



HEALTH ESTATES

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**DECONTAMINATION IN
GENERAL DENTAL PRACTICES**

**DHSSPS GENERAL DENTAL
SERVICES QUALITY
IMPROVEMENT SCHEME
TECHNICAL GUIDANCE**

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1. Introduction

This guidance supplements the Northern Ireland “Guidance for Control of Infection in Dental Practice”. It has been produced in support of the General Dental Services Quality Improvement Scheme and implementation of the DHSSPS Action Plan for General Dental Service Decontamination over the next 3 to 5 years.

The Decontamination of instruments appears to be a simple process in some ways, but the individual steps involved have detailed technical standards attached (often with legal requirements) which can on occasion be quite complex. This guidance document aims to give a simple overview and broad principles and to outline in straightforward pragmatic terms the critical issues to address in upgrading premises and equipment as part of the Quality Improvement Scheme. Guidance is also given on how to use the accompanying Technical Specifications for Washer Disinfectors and Benchtop Sterilizers that are available on the Health Estates website @ <http://www.dhsspsni.gov.uk/hea>.

- If sending instruments for repair or disposal, ensure they are decontaminated first.

All stages depend on the location of the decontamination area, the available facilities (space and resources), equipment and instruments, management of the process, and the practice policies and procedures for decontamination.

As effective decontamination cannot be verified simply by visual inspection, the only way to ensure that the required level of decontamination is consistently achieved is to manage and document the process properly. This requires:

- clutter-free facilities with sufficient space;
- segregated clean and dirty areas;
- equipment that is fit for purpose and subject to periodic maintenance and testing (including calibration) and annual re-validation;
- instruments that are compatible with available decontamination processes;
- training of staff in all decontamination procedures used in the practice;
- proper supervision and support of staff during decontamination procedures;
- comprehensive documentation for decontamination procedures, processes, equipment and staff training.

3. Prion decontamination

vCJD and the appearance of abnormal prion protein contamination have been the impetus for the recent changes to decontamination policy. It had been felt that such changes were less necessary in dental decontamination as the risk of abnormal prion protein contamination during dental surgery was much less than in other circumstances. Recent research has indicated that this assumption may not be correct.

Currently there is no sterilization process which can inactivate prion protein whilst not affecting instrument quality. It is the cleaning process and its ability to remove protein that has become the process targeting prion protein. It is essential, therefore, that cleaning processes in dental decontamination are no less rigorous than those cleaning processes used in acute Trusts.

It should be remembered that whilst it is the cleaning process that contributes most to reducing prion protein risk, the sterilization process remains the sole process targeting other contamination, especially bacterial spores. Subsequently, the decontamination process as a whole remains of prime importance and each stage should be assessed for efficacy before the following stage is performed. It is therefore preferable for the cleaning process to be automated (by using a Washer Disinfector) allowing continued validation and repeatability.

4. EU Directives, Standards and Guidance

The four UK Health Departments decontamination policies are generally driven by the EU Medical Devices Directive (MDD) 93/42/EEC and the Medical Device Regulations (MDR) 2005 and augmented to take national and local priorities into account.

Current Department of Health, Social Services and Public Safety (DHSSPS) policy for Health and Social Care organisations (Trusts, Boards etc) is that the decontamination of re-usable medical devices should be carried out in Sterile Services Departments accredited under the MDD and MDR. As part of the implementation of this policy, any local decontamination activity associated with hospital, community health and General Medical Services would eventually be transferred to Sterile Services Departments.

The Directive and Regulations cover the range of re-usable medical devices normally processed in a Central Sterile Supplies Department (CSSD) and is considered the industry standard for the production of sterile products for use in a healthcare setting. Medical Devices (including sterile instrument packs) meeting the requirements of the Directive are entitled to carry the “CE” marking, signifying that the device satisfies the requirements essential for its intended purpose. All devices, except custom-made devices and devices intended for clinical trials, whether used in public-sector or private-sector hospitals and nursing homes, or sold in retail outlets, have to carry the “CE” marking.

To support the Directives, the European Committee for Standardisation (Comité Européen de Normalisation, CEN) has prepared European Standards on operational procedures for different methods of decontamination of medical devices. Compliance with the relevant standard is considered to be a legal presumption of compliance with the decontamination requirements of the Directive it supports. The standards require that persons responsible for decontamination operate a quality system and that part of that system is validation and routine testing of the process.

The four UK Health Departments are currently working on the development of specific guidance for General Dental Practitioners as part of the suite of health service guidance in this area called Health Technical Memorandum (HTM).

HTMs give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare, such as decontamination processes, installations and equipment. The HTMs have no legal enforcement status however they provide the framework and advice relative to best practice to allow practitioners to be able to comply with national and local policy.

5. Setting Up a Decontamination Area

Dental practitioners work in a variety of premises, with varying available space and room shapes which can compromise the adoption of 'ideal' solutions. There are almost always pragmatic ways of dealing with this without sacrificing quality, but everyday ways of working are likely to become more complex if space is limited.

It is possible that whilst some practices have invested heavily in new premises or refurbishment of existing practices, they may continue to have fundamentally unsuitable decontamination facilities through simply not being aware of the basic principles of the decontamination process. It is important that the basic requirements for decontamination are taken into consideration at the design stage should you be considering a new practice or the refurbishment of an existing practice.

Use a dedicated decontamination area, separated from the patient treatment area, preferably in another room or rooms.

If, through lack of space, decontamination has to be carried out in a patient treatment room, minimise the risk to patients by deferring decontamination until the room is unoccupied and ensure that rigorous environmental cleaning is carried out between clinical and decontamination activities. As this takes time and will inevitably affect the frequency of patient appointments, plan to move towards a separate dedicated decontamination area as soon as possible.

When setting up new premises or planning significant modification to existing premises, consider having two rooms for decontamination that are separate from the patient treatment area(s): one for dirty activity (cleaning instruments) and one for clean activity (inspection, sterilization and wrapping instruments). This is the preferred arrangement.

Irrespective of the specific layout, a tidy working environment makes carrying out decontamination easier. Therefore, declutter your working environment.



Carry out the decontamination process as a dirty-to-clean workflow that ensures dirty instruments or splashes or aerosols generated during cleaning do not come

into contact with clean instruments. This is a one-way process that can be achieved by physical segregation or temporal separation.

Physical Segregation

Physical segregation means using different areas for different activities and this is the preferred option if possible.

Set up a decontamination area that preferably comprises a single run of sealed, easily cleaned worktop with the following items arranged in the order listed:

- a separate hand-washing facility;
- a setting-down area for dirty instruments;
- a washing sink with detergent for cleaning instruments;
- a setting-down area for washed instruments;
- an ultrasonic cleaner, if appropriate (see Sections 4 and 6);
- a rinsing sink;
- a setting-down area for rinsed instruments;
- an automated washer-disinfector (includes drying cycle);
- a setting-down area with task lighting and magnifier for inspection of all instruments (to check instruments for visible contamination and functionality or damage, and to ensure instruments are dry);
- an area for packing instruments (only if a benchtop vacuum sterilizer is to be used);
- a steam sterilizer;
- an area for setting down and wrapping instruments sterilized in a benchtop non-vacuum (bowl and instrument) sterilizer;
- clean, orderly, enclosed storage for instruments prior to use (not open shelving);
- a dedicated, clean, rigid, labelled box with a lid to transport instruments to the clinical area safely and securely.

Temporal Separation

Temporal separation means using the same area for two separate activities at different times.

If, through lack of space, a work surface is used for both dirty and clean instruments, ensure that the surface is thoroughly cleaned, and if necessary disinfected, between the two activities to avoid recontamination of cleaned instruments.

Regard temporal separation as a temporary arrangement and plan to increase the space for the decontamination area to enable physical segregation of decontamination activities as soon as possible. Plans should be documented on a risk based approach taking into consideration available options and constraints.

Ventilation

Within the decontamination area, ensure that air flow is maintained away from the patient area and does not carry contaminants from the dirty area to the clean area.

Do not use portable fans in the decontamination area because rapid uncontrolled air circulation can spread contamination.

Decontamination Room Layouts

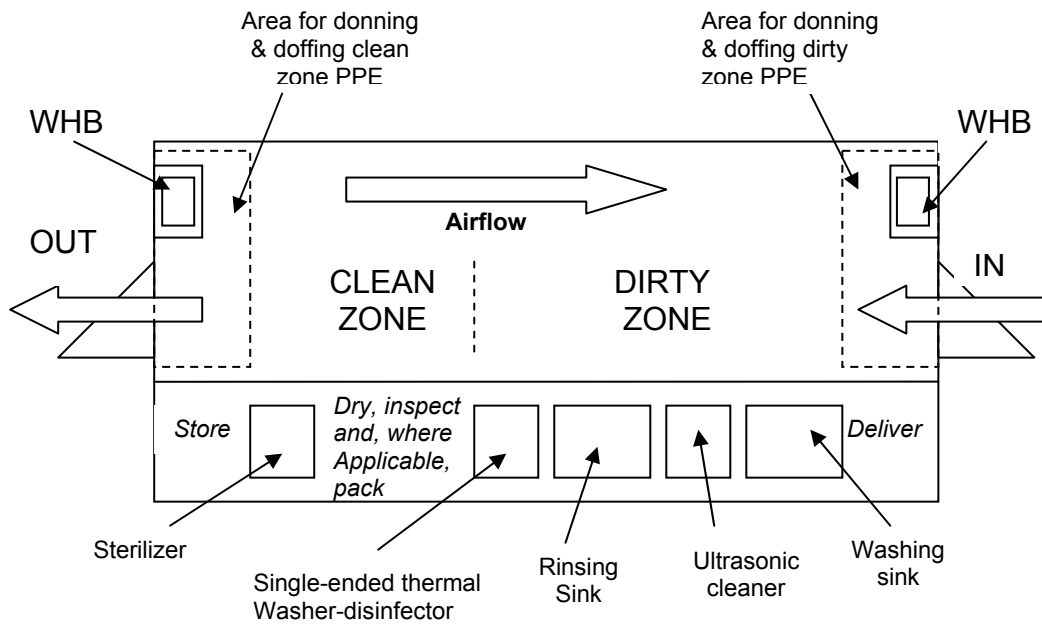
The attached layout drawings indicate best practice decontamination room layouts.

The single room layout is likely to be most appropriate for smaller practices with space limitations, and is shown with 2 doors providing a linear flow of instrumentation with an airflow in the opposite direction minimising adventitious recontamination.

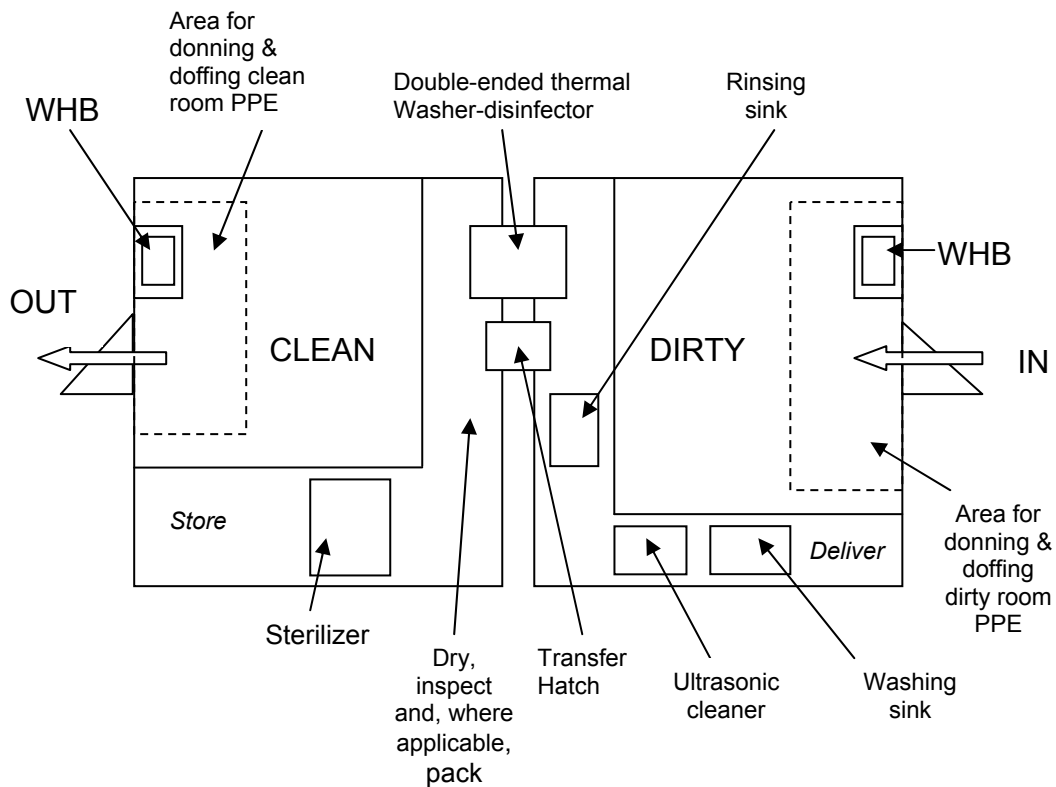
If the decontamination room has only 1 door then management procedures should ensure that the entry of dirty devices does not contaminate clean devices or packages exiting the room. These procedures should be documented, justified and regularly reviewed to ensure continuing compliance.

The double room is designed to minimise the potential for cross infection during the decontamination process, through physical segregation of “clean” and “dirty” activities. Additional washer-disinfectors and sterilizers should be incorporated in accordance with the required decontamination throughput and profile. The double room layout offers the potential to optimise local decontamination standards, and mimics the principles associated with a Sterile Services Department serving the acute sector.

Decontamination Room Layout – Single Room



Decontamination Room Layout – Double Room



6. Decontamination equipment, including installation, commissioning and periodic testing

Why is Testing Important?

Decontamination is the process used to make re-usable medical devices safe for further use on patients and for handling by staff. Regular testing of decontamination equipment is a fundamental process in protecting patient safety by ensuring decontamination processes remain within acceptable limits and risk is minimised.

The efficacy of the Decontamination process cannot be verified retrospectively by inspection or testing of the product (e.g. the dental instrument intended for use on a patient). For this reason, decontamination processes have to be validated before use, the performance of the process routinely monitored, and the equipment maintained.

Means of assuring that an item of decontamination equipment is fit for its intended purpose will include tests and checks carried out during the various stages of manufacture, after delivery, during validation (initially putting into service) and periodically thereafter. Tests will also be required before an item of decontamination equipment is returned to service after modification.

The scheduled test programmes include simple procedures undertaken by the user (the Dentist or Dental Nurse) as well as more complex tests undertaken by a competent test person to demonstrate that the equipment is **“doing what it says on the tin”** - a documented procedure for obtaining, recording *and* interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications.

The testing requirements included in the specifications for Washer Disinfectors and Steam Sterilizers (annual and quarterly) are based upon good practice in both the UK and Europe. The specifications include for the commissioning of the equipment on site, prior to use, by a suitably qualified person – they are not “plug in and use” machines, and believing that this is the case is a common mistake which could impact on patient safety should the equipment not be working within the necessary predetermined specifications.

Health Estates has been working with local suppliers of Decontamination equipment with the intention of building capacity in the local market for the provision of a suitably qualified testing service as part of the procurement and ongoing operational requirements of the equipment. The intention is that equipment will be supplied with a testing service offered as part of the package. The specification provided by Health Estates includes for this requirement for periodic testing of the equipment and Dental Practices will be expected to have as a minimum requirement, recorded evidence available for inspection of an annual validation test for both WDs and Benchtop Sterilizers.

Washer-disinfectors (WDs)

It is intended that as many Dental Practices as possible move to using automated washer disinfectors (WDs) within the next three years. There are now suitable models on the market that will comply with the Technical Specification provided on the Health Estates website.

It has to be the correct machine for your needs, correctly installed, in the right location, with the right plumbing connections, formally commissioned and periodically tested. The specification supplied by Health Estates covers many of the standard requirements for dental instrumentation however there may be particular requirements that need to be completed by the Dentist. For example, make sure you ask WD manufacturers/suppliers about appropriate connection devices to clean your particular dental handpieces and that that your dental instrument trays are compatible with the WD – instruments must be loaded appropriately to ensure adequate cleaning. Guidance on completion of the relevant parts is provided with the specification. Contingency arrangements should be in place to cater for non-availability of WDs, sterilizers and water treatment plant during periods of equipment repair, maintenance and periodic testing.

Benchtop Steam Sterilizers

The two types of sterilisers found in General Dental Practice are the Vacuum (wrapped instrument) sterilizers (classified as Type B) and unwrapped instrument & utensil sterilizers (classified as type N).

Vacuum Benchtop Sterilizers Type B are suitable for wrapped and unwrapped solid items, hollow items and porous loads, and as such are particularly suitable for sterilizing dental handpieces and this technology is increasingly becoming the standard for use in dental practice. Wrapped items processed in a vacuum benchtop sterilizer can be readily transported, remain sterile up to point of use, and can be stored for use at a later date, minimising the risk of cross-contamination. The provision of suitable stocks of wrapped sterilizer instruments can enable continued patient care while WD, sterilizer and water treatment plant are unavailable through repair, maintenance, and testing.

Benchtop Sterilizers Type N are suitable for solid devices that are not wrapped. Provided that the proper irrigation and cleaning of lumens and internals of handpieces has been achieved in combination with a WD, handpieces may also be processed in a Type N sterilizer. Where remaining hollow items used in the practice are single-use, a Type N sterilizer may be the appropriate solution, although as mentioned previously, this type of technology is being increasingly overtaken with the vacuum type sterilizer. Dental Practitioners should also be aware that instruments processed in a Type N sterilizer should ideally be used directly from the sterilizer as transportation and storage of sterilized items may pose a risk of re-contamination, and should be risk assessed and controlled to minimise the risk.

Dentists should be aware of the potentially increased intervals required for decontamination of equipment between patients when using a WD in combination with a vacuum type sterilizer and this needs to be considered as part of the evaluation of decontamination requirements. Such evaluations should include the potential increase in instruments required and this needs to be factored into funding bids submitted to Boards. Before purchasing new instruments, Dentists should check with the manufacturer (or supplier) whether they are suitable for use with the decontamination equipment available to you. If not, another brand or type of instrument should be chosen.

The specification also covers the provision of an independent process verification system to quality assure the process by recording pressure and temperature achieved during the sterilising cycle. A steriliser equipped with an independent verification system makes the process of record keeping easier.

The water used in WDs and Sterilizers needs to be free of chemicals and pyrogens. Tap water is not suitable on either count: this must be Sterile Water for Irrigation BP or freshly-produced reverse osmosis (RO) water or freshly-produced distilled water.

RO units are a practical solution and can be supplied with WDs as part of the procurement package which will avoid the need for prolonged storage. The specification for the WD therefore includes for this plant which also covers the necessary capacity to supply RO water to the practice sterilizers.

7. Sources of Advice

Your current equipment supplier should be able to provide you with the necessary advice concerning equipment. If you are considering setting up a decontamination area which may involve substantial changes to the layout and structure of your practice, it is recommended that you obtain professional advice from a registered Architect or Building Surveyor.

Health Estates are able to provide advice concerning decontamination processes and equipment by contacting:

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