WHTM 01-01

Welsh Health Technical Memorandum

Decontamination of medical devices within acute services

Part E: Alternatives to steam for the sterilization of reusable medical devices

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Gwasanaethau Cyfleusterau
Shared Services Partnership
Facilities Services

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Overview

Scope of Welsh Health Technical Memorandum 01-01 parts A to E

Welsh Health Technical Memorandum (WHTM) 01-01 gives guidance on the whole decontamination cycle in the management and decontamination of surgical instruments used in acute care.

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. The technical concepts are based on British (BS), European (EN) and International (ISO) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

The management of decontamination equipment is a critical engineering service.

WHTM 01-01 Part A provides a description of the overall structure of the guidance and the rationale behind the following:

- the regulatory framework;
- roles of key personnel;
- procedures for the reporting of adverse incidents and defective equipment;
- local reprocessing (decontamination in primary care, and local decontamination);
- the management of instruments potentially contaminated with transmissible spongiform encephalopathy (TSE) infectivity.

Part B covers common elements that apply to all methods of surgical instrument reprocessing such as:

- test equipment and materials;
- design and pre-purchase considerations;
- validation and verification.

Part C covers standards, technical guidance, operational requirements, and testing and validation protocols when using steam for sterilization within the acute care setting.

Part D covers standards, technical guidance, operational requirements, and testing and validation protocols when using washer-disinfectors as part of the decontamination cycle within the acute care setting.

Part E covers low temperature (non-steam) sterilization processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure).

Who should use WHTM 01-01 Part E

Part E is intended as a technical guide for management, for technical personnel with appropriate training and experience, and for users responsible for the procurement, maintenance, validation and operational management of non-steam sterilization systems used as part of the decontamination cycle of re-usable medical devices within the healthcare environment. It will also be of interest to microbiologists, infection control officers, architects, planners, estates managers, supplies officers, and others in both the public and private sectors.

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Andrew Thomas Royal College of Surgeons

Bill Keevil Southampton University

Brian Kirk IHEEM Decontamination Technology Platform

David Perrett Barts & the London School of Medicine & Dentistry, Queen Mary University of London

Gavin Maxwell Royal Society of Medicine Patients Support Group

Geoff Sjogren Institute of Decontamination Sciences

Geoffrey L. Ridgway, OBE, MD Clinical Microbiologist

Graham Stanton NHS Wales Shared Services Partnership – Facilities Services

Helen Baxter University of Edinburgh

Jackie Duggan Health Protection Agency

James Ironside University of Edinburgh

Jim Gray Birmingham Children's Hospital NHS Foundation Trust

Jimmy Walker Health Protection Agency

Ken Toal Health Estates, Northern Ireland

Margaret Hollis Great Ormond Street Hospital

Mike Painter Public Health Physician

Mike Simmons Public Health Wales

Peter Brigham Newcastle upon Tyne Hospitals NHS Foundation Trust

Peter Hoffman Health Protection Agency

Robert Baxter University of Edinburgh

Robert Kingston IHEEM Decontamination Technology Platform

Sylvia Martin University College Hospital London

Terry Durack Great Ormond Street Hospital

Tracy Coates Association for Perioperative Practice

Listed below are the contributors to this WHTM who sit on the WHTM Guidance Peer Group as directed by the Welsh Government's All Wales Decontamination Group.

Jenny Thorne Welsh Government

Tracey Gauci Welsh Government

Mike Simmons Public Health Wales

Eric Thomas NHS Wales Shared Services Partnership – Facilities Services

Graham Stanton NHS Wales Shared Services Partnership - Facilities Services

John Prendergast NHS Wales Shared Services Partnership - Facilities Services

Peter Wiles NHS Wales Shared Services Partnership - Facilities Services

Mark Campbell Cardiff and Vale University Health Board

Abbreviations

AE(D): Authorising Engineer (Decontamination)

CJD: Creutzfeldt-Jakob disease

COSHH: Control of Substances Hazardous to Health

EN: European norm

HSE: Health and Safety Executive

IFU: Instruction for use

IQ: Installation Qualification

ISO: International Standards Organisation

MDD: Medical Devices Directive

MSDS: Material Safety Data Sheet

NWSSP-FS: NHS Wales Shared Services Partnership - Facilities Services

OQ: Operational Qualification

PCD: Process challenge device

PQ: Performance Qualification

QA: quality assurance

SSD: sterile services department

TSEs: transmissible spongiform encephalopathies

vCJD: variant Creutzfeldt-Jakob disease

WHTM: Welsh Health Technical Memorandum

Contents

Chapter 1 Introduction

1.1 Steam sterilization is well-defined and has been used safely with the majority of medical devices for many years.

1.2 For some specialist instrumentation and devices, steam sterilization has a number of limitations particularly in regard to the reprocessing of medical devices that may be damaged by steam at high temperatures.

1.3 Non-steam sterilization is becoming increasingly required for the reprocessing of thermolabile new technology medical devices. In addition, some non-steam sterilization technologies may provide more significant inactivation of prions; this is the subject of current research.

1.4 Many alternatives to steam sterilization are available for use in sterile services departments (SSDs) and other specialist areas within the healthcare sector and other environments.

1.5 Current sterilization technologies include ethylene oxide, gaseous hydrogen peroxide and ozone. Future potential technologies include low temperature electronic gas plasmas.

Chapter 2 Guidance for healthcare providers

2.1 All Health Boards and healthcare establishments that may reprocess medical devices for use within the NHS in Wales should ensure that local policies for instrument management and decontamination are in place. They should plan for improvements to accommodate technological advances which will allow organisations to embrace new methods and systems to fit their needs.

2.2 The use of specialist surgical instrumentation may extend the range of surgical care available from a provider or may advance the quality of care and improve clinical outcomes.

2.3 In considering such service improvement, Health Boards and healthcare establishments are advised to consult with their users on the availability and capability of decontamination services in respect of new instrumentation and technologies and the ability to ensure adequate and validated decontamination and sterilization. More specifically: are viable cleaning and sterilization methods in place and, where applicable, can validated sterilization be provided?

Chapter 3 Need for guidance

3.1 A quality framework for alternative sterilization methods, based on a systems approach, is not currently provided within the European Norms (ENs) or BSI standards. Accordingly, policy guidance follows the broad outline of BS EN 14937, with significant adaptations to suit the technologies under consideration.

Note
BS EN ISO 14937 does not cover or apply to sterilization processes that rely on physical removal of microorganisms - e.g. filtration systems.

3.2 It is recommended that providers of a non-steam sterilization system and decontamination services use the WHTM risk assessment approach and guidance found in WHTM 01-01 Part A and WHTM 01-06 Part A, in conjunction with the recommendations of the manufacturers of the medical devices to be processed and of the sterilization equipment.

3.3 Providers should seek to minimize risks to the operator, patient and environment from the use of these technologies while promoting satisfactory clinical service outcomes.

3.4 Ensuring effective sterilization is considered to be a key outcome. Validation, defined as achieving an effective, reproducible, sterilization outcome, needs to be conducted to ensure that sterilization has been achieved.

3.5 The validation process should be carried out in agreement with the users, manufacturers and Authorising Engineer (Decontamination) (AE(D)) and be supported by an audit trail. Consultation with NWSSP-FS decontamination engineers is recommended when reviewing new systems and technology.

3.6 The purpose of the validation is to demonstrate that the sterilization process is effective and reproducible. Validation consists of a number of defined stages, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ). A periodic schedule of validation should be determined and agreed between manufacturer, User and AE(D) based upon a number of factors to include historical data, effectiveness of process repeatability and conformance with established specifications for process parameters.

3.7 Routine monitoring and control systems must be in place to demonstrate each process was delivered within the defined parameters identified during the formal validation process.

3.8 The operational responsibility for ensuring that these key objectives are addressed should rest with the Health Board and/or Decontamination Lead and possibly the Directorate Manager responsible for that particular department, working to the local policies agreed by the risk assessment group.

3.9 All Health Boards and healthcare establishments should ensure that such policies are in place and that operational protocols are appropriately employed. These structures should ensure that an adequate validation system is in place and that auditable records exist.

Chapter 4 Role of non-steam sterilization techniques

4.1 Any non-steam sterilization technology should fit in with the broad approach to instrument management and decontamination set out WHTM 01-01 Parts A and B.

4.2 The installation of the technology needs to work in an environment well-integrated with the local SSD and surgical facilities. The flow of work and items from dirty to clean needs to have the same characteristics as for any other process element within an SSD or external facility. It is recommended that NWSSP-FS and the Health Board's Estates Department are fully consulted during this process.

4.3 The risk of recontamination should be minimised. These considerations apply whether the reprocessing is done locally or by an external decontamination provider.

4.4 The compatibility of any alternative sterilization technology with the instruments for which it is intended is a key consideration. The advice of both the technology and instrument manufacturers should be sought when considering non-steam sterilization methods; it should be ensured that the requirements of both the technology and the instrument manufacturers can be reconciled.

Checks to be made

4.5 Before decisions concerning new technologies and equipment selection are made it is essential that a full consultation with relevant individuals is carried out. This should include the SSD Manager, the Infection Control Team, the Surgical Team and/or Endoscopy Unit along with the AE(D) and the Decontamination Engineer (Wales) (DE(W)).

4.6 The following checks should be made:

1. Prior to purchase, it is very important for the Health Board / healthcare provider to establish the needs of the process and consult with the equipment supplier on all aspects of the proposed installation. It is essential that all the operational, maintenance and testing protocols are established prior to installation.
2. The processes and equipment selected are compatible with the medical devices to be re-processed, are suitable and conform to the manufacturer's instructions for both the sterilization equipment and those of the medical devices to be reprocessed.
3. The installation site is suitable for space, ventilation and general engineering services required.
4. The ventilation and space requirements are correct for the equipment installation.
5. The site conforms to the process flow within the selected department.
6. Preventative maintenance schedules are clearly identified by the manufacturer. Such schedules shall determine the frequency of service activities to ensure the safe running and effective operation of the equipment. The maintenance regimes shall be reviewed annually by the User, Manufacturer and AE(D).
7. Agreement must be made to the testing protocols for any biological or chemical indicators used between the Healthcare establishment and the equipment supplier, ensuring the systems offered are compatible with the process and developed in compliance with the relevant BS ISO/EN standards.
8. Usually this type of specialist equipment is tested and maintained by the manufacturer/supplier. It is essential that the correct contracts are in place prior to installation for safe working of the equipment and that the testing regime is correct. The AE(D) and manufacturer should be consulted.
9. Testing regimes along with daily and weekly housekeeping operations should be supplied by the manufacturer to the Health Board / healthcare establishment to enable them to be included in the department quality manual and operation sheets.

10. The manufacturer has supplied the correct information on any chemicals to be used. This should include safe handling, storage and disposal of any out of date or unused substances.
11. Material Safety Data Sheet (MSDS) - this document specifies the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely.
12. Meet Control of Substances Hazardous to Health (COSHH) requirements for the safe storage of chemicals.
13. Packaging used during the sterilization process shall be compatible with the process, validated and used as recommended by the manufacturer. The type/manufacturer of the packaging system shall not be changed unless there is an agreed validation process to determine that the process effectiveness is not compromised.

Tests required

Installation qualification (IQ)

4.7 The process of obtaining and documenting evidence that the prescribed equipment has been provided to specification as agreed with the Health Board / healthcare establishment, and installed in accordance with the agreed installation and drawings.

Operational qualification (OQ)

4.8 The process of obtaining and documenting evidence that the installed equipment operates within predetermined limits when used in accordance with the manufacturer's design parameters and operational procedures.

Parametric release

4.9 A system has to be agreed between the manufacturer and the user which declares that the product is sterile, based on the records and parameters read on any printouts demonstrating that the process as seen was delivered within the specified tolerances. This procedure has to be agreed with the user prior to hand over to ensure that the correct documentation is in place.

Performance qualification (PQ)

4.10 The process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, manufacturer's parameters and specification, consistently performs in accordance with predetermined criteria and thereby yields the products in accordance with the correct specifications.

Performance Requalification tests

4.11 Tests may be required on each of the specialist items to be processed to ensure that all compatibility issues of materials and penetration of lumens are satisfied. No new items should be processed without an analysis of compatibility statements from equipment and medical device manufacturers and any Performance Requalification tests to prove the system or cycle.

Process challenge device (PCD)

4.12 PCD item is designed to constitute a defined resistance to sterilization process and used to assess performance of the process.

Reference microorganism

4.13 This is a microbial strain obtained from a recognized culture collection, usually supplied with a calibration certificate of standard.

Chapter 5 Quality and safety standards for non steam sterilization

5.1 In current practice, policy and procedures governing the use of non-steam sterilization methods rely on local risk analysis and manufacturers' advice and instruction. This approach is compatible with the WHTM approach. However, a framework is offered within this guidance in order to strengthen the background and provide guidance in decision-making.

5.2 There is a lack of definition for test methods and protocols together with associated validation across this area. This makes assessment of sterile status and assurance potentially more difficult compared to steam sterilization. However, a quality assurance process should be used with a plan as to how the technology and sterilization process fits into the overall quality assurance audit process. The reports and processes generated should be transparent and open for assessment and inspection.

Manufacturer's instructions (IFU – Instruction for use)

New technology and developments in surgical procedures very often drive the production of medical devices needed for surgical procedures that may not be compliant with EN standards for decontamination processes. This can cause SSD Managers, Health Boards and healthcare organisations problems in meeting the expectations of Notified Bodies when the assessments and inspections are carried out to meet the Medical Devices Directive. Very often the problems can be resolved by experience, risk assessments and consultation. What is important is that the medical devices that are being reprocessed should not be compromised by the selected sterilization process and equipment. Most importantly, patient safety should not be compromised and confidence in the cleaning process is paramount.

The re-processing of some medical devices and equipment carried out in SSDs may not be compatible with the requirements as specified in manufacturers' IFUs. As a result, major non-conformities have arisen in the past. To follow IFUs to the letter, because of non compliant standards, can sometimes reduce the cleanliness of the item. This may be due to operating a safer mode of temperature or chemical use that is more about device protection than patient safety. Some medical devices purchased from non EU countries may require procedures that are not compliant with IFUs for temperatures, disinfection, sterilization and chemical procedures.

It is recommended that the decontamination team, the SSD Manager and the AE(D) investigate and validate the preferred process that will match the guidance and standards as issued in the United Kingdom.

5.3 Safety when using non-steam sterilization methods must take into account:

- **safety** of the patient, in particular that no toxic residuals remain or are formed on the device following the process and that sterility is reliably obtained;
- **safety** of staff using the process, including physical, ergonomic and chemical considerations;
- **safety** of the devices, ensuring that they are not damaged by the process;
- **safety** of the environment.

5.4 **Workplace exposure limits are published by the Health and Safety Executive (HSE) for some of the chemicals involved in non-steam sterilization (for example, ethylene oxide, ozone, hydrogen peroxide) and the use of sterilization systems must adhere to these limits.**

5.5 Care should be taken regarding instrument package degassing after sterilization, where process chemicals may be retained in the processed device pack and eluted afterwards. This should form part of a full local risk assessment.

Chapter 6 Guidance on safety risk assessment

6.1 Factors to be considered in local risk assessment include, but are not limited to, the following:

a. consideration of environmental and workplace exposure limits for the chemical agents used and any secondary products generated;

b. appropriate application of environmental and personal monitoring. This is selectively referred to for some sterilization agents. However, it is advised that consideration should be given to monitoring whenever toxic gases or vapours are employed. In some instances, equipment may contain monitoring devices. The assessment should include the possible use of non-machine integrated monitors and alarms;

c. consideration to degassing associated hazards and the environments used in processing and storage;

d. containment and ventilation associated with the work environment;

e. constraint of splash and aerosol hazards from liquid agents in use, including hydrogen peroxide;

f. the use of secondary containment combined with negative pressure exhaust ventilation should be considered and may be an HSE requirement for some of the technologies.

6.2 Safety risk assessment should be applied to all decontamination technologies, regardless of type or status.

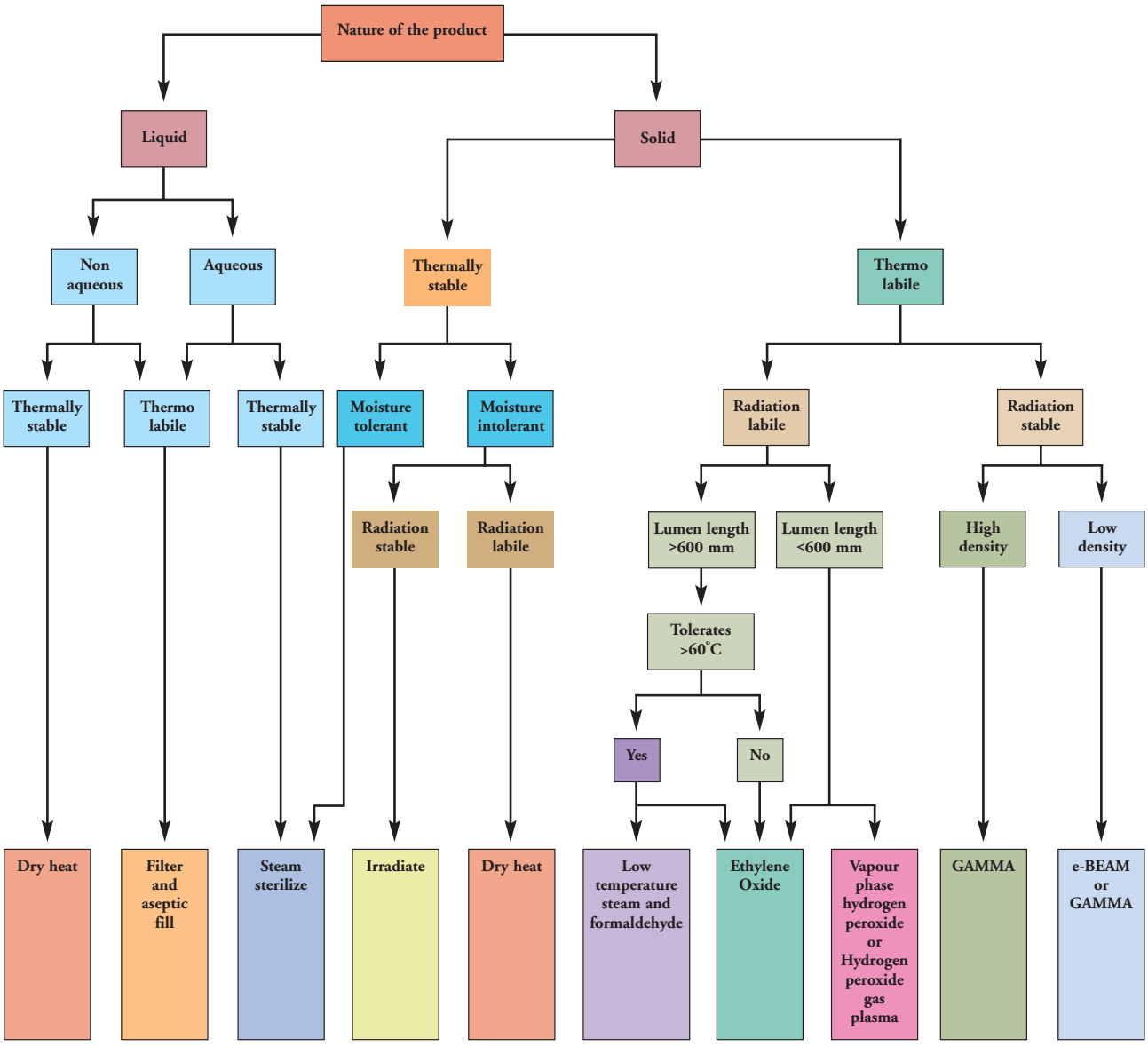
Chapter 7 Surgical instrument and other device compatibility

7.1 It is the responsibility of reprocessable medical device suppliers to inform users of compatible decontamination processes. However, guidance regarding specific incompatibilities of other processes is not always provided by the manufacturer. It is very important to obtain from each manufacturer of the medical device, clear guidance and instructions on the cleaning methods and instructions for use to be employed by the users. As mentioned in Chapter 5, there can be compatibility problems between IFUs and the relevant standards applied to medical devices.

7.2 Before any decontamination technology is used, (whether steam or otherwise), it must be determined as compatible by full consultation with the device supplier.

Chapter 8 Choice of the sterilization process and check list

8.1 The diagram below gives a guide on the selection of the process required for medical devices and will guide the user to select the correct pathway.



8.2 Characteristics of an ideal sterilization process

1. Effective against all infective agents
2. Sterilant and reaction products are non-toxic
3. Suitable for packaged goods
4. Not inactivated by soiling (protein)
5. Highly penetrative of the load items
6. Rapid action
7. Cost effective to install with operational costs that are reasonable and effective
8. No training needed for safe and effective operation
9. No environmental or other hazard
10. No residues on devices after process
11. The process can be continuously and independently monitored
12. Causes no damage to any of the products to be sterilized
13. Acceptable to all regulatory Authorities

8.3 What are the main factors that need to be considered?

1. The item or items that need to be processed - ensure that any lumens are correctly evaluated for penetration and, if required, tested via the use of a suitable surrogate device. Also ensure compatibility of the materials with the chemicals or process
2. The packaging materials and types should be checked for compatibility and to match the process/chemicals used
3. Process availability
4. Regulatory compliance issues - all aspects of the process to be checked against the standards
5. Economics of the process should be evaluated and costed per cycle or weekly use
6. The process time should be evaluated against the items to be processed and the cycles available - the validation process will dictate the time of each of the cycles available or used
7. Total process time - this time must be known as delays can occur because of aeration, or waiting times for the results of biological indictors and measurement systems
8. Process residuals (toxicity) - tests should be made or processes planned to ensure safe operation and handling
9. Materials of construction and compatibility issues must be known and assessed
10. Design of the items
11. Thermal tolerance should be sought from the medical device IFUs
12. Moisture tolerance should be sought from the medical device IFUs
13. Accessibility to sterilant
14. Sterilant compatibility with all items to be processed must be known and logged in the QA system
15. Materials of construction should be evaluated by the manufacturer
16. Permeability to sterilant - tests must be conducted in the validation process to ensure all items to be processed are compatible with the manufacturer's reference list of medical devices that achieve the correct result. A full consultation between the SSD manager, user, manufacturer and the AE(D) should take place

8.4 Process Availability

1. Location of the process is critical to the management and control of the process
2. Time of reprocessing and transportation times are critical
3. Accessibility and use must be known

8.5 Regulatory compliance documentation headings

1. Medicines
2. Medical devices
3. Clinical waste
4. Food, cosmetics, etc.

8.6 Economics of the process should be planned and evaluated as follows:

1. Capital costs involved for total installation of the equipment and any additional plant
2. Revenue costs for running the equipment - handling items, containers and chemicals
3. Chemicals - purchase costs against use and safe storage
4. Water use and costs per daily use or cycles
5. Any water treatment plant or filtration systems as required
6. Energy costs for use

7. Testing requirements for weekly, quarterly and annual tests
8. Maintenance schedules and costs as per manufacturer's requirements for optimum operation and safe working
9. Cost per item or unit volume if required for any outside contracting of the process
10. Packaging costs per item or loads
11. Product validation costs for specialist items, such as lumens, endoscopes, etc.
12. Laboratory costs, if required, for testing – e.g. biological indicators or water
13. Advice or consultancy costs if required

References

Acts and Regulations

All the acts and regulations shown below can be accessed from the www.legislation.gov.uk/ website

The Control of Substances Hazardous to Health Regulations

British Standards Institution

http://shop.bsigroup.com/en/

BS EN ISO 14937 Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

The following standards are required for the application of this guidance document. The latest date should be referenced.

BS EN ISO 10012 Measurement management systems. Requirements for measurement processes and measuring equipment.

BS EN ISO 10993-1 Biological evaluation of medical devices. Evaluation and testing within a risk management process.

BS EN ISO 10993-17 Biological evaluation of medical devices Establishment of allowable limits for leachable substances.

BS EN ISO 11138-1 Sterilization of healthcare products. Biological indicators. General requirements.

BS EN ISO 11140-1 Sterilization of Healthcare products – Chemical indicators. General requirements.

BS EN ISO 11737-1 Sterilization of medical devices – Microbiological methods – part 1: Determination of a population of microorganisms on products.

BS EN ISO 11737-2 Sterilization of medical devices. Microbiological methods Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

BS EN ISO 13485 Medical Devices – Quality management systems – Requirements for regulatory purposes.

BS EN 61010-2-040 Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-040: Particular requirements for sterilizers and washer disinfectors used to treat medical materials.

European legislation

The legislation below can be accessed from the eur-lex.europa.eu/homepage.html website

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

NHS Wales Shared Services Partnership – Facilities Services

The publications below are available from the NHS Wales Shared Services Partnership - Facilities Services websites
Intranet : howis.wales.nhs.uk/whe
Internet: www.wales.nhs.uk/whe

Welsh Health Technical Memorandum

WHTM 01-01 – Decontamination of medical devices within acute services, Part A: Management and environment

WHTM 01-01 – Decontamination of medical devices within acute services, Part B: Common elements

WHTM 01-06 – Decontamination of flexible endoscopes, Part A: Policy and management