



Department  
of Health

# Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care

Part B: Common elements

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# Preface

## Introduction

This HTM supersedes the Choice Framework for local Policy and Procedures (CFPP) series, which was a pilot initiative by the Department of Health.

The CFPP series of documents are reverting to the Health Technical Memorandum title format. This will realign them with HTM 00 – ‘Policies and principles of healthcare engineering’ and ‘HTM 01-05: Decontamination in primary care dental practices’ and the naming convention used for other healthcare estates and facilities related technical guidance documents within England. It will also help to address the recommendation to align decontamination guidance across the four nations.

In 01-01 and 01-06 DH will be retaining the Essential Quality Requirements and Best Practice format, this maintains their alignment with HTM 01-05 and the requirement of ‘The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance’ which requires that “decontamination policy should demonstrate that it complies with guidance establishing essential quality requirements and a plan is in place for progression to best practice”. We are aware that policy within the devolved nations differs on this particular issue but the aim is that the technical content should be consistent and able to be adopted by the devolved nations so that the requirements of the ACDP-TSE Subgroup’s amended guidance can be met.

HTM 01-01 forms a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.

## Purpose

The purpose of this HTM is to help health organisations to develop policies regarding the management, use and decontamination of reusable medical devices at controlled costs using risk control, which will enable them to comply with Regulations 12(2)(h) and 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 .

This HTM is designed to reflect the need to continuously improve outcomes in terms of:

- patient safety;
- clinical effectiveness; and
- patient experience.

## Essential Quality Requirements and Best Practice

The Health Act Code of Practice recommends that healthcare organisations comply with guidance establishing Essential Quality Requirements and demonstrate that a plan is in place for progression to Best Practice.

Essential Quality Requirements (EQR), for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. EQRs incorporate requirements of the current Medical Devices

Directive and Approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute provider operates safely with respect to its decontamination services.

A healthcare provider's policy should define how it achieves risk control and what plan is in place to work towards Best Practice.

Best Practice is additional to EQR. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; promote and encourage innovation and choice; and achieve cost efficiencies.

Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses guidance on the whole of the decontamination cycle, including, for example, improved instrument management, where there is evidence that these procedures will contribute to improved clinical outcomes.

The HTM 01 suite is listed below.

- HTM 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care
- HTM 01-04: Decontamination of linen for health and social care
- HTM 01-05: Decontamination in primary care dental practices [check title]
- HTM 01-06: Decontamination of flexible endoscopes.

### **Note**

This guidance remains a work in progress which will be updated as additional evidence becomes available; each iteration of the guidance is designed to help to incrementally reduce the risk of cross-infection.

# Abbreviations

ACDP-TSE [Subgroup]: Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies [Subgroup]	EN: European norm
ACDST: Advisory Committee on Decontamination Science and Technology	FITC: fluorescein isothiocyanate
AE(D): Authorising Engineer (Decontamination)	ISO: International Standards Organisation
AP(D): Authorised Person (Decontamination)	MDD: Medical Devices Directive
BCH: Birmingham Children's Hospital	MDR: Medical Devices Regulations
BS: British Standard	MHRA: Medicines and Healthcare products Regulatory Agency
BSE: Bovine Spongiform Encephalopathy	NDS: National Decontamination Survey
CFPP: Choice Framework for local Policy and Procedures	NICE: National Institute for Health and Clinical Excellence
CJD: Creutzfeldt-Jakob disease	NICE IPG 196 (2006): NICE's (2006) interventional procedure guidance 196 – 'Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures'
CMO: Chief Medical Officer	OPA/NAC: o-phthalaldehyde/N-acetyl-L-cysteine
CP(D): Competent Person (Decontamination)	PO: posterior ophthalmic
CQC: Care Quality Commission	sCJD: sporadic Creutzfeldt-Jakob disease
DH: Department of Health	SSD: sterile services department
DIPC: Director of Infection Prevention and Control	TSEs: transmissible spongiform encephalopathies
EDIC: episcopic differential interference contrast	UCHL: University College Hospital London
EDIC/EF: episcopic differential interference contrast/epifluorescence	vCJD: variant Creutzfeldt-Jakob disease
EFSCAN: epifluorescent surface scanner	

# Executive summary

Health Technical Memorandum (HTM) 01-01 offers best practice guidance on the whole decontamination cycle including 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 European (EN), International (ISO) and British (BS) 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.

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 and guidance on steam sterilization.

Part D covers standards and guidance on washer-disinfectors.

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

HTM 01-01 Part B 2016 supersedes all previous versions of CFPP 01-01 Part B.

## Why has the guidance been updated?

HTM 01-01 has been updated to take account of recent changes to the ACDP TSE Subgroup's general principles of decontamination ([Annex C](#)). In relation to the decontamination of surgical instruments, this principally relates to paragraphs C21 and C22:

### Protein detection

C21. Work commissioned by the Department of Health indicates the upper limit of acceptable protein contamination after processing is 5µg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments.

C22. It is necessary to use protein detection methods to check for the efficient removal of protein from surgical instruments after processing. Protein levels are used as an indication of the amount of prion protein contamination. Ninhydrin swab kits are commonly used for this purpose, but recent evidence shows that ninhydrin is insensitive. Furthermore, proteins are poorly desorbed from instruments by swabbing. Other commonly used methods have also been shown to be insensitive.

The ACDP TSE subgroup's guidance requires that there should be  $\leq 5$   $\mu\text{g}$  of protein *in situ* on the side of any instrument tested. The rationale for each of these elements is as follows:

- The figure of 5  $\mu\text{g}$  of protein has been shown to be achievable by effective cleaning processes. There is currently no definitive evidence base to link this with the absence of prion transmission risk, which is why lower levels for instruments making contact with high risk tissues (see ACDP TSE's [Annex J](#)) is necessary.
- The measurement is per side of instrument rather than per unit area of an instrument. Prion proteins have been shown to be infectious by contact (Kirby et al 2012). Infection transmission would be related to the total area of an instrument that makes contact with patient tissues. Thus, while not a perfect relationship, the assessment of protein levels per side of an instrument is likely to be a greater predictor of risk control than an assessment based on a unit area of an instrument.
- Protein levels on an instrument should be measured directly on the surface rather than by swabbing or elution (see the ACDP-TSE Subgroup's [Annex C](#) paragraph C23), as detection of proteins on the surface of an instrument gives a more appropriate indication of cleaning efficacy related to prion risk (see Table C2 in ACDP TSE's [Annex C](#)). As technologies become available that are able to detect residual protein *in situ* to  $\leq 5$   $\mu\text{g}$  per instrument side, they should be adopted. Prion proteins are very hydrophobic and will, once dry, adhere strongly to surfaces and resist removal by swabbing or elution for the purpose of protein detection.

## What SSDs can do to ensure implementation of the ACDP TSE's Subgroup's recommendations

Because of the risks of prion transmission, there is a need to optimise the whole of the decontamination pathway of surgical instruments.

### Reducing the time from close of procedure to reprocessing

Prions are easier to remove if they have not dried on the surface of an instrument. To enable efficient prion removal, theatre and SSD staff should ensure that instruments are transported to the SSD immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible. This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD.

### Cleaning validation and continuous monitoring

Traditionally, cleaning validation has been about removing visible soiling. Now the emphasis is on removing highly adherent proteins to very low levels. To be able have a greater chance of removing these sticky proteins, there needs to be as efficient a cleaning process as possible – therefore SSDs need to both optimise the cleaning performance of washer-disinfectors and remain within the validation parameters.

It is important to continuously monitor the residual protein on reprocessed instruments. SSDs should not view the 5  $\mu\text{g}$  limit as a single pass or fail, but rather use it as a way of working towards and below this value, that is, as part of trend analysis and a quality assurance system whose aim is to monitor not just the cleaning efficacy of washer-disinfectors but also the instrument journey leading up to that stage – in other words, ensuring results are



being monitored and actions are being taken based on these results. SSDs should include:

- daily testing using process challenge devices\* (along with the standard periodic tests);
- quarterly residual protein testing (see paragraphs 2.271–2.278 in HTM 01-01 Part D –‘Validation and verification’). See also Appendix B in HTM 01-01 Part A for example sampling rates.

Priority should be given to instruments used on high-prion-risk tissues as defined by ACDP (see ACDP TSE’s [Annex J](#)).

\* Commercial process challenge devices are being developed whose challenge simulates the attachment of prion protein to instruments and whose analysis is quantitative. When these become available and have been validated, SSDs are advised to consider their use in addition to process challenge devices based on soils in BS EN 15883-5 Annex N.

Results from the quarterly residual protein test should be used to analyse trends and act on that analysis.

### Methods for detecting residual protein

SSDs should no longer rely on elution or swabbing to detect residual protein on an instrument. The method should be validated as being able to detect protein equivalent to  $\leq 5$   $\mu\text{g}$  of BSA *in situ* on the surface of an instrument. Commercial technologies that can detect the 5  $\mu\text{g}$  limit *in situ* are being developed (see ACDP TSE’s [Annex C](#)). Devices to detect residual protein must be CE-marked as an accessory to a medical device (see the MHRA’s ‘Managing medical devices: guidance for healthcare and social services organisations’ and also ‘Medical devices: conformity assessment and the CE mark’).

Residual protein detection devices should be intended by their manufacturer to be used as an accessory to a surgical instrument that has undergone a cycle through a washer-disinfector validated to BS EN ISO 15883 Parts 1 and 2 for washing and disinfecting of surgical invasive devices and be capable of measuring and detecting residual protein *in situ* to levels of  $\leq 5$   $\mu\text{g}$  per side of used, washed surgical instruments. The manufacturer will need to have CE-marked the product under the Medical Devices Regulations and issued a declaration of conformity to demonstrate that the device has met all relevant essential requirements for the medical device and that they have followed an appropriate conformity assessment route.

**Until such time as these are available as medical devices, residual protein control relies mainly on controlling the decontamination process rather than on protein detection from instruments – that is, process control makes more of a contribution than product control. When high resolution methods of detecting residual protein *in situ* are available, then product control should be used to inform process control.**

### Continuous improvement plans

SSDs should have in place a plan of continuous process improvement. This plan should be carried out as part of a risk management plan (see BS EN ISO 14971 on medical device risk management). There should also be a specific record that relates to residual protein trend analysis.

### Major change to Part B since the 2013 edition

- CFPP 01-01 has reverted to the Health Technical Memorandum title format and now becomes Health Technical Memorandum 01-01.

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# 1 Introduction

**1.1** Potential purchasers of reprocessing equipment should ensure that they know whether the load items they intend to decontaminate are classified as medical devices.

## Medical devices

**1.2** This guidance covers the various types of decontamination equipment to be used for the reprocessing of medical devices (for example porous load sterilizers, and washer-disinfectors).

**1.3** Guidance on the application of medical devices legislation is beyond the scope of this guidance, and advice should be sought from the Medicines and Healthcare products Regulatory Agency (MHRA).

## Definitions

**1.4** For definitions of terms used in this guidance, see ISO 11139:2006 'Sterilization of health care products – vocabulary'.

## 2 Decontamination equipment: test equipment and materials

Refer to the 'Particular specifications' for sterilizers (see page 72 in HTM 01-01 Part C) and washer-disinfectors (see page 77 in HTM 01-01 Part D).

### General considerations

**2.1** This chapter reviews the key items of portable test equipment necessary to carry out the test procedures described in this guidance. Specifications for instruments fitted permanently to decontamination equipment are given in the relevant British, European and International Standards.

**2.2** Instrumentation technology continues to advance rapidly, making it increasingly difficult and undesirable to provide detailed specifications for the equipment to be used in testing equipment. There is a clear trend towards computer-controlled data recorders with software, which enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated or graphed data. Although these new systems may offer advantages in clarity of presentation, as well as reduced operator time, the traditional instruments, such as chart recorders, remain equally acceptable where they meet the accuracy defined in this section.

### Note

Retention of data for long-term use is important. Where modern technology/data-recording equipment is used, it should be equipped with memory devices that enable data to be retrieved at a later date. Traditional chart recorders allow the retention of the chart for long-term storage and follow-up.

**2.3** The objectives of this section 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.

**2.4** When it is proposed to use measurement and/or recording techniques that are not covered in this guidance, the advice of the Authorising Engineer (Decontamination) should be sought.

**2.5** All test equipment should be calibrated by a UKAS-accredited laboratory in accordance with ISO/IEC 17025, with traceability to the National Standard.

### Calibration and sources of error

**2.6** Errors of measurement occur for a number of reasons. These include inherent factors such as the design of the measuring equipment, common problems with sensors (such as loose or imperfect connections), damaged insulation,

and broken conductors, combined with changes in the environmental temperature around the instrument. Variations in the sensors themselves, the method of introducing the sensors into the machine and their location within the load may add to the error in the temperature measurement. Changes in conditions other than the one being sensed may also lead to errors, for example temperature fluctuations within pressure-sensing elements may lead to errors in pressure measurement.

**2.7** 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 minimise these errors. Systematic errors can be reduced by careful calibration.

**2.8** Instruments should be subject to a planned maintenance and calibration programme, in accordance with the instrument manufacturer's recommendations, occurring at least annually. Each instrument should be labelled with a calibration date and a reference from which its current calibration status may be traced.

**2.9** Instrument calibration should be carried out in accordance with the instrument manufacturer's instructions by a validated method, using a reference standard of suitable accuracy that has been certified within the previous 12 months by a UKAS test laboratory. The calibration laboratory should be instructed to adjust the instrument under test to read true values, and to report before and after calibration results so that instrument drift can be monitored. A full history record, including all maintenance and calibration details, should be kept for each instrument.

**2.10** The instrument should have a valid test certificate and the calibration data should include a temperature within the process temperature band.

**2.11** In use, 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 stabilise within the environment of the test site. The manufacturer's instructions should be followed.

## Data recorders

**2.12** Test recorders are required to measure temperature in all types of decontamination equipment and may also be required for the measurement of pressure, flow rates, and other critical parameters. They should be designed for use with the appropriate sensors, independent of those fitted to the machine.

**2.13** Sufficient connections to meet the testing requirements of the relevant HTM and EN standard should be provided.

**2.14** Recorders should comply with the requirements of BS EN 285 or BS EN ISO 15883.

**2.15** Data from digital recorders (dataloggers) can 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.

**2.16** Digital recorders should have the facility to record data immediately that can then be removed for secure storage. Alternatively, the recorder may be connected to a central computer and the data recorded to the hard drive. Software used with digital recorders should be developed and validated under a recognised quality system (see BS EN ISO 13485).

**2.17** The detailed specification for a test recorder will depend upon the range of equipment with which it is to be used. The measurement system (recorder and sensors) should be capable of measuring cycle variables to the required accuracy of the instruments fitted to the machine.

**2.18** The accuracy with which a variable can be read from the recorder will be affected not only by the sources of error discussed above but also by the precision of the calibration, the scale range, the integration time, the sampling interval and the intrinsic accuracy of the recorder. Digital instruments might display measured values with a greater level of discrimination than the accuracy of the system as a whole: care needs to be taken with the configuration of outputs and the interpretation of the measured values.

**2.19** 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. The system should be calibrated as a whole also.

**2.20** The scale ranges should include the expected maximum and minimum values of the cycle variables throughout the operating cycle, with sufficient leeway to accommodate any deviations resulting from a malfunctioning machine.

**2.21** At all stages of the cycle, the values of the variables are critical and the recorder should be capable of measuring them to sufficient accuracy to confirm that the process 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 180 independent measurements in each recording channel. This corresponds to a sampling interval of one second for the shortest holding time (three minutes, high-temperature steam sterilizers) for periodic testing. 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 1%.
- b. The integration time of the recorder (the response time) 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 should be accurate enough to show clearly whether the measured temperatures are within the band or not. For all the types of equipment covered by this guidance, the repeatability of the recorder should be  $\pm 0.25^{\circ}\text{C}$  or better, and the limit of error of the complete measurement system (including sensors) should be no more than  $0.5^{\circ}\text{C}$ .
- d. For pressure measurement, the limit of error should be no more than 0.5% of the absolute pressure during the plateau period.
- e. Attention should also be paid to the accuracy of the time base of the recording system, particularly on longer cycles where any error will become more obvious. This can be by means of a calibrated stopwatch against a calibrated time signal (for example the BT speaking clock).

**2.22** The scale range for each variable to be measured should be optimised to cover all values occurring during the process. As well as having calibration certificates for each item of the measuring chain, the complete system should be calibrated in the working environment (for example the sterile services department).

## Temperature measurement

### Temperature sensors

**2.23** Temperature sensors should be used to sense the temperature in locations specified in the tests described in this guidance. The sensors should be either platinum resistance elements and comply with class A of BS EN 60751 or thermocouples and comply with Tolerance Class 1 of BS EN 60584-2 and have a response time in water of  $t_{90} \leq 0.5$  seconds.



Other sensors of demonstrated equivalence can be used.

**2.24** Thermocouple wire should be single-strand, not exceeding 0.7 mm diameter over the covering of one core of a twin cable. The width of the cable should not exceed 2 mm. If bulkier cable is used, the tracking of steam along the outside of the cable may invalidate certain tests, such as those which require temperatures to be measured in the centre of a standard test pack (the standard test pack is described in BS EN 285).

**2.25** Thermocouples may be argon arc-welded or micro-welded. However, experience has shown that, provided the wires are cleaned, they may be satisfactorily twisted together to form the hot junction. Brazing, silver brazing and welding with filler rods may be no more reliable in respect of accuracy than freshly twisted wires. Thermocouples should not be fitted with a heat sink.

**2.26** The performance characteristics of the temperature sensor should not be adversely affected by the environment in which it is placed, for example pressure, hot detergent solution etc. Certain environments in which thermocouples may be used may be corrosive to certain metals. Thermocouple junctions should be regularly inspected for corrosion and remade and recalibrated as necessary.

### Thermometric recording instrument(s)

**2.27** 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 guidance.

**2.28** Guidance on test apparatus designed to introduce thermometric measuring equipment into the sterilizer chamber and washer-disinfector chamber is provided in BS EN 285 and BS EN 15883 Parts 1 and 2 respectively. Other methods of introducing temperature sensors into a chamber, which guarantee a

watertight or gas-tight seal, are equally acceptable.

**2.29** All reporting software should be validated, backed-up (with backed-up data being kept in a secure location off-site) and secure to ensure no unauthorised access.

### Use of sensors

**2.30** Guidance on use of sensors for sterilizers and WDs is provided in BS EN 285 and BS EN 15883 Parts 1 and 2.

### Instrument verification

**2.31** Before and after each series of tests on any item of decontamination equipment, the measured temperature recording system should be verified by comparison with an independent reference temperature source at the process temperatures.

**2.32** The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within  $\pm 0.1$  K and within the process temperature band should not differ by more than 0.5 K. The reference instrument(s) used on site as the recording system should be calibrated and/or adjusted in a controlled environment or laboratory with relevant UKAS traceable certification and laboratory references. Before and after each series of tests on any item or items of decontamination equipment the measured temperature-recording system should be verified by comparison with an independent reference temperature source at the required process temperatures. The comparison instrument used, such as a digital thermometer, should be traceable to UKAS calibration standards. No adjustment to the test instrumentation should be made on site in an uncontrolled environment unless the test contractor or organisation holds a UKAS site calibration procedure and certification that includes adjustment which should be available for inspection or audit. Any adjustments made to test instrumentation should be logged and included within the test report.



## Self-contained systems

**2.33** Where it is impractical to insert sensor leads into processing equipment, self-contained datalogging devices may be used.

**2.34** 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 computer on completion of the datalogging period.

**2.35** Care needs to be taken in selecting units that are capable of withstanding the high temperatures found in sterilizers and washer-disinfectors.

**2.36** The accuracy, resolution and sampling rate requirements should be identical to those specified for conventional recorders (see [Chapter 4, 'Validation and verification'](#)).

**2.37** Where two or more dataloggers are used together on the same process, the time bases of the instruments should be synchronised.

## Pressure measurement

### Measurement ranges

**2.38** Pressure measurement ranges for WDs should be up to 1000 kPa (10 barA) (for example for the water supply pressure). Differential pressures of 0.1 to 10 kPa (– 100 mbar) may need to be measured (for example for the determination of the pressure drop across filters).

**2.39** Pressure measurement ranges for steam sterilizers may be from 3 to 10 kPa (in vacuum leak testing) to typically 400 kPa at the working pressure of a high-temperature steam sterilizer.

### Sensors and gauges

**2.40** Pressure sensors should be used in the tests described in this guidance and should conform to BS 6447. The natural frequency of

the sensor and connected tubing should be not less than 10 Hz and the time constant for rising pressure (0 to 63%) should be not greater than 0.04 seconds.

**2.41** The performance characteristics of the pressure sensor should not be adversely affected by the environment in which it is placed (for example temperature, hot detergent solution etc). Certain environments in which sensors may be used may be corrosive to certain materials. Compatibility should be confirmed with manufacturers' instructions.

**2.42** The requirements for gauges required for testing decontamination equipment are shown in Table 1.

**2.43** Pressure gauges should be temperature-compensated and, except for the differential pressure gauge, be Bourdon-tube gauges conforming to BS EN 837-1 of nominal size 150 mm and accuracy class 0.25 (that is, the error should not exceed 0.25% of full scale deflection).

**Table 1** Requirements for pressure measurement

Scale range	Mark interval	Calibration	Application
0 to 16 kPa	0.1 kPa	Gas	Vacuum leak-testing
0 to 100 kPa	1 kPa	Liquid	Differential pressure across water filters
0 to 500 kPa	5 kPa	Liquid	Steam sterilizers
0 to 1000 kPa	5 kPa	Liquid	Water supply pressure. Recirculating pump pressure
0 to 50 kPa	1 kPa	Air	Differential pressure across air filter

**2.44** Gauges not designed for direct connection to steam at 380 kPa (2.8 bar) should be connected via a siphon or similar device to ensure that the accuracy of the gauge is maintained over the temperature range associated with changing steam pressure. If the low-pressure gauge used for vacuum leak testing cannot withstand the pressure in the chamber during sterilization, an automatic valve should be provided to protect it.

## Flow measurement

### Water

**2.45** The volume of water used for each stage of the operating cycle may be measured using a water meter complying with ISO 4064-1 Class A.

**2.46** The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 1700 kPa (16 bar).

**2.47** The meter should have a minimum scale division of 0.1 L or less and be designed to measure flow rates over the range 1 L/min to 25 L/min.

**2.48** 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 ISO 4064-1 Class B or Class C may also be used.

**2.49** The calibration of the flow meter should be verified by comparing the indicated flow rate with a measured volume collected over a measured time period. The collected volume of liquid may be determined by either gravimetric or volumetric measurement. The gravimetric method is generally more accurate as the temperature of the liquid increases.

### Chemical additives

**2.50** The volume of chemical additive used for each stage of the operating cycle may be measured using a flow meter. A number of commercially available flow sensors designed to monitor flows in the range 0 to 2 L/min are suitable for interfacing to a recorder or datalogger.

**2.51** The sensor should be suitable for use with fluids having viscosity in the range 0.8 to 20 centiStokes and should be calibrated for the viscosity of the fluid to be measured.

**2.52** The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 1100 kPa (10 bar).

**2.53** The meter/recorder should have a minimum scale division of 10 mL or less and be designed to measure flow rates over the range 50 mL/min to 1500 mL/min.

**2.54** The system should have an accuracy of  $\pm 2.5\%$  of full scale or better.

**2.55** The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing this with the collected volume determined by gravimetric or volumetric measurement.

### Note 1

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 washer-disinfector and therefore should not be used during tests for other characteristics than the volume of water used.

### Note 2

A meter of the rotating vane type calibrated using water at 20°C as the flowing medium and then subsequently used to measure the flow of a detergent solution with a viscosity of 30 centiStokes would have an error of 15–20% if no correction was applied.

## Volume measurement

**2.56** The volume of chemical additives and the volume of water used in each stage are critical variables in the control of the washing-disinfecting process.

**2.57** The volume used may be measured directly by collection in a graduated vessel of appropriate size.

**2.58** Alternatively, for liquids of known density, the volume may be determined by collection in an appropriate size vessel of known mass (empty), determination of the mass of the vessel

and contents, calculation of the mass of the liquid and hence (by dividing this volume by the density) calculating the volume of liquid.

**2.59** Whichever method is used, the accuracy should be such that the error is less than  $\pm 2\%$ .

**2.60** Volumetric measuring containers complying with BS 5898, ISO 384 are suitable.

## Other instruments

### Sound level meter

**2.61** An integrating sound level meter is required for the sound pressure test. It should comply with Type 2 of BS EN 61672-1 and BS EN 61672-2. Ten microphones are required for the test on a single piece of equipment.

### Airflow metering device

**2.62** A metering device (such as a needle valve) is required to admit air into the sterilizer chamber for the air detector tests, and vacuum and pressure leak tests. The device should be capable of controlling the flow of air into an evacuated chamber. It should be adjustable and have a range that includes a flow of 0–5 mL/ min per litre volume of the sterilizer chamber. The error in repeatability between 10% and 90% of the setting range should not exceed  $-5\%$ . The device is connected to the chamber by a valved port provided by the sterilizer manufacturer.

### Balance

**2.63** A laboratory balance is required for steam dryness tests, load dryness tests, calibration of flow meters (for measuring the flow of water and/or chemical additives) and coolant quality tests. It should be capable of measuring the mass of loads up to 4 kg to an accuracy of 0.1 g and up to 400 g to an accuracy of 0.01 g.

**2.64** An analytical balance is required for determination of the TDS (evaporative residue) in feed water. It should be capable of measuring a mass of up to 100 g with an accuracy of 0.1 mg.

**2.65** A balance is also required for weighing the standard textile test pack (7 kg) and the metal load (15–20 kg) to a 10 g resolution.

### Gas-monitoring equipment

**2.66** A gas-monitoring instrument is required for tests on equipment using chemical additives that have a significant vapour pressure and are a potential risk.

**2.67** 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 AE(D).

**2.68** 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

**2.69** An aerosol generator is required for tests on machines incorporating air filters intended to deliver air free from microorganisms.

**2.70** The device should be capable of generating a polydisperse aerosol with particles having the size distribution shown in Table 2 below.

### Particle-counting photometer

**2.71** A particle counter is required for tests on machines incorporating air filters intended to deliver air free from microorganisms. The device should be suitable for estimation or comparison of the mass concentration of airborne particles as defined in Table 2.

Table 2 Particle size distribution for aerosol generator

Particle size [ $\mu\text{m}$ ]	Fraction % by mass
<0.5	>20
<0.7	>50
<1.0	>75

Source : BS EN ISO 14644-1

**2.72** It should have an accuracy of better than  $\pm 5\%$  over the range of a five expandable, six-decade resolution (that is 0.01% to 100% of the test cloud) as specified in BS EN ISO 14644-1.

**2.73** The photometer should have a minimum threshold sensitivity of  $0.0001 \mu\text{g/L}$  and should

be capable of measuring aerosol concentration in the range 80 to  $120 \mu\text{g/L}$ .

**2.74** The sampling flow rate should be  $0.40 \pm 0.05 \text{ L/s}$  and sampling should be via a suitable probe.

## 3 Design and pre-purchase considerations

**3.1** This chapter of the guidance provides advice on the specification, purchase and installation equipment used for the decontamination of surgical instruments in hospitals, laboratories and other healthcare facilities.

### Pre-purchase considerations

#### Introduction

**3.2** It is essential that the purchase of an item of decontamination equipment is planned correctly. This section aims to help the purchaser with a step-by-step discussion of the issues to be included. As this section is designed to be universally applicable, it might be necessary to vary the procedure according to local circumstance or requirements.

#### Specialist advice

**3.3** The efficient completion of procurement documentation will require advice and help from a decontamination specialist, for example an AE(D).

**3.4** This assistance should be sought in the following areas:

- determining initial User requirements;
- choosing and completing the relevant “Particular specification” (see appendices in HTM 01-01 Parts C and D);
- determining throughput parameters;
- advising on relevant performance qualification (PQ);

- post-tender analysis;
- advising manufacturer/contractor on validation protocols;
- monitoring validation performance;
- auditing validation report;
- advising on specification qualification, installation qualification (IQ), operational qualification (OQ) and PQ.

#### Quality systems

**3.5** Adherence to engineering standards and quality systems ensures that decontamination equipment is manufactured, installed, validated and subject to the necessary periodic testing to establish the initial and then on-going satisfactory performance of the machine to ensure optimum decontamination of surgical instruments and safety of both operators and patients.

#### Product listing

**3.6** The purchaser should list all load items proposed and projected to be re-processed by the decontamination equipment. This should include the following for each item:

- number;
- size;
- materials of construction;
- temperature sensitivity;
- moisture sensitivity;
- pressure-variation sensitivity;

- requirements for disassembly;
- manufacturer's decontamination instructions;
- usage time constraints (to determine requirements for extra instrumentation only).

### Spatial requirements

**3.7** A full assessment of current space available should be made. It can be that additional machine numbers will require additional space. The possibilities should be considered and checked once a throughput calculation has been made. The machine configuration (number of doors etc) can affect the spatial requirements.

### Machine configuration

**3.8** Advice on throughput calculations, equipment number determination, SSD design and floor suitable areas is given in Health Building Note 13 – 'Sterile services department'.

### Protein removal and protein optimisation

**3.9** All decontamination equipment should have the ability to have cycle parameters varied (for example for washer-disinfectors – time, temperature, number of stages of main wash, use of different detergents etc) to enable equipment to have cycles optimised as more data becomes available on more effective cycles and chemicals for protein removal (see Chapter 4, 'Validation and verification').

### Specification preparation

**3.10** The use of the 'Particular specifications' (see HTM 01-01 Parts C and D) will enable data provided by the tenderer on technical points as well as financial data to be compared. Not only will this enable the purchaser to confirm the acceptability of current services, spatial requirements and portage, but also it will enable a like-for-like tender analysis to be made. Tender analysis will be best achieved by formalising tender comparison with respect to performance and cost in all key areas.

Qualifying statements by the tenderer should be taken into account. Their effect on tender content or eligibility should be assessed before making a choice.

**3.11** The specifications allow the purchaser to define post-validation service or contract work requirements. A choice on the relevance of these issues will need to be made prior to distribution of the procurement documentation.

## Procurement of equipment – an overview

### Introduction

**3.12** This section gives a short overview of the process of purchasing decontamination equipment. It refers to more detailed information in subsequent sections, including information specific to each type of decontamination equipment given in subsequent sections.

### Purchasing decontamination equipment

**3.13** The purchase of decontamination equipment can be broken down into the following sequence of steps.

*What type of load will be processed?*

**3.14** A knowledge of the load(s) to be processed is a prerequisite to make the correct decision about which piece of equipment to purchase; the difficulty in obtaining a clean product, the standard of cleanliness and the disinfection required vary for different product types. For example, some products with intricate interstices or long narrow lumens require specific provision if they are to be cleaned satisfactorily.

**3.15** Purchasers should specify all items that may present a challenge to decontamination in order to allow the tenderer to offer the most appropriate machine and accessories.

**3.16** Manufacturers' reprocessing instructions should be taken account of. Where instructions



are particularly onerous, these should be included as an annex in the tender document.

*What type of machine is required?*

**3.17** In this guidance, washer-disinfectors are classified by:

- the product range which they are intended to process;
- their configuration and load handling type;
- the nature of the cleaning and disinfection process.

**3.18** Sterilizers are classified as either clinical or laboratory sterilizers. Clinical sterilizers can use one of a number of different sterilizing agents (sterilants): purchasers should give due consideration to the compatibility of the items to be processed with the process itself.

*Where will the machine be sited?*

**3.19** The location available for the equipment will have a significant influence on the type of machine that can be used. Many of the larger continuous process machines require considerable space. Some machines will require considerable building work.

*What services are available?*

**3.20** Decontamination equipment will require several of the following services: steam, electricity, water, compressed air, drainage, effluent handling, ventilation and bulk or integral storage/supply of chemical additives/sterilant gas supply. The manufacturers' data will show which services are required for each model. Determine which of these are available at the proposed site and the capacities of each service. It might be necessary to plan for a new service, which would add greatly to the cost of the installation.

*Who will operate the equipment?*

**3.21** Equipment located in a centralised processing unit under the care of specially

trained staff – whose sole or principal activity will be the operation of the machine – may be complex. Operators should thus be designated. Further requirements may be found in BS EN ISO 13485.

*What capacity is required?*

**3.22** The likely daily and weekly workload, and the peak hourly workload, that the equipment will have to process should be established, then the number of machines required to process the workload should be calculated. Throughput figures for different manufacturers' machines and different models within any given range vary considerably. For continuous process machines a distinction should be made between the time required to process one load and the total number of loads that can be processed in a period of one hour. Further guidance is given in Health Building Note 13. Consideration should be given to the time and spatial aspects of post-process conditioning.

*What ancillary equipment will be needed?*

**3.23** A sterilizer installation might require ancillary equipment such as special ventilation water treatment for steam generators, air compressors, preconditioning facilities, degassing facilities and gas disposal plants.

**3.24** A washer-disinfector might require ancillary equipment such as water softeners, deionization or reverse osmosis (RO) water treatment plants, steam generators, air compressors, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals.

**3.25** In addition some machines will require load staging facilities, before and after processing, purpose-built load carriers for different categories of product, and means for returning load carriers from the unloading side of the machine back to the loading side.

*What standards or specifications are relevant?*

**3.26** Most items of decontamination equipment will be constructed to either a BS, EN or ISO

Standard. In some cases additional specifications will be required.

*What sort of contract?*

**3.27** Once the specification has been completed, a contract should be drawn up for the supply and installation of the machine.

*Which manufacturer?*

**3.28** Three or more manufacturers should be invited to tender for supplying the decontamination equipment. While no manufacturer should be excluded unnecessarily from the tendering process, they should not be invited to tender unless there is a realistic prospect of their being awarded the contract.

*What installation and commissioning arrangements?*

**3.29** After delivery and installation, the decontamination equipment should be subjected to a formal documented programme of validation.

*What arrangements for service and repair?*

**3.30** It is common practice for the initial purchase contract to include all service and repair costs for the first year after installation, that is, during the warranty period. A number of manufacturers also offer an extended warranty facility that, sometimes for an additional fee, provides an all-inclusive service and repair option.

*What are the likely running costs?*

**3.31** Advice should be sought at the time of tender on the operational costs of the various machines that would be suitable. The operational costs should include the anticipated requirements for services (water, electricity, steam etc), consumable items (detergents, rinse aids etc) and maintenance. This data should be used in the evaluation of the tender bids.

## Choice of equipment

### Introduction

**3.32** This section contains information relevant to the choice of new decontamination equipment. It discusses the types of machine and the loads for which they are suitable, and gives guidance on selecting the size and number of machines required for a given application.

### Choice of equipment

**3.33** The choice of machine should be governed by the nature of the loads to be reprocessed. Detailed guidance on appropriate processes for different load items can be obtained from the manufacturers of the medical devices.

### Sizes and numbers

**3.34** Precise information on the sizes and numbers of machines required for particular applications is difficult to give since there are considerable variations in patterns of use. The number of machines required will depend on the cycle time and the loading capacity of the machine and in some circumstances on the flexibility of operation that might be required, for example whether items to be processed can wait until there is a full load for the decontamination equipment or need to be processed immediately.

**3.35** Consideration should be given to contingency plans for machine usage, and sufficient time should be included for testing, maintenance and service. Thus reliance on a single item of equipment is not advisable.

## Specification and contract

**3.36** This section discusses general specifications for decontamination equipment and the steps to be taken to invite tenders and issue a contract. Specific advice for sterilizers can be found in HTM 01-01 Part C and for washer-disinfectors in HTM 01-01 Part D.



## Preparing a specification

**3.37** Purchasers should seek assistance from the AE(D) when preparing a specification for decontamination equipment.

**3.38** Standards and other specification documents are continually being updated, and purchasers should ensure that they consult the latest editions of such documents, including any amendments issued after publication, to keep abreast of changing requirements. Advice should be sought from the AE(D).

## General design considerations

**3.39** The following design considerations are applicable to all or most types of decontamination equipment, but are not necessarily required by the current Standards. Where applicable they should be included in the specification for any decontamination equipment to be operated in the healthcare sector.

**3.40** All decontamination equipment and associated equipment is classed as work equipment and should comply with the Provision and Use of Work Equipment Regulations 1998 (amended 2002 by the Health and Safety (Miscellaneous Amendments) Regulations). Purchasers are reminded that under the Regulations it is the responsibility of the employer, not the manufacturer, to provide decontamination equipment that is “suitable for the purpose for which it is used or provided”. Further information is available in HTM 01-01 Part A.

**3.41** All decontamination equipment made or sold in the UK from 1 January 1996 must conform to the emission and immunity requirements of the current Electromagnetic Compatibility Regulations 2005. This may be achieved by compliance with BS EN 61000-6-3 (emission) and BS EN 61000-6-1 (immunity). The manufacturer should be informed of any local sources of electromagnetic disturbance that could affect the operation of the machine.

**3.42** For maintenance purposes, one or more panels of free-standing WDs, and side, back and top panels on sterilizers, should be easily removable and replaceable. Pressure regimes should not be affected by this.

## Safety features

**3.43** Safety features should be designed in accordance with the British Standard code of practice for safety of machinery, PD 5304, and the European Standards for the safety of electrical equipment, BS EN 61010-1 and BS EN 61010-2-040.

**3.44** The design of the control system should ensure that the door cannot be opened until the cycle is complete. When a fault is indicated the door should only be able to be opened by a key code or tool, when the equipment is returned to a safe condition.

**3.45** Steam sterilizers should conform to the requirements listed under “Safeguards” and “Interlocking” in HSE Guidance Note PM73 “Safety at autoclaves”.

**3.46** The manufacturer should provide a list of all safety devices together with their settings and methods of adjustment.

**3.47** All safety devices should be designed to fail in a manner that does not cause a safety hazard to personnel.

**3.48** Any error in the control or indication system should not cause a safety hazard.

## Instrumentation

**3.49** Where an instrument can be adjusted the adjustment should require the use of a key code or tool that is not available to the Operator.

**3.50** Where a fault is indicated as an error message shown on a visual display unit, it should be clearly distinguishable from normal messages, for example by use of a different colour or larger size of text. The indication

should remain displayed until acknowledged by the Operator.

**3.51** Where required within the specification, the Contractor should be required to carry out adjustments to the instruments on site so that the accuracies specified at the sterilization temperature can be met with the plant running and under the conditions normally prevailing on site.

**3.52** There should be an indicator that shows which stage of the operating cycle is in progress and indicates “cycle complete” at the end of the cycle. For continuous process WDs, separate indication of the operational status should be provided for each chamber or section.

**3.53** A counter with a minimum of five digits should be provided to indicate the cumulative total of cycles started. The counter should be tamper-evident or sealed. For continuous process WDs the counter should indicate the number of loads that have entered the machine.

**3.54** For pressure or flow testing, test tees and valve cocks with sealing plugs should be fitted to permit connection of test instruments for the verification and calibration of all instruments permanently fitted to the machine. The connection should be as described in BS EN 285.

### Programmable electronic systems

**3.55** Modern decontamination equipment frequently uses programmable electronic systems (PES) for control and data recording. Where such systems are used, they should be designed in accordance with the principles set out in the HSE document ‘Programmable electronic systems in safety related applications’.

**3.56** Where a PES is used for control or monitoring of the process, the values of cycle variables critical to process performance and determined during validation should be documented in the validation report regardless of whether or not they are held in the PES

memory. The version number of the software should be available for display when required.

**3.57** Combined control and instrumentation systems that are wholly operated by means of PES should incorporate at least two timing systems, independent of each other, such that the timer used to control the holding time is verified by the other timer.

### Doors

**3.58** The choice of design for any particular installation will depend on the workload, space restrictions, price and ease of maintenance. With hinged doors there is a risk of the Operator touching the hot inside face as the door is opened. If hinged doors are required, the specification should state whether they are to be hinged on the left-hand or right-hand side or top or bottom of the opening. Where sliding doors are incorporated, the direction of opening should be specified. The method of door opening will impact on load handling equipment design, the method of loading and unloading, the height of the chamber above floor level, and manual handling issues.

**3.59** It should be possible to clean the contact surfaces of the door seal without removing parts of the machine.

### Invitation to tender

**3.60** Once detailed specifications have been drawn up, manufacturers should be invited to tender for the supply and, if required, the installation of the decontamination equipment.

**3.61** Prospective contractors should be given the following information:

- a. that each machine will be subject to a validation process as described in the validation and verification section (see [Chapter 4, ‘Validation and verification’](#));
- b. that unless otherwise specified, the installation checks and tests specified in the validation process should be satisfactorily completed before the machine can be accepted;

- c. whether the factory/works tests, site visits or installation checks and tests are to be witnessed by the appropriately-qualified purchaser's representative (normally the AE(D), AP(D) or CP(D));
- d. the date by which all services will be available;
- e. the date by which the validation process is expected to be completed.

## Contract

NHS Supply Chain has in place a national framework agreement that covers sterilizers and washer-disinfectors, water treatment systems, training, maintenance and validation. The framework enables procurement of these products and services tailored to specific reprocessing needs, without the need to instigate an OJEU tender (see link in the References section).

**3.62** Consideration may also be given to the use of alternative forms of contract, for example MF/1 (available from the Institution of Electrical Engineers, the Institution of Mechanical Engineers or the Association of Consulting Engineers) or the Joint Contracts Tribunal (JCT) suite of documents (available from RIBA Publications).

**3.63** Purchasers using other forms of contract are strongly advised to seek legal advice. Purchasers should not purchase equipment or services under the supplier's terms and conditions of contract.

**3.64** Where currently not in place, other contracts, notably for the AE(D), the CP(D), the CP(PS) and the Microbiologist, may need to be considered at this time. In awarding these contracts, purchasers should ensure that there is no conflict of interest that would compromise the validation process.

## Delivery

**3.65** On or before delivery of the machine, the manufacturer should provide the purchaser with the information specified in Table 3.

**3.66** Decontamination equipment for a particular scheme should not be ordered and stored on site for long periods prior to installation and validation. Disregard of this recommendation can invalidate the manufacturer's warranty and cause deterioration of the machine prior to installation. Where a long delay is unavoidable, conditions for storage should be agreed with the manufacturer.

## Siting

**3.67** A comprehensive review of the requirements for SSDs is given in Health Building Note 13 and for operating departments in Health Building Note 26 – 'Facilities for surgical procedures'.

**3.68** The area in which decontamination equipment is installed should meet the requirements of the Workplace (Health, Safety and Welfare) Regulations 1992 amended 2002, which have far-reaching implications for the design of decontamination equipment accommodation and services to be installed.

**3.69** Fire safety precautions should comply with the current "Approved Document B" of the Building Regulations and the "Firecode" series.

## Engineering services

### Introduction

**3.70** Decontamination equipment installation will require one or more external services including steam, electricity, hot and cold water, compressed air, ballast air, drainage, ventilation and purified water. The manufacturer should make clear at an early stage which services will be needed and the detailed requirements for each, as outlined in Table 3.

**Table 3 Information on services to be obtained from the manufacturer for sterilizers and washer-disinfectors**

Steam	a) acceptable range of supply pressures
	b) maximum flow and usage rates
	c) usage per operating cycle
	d) when steam is generated within the machine, the acceptable limits for hardness, pH and conductivity of feed water.
Electricity	a) type of supply e.g. AC or DC
	b) number of phases (normally one or three) and whether neutral is required for a three-phase supply
	c) supply voltage and frequency including nominal and acceptable minimum and maximum values
	d) maximum continuous power demand in kW or kVA
Compressed air	a) acceptable range of supply pressures
	b) the flow required at minimum pressure
	c) the volume of air used for each cycle
	d) the quality or quantity of air required including dew point, maximum size and concentration of particulate material, oil content and microbial contamination level as relevant
Water	For each grade of water required:
	a) the acceptable range of supply pressures
	b) the flow at minimum pressure
	c) the volume used per cycle
	d) the acceptable temperature range for incoming water
	e) the quality of water required when relevant: <ul style="list-style-type: none"> <li>• the maximum permissible hardness expressed as mg/CaCO<sub>3</sub>;</li> <li>• the acceptable range of pH;</li> <li>• the maximum permissible conductivity;</li> <li>• the limiting concentration of heavy metals, halides, phosphates, silicates and nitrates;</li> <li>• the maximum acceptable microbial population.</li> </ul>
Drainage	a) the maximum flow of effluent to the drain
	b) the maximum temperature of the effluent on leaving the machine
	c) the maximum effective diameter of the discharge orifice from the machine's chamber
	d) requirement for sealed drainage system if hazardous fumes or gases are produced from chemicals used in the process
Ventilation	a) the peak value during a cycle and the average value throughout a cycle of the heat in watts transmitted to the environment when the decontamination equipment is operated in still air at an ambient temperature of 23°C ± 2°C
	b) the heat in watts transmitted by a full load being unloaded from the machine into still air at an ambient temperature of 23°C ± 2°C
	c) the maximum flow of air extracted from the environment of the decontamination equipment as exhaust ventilation
	d) ventilation requirements for removal of fumes or gases from hazardous chemicals used in the process
Process chemicals	Details of all process chemicals required (e.g. detergents, rinse aids, sequestering agents, descalers, microbicides, process gases) for the operation of the decontamination equipment, including any requirement for regeneration of integral water treatment system, the quantity required per cycle, the nature and size of containers in which they are supplied, the necessary storage conditions and instructions for safe handling.

**3.71** The specification should make it clear where services are to be connected. Care should be taken when contracts are awarded

that precautions regarding termination and availability of all engineering services are taken.

## Electricity

**3.72** The electrical power requirements will depend on a number of factors, such as the type of machine and the method used to heat water and hot air dryers, and generate steam. Local or integral electrical steam generators will result in a high electrical load. Some machines will require a three-phase supply. The manufacturer should provide details of the type of supply (AC or DC), number of phases, frequency, and voltages with tolerances and loading.

**3.73** Each machine should be connected via an isolator. The type of isolator will depend on the nature of the supply. Where a three-phase-and-neutral supply is necessary, or where a maximum single-phase current demand is more than 13 A, the machine should be wired directly to the isolator. The switch should isolate all poles simultaneously and each pole should be fused separately. The cable from isolator to decontamination equipment should be fixed and protected from the effects of heat, water and, if applicable, steam.

**3.74** Within the loading area an additional switch should be provided so that the Operator can electrically isolate the machine or group of machines in the event of an emergency. The switch should be placed between the normal operating position and the exit door.

**3.75** Sterilizers used to process heat-sensitive loads should be connected to the essential supplies circuit, if available, to avoid heat damage in the event of a power failure. It is not normally necessary for washer-disinfectors to be connected to the essential supplies circuit. Exceptions might include the decision to ensure that one washer-disinfector within the SSD remains on the essential supplies circuit.

**3.76** All electrical installations should conform to the Institution of Engineering and Technology (IET) Regulations contained in BS 7671. Further guidance is given in Health Technical Memorandum 06-01 – ‘Electrical services supply and distribution’.

## Compressed air

**3.77** A compressed-air supply may be required in some types of decontamination equipment. Where the machine does not contain an integral air compressor, the air may be supplied from a piped service (mains supply) or from a local compressor.

### *Compressed air: mains supply*

**3.78** If air is supplied by pipeline from a central air-compressor system, a pressure gauge of the Bourdon type complying with BS EN 837 should be fitted inside the plantroom and terminated with an isolation valve.

**3.79** A reducing valve or other automatic device should be fitted to reduce the pressure of air delivered to the machine to no more than the maximum supply pressure specified by the manufacturer. A pressure relief valve will normally be required.

### *Compressed air: local compressors*

**3.80** Where it is not practicable to obtain compressed air from a mains supply, a dedicated compressed-air facility should be installed to supply machines.

**3.81** At least two compressors should be provided, with auto-change between the two. The system should be sized to meet all the compressed air requirements of the unit.

**3.82** The compressors are likely to be too noisy to be installed with the machine, and it is better to place them in a dedicated location away from any noise-sensitive areas.

**3.83** Components of the compressed air system that require servicing and maintenance, such as dryers and filters, should be located where they are readily accessible for service or exchange.

### *Air quality*

**3.84** The quality of air can be critical for some applications, and some machines will



incorporate appropriate filters. When the purchaser is to be responsible for the provision of filtered air the CP(D) should ensure that the quality of air available meets the manufacturer's specification or the requirements given below.

- a. air for controls should be free of liquid water, filtered to 25 µm (5 µm for precision controls) and lubricated with micro-fog oil particles of 2 µm or less;
- b. air that could come into direct contact with the load, such as air for pressure ballasting or drying the load, should be filtered to remove contaminating oil-mist and microorganisms.  
It should have not more than 0.5 mg of oil per cubic metre of free air (measured at 1013 mbar and 20°C; see ISO 554), be filtered to an efficiency of at least 95% when tested in accordance with BS 3928, and be free of bacteria.

## Drainage

**3.85** Condensate from the jacket, heat exchangers and steam traps is suitable for recovery and should be returned to the steam generating plant where there are means for recovery.

**3.86** All other effluent from decontamination equipment is potentially contaminated and should be disposed of to the main drain. Effluent can originate from one or more of the following sources:

- a. air, condensate and steam from the chamber drain, which might contain chemicals and microorganisms, especially those from a make-safe process;
- b. discharge from a water-sealed vacuum pump, ejector or chamber vent, which might also contain microorganisms;
- c. water from a chamber cooling system;
- d. water introduced to cool and dilute the discharge from the chamber;

- e. effluent discharge to sewer/foul drainage.

## Ventilation

**3.87** Ventilation of the area near the machines should be ensured, to remove excessive heat and odours, and sterilant gases or vapours from disinfectants.

**3.88** General room ventilation will be sufficient for most machines; local exhaust ventilation will be required for chemical disinfection systems.

**3.89** Electrical systems used in ventilation systems should take account of the high levels of humidity that might be discharged and the potential for this to condense within the ventilation system, as well as the explosion risk associated with ethylene oxide, and should comply with the requirements of BS EN 61010-2-042.

**3.90** Owing to the air leakage from clean to dirty across pass-through machines (based on the design pressure differential across these rooms of, for example, 15 Pa), information on the impact of these machines on ventilation system design should be sought from manufacturers.

**3.91** All ventilation systems should meet the ventilation requirements of the Workplace (Health, Safety and Welfare) Regulations 1992.

**3.92** Further guidance on ventilation systems can be found in Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises'.

## Information to be supplied by the manufacturer

**3.93** For each purchase of decontamination equipment, the tenderer is bound to supply detailed information on items including construction, delivery, service requirements, heat emissions and contract performance (see the 'Particular specifications' for sterilizers and washer-disinfectors in HTM 01-01 Parts C and D).

## 4 Validation and verification

### General

**4.1** This chapter of the guidance covers the validation and periodic testing of the various types of decontamination equipment used in hospitals, laboratories and other healthcare facilities.

### Permit-to-work

**4.2** The use of permit-to-work system should be used for all maintenance and testing procedures on decontamination equipment. This should ensure the formal removal of equipment from, and return to, service and will provide certification of acceptance by the User. A suggested permit-to-work form is shown on the following pages.

### Testing of decontamination equipment

#### Introduction

**4.3** Good decontamination practice is based on four key aspects that ensure that the required standards of performance and safety are met and sustained:

- a. all decontamination equipment is subjected to a programme of validation;
- b. all decontamination equipment is subjected to a planned programme of periodic tests performance;
- c. all decontamination equipment is operated by trained staff in its use in accordance with a written procedure

including manufacturers' instructions and local procedures;

- d. all decontamination equipment is subjected to a programme of planned preventative maintenance irrespective of whether a preventative maintenance scheme is operated on the premises.

**4.4** Expertise on all aspects of the operation and testing of decontamination equipment is available from several sources including the AE(D), AP(D), CP(D), User and manufacturer.

**4.5** Schedules of tests for washer-disinfectors and sterilizers are included in HTM 01-01 Parts C and D. Most tests are defined in the relevant British, European or International Standard. These documents should be used as the prime reference for such testing. Where there is no current Standard, testing protocols are defined within this guidance. Future publication of new Standards, or revisions of existing Standards, will render some of the content of this guidance no longer applicable. Advice should be sought from the AE(D) regarding the state of any relevant Standard and the current relevance of testing protocols defined within this HTM.

**4.6** Maintenance of all decontamination equipment is dealt with in HTM 01-01 Parts C and D.

### Responsibilities

#### General

**4.7** Decontamination equipment should be subjected to a planned programme of testing

## PERMIT TO WORK ON DECONTAMINATION EQUIPMENT

This permit only relates to the hazards caused by the possible microbiological or chemical contamination of the decontamination equipment. The decontamination equipment is not guaranteed safe against any other source of risk. Information regarding point of isolation and methods statements can be obtained separately from the AP (D).

**Location/department of decontamination equipment:** \_\_\_\_\_

**Manufacture:** \_\_\_\_\_ **Asset No** \_\_\_\_\_

**Serial No:** \_\_\_\_\_ **Model: No** \_\_\_\_\_

**Permit issued by AP(D). Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Re-issued permit (Yes ☐ / No ☐ ) Relates to previously issued permit No:** \_\_\_\_\_

**Date of issue** \_\_\_\_\_ **Time of issue** \_\_\_\_\_

**Permit expires Date: :** \_\_\_\_ / \_\_\_\_ /20 \_\_\_\_ **Time:** \_\_\_\_\_ **Hr:min (24hr)** \_\_\_\_\_

I confirm that the decontamination equipment has been decontaminated and cleaned as required to render it safe for maintenance or repair.\*

OR

It is not possible to guarantee that the decontamination equipment is free of contamination. Guidance on safe working practices is attached.\*

*\*delete as applicable.*

**User details:**(to be completed by Authorised user / Department manager / person in charge)

**Name:** \_\_\_\_\_ **Signature** \_\_\_\_\_

**Date:** \_\_\_\_ / \_\_\_\_ /20 \_\_\_\_ **Time:** \_\_\_\_\_ **Hr:min (24hr)** \_\_\_\_\_

**Receipt :**( delete as applicable)

I accept responsibility for carrying out the work on the above decontamination equipment.\*

I have received the guidance on safe working practices.\*

**CP(D) Name:** \_\_\_\_\_ **Signature** \_\_\_\_\_

**Date:** \_\_\_\_ / \_\_\_\_ /20 \_\_\_\_ **Time:** \_\_\_\_\_ **Hr:min (24hr)** \_\_\_\_\_

both before delivery and on-site. The on-site testing should be carried out using the procedures described in this guidance and should include installation qualification, operational qualification and process qualification. The purchaser, manufacturer, contractor AE(D), AP(D) and CP(D) have distinct responsibilities.

**4.8** The AE(D) should review the results of pre-delivery works tests carried out by the manufacturer, and review the test instruments provided by the contractor and/or the CP(D) to ensure that their accuracy, calibration and condition meet the standards for test instruments described in 'Validation and verification'. The AE(D) should witness such

installation, operational and performance qualification testing as appropriate to verify that the requirements of the specification are met and that the equipment is fit for purpose. New equipment should only be brought into use after written confirmation from the AE(D).

**4.9** The CP(D) 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 should arrange for test loads to be supplied as required. The CP(D) should carry out the installation qualification tests, operational qualification and performance qualification.



<b><u>Details of work Carried out</u></b>			
Warranty <input type="checkbox"/>	Contracted Service / Test <input type="checkbox"/>	Repair <input type="checkbox"/>	Other <input type="checkbox"/> _____
Quarterly maintenance / Test <input type="checkbox"/>	Bi-annual maintenance / Test <input type="checkbox"/>	Annual maintenance / Test <input type="checkbox"/>	
<b><u>Explanation of work carried out</u></b>			
<b><u>Hand back</u> :( delete as applicable*)</b>			
The work on the above decontamination equipment has been completed / suspended.*			
Or			
The decontamination equipment may / may not be returned to service.*			
CP(D) Name: _____		Signature _____	
Date: ____ / ____ /20____		Time: _____ Hr:min (24hr)	
<b><u>Cancellation</u></b>			
This permit is now cancelled.			
The above equipment is safe and fit for use.			
AP(D) Name: _____		Signature _____	
Date: ____ / ____ /20____		Time: _____ Hr:min (24hr)	
I accept the above equipment back into service as fit for use.			
User Name: _____		Signature _____	
Date: ____ / ____ /20____		Time: _____ Hr:min (24hr)	

**THIS PERMIT IS ONLY VALID WHEN COMPLETED BY AP (D).CP(D) AND USER.**  
**NO WORK IS PERMITTED UNLESS A VALID PERMIT IS IN PLACE.**

CP(D) MUST REPORT TO THE PERSON IN CHARGE ON ARRIVAL & DEPARTURE  
 FROM THE DEPARTMENT.

!

### Authorising Engineer (Decontamination) (AE(D))

**4.10** See paragraphs 6.30–6.58 on staff roles and responsibilities in HTM 01-01 Part A.

### Authorised Person (Decontamination) (AP(D))

#### *Role and responsibilities*

**4.11** The AP(D) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the

AE(D)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of decontamination equipment including the operation of the permit-to-work system (see [paragraph 4.2](#)).

**4.12** The AP(D) should be able to undertake the safe and effective management aspects of the service.

**4.13** The role of AP(D) is intended to provide the organisation with an individual who, as part of the management infrastructure, will provide day-to-day operational management responsibility for the safety of the system. This

should be an internal appointment from within the organisation. It is, however, recognised that in some organisations there are so few items of decontamination equipment in use that a service provided by a third party may be adequate.

**4.14** In most organisations the role of AP(D) would only be one of a number of areas of similar responsibility for the individual(s) concerned. However, any additional responsibilities should not reduce the importance of the role nor impair the ability of the AP(D) to carry out his/her duties effectively.

**4.15** When the scope and range of services dictates, healthcare organisations may wish to consider the appointment of more than one AP(D) to ensure that appropriate cover is provided. In these circumstances the organisation should appoint a senior AP(D). In any event, organisations will need to ensure that cover is available during the absence of the AP(D) due to annual leave, sick leave etc.

**4.16** Larger organisations may be able to warrant the appointment of an AP(D) dedicated full-time to the role. Even where estates roles are contracted out, it is recommended that the AP(D) function remains the responsibility of the healthcare organisation. The AP(D) should report to the Designated Person.

**4.17** The AP(D) will also be responsible for:

- the engineering management of decontamination equipment;
- line management and/or appointment of the CP(D);
- the safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility;
- the acceptance criteria for operational and performance testing of all installed decontamination equipment;
- liaison with the AE(D), Decontamination Lead and other interested professionals;

- authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests.

### Competent Person (Decontamination) (CP(D))

**4.18** The CP(D) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of washer-disinfectors and sterilizers. The CP(D) should report directly to an appropriate member of the estates department (for example AP(D)) or should be subcontracted by them.

**4.19** The principal responsibilities of a CP(D) are:

- a. to carry out maintenance tasks;
- b. to carry out repair work;
- c. to conduct validation tests as given in HTM 01-01 Parts B, C and D;
- d. to conduct periodic tests as given in HTM 01-01 Parts B, C and D.

### Manufacturer

**4.20** The manufacturer should ensure that the decontamination equipment is designed, manufactured and tested within a quality system. The manufacturer should also 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 with the relevant British or European Standard by means of a type test for the particular type and size of decontamination equipment. (See BS EN 15883 Parts 1 and 2 for type-test details for washer-disinfectors and BS EN 285 for type-test details for sterilizers.)

### Contractor

**4.21** The contractor, who might also be the manufacturer, should complete the installation checks and tests specified in HTM 01-01 Parts

C and D to the satisfaction of the CP(D) before the decontamination equipment can undergo full validation to allow acceptance. The contractor should provide such test instruments and equipment necessary to complete installation checks and tests.

**4.22** The CP(D) should provide the test instruments and equipment for the remainder of the validation tests (unless otherwise specified in the contract). The test instruments provided should meet the standards for test instruments described in this chapter.

**Purchaser**

**4.23** The Purchaser is defined as the person or organisation that orders the washer-disinfector or sterilizer and is responsible for paying for it.

**Works tests**

**4.24** Works tests before delivery of the decontamination equipment are intended to verify that the equipment performs in conformity with the results obtained from type testing in respect of various critical attributes. (See BS EN 15883 Parts 1 and 2 for works test details for washer-disinfectors and BS EN 285 for works test details for sterilizers.)

**4.25** 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 might wish to arrange for their representative (either the AE(D) or CP(D)) to attend the factory to witness these tests before accepting delivery of the decontamination equipment.

**Validation**

**4.26** 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, and should be conducted on site. Performance qualification may refer to testing of reference loads and reference loading conditions performed with a test sterilizer. A summary is shown in Table 4.

Table 4 The validation process

Validation		
Purchase specification review	Commissioning	Performance qualification
	Installation tests	Thermometric tests
	Operational tests	Microbiological tests
		Residual gas/additive tests
		Cleaning efficacy tests (to extend to protein removal tests)
		Load dryness tests

**4.27** Validation consists of tests performed by the manufacturer/supplier/manufacturer’s agent or another Competent Person (Decontamination) defined in the following categories:

- installation qualification (IQ);
- operational qualification (OQ); and
- performance qualification (PQ).

**Installation qualification**

**4.28** Installation qualification is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

**4.29** The contractor or agreed alternative should carry out the required installation checks on delivery of the decontamination equipment, to ensure that the machine has been supplied and installed correctly, is safe to operate, has been provided with satisfactory services that do not impair the performance of the machine, and

that in operation the machine does not interfere with other equipment.

**4.30** Ancillary equipment such as service supplies and ventilation systems should be checked by the contractor responsible for their installation.

**4.31** When these checks have been completed and found satisfactory, the contractor should carry out the installation tests necessary to demonstrate that the decontamination equipment 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.

**4.32** If any modification, maintenance or repair work is carried out on the steam, water, compressed air ventilation, piped gas services or drainage systems after the installation tests have been completed, the relevant installation tests should be repeated by the CP(D) before the operational tests are undertaken.

**4.33** The schedule for installation checks and tests is set out in HTM 01-01 Parts C and D.

### Operational qualification

**4.34** Operational qualification is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

**4.35** When the decontamination equipment has been installed and accepted the CP(D) should carry out a sequence of operational performance tests to evaluate the basic performance and safety of the decontamination equipment. 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.

**4.36** The schedule for operational tests is set out in HTM 01-01 Parts C and D.

### Performance qualification (PQ)

**4.37** PQ is defined as the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

**4.38** PQ consists of tests designed to show that:

- a. for washer-disinfectors, soil removal and cleaning have been effective throughout the load and the washer-disinfector chamber, and the products are of the required standard of cleanliness, free from process residues (when applicable). Again, the use of a test that enables quantitative analysis of protein removal is to be used when appropriate technologies become available. These tests will be conducted on sample instruments derived from the normal decontamination stream. The use of test soils for specifically for this purpose is not envisaged;
- b. decontamination conditions have been attained throughout the load and the machine's chamber, and to the required standard for the type of load being processed. A thermometric test is sufficient for most items of decontamination equipment. Additional microbiological tests will be required for washer-disinfectors that use chemical disinfectants.

**4.39** In principle, it might be argued that a PQ test is required for each loading condition that an item of decontamination equipment is required to process. In practice, it is possible to identify reference loads and reference loading conditions that present an equal or greater challenge to the process than the loads that might be encountered in normal use. New load items should not be processed until one of the following is the case:

- a. PQ tests, as specified in the appropriate validation and verification section, have



been conducted by the CP(D) to the satisfaction of the User and the AE(D);

- b. the User is satisfied that the new load item is represented by one of the existing loading conditions/process cycles for which a PQ report exists;
- c. the instructions from the manufacturer of the item are sufficiently detailed and specific that the appropriateness of the proposed treatment is readily apparent.

**4.40** The User, in consultation with the manufacturer(s) of the load items, the AE(D) and the control of infection officer as necessary, should ensure that the load is suitable for the process to which it is to be exposed. This should include consideration of the compatibility of all process chemicals used.

**4.41** The process selected will depend on the nature of the load and its ability to withstand the environmental conditions present during the operating cycle. The rates of change of cycle variables, such as temperature and pressure, might also need to be considered.

**4.42** Before selecting a process it might be necessary to carry out preliminary tests on the product, or on a surrogate product, to determine both the levels and rates of change of the cycle variables necessary to achieve the required result, and to determine which can be tolerated by the product without causing unacceptable changes in its performance. Otherwise, manufacturers' instructions may be used.

## Loading

**4.43** The User should ensure that each load is presented to the process in accordance with documented procedures established and tested during PQ.

**4.44** Baskets or load carriers should not be overloaded, as this will result in inefficient cleaning and disinfection.

**4.45** Cannulated load items, which are intended to be connected to spigots on the load carrier to ensure flushing of the lumen, should be properly connected, as otherwise they will not be adequately cleaned and disinfected.

**4.46** Small and light items should be secured with a hold-down screen or by other means; if they are free to move around there is a serious risk of damage to the instruments. Small, sharp instruments that have moved within the load could also represent a hazard to staff who have to subsequently handle the load.

**4.47** Load carriers should only be used with the items for which they were intended.

## Documentation

**4.48** Accurate and efficient record-keeping is an essential part of the management of decontamination equipment. The extent and nature of the records that are necessary varies with the type of machine and the use to which it is put. Guidance is given in HTM 01-01 Parts C and D.

## Summary sheets

**4.49** On completion of the validation process, and before leaving the premises, the CP(D) should prepare a summary report containing the results of the commissioning and PQ tests and essential working data.

**4.50** At the request of the User the CP(D) should also supply graphical representations of cycle variables obtained from the thermometric tests.

**4.51** The summary report should be signed by the CP(D) and countersigned by the AP(D) to certify that the machine is fit for use.

**4.52** Summary reports should be securely retained by the User and be available for ready reference.

**4.53** At the same time the CP(D) should provide the User with copies of any master process records required for routine production.

## Validation report

**4.54** Within one month of the completion of the validation process the CP(D) 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 calibration of all measuring instruments fitted to the machine have been verified;
- c. all the data collected during the commissioning tests, with written confirmation from the CP(D) that they meet the specified requirements;
- d. data showing the correlation between the performance of the measuring instruments fitted to the machine and the test instruments used during commissioning and PQ;
- e. reports containing all the data collected during the PQ tests, with written confirmation from the CP(D) and the User of the loading conditions and types of load (including, when necessary, reference to specific individual items) that may be satisfactorily processed in the machine;
- f. data from the instruments fitted to the machine, independent monitoring system data and validation instrument data, along with comments on any changes or adjustments made.

**4.55** When data is in the form of electronic data files, the report should include copies of disks/ DVD or CD or tapes containing the data in a format compatible with local systems and policies and a printout of the directory of each, annotated to show where the data for each test is to be found.

**4.56** The CP(D) should certify that all necessary tests have been carried out and that the results were satisfactory.

**4.57** The records of any microbiological tests should be signed by the Microbiologist.

**4.58** The AP(D) should forward the completed validation report to the AE(D) for audit. The AE(D) should issue a report of findings to the User, with a copy to the AP(D) and Decontamination Lead. The validation report should be returned to the User via the AP(D).

**4.59** The validation report should be retained by the User. Copies may be retained as necessary by the CP(D), the AE(D), the Microbiologist and, where applicable, the Quality Controller.

## Periodic tests

**4.60** After validation and when the machine is passed into service, it should be subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals, to provide evidence that the machine continues to operate within the limits established during commissioning.

**4.61** The User and the CP(D) (under the management of the AP(D)) are responsible for the periodic tests.

**4.62** 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 PQ remain valid.

## Revalidation

**4.63** In addition to annual revalidation, revalidation is required under the following circumstances:

- a. when the machine is to be returned to service after repair or component replacement of part of the systems that 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 AE(D) advises that revalidation is necessary:

(i) when the pattern of a batch process record is outside the limits specified on the master process record;

(ii) when the equipment fails a periodic test;

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

**4.64** The full revalidation procedure is identical to that specified for the yearly test.

**4.65** It will not always be necessary to carry out a full revalidation, and the advice of the AE(D) should be sought on which tests are required following any particular event.

## Repeat validation

**4.66** 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.

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

**4.68** Repeat validation should be carried out if:

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

b. a machine has been moved and installed at a new site;

c. the machine has been dismantled or extensively overhauled;

d. a new operating cycle has been introduced;

e. the User or AE(D) advises that repeat validation is necessary;

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

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

h. there have been time and temperature adjustments or parameter changes.

**4.69** It will not always be necessary to carry out a full repeat validation, and the advice of the AE(D) should be sought as to which tests are required following any particular event.

## Types of test

**4.70** The tests listed in the schedules 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 machine;

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

c. Thermometric tests for a **small load**, which are designed for two purposes. In sterilizers with an **active air removal system** they demonstrate that the sterilizer is capable of removing air from a small load in which air from a near-empty chamber has been retained. Thermometric tests for a **full load** are designed to show that services provided to the machine are adequate for purpose. In certain circumstances they may also serve as PQ tests for loading conditions that present a lesser challenge to the

operating cycle than the specified full loads;

d. **Microbiological tests**, which are designed to show that disinfection (sterilization) conditions are attained when thermometric methods alone are inadequate for this purpose;

e. **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.

**4.71** Other tests, specific to certain types of sterilizer, are designed to show that the steam supply is suitable, the sterilizer does not produce too much noise, the chamber is airtight, gaseous sterilants are not released into the environment, and safety devices are functioning correctly.

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

## Procedure on failure of a test

**4.73** There should be no difficulty in ensuring that a correctly installed and maintained piece of decontamination equipment will comply with both the validation tests and periodic tests described.

**4.74** Failure of a test generally indicates that a machine is not working to specification; it should be withdrawn from service and the failure investigated.

**4.75** 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 machine is being put. It might be acceptable for the equipment to continue operating under carefully defined restrictions until the cause of the failure can be established and rectified.

**4.76** The AE(D) and the User should agree the course of action to be taken.

**4.77** The User has the ultimate responsibility for certifying that decontamination equipment is fit for use.

## Principles of installation and operational tests

**4.78** On delivery of decontamination equipment, the contractor should carry out the installation checks included in the contract and as set out in this chapter to establish that:

- a. the equipment has been provided and installed correctly;
- b. the equipment is safe to operate;
- c. the equipment does not interfere with other equipment;
- d. all connected services are satisfactory and do not prevent attainment of the designed cleaning and disinfection/sterilization performance of the equipment.

**4.79** The contractor responsible for installing the equipment 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 equipment itself.

**4.80** The contractor responsible for installing the decontamination equipment should carry out any additional checks specified by the manufacturer.

**4.81** The CP(D) should carry out any checks specified in this chapter that were not included in the purchase contract for the decontamination equipment.

**4.82** Installation tests are defined in HTM 01-01 Parts C and D.

**4.83** Operational tests are performed in standard specified manner using defined



reference loads. Details of operational tests are defined in HTM 01-01 Parts C and D.

## Principles of performance qualification tests

### Introduction

**4.84** Performance qualification (PQ) is defined as the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

**4.85** PQ tests should be 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 AE(D), judges that new loading or operating conditions require a new PQ test.

**4.86** Circumstances that might 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 or packing arrangements for decontamination equipment.

**4.87** PQ should not be undertaken on any piece of equipment until the requirements of the installation and operational tests specified in HTM 01-01 Parts C and D have been met.

**4.88** Soil removal efficacy tests should be carried out on all washer-disinfectors as part of the PQ (see HTM 01-01 Part D).

**4.89** Thermometric PQ may not be required for all loads. Consideration should be given to tests for effective sterilization and drying of metal loads, and of any particular loads agreed between the User and the AE(D).

**4.90** PQ tests should be carried out by the CP(D).

**4.91** Each test should be cross-referenced to a detailed description of the test procedure. Unless otherwise specified, the tests should be carried out with the decontamination equipment at normal working temperature, which might require a “warm-up” run to be carried out before commencement of the tests.

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

**4.93** The User should employ the PQ report to confirm the suitability of the process for loads that are to be processed. It should be used by the CP(D) and AE(D) as the basis for comparison with subsequent performance requalification tests.

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

**4.95** PRQ 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.

**4.96** Before undertaking PRQ tests the CP(D) should confirm, either by testing or by reference to current test records, that the machine meets the requirements of the installation and operational tests.

### Loading conditions

**4.97** 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 top-most level of a four-level load carrier constitutes a different loading condition from the same load placed on the lowest level.

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

**4.99** In practice, the loading conditions specified in the tests to be carried out during commissioning are designed to represent the majority 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.

**4.100** 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, washer-disinfectors 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. Also, while porous load sterilizers rarely need PQ tests, such tests will be required if the density of the porous material exceeds that of the standard test pack (see 'Testing: additional information' in HTM 01-01 Part C) or if narrow lumens restrict air removal and steam penetration;
- b. when the nature of the load is not represented by the commissioning tests; for example, certain loads might be damaged by exposure to the normal cycle temperature. In these cases, the settings of cycle variables and their permitted tolerances should ensure not only that the load is correctly processed, but also that it is not unacceptably degraded by long exposure to high temperatures.

**4.101** 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. For sterilizers, reference should be made to BS EN 17665 prior to commencing this process.

**4.102** A microbiological PQ test may be required for determining air removal and steam penetration into complex devices where thermometric methods may prove inadequate. The advice of the AE(D) should be sought in such cases.

**4.103** The responsibility for deciding which loading conditions require PQ tests should be considered by the User, CP(D) and AE(D). The AP(D) should be made aware of the decisions made.

### PQ report

**4.104** 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.

**4.105** The PQ report should contain or refer to the complete specification for the decontamination 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.

**4.106** 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 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 preconditioning, conditioning and degassing process;
- e. a specification of any pre-test operation of the decontamination equipment, for example a warm-up cycle;
- f. a specification of any pre-treatment of the test load, for example manual cleaning, ultrasonic cleaning etc;
- g. 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;
- h. for loads which require the removal of air before sterilization, the method used to verify whether the minimum conditions of steam penetration into the load are attained (for porous load sterilizers, this is by use of the air detector);
- j. for machines equipped with process recording, the original of the process record derived from the test should also form part of the record.

**4.107** Immediately following the PQ tests, the CP(D) should prepare PQ summary sheets and working copies of any necessary master process records. These should be given to the User and kept with the sterilizer process log.

**4.108** If PQ tests are not required, the PQ summary sheet should contain data from the thermometric test for a full load and be marked accordingly.

## Product release

**4.109** The User, in consultation with the AE(D), should establish and document procedures to ensure that loads are not released for use until the User is satisfied that the product has been processed within permitted equipment cycle parameters established during validation/ performance qualification, for each stage of the decontamination process.

**4.110** Product release procedures should confirm, for example:

- that the process equipment loading arrangement is consistent with that used during validation/PQ testing;
- that the products have been packaged and assembled in accordance with the PQ specification, and that the process has not resulted in any damage or deterioration of packaging;
- that the operating cycle for process equipment is in accordance with the PQ specification;
- that the process equipment batch process record meets PQ specification for all cycle variables.

**4.111** Confirmation that the process equipment batch process record meets PQ specification for all cycle variables may be achieved automatically via an independent process variable monitoring system (IMS) which compares cycle process control data and independent process variable monitoring data and confirms cycle performance within validated cycle parameters; or by manually comparing the batch process record (BPR) with a master process record (MPR) of the validated PQ test, and noting the outcome on the BPR together with the operator's signature and reference number of the MPR used.

**4.112** The performance and requirements of independent process variable monitoring systems are detailed in the 'Particular specifications' for sterilizers and washer-

disinfectors given in the appendices of Parts C and D respectively.

**4.113** A master process record may take the form of a transparent copy of the batch process record for the equipment validated PQ test, with variable limits specified and the MPR suitably referenced; or other convenient system which allows the operator to confirm that the production cycle parameters are within those established during the validated PQ test. Differing process cycles will require different MPRs.

## Tests for performance requalification (PRQ)

**4.114** PRQ tests should be performed once a year to ensure that the established criteria for decontamination are still being met. The PRQ tests should follow the yearly schedule of tests and checks listed in the specific sections for sterilizers and washer-disinfectors.

**4.115** For a given operating cycle the PRQ tests should only be carried out for those reference loads for which a PQ test was performed and reported.

**4.116** 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 CP(D).

**4.117** 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.

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

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

**4.120** The PRQ test should meet the specified requirements without difficulty for decontamination equipment that has passed the yearly test programme. If the PRQ test is not satisfactory the advice of the AE(D) and/or the manufacturer should be sought.

**4.121** Full details of PRQ tests can be found in HTM 01-01 Parts C and D.

## References

Choice Framework for local Policy and Procedures 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part A – The formulation of local policy and choices.

Choice Framework for local Policy and Procedures 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part C – Steam sterilization.

Choice Framework for local Policy and Procedures 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care. Part D – Washer-disinfectors.

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Medicines and Healthcare products Regulatory Agency (MHRA).

ISO 11139:2006 'Sterilization of health care products – vocabulary'.

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BS EN 285.

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BS EN 15883-1.

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BS EN 60751.

BS EN 60584-2.

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BS 5898, ISO 384.

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BS EN 61672-2.

BS EN ISO 14644-1.

Health Building Note 13 – 'Sterile services department'.

Provision and Use of Work Equipment Regulations 1998.

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NHS Supply Chain.

Firecode (Health Technical Memorandum 05-series).

Health Building Note 26 – ‘Facilities for surgical procedures’.

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