

WHTM 01-05

Welsh Health Technical Memorandum

**Decontamination in primary care
dental practices and
community dental services**



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Intranet: howis.wales.nhs.uk/whe

Internet: www.wales.nhs.uk/whe

Published by NHS Wales Shared Services Partnership – Facilities Services

This guidance is based on the HTM *01-05 Decontamination in primary care dental practices* Welsh edition 2011 guidance published by Welsh Health Estates which, in turn, was based on the 2009 edition produced by the Department of Health

This publication can be accessed from the NHS Wales Shared Services Partnership – Facilities Services website www.wales.nhs.uk/whe

ISBN ISBN: 978-1-909899-10-0

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Supersedes Health Technical Memorandum 01-05 Decontamination in primary care dental practices Welsh edition 2011

Cover image of Neath Port Talbot Primary Care Resource Centre by courtesy of Abertawe Bro Morgannwg. Photograph by Stewart Brooks, NWSSP-FS

Cover designed by Keith James

Foreword by David Thomas, Chief Dental Officer

Patients deserve consistent standards of care every time they receive treatment. It is essential that they are treated in a safe and clean environment with minimal risk of person-to-person transmission of infections.

This document has been produced after wide consultation and reflects our commitment to improving standards in dental practices.

We believe that, by building on existing good practice, this guidance can help us to deliver the standard of decontamination that our patients have a right to expect.

The policy and guidance provided in this WHTM are aimed at establishing a programme of continuous improvement in decontamination performance. The

guidance suggests options to dental practices within which choices may be made and a simple progressive improvement programme established. It is expected that at publication of this guidance all primary care dental practices will be working at or above the requirements described in my letter of May 2012 CDO(2012)2.

(<http://wales.gov.uk/topics/health/cmo/professionals/dental/publication/cdo-letters/compliance/?lang=en>).

This revised guidance is intended to support and advance good practice throughout primary care dentistry including that delivered by general dental practices, community dental services and where primary care is delivered in acute settings.

Overview

Scope, status and structure of WHTM 01-05

Welsh Health Technical Memorandum (WHTM) 01-05 is intended to progressively raise the quality of decontamination work in primary care dental services by covering the decontamination of reusable instruments within dental facilities.

The guidance relates to locally conducted decontamination procedures, which are the most common method of decontamination in primary dental care. As such, this includes all work where the end-user and the persons conducting decontamination are employees of the same organisation working in the same or related premises. Ordinarily this will be a general dental practice or community dental services functioning as part of the local health community.

Where practices choose to make use of an external service, such as a central sterile services department, which is fully compliant with the Medical Devices Regulations 2002 and is registered with the Medicines and Healthcare products Regulatory Agency (MHRA), the guidance contained in WHTM 01-01 'Decontamination of medical devices within acute services' will be appropriate.

The CDO (Wales) letter (2006)1- 'Decontamination/ Sterilisation of Re-usable Instruments in General Dental Practice' states 'The Medical Device Regulations 2002 require the manufacturer of medical devices to supply information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization. If correctly followed, these instructions will ensure that the device will be safe for another episode of use'. This implies that dental practices ensure their local policies give rise to the production and use of sterilized instruments for use with patients.

This document is divided into three Sections:

- **Section A: Decontamination policy**

This section outlines the policy and principles of decontamination in dental practices, and explains the requirements for decontamination.

- **Section B: Advice to dentists and practice staff**

This section gives plain advice to dentists and practice staff on how to achieve **improved good practice**; how to clean and sterilize instruments; and how to set up a decontamination area within the practice.

- **Section C: Engineering, technology and standards**

This section gives technical advice to engineering and technical staff, including the roles and responsibilities of staff in the decontamination process. Such as the User Authorising Engineer (Decontamination) (AE(D)), Authorised Persons (Decontamination) (AP(D)), Competent Persons (Decontamination) (CP(D)) and others.

Reference to guidance and standards provided by the Welsh Government and MHRA is provided and explained throughout this document.

Where engineering and technical information is provided (**Section C**), references to source standards and evidence are given. However, such references are omitted in **Section B** to aid clarity of presentation and explanation.

It is important to remember that this is a working document; changes to it may be necessary as new evidence around the methodology of decontamination becomes available. The user should always seek advice on policies, technical issues and guidance to ensure improvements are maintained.

Who should use WHTM 01-05

WHTM 01-05 will be of interest to all staff involved in decontamination in primary care dental services in Wales.

It is intended to be used, or referred to, by all members of a dental team providing primary care dental services that is, dentists and support staff as well as engineering staff providing services in key areas. In addition, Health Boards will find the contents of value.

Reference to other parts of the WHTM 01 series may be necessary on a limited basis only.

Acknowledgements

Listed below are the contributors to the original Department of Health Publication on which this Welsh Edition is based.

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Abbreviations

ACDP-TSE: Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy Risk Management Subgroup

AE(D): Authorising Engineer (Decontamination)

AP(D): Authorised Person (Decontamination)

BS: British Standards

CAPR: Clinical Audit and Peer Review

CDO: Chief Dental Officer

CE: Conformité Européenne

CPD: Continuing Professional Development

CP(D): Competent Person (Decontamination)

COSHH: Control of Substances Hazardous to Health

DUWL: Dental unit water line

EN: European Norm

EU: European Union

EWC: European Waste Catalogue

HCAI: Healthcare associated infections

IHEEM: Institute of Healthcare Engineering and Estate Management

ISO: International Standards Organisation

MDD: Medical Devices Directive

MHRA: Medicines and Healthcare products Regulatory Agency

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

PGMDE: Postgraduate Medical & Dental Education

PPE: Personal Protective Equipment

RO: Reverse osmosis

SSD: Sterile Services Department

TVC: Total viable counts

WHTM: Welsh Health Technical Memorandum

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Section A: Decontamination policy

Chapter 1 Policy

Registration

- 1.1 The registration of dentists providing dental treatment privately has been in place since 2009. Healthcare Inspectorate Wales will continue to oversee this process and have regulatory responsibility to ensure that the requirements for registration are met. This includes the provision of a safe, clean environment and appropriate decontamination of dental equipment.
- 1.2 The registration scheme will place strong emphasis on effective management and self-audit. (For further information, see the **Note after paragraph 8.10**).

Introduction

- 1.3 This document is a guide for those conducting decontamination at a local level – that is, within the dental practice itself. However, this policy statement respects the option to transfer instruments/medical devices to other organisations for reprocessing under the Medical Devices Regulations 2002.
- 1.4 To help dental practices to improve their decontamination procedures, this document introduces methods that provide an approved code of practice for decontamination of devices used with dental practices.
- 1.5 The requirements described in this guidance are intended as a clear indication of good practice and designed to promote continuous improvement in the performance of dental practices. They will help to demonstrate to patients and those observing quality standards in dentistry that the local provider of a dental service is capable of operating in a safe and responsible manner with respect to decontamination of instruments and dental equipment. Where new practices are commissioned or new premises contemplated, it is advised that the full best practice provisions of this guidance be utilised wherever reasonably practicable.
- 1.6 This guidance supports and is in keeping with the strategic aim of Welsh Government to eliminate all

preventable healthcare associated infections as outlined in the framework for actions for healthcare organisations in Wales: ‘Commitment to purpose: Eliminating preventable healthcare associated infections (HCAIs)’.

<http://wales.gov.uk/topics/health/publications/health/guidance/eliminating/?lang=en>

It is essential that all staff understand the impact of infection and infection control practices to enable them to discharge their personal responsibilities to service users, other staff and themselves.

Note

The strategy for Wales does not specifically mention WHTM 01-05, however, the two should be seen as complementary.

The need for guidance

- 1.7 This guidance provides a mechanism to comply with the legislation and relevant regulations. It also assists healthcare providers to encapsulate the latest standards and practice.

Improvements and enhancements in practice with the latest guidance, policy and standards

Note

Service quality improvements will involve keeping up to date with developments and new equipment in the decontamination field. This guidance may be amended when such new developments are apparent. **Seek technical advice on the latest guidance as issued.**

- 1.8 Every practice should be capable of meeting the quality requirements as stated below:
 - Regardless of the technology used, the cleaned instruments, prior to sterilization, should be free of visible contaminants when inspected. Instruments should be reprocessed using a validated decontamination cycle including: cleaning/washing (in terms of manual cleaning, this includes having a written protocol - see

Section C, **Chapter 16**); a validated steam sterilizer and, at the end of the reprocessing cycle, they should be in a sterilized state.

- Reprocessed dental instruments should be stored in such a way as to ensure restraint of microbiological recolonisation. These measures should be backed by careful controls on the storage times to which instruments that are less frequently used are subject.
- Practices should audit their decontamination processes. An audit tool has been developed by Postgraduate Medical & Dental Education (PGMDE), Cardiff University and is available from PGMDE as part of the CAPR process for practices providing NHS funded services. Wholly private practices can access the audit tool but will not be reimbursed.
- Following audit, practices should develop a plan to improve those aspects where they could do better.
- Use of improvement methodologies in Wales requires practices to regularly review progress against their improvement plans rather than simply re-audit. However, practices are advised to review their audit results at least annually, or when a decontamination issue arises, to ensure that good practice is maintained.

1.9 To demonstrate improvements in the decontamination process, the following main areas should be constantly reviewed:

- The environment in which decontamination is carried out should be such as to minimise the risk of recontamination of instruments and the possibility of generating aerosols, which may reach patients or unprotected staff. To achieve as good a practice as possible, the decontamination facilities should be clearly separate from the clinical treatment area.
- Where practical the use of a separate room or rooms for the accommodation of clean (output) and dirty (input) work is recommended. In these facilities, the room(s) should be used for this purpose only and access should be restricted to those staff performing decontamination duties. The design of such a facility is a matter of scale, depending on use, throughput and lists, plus the space available. Advice should be sought for the design and layout(s) for the facility.
- A well designed single room application could be sufficient for the purpose providing the instrument paths are clearly indicated from use,

cleaning (both manual and automated), sterilization, sorting and recording to storage, and finally use. Again, it is a matter of scale, as larger units or practices will want to consider separate rooms for the process.

- Plant and equipment not necessarily used for decontamination may be located in these rooms, but preferably in the dirty room or sector, provided it can reasonably be shown that the devices do not conflict with the requirement for a clean environment.
- Where possible, reprocessed dental instruments should be stored in a dedicated area/zone that provides a dry and clean environment. This may be an appropriately designed room or designated area set aside for storage that is clearly separate from the clinical treatment area. The facility should take account of the need to reduce recolonisation of sterilized instruments and also make the identification and selection of instruments easy. This storage facility will ordinarily be part of the clean area within the decontamination room(s). It is a requirement to log and trace this process of instrument decontamination, storage and use.
- As part of continuous improvement, practices should consider using a validated automated washer-disinfector that is compliant with BS EN ISO 15883 for cleaning medical devices.

1.10 The overall aim is to achieve a reprocessed medical device (dental instrument) that is fully compliant with the requirements of the Medical Devices Regulations 2002. This implies that the instrument should be:

- clean and sterilized at the end of the decontamination process; and
- maintained in a clinically satisfactory condition up to the point of use.

1.11 Following the guidance in this document will help to achieve a satisfactory level of risk control together with equivalent compliance with the regulatory framework.

“Sterile” and “sterilized”

As the environment in which dental instruments are used is not sterile, it follows that dental instruments will not be sterile at the point of use. They should, however, be in a sterile state at the end of the decontamination process when the sterilizer door is opened.

Accordingly, this guidance accepts that dental instruments may be defined as “cleaned and sterilized”

rather than “sterile” at the point and time of use, a somewhat different approach from that in invasive surgical procedures.

In some instances, the decontamination process may not generate full sterilization, for example, in the reprocessing of dental handpieces; however, the guidance will nevertheless seek to raise standards and minimise infection risk to patients.



The clinical treatment area should be clearly separate from the decontamination facilities.

Improvements and enhancements in practice

1.12 Not all practices can meet the recommendations required to achieve the highest standards and policies. Every practice will need to investigate and audit their facility and their way of working via a well defined risk assessment. Decisions need to be made on what quality enhancements are required to make improvements and meet the recommendations and a detailed plan prepared to implement the necessary changes.

1.13 The expectation in Wales by the Welsh Government is that all practices have had assessments made in time to implement basic improvements to their facilities since the introduction of the Welsh version of HTM 01-05 in 2011. The Chief Dental Officer (CDO) Wales letter CDO (2012)² outlined the necessity for all dental practices to comply with the requirements.

1.14 It is recognised that not only are improvements in premises and equipment required to achieve higher standards, but also changes in practice management and the culture in which patients are treated by the dental team.

1.15 This guidance is based upon a principle of continuous improvement in the quality of decontamination practices and the environment used. Where dental practices use the same room for patient treatment and decontamination they need to develop a plan that facilitates a move towards suitably designed decontamination area or room(s). This plan will normally also contain statements on staff training and development to suit work in a dedicated decontamination room, area or suite.

1.16 In addition, the plan should realistically outline the way forward for improvements in relation to **meeting the standards**, for example:

- measures to purchase and incorporate a washer-disinfector;
- the separation of decontamination processes from the patient treatment area.

Prion decontamination

1.17 Recent research has indicated that a low level of prion contamination may theoretically be present on some instruments following contact with dental tissues. This applies if these instruments have previously been used in the care of a prion disease carrier who may exhibit no symptoms and may indeed not go on to develop the disease. For those tissues where evidence suggests this risk is most pronounced, the CDO for Wales has published requirements for endodontic files and reamers to be single-use instruments in all cases. Other instrument or device types for which a reliable cleaning regime is not available should also be considered for replacement by single-use types or by the single use of re-processible instruments e.g. matrix bands. Information regarding risk in this important area is contained in ‘Potential vCJD transmission risks via dentistry: an interim review’ (December 2007).

Note

Where patients indicate that they are in a high-risk group, guidance provided by the Advisory Committee on Dangerous Pathogens – Transmissible Spongiform (ACDP TSE) Risk Management Subgroup should be followed <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>. The guidance suggests that special precautions beyond full instrument decontamination will not be necessary. However, specific advice is available by contact with the committee secretariat.

- 1.18 For all other instruments used in dentistry, the risk of prion transmission will be usefully reduced by compliance with the decontamination procedures described in this WHTM. This statement is based on various studies conducted on behalf of the Department of Health that examined the effect of steam sterilization on prion infectivity. These studies showed that the team sterilization methods described in this guidance provide a useful level of deactivation of prion infectivity. While this would not be adequate in high-risk tissue surgery, the effect is large enough to be of significance in dentistry, excluding endodontic procedures as mentioned in [paragraph 1.17](#). In addition, there is a risk of prion transmission through protein contamination of instruments, hence the measures outlined in this guidance to improve washing and disinfection of dental instruments.
- 1.19 Currently there is no recognised process that can fully deactivate prion protein in the sense of removing any foreseeable level of contamination. In this WHTM, the cleaning process and its ability to remove protein in tandem with a validated steam sterilization procedure is emphasized, as this is known to at least reduce the risk of prion transmission through dental instruments.

Infection prevention and control policy

- 1.20 All dental practices should have the latest infection prevention and control policies in place and available for external inspection.
- 1.21 Public Health Wales via the Welsh Healthcare Associated Infection Programme (WHAIP) have developed a number of model standard and transmission based precaution policies and procedures including:
- Hand hygiene
 - Respiratory hygiene and cough etiquette
 - Personal Protective equipment (PPE)
 - Management of care equipment
 - Control of the environment
 - Safe management of linen
 - Management of blood and body fluid spillages
 - Safe disposal of waste
 - Occupational exposure management (including sharps safety)
- These can be accessed at <http://www.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=38960>
- 1.22 The infection prevention and control policy statement for each practice must include all aspects included in [paragraphs 2.6–2.7](#). In addition, a written assessment of the improvements the practice needs to make to progress towards meeting the requirements for best practice should be available together with an implementation plan (as outlined in [paragraph 2.25](#)).

Note

This statement is subject to staged implementation and to local constraints, for example, the physical inability to provide a separate room.

- 1.23 Infection prevention and control needs to include all aspects of the running of a dental practice: from attention to personal hygiene – hand-washing, masks, protective clothing – to the cleaning and sterilization of instruments and the maintenance of the equipment.
- 1.24 Selective record-keeping on decontamination for infrequently used instruments is required as a key means of avoiding excessively long periods of storage for sterilized instruments, during which micro-organism recolonisation may occur. While local implementation may vary, this will ordinarily involve creating a written or computer-based record, which clearly identifies the instruments concerned either directly or by association with their container. The record should show the date of decontamination and also an expiry date for safe practice (see [paragraph 2.4k](#) in Section B Chapter 2 ‘Improvements and enhancements of the decontamination process’) after which the process should be repeated before the instrument is used.
- 1.25 For instruments that are wrapped prior to sterilization in a vacuum sterilizer (i.e. Type B and Type S sterilizers), the storage period may be extended to a maximum of one year. This procedure can only be adopted if the vacuum sterilizer used for this process has been correctly

validated to the requirements of this document, the correct periodic testing regime is in place and a record of all the correct periodic thermometric and test reports is maintained. The sterilizer should be subjected to the manufacturer's maintenance schedule, complete with log books and records. On cycle completion no water or condensate should be visible in the packs or on the instruments before putting into storage, as this can cause microbiological growth and tracking to the instrument.

Note

The Welsh Government recognises that recolonisation of instruments, particularly those that are wrapped following sterilization, is likely. Accordingly, while recommendations are made in respect of maximum storage times, dental staff should visually check all instruments prior to use for any obvious deterioration in their quality.

Note

Vacuum bench top autoclaves do not attain the same levels of vacuum or air removal as larger porous load sterilizers utilised in the hospital based departments. Therefore guidance should be sought on the types of instrumentation that can be processed through these machines, to ensure that the correct procedures, packing, air removal, air performance depression tests, drying times, correct sterilization criteria and thermometric tests are carried out to ensure a sterile instrument is produced.

Training and education

1.26 Training and education in the processes of pathogen control, decontamination, cleaning and hygiene (including hand hygiene), exposure to blood-borne viruses and infection risk reduction, including waste disposal, should be part of staff induction programmes. They are key aspects of patient safety and service quality. Accordingly, the provision of training and competency records is a key requirement. As part of verifiable continuous professional development (CPD), professionals working in this area will receive not less than five hours' training over a period of five years for both dentists and dental care professionals.

Exclusions

1.27 This WHTM does not cover the following:

- Decontamination in sterile services departments (SSDs). This is covered in Welsh Health Building Note 13.

- Decontamination of laundry and infected linen (covered in the forthcoming WHTM 01-04).

Note

Advice can be sought from NHS Wales Shared Services Partnership – Facilities Services (NWSSP-FS) on guidance documentation.

Relationship to other sources of information and guidance

1.28 This WHTM was prepared for publication in Wales during 2013. The main sources of information used in its preparation are listed in the References section. Readers should ensure they use the latest edition of all building legislation, British Standards (BS), health and safety regulations, etc. and give first preference to products and services from sources that have been registered under a quality assurance procedure.

Note

Throughout this guidance, references are made to International Standards Organisation (ISO), European Norm (EN) and BSI Standards. In some instances, these standards have been harmonised so that the content of the output for all three standards institutions is the same. These harmonised standards support the essential requirements of the medical device directives and their equivalent enactments in UK law.

Where a product or process is stated as compliant with a specified standard this will assist in meeting the appropriate essential requirement of the European Union (EU) Medical Devices Directives (MDD). Where manufacturers do not use the harmonised standard to state compliance, the technical file for the product should identify by what means compliance with that essential requirement is being met. For some medical devices the approval of a Notified Body may be necessary in making the assessment of compliance, with the essential requirements and appropriate standards coupled to the use of a Conformité Européenne (CE) marking. The Competent Authority for the MDD structure in the UK is the Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk/). Amongst a range of duties, the agency audits the performance of Notified Bodies.

For low-risk category devices the approach is less complex and the manufacturer is simply registered with the Competent Authority.

Further guidance

- 1.29 This 2013 edition of WHTM 01-05 supersedes the 2001 edition, taking into account amendments to BS EN and ISO standards.
- 1.30 More information on decontamination for Wales for Medical Devices is found in WHTM 01-01 Parts A, B, C and D. Part E covers non-steam sterilization processes.

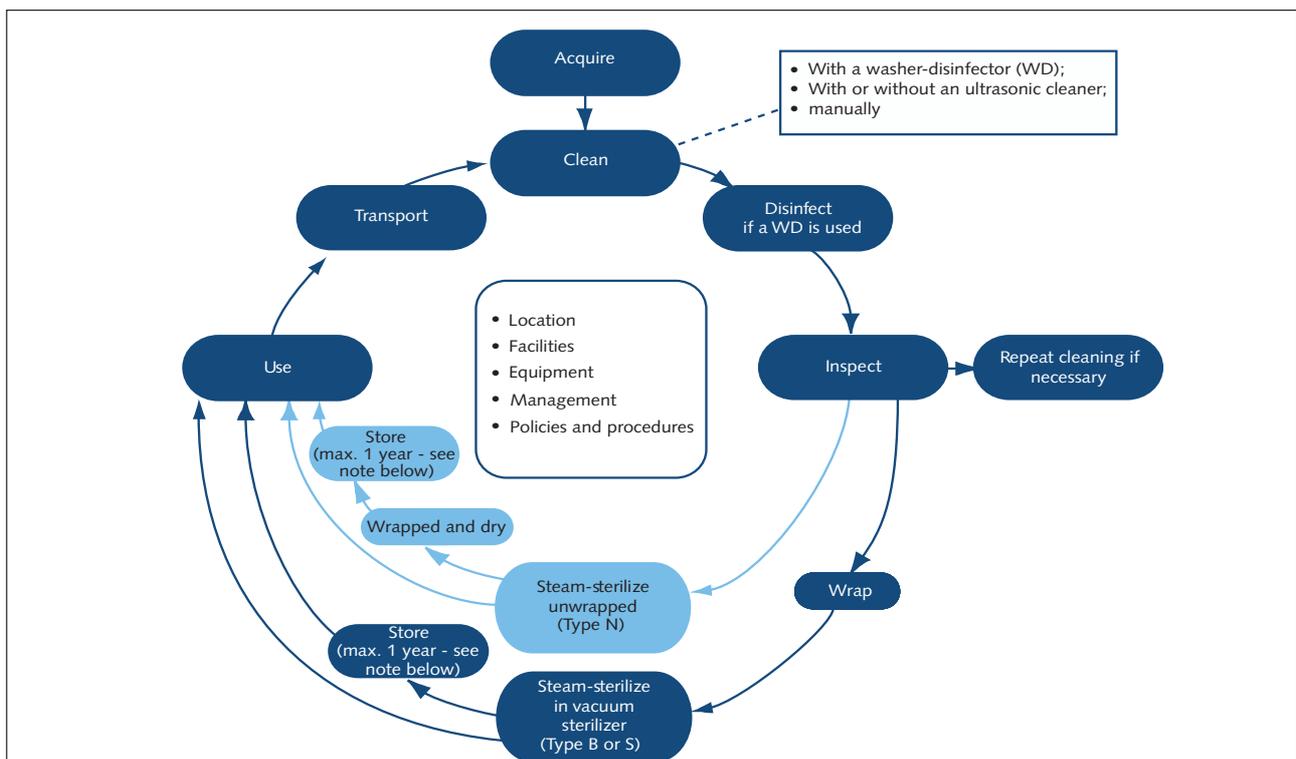
Section B: Advice to dentists and practice staff

Chapter 2 Improvements and enhancements of the decontamination process

Decontamination of instruments – an overview

2.1 Decontamination is the process by which reusable items are rendered safe for further use and for staff to handle. Decontamination is required to minimise the risk of cross-infection between patients and between patients and staff.

2.2 Decontamination of instruments, also known as reprocessing, is a complex process that involves several stages, including cleaning, disinfection, inspection and a sterilization step. The diagram below summarises how the individual stages ideally link together to complete the process of instrument decontamination.



Notes:

1. As an alternative to storing instruments immediately after sterilization, instruments that are anticipated to have a rapid turnover may be put out on sets of individual covered trays. The number of trays should correspond to the expected number of treatment episodes for that particular working session. This will negate the need to keep packing and unpacking instruments throughout the day. Each tray should be for use on a single patient.
2. Any instruments on unused trays at the end of the clinical session – even though they have not been used – should be reprocessed before further use.
3. Instruments that have remained unused for more than the maximum storage times indicated (reference paragraph 1.25 for Type B and S sterilizers and paragraph 2.4j(i) for Type N sterilizers) should be subjected to a further cycle of decontamination before being used.

Compliance

The principles identified within this WHTM provide an approved code of practice to ensure compliance with the regulatory framework for the decontamination of medical devices used within dentistry.

Guidance contained within this document will assist dental practices in maintaining good operating practices and developing and constantly improving methods towards higher levels of achievement. The use of an audit tool will assist dental practices in reaching the necessary standards (see [paragraph 2.23](#)).

In order to demonstrate compliance to the requirements of external bodies, for example, the Healthcare Inspectorate Wales, Health Boards and Welsh Government, practices will be expected to provide a statement on plans for future improvement. Details on registration requirements are given in [Chapter 8](#).

Compliance

Meeting the standards required

2.3 Instruments should be reprocessed using a validated decontamination process, including a washing process and a steam sterilizer, and at the end of the reprocessing cycle they should be sterilized.

2.4 In maintaining and developing dental decontamination practices, all the following should be included:

- a. A local infection control policy subject to regular update, with reference to the all-Wales model policies.
- b. The above policy should have detailed requirements and procedures for the decontamination of instruments.
- c. The practice should have a nominated lead member of staff responsible for infection control and decontamination.
- d. The storage, preparation and use of materials should take full account of the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations (latest amendment document). Particular care should be taken in the storage and preparation for use of decontamination chemical products. Manufacturers' instruction sheets should be consulted for further information. Guidance on COSHH is available from the Health & Safety Executive (www.hse.gov.uk/coshh).
- e. Practices should have a clear procedure for ensuring appropriate management of single-use and reusable instruments, which safeguards

their status. ([Section C](#) contains detailed guidance on instrument purchase and disposal.)

- f. Reprocessing of dental instruments should be undertaken using dedicated and compliant and validated equipment (see [Section C](#)).
- g. Dedicated hand-washing facilities should be provided.
- h. Cleaning and inspection are key parts of satisfactory dental instrument reprocessing. Instruments may be cleaned using an ultrasonic bath, but this should be covered during use to restrict the release of aerosols. Manual cleaning may also be used as required. To provide practices with a consistent level of cleaning and disinfection of devices, the use of automated and validated washer-disinfectors designed for purpose is strongly recommended. Inspection processes should ensure that the standards of cleaning achieved are visually satisfactory, that is, that instruments are free from particulate contamination, salt deposits or marked discoloration. The use of a simple magnifying device with task lighting will improve the value of this part of the process.
- i. As far as practical, instrument reprocessing procedures should be kept separate from other activities, including clinical work (see [paragraph 5.7](#) and [paragraph 5.8](#))
Decontamination equipment including sterilizers should accordingly be located in a designated area or rooms. The layout within this area should reflect the progression from the receipt of dirty, used instruments towards clean instruments sterilized in a specifically controlled clean area. In the first instance, where practices are meeting the requirements defined by this guidance, the designated area for decontamination may be in, or adjacent to, a clinical room. At a later stage of development, more complete separation involving the use of a designated room or rooms will become appropriate depending on the scale of operation and size of practice (see [Figures 1–3](#) in [Chapter 5](#)).
- j. **Instrument storage and wrapping recommendations:**
The methods used for packing and wrapping of instruments are of prime importance to the quality of the system and safety of the patient:
 - (i) Where non-vacuum sterilizers (type N) are used, post-sterilization drying using disposable non-linting cloths should be

carried out before the packing of instruments; this will improve resistance to contamination and recolonisation by an appropriate method or storage container.

- (ii) Where packing is not applied, instruments should be used within that treatment session, usually defined as no more than 1 operational day. Unpacked instruments will need to be reprocessed within that specified period whether used or not.
 - (iii) Instruments should be dry.
 - (iv) Instruments should be protected from contamination in racks placed in cupboards or covered drawer inserts. Instruments should not be stored on open work surfaces, particularly in clinical areas. It is important that practices have well developed protocols and procedures in place to prevent contamination of these instruments by ensuring that those required for a particular patient are removed from their protected environment before treatment commences. This eliminates the need to open cupboards or drawers during patient treatment. If an instrument needs to be retrieved from storage during treatment, the practice should have protocols in place to prevent contamination and ensure staff hands are clean and that new gloves are used before handling unwrapped and sterilized instruments.
 - (v) All instruments set out for each patient should be regarded as contaminated after the treatment whether or not they have been used.
- k. Where wrapped instrument storage is used, they can be stored up to one calendar year. **(For qualification for this period see following Note).**
- Pre-sterilization wrapped and processed in a type B or S validated sterilizer (see [paragraph 1.24](#) and [paragraph 1.25](#)).
 - Post sterilization wrapped if type N validated sterilizer.
- l. Develop a quality system approach so that the storage of wrapped instruments does not exceed one year for instruments sterilized in a non-vacuum (type N) sterilizer providing all processes are validated and the storage method has been audited, inspected and risk assessed.

Subject to local policy and any risk assessment procedures carried out, these measures will help to ensure stock rotation and will tend to limit recontamination of stored instruments. Simple but clear record-keeping will be required to make these measures effective.

Note

It is important that sterilized instruments should be dry and clean before wrapping after reprocessing in a type N sterilizer. This procedure carries an element of risk and should be fully assessed by the user as it is not to be deemed to be a sterile instrument, such as an instrument taken from a type B or S, where the instruments are pre-wrapped and have been subjected to an air removal stage prior to sterilization.

It must also be noted that both procedures are not as assured as an instrument reprocessed in sterile services departments operating under the Medical Directive and inspected by Notified Bodies.

The previous Welsh version of HTM 01-05 stated one calendar month for this post wrapping method from a type N sterilizer. It is recommended that this time scale should be continued or adopted, although it is possible to store properly sterilized and wrapped instruments for up to one year. It is important to recognise that any extension to the one month storage period carries elevated risks to patients and should be fully risk assessed for audit. In general practice it is likely that the instrument stock would have a week's turnover of use and therefore the storage of up to one year may be irrelevant.

Guidance on formal risk assessments with the use of medical device applications refer to BS EN ISO 14971 – Medical Devices – Application of risk management to medical devices.

- m. Equipment used to decontaminate dental instruments should be fit for purpose and fully validated to the test requirements of this document (see [Section C](#) for details). This means that the device should be commissioned, maintained and periodically tested by a CP(D), that records of testing and maintenance should be kept, and that correct functioning should be monitored and recorded in the log book for that machine.
- n. The appropriate and controlled disposal of waste is a key aspect of risk control in local dental practices (see [Appendix 1](#)).
- o. A documented training protocol should be in operation with individual training records for all staff engaged in decontamination (see

Section C for details). The practice should carry out regular assessments of the changes needed to continually improve the methods of working and the standards required.

- p. Staff involved in decontamination must be able to provide evidence of immunisation in line with extant guidance, including hepatitis B. Staff must be informed of the benefits, for example, protection against serious illness, protection against spreading illness, and drawbacks of vaccination, for example, reactions to the vaccine.

Note

Vaccination is considered additional to, and not a substitute for, other control measures.

- q. It is a requirement that the effective cleaning of handpieces is in accordance with manufacturers' guidance. Dedicated cleaning equipment is available and may be of value. However, validation in this area is difficult, and the advice of manufacturers/suppliers should be sought.
- r. Separate wash-hand basins for use by staff conducting decontamination should be provided in the appropriate areas. In addition, two dedicated sinks should be available for decontamination work, one for washing and cleaning of the instruments, the second for rinsing – including where an automated washer-disinfector is in use. (See note below on use of 2 bowls in single sink) These sinks *should not be used* for hand-washing.

Note

Two sinks incorporated into a single unit or, as an interim solution two bowls, are recommended because after cleaning instruments in the first sink or bowl, the operator can efficiently rinse the cleaned instruments in the second sink or bowl, at a greatly reduced risk of recontaminating the instruments with cleansing agents/detergents or previously removed biofilm.

Continual improvement plans should negate the need for bowls, replacing with dedicated sinks designed for purpose as facilities develop.

Infection prevention and control policies and procedures

- 2.5 This guidance is primarily focused on medical devices and instruments used in dentistry. However, local policies must be broad-based and consider a comprehensive view of hygiene and cleanliness across all aspects of dental practice and associated facilities.

- 2.6 All dental practices should have an infection control policy together with guidelines and procedures that contain the following information:

- a written policy with regard to minimising the risk of blood-borne virus transmission, with particular attention to the possibility of sharps injuries. The policy should include arrangements for access to occupational health advice for all staff thought to be at risk of blood-borne virus exposure. This is related to risk reduction in blood-borne virus transmission and general infection. In addition, a record of all sharps injuries must be maintained in accordance with current health and safety legislation;
- a policy on decontamination and storage of dental instruments, i.e. decontamination guidelines;
- procedures for cleaning, disinfection and sterilization of dental instruments. This should outline the approach used locally in sufficient detail as to allow the ready identification of areas and equipment used;
- a policy for the management and disposal of clinical waste (for further details see [Appendix 1](#));
- a policy for hand hygiene (see [Appendix 2](#));
- a policy for decontamination of new reusable instruments (see [paragraphs 10.24–10.30](#));
- local policies and procedures for the use of personal protective equipment (PPE);
- procedures for the management of dental instruments and associated equipment in the context of infection control;
- the recommended disinfectants to be used within the practice, their application, storage and disposal i.e. disinfectant guidelines;
- spillage procedure as part of local COSHH arrangements;
- local policies and procedures for environmental cleaning and maintenance. This should include, as a minimum, the methods used, the frequency of each procedure and appropriate record-keeping practices. Policy documents may be incorporated into one 'Standard operating policy' incorporating all decontamination policies within the practice.

- 2.7 Dental practices should be aware that Public Health Wales have developed model infection prevention and control policies that can be adopted and adapted for local use. These can be accessed at <http://www.wales.nhs.uk/sites3/page.cfm?orgid=>

379&pid=38960 (see also [Chapter 6](#), which gives general guidance on cleaning and disinfection protocols within the practice).

Use of dental instruments during and after treatment on a patient

- 2.8 The number of instruments provided for each treatment should be kept to a minimum – only those instruments that are needed should be put out on trays ready for use.
- 2.9 Care over the process of putting out instruments into trays in relation to the procedures being performed will reduce decontamination workload.
- 2.10 Regard all instruments set out for each patient as contaminated after the treatment whether or not they have been used.

Movement of instruments to and from adjacent decontamination areas

- 2.11 The object of the measures outlined below is to reduce the risk of cross-contamination between instruments.
- 2.12 The practice should have safe procedures for the transfer of contaminated items from the treatment to the decontamination area.
- 2.13 Sterilized instruments and single-use instruments should be clearly separated from those that have been used and are awaiting decontamination.
- 2.14 A clean sterilized instrument tray should be used to transfer sterilized instruments to the treatment area. These trays should be of a suitable size to enable them to be placed in the sterilizer. Alternatively, single-use disposable instrument trays may be used, provided these have been stored in a clean and dry environment.
- 2.15 Instruments for decontamination should be transferred as soon as possible after use to the decontamination area in order to avoid the risk of drying. Prompt decontamination is appropriate. Water immersion or the use of commercial gels or sprays may be considered. These measures reduce the adsorption of proteins to the instrument surfaces and makes cleaning easier.

Segregating instruments

- 2.16 Prior to cleaning, reusable instruments to be cleaned should be segregated from items for disposal.
- 2.17 A single-use device should only be used during a single treatment episode and then disposed of. It is not intended to be reprocessed and used again – even on the same patient at a later session.

- 2.18 The re-use of a single-use device has implications under the Medical Devices Regulations. Anyone who reprocesses or re-uses a device CE-marked for use on a single occasion bears the responsibilities normally carried by the manufacturer for the safety and effectiveness of the instrument.
- 2.19 The symbol that identifies single use items is shown below. This will appear on packaging but might not be present on individual items. If in doubt, further advice should be sought from the manufacturer.



- 2.20 Where instruments are difficult to clean, consideration should be given to replacing them with single-use instruments where possible. In dentistry this includes, but is not limited to, instruments such as matrix bands, saliva ejectors, aspirator tips and three-in-one tips.
- 2.21 Dentists should ensure that all endodontic reamers and files are treated as single-use – regardless of the manufacturer's designation.

Quality assurance system and audit

- 2.22 Dental practices are required to establish and operate a quality assurance system that covers the use of effective measures of decontamination and infection prevention and control. This may best be demonstrated by undertaking audits and assessments of their infection prevention and control and decontamination practices. These audits should be filed for inspection as part of their risk management system.
- 2.23 This WHTM is regarded as base line guidance and compliance with its contents is indicative of the presence of valid quality assurance systems. Audits should be carried out in compliance with individual Health Board policies. As a minimum, practices must audit their decontamination processes, with an appropriate review, and demonstrate progress against a plan for improvement.

Note

An audit tool has been developed by PGMDE, Cardiff University and is available from PGMDE as part of the CAPR process for practices providing NHS funded services. Wholly private practice can access the audit tool but will not be reimbursed (see <http://www.walesdeanery.org/index.php/en/dentistry-cpd-programmes/385-clinical-audit-a-peer-review.html>). Practices with NHS contract can contact their PGMDE Audit Tutor for further information.

- 2.24 It is important that the audits are made available to the auditing body on request and should form part of the Health Board's own risk assessment for inspection when required.
- 2.25 Audit documents should be stored for at least two years. They should not be removed from the premises or destroyed.

Taking instruments to other locations

- 2.26 The practice should have safe procedures for the transfer of contaminated items from the treatment area to the decontamination facility.
- 2.27 Transport containers should be such as to protect both the product during transit and the handler from inadvertent contamination, and therefore should be:
- leak-proof;
 - easy to clean;
 - rigid, to contain instruments, preventing them becoming a sharps hazard to anyone handling the goods and to protect them against accidental damage;
 - capable of being closed securely;
 - robust enough to prevent instruments being damaged in transit. Subject to local policy, the containers may be labelled to identify the user and/or the contents.
- 2.28 Without exception, after each use transport containers should be cleaned, disinfected and dried, ideally using a washer-disinfector, or discarded, as appropriate. If this is not possible, containers should be cleaned with a fresh detergent solution, then rinsed and dried. Bleach including hypochlorite solutions should not be used as residues may damage instruments.
- 2.29 Where contaminated instruments are to be transported outside the healthcare premises on a public highway, those responsible for such transportation should refer to the requirements of the Carriage of Dangerous Goods and Use of

Transportable Pressure Equipment Regulations and the Health and Safety at Work etc. Act.

- 2.30 A protocol for transportation that ensures the segregation of contaminated product from clean or sterilized instruments should be followed.
- 2.31 Contaminated instruments will be regarded as low biohazard materials and must be part of a noted consignment. This means recording details of the group of items transported i.e. dental instruments, the time of dispatch and the intended recipient. Records should be such as to allow each movement to be traced and audited if necessary. The consignment note should be positioned prominently within any vehicle used for transportation and should carry a contact telephone number, see the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations.
- 2.32 Where instruments travel in a vehicle with a dentist or other expert person, record-keeping may be simplified to cover the date and vehicle used only. This rule is applicable to school and domiciliary visits, for example.

Improvements to meet the standards

Improvements towards achieving **approved codes of practice in compliance with the latest standards and guidance** should include the following:

- Install a modern validated washer-disinfector of adequate capacity to remove the need for manual washing.
- Improve separation of decontamination processes from other activities and enhance the distinction of workflows of the instruments between dirty and clean.
- Provide suitable storage for instruments, which reduces exposure to air and a possible risk of microorganism contamination. **Current standards** will include the development of a local quality system focused on safe and orderly storage of instruments. This will ensure that instrument storage is well protected in the appropriate clean room or storage facility against the possibility of exposure of stored instruments to contaminated aerosols. In addition, the management approach will ensure that commonly-used instruments are dealt with on a first-in first-out principle and less frequently used instruments are stored for clear identification and reprocessed if not used within the designated storage periods.

Chapter 3 Cleaning instruments

Note

Guidance on the installation, validation, maintenance and testing of ultrasonic cleaners and washer-disinfectors can be found in [Section C](#).

Introduction

- 3.1 The principal methods of cleaning reusable dental instruments currently available are:
 - cleaning using a washer-disinfector;
 - manual combined with ultrasonic cleaning;
 - manual.
- 3.2 Effective cleaning of instruments is an essential prerequisite before sterilization and will reduce the risk of transmission of infectious agents. Wherever possible, cleaning should be undertaken using an automated and validated washer-disinfector in preference to manual cleaning, as a washer-disinfector includes a disinfection stage that renders instruments safe for handling and inspection.
- 3.3 Manual cleaning should be considered only where the manufacturer specifies that the device is not compatible with automated processes, including ultrasonic cleaning, or when the washer-disinfector is temporarily unavailable, for example, for repair or validation. Exceptionally, where local experience indicates that removal of tenacious dental materials requires manual cleaning, such action may be appropriate before automated cleaning.
- 3.4 New instruments should be cleaned and sterilized before using for the first time, unless supplied as sterile or for single use.
- 3.5 Instruments cleaned as soon as possible after use may be more easily cleaned than those left for a number of hours before reprocessing. Where this is not possible, water immersion or the use of a foam spray intended to maintain a moist or humid environment are thought useful in aiding subsequent decontamination.
- 3.6 When working with substances that can harden on instruments, for example, cements, the

instruments should be cleaned immediately. Instruments that cannot be cleaned should be discarded.

- 3.7 Where recommended by the manufacturer, instruments and equipment that consist of more than one component should be dismantled to allow each part to be adequately cleaned. Members of the dental team should be appropriately trained to ensure competence in dismantling, cleaning, sterilizing and reassembling of instruments. Amalgam carriers are an example of instruments requiring this approach.

General requirements for cleaning methods

- 3.8 Where possible, refer to manufacturers' instructions relating to instruments, dental equipment, cleaning devices and cleaning solutions.
- 3.9 Whenever possible, cleaning should be undertaken using an automated and validated process in preference to manual cleaning. Manual cleaning should be considered where manufacturer's instructions specify that the device is not compatible with automated processes.
- 3.10 Ensure that instruments can be cleaned using a method available to the practice.
- 3.11 Validation is the means by which an entire process is verified, tested and documented, with the ability to be consistently reproducible. Ensure that ultrasonic and washer-disinfector cleaning procedures used in the practice are validated. This will demonstrate that all instruments and equipment cleaned by these methods are reliably and consistently cleaned using predetermined and reproducible conditions.
- 3.12 Technical details for validation standards and procedures are provided in [Section C](#). The assistance of decontamination specialists will be necessary from time to time in order to ensure that equipment and procedures remain valid in engineering terms. These services may be available

through the local Health Board, NWSSP-FS or as part of a commercial package.

Automated cleaning: washer-disinfectors

3.13 Each stage of the decontamination process should contribute to the reduction of bioburden on the device being reprocessed. Using a washer-disinfector is preferred for cleaning dental instruments because it offers the best option for the control and reproducibility of cleaning; in addition, the cleaning process can be validated under ENs.

Note

The installation and plumbing of washer/disinfectors must comply with the requirements of the Water Supply (Water fittings) Regulations, see also the Water Regulations Advisory Scheme www.wras.co.uk.

3.14 Washer-disinfectors are used to carry out the processes of cleaning and disinfection consecutively in an automated cycle. A typical washer-disinfector cycle for instruments includes the following five stages:

- **Flush** – removes “difficult” gross contamination, including blood, tissue debris, bone fragments and other fluid and solid debris. The latest standards indicate that a water temperature of less than 45°C prevents protein coagulation and fixing of soil to the instrument.
- **Wash** – removes any remaining soil. Mechanical and chemical processes loosen and break up contamination adhering to the instrument surface. Detergents used in this process must be specified by the manufacturer as suitable for use in a washer-disinfector. They should also be compatible with the instruments being processed and supplied so as to perform correctly and avoid instrument degradation including discoloration, staining, corrosion and pitting.
- **Rinse** – removes detergent used during the cleaning process. This stage can contain several sub-stages. The quality of the water used for this stage is an important consideration in ensuring a clean, unmarked product after sterilization. Good quality potable water direct from the mains supply exhibits satisfactory low endotoxin levels which are unlikely to harm health in this application. However, where the local potable water is unsatisfactory for processing, not compatible with process

chemicals or spotting is observed on instruments, then final stage purification systems should be considered to improve the process, e.g. high level filtration, RO. Note: Advice on consistency of potable water supplied can be sought from local supplier, e.g. Welsh Water.

- **Thermal disinfection** – the temperature of the load is raised and held at the pre-set disinfection temperature for the required disinfection holding time, for example, 80°C for 10 minutes; or for 90°C for 1 minute.
- **Drying** – Purges the load and chamber with heated air to remove residual moisture.



Using a washer-disinfector is the preferred method for cleaning dental instruments because it offers the best option for the control and reproducibility of cleaning.

Note

Some systems with a water capacity and delivery rate specially suited for use in this and other dental applications are available. The supply arrangements will frequently include a comprehensive package so that water is supplied as a service.

Using a washer-disinfector

- 3.15 For details of all operational aspects of using a washer-disinfector, follow the manufacturer's instructions. This will include details of both the water quality/type to be used and directions on the detergents and/or disinfectants recommended for use with the device. These instructions form part of the EN requirements for CE marking and are considered to be part of the regulated product.
- 3.16 Ensure that staff are trained in the correct operation of a washer-disinfector, including how to perform daily tests and housekeeping tasks. Records of training and the achievements of staff should be maintained (see [Section C](#)).

- 3.17 It is crucial to load a washer-disinfector correctly, as incorrectly loaded instruments will not be cleaned effectively. Therefore, follow an instrument-loading procedure that has been shown to achieve effective cleaning in the washer-disinfector used in the practice. To do this:
- do not overload instrument carriers or overlap instruments;
 - open instrument hinges and joints fully;
 - attach instruments that require irrigation to the irrigation system correctly, ensuring filters are in place if required, for example, for handpieces if specified by the manufacturer.
- 3.18 After cleaning, inspect instruments for cleanliness and check for any wear or damage before sterilization. The use of a simple magnifying device with task lighting will improve the value of this part of the process. The satisfactory completion of this step means that these instruments may be clearly designated as ready for sterilization.

Records

- 3.19 Washer-disinfector logbooks and records should be kept by the designated “user”, an identified member of the practice staff. Cycle parameters should be recorded together with details of routine testing and maintenance of the equipment used. The use of automated data-loggers or interfaced small computer-based recording systems is acceptable, provided the records are kept securely and replicated. It is recommended that records be maintained for not less than two years.

Considerations for cleaning handpieces

- 3.20 Check with the handpiece manufacturer that a washer-disinfector can be used to clean them.
- 3.21 Certain types of washer-disinfector can be adapted to clean handpieces, and these can be validated independently as being effective.
- 3.22 Where a handpiece manufacturer does not recommend a washer-disinfector for cleaning them, use of a dedicated handpiece-cleaning machine may be considered. This uses a pressurised system to clean and lubricate handpieces. However, unlike a washer-disinfector, it does not disinfect.
- 3.23 Always consult the washer-disinfector manufacturer for operating details (for example, whether filters are required) and running costs before purchase.
- 3.24 Washer-disinfectors might remove all lubricants during the cleaning cycle; therefore, handpieces might require further lubrication after cleaning.

Follow the handpiece manufacturer’s recommendations for lubrication (see also [paragraphs 3.55–3.57](#) and [Chapter 18](#) in Section C).

Note

1. Some washer-disinfectors that have a handpiece irrigation system require that a special filter be fitted to protect the internal mechanism of the handpiece from extraneous debris during the operating cycle. These filters need to be replaced at regular intervals in accordance with the manufacturer’s instructions.
2. There are certain commercial products that claim to be able to sterilize as well as wash and disinfect dental handpieces. Please seek advice from NWSSP-FS or your local infection prevention and control team.

Automated cleaning: ultrasonic cleaning

- 3.25 Evidence on the effectiveness of ultrasonic cleaning gives support to its use in dentistry. However, it is important to ensure that the water or fluid is maintained, cleaned and changed at suitable intervals (see [paragraph 3.30\(j\)](#)). The ultrasonic bath should also be kept free of dirt released in the cleaning process. Good maintenance is also essential. The appearance of instruments following ultrasonic cleaning should be checked to ensure that the process is operating effectively (see also [Section C](#)).
- 3.26 Ultrasonic cleaning in a well-maintained machine enhances removal of debris. Thus, although a washer-disinfector is preferred and should be incorporated into new plans or upgrades, an ultrasonic cleaner can be used as a cleaning method, including being used as an extra cleaning stage prior to an automated washer-disinfector process, i.e. a pre-cleaning process. This may be particularly helpful for instruments with hinges or intricate parts. When using these baths, it is essential that the water is changed frequently (see [paragraph 3.30](#)).
- 3.27 To enable consistent cleaning of instruments, follow the manufacturer’s operating instructions and ensure that all staff use a specified and documented operating procedure. Details on validating ultrasonic cleaners are supplied in [Section C](#).
- 3.28 The use of ultrasonic cleaners to clean dental handpieces should not be undertaken without confirmation from the manufacturer that the devices are compatible.

- 3.29 The ultrasonic cleaner should be tested quarterly to ensure that it is fully functional and operates in accordance with the manufacturer's specification (see **Section C**).

Ultrasonic cleaning procedure

- 3.30 The following procedures should be followed:

- a. Instruments should be briefly immersed in cold water, with detergent, to remove some of the blood and other visible soil before ultrasonic cleaning. Care should be taken to minimise aerosol production in this process and to safeguard against inoculation injury. The use of a purpose-designed container with sealing lid is recommended.
- b. Follow the manufacturer's recommendations for the safe operating procedure of the ultrasonic cleaner and follow the points outlined below regarding loading and unloading the cleaner.
- c. Ensure that joints or hinges are opened fully and **instruments that need taking apart are fully disassembled before they are immersed in the solution.**
- d. Place instruments in a suspended basket and fully immerse in the cleaning solution, ensuring that all surfaces are in contact with the solution. The solution should be made up in accordance with the manufacturers' instructions.
- e. Do not overload the basket or overlap instruments because this results in poor cleaning and can cause wear to the instruments.
- f. Do not place instruments on the floor of the ultrasonic cleaner because this results in poor cleaning and excessive instrument movement, which can damage the instruments.
- g. To avoid damage to delicate instruments, a modified basket or tray system might also be necessary depending on operational requirements.
- h. Set the timer to the correct setting according to the ultrasonic cleaner manufacturer's instructions. Close the lid and do not open it until the cycle is complete.
- i. After the cycle is complete, drain the basket of instruments before rinsing.
- j. Change the solution either when it becomes heavily contaminated or at the end of every clinical session, because the build-up of debris will reduce the effectiveness of cleaning and

could be a source of cross contamination.

Ensure that staff are aware of the need to assess when a change of solution is necessary as advised in the operational requirements.

- k. After ultrasonic cleaning, rinse and inspect instruments for cleanliness, and, where possible, check for any wear or damage before placing in the washer-disinfector and sterilizer.
- 3.31 Instruments cleaned in an ultrasonic cleaner or by hand should be rinsed thoroughly to remove residual soil and detergents. A dedicated sink or bowl, separate from the one used for the original wash, should be used and the instruments immersed in satisfactory potable water or, where this is not available, in RO or freshly distilled water. Wash-hand basins should not be used. This step may be omitted if the local policy and procedure involves the use of a washer-disinfector as the next stage in the decontamination process. Note: Advice on potable water supplied can be sought from local supplier.

Note

Hard-water contamination of wet instruments, which then go on to sterilization, can compromise the proper function of a small steam sterilizer. Rinsing satisfactory, soft, potable water or other purified source will be necessary as a precaution. When potable water is used, a water softener maybe needed. Consult the local water advisor at not less than annual intervals.

- 3.32 Instruments should be sterilized as soon as possible after cleaning to avoid air-drying, which can result in corrosion and microbial growth. Instruments processed in a vacuum steriliser should be dried using a disposable non-linting cloth before being wrapped.

Manual cleaning

- 3.33 In principle, manual cleaning is the simplest method to set up, but it is difficult to validate because it is not easy to ensure that it is carried out effectively on each occasion.
- 3.34 Compared with other cleaning methods, manual cleaning presents a greater risk of inoculation injury to staff. However, despite the limitations of manual cleaning, it is important for each practice to have the facilities, documented procedures and trained staff to carry out manual cleaning as a backup for when other methods are not appropriate.
- 3.35 For dental services that are working towards the requirements outlined in this document, manual

cleaning should only be used for equipment that cannot be cleaned by automated methods.

- 3.36 This method should have systems in place to avoid recontamination of clean instruments.
- 3.37 An effective system for manual cleaning should be put in place, as outlined in **Section C**, and all staff should follow an agreed written procedure. A visual inspection for cleanliness, wear and damage should be carried out.
- 3.38 Consider routinely using an automated method, such as the recommended washer-disinfector, and aim to phase in instruments that are suitable for cleaning in this way.

Avoiding instrument damage

- 3.39 Most dental instruments are made of high-quality materials designed to minimise corrosion if reprocessed correctly. The corrosion resistance is based on their alloy composition and structure, which forms a protective passivation layer on the surface. The ability of the instruments to resist corrosion depends on the quality and thickness of this layer.
- 3.40 It is important to avoid damage to the passivation layer during cleaning. Accordingly, methods such as the use of wire brushes, which may give rise to surface abrasion, should be avoided.
- 3.41 Any instruments that have rust spots should be removed.

Cleaning procedure summary

- 3.42 Effective cleaning of dental instruments before sterilization is of the utmost importance to reduce the risk of transmission of infectious agents.
- 3.43 Research suggests that instruments cleaned as soon as possible after use are more easily cleaned than those left for a number of hours before reprocessing.
- 3.44 Instruments should be transferred from the point of use to the decontamination areas as soon as practical to ensure they are processed as soon as possible after use. Gathering evidence indicates that keeping instruments moist after use and prior to decontamination improves protein removal and overall decontamination outcomes.
- 3.45 It should be noted that certain solutions are corrosive to stainless steel instruments and will cause pitting and then rusting if allowed to remain for any length of time. Dental professionals should consult with the suppliers and manufacturers of decontamination agents to ensure that the products used are appropriate and unlikely to

cause significant long-term corrosion (refer to COSHH regulations for further advice).

- 3.46 Always check packaging for the single-use symbol before use and note that it might be difficult to see (see also **paragraphs 2.17–2.21**).

Rinsing of instruments after cleaning and/or disinfection

- 3.47 Instruments cleaned in an ultrasonic cleaner or manually should be rinsed thoroughly in a dedicated sink or bowl, separate from the one used for the original wash, using satisfactory potable water, high level filtration systems or other method of purifying the supply in order to remove residual soil and detergents with minimum risk of salt deposition.

Note

This step may be omitted if the local policy and procedure involves the use of a washer-disinfector as the next stage in the decontamination process.

- 3.48 Instruments should be sterilized as soon as possible after cleaning to avoid air-drying which can result in corrosion and/or microbial growth. However, where instruments are to be wrapped prior to vacuum sterilization, the instruments should be dried using non-linting cloth.

Inspection and care of instruments before sterilizing

- 3.49 All instruments that have been through any cleaning procedure, including processing by a washer-disinfector, should be inspected to ensure they are clean, functional and in good condition.
- 3.50 Any instruments that are blunt, bent or damaged or show any signs of pitting or other corrosion should be discarded. An illuminated magnifier is recommended because it makes it much easier to see residual contamination, debris or damage.
- 3.51 Dental staff should ensure that:
- there is free movement of all parts and that joints do not stick;
 - the edges of clamping instruments meet with no overlap and that teeth mesh together;
 - scissor edges meet to the tip and move freely across each other with no overlap or burrs (rough edges);
 - all screws on jointed instruments are tight and have not become loose during use.

- 3.52 Instruments should be inspected for any visible soiling such as blood or dental materials. It is especially important to check joints, hinges or the serrated surfaces of jaws, which are difficult to clean. If there is any residual contamination, the instrument should be rejected and should undergo another cycle of the cleaning process.
- 3.53 Occasional use of a lubricant may be required where hinged instruments are found to be stiff. A non-oil-based lubricant should be used to avoid it interfering with the sterilization process, that is, preventing the steam coming into contact with the instrument surface.
- 3.54 Instruments may become damaged during use or suffer from general wear and tear over their lifespan. If devices are found to be faulty or damaged during inspection and function-testing, or if users identify that they are faulty, they should be taken out of use and either repaired or replaced. Instruments for repair should be decontaminated, labelled to identify they have been through the decontamination process and then returned to either the manufacturer or a reputable repair company.

Handpiece care

- 3.55 Handpieces should be lubricated according to the manufacturer's instructions. Those that have been processed in a washer-disinfector might have had the lubricant removed and require lubrication again before going into the sterilizer.
- 3.56 A separate canister of lubricant should be used for cleaned instruments. The canisters should be labelled so that it is clear which canister is used for unclean instruments and which is used for instruments that have been cleaned in a washer-disinfector. Another canister for use with handpieces after sterilization might be required if the manufacturer recommends it.
- 3.57 Inadequate lubrication can lead to unnecessary damage to the internal mechanism.

Chapter 4 Sterilization

Guidance on the installation, validation, maintenance and testing of sterilizers can be found in [Section C](#).

4.1 This chapter should be read in conjunction with [Section A](#).

Types of sterilizer

- 4.2 Saturated steam under pressure delivered at the highest temperature compatible with the product is the preferred method for the sterilization of most instruments used in the clinical setting.
- 4.3 To facilitate sterilization, load items should first be thoroughly cleaned (and disinfected where a washer-disinfector has been used). In the case of newer machines, the parameters monitored for each cycle of use will be stored and/or available as a print-out to provide a short-term record. The use of automated dataloggers or interfaced small computer-based recording systems is acceptable provided the records are kept securely on a reliable network and replicated. These records should be photocopied, as the quality of the print-out fades over time. Manual recording using a logbook is also acceptable and, in any case, will be a necessity if a machine does not have any automatic print-out function (see [paragraph 4.16](#) for further details on manual recording). The record should, as a minimum, document the absence of a failure warning or the temperature and pressure achieved, as appropriate to the indications provided. Records are required for every sterilization cycle. It is recommended that records be maintained for not less than two years.
- 4.4 It is likely that steam sterilizers used in dental practices will have a chamber volume of less than 60 L and thus be considered to be small devices within the standards applied by national and international bodies.
- 4.5 Standards describe three types of small sterilizer used within the healthcare setting:
- Type N: air removal in type N sterilizers is achieved by passive displacement with steam. They are non-vacuum sterilizers designed for



Sterilization process data can be recorded by an automatic printer.

non-wrapped solid instruments. These sterilizers are not designed for reprocessing instruments with a lumen.

- Type B (vacuum): type B sterilizers incorporate a vacuum stage and are designed to reprocess load types such as hollow, air-retentive and packaged loads. A number of different cycles may be provided. Each cycle should be fully validated and used in accordance with instructions provided by both the sterilizer and the instrument manufacturer. Users should be aware that Type B benchtop sterilizers can incur financial implications in comparison with a Type N design, as the technical nature of design will require additional maintenance, and also require an in-depth validation regime in accordance with current guidance to include regular steam penetration and air testing.



Sterilization process data should be recorded for each cycle by an automatic printer.

- Type S: these sterilizers are specially designed to reprocess specific load types. The manufacturer of the sterilizer will define exactly which load, or instrument, types are compatible. These sterilizers should be used strictly in accordance with these instructions.

Advice can be sought from NWSSP-FS.

Types B and N are most frequently used in dental practices.

Where a sterilizer is installed with multiple cycle options it is important to note that all the cycles configured within the control memory requires periodic validation to current guidance. If there are cycle options that are configured and not used, they should be deleted or disabled to prevent unauthorized use. Single cycle options are preferred where bench top sterilizers are used.

Note

All cycles to be used on the sterilizer must be validated and periodically tested, with written reports and charts for audit.

- 4.6 In each case, practice staff should consult with the manufacturer and supplier of the sterilizer to ascertain the status of the machine in respect of validation and verification and the recording of parameters achieved during sterilization cycles.

Dental handpieces

- 4.7 Dental handpieces are constructed with a number of internal channels and pathways. These features are often difficult to clean, although the use of a validated automated washer-disinfector may be successful provided that handpiece and washer-disinfector are of known compatibility. Where this is established, sterilization using a type B or type S sterilizer is likely to be useful, although it should be accepted that it is unlikely that sterility will be achieved, whatever sterilizer is used, due to the presence of lubricating materials.
- 4.8 If no validated and compatible washer-disinfector is available, steam sterilization will still be of value in generating a reduction in contamination levels and bioburden.

Small sterilizers

- 4.9 Small sterilizers should be operated to ensure that:
- they are compliant with the safety requirements stated in this guidance and in the manufacturer's notes;
 - they are installed, commissioned, validated and maintained appropriately in compliance with the manufacturer's instructions (see [Section C](#));
 - they are operated in accordance with the equipment manufacturer's instructions.
- 4.10 Where sterilization equipment has been used for significant periods, water quality can influence calcification build up. Under these circumstances, the machine should be inspected by an engineer or returned to the supplier or manufacturer for refurbishment.
- 4.11 Users should be aware of this cautionary note relating to the improper use of small sterilizers:

Note

Pre-wrap instruments only where this is recommended by the manufacturer and where the sterilizer is vacuum-assisted. The sterilizer should be validated for the intended load and is likely to be of type B or S. **The use of a type N sterilizer is not appropriate for wrapped instruments.**

- 4.12 All steam sterilizers are subject to the Pressure Systems Safety Regulations and must be examined periodically by a Competent Person (Pressure Vessels).

Use and testing of small sterilizers

- 4.13 To ensure the safety of this device, the following points should be adhered to:
1. Each sterilizer will have a reservoir chamber from which the water is delivered for steam generation; this should be filled daily using water of a suitable quality. A practical approach should be adopted using good operational practice as with previous healthcare guidance, e.g. WHTM 01-01 Parts A, B and C. The use of 'water for irrigation' is used to meet the requirements for 'clean steam'. Sterile water for irrigation is nonpyrogenic distilled water that has been sterilized. It has an endotoxin level less than 0.25Eu/ml and is readily available from pharmacies for bulk supply. Alternative water supplies can be RO if there is a problem sourcing water of the required standard (see [Chapter 17](#) for further guidance). The use of water for irrigation is preferable to distilled water as the quality of distilled water cannot be guaranteed. At the end of the day or whenever

the sterilizer is to be unused for several hours, the chamber should be drained after the water has cooled and all internal surfaces that are accessible should be rinsed with suitable quality water, dried and left empty with the door kept open. For single-shot types, which do not store water between cycles of use, these rules still apply in terms of the water quality to be used. When the sterilizer reservoir is to be replenished, it should be refilled with suitable water quality to the level recommended by the manufacturer.

2. Validation is necessary to demonstrate that the physical conditions required for sterilization (temperature, pressure and time) are achieved. Consultation with appropriately qualified engineers through the Health Board or commercial arrangements will be necessary in this area. A CP(D) or service engineer will be able to ensure that validation is achieved and that the instrumentation used for parametric release is functioning and calibrated appropriately. The CP(D) or service engineer will be needed to validate or revalidate the equipment (see [Section C](#)).

Parametric release is defined as the release of a batch of sterilized items based on data from the sterilization process. All parameters within the process have to be met before the batch can be released for use.

3. Testing is an integral part of ensuring that a small sterilizer consistently performs to operating parameters set during the machine's commissioning. Failure to carry out routine periodic tests and maintenance tasks could compromise safety and have legal and insurance-related implications for the Registered Manager (see [paragraph 9.3](#)).
 4. A schedule for periodic testing should therefore be planned and performed in accordance with [Section C](#). The schedule should provide details of daily, quarterly and yearly testing or be in accordance with manufacturers' guidelines. Each sterilizer should have a logbook in which details of the following are recorded:
 - maintenance;
 - validation;
 - faults;
 - modifications;
 - routine tests (see [Appendix 3](#)).
- 4.14 Every organisation **must** have a records management policy which is promulgated throughout the organisation and of which all staff are aware. Equally important are the adoption of

retention and disposal schedules which give clear guidance on how long records, including Health Records, should be maintained. The requirements for NHS Wales are set out in WHC (2000)71. More recent guidance for the Department of Health England is available at <http://www.gov.uk/government/publications/records-management-nhs-code-of-practice>.

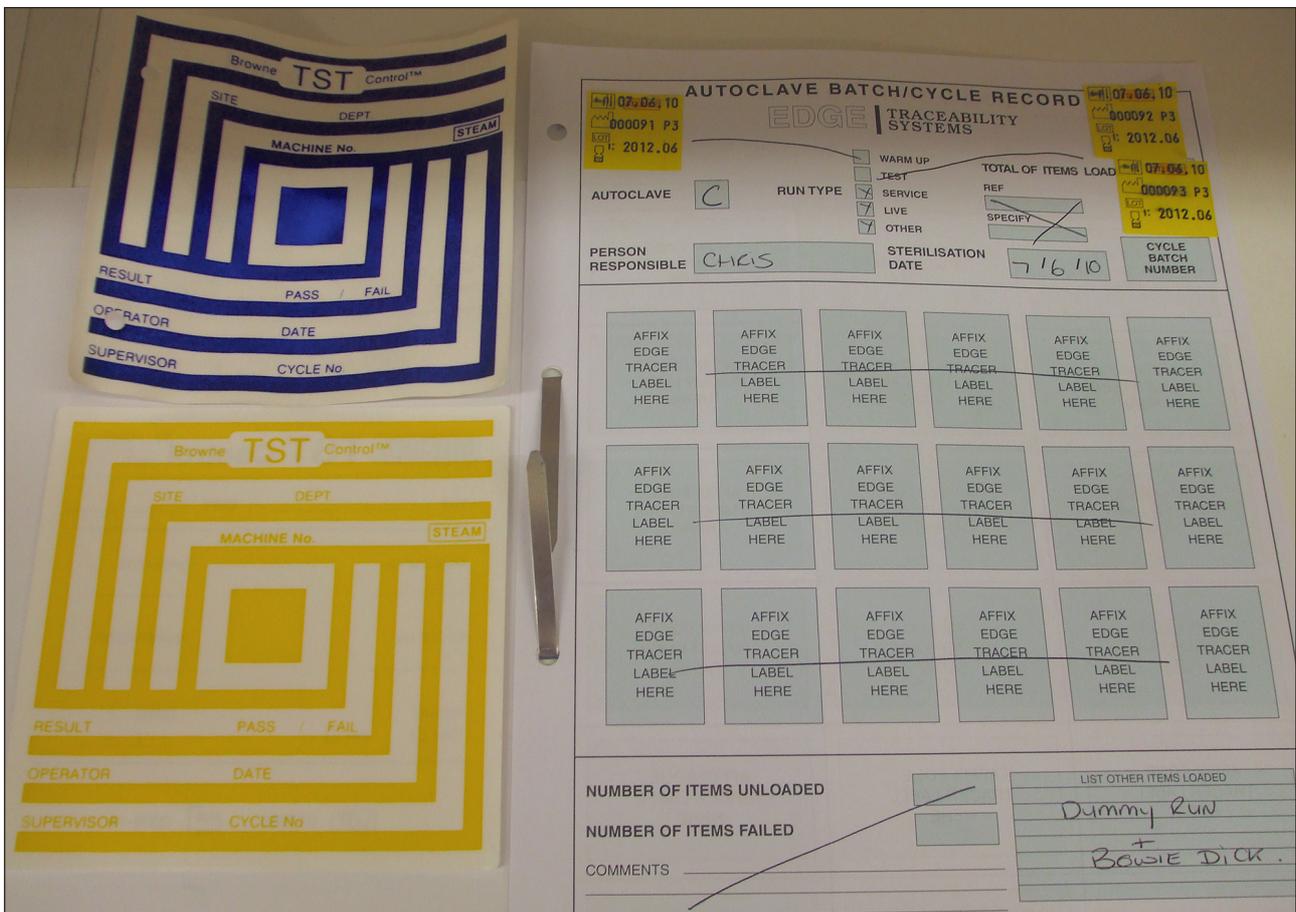
- 4.15 The logbook should contain all information pertaining to the lifecycle of the equipment, from purchasing through to disposal.
- 4.16 If the sterilizer has an automatic printer, the printout should be retained or copied to a permanent record. If the sterilizer does not have a printer, the user will have to manually record the following information in the process log:
- date;
 - satisfactory completion of the cycle (absence of fault recognition indicator);
 - temperature/pressure achieved;
 - signature of the operator.

It is a recommendation that, where possible, sterilizers are upgraded to include printers or data-

recording devices to provide automated methods of recording the sterilization process.

Daily testing and housekeeping tasks

- 4.17 Some small sterilizers require a warm-up cycle before instruments can be processed. The manufacturer's instruction manual should be consulted to find out whether this is the case.
- 4.18 The daily tests should be performed by the operator or user and will normally consist of:
- a steam penetration test – Helix or Bowie and Dick tests for vacuum sterilizers only;
 - an automatic control test for all small sterilizers in line with manufacturers' instructions;
 - a record of temperature and pressure achieved at the daily test, to ensure this is satisfactory before the autoclave is used for sterilization of instruments.
- 4.19 These outcomes should be recorded in the logbook together with the date and signature of the operator.
- 4.20 The tests may be carried out at the same time.



The outcomes of daily tests should be recorded in the logbook.

- 4.21 Sterilizers should not be used until the daily tests and housekeeping tasks have been carried out and the results found to be satisfactory.
- 4.22 Before carrying out the daily tests, the user should:
- clean the rubber door seal with a clean, damp, non-linting cloth;
 - check the chamber and shelves for cleanliness and debris;
 - fill the reservoir with water of a suitable quality (e.g. water for irrigation) or RO if no alternative is available (see [paragraph 4.13](#));
 - turn the power source on.
- 4.23 If the sterilizer fails to meet any of the test requirements, it should be withdrawn from service and advice should be sought from the manufacturer or maintenance contractor. Any instruments processed in an unsuccessful cycle should not be used.

Packaging and related decontamination strategy

- 4.24 There are three combinations of steam-sterilization and instrument-wrapping strategies that can be used within dental practices:
- a. With a type B vacuum steam sterilizer, instruments will be pre-wrapped using purpose-designed materials that are compatible with the sterilizer. With a type S sterilizer, instruments may be placed in purpose designed cassettes. In both cases, instruments should be dry before they are placed in the purpose-designed packaging. Wrapping should take place with a dry product shortly after washing and disinfection. Once the wrapped instruments have been sterilized satisfactorily, the product may be stored for up to one year (see section B [paragraph 2.4](#)).
 - b. With a displacement steam sterilizer (type N), the instruments will not be wrapped prior to sterilization. Immediately after removal from the sterilizer, instruments may be wrapped using suitable sealed view-packs. Instruments should be dry before being packed. In addition, the entire tray may be placed within a sealed pack for storage purposes. In both of these instances, storage for up to 1 year is possible although the one month rule is a safer option unless the practice has carried out a full risk assessment and written policy.
 - c. Products from a type N sterilizer may also be transferred for use within the current session. In this instance, while covering the instruments is essential to protect against dust

and aerosols, wrapping is not required. However, the instruments are not regarded as “stored” and should therefore be used or streamed for a further decontamination process within one session. Instruments should be dry before being transferred for clinical use.

Note

BS EN ISO 11607-1 Annex A provides a useful summary of “sterile barrier systems”. In practice, these are sealable trays or wrappings, which may be of value in dental practices. In summary, the systems referred to are:

- a. Flexible peel pouch (sealed view pack). This is typically supplied sealed on three sides with the remaining side open for the insertion of dental instruments. This packaging, subject to manufacturers’ advice, may be used to post-wrap instruments after steam sterilization in order to protect against recontamination.
- b. Pre-formed rigid tray with die-cut lid. The lid may be permeable or impermeable. These trays are potentially suitable for use with displacement or vacuum sterilizers. Subject to manufacturers’ instructions, the trays may be used to contain dental instruments during the sterilization process and in subsequent storage.
- c. Sterilization bag. This is constructed from porous medical paper and sealed before sterilization of the contents. The bag is essentially designed for use with vacuum sterilizers.
- d. Header bag. This is manufactured as a sealed bag with a heat-sealed permeable closure, which can be peeled off. This type is suitable for storage of larger items.
- e. In larger-scale operations, automated systems such as form/fill/seal (FFS) or four-side-sealing products may also be used. The choice of system used will depend on the decontamination, sterilization and storage options chosen by the practice. The manufacturers of each of the products should be consulted on the standards applied and compatibility with the other products employed.

BS EN ISO 11607-2: Sets out the validation requirements for forming, sealing and assembly processes.

It is important that a risk assessment should be carried out in accordance with BS EN ISO 14971 ‘Application of risk management to medical devices’ to identify any hazards associated with the medical devices being sterilized and the ongoing storage thereafter. If carried out correctly a number of hazards could be identified, i.e. staff training, storage, validation of the equipment, etc. which may require the Dentists to investigate using an accredited Sterile Services Unit for their reprocessing.

- 4.25 In all three cases, if the instruments are damp, they should be dried using disposable non-linting cloths and be appropriately handled. It is essential to ensure that the cloth is adequately dry and free from contamination. Accordingly, the cloth should be disposed of after each sterilizer load.
- 4.26 Regardless of the packaging used, where instruments are to be stored, the date by which they should be used or by which they are subject to a further decontamination cycle should be clearly indicated on the packaging.

Storage of sterilized instruments/ devices

- 4.27 Regardless of the approach described above, it is essential that stored instruments are protected against the possibility of recontamination by pathogens. A barrier should therefore be maintained between the instruments and the general practice environment. This may be achieved by ensuring that instruments are stored in an environment where they are protected against excessive heat and where conditions remain dry.
- 4.28 There should be control of storage of wrapped instruments, including maintenance of records, clear identification of content of instruments packs, if not visible and storage times. For the majority of commonly-used instruments, a first-in first-out principle will be helpful.

Note

Where packs are non-transparent, it may be useful to use a simple coded label to indicate the contents.

- 4.29 As a general rule:
- The storage of reprocessed surgical instruments should ensure restraint of recolonisation. This will often mean protection against aerosols and sundry contact with other equipment. The area in which the packaging of sterilized instruments, that is, those reprocessed in a type N sterilizer, takes place should be an open bench area. It should be kept free of clutter and wiped clean by the use of detergent or antimicrobial wipes at sessional intervals.
 - The storage area should be dedicated for the purpose. It is recognised that some practice arrangements will involve storage of instruments within rooms that are also used for

clinical work. In meeting the **requirements of this document**, this will require that the instruments be as far from the dental chair as reasonably practicable. Where practical, instruments not scheduled for use with the current patient should be stored in a separate environment, ideally in the clean area of the separate decontamination room. Where instruments need to be stored within the clinical area, the use of a purpose-designed storage cabinet that can be easily cleaned will be required.

- The storage area should be appropriately designed to prevent damage to instruments and to allow for the strict rotation of stocks.
 - Cupboards should be capable of being easily cleaned and used in conjunction with sealed view-packs or covered or sealed trays.
 - Products should be stored above floor level away from direct sunlight and water in a secure, dry and cool environment.
 - Although air movement is often difficult to control in non-purpose-designed premises, whenever possible, airflow should be from the clean to dirty areas.
- 4.30 Before being used, the instruments should be checked to ensure that:
- if packed, including the use of view-packs, the packaging is intact;
 - the sterilization indicator confirms that the pack has been subjected to an appropriate sterilization process, if a type B sterilizer is used;
 - if a covered container is used, the instruments have remained covered;
 - visible contamination is absent; this is to comply with BS EN Standards.
- 4.31 It is a requirement that the practice has a strict policy on the reprocessing of unused instruments in line with the statements given in 2.4 k and the note on wrapping. The Department of Health in England have stated the one year rule for both Type B, S and N sterilizers. In Wales the previous guidance was one calendar month for type N sterilizers. The one month rule is a safer option unless the practice has carried out a full risk assessment and written policy.

Chapter 5 Setting up a decontamination area

- 5.1 There is a clear need to maximise the separation of decontamination work from clinical activity within the constraints of space and room availability. Where instruments are reprocessed in the same room as the patient treatment area, the reprocessing area should be as far from the dental chair as practicality allows. Dental practices should make every practical effort to progress towards higher standards, removing the decontamination process from the treatment room. For example layouts, see **Figures 1–3**.
- 5.2 If decontamination has to be carried out in a patient treatment room, to minimise the risks both to the patient and of cross-contamination of

instruments, appropriate controls should be in place. Uncontrolled procedures that generate the risk of exposure to aerosol dispersion or splashes, such as manual washing, the use of an ultrasonic cleaner without a sealed chamber or lid or the opening of decontamination equipment, should NOT take place while the patient is present.

- 5.3 Regardless of the choice of location used for the reprocessing facilities, a dirty-to-clean workflow should be maintained so that used instruments are at a lower risk of coming into contact with decontaminated instruments. This requires a well developed routine for surface cleaning and decontamination within the facilities:

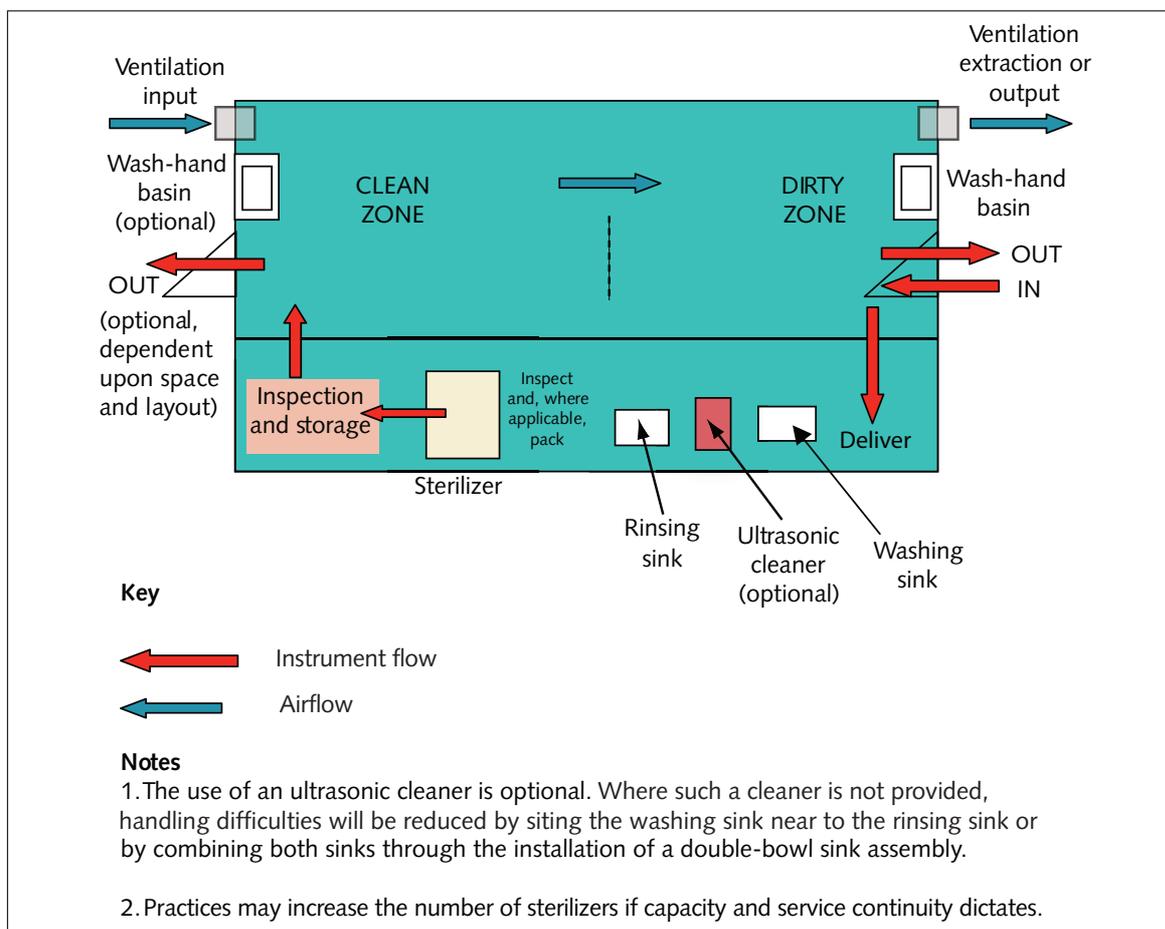


Figure 1: Example layout of facility for basic decontamination requirements

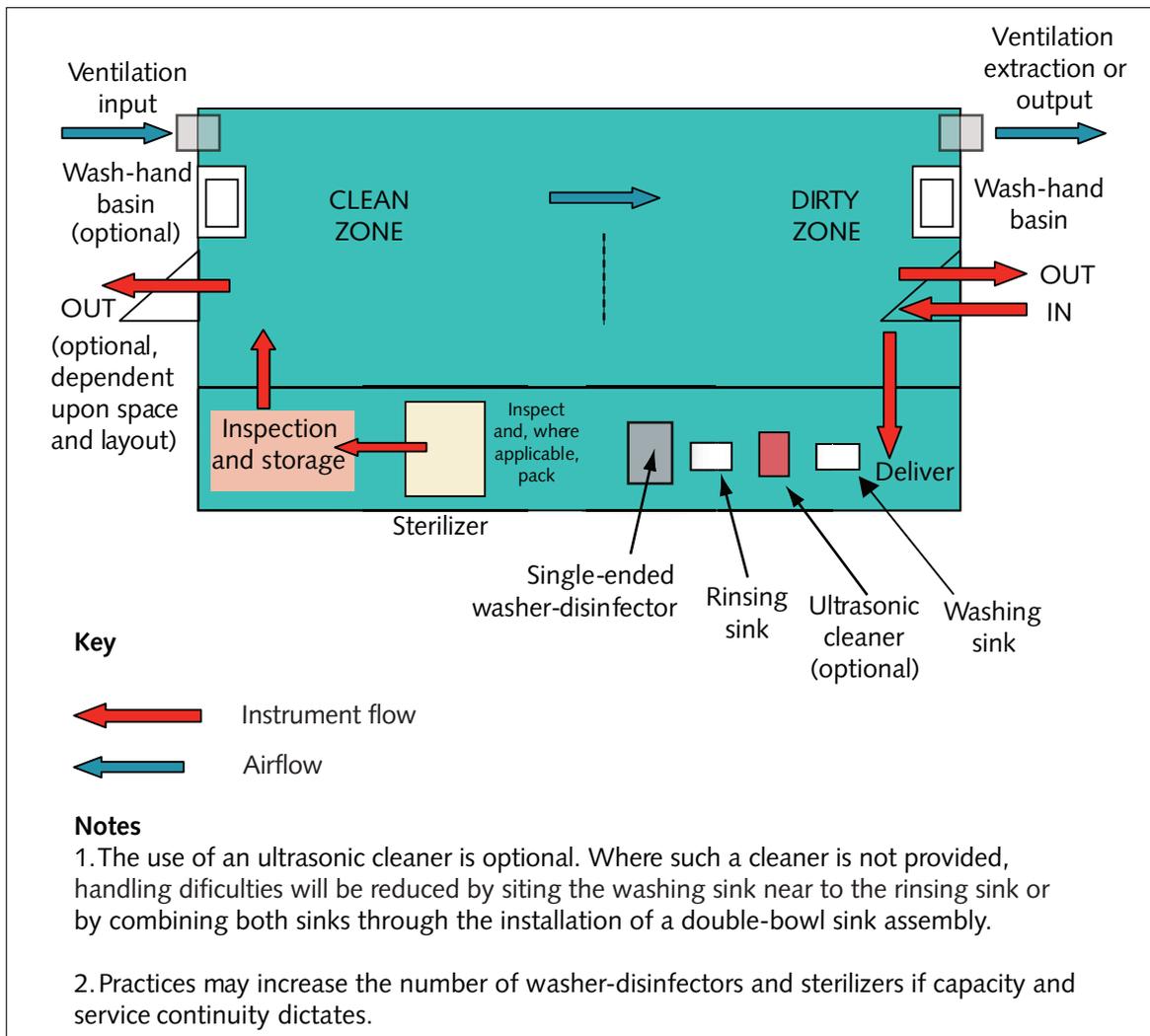


Figure 2: Example layout for single decontamination rooms

- the decontamination area should be wiped down carefully after each decontamination cycle is completed;
- for clinical areas, a similar wipe-clean is required after each patient procedure and before the next patient is admitted. Procedures for the wipe-down processes are described in [Chapter 6](#).

- 5.4 Where a dedicated decontamination area has been developed, separated from the patient treatment area in another room or rooms, enhanced dirty-clean separation should be a priority in design and operation.
- 5.5 When setting up new premises or planning significant modification to existing premises, the separation of the decontamination area from the clinical area is recommended. The provision of two separate rooms is the preferred option as it provides for a higher degree of separation between

dirty instruments awaiting decontamination and cleaned or sterilized instruments that are to be placed in trays, packs or containers for use:

- one room for dirty activity (cleaning and preliminary inspection of instruments); and
- one room for clean activity (inspection, sterilization and wrapping instruments).

The clear intention is to reduce the risk and extent of recontamination as well as providing for a very clear operational distinction between clean and dirty.

Note

The final design of any decontamination room or rooms must be clearly risk assessed and investigated by a consultation process to ensure the correct facility is built specifically for the needs of that practice and meets the requirements of this document. The main factors that will need to be included are

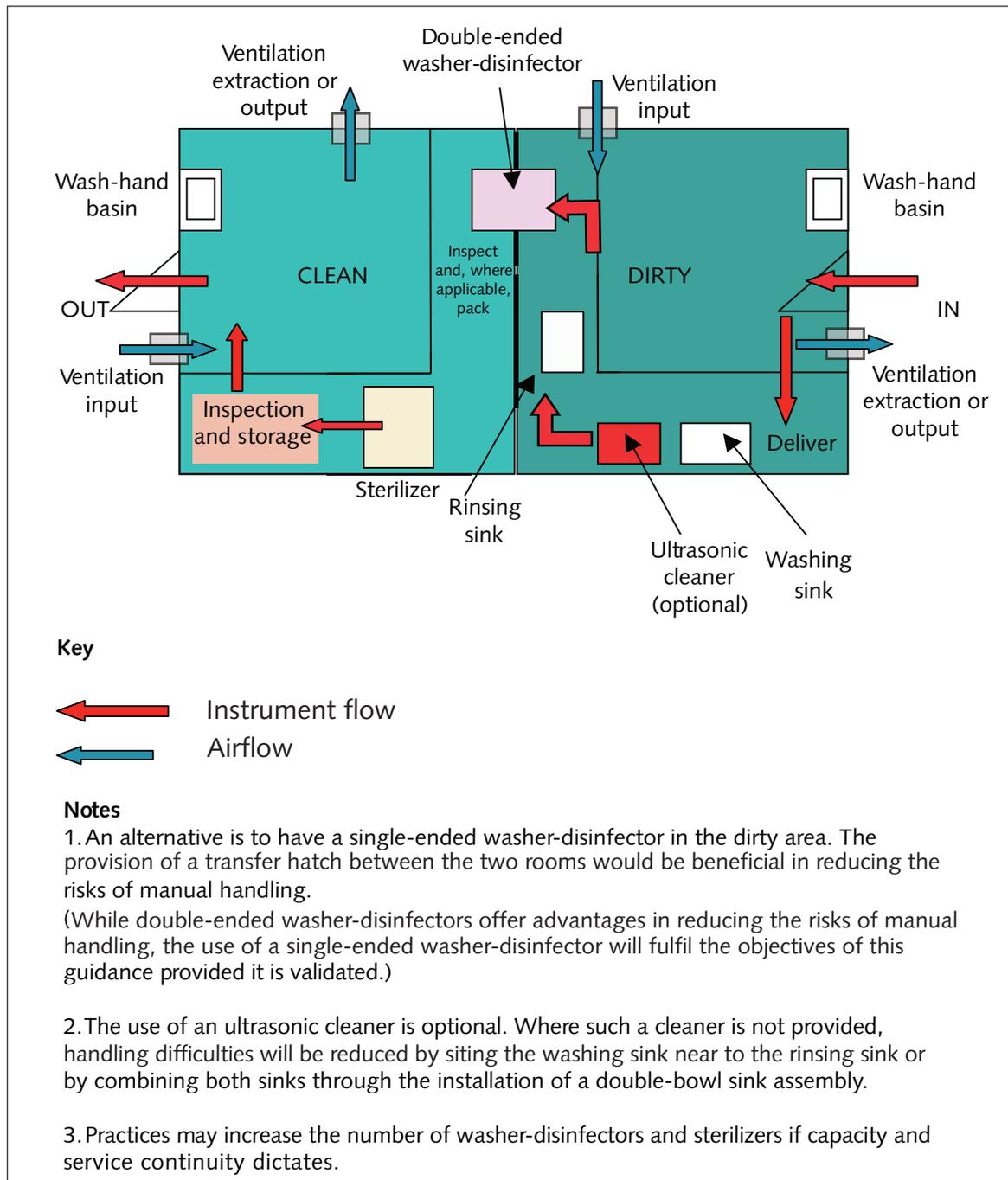


Figure 3: Example layout for two decontamination rooms

available space, depending on an upgrade of existing or a new build, frequency of use with patient workload sessions, staffing levels for good working practice, numbers of washer disinfectors and sterilizers required. The following questions should be addressed:

- What type of room is required?
- Is segregation needed or a well designed single room application?

5.6 Irrespective of the specific layout, a tidy working environment makes carrying out decontamination easier. Therefore, the working environment should be uncluttered. The decontamination process should be carried out by ensuring that a dirty-to-clean workflow is maintained (as outlined in [paragraph 5.7](#)). This is a one-way process that can be achieved by physical segregation or temporal separation (see [paragraph 5.2](#)). In some cases

where there is sufficient space, a physical screen such as glass or acrylic can be used as a splash barrier for decontamination processes in segregating of areas.

Physical segregation

Note

A two room decontamination facility with both dirty and clean rooms is designed for larger practices with large patient throughputs, such as a Health Centre.

5.7 Physical segregation within the decontamination rooms can be a physical barrier, as in the twin room layout, or by the good management of space and flow in a single room design by using different areas for different activities. A decontamination area should be set up which preferably comprises a single run of sealed, easily cleaned worktops. The following key design points should be observed:

- The dirty zone will be used to receive contaminated instruments. An area of benching should be clearly designated for this purpose and used for no other activity.
- The washer-disinfector, washing and rinsing sinks or separate bowls within a single sink unit should be installed adjacent to the receiving area. Where necessary, usually owing to space constraints, it is acceptable to use a single sink unit incorporating two bowls with common supply and taps for the functions described here.
- The ultrasonic cleaner, where used, should be separated from the receiving area and adjacent to the rinsing sink/bowl.
- After washing and disinfection the instruments and devices require inspection. A dedicated clean area of benching with good task lighting should be provided.
- Adequate space should be provided for the washer-disinfector for loading and unloading as well as access for maintenance and testing. The washer-disinfector could be a pass through unit of bench top or under bench design depending on the room layouts.

- The sterilizer should be situated well away from the other activities and facilities in order to promote staff and patient safety and good decontamination practice. Adequate space should be provided for the sterilizer for good maintenance and testing.
 - After sterilization, the sterilizer will need to be unloaded into another clean, well-lit area. Ensure that this area is kept clean, particularly just before the sterilizer is emptied.
 - Where possible, air movement should be from clean to dirty areas (see [paragraphs 6.41–6.42](#)).
 - A wash-hand basin should be provided for use by staff at the completion of each stage in the decontamination process. Where this work is conducted adjacent to the treatment area, it is acceptable for a single wash-hand basin to be used for this and clinical hand-washing. However, this basin should be distinctly separate from the sinks used in decontamination. A screen could be utilised depending on space.
 - Where a double-ended washer-disinfector is used in a pass through facility, the input door in the dirty area and that used to empty the clean instruments should be separated by a barrier. Alternatively, the washer-disinfector should be built directly into the separating wall between the dirty and clean areas.
- 5.8 This guidance recognises that, because of physical limitations on space and costs, some practices may not meet the required standards and policies. In areas where building alterations to existing premises are restricted or purpose-built premises may be difficult to upgrade, progress to improve standards may prove difficult and a full risk assessment should be carried out highlighting the problems and formulating an action plan to improve the facility and working practices.

Chapter 6 General hygiene principles

Hand hygiene

- 6.1 The term hand hygiene covers not only handwashing, but also alternative and additional measures such as hand disinfection using antibacterial-based hand-rubs and gels.
- 6.2 Hand hygiene is crucial in preventing the spread of infection and the recontamination of surgical instruments and devices. Clean hands are an essential counterpart to the use of gloves. Neither measure is a substitute for the other.
- 6.3 As part of the constant improvement in delivery of the service, training in hand hygiene should be part of staff induction and be provided to all relevant staff within dental practices periodically throughout the year. Advice is available from www.npsa.nhs.uk/cleanyourhands.
- 6.4 There are three different levels of hand hygiene (see [Appendix 2](#)). The level required depends on the potential for contamination of the hands and the risk factors related to the process to be undertaken. For the decontamination of devices, as described here, good levels of social hand hygiene will be sufficient. Accordingly, the aim is to render the hands physically clean and to remove transient microorganisms encountered in the performance of normal duties.
- 6.5 Hand hygiene should be practised at the following key stages in the decontamination process so as to minimise the risk of contamination:
 - before and after each treatment session;
 - before donning and after the removal of PPE;
 - following the washing of dental instruments;
 - before contact with instruments that have been steam-sterilized, whether or not these instruments are wrapped;
 - after cleaning or maintaining decontamination devices used on dental instruments;
 - at the completion of decontamination work.
- 6.6 Mild liquid soap should be used when washing hands. Bar soap should not be used. Apply the liquid soap to wet hands to reduce the risk of

irritation and perform hand-washing under running water. Ordinarily, the hand-wash rubbing action should be maintained for about 15 seconds. After the exercise, the hands should be visibly clean. Where this is not the case, the hand hygiene procedure should be repeated.

Drying of hands

- 6.7 Effective drying of hands after washing is important because wet surfaces transfer microorganisms more easily than when they are dry and inadequately dried hands are prone to skin damage. To prevent recontamination of washed hands, disposable paper towels should be used.

Skin care

- 6.8 Hand cream, preferably water-based, should be used to avoid chapped or cracking skin. Communal jars of hand cream are not desirable as the contents may become contaminated and subsequently become an infection risk. Ideally, wall-mounted hand cream dispensers with disposable cartridges should be used. Any staff who develop eczema, dermatitis or any other skin condition should seek advice from their occupational health department or general practitioner (GP) as soon as possible.
- 6.9 Fingernails should be kept clean, short and smooth. When viewed from the palm side, no nail should be visible beyond the fingertip. Staff undertaking dental procedures should not wear nail varnish or false nails.
- 6.10 Rings, bracelets and wristwatches should not be worn by staff undertaking clinical procedures. Staff should remove these prior to carrying out hand hygiene. A wedding ring is permitted but the skin beneath it should be washed and dried thoroughly, although it is preferable to remove the ring prior to carrying out dental procedures.

Facilities and procedures for hand-washing

- 6.11 A separate wash-hand basin should be provided (see [paragraph 5.7](#)). Practices are encouraged to replace existing wash basins that do not comply with the following:

- The basin should not have a plug or an overflow and be fitted with a remote running trap, that is, the U-bend is not directly under the plughole.
 - It should have a sensor-operated or lever operated mixer tap.
 - Taps should not discharge directly into the drain aperture as this might generate aerosols.
- 6.12 Wall-mounted liquid hand-wash dispensers with disposable cartridges should be used and the nozzle kept clean. Refillable hand-wash containers should not be used as bacteria can multiply within many of these products and are therefore a potential source of contamination.
- 6.13 Hand hygiene is an essential part of preventing infection in the practice. A cleanable poster depicting a six- or eight-step method should be displayed above every clinical wash-hand basin in the practice (see [Section C](#)).

Personal protective equipment for decontamination processes

- 6.14 The local infection prevention and control policy should specify when personal protective equipment (PPE) is to be worn and changed. PPE training should be incorporated into staff induction programmes.
- 6.15 Appropriate PPE should be worn during decontamination procedures. PPE includes disposable clinical gloves, household gloves, plastic disposable aprons, face masks, eye protection and adequate footwear. PPE should be stored in accordance with the manufacturers' instructions.
- 6.16 When used appropriately, and in conjunction with other infection control measures, PPE forms an effective barrier against transmission of infection.

Gloves

- 6.17 Gloves are needed to:
- protect hands from becoming contaminated with organic matter and microorganisms;
 - minimise the risks of cross-infection by preventing the transfer of organisms from staff to patients and vice-versa;
 - protect hands from certain chemicals that will adversely affect the condition of the skin. Particular care should be taken when handling caustic chemical agents, particularly those used in disinfection and for washer-disinfectors.
- 6.18 A new pair of gloves must be worn for every patient and, if necessary, changed during

treatment. Used gloves should be replaced before performing activities that require strict aseptic precautions or when touching equipment that is difficult to clean.

- 6.19 It is important that gloves fit properly if they are to produce the level of protection against the expected contaminants. The use of latex gloves is subject to a Health & Safety Executive recommendation, which calls for local risk assessment. This is partly attributable to reports of long-term allergy development in some users. The use of vinyl or nitrile gloves may be a satisfactory substitute and should be made available to staff within the practice.
- 6.20 Powdered gloves should not be used. Individuals who are sensitised to natural rubber latex proteins and/or other chemicals in gloves should take advice from their GP or occupational health department for an alternative to latex gloves.
- 6.21 All disposable clinical gloves used in the practice should be CE-marked and should be:
- low in extractable proteins (<50 µg/g);
 - low in residual chemicals;
 - powder-free.
- 6.22 Gloves, other than domestic household types, are single-use only. They should be discarded as clinical waste.
- 6.23 Jewellery, for example, watches, dress rings and bracelets may damage the integrity of the glove and may pose an infection risk.
- 6.24 The following additional guidance is provided:
- Long or false nails may also damage the glove, so nails should be kept short and clean.
 - Glove integrity can be damaged if in contact with substances such as isopropanol or ethanol; therefore, alcohol rubs/gels should not be used to decontaminate gloves.
 - Gloves, except household gloves, should not be washed as liquids may be absorbed into the glove and compromise the efficacy of the barrier.
 - Storage of gloves should follow manufacturers' recommendations.
 - Domestic household gloves, if used, should be washed with detergent and hot water and left to dry after each use to remove visible soil. Gloves should be replaced weekly or more frequently if worn or torn or if there is any difficulty in removing soil.

Disposable plastic aprons

- 6.25 These should be worn during all decontamination processes.
- 6.26 Aprons should be changed at the completion of each procedure, be used as a single-use item and disposed of as clinical waste (see [Appendix 1](#)).

Face and eye protection for decontamination procedures

- 6.27 During cleaning procedures, there is a risk of contaminated fluids splashing onto the face and into the eyes. Therefore, the dental team should ensure protection of their mucosa from splashes and other contaminated fragments that may escape during these procedures.
- 6.28 Face masks are single-use items and should be disposed of as clinical waste.
- 6.29 Spectacles do not provide sufficient eye protection unless specifically designed for the purpose. It is advisable to wear a visor or face shield over spectacles; this gives added protection for prescription glasses.
- 6.30 Eye protection may be reusable but is often difficult to clean. It may be reused if cleaned according to manufacturers' instructions. This should take place when it becomes visibly dirty and/or at the end of each session. Disposable visors are available and may be used.

Footwear

- 6.31 Footwear should be fully enclosed, in good order and comply with health and safety guidance. Particular care should be taken concerning the risk of chemical or hot water spillage onto feet.

Clothing, uniforms and laundry

- 6.32 A wide variety of clothing is worn in dental surgeries and in many practices is used to reinforce the corporate image.
- 6.33 Clothing worn to undertake decontamination should not be worn outside the practice. Adequate changing and storage facilities that are accessible from the decontamination area should be provided. A similar approach is recommended for clinical clothing.
- 6.34 Short sleeves allow the forearms to be washed as part of the hand hygiene routine. Dental staff need to be aware of the hazards that may be encountered in the decontamination process and may wish to wear long-cuffed gloves or disposal long-sleeved gowns to protect their arms.
- 6.35 Clothing and uniforms can become contaminated with microorganisms during procedures. It is

important that freshly laundered uniforms are worn every day. Sufficient uniforms for the recommended laundry practice should be provided, as staff who have too few uniforms may be tempted to reduce the frequency of laundering.

- 6.36 Uniforms and clothing should be washed at the highest temperature suitable for the fabric, e.g. 10 minutes with a suitable detergent at a minimum temperature of 60°C, to reduce any potential microbial contamination. For guidance relating to contact with chemical substances, see the Health & Safety Executive's guidance on COSHH – www.hse.gov.uk/coshh.

Removal of PPE

- 6.37 Depending on the type of PPE worn, items of PPE should be removed in the following order:
 - a. Gloves. Gloves should be removed first so that they end up inside-out. When removing them, make sure hands do not become contaminated. Hands should be washed thoroughly, if visibly contaminated, before removing the rest of the PPE.
 - b. Plastic disposable apron. The apron is removed by breaking the neck straps and carefully gathering together by touching only the inside, avoiding touching the outer contaminated area.
 - c. Face mask. The mask is removed by breaking the straps or lifting over the ears and disposing into a clinical waste receptacle (see [Appendix 1](#)). Touching the outer surface should be avoided and the mask should not be crushed before disposal. Masks should never be left to hang around the neck and should be disposed of immediately after use.
 - d. Face and eye protection. Care should be taken not to touch the outer surfaces. Single-use eye protection should be disposed of into the clinical waste receptacle.
 - e. Wash hands thoroughly again.

Surface and equipment decontamination

General

- 6.38 Surfaces and equipment used in the decontamination of dental instruments should be cleaned carefully before and after each decontamination process cycle. The procedure used should comply with written local policies.
- 6.39 All surfaces should be such as to aid successful cleaning and hygiene. Wherever possible, surfaces, including walls, should be continuous and free

from damage and abrasion. They should be free from dust and visible dirt.

Environmental conditions

- 6.40 The environmental conditions in decontamination facilities should be controlled to minimise the likelihood of recontamination of sterilized instruments. Key considerations include the cleanability of surfaces, fittings and equipment.
- 6.41 Ventilation and air quality are important considerations. In non-purpose-built facilities, the control of airflow is a challenging issue. Responsible Persons (see **Section C**) will need to consider how good standards can be achieved without resorting to unreasonably complex or expensive ventilation systems. Through-wall fan-based ventilation and extraction units will often be useful in this context. In particular, cassette-based systems can be simple to install and produce a balanced airflow at low cost. The use of freestanding or ceiling-mounted fan units, however, is not recommended.
- 6.42 Mechanical ventilation systems may be advantageous, particularly where **best practice** requirements are being pursued. However, these systems can be expensive in terms of both capital and running costs. Accordingly, designs that make best use of natural ventilation in clinical areas may be advantageous, while the use of simple fan-based systems in decontamination areas will be helpful. It should be remembered that protecting against recontamination of instruments is always a key aim.

Detailed guidance can be found in WHTM 03-01 - 'Specialised ventilation for healthcare premises'.

- 6.43 The ventilation system in the decontamination area or room(s) should be designed to supply reasonable quantities of fresh air to the positions where persons work and to remove excess heat from equipment and processes.
- 6.44 Where used, mechanical extract units should be ceiling- or wall-mounted. Care should be taken to ensure that airflow is from clean to dirty.
- 6.45 Where full mechanical ventilation solutions are used, the extract system should be located and sized to draw about one-third of the air across the decontamination benches in the clean-to-dirty direction. Mechanical ventilation equipment should include coarse air filtration on the input side. This will require periodic maintenance. Practices are advised to consult a heating and ventilation engineer if choosing to install a mechanical ventilation system.

Surfaces and equipment – key design issues

- 6.46 All surfaces and equipment should be impervious and easily cleanable. Work surfaces and floor coverings should be continuous, non-slip and, where possible, jointless. Welsh Health Building Note 00-09 – Infection control in the built environment states that the use of carpets is not advised within any clinical or associated decontamination area. Attractive vinyl flooring materials are available which can provide aesthetic appeal.
- 6.47 Flooring in clinical care and decontamination areas should be impervious and easily cleanable. Carpets, even if cleanable, should not be used. There should be coving between the floor and the wall to prevent accumulation of dust and dirt in corners and crevices.
- 6.48 Any joints should be welded or sealed where they are unavoidable. Sealing prevents damage due to water ingress under the flooring.
- 6.49 It should be ensured that surfaces:
- can be easily accessed;
 - will dry quickly.
- 6.50 Manufacturers' advice should be sought in terms of the compatibility of detergents and disinfectants with the surface materials used.

Decontamination equipment

- 6.51 Specialist items of equipment, for example, ultrasonic baths, washer-disinfectors, sterilizers and RO or water treatment plant, may require cleaning and decontamination processes that are purpose designed. Although information will be provided by manufacturers it is recommended that, when writing local protocols, assistance is sought from a qualified decontamination engineer or other trained person. This may be a CP(D) employed by the equipment provider or local SSD manager. In the latter case, it should be possible to contact the local AP(D) via the Health Board or contact NWSSP-FS for the AE(D) or Decontamination Engineers (Wales) for advice.
- 6.52 Planned cleaning programmes will have links to preventive maintenance and the validation process. Local policies should reflect these requirements and clearly state the intervals at which actions are to be taken and a procedure for the keeping of records.
- 6.53 It is often during cleaning work that minor defects, wear or damage to equipment will be detected. Local policies should ensure that such defects are reported to the responsible person.

Note

For floor and general surface cleaning, NHS England has published a guidance package backed by a colour coding system for use with materials and equipment.

This system should also be useful for dental practices (visit <http://www.nrls.npsa.nhs.uk/resources/?entryid=45=59810>).

The colour codes used in primary care are:

- red – for wash-rooms;
- blue – for offices;
- green – for kitchens;
- yellow – for clinical and decontamination areas.

Cleaning protocols and techniques

- 6.54 The dental practice should have a local protocol clearly outlining surface and room cleaning schedules. The cleaning process will be most effective if the more contaminated areas are cleaned first. Materials and equipment used to clean clinical areas and other higher-risk areas should be stored separately from those used for general and non-clinical areas. Simple records should be maintained.
- 6.55 Cleaning staff should be briefed on the special measures to be observed in cleaning of patient care areas or rooms used for decontamination. In some instances, full training of personnel will be needed.
- 6.56 If instruments become contaminated through, for example, being dropped or placed in a dirty area, they should be sent for further reprocessing.
- 6.57 Evidence suggests that the use of commercial bactericidal cleaning agents and wipes is helpful in maintaining cleanliness and may also reduce viral contamination of surfaces. Care should be taken in the use of alcohol wipes which, though effective against viruses on clean surfaces, may fix protein and biofilm. However, the careful use of water with suitable detergents, including those CE marked for clinical use, is satisfactory provided the surface is dried after such cleaning.

Note

Alcohol has been shown to bind blood and protein to stainless steel. The use of alcohol with dental instruments should therefore be avoided.

- 6.58 The Department of Health in England has sponsored research on the use of both microfiber cloth and steam-cleaning technology in clinical and support-service areas. This work suggests that, provided deep cleaning is performed as an initial

exercise, the subsequent use of microfibre-based techniques, essentially involving dry or wet wiping with microfibre cloth, can be helpful in achieving satisfactory removal of infectious agents from surfaces. The special fibre is capable of entangling and thus removing a wide range of pathogenic particles from surfaces to which they are otherwise adherent. However, as infective material is efficiently transferred to the microfibre, its reprocessing or disposal must take account of the infection risk. Reprocessing takes the form of washing through a conventional laundry process. This should take place at the end of each session or when obviously contaminated. The life of the cloth is likely to allow for repeated use on many occasions. The materials are available at relatively modest cost from infection control companies.

Note

Detailed information is provided in 'An integrated approach to hospital cleaning: microfibre cloth and steam cleaning technology' available from the Department of Health's website.

- 6.59 Local provision of steam cleaning from practice resources is unlikely to be economic. The use of a contractor may be advantageous.
- 6.60 Cleaning equipment should be stored outside patient care areas.

Decontamination of treatment areas

- 6.61 The patient treatment area should be cleaned after every session using disposable cloths or clean microfibre materials even if the area appears uncontaminated.
- 6.62 Areas and items of equipment local to the dental chair that need to be cleaned between each patient include:
- local work surfaces;
 - dental chairs;
 - dental inspection light;
 - hand controls including replacement of covers;
 - trolleys and delivery units;
 - spittoons;
 - aspirators;

Other equipment that is not directly attached to the dental chair, such as curing lamp and x-ray unit, must be wiped down if it has been used.

Note

Dental chairs should be free from visible damage, for example, rips and tears.

6.63 Areas and items of equipment that need to be cleaned after each session include:

- taps;
- drainage points;
- splashbacks;
- sinks.

In addition, cupboard doors, other exposed surfaces (such as dental inspection light fittings) and floor surfaces, including those distant from the dental chair, should be cleaned daily.

Note

Spittoons and aspirating units need to be washed through at the end of a session according to manufacturers' instructions.

6.64 Items of furniture that need to be cleaned at weekly intervals include:

- window blinds;
- accessible ventilation fittings;
- other accessible surfaces such as shelving;
- radiators and shelves in cupboards.

6.65 Purpose-made disposable single-use covers are available for many of the devices mentioned above, including inspection light handles and headrests. The use of these is encouraged but should not be taken as a substitute for regular cleaning. Covers should be removed and surfaces should be cleaned after each patient contact.

6.66 Computer equipment in clinical areas can readily become contaminated. Solutions are available to minimize risks, e.g.

- purpose designed covers over computer keyboards.
- "easy-clean" waterproof keyboards.

Where covers for conventional keyboards are provided, care should be taken to ensure that covers are changed or that washing is performed at frequent intervals.

6.67 Cleaning centres on simple techniques using disposable cloths wetted with clean water and a detergent.

6.68 Damp dusting is preferable to dry dusting, which should be avoided wherever possible as this may result in dust suspension.

6.69 Care should be taken to keep water well away from electrical devices, even though many of those provided in dentistry will have water-resistant housings.

6.70 After some clinical procedures it is necessary to start cleaning as soon as care of the individual patient is complete. In these cases, staff should not wait until the end of the session to start cleaning the area.

6.71 Portable aspirators with reservoir bottles are not recommended. They are not fitted with filters and pose a considerable hazard when disposing of the contents.

6.72 Intra-oral radiology film and devices used in digital radiology imaging are potential sources of cross-infection. Accordingly, where reusable devices are used, they should be decontaminated in accordance with the manufacturer's instructions. For intra-oral holders this will require the use of steam sterilization following washing and disinfection.

6.73 Soft toys are often difficult to clean and should not be provided within practices.

6.74 For blood spillages, care should be taken to observe a protocol that ensures protection against infection. The use of hypochlorite at 1000 ppm available chlorine is recommended unless Health Board policy suggests otherwise. Hypochlorite should be made up either freshly using hypochlorite generating tablets or at least weekly in clean containers. Contact times should be reasonably prolonged, not less than five minutes. A higher free chlorine yield of up to 10,000 ppm is useful, particularly for splash contamination. The process should be initiated quickly and care should be taken to avoid corrosive damage to metal fittings, etc. The use of alcohol within the same decontamination process is not advised.

Dental unit water lines (DUWLs)

Note

In view of the expertise required in this specialised field, practices (through the Registered Manager) should engage with an external specialist to assist in meeting the recommendations given in **Section C** of this guidance. This may be a locally-based engineering consultant with specialist knowledge of legionella and other water-borne organisms.

It is likely that Health Boards and representatives from professional organisations, such as the Legionella Control Association, will be able to recommend a suitable contractor.

General

- 6.75 Best practice guidelines on the control of legionella are provided in the Health & Safety Commission's 'Legionnaires' disease – the control of legionella bacteria in water systems. Approved Code of Practice and guidance on regulations' L8, HSG 274 Legionnaires disease- Technical guidance and WHTM 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'.

Note

The Health & Safety Commission's Approved Code of Practice L8 gives practical advice on how to comply with UK health and safety law with respect to the control of *legionella* bacteria. This Code is important in that it has a special legal status. If a healthcare organisation is prosecuted for a breach of health and safety law, and it is held that it did not follow the relevant provisions of the Code, that organisation would need to demonstrate that it had complied with the law in some other way or a court would find it at fault.

- 6.76 The use of water in dentistry must comply with a series of regulations which are designed to ensure the safety of patients, staff and the public. The application of these regulations and codes is covered in detail in [Chapter 19](#) of this guidance.
- 6.77 The Registered Manager (see [paragraph 9.3](#)) should ensure that arrangements are made so that the practice can continuously achieve compliance with the requirements of these regulations. Registration with the Legionella Control Association or other recognised body is recommended.

Microbiological monitoring

- 6.78 Apart from situations where there are indications from taste or odour, microbiological monitoring using dip slides for total viable counts (TVCs) is not considered essential. However, some companies and other institutions offer comprehensive water-purification services that include periodic microbiological sample monitoring. Such services, provided they are quality-controlled, may contribute usefully to risk reduction in this area.
- 6.79 Where taste or odour problems are encountered, advice may be sought from the local authority environmental health department. They can arrange for testing, if necessary, as part of their service level agreement with Public Health Wales or alternative commercial services.

Note

This is a complex procedure and the use of in-house test kits is not recommended.

DUWLs

- 6.80 No currently available single method or device will completely eliminate biocontamination of DUWLs or exclude the risk of cross-infection. To reduce contamination risk, a combination of methods is applicable (see also [Section C](#)).
- 6.81 With regard to legionella and other water-borne pathogenic agents, the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance (2009) states: "*Premises should be regularly reviewed for potential sources of infection and a programme should be prepared to minimise any risks. Priority should be given to patient areas although the exact priority will depend on local circumstances*". Whilst the Code of Practice does not apply in Wales, the statement referred to above is considered to provide sound guidance.
- 6.82 Guidance from HSG 274 Part 3 advises that at-risk systems, particularly those used with the patient, be drained down twice daily (typically at the start and finish of each working day). Where manufacturers provide protocols for daily cleaning, these should be applied.
- 6.83 Self-contained water bottles (bottled water system) should be removed, flushed with distilled or RO water and left open to the air for drying overnight. They should be stored inverted.
- 6.84 Where visual contamination is present, flushing with a suitable disinfectant followed by thorough washing is necessary. The manufacturer's instructions will specify the disinfectant to be used and may also require the continuous presence of antimicrobial agents to prevent the build-up of biofilms.

Note

The self-contained water supplies used with dental care systems should be freshly distilled or RO water (see [Section C](#)). Certain systems recycle water back to a storage facility. Where this is done, repurification will be necessary at each cycle.

If self-contained water bottles are not used, an appropriate air gap (Type A) should separate the DUWLs from the mains water supply. Such arrangements should be subject to consideration of local water quality, particularly where hard water is used.

6.85 DUWLs should be flushed for at least two minutes at the beginning and end of the day and after any significant period when they have not been used, for example, after lunch breaks. In addition, they should also be flushed for at least 20–30 seconds between patients. Whilst these actions have been shown to have only a small effect on biofilm build-up within the DUWL system, they do usefully reduce microbiological counts in the water delivery tube during the period when patients are likely to be exposed. Some water-purification systems are capable of supplying DUWLs and may be able to reduce microbiological risks.

Note

Care should be taken to minimise the occurrence of splashing and aerosol formation.

6.86 Disinfection of DUWLs should be carried out periodically. In all cases the manufacturer's instructions should be consulted. Sodium hypochlorite and isopropanol and a number of other agents have been shown to be effective in the removal of biofilm as well as the reduction of microbacterial contamination. However, these agents should only be used where recommended by manufacturers. If they are used, care should be taken to ensure that DUWLs are thoroughly flushed after disinfection and before being returned to clinical use.

Note

(1) There is disagreement within the scientific literature concerning the effectiveness of water-based flushing of DUWLs, particularly in respect of biofilm control. For systems making use of potable water, that is, where the water supply is drawn from a mains water system, the nature of the building's water-supply arrangements may be an important consideration. This is particularly so where storage tanks are used. Where delivered water quality is in doubt, dental practices should consider adopting continuous dosing systems if permitted by the DUWL manufacturer's recommendations. If dosing is used, it is important to ensure that the dose rates delivered are within the recommended safe limits for the product used. Dental practices that use a potable water option, through air-gap supply or the use of bottles, should consult with their appointed Competent Person (Decontamination) in respect of local water quality and suitability.

- (2) For those using purified water, such as freshly distilled or RO, possibly with UV treatment, the rate of biofilm build-up is likely to be low, provided that water lines are regularly disinfected and maintained.
- (3) Particular caution should be taken with regard to dental handpieces where dosing is applied, as a number of instances of damage have been reported.

6.87 Dental equipment requiring protection against backflow should have anti-retraction valves incorporated on all handpieces, ultrasonic scalers and water lines (see [Section C](#)). Responsible Persons should ensure these are fitted where required. They must be regularly monitored and maintained.

6.88 Examples of dental equipment requiring backflow protection are:

- dental spittoons;
- three-in-one syringes;
- wet-line suction apparatus; and
- self-filling automatic radiographic processors where still used.

Note

Adherence to the equipment manufacturer's recommended cleaning procedures, including the use of the manufacturer's recommended chemicals, is a requirement for medical devices such as those listed above.

6.89 Where in-line filters are used, these will require treatment using an appropriate cleansing solution at intervals recommended by the manufacturer – but always at the end of each session. This step should be performed after first flushing the DUWL.

6.90 If the DUWL has disposable filters, they should be replaced daily.

Note

See [Section C](#) for further guidance on DUWLs.

6.91 For dental surgical procedures, surgical flaps or other access into body cavities involving irrigation, the use of sterile water or sterile isotonic saline provided from a separate single use source is recommended.

Chapter 7 Impressions, prostheses and orthodontic appliances

7.1 Decontamination of these devices is a multi-step process to be conducted in accord with the device or material manufacturer's instructions. In general terms, the procedure will be as follows:

- a. Immediately after removal from the mouth any device should be rinsed under clean running water. This process should continue until the device is visibly clean.
- b. All devices should receive disinfection according to the manufacturer's instructions. This will involve the use of specific cleaning

materials noted in the CE-marking instructions. After disinfection the device should again be thoroughly washed. This process should occur before and after any device is placed in a patient's mouth.

- c. If the device is to be returned to a supplier/laboratory or sent out of the practice, a label to indicate that a decontamination process has been used should be affixed to the package.

Section C: Engineering, technology and standards

Chapter 8 Regulatory framework and compliance

BS/EN/ISO Standards

- 8.1 BS EN Standards for sterilization were first published in 1994. They included:
- BS EN 285 on larger steam sterilizers;
 - BS EN ISO 17665 on the monitoring of steam sterilization; and
 - BS EN 556 on the definition of sterilization.
- 8.2 Subsequent standards covered small sterilizers (BS EN 13060).
- 8.3 Reviews and rewrites of the above Standards coupled with the production of new Standards has led to a revision of the content of Health Technical Memoranda, including this document, in order to bring their content in line with that of the BS EN ISO Standard portfolio.
- 8.4 A list of these Standards is provided in the References. It is in the light of these changes that this WHTM is published. Reference to the content of a relevant Standard is made where necessary but the content is not included in this document.

NHS Wales guidelines

- 8.5 Guidance produced by the Welsh Government for decontamination has evolved in recent years.
- 8.6 The CDO letter Advice for dentists on re-use of endodontic instruments and variant Creutzfeldt-Jakob Disease (vCJD) (April 2007) advised the single-use of all endodontic files and reamers, as well as any other instruments for which effective decontamination was difficult. This was reinforced by the release of 'Potential vCJD transmission risks via dentistry. An interim review' (DH - December 2007).
- 8.7 WHTM 01-05 has drawn upon all guidance issued previously.
- 8.8 It is issued specifically to improve standards in decontamination for primary care dental practices, where decontamination is carried out locally within the practice.
- 8.9 For secondary care, the Welsh Government commissioned the decontamination project which

successfully reviewed and reported that all hospital sterilization and decontamination units in Wales achieved accreditation to the standards required by the Medical Device Regulations. Accreditation status allows HSDUs to undertake decontamination for third parties, including primary care. This allows primary care in Wales to consider:

- In-house decontamination to the correct standards and policies;
 - Use of single-use devices as advised and where possible;
 - Outsource decontamination to an accredited HSDU;
 - A combination of the above.
- 8.10 WHTM 01-05 sets out the requirements for the first of the above options.

Healthcare regulation and standards

Health Boards must ensure that the provision of health services meets Doing well, doing better - Standards for Health Services in Wales. Infection prevention and control, including decontamination, is a requirement that will apply to all NHS healthcare providers.

All private primary care dental services have been regulated in Wales since 1 January 2009. All providers of private dental services activities will continue to register with the Healthcare Inspectorate Wales in accordance with regulatory requirements.

For 2013, the registration requirements for infection control and prevention, including decontamination, are supported by the Private Dentistry (Wales) Regulations 2008. This WHTM will be referenced in any National Minimum Standards for Private Dental Services and enforced through the above regulations. Adherence to the WHTM will, with regard to decontamination, contribute towards evidence of compliance with registration requirements.

Chapter 9 Staff roles and responsibilities in decontamination

Note

WHTM 01-01 Part A outlines roles and responsibilities and structure of decontamination for the Welsh Health Service.

- 9.1 It is essential that all staff working in the dental practice/service understand the importance of cross-infection control. Staff involved in decontamination must be suitably trained, have their roles and responsibilities defined and everyone must be aware of each other's responsibilities.
- 9.2 WHTM 01-01 Parts A, B, C and D provide advice for the acute sector on the decontamination processes and standards to meet the directive.
- 9.3 Each practice can, therefore, establish its own system concerning staff responsibilities but will be expected to demonstrate the same degree of understanding, competency and management, regulatory compliance as required by WHTM 01-01 Parts A and B. The following may be used as a guide to these roles. The terminology of Part A is used for clarity but it is likely that local personnel may have differing titles.

Note

It should be borne in mind that it is likely that one individual may carry out two, or possibly more, of the following roles depending on the structure and size of the organisation and the numbers of staff involved in that process.

Registered Manager (Executive Management): this will be the individual with ultimate responsibility for decontamination equipment ownership and the definition and appointment of the following staff. In a dental practice, this could be the NHS provider, practice owner or a person of similar authority.

Decontamination Lead: Healthcare Associated Infections – A Community Strategy for Wales makes it a requirement that an individual is given the responsibility for infection control and decontamination. This person should have the experience and authority to perform this task and should be accountable to the Registered Manager. The Decontamination Lead may be either directly

employed by the practice or provided as a service by the Health Board.

Designated Person: this role acts as the interface between the practice and support services supplied externally, including service, maintenance and testing. This could be the Dental Practice Manager. The Decontamination Lead could also act as the Designated Person.

User: This person has day-to-day responsibility for the management of the decontamination equipment and processes **for the practice**. A likely overlap may mean that this role is duplicated, but the responsibility must be demonstrated. An important function of the User is to ensure that anyone operating and testing decontamination equipment, that is, an Operator, is suitably trained and competent.

Note

The User should seek advice from manufacturers and NWSSP-FS, the AP(D) or AE(D) or the appointed CP(D) on how to carry out the testing of equipment and daily tasks as stated in this document. The service engineer can advise on maintenance schedules and specific requirements of the machines.

Authorising Engineer (Decontamination) (AE(D)): this is a role that provides guidance and advice on the compliance issues of decontamination, including the implementation of this WHTM and associated guidance documentation. A list of suitable persons is available from the register held by the Institute of Healthcare Engineering and Estate Management (IHEEM) (www.iheem.org.uk/Decontamination).

Decontamination Engineer (Wales): This role, fulfilled by NWSSP-FS, can advise the User on all technical issues within this document (see WHTM 01-01 Part A).

Authorised Person (Decontamination) (AP(D)): The Authorised Person provides technical advice to the Competent Person and User and liaises with the Authorising Engineer. The AP(D) can offer advice to the practice and User, or Health Boards / Trusts.

Competent Person (Decontamination)

(CP(D)): The Competent Person is responsible for servicing, testing and maintaining the decontamination equipment within the practice. The Competent Person may be either directly employed by the practice as a contractor, or provided as a service by the Health Board or by a third party. The CP(D) should have attended the specific training courses on testing of washer-disinfectors and sterilizers and have certification for quality assurance of the process.

Competent Person (Pressure Vessels): each practice will have a legal responsibility for the safety of its decontamination equipment, particularly the sterilizers that are pressure vessels. The need for insurance and a Written Scheme of Examination is a legal liability and can be provided by the Competent Person (Pressure Vessels). This is likely to be provided by an insurance company.

Service engineer: A person provided under a service level agreement or contract who is certified by the service agent or equipment manufacturer to be competent to both service and possibly act as the CP(D) to test specified decontamination equipment. This person may, among other duties, perform validation tests in accordance with the EN standards cited in this document. The service engineer may give an opinion on the outcomes of validation testing as well as providing data to an AE(D) or AP(D) for validation approval.

Operator: This is the person with authority to operate decontamination equipment. This person will also carry out daily and weekly periodic tests.

Manufacturer: the manufacturer, supplier or agent of any decontamination equipment.

Purchaser: the purchaser of any decontamination equipment, likely to be the practice.

- 9.4 In addition to these roles the practice may require specialist clinical advice and guidance and should possess the ability to source the following responsibilities, either within the practice or externally.

Control of Infection Officer: advice regarding infection prevention and control and the ability to audit and implement relevant advice.

Microbiologist (Decontamination): while most decontamination processes are a matter of parametric management and control, that is, ensuring that values of key measurements or indicators are within a specified range for decontamination, advice from a **Microbiologist (Decontamination)** may be required for certain procedures and practices. This advice should be

sought where the practice is in doubt about its relevance. Access to a Microbiologist can be made via the local Health Board. Institutions that employ such professionals would include the Health Boards, pathology departments and Public Health Wales laboratories.

- 9.5 The Registered Manager should ensure that all personnel fulfilling the roles defined above should receive appropriate training, that they can demonstrate competency in their duties and that individual training records for all staff are retained. Training should always be supported by defined learning outcomes and competencies and may include, where appropriate, the following:
- an understanding of the whole decontamination process;
 - an understanding of their roles and those of others;
 - an understanding of the need for infection prevention and control and all relevant infection prevention and control policies and procedures;
 - an understanding of, and an ability to understand the need for periodic testing of decontamination equipment where appropriate;
 - an understanding of auditing of decontamination processes and facilities.
- 9.6 It is likely that small practices will be unable to appoint all these responsible posts and a local decision regarding them will need to be made. Essentially, a practice should be able to demonstrate the following responsibilities:
- the owner has an understanding of legal liabilities and current best practice;
 - it has obtained professional advice, where necessary, in equipment purchase, maintenance, the validation, testing and operation activities;
 - it can evidence the performance of all relevant maintenance and testing duties;
 - it can demonstrate compliance with the Pressure Systems Safety Regulations.
- 9.7 Full identification of the individuals fulfilling these roles should be documented. It may be acceptable if staff of other titles fulfil the responsibilities as long as the post-holder's authority and experience is sufficient for their full implementation.
- 9.8 It is likely in a dental facility that some of the roles above will be provided by a number of entities/organisations. All roles should thus be

identified and all individuals aware of each other. The systematic approach to these roles should ensure that they function correctly and that they are not individual-based but can withstand changes of personnel without affecting the systematic approach. Advice on relevant training programmes is available from NWSSP-FS. In addition, the local Health Board may also be able to provide advice.

Chapter 10 Procurement of decontamination equipment and instruments

Note

In addition to the guidance given in this chapter, readers may also find Scottish Dental's website useful. On its decontamination page, it has included a list of decontamination equipment that has been tested and approved for use in dental practices, and is used in the national contract in Scotland (www.scottishdental.org/).

Determining the load to be processed

- 10.1 In order to ensure full compatibility of the equipment with the decontamination process, the need for packaging and storage should be considered, as this will affect the type of air removal process and therefore the type of sterilizer chosen (vacuum types B or S or downward displacement type N).
- 10.2 Instrument design will also affect the choice of the cleaning process, particularly regarding the designs and types loading carriages for thermal washer-disinfectors.
- 10.3 If cannulated devices are to be cleaned, ultrasonic irrigators, that is, ultrasonic pre-cleaners with the additional ability to clean and flush internal channels of cannulated devices, or loading carriages with lumen connections may be required.
- 10.4 In addition to the types of load items:
 - their quantities should also be assessed. This will enable the number of equipment items to be determined;
 - realistic cycle times should be assumed when capacity planning is calculated;
 - it should be remembered that all decontamination equipment will require maintenance, servicing and testing and reasonable time during the normal working day should be set aside for these procedures. It must be stated that service and testing are separate functions and responsibilities;
 - all capacity planning should be documented.

Note

Periodic testing for washer-disinfectors, sterilizers and ultrasonic cleaning baths take up a specified time, especially a type B sterilizer. Accordingly, Registered Managers should plan schedules and time to allow for this important function, particularly if the equipment is located close to clinical areas. The process effectively takes the machines out of use for that specified time scale, depending on the machine and type. Times will be different for sterilizer types N, B and S. It is highly recommended that removal, or disablement, of unwanted cycles on multi-cycle machines is carried out, as all cycles available on a machine have to be tested and verified. Therefore the minimal cycles in operation will reduce the testing time and reduce costs.

Decontamination equipment: washer-disinfectors and sterilizers

- 10.5 Decontamination equipment should be procured against a formal specification. Such specification templates are currently available for washer-disinfectors and sterilizers. Advice on completing the specifications for sterilizers and washer-disinfectors and on the production of a specification for ultrasonic cleaners and irrigators is available from the AE(D) and NWSSP-FS

Note

All Model Engineering Specifications are being progressively revised and retitled Technical Specification Templates and are available through NWSSP-FS.

- 10.6 New decontamination equipment should display a CE mark (see below) to demonstrate compliance with the Medical Devices Regulations.



- 10.7 When selecting new equipment, the size, model and type should be considered against workload and throughput requirements, together with the availability of space and the service infrastructure available.
- 10.8 Further consideration should also be given to the following:
- What are the delivery and acceptance requirements?
 - Will the equipment selected be fit for purpose and is it compatible with other equipment in use?
 - What are the manufacturer's recommendations for staff and operator training and cleaning, and will they be achievable in practice?
 - Does it have an automated cleaning process?
 - What cleaning agents are recommended and will they comply with COSHH and health and safety requirements?
 - What commissioning and validation is required for the equipment?
 - What are the ongoing costs?

- 10.9 The following will also need consideration:
- testing: there will be a need to identify who is to perform the testing and where and when it is to be performed;
 - service response: there is a need to be clear about service-response times with appropriate costs in the event of breakdown;
 - process data capture, that is, chart recorder, data recorder, and printer: this information is needed to clarify the audit process on product release. Manual recording of displayed parameters at the end of a cycle should be recorded to an appropriate log and stored.

Note

In general terms, as primary-care dentists may not have in-house engineering staff, robust contractual arrangements to ensure breakdown cover, routine maintenance and continuity of validation will be needed.

- 10.10 The equipment should come with an easily-readable operating, maintenance and technical manual that includes:
- make, model, serial number and installation and warranty requirements with an explanation of the purpose of the equipment and the cycles required for the medical devices to be reprocessed;
 - suitable and type tested chemicals to be used with the equipment;

- optimum working temperatures and times;
 - cleaning instructions for the user, stipulating suitable detergents;
 - safety instructions, including lifting and handling, PPE requirements etc;
 - explanation of warning indications such as cycle failure and fault-finding (diagnostic) procedures;
 - all maintenance requirements, easily copied so that it can be displayed and undertaken by an operator including frequencies etc;
 - monthly maintenance requirements;
 - yearly testing and validation requirements and procedures;
 - consumable parts list and spares components list incorporating identification numbers.
- 10.11 Information on periodic testing protocols can be found in **Chapters 12–14**. These chapters also provide advice on the required actions if tests indicate unacceptable results.

Decontamination equipment: ultrasonic cleaners

- 10.12 The following are more specific considerations when procuring ultrasonic cleaners.
- 10.13 Ultrasonic cleaners can be freestanding or integral to the washer-disinfector.
- 10.14 They should comply with the electrical safety specifications given in BS EN 61010-1.
- 10.15 Consideration should be given to the:
- voltage (V) supply of the equipment (single 230 V or three-phase 400 V) to help establish whether the electrical infrastructure needs modification;
 - power (kW/h) consumption of the equipment this will help to establish running costs.
- 10.16 Ultrasonic cleaners may be designed to operate at a single frequency, across a frequency range, and/or with a controlling system to adjust the frequency in response to the loading conditions.
- 10.17 An active ultrasonic sensor indicator should be provided to show the power consumption in Watts or electrical demand in Amperes of the ultrasonic transducers.
- 10.18 Siting of the ultrasonic cleaner within the workplace should be in a defined area, following a strict dirty-to-clean workflow.
- 10.19 It should be easy to wipe down and disinfect the ultrasonic cleaner.

10.20 An ultrasonic cleaner needs to be maintained by a CP(D) or a suitably qualified person.

Specifications

10.21 When procurement of ultrasonic cleaners is pursued, the following specification points should be considered:

- a reservoir or tank large enough to accommodate the required throughput;
- a reservoir that should be of a polished stainless-steel construction with internal rounded edges and corners to aid in the cleaning process;
- the maximum and minimum fluid levels clearly visible to the user marked on the reservoir;
- a reservoir drainage facility that does not affect performance, does not leave pools of fluid in the reservoir and allows the tank to be emptied without the need for operatives to put their hands into the fluid;
- an integral purpose-built holding basket, which enables all equipment to be held within the ultrasonic bath in the optimum position, so that micro-dental instruments or instruments with fine points are not blunted by the impacts resulting from fine mechanical shaking;
- a hinged auto-locking lid that prevents interaction with the load once the ultrasonic equipment is in use and also reduces the risk of aerosols and noise. If not interlocked, the equipment should be clearly labelled, warning users not to put their hands in the device when it is activated;
- a means to control the detergent's concentration;
- an automatic printer and data-logger which can be integrated and records:
 - time and date,
 - cycle type,
 - unique cycle number,
 - duration of cycle,
 - equipment serial number,
 - minimum and maximum temperatures,
 - a sensor recording ultrasonic activity,
 - electrical demand in Watts or Amperes,
 - cycle failure indication;
- a display indicator integral to the unit clearly displaying:
 - time and date,

- elapsed cycle time,
- maximum and minimum temperatures,
- ultrasonic activity,
- cycle failure indication,
- lamp warning indicators;

- lower-level fluid sensor and auto cut-off;
- thermostatic control;
- over-temperature sensor, with automatic cut-off and warning indication;
- a cleaning cycle ideally identified by a unique cycle number.

10.22 Ultrasonic equipment should come with an easily-readable operating, maintenance and technical manual that includes:

- installation requirements;
- suitable chemicals, for use as agreed by the manufacturer;
- degas requirements, prior to use;
- optimum working temperatures;
- cleaning instructions for the user, stipulating suitable detergent;
- safety instructions;
- explanation of warning indication, cycle failure etc.;
- all maintenance requirements;
- monthly maintenance requirements or as per manufacturers' recommendations;
- yearly testing and validation requirements and procedures;
- consumable parts list;
- spares components list incorporating identification numbers;
- make, model and serial number;
- lifting and handling requirements;
- staff training;
- appropriate PPE.

Selecting instruments

10.23 When selecting new instruments, the following should be considered:

- For what purposes will the instruments be used and will the instruments selected be fit for this purpose?
- Are they compatible with other instruments in use?

- All instruments must be inspected when purchased to ensure the quality, and that no defects are apparent before use such as joints, burrs and finishes.
- Are there any appropriate single-use device that would meet the requirements?
- If reusable, how easy will they be maintained?
- Do the instruments need dismantling before cleaning and do they have manufacturers' instructions?
- Do the instruments have a limited lifecycle specified by the manufacturer?
- What are the manufacturer's recommendations for cleaning and will they be achievable in practice?
- Will the instruments withstand automated washer-disinfector processes and are they compatible with the chemicals and temperatures?
- What cleaning agents are recommended? Do they comply with COSHH and health and safety requirements? Are these cleaning agents compatible with the washer-disinfector, ultrasonic cleaner and instruments already used in the practice?
- Is steam sterilization (134–137°C for a minimum of three minutes at temperature) appropriate for the instruments?
- If another time/temperature range is recommended, is there a validated cycle available on the sterilizer?
- Is training required? Will the manufacturer provide it?
- Ensure commissioning and validation is carried out for the equipment to the schedules given in this WHTM.
- Evaluate and obtain costs for the maintenance of all the machines, servicing and testing schedules.
- Obtain costs for all consumables, printers, chemicals and spares.

Note

Difficult-to-clean serrated handles should be avoided and it should also be ensured that hinges are easy to clean.

Policy on new reusable instruments

- 10.24 Before being put into use, new dental instruments should be inspected carefully to ensure there is no evidence of manufacturing defects. They should be fully decontaminated before their first use. The manufacturer should provide instructions for decontamination.
- 10.25 Reusable dental instruments should be separated into:
- those that can withstand either processing in a washer-disinfector or ultrasonic cleaning; and
 - those that will require manual cleaning, although practices should aim to phase in instruments that can be cleaned via automated processes.
- 10.26 Some instruments consisting of more than one component will need to be dismantled for cleaning. The manufacturer's instructions should always be followed.
- 10.27 Personal training records should show that:
- staff have been appropriately trained;
 - staff are competent to decontaminate the reusable dental instruments presently in use; and
 - training is updated for any new instruments introduced into the dental environment.
- 10.28 Items that cannot be immersed in water, for example, electrical and electronic equipment, should be cleaned in accordance with the manufacturer's instructions.
- 10.29 If recommendations include wiping with a detergent solution, then a clean non-linting cloth plus the recommended detergent solution to wipe the instrument should be used. This should be followed by wiping with a clean damp non-linting cloth to remove residues. The instrument should be dried thoroughly using a clean non-linting cloth. Advice on these issues can be sought from the infection prevention and control team.
- 10.30 If disinfection with alcohol is advised, the advice given in [paragraph 10.29](#) should be followed. While this procedure may be advised, it should be understood that alcohol may have the property of fixing certain contamination.

Chapter 11 Decontamination equipment: general guidance on maintenance and testing

Maintenance and servicing

- 11.1 All decontamination equipment should be subjected to validation, maintenance and servicing as recommended by the manufacturer and supplier. All records of these procedures should be retained for audit and inspection.
- 11.2 All equipment should also be periodically tested as advised in [Chapters 12–14](#). An unsatisfactory test result indicates that the decontamination equipment should not be used until the fault has been rectified.
- 11.3 Failure to perform these tasks or retain evidence of their performance may indicate noncompliance of the decontamination process. Alternative protocols of maintenance should be equal to, or exceed, the manufacturer's specification and must be justified.

Validation and testing

- 11.4 All pieces of decontamination equipment will need a protocol for validation at installation.
- 11.5 For steam sterilizers, the preferred protocol is as follows:
 - a. The CP(D) or service engineer who has carried out a certified testing course should test or validate the equipment.
 - b. The CP(D) or service engineer should then submit the validation or service report to the Registered Manager for audit and acceptance before the equipment is put into service. The report should clearly state the test methods and standards that have been applied with all results and recommendations.
 - c. The Registered Manager should retain a copy of the report and make it available to the Health Board on request.
 - d. NWSSP-FS undertakes the role of AE(D) for the NHS in Wales and provides advice and guidance on periodic validation regimes.
 - e. Periodic audit of the reports will be carried out using the online QAS system and RDS function.

11.6 Work carried out on the equipment:

- a. The service engineer produces a service report with the work carried out in accordance with manufacturers' recommendations.
 - b. By this process, the contract between the Registered Manager, the equipment manufacturer and the service engineer acts as a form of record.
- 11.7 This should be performed in full prior to [Chapters 12–14](#).
 - 11.8 The validation report provides auditable evidence of testing (see [paragraph 11.5](#)).
 - 11.9 These protocols will require full implementation and all results need recording in a logbook dedicated to individual equipment. Standard logbooks summarising all required tests are available for most types of decontamination equipment. Manufacturers should be consulted on the contents of the logbook (see also [Appendix 3](#)).
 - 11.10 If local or in-house documentation is used, its suitability should be discussed and agreed with the decontamination equipment manufacturer. Consultation with the responsible officers, such as the Primary Care Dental lead of the Health Board, would also be useful. In addition, where available, NWSSP-FS and the AE(D) would also be able to advise.
 - 11.11 Periodic inspections, testing and service logs will need to be signed by the CP(D) or the appointed service engineer and be countersigned by the Registered Manager.
 - 11.12 Daily and weekly records should be signed by the User before equipment is returned for use. This signature acts as a "certification of fitness for use" based on information and advice from the manufacturer, often represented by the CP(D). The User signature will indicate acceptance for use.

Note

The User is defined as the person designated by the Registered Manager to be responsible for the management of the decontamination equipment and

process. For a dental practice, this would normally be dentists themselves.

11.13 The validation schedules for sterilizers outlined in [paragraph 11.5](#) and [Chapter 12](#) detail the testing required. However, in terms of testing schedules for washer-disinfectors and ultrasonic cleaners, manufacturers' guidance should be sought. In the absence of manufacturers' guidelines, the testing schedules in [Chapters 13](#) and [14](#) should be followed.

Documentation

11.14 Documentation **and signatures** provide the only evidence of completed work. Absence of documentation for any work item will indicate omission of that item. It is important that all documentation relating to decontamination equipment is up-to-date and is retained locally for audit and inspection purposes.

11.15 The following documentation should be retained for the equipment and be readily available at any time:

- test results and performance qualification details, loading patterns and required parameter values. These results for both the washer-disinfector(s) and sterilizer(s);
 - logbook(s) of periodic testing for both washer-disinfector(s) and sterilizer(s);
 - logbook(s) of plant history, component replacement, etc;
 - process log of items being reprocessed;
 - training and competency records of staff operating the decontamination equipment;
 - documentation for Pressure Systems Safety Regulations including written scheme of examination and examination reports;
 - list of all named designated Responsible Persons;
 - other relevant documentation and records on the decontamination equipment.
- specification(s) of purchased equipment;
 - validation report(s), independently monitored by the AP(D) or AE(D) and signed by the CP(D) on behalf of the manufacturer or agent;

Chapter 12 Installation, validation, maintenance and testing of sterilizers

Maintenance and servicing

12.1 The sterilizer should be maintained and serviced in accordance with the manufacturer's instructions. However, in the absence of these instructions, the schedules outlined in this chapter should be followed.

Validation and testing

Definition of validation
A documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

12.2 The specification will include a protocol for validation. Validation is needed for new equipment at installation and annually thereafter. It will also be necessary to validate equipment after any major repairs have been carried out. The following protocol is suggested (see [paragraph 4.13 \(2\)](#)).

12.3 The following test results from type-tests or works tests will be required.

Test	Type	Performed by	European Norm (EN) reference
Dynamic chamber pressure	B S N	Manufacturer	EN 13060
Air leakage	B S	Manufacturer	EN 13060
Empty chamber	B S N	Manufacturer	EN 13060
Solid load Non-wrapped Single-wrapped Double-wrapped	N S S B S	Manufacturer	EN 13060
Small porous items Single-wrapped Double-wrapped	S S	Manufacturer	EN 13060
Small porous load Single-wrapped Double-wrapped	S B S	Manufacturer	EN 13060
Full porous load Single-wrapped Double-wrapped	S B S	Manufacturer	EN 13060
Hollow load	B S	Manufacturer	EN 13060

Solid load dryness Non-wrapped Single-wrapped Double-wrapped	S S B S	Manufacturer	EN 13060
Small porous items: dryness Single-wrapped Double-wrapped	S S	Manufacturer	EN 13060
Small porous load: dryness Single-wrapped Double-wrapped	S S	Manufacturer	EN 13060
Full porous load: dryness Single-wrapped Double-wrapped	S B S	Manufacturer	EN 13060
Microbiological test optional	B S N	Manufacturer	EN 13060

12.4 Tests not defined in the referred Standards are further defined in [Chapter 15](#).

Periodic tests

12.5 The following testing protocol (shown overleaf,) is recommended. Additional tests as defined by the manufacturer should also be performed.

Note

Users and operators, when delegated, should receive the appropriate training before carrying out any of these tests. This training should be documented on personal training records. The Registered Manager should liaise with the equipment manufacturer with regard to training.

Test	Type	Performed by	Reference
DAILY			
Steam penetration	B S	User or, by delegation, Operator	MDA DB 2002(06)
Automatic control test	B N S	User or, by delegation, Operator	Paragraphs 15.3–15.5
WEEKLY including daily tests plus:			
Air leakage	B S	User or, by delegation, Operator	MDA DB 2002(06)
QUARTERLY (or to manufacturers' recommendations) including weekly tests plus:			
Thermometric tests	B N S	CP(D)/service engineer	MDA DB 9804*
ANNUALLY including quarterly tests plus:			
Steam generator overheat cut-out test	B N S	CP(D)/service engineer	MDA DB 9804*
Thermometric tests Small load Large load	B N S	CP(D)/service engineer	EN 13060
Dryness tests Small load Large load	B S	CP(D)/service engineer	EN 13060

* The Device Bulletin MDA DB 9804 has been withdrawn from circulation. However, for the purposes of the **Thermometric tests** and the **Steam generator overheat cut-out tests** this document is still considered to be 'best practice' until the proposed WHTM 01-07 Decontamination in primary care document is published. (See table included in Appendix 4).

For further information refer to the Medical and Healthcare Products Regulatory Agency publications accessible through the current decontamination document page of the NWSSP-FS website.

Chapter 13 Installation, validation, maintenance and testing of washer-disinfectors

Maintenance and servicing

13.1 The washer-disinfector should be maintained and serviced in accordance with the manufacturer's instructions. However, in the absence of these instructions, the schedules outlined in this chapter should be followed.

Validation and testing

13.2 Validation is needed for new equipment at installation and annually thereafter. It will also be necessary to validate equipment after any major repairs have been carried out. The following protocol is suggested in the table shown below.

13.3 Tests not defined in the referred Standards are further defined in [Chapter 16](#).

Test	Description	Performed by	Reference
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Automatic control test	The values of cycle time and temperature are noted at relevant stages of the cycle so that a fingerprint of the automatic cycle can be made	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Rinse-water quality test	Indicates acceptable values for all critical chemical purity parameters	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Pipework	Ensures free-flowing drainage	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Doors and door interlocks	Confirms safety to operator and exposure to complete cycle only	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Fluid emission	Confirms door-seal prevents contamination to surroundings	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Detergent dosing test	Confirms repeatable detergent addition	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Cleaning efficacy test	Using an artificial soil to clean a worst-case load, chamber walls and load carriers to confirm the exposure to cleaning parameters is sufficient to remove soil	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Thermometric test	Thermocouples are attached to worst-case load, chamber walls and load carriers to confirm that disinfection parameters are acceptable	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Load carriers	Confirms mechanical alignment of all load carriers	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2

Periodic tests

13.4 The following testing protocol is recommended. Additionally, any additional tests defined by the manufacturer should also be performed.

Test	Description	Performed by	Reference
DAILY			
Remove and clean strainers and filters	Ensures filters and strainers are clean	User or, by delegation, Operator	BS EN ISO 15883:1 and BS EN ISO 15883:2
Cleaning efficacy	Visual examination of all load items	User or, by delegation, Operator	BS EN ISO 15883:1 and BS EN ISO 15883:2
WEEKLY including daily tests plus:			
Protein residue test	Confirms that cleaning process retains the capability of removing protein	User or, by delegation, Operator	BS EN ISO 15883:1 and BS EN ISO 15883:2
Safety checks	Check condition of door seal	User or, by delegation, Operator	Manufacturer
QUARTERLY (or to manufacturers' recommendations) including weekly tests plus:			
Safety checks	Check safe operation of doors and door interlocks	CP(D)/service engineer	Paragraphs 15.14–15.18
Automatic control test		CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Cleaning efficacy test		CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Chemical dosing	Confirm delivery of detergent (and any other additives) is repeatable and the machine reacts correctly to low levels of any additive	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Thermometric disinfection test	Use of thermocouples on worst-case load to confirm disinfection parameters are acceptable	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
ANNUALLY including quarterly tests plus:			
Completion of all validation tests above		CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2

Chapter 14 Installation, validation, maintenance and testing of ultrasonic cleaners

Maintenance and servicing

14.1 The ultrasonic cleaner/irrigator should be maintained and serviced in accordance with the manufacturer's instructions. However, in the absence of these instructions, the schedules outlined in this chapter should be followed.

Validation and testing

14.2 The specification should include a protocol for validation. The following protocol is suggested.

14.3 Tests not defined in the referred Standards are further defined in [Chapter 15](#).

Test	Description	Performed by	Reference
Verification of calibration	The accuracy of indicating and recording instruments is checked against certificated source instruments	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Automatic control test	The values of cycle time and temperature are noted at relevant stages of the cycle so that a fingerprint of the automatic cycle can be made	CP(D)/service engineer	Paragraphs 15.3–15.5
Drainage test (where applicable)	Ensures free-flowing drainage	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Lid (i.e. door) interlock	Confirms safety to operator and exposure to complete cycle only	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Fluid emission	Confirms door-seal prevents contamination to surroundings	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Chemical dosing test (where automated)	Confirms repeatable detergent addition	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Cleaning efficacy test	Using an artificial soil to clean a worst-case load, the exposure to ultrasonic activity for a sufficient time period is confirmed	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Thermometric test (where machine also disinfects)	Thermocouples are attached to worst-case load to confirm that disinfection parameters are acceptable	CP(D)/service engineer	BS EN ISO 15883:1 and BS EN ISO 15883:2
Ultrasonic activity test	The use of aluminium foil within the cleaner tank indicates a uniform distribution of ultrasonic activity. A wand meter may be used as long as points of measurement are compatible with the foil test and are fully recorded	CP(D)/service engineer	Paragraphs 15.6–15.13

Periodic tests

14.4 The following testing protocol is recommended. Additionally, any additional tests defined by the manufacturer should also be performed.

Test	Description	Performed by	Reference
DAILY			
Remove and clean strainers and filters	Ensures filters and strainers are clean	User or, by delegation, Operator	Manufacturer
Drain machine at end of day/ session	Ensures contaminated water is not stored in tank	User or, by delegation, Operator	Manufacturer
Cleaning efficacy	Visual examination of all load items	User or, by delegation, Operator	Manufacturer
WEEKLY including daily tests plus:			
Safety checks	Check condition of door seal	User or, by delegation, Operator	Manufacturer Paragraphs 15.14–15.18
Protein residue test	Confirms that cleaning process retains the capability of removing protein	User or, by delegation, Operator	BS EN ISO 15883:1
QUARTERLY (or to manufacturers' recommendations) including weekly tests plus:			
Automatic control test		CP(D)/service engineer	BS EN ISO 15883:1
Verification of calibration		CP(D)/service engineer	BS EN ISO 15883:1
Cleaning efficacy test		CP(D)/service engineer	BS EN ISO 15883:1
Ultrasonic activity test		CP(D)/service engineer	BS EN ISO 15883:1
ANNUALLY including quarterly tests plus:			
Completion of all validation tests above		CP(D)/service engineer	As above

Note

For cleaning efficacy tests and protein residue tests, where the cycle does not have a rinse stage, items should be rinsed as a normal procedure before these tests are carried out, otherwise the tests could return false positives.

Chapter 15 Additional information on test procedures (in addition to those provided in the Standards)

15.1 Most test procedures are defined in the referenced Standards shown in the testing protocols in **Chapters 12–14**. Unless these tests are to be performed by suitably-qualified and certificated practice staff (see Chapter 5 in WHTM 01-01 Part A for further guidance on training and certification), it will not be necessary for the practice to possess copies of these Standards. It will, however, be necessary that any contracted test performance includes reference to the requirements of these Standards.

15.2 The following tests are additional to those shown in the referred Standards. These additional test procedures are compliant with BS EN Standards and should be applied where necessary and if relevant to the type of decontamination equipment being used.

Automatic control test

15.3 This test (see list of tests in **Chapters 12–14**) is designed to show that the operating cycle functions correctly as shown by the values of the cycle variables indicated and/or recorded by the instruments fitted to the decontamination equipment.

Method

15.4 Place the test load, as defined in BS EN 13060, appropriate to the cycle to be tested and the load to be processed in the chamber. Select and start the cycle to be tested. If a process-data recording is not made by the machine, the elapsed time, chamber temperatures and pressures at all significant stages of the cycle should be observed and noted.

15.5 At the approximate mid-point of the hold time (disinfection, cleaning, sterilizing), note the elapsed time and indicated critical parameters. The test will be considered satisfactory if the following requirements are met:

- a visual display of “cycle complete” occurs;
- during the whole of the cycle the values of the cycle parameters, as indicated or shown on the process-data record, are within the limits

established as giving satisfactory results either by the manufacturer or the validation tests;

- during the hold period, the disinfection/cleaning/sterilizing temperatures are within an appropriate temperature band;
- the time for which the temperatures above are maintained is not less than that previously established either by the manufacturer or validation tests as necessary;
- the door cannot be opened until the cycle is complete. It is not advisable to attempt to open the door in case the safety devices are malfunctioning. This test should only be performed by someone fully trained to do so;
- the person conducting the test does not observe any mechanical or other anomaly.

Ultrasonic activity test

15.6 The ultrasonic activity can be investigated by the erosion pattern created on aluminium foil exposed in the tank for a short period. This activity may not be uniform throughout the tank. Validation tests will determine the pattern variation at defined positions and the time required to produce this pattern.

15.7 The exposure time will depend upon the type of foil used. Standard test foil is now available to maximise repeatability.

15.8 The following equipment will be required:

- aluminium foil provided for ultrasonic cleaner testing;
- adhesive tape, for example, autoclave indicator tape or masking tape;
- a watch or clock with a second hand;
- a rule or tape measure.

Method

15.9 The following method should be used:

- Cut strips of aluminium foil in lengths 120 mm longer than the bath is deep. Roll up one end of the foil so that the foil is now as long as the bath is deep.

- Ensure that:
 - the water in the tank is at the required level;
 - the required amount of any chemical additive specified by the manufacturer has been added; and
 - the water in the tank is at the specified operating temperature.
- Carry out the manufacturer's recommended start-up procedure. This will normally include a period of operation to eliminate dissolved gases from the solution in the bath (the degassing procedure).
- Using strips of adhesive tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3 x 3 grid. Ensure that the rolled bottom end of each foil strip is no more than 10 mm above, but not touching, the bottom of the bath.
- Operate the bath for the predetermined exposure time. This varies typically between 30 seconds and 10 minutes depending on the power rating of the ultrasonic transducers.
- Remove the strips from the bath, blot-dry and examine. The strips can be filed conveniently by sticking them to a sheet of plain paper using a transparent adhesive tape.
- Drain the bath and clean to remove debris of eroded aluminium foil.

Results and interpretation

- 15.10 When the foil strips are inspected, the areas that show maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent.
- 15.11 On re-testing the extent of erosion, the erosion pattern should remain consistent. If the zones of erosion are markedly different on the nine foils, it indicates poor uniformity of cleaning. Poor uniformity of cleaning might be due to failure of one or more of the transducers that produce the ultrasonic vibration in the base of the bath.
- 15.12 A significant change between tests indicates a deterioration or failure in the transducers. If there is no erosion, this indicates complete failure. In the event of any of these findings withdraw the ultrasonic cleaner from use and either send it for repair or replace it.

Wand meters

- 15.13 Ultrasonic energy meters are now available to monitor the efficiency and operating frequency of ultrasonic baths. They are much quicker and more convenient than the classic foil ablation test but should be used with care. Precise positioning of the wand will need to be noted in order to make the test repeatable.

Safety checks

Weekly checks

- 15.14 The User should check the following before proceeding:
- Examine the door seals.
 - Check the security and performance of the door safety devices.
- 15.15 Where the equipment possesses a pressure vessel, the following checks should be performed:
- Ensure safety valves and other pressure-limiting devices are free to operate.
 - Carry out any other checks required by the Competent Person (Pressure Systems) or the written scheme of examination.

Yearly checks

- 15.16 The CP(D) or service engineer should conduct a series of safety checks before proceeding. Advice on the yearly programme of safety checks may be sought from the AE(D) or NWSSP-FS.
- 15.17 The validation checks and tests may be used as a basis for yearly safety checks, paying particular attention to those factors affecting safety and those which may have changed since the previous annual safety check or validation test.
- 15.18 The CP(D) or service engineer should ensure verification of the adequacy and safe connection of engineering services.

Chapter 16 Approach and protocol for manual cleaning

Note

The use of manual cleaning presents particular problems. Because the process is not automatic, it is not possible to fully validate the process. Manual cleaning is thus not the preferred method of cleaning and, where possible, should be replaced with automated cleaning in a validated washer-disinfector. Where manual cleaning is required or deemed necessary, for example, as advised by the manufacturer, the practice should be operating under the correct parameters and should be controlled as much as possible to reduce the variability in cleaning performance. The following advice aims to enable this control.

- 16.1 A dirty-to-clean workflow should be maintained throughout the cleaning procedure. Two sinks, or bowls as an interim measure, should be provided, one for manual cleaning and one for rinsing. In addition, separate setting-down areas should be used for dirty instruments and for clean instruments.
- 16.2 If lack of space means that a setting-down area has to be used for both dirty and clean instruments at different times during the decontamination process, the surface should be thoroughly cleaned between stages using a water–detergent solution to minimise the risks of cross-contamination.
- 16.3 Always use detergents specifically formulated for manual cleaning of instruments.

Note

Do not use chlorhexidine handscrub, for example, Hibiscrub, washing-up liquid, cleaning creams or soap. Chlorhexidine in particular makes proteins stick to steel.

Cleaning procedure for dental instruments

- a. Measure the volume of water and detergent to achieve the concentration specified by the detergent manufacturer. A line painted on the

sink is useful to indicate the required volume of water. The detergent should be designed for the manual cleaning of dental instruments.

- b. Using a mercury-free thermometer, monitor the temperature of the water throughout the cleaning procedure to ensure the temperature of the water is 45°C or lower. A higher temperature will coagulate protein and inhibit its removal. The temperature of the fluid should be as recommended by the detergent manufacturer.
- c. Where manufacturers' instructions permit, fully submerge items to be cleaned in the detergent solution.
- d. Scrub instruments using long-handled brushes with soft plastic bristles. To minimise aerosol risk, fully immerse the instruments in the solution and keep under water during the cleaning process.
- e. Following cleaning, drain the water, avoiding splashing. If the water is heavily soiled, repeat the cleaning procedure.
- f. Brushes should be single use. Where they are reusable, after each use the brushes should be washed in hot water, using the manufacturer's recommended detergent, in order to remove visible soil, and be stored dry and head up. Dispose of brushes if they are single-use. Reusable brushes should be replaced at the manufacturer's recommended interval or more frequently if the brush is seen to have significantly deteriorated.
- g. Carry out a final rinse in the clean sink using satisfactory potable water, RO or freshly distilled water.
- h. After rinsing, drain and dry if instruments are to be wrapped.

Protocol for the manual cleaning of dental instruments

Immersion method

All personnel involved in the decontamination of dental instruments should be trained in the content and application of this protocol and associated guidance.

To minimise the risk to personnel undertaking manual cleaning, the splashing and creation of aerosols **should be avoided** at all times.

Remember: Maintaining a dirty-to-clean workflow procedure will assist in the cleaning process.

- Wash hands.
- Wear personal protective clothing (PPE).
- Prepare sinks, equipment and setting-down areas.
- Dismantle and open the instruments, as applicable, ready for immersion.
- Fill the clean sink, NOT wash-hand basin, with the appropriate amount of water and detergent specified for the purpose. Note: ensure correct temperature as recommended by the detergent manufacturer is maintained.
- Fully immerse the instruments in the solution and keep under water during the cleaning process to prevent aerosols.
- Agitate/scrub the instruments using long-handled brushes with soft plastic bristles.
- Drain any excess cleaning solution prior to rinsing.
- Rinse in a second sink with freshly distilled or RO water.
- After rinsing, drain and dry if instruments are to be wrapped.
- Visually inspect all items under an illuminated magnifier ensuring they are clean, functional and in good condition.
- Lubricate any relevant items prior to sterilization with a non-oil-based lubricant.
- Dispose of cleaning materials safely in accordance with local policy.
- Replace cleaning solution and the rinse-water after each use.
- Complete any relevant documentation.
- Where two separate sinks are not available, two bowls in one sink can be used.

Chapter 17 Steam and water quality

- 17.1 For the purposes of this document, either one of the following types of water are considered suitable:
- suitable potable water (see [paragraph 3.14](#))
 - sterile water for irrigation. Sterile water for irrigation is a sterile, non-pyrogenic preparation of water for injections BP, containing no antimicrobial agent or other substance;
 - freshly distilled water. The quality of the water should be checked;
 - Reverse osmosis water.

Steam

- 17.2 The quality of steam, for example, dryness and purity, is important for large-scale decontamination in SSDs.
- 17.3 Decontamination within a dental decontamination facility should ensure that the quality and safety of the instruments are not affected by the decontamination process itself.
- 17.4 While an SSD utilises steam from an external source, most dental facilities generate steam within the sterilizer chamber. Factors affecting the quality of the steam, and thus the safety of the instruments, include the following:
- material of chamber construction;
 - quality of feed-water, including any storage containers;
 - conditions of storage of feed-water;
 - period between changes of feed-water and usage;
 - cleanliness and cleaning regimes of water tank and pipework.

Quality of input water

- 17.5 The quality of input water for small sterilizers is defined in Annex C of BS EN 13060.
- 17.6 Care should be taken to observe use-by dates. Any water unused or left in opened containers at the end of the day should be discarded.

Conditions of storage and frequency of change

- 17.7 Feed-water may be stored in a reservoir on the machine and can be either reused or used once only, depending on the sterilizer design. While both are acceptable, there is some advantage in using the water once only in that there is no build-up of contamination within the reservoir.
- 17.8 However, even high-quality water is subject to microbial contamination. For this reason, irrespective of whether the water is used once only, the reservoir should be emptied at such a frequency as to eliminate microbiological build-up. **This policy must be extended to any portable water storage containers, and any containers opened should be discarded within a reasonable period once they have broken the seal, usually 24 hours.**
- 17.9 Current recommendations are for the reservoir to be drained down and cleaned at the end of each working day or daily shift. The machine should not be left for any lengthy period, especially overnight, with water in the reservoir. The possibility of pyrogens accumulating in the reservoir is of particular concern. Some pyrogens will be washed down from load items, while others may arise from bacterial growth, especially where the sterilizer is unused for long periods between refills. Even if such bacteria are subsequently killed by the sterilization process, pyrogens will not be inactivated and will be deposited on the next load. The levels of pyrogens in the steam may exceed the permitted maximum even though sterilized water for irrigation was used as the original feedwater.

Water

Cleaning

- 17.10 Cleaning and rinsing, either manual or automated, can be performed with potable water as long as the water hardness is low enough not to reduce the effectiveness of any part of the process and other aspects of the water quality are satisfactory. It is recommended that water for cleaning should have a suitable hardness level. This is part of the

consideration for defining satisfactory potable water. The local water advisor should be consulted on endotoxins, hardness, silicates, ammonia concentrations at not less than annual intervals.

- 17.11 If the input water has a hardness higher than recommended, water softening may be a considered option. An ongoing knowledge of the hardness of the incoming water feed is therefore necessary and the hardness values themselves should be documented at intervals recommended by the local water advisor.

Final rinsing

- 17.12 The final rinsing of instruments, those washed manually, in an ultrasonic bath or in a washer-disinfector, should be carried out using satisfactory potable water, RO or freshly distilled water.

Detergents

- 17.13 The efficacy of cleaning will depend on the relationship between potable water quality and detergent performance. The detergent should be chosen not only for its cleaning efficacy but also for its compatibility with the potable water quality and parameters of its use.

Chapter 18 The use of lubricants

18.1 Lubricants, usually in aerosol form, are often used during the decontamination and preparation process. This is often required by the manufacturer in order to lengthen the working life of some instruments. Such instructions should be followed. Any doubts about the relevance of these instructions should be checked and confirmed in writing by the manufacturer.

18.2 It should be noted that using lubricants will inevitably introduce oils into a process designed to remove contamination. Where water is reused in the sterilizer, this contamination may build up within the reservoir and the sterilizer chamber.

However, this effect will be limited if guidance given in this document requiring that water be changed at least once per day is carefully applied.

18.3 There is a limited conflict between decontamination and the use of lubricant. If lubrication is practised in accordance with manufacturer's instructions, the consequence of this recontamination should be assessed. This assessment will require consultation with the equipment manufacturer or service agent who should be asked to approve the choice of lubricant used.

Chapter 19 Hot and cold water systems and dental unit water lines

19.1 Registered Managers of dental practices have an overriding general duty of care under the Health and Safety at Work etc Act 1974. Therefore, they should ensure that the water supply, storage and distribution services should comply with the best practice guidance given in:

- the Health & Safety Commission's 'Legionnaires' disease – the control of legionella bacteria in water systems. Approved Code of Practice & Guidance' (also known as L8); and
- HSG 274 Legionnaires' disease: Technical guidance
- Health Technical Memorandum 04-01 – 'The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems'.

Advice can be sought from NWSSP-FS on these systems.

Note

The Approved Code of Practice L8 has a special legal status. Health and safety inspectors seek to secure compliance with the law and may refer to L8 and HSG 274 as illustrations of good practice.

Compliance with WHTM 04-01 and this guidance document will satisfy L8.

19.2 All premises are required to have a **written scheme** and a legionella **risk assessment** for controlling any identified risks in accordance with L8:

- Written schemes, to the required standard, can be produced by competent persons, generally members of the Legionella Control Association.
- A **risk assessment** for the water services will be necessary to identify potential problems in the system, for example, excess storage capacity, temperature distribution problems, low water usage, inappropriate materials. The risk assessment should be carried out by a Competent Person.
- The Registered Manager should ensure that an operational plan is in place for each site under their control. This document should comprise:

- up-to-date as-fitted drawings, schematic diagrams and descriptions of all the supply, storage and distribution systems within those premises;

Note

As-fitted drawings can be obtained from third parties such as architects.

- step-by-step instructions to operate, maintain, control and shut down the water, storage and distribution systems within those premises;
- a schedule of possible emergency incidents causing loss of the water supply from the water undertaker. Each item in the emergency incident schedule should include guidance on operational procedures to re-establish a stable wholesome water supply.

19.3 The Registered Manager should implement a programme of staff training to ensure that those appointed to devise strategies and carry out control measures are appropriately informed, instructed and trained and should be assessed as to their competency. It is also essential that they have an overall appreciation of the practices affecting water hygiene and safety and that they can interpret the available guidance and perform their tasks in a safe and technically competent manner.

Safe hot water temperature

19.4 To reduce the risk of scalding, thermostatic mixing devices should be installed where applicable. A risk assessment will be necessary to establish the need and type of device to be installed.

19.5 Routine checks are essential to ensure continued satisfactory operation.

Utilisation

19.6 One of the critical factors affecting the quality of water within hot and cold water distribution systems is the extent of utilisation. The Registered Manager needs to ensure that there is good liaison between staff members in the dental practice to ensure that the water services are sufficiently used.

- 19.7 L8 recommends that, for sporadically used taps, flushing is carried out once a week. The procedure for such practice should be fully documented and covered by written instructions.

Flushing dental unit water lines (DUWLs)

- 19.8 For procedures on flushing DUWLs between treatment sessions and at the beginning and end of each working day, see [paragraphs 6.84–6.86](#).

Decommissioning of DUWLs

- 19.9 Follow the manufacturer's guidance for the temporary decommissioning of DUWLs.
- 19.10 In the absence of manufacturers' guidance, DUWLs should be flushed, drained and left disconnected during any temporary closure of the treatment room. If this is not practicable, they should be flushed on a weekly basis as per the guidance above.
- 19.11 Self-contained water bottles (bottled water systems) should be removed, flushed with distilled or fresh RO water and left open to the air for drying. They should then be stored inverted to prevent contamination during the temporary closure.

Recommissioning of DUWLs

- 19.12 In the absence of manufacturers' guidance, the DUWL should be flushed for at least three minutes, disinfected with a suitable disinfectant, as recommended by the manufacturer for routine disinfection of the DUWL, then flushed for a further three minutes.
- 19.13 Where in-line filters are used, these will require treatment using a cleansing solution that has been recommended by the manufacturer. This step should be performed after first flushing the DUWL.

Note

Care should be taken to minimise the occurrence of splashing and aerosol formation.

- 19.14 If DUWLs have disposable filters, they should be replaced.
- 19.15 Self-contained water bottles (bottled water systems) should be flushed with distilled or clean RO water. Where visual contamination is present, flushing with a suitable disinfectant followed by thorough washing is necessary. The manufacturer's instructions will specify which disinfectant to use. In instances where visual contamination is

routinely detected, it will be necessary to decrease the interval between flushing operations. If good practice is followed, practices should not routinely detect evidence of visual contamination.

Note

The self-contained water supplies used for dental care systems should be freshly distilled or RO water (see [Chapter 17](#)).

- 19.16 As part of the recommissioning, dental equipment requiring protection against backflow should have the anti-retraction valves, incorporated on handpieces or waterlines, checked by the Responsible Person. They should ensure they are suitably decontaminated, refitted correctly and are operating in the correct manner. Examples of dental equipment requiring backflow protection are:
- dental spittoons;
 - three-in-one syringes;
 - ultrasonic scalers;
 - wet-line suction apparatus; and
 - self-filling automatic radiographic processors, where still used.
- 19.17 Adherence to the equipment manufacturer's recommended cleaning procedures, including use of their recommended chemicals, is a requirement for medical devices such as those listed above.

Maintenance policy

- 19.18 The Registered Manager is ultimately responsible for the provision of a wholesome water supply in the premises under their authority.

Contract maintenance

- 19.19 When selecting subcontractors, particularly in relation to the control of legionella, their competence should be established beforehand, for example, companies or individuals who are members of the Legionella Control Association.

Emergency action

- 19.20 Contingency plans should be available in the event of the following:
- a. A power failure:
 - This may result in a failure to maintain temperature in the hot water system.
 - If the dental practice produces its own distilled water, this will restrict the amount of distilled water that can be produced in a set time period.

- b. A mains-water failure that could last beyond the period for which storage capacity has been designed:
- may result in the temporary cessation of the production of RO water;
 - may require the temporary cessation of sterile supply activities;
 - may result in hygiene issues for patient and staff WCs and washrooms.

Note

The emergency action to be taken during an outbreak of healthcare-associated legionellosis is covered in WHTM 04-01 Part B Appendix 1.

Documentation

- 19.21 It is essential to have comprehensive operational manuals for all items of plant; they should include requirements for servicing, maintenance tasks and frequencies of inspection.
- 19.22 This information should be kept together with all commissioning data.

As-fitted drawings

- 19.23 The availability of accurate as-fitted drawings is essential for the safe operation of hot and cold water service systems. The drawings are necessary to perform the temperature control checks on the systems and will assist in identifying any potential problems with poor hot water circulation and cold water dead-legs, where flow to sporadically-used outlets can be low. Such information should identify all key components in the installations, for example, water meters, storage tanks, filtration equipment, where fitted, calorifiers and the location of isolating valves in the systems. As-fitted drawings can be obtained from third parties such as architects.
- 19.24 In addition to drawings, there should be comprehensive schedules of outlets, lists of sentinel taps (outlets), other outlets to be tested annually and other components in the system.

Note

The information required above could be compiled by the Competent Person employed to produce the written scheme, since much of the information is an integral part of the written scheme itself.

Record-keeping

- 19.25 The User should ensure that an accurate record of all assets relating to the hot and cold water distribution systems is set up and regularly maintained.
- 19.26 The User should also ensure that records of all maintenance, inspection and testing activities are kept up-to-date and properly stored. Records should be kept for at least five years. As a minimum, the following items should be recorded:
- the names and positions of those responsible for performing the various tasks under the written scheme;
 - a legionella risk assessment and a written scheme of actions and control measures;
 - details of precautionary measures that have been carried out, including sufficient detail to identify that the work was completed correctly and when the work was carried out.
- 19.27 Planned preventive maintenance will help to ensure that systems perform correctly, and an essential element of this process is the maintenance of accurate records.
- 19.28 Maintenance records should include the following:
- details of remedial work required and work carried out;
 - details of cleaning and disinfection procedures;
 - results of any chemical or microbiological analyses of water.
- 19.29 When alterations to equipment or systems are implemented, any drawings kept with the records should be updated to reflect the modifications carried out.
- 19.30 The asset register should be designed to provide the following information:
- an inventory of equipment;
 - a basis for identifying equipment details;
 - a basis for recording the maintenance requirements;
 - a basis for recording and accessing information associated with disinfection and maintenance.
- 19.31 When completing records, it is essential that the individual concerned signs and dates the entries and that there is an audit trail in place.

Water supply hygiene

- 19.32 After any installation work, all piping, fittings and associated services used for the conveyance of

water for domestic purposes must be disinfected before being brought into use. The method generally used for disinfection is chlorination. Disinfection using chlorine should be carried out in accordance with BS EN 806-2, BS EN 806-3, BS EN 806-5 and BS 8558 (see also WHTM 04-01 Part A Chapter 17) and under the direct supervision of a nominated person.

- 19.33 Despite disinfection of systems, some outbreaks of disease related to treated water supplies still occur. To reduce the risk of such outbreaks, the design should eliminate:
- direct contact with the internal parts of water pipes and structures by people, animals or birds, for example, ensure covers are in place on storage tanks and cisterns;
 - backflow (back-siphonage) of contaminated water into systems conveying potable water (mains and storage structures).

Water treatment

- 19.34 In a properly installed and commissioned hot water system, it should be possible to maintain a temperature of at least 55°C at the furthest drawoff point in the circulating system, and 50°C in the circulating system's return connection to the calorifier.
- 19.35 In older premises this may not be possible, and in the case of cold water systems it is not always possible or practicable to maintain water temperature below 20°C because of utilisation and complexity. In addition, therefore, it may be necessary to apply a residual biocidal water treatment that has been shown to destroy and remove biofilm. Information on these techniques, which include chlorine dioxide and copper and silver ionisation, can be found in WHTM 04-01 Part B.

Note

In addition to residual biocidal techniques, there are other manufacturer-specified treatments that are developed for use on DUWLs and other associated dental equipment. Refer to the manufacturer's instructions for their correct use.

- 19.36 Where automatic equipment is used for disinfection, it should indicate any change in the amount or concentration of material injected into the water so that immediate action can be taken.
- 19.37 Continuous dosing with appropriate biocides that have proven efficacy should be considered during construction to prevent the accumulation of

biofilm. A regular flushing programme for all outlets should also be implemented.

- 19.38 The continuous chlorination of hot and cold water service systems to control the growth of legionella is not generally recommended. Treatment using chlorine dioxide or copper and silver ionisation can be used. Advice should be sought from the Health Board Responsible Person (Water).
- 19.39 In defining their responsibilities, service providers should be asked to advise on test methods and anticipated concentrations of residual chemicals within the system. (See also Chapter 3 of WHTM 04-01 Part A for more guidance on water treatment regimens.)

Purging the systems

- 19.40 Where chemical treatment is introduced, it is essential to ensure that all parts of the system are purged so that adequate concentrations are achieved.
- 19.41 As temperature monitoring is performed on sentinel and representative outlets on a rolling basis only, additional draw-off will be required at all points on a regular basis.

Ozone and ultraviolet treatment

- 19.42 Whereas treatments such as chlorine dioxide and copper and silver ionisation are intended to be dispersive, that is, they result in a residual agent within the system; ozone and ultraviolet are intended to be effective close to the point of application. They are not, therefore, necessarily effective in hot and cold water service systems (see Chapter 15 of WHTM 04-01 Part A).

Metal contamination

- 19.43 See WHTM 04-01 Part A Chapter 6.

Filtration

- 19.44 It is essential for filter cartridge elements to be changed at appropriate intervals in accordance with the manufacturer's recommendations, taking into account local conditions.
- 19.45 Filter membranes should also be chemically cleaned or replaced at the recommended periods, and care must be taken to ensure that the "vessel" or "housing" containing the filter assembly is also disinfected appropriately during filter or membrane maintenance.

Water storage

19.46 For general information on water storage, see WHTM 04-01 Part A (paragraphs 7.1–7.2) and WHTM 04-01 Part B (paragraphs 7.54–7.61). Advice can be sought from NWSSP-FS.

Cold water distribution system

19.47 The design and installation of the cold water distribution system should comply with the Water Supply (Water Fittings) Regulations 1999 and relevant parts of BS EN 806-2, BS EN 806-3 and BS 8558 (See Chapter 8 of WHTM 04-01 Part A for further information.)

19.48 The control of water temperature in the cold water service will essentially rely on good insulation and water turnover. Cold water services should be sized to provide sufficient flow and should be insulated and kept away from areas where they are prone to thermal gains. This also applies to water supplies for spittoons. Stagnation must be avoided. Special attention should be given to the maintenance and monitoring of these systems.

19.49 Schematic drawings of the system with numbered and labelled valves will reduce confusion and save time in trying to identify appropriate isolating valves and other system components.

19.50 Checks and actions should be carried out to show that:

- the system components show no sign of leakage or corrosion;
- the system insulation is in good condition;
- the system filters have been changed and/or cleaned in accordance with manufacturer's recommendations. Strainers should be checked and cleaned regularly;
- all isolating valves have periodically been worked through their full range of travel;
- every water outlet complies with the backflow protection requirements of the Water Supply (Water Fittings) Regulations 1999.

Drinking water

19.51 If separate drinking water supplies are provided, reference should be made to WHTM 04-01 Part A (paragraphs 8.13 and 8.14).

Hot water storage and distribution

19.52 Hot water services should be designed and installed in accordance with the Water Supply (Water Fittings) Regulations 1999 and relevant

parts of BS EN 806-2, BS EN 806-3 and BS 8558. The hot water system may be of either the vented or the unvented type. (See WHTM 04-01 Part A Chapter 9 for further information.)

19.53 To control possible colonisation by legionella, it is essential to maintain the temperature within the hot water circulating system. To some extent, if properly maintained, the calorifier/water heater will provide a form of barrier to legionella and other water-borne organisms. The minimum flow temperature of water leaving the calorifier/water heater should be 60°C at all times and 55°C at the supply to the furthestmost draw-off point in the circulating system.

Note

A minimum of 55°C may be required for the operation of suitable mixing devices to provide "safe" hot water at the upper limit of the recommended range.

In large non-recirculating systems, the minimum of 55°C should be maintained by electric trace-heating.

19.54 The minimum water temperature at the connection of the return to the calorifier/water heater should be 50°C. To achieve the required circulating temperatures, it will be necessary to maintain the balance of flows to individual pipe branches and drawoff points.

19.55 Calorifiers, where fitted, should be subjected to regular procedures that include the following:

- cleaning and maintenance;
- quarterly draining to minimise the accumulation of sludge. This may be extended to annual draining if, during inspection, it is found that there is little accumulation of debris;
- whenever dismantled for statutory inspection, or every year in the case of indirect calorifiers, they should be thoroughly cleaned to remove sludge, loose debris and scale;
- whenever a calorifier is taken out of service, it should be refilled, drained, refilled again and the entire contents brought up to, and held at, the nominal operating temperature of 60°C for at least an hour. See also WHTM 04-01 Part B paragraphs 7.74–7.76 for further advice.

Instantaneous water heaters for single or multi-point outlets

19.56 The general principles and limitations of instantaneous water heaters are given in the relevant parts of BS EN 806-2, BS EN 806-3 and BS 8558:

- the flow rate is limited and is dependent upon the heater's hot water power rating;
- where restricted rates of delivery are acceptable, the heater can deliver continuous hot water without requiring time to reheat;
- they are susceptible to scale formation in hard water areas where they will require frequent maintenance;
- this form of hot water heating should only be considered for smaller premises or where it is not economically viable to run hot water distribution to a remote outlet.

Safe hot water delivery devices

- 19.57 Appropriate types of thermostatic mixing device are specified in WHTM 04-01 Part A Table 4.
- 19.58 It is essential to check the temperature settings and operation of all water mixing devices regularly, preferably every six months, provided that there is no "drift" in excess of 1°C. Other maintenance should be strictly in accordance with the manufacturer's instructions.
- 19.59 Local water quality will influence the maintenance frequency for any installation. A relatively small piece of debris may restrict the operation of the temperature control and fail-safe mechanisms.
- 19.60 The recommendations regarding safe water temperature apply to all areas to which patients and visitors have free access.

Materials of construction

- 19.61 Systems should comply with the requirements of the Water Supply (Water Fittings) Regulations 1999. Materials used in contact with water that is for drinking etc. should comply with BS 6920-1 and be listed in the latest edition of the 'Water Fittings and Materials Directory' published by WRAS.

Temperature control regimen

- 19.62 Temperature control regimen is the preferred strategy to maintain systems free from legionella and other water-borne organisms. This will require monitoring on a regular basis. The test frequencies are listed in [Table 1](#).

Point-of-use filtration

- 19.63 Point-of-use filters must be changed in accordance with manufacturers' recommendations, typically at least once a month. When changing filters, it is recommended that water-quality sampling takes place at outlets identified as sentinel points before refitting a replacement filter. Except where taking samples as above, once point-of-use filtration has been introduced, taps or showers must not be used without a filter in place.
- 19.64 Where point-of-use filters are no longer required, the outlet and associated pipework must be disinfected to remove any accumulated biofilm before the system is returned to service (see also WHTM 04-01 Part A paragraph 5.16).

Summary checklist

- 19.65 A summary checklist for hot and cold water services showing recommended frequency of activity is given in [Table 2](#).

Note

The checks and tasks outlined in [Tables 1](#) and [2](#) could be carried out by trained user or contracted-out to a third party, for example, a Health Board.

Table 1: Tests for temperature performance

Frequency	Check	Cold water	Hot water	Notes
Monthly	† Sentinel outlets	The water temperature should equilibrate below 20°C after draw-off for 2 minutes ^{1,2}	The water temperature should equilibrate to at least 50°C after draw-off for 1 minute ³	These measurements are applicable to non-mixed outlets only
Monthly	Inlets to sentinel TMVs	Temperatures as above	Temperatures as above	Measurements can be made by means of surface temperature probes
Monthly	Water leaving and returning to calorifier			Also to be monitored continuously by BMS
6-monthly	In-coming cold water at inlet to building – in the winter and in the summer	The water should be below 20°C ²		Also to be continuously monitored by BMS
Annually	‡ Representative outlets	The water temperature should equilibrate below 20°C after draw-off for 2 minutes ^{1,2}	The water temperature should equilibrate to at least 50°C after draw-off for 1 minute ³	

Notes:

† Sentinel outlets are normally those that, on a hot water service, are the first and last outlets on a recirculating system. On cold water systems, or non-recirculating hot water systems, they are the closest and furthestmost from the storage tank or water heater. The choice of sentinel taps should also include other outlets that are considered to represent a particular risk, for example, those installed in accommodation in which particularly susceptible patients are treated, or others identified in the risk assessment and temperature mapping exercise as having the least satisfactory temperature performance.

‡ Representative outlets include conventional and mixed-temperature taps; 20% of the total number installed throughout the premises would be tested annually on a rotational basis: that is, all taps checked every five years.

1. The Health & Safety Commission’s HSG274 Legionnaires’ disease: Technical guidance permits a period of two minutes to achieve an equilibrium temperature below 20°C. Achieving this minimum requirement would be indicative of an exceptionally underutilised water system. (At a typical flow to a wash-hand basin of 4.5 L/m, 2 minutes to achieve temperature would indicate a 50 m dead-leg of 15 mm pipe.)
2. The Water Supply (Water Quality) Regulations (latest amendment) permit water undertakers to supply water to premises at temperatures up to 25°C. In practice, the water temperature is likely to be below this maximum value, typically below 10°C in winter

and 20°C in summer. If, during prolonged periods of high environmental temperature, the water temperature starts to exceed 20°C, the water undertaker should be asked to see whether remedial action could be undertaken. Within the curtilage of the premises, the aim should be to ensure that the temperature difference between the in-coming supply and most distal parts of the distribution system is below 2°C.

3. The Health & Safety Commission’s HSG274 Legionnaires’ disease: Technical guidance permits a period of 1 minute to achieve an equilibrium temperature of 50°C. A minimum of 55°C may be required for the operation of suitable mixing devices required to provide “safe” hot water at the upper limit of the recommended range. Hot water at 55°C is required in many cases for reasons of food hygiene or decontamination requirements, for example, in kitchens and sluice rooms etc. In a properly balanced hot water circulating system, with the circulation taken close to the drawoff point, achieving temperature should be virtually instantaneous. (At a typical flow to a wash-hand basin of 4.5 L/m, 1 minute to achieve temperature would indicate a 25 m dead-leg of 15 mm pipe.)

Table 2: Summary checklist for hot and cold water services

Service	Task*	Frequency
Hot water services	Arrange for samples to be taken from hot water calorifiers/ water heaters in order to note condition of drain water	Annually
	Check temperatures in flow and return at calorifiers/water heaters	Monthly ⁴
	Check water temperature after draw-off from outlets for 1 minute to ensure that 50°C has been achieved in sentinel outlets ^{1,2,5}	Monthly ⁴
	Visually check internal surfaces of calorifiers/water heaters for scale and sludge. ⁵ Check representative taps for temperature as above on a rotational basis	Annually
	Manual check to confirm secondary hot water recirculation pumps are operating effectively	Monthly
Cold water services	Check tank water temperature remote from in-coming ball valve and mains temperatures. Note maximum temperatures recorded by fixed max/min thermometers, where fitted	6-monthly ⁴
	Check temperature in sentinel outlets after draw-off for 2 minutes to establish that it is below 20°C ^{2,3}	Monthly
	Visually inspect cold water storage tanks and carry out remedial work where necessary. Check representative taps for temperature, as above, on a rotational basis	Annually
Dental equipment	Drain down and clean	At the end of each working day
Emergency eye wash sprays	Flush through and purge to drain	6-monthly or more frequently if recommended by manufacturers
Mixed-temperature outlets	Check delivery temperature in accordance with D08	6-monthly
Showerheads	Dismantle, clean and descale showerheads and hoses	Quarterly, or as necessary
Sporadically-used outlets	Flush through and purge to drain, or purge to drain immediately before use without release of aerosols	At least twice weekly ⁶

Notes:

* See paragraph 182 in the Health & Safety Commission's HSG274 Legionnaires' disease: Technical guidance further guidance on tasks that should be undertaken.

1. For effective operation of hot water services, the minimum equilibrium temperature should be 55°C and be achieved within seconds.
2. For thermostatic mixing devices, temperatures should be measured at the inlet.
3. For satisfactory operation of cold water services, temperature equilibrium to below 20°C should be achieved well within one minute.

4. Temperatures should be continuously monitored by the BMS.

5. Additional checks should be made on the hot water circulating system and systems using trace heating at distal points.

6. Risk assessment may indicate the need for more frequent flushing of outlets. It is preferable that this form part of the daily cleaning routine where appropriate. Alternatively, self-purging showers that discharge water to a drain prior to use and without the release of aerosols can be considered.

Microbiological monitoring

- 19.66 Apart from situations where there are taste or odour problems, microbiological monitoring for total viable counts (TVCs) is not considered to be necessary.
- 19.67 If performed for these purposes, the detection of low TVCs is not necessarily an indication of the absence of legionella, but is an indication of the overall water quality and signifies a generally unfavourable environment for bacteria.
- 19.68 All microbiological measurements should be by approved methods and/or be carried out by United Kingdom Accreditation Service (UKAS)-accredited laboratories. Dip slides are not acceptable.

Appendix 1: Waste disposal

Note

Dental practitioners should read Welsh Health Technical Memorandum 07-01 – ‘Safe management of healthcare waste’, which provides a good-practice framework for the management of healthcare waste, helping healthcare organisations such as dental practices to meet legislative requirements. The guidance includes:

- a unified approach to identifying and classifying infectious and medicinal waste to comply with health and safety, transport and waste regulations;
- a revised colour-coded waste segregation and packaging system to allow standardised identification of waste;
- the use of European Waste Catalogue (EWC) codes on all waste documentation;
- a new offensive/hygiene waste stream for non-infectious waste (human hygiene waste and sanpro (sanitary protection) waste);
- items and equipment that do not pose a risk of infection, including gowns, gloves, plaster casts.
- Check with the local waste contractor to ensure that colour-coded waste containers, labels and documentation comply with the latest guidance.

Note

The Hazardous Waste (England and Wales) Regulations require that dental amalgam waste is kept separate from other waste and consigned to an appropriate waste management facility. To comply with these requirements, Registered Managers need to fit amalgam separators and consign the amalgam to an appropriate facility for disposal or recovery.

What are the responsibilities of the dental practice?

It is the responsibility of the Registered Manager (or nominated other) to ensure that waste is:

- correctly segregated;
- stored safely and securely away from areas of public access within the premises;
- packaged appropriately for transport;
- described accurately and fully on the accompanying documentation when removed;
- transferred to an Authorised Person for transport to an authorised waste site;
- appropriately registered, with necessary records and returns at premises.

The Registered Manager should also ensure that all staff are trained and aware of the waste procedures and comply with them.

Appendix 2: Hand-hygiene policy

A hand-hygiene policy must be available within the practice and should contain, at least, the following:

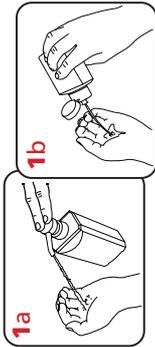
- Wash hands between each patient treatment, and before donning and after removal of gloves. Antibacterial-based hand-rubs and gels can be used instead of hand-washing between patients during surgery sessions.
- Bar soap must not be used or made available in the practice.
- Do not use abrasive sponges or nail brushes because these can cause abrasion of the skin where microorganisms can reside.
- Nails must be short and clean. Nails should be free of nail art, permanent or temporary enhancements (false nails) or nail varnish.
- Nails should be cleaned using a blunt “orange” stick.
- Use good-quality soft paper hand-towels.
- Ensure that paper towels and drying techniques do not damage the skin.
- Use a hand cream following hand-washing at the end of a session to counteract dryness, but do not use hand cream under gloves because this can encourage the growth of microorganisms.
- Antibacterial-based hand-rubs and gels formulated for use without water can be used on visibly clean hands in conjunction with a good hand-washing technique for invasive dental procedures.
- Follow local infection control guidance or manufacturers’ instructions on the maximum number of applications of antibacterial-based hand-rubs and gels that can be used on physically clean hands before hand-washing is required. Be aware that build-up of product on the hands occurs with repeated application. If hands become “sticky”, they must be washed as normal using a proper hand-hygiene technique.
- Alcohol-impregnated wipes used for cleaning surfaces should not be used in place of hand-rubs and gels, as they are not effective in hand decontamination.
- Use a foot-operated or sensor-operated waste bin

Table A1: Levels of hand hygiene

	Level 1: Social hand hygiene	Level 2: Hygienic hand hygiene	Level 3: Surgical scrub
Why?	To render the hands physically clean and to remove transient microorganisms, picked up during social activities.	In addition to level 1, to destroy microorganisms and to provide residual effect during times when hygiene is particularly important in protecting yourself and others.	In addition to level 2, to substantially reduce the numbers of resident microorganisms that normally live on the skin during times when surgical procedures are being carried out.
When?	<p>Before:</p> <ul style="list-style-type: none"> commencing/leaving work using computer keyboards eating or handling food or drinks carrying out decontamination procedures preparing or giving medications direct patient contact where no exposure to blood or other bodily fluids or non-intact skin has occurred. <p>After:</p> <ul style="list-style-type: none"> becoming visibly soiled visiting the toilet patient contact even where no exposure to blood or other bodily fluids, or non-intact skin has occurred carrying out decontamination procedures using computer keyboard handling laundry, equipment or waste blowing, wiping or touching nose. 	<p>Before:</p> <ul style="list-style-type: none"> aseptic procedures contact with immunocompromised patients before wearing gloves and carrying out minor surgical or routine dental procedures. <p>After:</p> <ul style="list-style-type: none"> Contact with blood, other bodily fluids, excretions, secretions, mucous membranes, non-intact skin, wound dressings, spore-forming organisms. 	<p>Before:</p> <ul style="list-style-type: none"> surgical or invasive procedures, oral surgery, perio or implant surgery <p>(Specific policies and procedures on surgical preparation should be available at local level)</p>
What hand hygiene to use?	<p>Mild liquid soap – does not need to be antibacterial or antiseptic.</p> <p>Antibacterial-based hand-rubs/gels can be used when hands have not been soiled.</p> <p>Bar soap should not be used.</p>	<p>An approved antibacterial hand cleanser (for example, 2–4% chlorhexidine, 5–7.5% povidone iodine, 1% triclosan or plain soap from a dispenser).</p> <p>Antibacterial-based hand-rubs/gels (for example, when performing aseptic techniques) to provide further cleansing and residual effect, and may be used with plain (liquid) soap where necessary.</p>	<p>An approved antibacterial hand cleanser (for example, chlorhexidine gluconate 4%, povidone iodine 7.5%).</p> <p>People who are sensitive to antiseptic cleaners can wash with an approved plain liquid soap followed by two applications of an antibacterial-based hand-rub/gel. Skin problems should be reported and discussed with a GP or occupational health, and a local procedure followed.</p>
How long for?	10–15 seconds	15–30 seconds	2–3 minutes, ensuring all areas of hands and forearms are covered.

HAND CLEANING TECHNIQUES

How to handrub?



Apply a small amount (about 3ml) of the product in a cupped hand, covering all surfaces

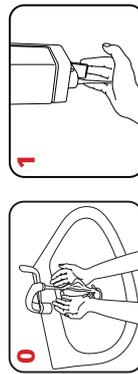
- 2** Rub hands palm to palm
- 3** Rub back of each hand with the palm of other hand with fingers interlaced
- 4** Rub palm to palm with fingers interlaced
- 5** Rub with backs of fingers to opposing palms with fingers interlocked
- 6** Rub each thumb clasped in opposite hand using rotational movement
- 7** Rub tips of fingers in opposite palm in a circular motion
- 8** Rub each wrist with opposite hand



Once dry, your hands are safe

20-30 sec

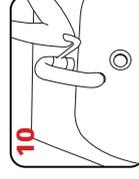
How to handwash? WITH SOAP AND WATER



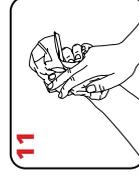
Wet hands with water
Apply enough soap to cover all hand surfaces



Rinse hands with water



Use elbow to turn off tap



Dry thoroughly with a single-use towel



Your hands are now safe

40-60 sec



Appendix 3: Examples of logbook pages

Table A2: Summary details

Steam sterilizer details		
Dental practice address	Room	Make
Model	Ref. No	Serial No.

Contents – the following forms:					
Name of form	Code	No.	Copy	Purpose	Table
Daily test sheet			Yes	A record of all daily testing	A3
Weekly test sheet plant history record			No	A record of faults/maintenance	A4
Quarterly and yearly test sheets			Yes	Competent Person's (Decontamination) quarterly and yearly test sheets	–
Test history record			Yes	History of the weekly, quarterly and yearly tests	–
Autoclave history record sheet			Yes	Record of all faults, maintenance and repairs to the autoclave	A5
Process log sheet			No	Provides a record of every sterilizer load processed	A6

Personnel	Name/organisation	Tel. No.
Registered manager		
User		
Operator(s)		
Decontamination Lead		
Designated Person		
Authorised Engineer (Decontamination)		
Competent Person (Pressure vessels)*		
Authorised Person (Decontamination)		
Competent Person (Decontamination)*		
Service engineer		
Microbiologist		

*These personnel should have qualifications/training/registration defined in WHTM 01-01 Part A

Pressure Systems Safety Regulations 2000

This section to be filled in by the Competent Person (Pressure vessels)

Written scheme of inspection exists/is suitable

Inspection carried out on Date:

Inspected by:

Result of examination/comments

Review of records by Nominated Person e.g. Designated Person/AP(D)/AE(D)		
Date	Comments on review	Name/signature

Table A4: Weekly test sheet

Tests to be carried out in accordance with WHTM 01-05

Sterilizer location		Serial No.			Department	
Make/model					Ref. No.	
Week beginning	Cycle number	Automatic air leakage test result* Pass/Fail	Automatic control test result Pass/Fail	Steam penetration test Pass/Fail/Not applicable	Weekly safety checks Satisfactory/ Unsatisfactory	Certified fit for use by user
	P/F	P/F	P/F/NA	S/U		
	P/F	P/F	P/F	S/U		
	P/F	P/F	P/F	S/U		
	P/F	P/F	P/F	S/U		
	P/F	P/F	P/F	S/U		
	P/F	P/F	P/F	S/U		
	P/F	P/F	P/F	S/U		
	P/F	P/F	P/F	S/U		

* Only where the sterilizer has an in-built self-test programme. Otherwise the test should be carried out by a CP (D) and copies of the CP(D)'s test sheets should be inserted.

Weekly safety checks (tick if satisfactory)						
Week beginning	Cycle number	Door seal	Door pressure interlock	Door closed interlock	Satisfactory/Unsatisfactory	Tested by
					S/U	
					S/U	
					S/U	
					S/U	
					S/U	
					S/U	

Faults – new or existing (also enter in plant history record)

References

It should be noted that this list may not be totally inclusive at the time of reading. Advice should be sought on the currency of these references and the need to include new or revised documents.

Acts and regulations

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

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations

Control of Substances Hazardous to Health Regulations (COSHH)

Hazardous Waste (England and Wales) Regulations

Health and Safety at Work etc. Act

Medical Devices Regulations

Pressure Systems Safety Regulations

The Private Dentistry (Wales) Regulations

Water Supply (Water Fittings) Regulations

Water Supply (Water Quality) Regulations

British, European and International Standards

<http://shop.bsigroup.com/>

BS 6920-1. Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water. Specification. British Standards Institution, 2000.

BS 8558. Guide to the design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages. Complementary guidance to BS EN 806.

BS EN 285. Sterilization. Steam sterilizers. Large sterilizers.

BS EN 556-1. Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices.

BS EN 556-2. Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for aseptically processed medical devices.

BS EN 806-2. Specifications for installations inside buildings conveying water for human consumption. Design.

BS EN 806-3. Specifications for installations inside buildings conveying water for human consumption. Pipe sizing. Simplified method.

BS EN 806-5. Specifications for installations inside buildings conveying water for human consumption. Operation and maintenance.

BS EN 13060. Small steam sterilizers.

BS EN 61010-1. Safety requirements for electrical equipment for measurement, control and laboratory use.

BS EN ISO 11607-1. Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems.

BS EN ISO 11607-2. Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes.

BS EN ISO 14971. Medical Devices – Application of risk management to medical devices.

BS EN ISO 15883-1. Washer-disinfectors. General requirements, terms and definitions and tests.

BS EN ISO 15883-2. Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

BS EN ISO 17665-1. Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices.

Department of Health (England) publications

www.gov.uk/government/organisations/department-of-health

Advisory Committee on Dangerous Pathogens – Transmissible Spongiform (ACDP TSE) Risk Management Subgroup

www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

An integrated approach to hospital cleaning: microfibre cloth and steam cleaning technology.

www.gov.uk/government/uploads/system/uploads/attachment_data/file/143264/Microfibre_report_revised_Mar_08.pdf

Potential vCJD transmission risks via dentistry: an interim review.

webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081170

Health and Safety Executive

www.hse.gov.uk/

Control of Substances Hazardous to Health Regulations (COSHH).

www.hse.gov.uk/coshh/

Legionnaires' disease -Technical guidance HSG 274.

www.hse.gov.uk/pubns/books/hsg274.htm

Legionnaires' disease – the control of legionella bacteria in water systems. Approved Code of Practice and guidance on regulations L8.

www.hse.gov.uk/pubns/books/l8.htm

Health Inspectorate Wales

www.hiw.org.uk/

National Infection Control Policies for Wales.

www.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=38960

NHS Wales Shared Services Partnership – Facilities Services

The publications below are available from the NHS Wales Shared Services Partnership - Facilities Services websites:

Intranet: howis.wales.nhs.uk/whe

Internet: www.wales.nhs.uk/whe

Welsh Health Building Note 00-09 – Infection control in the built environment

Welsh Health Building Note 13 – Sterile services department.

Welsh Health Technical Memorandum 00 – Policies and principles: best practice guidance for healthcare Engineering.

Welsh Health Technical Memorandum 01-01 – Decontamination of medical devices within acute services Part A: Management and environment.

Welsh Health Technical Memorandum 01-01 – Decontamination of medical devices within acute services Part B: Common elements.

Welsh Health Technical Memorandum 01-01 – Decontamination of medical devices within acute services Part C: Steam sterilization and steam for sterilization.

Welsh Health Technical Memorandum 01-01 – Decontamination of medical devices within acute services Part D: Washer-disinfectors.

Welsh Health Technical Memorandum 01-04 –Decontamination of laundry and infected linen.

Welsh Health Technical Memorandum 03-01 - Specialised ventilation for healthcare premises.

Welsh Health Technical Memorandum 04-01 – The control of Legionella, hygiene, “safe” hot water, cold water and drinking water systems.

Welsh Health Technical Memorandum 07-01 – Safe management of healthcare waste.

NHS Scotland

Survey of decontamination in general dental practice. Sterile Services Provision Review Group, 2004

www.scotland.gov.uk/Publications/2004/11/20093/45208

Public Health Wales

www.wales.nhs.uk/sitesplus/888/home

National Infection Control Policies for Wales.

www.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=38960

Welsh Healthcare Associated Infection Programme (WHAIP).

www.wales.nhs.uk/sites3/home.cfm?orgid=379

Water Regulations Advisory Scheme (WRAS).

Water Fittings and Materials Directory.

www.wras.co.uk/directory/default.htm

Welsh Government

www.wales.gov.uk/?lang=en

Commitment to purpose: Eliminating preventable healthcare associated infections (HCAIs).

www.wales.gov.uk/topics/health/publications/health/guidance/eliminating/?lang=en

Healthcare associated infections – a community strategy for Wales.

www.wales.gov.uk/topics/health/protection/communicable-disease/publications/community/?lang=en

WHC(2000)71 - For the record - Managing Records in NHS Trusts and Health Authorities.

[www.wales.nhs.uk/documents/WHC\(00\)71.htm](http://www.wales.nhs.uk/documents/WHC(00)71.htm)

Chief Dental Officer.

www.wales.gov.uk/topics/health/cmo/professionals/dental/?lang=en

Advice for dentists on re-use of endodontic instruments and variant Creutzfeldt-Jakob Disease (vCJD) Letter April 2007 -.

www.wales.gov.uk/topics/health/cmo/professionals/dental/publication/cdo-letters/cjd/?lang=en

PSD/CDO (2006)1-‘Decontamination/Sterilisation of Re-usable Instruments in General Dental Practice.

CDO(2012)2 Health Technical Memorandum 01- 05: ‘Decontamination in primary care dental practices’ (Welsh Edition) - Compliance with essential requirements.

www.wales.gov.uk/topics/health/cmo/professionals/dental/publication/cdo-letters/compliance/?lang=en

World Health Organization

www.who.int/en/

Guidelines for drinking-water quality, 2011.

www.who.int/water_sanitation_health/publications/2011/dwq_guidelines/en/index.html

Water safety in buildings. 2011.

www.who.int/water_sanitation_health/publications/2011/9789241548106/en/

Other publications

Meiller, TF et al (1999), ‘Dental unit waterlines: biofilms, disinfection and recurrence’. *The Journal of the American Dental Association*, Vol 130 No 3, January, pp 65–72.

Pankhurst CL, Johnson NW and Woods RG, Microbial contamination of dental unit waterlines: the scientific argument. *International Dental Journal*, Vol 48, 1998, pp 359–368.

Pankhurst CL, Woods RG and Johnson NW, Causes and prevention of microbial contamination of dental unit water. *FDI World*, Vol 8 No 1, 1999, pp 6–13.

Smith AJ, To flush or not to flush? *Dentistry*, 20 September 2001.

Walker JT et al, Microbial biofilm formation and contamination of dental-unit water systems in general practice. *Applied and Environmental Microbiology*, Vol 66, 2000, pp 3363–3367.

Useful links

Institute of Healthcare Engineering and Estate Management (IHEEM)

www.iheem.org.uk/

Medicines and Healthcare product Regulatory Agency

www.mhra.gov.uk/

Legionella Control Association

www.legionellacontrol.org.uk/

Scottish Dental Clinical Effectiveness Programme (SDCEP)

www.sdcep.org.uk/