level which would damage the load in the WD.

Equipment and materials

9.112 A temperature recorder complying with the requirements specified in Chapter 8 and having not less than 4 sensors is necessary.

Method

9.113 Temperature sensors should be located at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature.

9.114 The WD, empty except for the load carrier, should be operated on a normal operating cycle. For multi-cycle machines the two cycles that have the highest and lowest operating temperatures should be tested.

Results

9.115 The over-temperature protection should operate at a temperature not more than 5°C higher than that provided by any temperature control or temperature limiting device.

Load dryness

Introduction

9.116 The presence of residual water on cleaned and disinfected items may interfere with the correct functioning of the item, promote re-contamination and microbial growth or prevent attainment of sterilizing conditions.

9.117 The dryness of most items may be evaluated visually. The dryness of the internal surface of lengths of tubing may be tested by blowing through with dry compressed air onto a mirror; misting of the mirror will indicate residual internal moisture.

Air quality

Introduction

9.118 Many WDs are fitted with air filters to remove particulate material from the air supplied to the drying stage. These filters are often HEPA filters (for example EU 12/13) of the type used to remove bacterial contamination from the air supply. When they are used as general particulate filters, performance tests will not normally be required for the filter or the filter housing. The filter and filter housing should be tested when the intention is to provide air free from bacterial contamination when the load is intended for use without further processing (for example sterilization).

9.119 Microbial sampling will not normally be required for either system unless otherwise specified.

Method

9.120 The complete installation should be tested using the method described in BS 5295: Part 1 Appendix C: 'Method of testing for the determination of filter installation leaks'. A challenge aerosol of inert particles of the type produced by a dispersed oil particle generator should be introduced into the air upstream of the filter. The downstream face of the filter and its housing should then be scanned for leakage using a photometer.

Results

9.121 The reading on the photometer should be steady and repeatable and should not exceed 0.01% of the upstream reading.

10. Disinfection efficacy tests

Introduction

10.1 Thermometric tests are required for both thermal disinfection processes and chemical disinfection processes. For thermal disinfection processes, the time temperature relationships which are generally regarded as acceptable are shown in Table 2. Microbiological testing is only required for chemical disinfection processes.

10.2 Temperature monitoring of the load should be used to determine the attainment of the required time-temperature conditions.

Thermometric test for disinfection

10.3 This test is suitable for all WDs and should be used to establish the adequacy of temperature control during chemical disinfection as well as for verifying attainment of thermal disinfection conditions.

10.4 The load under test will consist of a reference load (see Chapters 12 to 18) or a performance qualification load of discrete items of the type which the WD under test is intended to process, or of surrogate devices used to simulate such load items.

Equipment

10.5 The following equipment is necessary.

10.6 A temperature chart recorder calibrated 0°C–120°C in accordance with UKAS/NAMAS traceability.

NOTE: For type 1 machines and type 2 machines without physical separation of compartments (Conveyor WDs) sensors may be passed into the chamber through the thermocouple entry port into the chamber.

10.7 **Method**

Temperature sensors should be placed in the following positions:

a. sensors on product items at each level in the load carrier;

b. one on an item in the region known to be slowest to attain the disinfection temperature;*

c. one on an item in the region known to be fastest to attain the disinfection temperature;*

d. one adjacent to the automatic control temperature sensor;

e. one adjacent to the process recorder sensor (if fitted) in each chamber or compartment;

f. one on each door of double door cabinet WD.

NOTE: *These positions should be specified by the manufacturer and supported by data type tests. If these data are not available from the manufacturer, preliminary tests to map the temperature throughout the load will be necessary.

10.8 The sensors should be in good thermal contact with the item or installed sensor which they are monitoring and placed, if possible, in or on the part of the item which will be slowest to heat up.

10.9 The test should be performed in triplicate.

Results

10.10 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test;

b. the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that specified for the appropriate disinfection temperature band in Table 3;

c. during the holding time the measured temperatures are within the disinfection temperature band specified for the operating cycle; the indicated and recorded chamber temperatures are within 2°C of the temperature measured at the automatic control sensor; the temperature measured on the surface of each load item does not fluctuate by more than ± 2°C and does not differ from that in other load items by more than 4°C;

d. at the end of the cycle: the temperature sensors have remained in position.

10.11 If having completed the commissioning tests based on a reference load the WD fails to meet the above requirements for the specific performance qualification load then it is possible that the WD is not capable of processing loads of the type intended. Advice should be sought from the Independent advisor.

11. Automatic control test

Introduction

11.1 The automatic control test is designed to show that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the WD.

11.2 It is carried out once a week on most WDs and is the main test for ensuring that the WD continues to function correctly.

11.3 During the commissioning, yearly and quarterly test programmes the temperature sensors for subsequent thermometric tests will be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments the calibration of these instruments may be checked during periods of stable temperature in the automatic control test.

Test procedure

11.4 Place the test load appropriate to the type of WD, contained within any load furniture normally used, in the chamber.

11.5 For WDs equipped with multiple cycle capability select the operating cycle to be tested. Start the cycle.

11.6 Ensure that a batch process record is made by the recording instrument fitted to the WD. If the WD does not have a recorder, observe and note the elapsed time indicated chamber temperatures and pressures at all significant points of the operating cycle, for example the beginning and ending of each stage or sub-stage, and the maximum values during the holding time.

11.7 At the approximate mid-point of the disinfection hold time, note the elapsed time and the indicated chamber temperature.

11.8 The test should be considered satisfactory if the following requirements are met:

a. a visual display indicating ‘cycle complete’ occurs;

b. during the whole of the operational cycle the values of the cycle variables as indicated by the instruments on the WD or shown on the batch process record are within the limits established as giving satisfactory results either by the manufacturer or during performance qualification;

c. during the disinfection hold period determined from the indicated and/or recorded chamber temperature:

(i) the indicated and recorded chamber temperatures are within the appropriate disinfection temperature band specified in Table 2;

(ii) the time for which the disinfection temperature is maintained is not less than that previously established, by either the manufacturer or performance qualification tests, as necessary to ensure that the load is maintained at temperatures within the disinfection temperature band for the time specified in Table 3;

d. the door cannot be opened until the cycle is complete;

e. the person conducting the test does not observe any mechanical or other anomaly.

12. Specific tests for WDs for human-waste containers

Introduction

12.1 WDs for human-waste containers are used to process bedpans, commode bowls, vomitus bowls, urine bottles, suction bottles, kidney dishes and sputum cups etc. The WD is usually a dedicated machine intended solely for human-waste containers.

12.2 WDs for human-waste containers (Bedpan WDs) are Type 1 (single or double door) machines only. The following tests are specific to WDs for human-waste containers.

12.3 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Test for safety of loading and/or emptying of containers

Introduction

12.4 The test is intended to ensure that containers can be emptied without spillage or splashing which would cause a hazard to the operator. The WD should be tested for either manual or automatic emptying.

Equipment and materials

12.5 A full load of each type of container which the WD is intended to process is necessary.

Method: manual emptying

12.6 Each type of container which the WD is designed to process should be tested. Fill each container to not less than 75% of its brim full capacity and empty it and locate it in the load carrier in accordance with the manufacturer's instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid is spilled or splashed. Carry out the test in triplicate on each type of container.

Method: automatic emptying

12.7 Each type of container which the WD is designed to process should be tested. Fill each container to 75% ± 5% of its brim full capacity and locate it in the load carrier in accordance with the manufacturer's instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid is spilled or splashed. Carry out the test in triplicate on each type of container.

Results

12.8 There should be no spillage or splashing of the contents of the containers during the emptying process.

13. Specific tests for WDs for surgical instruments

Introduction

13.1 WDs for surgical instruments may be Type 1 (double or single door) or Type 2 (multiple cabinet or conveyor).

13.2 'WDs for surgical instruments' is a description often given to a WD for general purposes which is used for other specific applications by using suitable load carriers (for example hollowware, anaesthetic accessories, laboratory ware). The tests described for WDs for each of these specific purposes (see Chapters 14, 15 and 16) should be carried out in addition to the test described in this Chapter, when relevant.

13.3 WDs for surgical instruments are used also to process those rigid endoscopes which are able to withstand thermal disinfection. Specific tests for WDs used for this purpose are considered in this category.

13.4 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Water quality

13.5 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

13.6 Water which is too hard or has too high a concentration of dissolved solids may impair the activity of detergents (or require the use of increased quantities of chemical additives) and cause deposits, scaling or corrosion of items being processed. Water for washing and subsequent stages of the process should be tested to ensure that it is not.

13.7 Trace elements in the water supply may cause corrosion of surgical instruments. The water supplied for the final rinse stage should be of high purity and this should be confirmed by testing.

13.8 It is necessary for the user and microbiologist to establish microbiological quality of the water, particularly final rinse water, and ensure that the quality is maintained. This should include discussions on microbiological testing, including the advisability of monitoring bacterial endotoxin levels.

Reference test loads

13.9 The following general equipment is suggested:

a. 3 cuscoe speculae;

b. 3 artery forceps (Crile, Kelly or Spencer Wells) with box joints;

c. 3 No 3 scalpel handles;

d. 3 Yankauers or Pooles suction tubes;

e. sufficient additional instruments to make up a full load;

f. dissecting forceps;

And where appropriate the following endoscope/MAT instruments are required:

g. 2 Trochar and Cannulae;

h. 2 MAT forceps;

i. 2 surrogate endoscopes (see below);

j. sufficient additional instruments to make up a full load.

14. Specific tests for WDs for hollowware

Introduction

14.1 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

14.2 WDs for hollowware are used to process bowls, receivers, instrument trays, containers and lids etc. The WD may be a dedicated machine intended solely for hollowware or a WD for surgical instruments with an appropriate load carrier and operating cycle. In the latter case, the tests and reference loads described in this Chapter should also be applied to the WD for surgical instruments (see Chapter 13).

14.3 WDs for hollowware may be Type 1 (single or double door) or Type 2 (multiple chamber or conveyor).

14.4 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Reference test loads

14.5 Metal and plastic hollowware has significantly different drying characteristics and may also have different carrier requirements since plastic containers are easily ‘flipped over’ and may then become filled with water. When this happens, not only are the containers impossible to dry but also, there may be a serious risk of scalding when unloading the WD. Plastic items are usually more difficult to dry and are therefore chosen for the standard test load.

14.6 The suggested standard test load for hollowware should consist of items conforming to BS 5452: 1977 (1989) as follows:

a. instrument tray 200 mm x 150 mm;

b. instrument tray 300 mm x 250 mm;

c. compartmented instrument tray 270 mm x 180 mm;

d. kidney dish of 150 mm x 300 mm;

e. wash bowl of 350 mm x 135 mm;

f. lotion bowl of 100 mm x 45 mm;

g. lotion bowl of 250 mm x 110 mm;

h. gallipot of 40 mm (30 ml to 60 ml);

i. gallipot of 80 mm (250 ml to 280 ml);

j. sufficient additional items of the same type to form a full load.

Performance qualification tests

14.7 Additional tests are unlikely to be required for particular load items other than for WDs which are used to clean and disinfect re-usable containers for sterile products (see EN 868 Part 8 – Yet to be formally published).

14.8 A test load consisting of the following should be used:

- full size container (600 mm x 300 mm x 300 mm);
- 1 half height container (600 mm x 300 mm x 150 mm);
- 2 half-size half-height containers (300 mm x 300 mm x 150 mm).

14.9 Further tests may be necessary also for particular loading configurations. When load carriers are heavily loaded there may be ‘shadowing’ of some parts of the load causing inefficient cleaning and/or failure to achieve disinfection conditions throughout the load.

15. Specific tests for WDs for anaesthetic accessories

Introduction

15.1 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

15.2 WDs for anaesthetic accessories are used to process breathing tubes, reservoir bags, connectors, endotracheal tubes, tracheostomy tubes, face masks and similar items. The WD may be a dedicated machine intended solely for anaesthetic accessories or a WD for surgical instruments with an appropriate load carrier and operating cycle. In the latter case the tests and reference loads described in this chapter should be applied also to the WD for surgical instruments (see Chapter 13).

15.3 WDs for anaesthetic accessories may be Type 1 (single or double door) or Type 2 (multiple chamber or conveyor).

15.4 Long lengths of tubing are difficult to clean internally and the attainment of cleanliness is difficult to verify. Anaesthetic tubing is also difficult to dry; this is particularly the case for plastic tubing which cannot withstand high (100°C+) drying temperatures.

15.5 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Reference test loads

15.6 A suggested test load consisting of the following should be used:

a. Breathing tubes > 600 mm in length (conforming to BS EN 12342: 1998) (transparent/translucent tubing should be used);

b. anaesthetic reservoir bag of 15 mm, 1.5 litre capacity (conforming to BS 1820:1970);

c. anaesthetic reservoir bag of 22 mm, 1.5 litre capacity (conforming to BS 1820:1970);

d. dis-assembled conical connectors of 15 mm, screw threaded with cone and socket joints (conforming to BS 3849-4);

e. dis-assembled conical connectors of 22 mm, screw threaded with cone

and socket joints (conforming to BS 3849-4);

f. tracheostomy tube and connector of 11mm size (conforming to BS EN 1282-1:1997);

g. endotracheal tube connector of 11 mm size (conforming to BS EN 1782:1998); face masks.

Performance qualification tests

Cleaning and disinfection

15.7 The inner surfaces of anaesthetic accessories are often those for which successful cleaning and disinfection are most critical. Some items may be used after disinfection without further decontamination (for example sterilization). Performance qualification tests, in addition to the operational tests specified may be required for all aspects of the process. The use of surrogate devices may be advantageous.

Drying

15.8 Items which are left warm and damp after an ineffective drying stage will rapidly become recontaminated with micro-organisms.

16. Specific tests for WDs for laboratory glassware

Introduction

16.1 WDs for laboratory use are generally of Type 1 (single or double door) only. Their major use is for cleaning laboratory glassware and this is reflected in the reference load specified. However, there is a wide range of possible loads and load carriers adapted for particular purposes and specific performance qualification tests may therefore be required.

16.2 The disinfection stage may not be required for many laboratory applications.

Reference test loads

16.3 The suggested reference test load to be used in tests for cleaning efficacy, thermal disinfection efficacy and (when applicable) load dryness consists of a full load of glassware. This should contain:

a. rimless test tubes of 16 mm x 150 mm with 1.2 mm wall thickness(conforming to BS 3218: 1982);

b. low form beakers, 1000 ml volume, 106 mm diameter by 145 mm high (conforming to BS 6523: 1984);

c. additional items as may be required to fully load the chamber of the WD.

Performance qualification tests

Load items

16.4 For laboratory items other than general purpose glassware of the type included in the reference load, or of other items (for example hollowware) for which standard reference loads have been defined, it will be necessary to review how well they are represented by the items of which the reference loads are composed. If the reference loads do not adequately represent the loads which will be used further tests should be carried out using loads composed of items which will be in normal production loads.

Nature of soiling

16.5 Laboratory items may be subjected to soiling of a variety of types many of which are very difficult to remove. The test soil for operational testing is chosen to represent biological fluids which may be present. If other types of soiling will be encountered, tests should be conducted using items soiled in the manner which will occur for normal production loads.

Process residue tests

16.6 In many cases there will be a need for laboratory items to be free from residues of chemical additives used during the cycle since these may interfere with the subsequent use of the load items. The manufacturer(s) of the chemical additives which it is intended to use should be asked to provide appropriate test methods for the determination of residual levels.

17. Specific tests for ultrasonic cleaners

Introduction

17.1 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

17.2 Ultrasonic cleaners may be of the 'stand-alone' ultrasonic bath type or may be WDs of Type 1 or Type 2 (multiple chamber or conveyor) or they may be one stage of a Type 2 WD. Many Type 1 ultrasonic cleaners do not incorporate a disinfection stage and are intended for use as a pre-cleaning process before final cleaning and disinfection in a WD for surgical instruments (see Chapter 13).

17.3 Some ultrasonic cleaners are equipped with means to irrigate hollow instruments such as endoscopes. These WDs should be tested both with the general reference load and the endoscope/MAT reference load (see below).

Test for ultrasonic activity

Introduction

17.4 The activity of an ultrasonic cleaner may be investigated by the erosion pattern which is created on aluminium foil exposed in the bath for a short period. The activity will not be uniform throughout the ultrasonic bath. Tests carried out during commissioning are intended to establish the variation in activity at different positions and levels within the bath and the time required to obtain a characteristic erosion pattern.

17.5 The exposure time will depend on the thickness of the foil, the hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.

Equipment and materials

17.6 The following equipment and materials are necessary:

a. aluminium foil of nominal thickness 0.015 mm to 0.025 mm (sold as an aluminium foil wrap for cooking);

b. autoclave indicator tape;

c. stopwatch, graduated in 0.2 s and with an accuracy over a period of 15

min of ± 0.5 s, or better;

d. ruler/tape measure graduated in mm.

Method

17.7 Measure the depth of the bath from the level of the lid to the bottom of the bath. Let the depth be D mm.

17.8 Cut strips of aluminium foil 15 mm to 20 mm wide and {D + 120} mm.

17.9 Carry out the manufacturer's recommended start-up procedure; this will normally include a period of operation to eliminate dissolved gases from the solution in the bath (the de-gassing procedure).

17.10 Ensure that the water in the tank is at the required level, that the required amount of any chemical additive specified by the manufacturer has been added and that the water in the tank is at the specified operating temperature.

17.11 Using strips of autoclave indicator tape across the top of the bath suspend nine strips of the prepared foil in the bath in a 3 x 3 grid.

17.12 The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should be not more than 10 mm above, but not touching, the bottom of the bath.

17.13 Operate the bath for the predetermined exposure time. This may vary typically between 30 seconds for a watt density of 20 Wdm^{-3} and 10 minutes for a watt density of 5 Wdm^{-3}.

17.14 Remove the strips from the bath, blot dry and examine.

17.15 The strips may be filed conveniently by sticking them to an A4 sheet of plain paper using a transparent adhesive tape.

17.16 Drain the bath and clean to remove debris of eroded aluminium foil.

Results

17.17 The zones of maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent (by visual inspection).

17.18 On re-testing the extent of erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

NOTE: For precise evaluation the foils should be weighed before and after exposure to ultrasonication and the loss in weight recorded. The variation in loss of weight should be such that the weight of any one foil is within ± 20% of the mean loss of weight.

Reference test loads

17.19 The suggested test load should contain the following general equipment:

a. cuscoe speculae;

b. artery forceps (Crile, Kelly or Spencer Wells) with box joints;

c. no. 3 Scalpel handles;

d. Yankauers or Pooles suction tubes;

e. sufficient additional instruments to make up a full load.

17.20 The test load should contain the following endoscope/MAT instruments:

a. Trochar and Cannulae;

b. MAT forceps;

c. surrogate endoscopes (see below).

17.21 Sufficient additional instruments to make up a full load.

17.22 The surrogate endoscope should be constructed from 6 mm o.d./4 mm id stainless steel tubing. The overall length should be 450 mm. At the midpoint of the tube should be a 50 mm length of tubing connected to the tubing on either side with compression fittings.

17.23 The 50 mm demountable length may be used to provide a more readily visible section for determination of cleaning efficacy.

Performance qualification tests

Load items

17.24 For ‘difficult to clean’ laboratory items other than those of the type included in the reference load, or of other items (for example hollowware) for which standard reference loads have been defined, it will be necessary to review how well they are represented by the items of which the reference loads are composed. If the reference loads do not adequately represent the loads which will be used further tests should be carried out using loads composed

of items which will be in normal production loads.

Nature of soiling

17.25 Ultrasonic cleaners are often used for items which are contaminated with soiling which is difficult to remove by other cleaning processes.

17.26 The test soil for operational testing is chosen to represent biological fluids which may be present. If other types of soiling will be encountered (for example orthopaedic bone cement) tests should be conducted using items soiled in the manner which will occur for normal production loads.

18. Specific tests for WDs for endoscopes

Introduction

18.1 WDs for flexible thermolabile endoscopes are machines of Type 1 (single and double door) only. (Rigid endoscopes able to tolerate terminal steam sterilization are considered under WDs for surgical instruments).

18.2 These WDs are characterised by a chemical disinfection stage because the products which are intended to be processed will not withstand the high temperatures required for thermal disinfection. It is necessary to ensure that the disinfectant is removed from the endoscope before it is used on a patient; this is achieved by a post-disinfection rinsing stage. It is apparent that the microbiological control of this stage is of critical importance to the microbial status of the processed item. A number of additional tests are required to ensure that this aspect of the process is properly controlled.

WD self-disinfection test

Introduction

18.3 It is necessary to verify that the WD 'machine disinfection' mode will disinfect those parts of the WD which come into contact with fluids which are intended to, or may, contact the load.

18.4 The WD may be equipped with an auto or manually selected 'self-disinfect' mode; it may be thermal or chemical and in the latter case may be the same or a different germicide from that used for chemical disinfection of the load. The preferred method is thermal disinfection or, if this is not possible, the use of a different germicide. The use of the same germicide carries the risk of allowing organisms resistant to that particular germicide to proliferate.

18.5 The process is intended to deal with the situation where the WD has become contaminated. The piping used to convey rinse water to the endoscope, if contaminated, may easily develop a layer of biofilm containing many micro-organisms in a state which is highly resistant to chemical disinfection. This tubing should normally be replaced at the interval specified by the manufacturer. Normally this should not exceed 500 operating cycles or 3 months.

18.6 Thermal disinfection systems should be evaluated by thermometric monitoring of the system with sensors placed at the parts of the system most remote from the heat source. The entire system should attain the required disinfection temperature (see Table 3).

NOTE: Advice on microbiological testing should be sought from the microbiologist.

Final rinse decontamination test

18.7 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

18.8 Various methods are used to ensure that the final rinse water is decontaminated before use. The test should verify the performance of the particular system by the method specified by the manufacturer.

18.9 This may include:

a. verification of filter performance by a bubble point test or by measuring the differential pressure drop across the filter;

b. verification of thermal disinfection by thermometric testing;

c. verification of UV activity by confirmation that the illumination is at the wavelength and intensity specified by the manufacturer and that the residence time is also as specified.

NOTE: Advice should be sought from the microbiologist.

Channel patency detection test

18.10 WDs for endoscopes should be fitted with means to ensure that each of the channels is patent so that germicidal and rinse solutions will flow through each channel.

18.11 A surrogate device should be used to demonstrate that the system for determining the patency of each channel is functioning correctly. The surrogate device may be constructed by using a 1.5 metre length of 1mm ID PTFE tubing.

18.12 For each channel (air/water, biopsy, elevator as relevant) connect a 1.5 metre length of tubing of the appropriate diameter and run a operating cycle. On completion of the cycle replace one of the tubes with a similar tube which has a 100 mm long 1.1 mm OD 0.5 mm ID melting point tube (Borosilicate glass) inserted and secured in the distal end and run another operating cycle. Repeat the test changing the position of the partially obstructed tube on each test.

18.13 The WD should indicate a fault for any channel to which the partially obstructed surrogate device is fitted.

Disinfectant concentration test

18.14 WDs employing a chemical disinfection stage may re-use the chemical germicide a number of times.

18.15 When such a system is employed the WD should be equipped with means to establish that the concentration of the active ingredient(s) in the germicide is above the concentration specified as the minimum acceptable. This may be in the form of a test kit to be employed by the user.

18.16 The disinfectant concentration test is carried out to establish that the means provided is effective.

18.17 The full strength solution, unused (and if necessary freshly prepared or activated), should be prepared according to the manufacturer's instructions. When this requires the addition of water, only distilled or purified water should be used.

18.18 A dilution series should be prepared using distilled or purified water.

NOTE: Handling of disinfectant solutions may need to be carried out in a laboratory with appropriate safety precautions. Seek advice from the Microbiologist or Independent Advisor.

Reference test loads and soil tests

18.19 For advice on reference test loads and test soil, consult the microbiologist/ Independent Advisor.

Microbiological tests for disinfection efficacy and performance qualification test

18.20 For advice on the above tests, consult the Microbiologist/Independent Advisor.

Appendix 1: Glossary

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

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.

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

Chemical additive: one or more chemicals added to the chamber and load of a WD during one or more stages of the process.

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 microbiocidal.

Commissioning: obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within pre-determined limits when operated in accordance with operational instructions.

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

D value: for a microbiological process the extent of exposure under defined conditions which cause a 90% decrease in the viable population of a specified micro-organism.

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.

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

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.

Installation qualification: see commissioning.

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.

Medical device: see BS EN 46001: 1997 'Specification for application of EN ISO 9001 to the manufacture of medical devices'.

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.

Performance qualification: obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

Product compatibility: ability of the WD operational cycle to achieve the intended results without detrimental effect on the product or its intended use.

Reference load: specified load made up to represent the most difficult combination of items to be processed in a particular WD operational cycle.

Routine test: series of tests intended to be performed by the user, or their representative, at various pre-determined intervals to demonstrate that the performance of the WD remains within the limits established during type/works/installation and validation testing.

Steam generator: vessel designed to contain water and a heating system (e.g. 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 of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile''.

Sterilization: the killing or removal of all micro-organisms including bacterial spores.

Surrogate device: a test piece designed and constructed to emulate those characteristics of a device which influence the facility with which it may be cleaned and disinfected.

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

Test soil: substance used to test the washing efficacy of WDs.

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.

Validation: documented procedure for obtaining, recording and interpreting data to show that a process will consistently produce product complying with pre-determined specifications.

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

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 deigned specifically to wash linen or clothing.

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

Z value: for a thermal microbicidal process the change in temperature required to cause a tenfold change in D value.

Appendix 2: Abbreviations

AP(S)	Authorised Person (Sterilizers)
BS	British Standard
°C	degrees Celsius
CEN	Committee European de Normalisation
COSHH	Control of Substances Hazardous to Health
DOE	Department of the Environment
EN	European Norm
EU	European Union or Endotoxin Unit
FSD	Full scale deflection
GGMP	'Guide to good manufacturing practice for medicinal products' (GGMP) published in Volume IV of 'The rules governing medicinal products in the European Community'
HEPA	High Efficiency Particulate Arrestance
HMSO	Her Majesty's Stationery Office
HSE	Health and Safety Executive
HTM	Hospital Technical Memorandum
Hz	Hertz
ID	Internal Diameter
IEC	International Electrotechnical Commission
ISE	Iron selective electrodes
ISO	International Standards Organisation
ISSM	Institute of Sterile Services Management
kPa	kilo Pascal
LAL	Limulus Amoebocyte Lysate
l/s	litres/second
MAT	Minimal Access Therapy
mbar	milli bar
MCA	Medicines Control Agency
MDA	Medical Devices Agency
min	minute
ml	milli litre
mm	millimetre
MP	Maintenance Person
MPR	Master Process Record
NAMAS	National Measurement Accreditation Scheme
NDT	Non-destructive Testing
NHS	National Health Service
OD	Outside diameter
OEL	Occupational exposure limit
PES	Programmable Electronic System
P&EF	Property and Environment Forum
P&EFEx	Property and Environment Forum Executive
PQ	Performance qualification
PRQ	Performance re-qualification

S	Second
SHPN	Scottish Hospital Planning Note
SHTM	Scottish Health Technical Memorandum
T.C.	Technical committee
TP	Test Person
UK	United Kingdom
UKAS	United Kingdom Accreditation Services
WD	Washer-disinfector
Wdm-3	Watts/cubic decimetre = Watts/litre
WHO	World Health Organisation
μ**gl**$^{-1}$	microgram/litre
<	less than
>	greater than

Appendix 3: Useful addresses

UK health agencies

NHSScotland
Property and Environment Forum Executive,
4th Floor St Andrew House,
141 West Nile Street,
Glasgow, G1 2RN

Scottish Healthcare Supplies,
Trinity Park House, South Trinity Road,
Edinburgh, EH5 3SH
Tel 0131 552 6255

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

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

Health and Safety

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

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

Health and Safety Executive Information Line
Tel 0870 154 5500

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,
Northumberland Road,
Portsmouth PO5 1DS.
Tel. 02392 823 186

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	1993	
	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 (as amended)	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 (as amended)	HMSO	1988 (amd. 1994)	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health and Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health and Safety (Information for Employees) Regulations	HMSO	1989	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SI 341	Health and Safety (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	1999	
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 (as amended)	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
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	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 853	**Specification for vessels for use in heating systems** **Part 1:** Calorifiers and storage vessels for central heating and hot water supply **Part 2:** Tubular heat exchangers and storage vessels for building and industrial services	BSI Standards	1996 1996	
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 1752	**Specification for laboratory sintered or fritted filters including porosity grading**	BSI Standards	1983	
BS 2745	**Washer disinfectors for medical purposes** **Part 1:** Specification 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	
BS 3218	**Specification for test tubes and boiling tubes**	BSI Standards	1982	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**	BSI Standards	1992	
BS 3849-4	**Concial connectors for anaesthetic and respiratory equipment. Specification for 8.5 mm cones and sockets**	BSI Standards	1990	
BS 3928	**Method for sodium flame test for air filters (other than air supply to IC engines and compressors)**	BSI Standards	1969	
BS 5164	**Specification for indirect-acting electrical indicating and recording instruments and their accessories**	BSI Standards	1975	
BS 5295	**Environmental cleanliness in enclosed spaces**	BSI Standards	1989	
BS 5452	**Specification for hospital hollow-ware made of plastics material**	BSI Standards	1977	
BS 5500	**Specification for unfired fusion welded pressure vessels**	BSI Standards	2000	
BS 5728	**Measurement of flow of cold potable water in closed conduits** **Parts 2, 3, 5, 6,and 7**	BSI Standards	1980 - 1987	
BS 6253	**Specification for glass beakers for laboratory use**	BSI Standards	1984	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**	BSI Standards	1984	
BS 7320	**Specification for sharps containers**	BSI Standards	1990	
BS EN 285	**Sterilization. Steam sterilizers. Large sterilizer**	BSI Standards	1997	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
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 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 837	**Pressure gauges** **Part 1:** Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing **Part 2:** Pressure gauges. Selection and installation recommendations for pressure gauges **Part 3:** Diaphragm and capsule pressure gauges. Dimensions, metrology, requirements and testing	BSI Standards	1998 1998 1998	
BS EN 866	**Biological systems for testing sterilizers and sterilisation processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterlizers **Part 3:** Particular systems for use in moist heat sterlizers	BSI Standards	1997 1998 1997	
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: Tubes for use in adults	BSI Standards	1997	
BS EN 1782	**Tracheal tubes and connectors**	BSI Standards	1998	
BS EN 1820	**Anaesthetic reservoir bags**	BSI Standards	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	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 12342	**Breathing tubes intended for use with anaesthetic apparatus and ventilators**	BSI Standards	1998	
BS EN 46001	**Specification for application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1998 1995	
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 device industry**	BSI Standards	1996	
BS EN 60584	**Thermocouples** **Part 1:** Reference tables	BSI Standards	1996	
BS EN 60751	**Industrial platinum resistance thermometer sensors**	BSI Standards	1996	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **Part 1:** General requirements	BSI Standards	1993	
BS EN ISO 14644-1	**Cleanrooms and associated controlled environments. Classification for air cleanliness**	BSI Standards	1999	
BS EN ISO 9000	**Quality management and quality assurance standards.**	BSI Standards	2000	
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing.**	BSI Standards	1994/ 2000	
BS EN ISO 9002	**Quality assurance. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
PD 5304	**Safe use of machinery**	BSI Standards	2000	
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)		
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	P&EFEx	2001	CD-ROM
SHTM 2010	Sterilization	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems Supplement 1: Dental compressed air and vacuum systems Supplement 2: Piped medical gases in ambulance vehicles	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilization	P&EFEx	2001	CD-ROM

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	Scottish Office	1994	
SHPN 15	Accommodation for pathology service	Scottish Office	1994	
SHPN 26	Operating department	Scottish Office	1992	
SHPN 26 Supp.1	Operating department activity space data sheets	Scottish Office	1993	
HBN 13 Supp 1	Oxide sterilization section			
	NHS in Scotland PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1998	CD-ROM
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	

Publication ID	Title	Publisher	Date	Notes
(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	3rd 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	
(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	

Publication ID	Title	Publisher	Date	Notes
	Safe working and the prevention of infection in the mortuary and post-mortem room. Health and Safety Executive			
(L22)	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	
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	Rollnick M, *How You Spend Your Pennies*	Health Estate Journal	1991	May, p12-15
	Dawson M, Novitsky T J, Gould M J. *Microbes, endotoxin and water*	Pharm Eng	1988	Mar/Apr vol 8, no2
	Twohy C W, Nierman ML, Duran A P *et al*, *Comparison of limulus amoebocyte lysates from different manufacturers*	Journal of Parent Science & Tech	1983	May/Jun vol 37, no3, p93-96
	Bacterial endotoxin test USP 8th Supp. Pharmacopoeial Convention		1993	Mar XXII NF XVII, p3349-3350
	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	
	Deprygogenation 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

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	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 parenteal 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 Byelaws: Dept. of the Environment	HMSO	1986	
	Ninhydrin test	Analytical Bio-chemistry	1993	Vol 211, p240-242
	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	

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	Total hardness, calcium hardness and magnesium hardness in raw and potable waters	DOE/Nat Water St Committee	1981	
	Water Supply Byelaws Guide. Water Byelaws Advisory Service Water Research Centre		1989	2nd Edition