Standards for Dental Clinics

February 2019

Preface

The focus of these standards is to have up-to-date established good practice policies for dental clinics in Malta. The aim of these standards is to safe guard the worker and ensure patient safety. Healthcare providers have a duty of care to ensure that the appropriate arrangements are in place and are managed effectively.

For queries regarding these standards kindly contact the Health Care Standards Directorate on 25953330 or healthstandards.sph@gov.mt , or the Dental Public Health Unit on 25953314 or dentalpublichealth@gov.mt .

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Essential Criteria for obtaining a Dental Clinic License

The Licensee has to ensure that the clinic premises and personnel conform to the following essential criteria:

1. General

1.1. The valid Clinic License should always be on display in a prominent place in the premises.

1.2. The premises must be kept clean and maintained in a state of good repair and condition, and follow all Maltese sanitary laws.

1.3. The layout, design, construction and size of a dental practice premises shall:

a) Permit adequate cleaning or, where relevant, disinfecting of all areas;

b) Include an instrument processing area, which has a washbasin for processing of used instruments. It also should include a "clean area", including a washbasin for hand washing. These should be separate from each other. New practices must have a dedicated enclosed area for processing of used instruments.

c) Facilitate and permit the implementation of good infection control practice or standards for ensuring no cross-contamination;

d) Provide privacy and dignity for the patient while undergoing treatment procedures.

1.4 Separate washbasins must be used for hand washing and instrument processing. They should be supplied with water at a suitably controlled temperature and washbasins used for hand washing in clinical areas should have a single lever tap which is elbow, sensor or foot operated. Hot water heaters must be set at a minimum of 60^{o}C. Every washbasin must be kept clean.

1.5 There must be suitable and sufficient means of natural or mechanical ventilation in all rooms of the premises to the satisfaction of the health authority, in accordance to current sanitary laws or standards.

1.6 Floor and wall surfaces must:

a) be maintained in a sound condition; and

b) be easy to clean and, where necessary, disinfect.

1.7 Ceilings and overhead fixtures must be designed in such a fashion, and constructed and finished in such a manner as to prevent the accumulation of dirt and to reduce to a minimum condensation, the growth of undesirable moulds and the shedding of particles.

1.8 Firefighting equipment and facilities shall be such as may be determined from time to time by the Commissioner of Police.

1.9 Proper care should be taken for the safe storage and disposal of medicinals. Proper records are to be kept of disposal of psychotropic substances and of any narcotic substances.

1.10 Suitable products for cleaning and maintaining hands (hand wash, hand rubs and non-petroleum based hand creams) in appropriate dispensers and for hygienic drying of hands (hand towels) must be available at all times.

1.11 Materials, tools and instruments must be available in sufficient quantity for use at all times.

2. Furniture and dental units

2.1 Centrifugal amalgam separation should be available on all suction systems in the clinic (EU Waste Directive 2008/98/EC and any subsequent EU or national legislation) and amalgam waste should be disposed of in line with current policy. Documented evidence has to be shown that such waste is removed from the clinic by a licensed waste collector (Environment and Planning Act LN 184/2011 and any subsequent EU or national legislation).

2.2 Cupboard surfaces shall be smooth, impervious and washable.

2.3 Surfaces, including surfaces of equipment and upholstery that come in contact with the patient or with contaminated instruments/materials must be:

- 2.3.1 Maintained in a sound condition (have no tears, chips or breakages which could harbour bacteria); and
- 2.3.2 Be easy to clean and, where necessary, disinfect.

3. Staff working in the Dental Clinic

3.1 On the engagement of any new member of staff/associate the licensee is to inform the Health Care Standards Directorate in writing of their name, Registration Number (in the case of dental surgeons) and supply a copy of their anti-HBs titre result (in the case of all staff performing exposure prone procedures).

3.2 An updated list of Staff working in the dental clinic together with their Registration Number (in the case of dental surgeons) and their anti-HBs titre (in the case of all staff performing exposure prone procedures) needs to be kept by the licensee, and shown to the inspectors during the annual inspections carried out by the Superintendence of Public Health.

3.3 It shall be the duty of the employer to offer all vaccinations and, if necessary, re-vaccination in accordance with the schedules and recommendations established by the Superintendent of Public Health.

3.4 All members of staff performing exposure prone procedures in the clinic should be (or have been) vaccinated against Hepatitis B and have had a documented positive anti-HBs titre at the accepted guideline (currently ≥10 mIU/mL). There is no need to receive subsequent hepatitis B booster vaccines if a titre above the minimum threshold has been reported at least once, even if the titre subsequently wanes.

- 3.4.1 Exposure Prone Procedures (EPP) are those procedures where the worker's gloved hands may be in contact with sharp instruments, needles, tips or sharp tissues (e.g. bone or teeth) inside a patient's open body cavity and/or where the hands or finger tips may not be completely visible at all times.
- 3.4.2 If staff undertaking EPP were non-responders to the vaccine or have not been vaccinated due to personal refusal or for medical reasons, they are to undertake yearly screening for Hepatitis B.

3.5 Staff undertaking EPP have a duty of care to report every exposure incident and to undertake any testing needed to verify that they have not been exposed to a blood-borne virus as a result of the event.

3.6 Workers shall be informed of the benefits and drawbacks of both vaccination and non-vaccination, and should always be trained in preventing sharps injuries.

3.7 Any refusal for vaccination must be documented.

3.8 Clinical staff should be regularly trained to deal with medical emergencies, including resuscitation and basic life support.

4. Decontamination Practices

4.1 The clinic shall have an effective system in place for decontamination. There shall be a lead person with responsibility for decontamination in the clinic, with line management responsibility to the licensee. This individual should have received necessary training in cleaning and decontamination of dental devices.

4.2 The clinic shall have a written decontamination policy and staff shall be trained according to this policy, based on the Standards for the Processing of Dental Instruments, published by the Health Care Standards Directorate.

4.3 A type B Steam Steriliser or scientifically proven equivalent is to be used as part of instrument decontamination.

4.4 The Licensee shall be in a position to provide an **organised** record of **autoclave logs** and **relevant autoclave testing** (Standard 5 of Instrument Processing) being carried out in the Dental Clinic, at all times.

5. Prevention of Sharps Injuries

5.1 In line with EU Directive 2010/32/EU the clinic will have to undertake and document a risk-assessment exercise to identify potential exposures. It should take into account all situations where there is injury, blood or other potentially infectious material and consider possible alternative systems how these injuries can be eliminated.

Where the results of the risk assessment reveal a risk of injuries by medical sharps and, or infection, workers' exposure shall be eliminated by:

5.1a) implementation of safe procedures for the use and disposal of sharp medical instruments and contaminated waste;

5.1b) elimination of the unnecessary use of sharps by implementing changes in practice;

5.1c) providing medical devices incorporating safety-engineered protection mechanisms;

5.1d) banning of the practice of recapping;

5.2 Sharps are to be placed in technically safe and appropriate puncture-proof containers as close as possible to the areas where sharps are being used. They should be disposed of as hazardous waste. Documented evidence has to be shown that all puncture-proof sharps containers are removed from the clinic by a licensed waste collector.

5.3 Employers shall provide the necessary training on a regular basis including induction programmes for all new and temporary staff on:

5.3a) the correct use of medical devices incorporating sharps protection mechanisms;

5.3b) the risk associated with blood and body fluid exposures;

5.3c) preventive measures including standard precautions, safe systems of work, the correct use and disposal procedures,

5.3d) the importance of immunisation,

5.3e) the reporting, response and monitoring procedures and their importance as well as measures to be taken in case of injuries.

6. Case Records

6.1 Case records should be kept in respect of each patient. These records shall show the name, age, and address of patient, the treatment plan, the date of treatment and type of treatment given, and need to be kept for a minimum of 10 years. If a patient refuses to disclose these details, this is to be recorded in the patient record. Personal data should only be processed in accordance to the Data Protection Act (ACT XXVI of 2001, as amended by Acts XXXI of 2002 and IX of 2003; Legal Notices 181 and 186 of 2006, 426 of 2007; Acts XVI of 2008 and XXV of 2012; and Legal Notice 426 of 2012).

6.2 The licensee must be able to demonstrate to the inspecting officers authorised by the Minister responsible for Health that these records are being kept accordingly.

7. Approvals from/Notifications to other entities

7.1 Approval is to be obtained from the regulatory entity responsible for radiation and ionising radiation protection for operation of imaging equipment. All imaging equipment is only to be used by competent licensed staff approved by the regulatory entity. (LN44/2003; LN 353/2012)

Standards for Dental Clinics

Aims and Objectives

This document aims to introduce evidence-based minimum standards on the preferred methods for provision of safe oral health practice, for the ultimate benefit and safety of the patient.

Standards for Clinical Staff

Hand Hygiene

All Staff need to follow the five (5) Moments of Hand Hygiene recommendations (Appendix 1).

Rationale

Hand hygiene substantially reduces potential pathogens on the hands and is considered the single most critical measure for reducing the risk of transmitting organisms to patients and health care professionals.

Essential Criteria

1. Long sleeved clothing should not be worn so as not interfere with effective hand hygiene practice.

2. Hands should be washed with soap and water at the beginning of a session and whenever they are soiled with body fluids. (Appendix 2 WHO How to Handwash) Otherwise, alcohol hand rub is recommended for hand hygiene because it is more effective and results in less skin dryness (Appendix 3 WHO How to Handrub).

3. For routine dental examinations and nonsurgical procedures, hand hygiene should be performed before putting on gloves, by using a plain soap or alcohol hand rub. After removal of gloves, if hands are not visibly soiled, hand hygiene must be performed using an alcohol-based hand rub (or soap and water).

4. For surgical procedures, a surgical hand scrub (using either a saponaceous disinfectant or an alcohol rub product appropriate for the indication) should be performed before putting on sterile gloves.

5. Gloves are NOT a substitute for hand hygiene. Hand hygiene should be undertaken every time both before gloves are donned and after every time they are removed.

6. Soaps and disinfectants tend to cause drying and abrasion of the hands, which in some cases can even lead to an irritant dermatitis. Applying hand cream several times a day reduces these problems. Hand cream has also been shown to reduce

cross infection by preventing bacterial shedding. Do not use petroleum based products which can weaken latex and increase glove permeability and do not use hand cream in pots as these can become contaminated.

7. Fingernails should be short enough to allow dental health care professionals to thoroughly clean underneath them and prevent glove tears (should not extend beyond the tip of the finger). Sharp nail edges or broken nails are likely to increase glove failure. Long artificial or natural nails can make putting on gloves more difficult and can cause gloves to tear more readily. Artificial fingernails or extenders have been epidemiologically implicated in hand carriage of gram negative organisms and in multiple outbreaks involving fungal and bacterial infections in hospital intensive-care units and operating rooms, so dental health care professionals should not wear them at work. Nail polish should not be applied by staff having direct contact with patients because, if chipped or cracked, nail polish can harbour added bacteria.

Protective clothing and equipment

Protective clothing and equipment (e.g., plastic aprons, gowns, lab coats, gloves, masks, and protective eyewear or face shield) must be worn to prevent contamination of street clothing and to protect the skin of Dental Health Care Professionals from exposures to blood and body substances. Eye protection should be worn by both Dental Health Care Professionals and patients.

Personal Protective Equipment (gloves, surgical masks, protective eyewear, face shields, and protective clothing) must also be worn in patient care and instrument processing areas. Eye protection should be worn by both Dental Health Care Professionals and patients. Scrubs and lab coats need to be short sleeved. All protective clothing should be used only once prior to being thrown away if disposable, or laundered (lab coats and scrubs). Personal Protective Equipment needs to be removed before leaving the work place.

Vaccinations, Sharps Injuries and Exposure to Body Fluids

Rationale

Dental Health Care Professionals are at risk for exposure to, and possible infection with, infectious organisms. Immunizations substantially reduce both the number of professionals susceptible to these diseases and the potential for disease transmission to other professionals and patients.

All staff working in the clinic should follow Standard Number 3 Staff Working in the Dental Clinic in the Essential Criteria in previous section.

1. If any member of staff is exposed to body fluids or sharps injury, they are to:
   a) Wash the affected site under running water and, in case of sharps injuries, encourage bleeding without rubbing.

   b) Attempt to identify the patient source **(before the patient leaves the clinic)** and if identified, he/she should be asked to immediately (within the hour) accompany the injured staff member to the nearest health centre, so that advice can be sought from

a doctor regarding proper exposure management, including blood virological screening. The doctor will liaise with the Primary Healthcare Department Infection Prevention and Control nurse, and further advice and support will be provided depending on the case scenario. **It is important to note that the patient has the right to refuse having his/her blood tested and that testing can only be done once consent is obtained.** When the patient source is unknown or refuses to attend for testing, the injured staff member should still attend him/herself for the necessary advice and support.

It is very important that all sharps injuries and body fluid exposures are reported for necessary action to reduce the risk of transmission for Hepatitis B, Hepatitis C and HIV.

Medical Emergency Training

Rationale

A patient could collapse in any premises at any time, whether they have received treatment or not.

All clinical staff should be trained regularly to deal with medical emergencies, including resuscitation, and possess up to date evidence of capability.

Standards for the Processing of Dental Instruments

Reprocessing of dental instruments shall comply at all times with the Medical Devices Regulations (Legal Notice 210 of 2008).

A. Background

Decontamination is the process of rendering an item free from all forms of viable micro-organisms, including spores. In office-based dental practice, the most efficient and simplest means of decontaminating dental instruments is cleaning, disinfection and sterilisation using steam under pressure (commonly called steam sterilising or autoclaving). It involves the adequate pre-cleaning of instruments, using an appropriate disinfectant, after which, a combination of heat and moisture maintained at the right temperature and pressure for the right length of time to kill micro-organisms.

The sterilisation process requires that all air in the chamber be replaced by steam. Small, portable or bench top **type B steam sterilisers** or their evidence-based equivalent, are the most reliable and efficient sterilising units for use in office-based practice. They must be operated according to manufacturer's instructions. There are several types of sterilisation cycles including:

• N class cycles – steam pushes the air downwards and forces it out a port in the bottom of the chamber;
• S class cycles – multi-pulse vacuum steam sterilisers; and
• B class cycles – air is exhausted by a mechanical pump to create a vacuum before steam is introduced into the chamber.

Some steam sterilisers are capable of being operated through more than one kind of cycle, depending on the circumstances and the type of instruments. Packed items and instruments with a narrow lumen need to be sterilised using a vacuum cycle.
In order to ensure the proper performance of these steam sterilisers a number of periodic tests and checks need to be done. Only in this way can the dentist be sure that the instruments being used are properly sterilised.

B. Scope
This document contains standards related to the periodic testing that needs to be done to ensure that dental instruments are being sterilised properly by vacuum autoclaves.

C. Applicability
These standards are intended for those responsible for the day-to-day running of dental vacuum autoclaves and the sterilisation process.

D. Responsibilities
The health professional using the instrument/s is him/herself responsible to ensure that the instrument being used has been appropriately sterilised.

STANDARD 1: Cleaning of dental instruments must be done prior to disinfection and sterilisation.

Rationale
The presence of organic material left on instruments/equipment may prevent the penetration of steam during sterilisation; therefore instruments must be completely cleaned before they are disinfected or sterilised. Cleaning significantly reduces the number of micro-organisms which need to be killed during sterilisation or disinfection, and also the chances of the instrument rusting. In addition, removing the organic material lessens the chance of micro-organisms multiplying on the instruments before reprocessing commences. Even when these potentially disease-producing organisms are killed, released endotoxins may remain and may sometimes cause fevers in patients if introduced into cuts or wounds. Similarly, dislodged soil and foreign particles, even if sterile, can produce severe complications such as granulomas if they enter a cut or ulcer in a breach of the oral epithelium. Sufficient numbers of instruments must be available on the premises to ensure continuous operation with sterilised instruments.

Essential Criteria
1a) Grossly soiled instruments which are unable to be cleaned immediately, should be sprayed with an enzymatic product validated by the manufacturer for such use, to prevent dehydration and chemical bonding of the residue to the surface.
1b) All instruments should be either i) manually scrubbed OR ii) rinsed from soil then mechanically cleaned from visible and non-visible soiling.
1c) Cleaning should be undertaken in a sink dedicated solely for this purpose.
1d) Heavy duty (puncture and chemical-resistant) gloves, eye protection/face shield/visor/mask and a waterproof/fluid-resistant gown/apron must be worn by the staff cleaning the instruments. Cleaning techniques should aim to avoid spraying liquid into the air. Splashes of cleaning agents on a person's skin must be washed quickly with clean water and then treated in accordance with the manufacturer's instructions.

1e) After cleaning and decontamination, instruments should be checked visually under good lighting to ensure all soil/contaminant is removed. Damaged or rusted instruments must be repaired or discarded and those with visible residue soil/contamination must be re-cleaned. Rust on instruments prevents sterilisation from happening.

1f) Dental staff that cleans and processes instruments must be given formal training in the appropriate methods of cleaning and processing instruments.

STANDARD STATEMENT 1.1 – Manual Cleaning

Rationale

Cleaning dental instruments by hand is the least efficient method, but if used, the instruments should be fully immersed in a dedicated instrument cleaning sink pre-filled with warm water and detergent and a long-handled instrument brush used to remove debris.

Essential Criteria

1.1a) The instrument washing sink should be prepared with an appropriate detergent specifically formulated for manual cleaning of medical devices.

1.1b) The water temperature must not exceed 45°C; this should be measured using a mercury-free thermometer. Hot water is not used at this stage as it coagulates protein which increases the difficulty of cleaning. In a like manner, cold water solidifies lipids and should not be used.

1.1c) A mildly alkaline, low foaming, free rinsing non-abrasive liquid detergent designed for cleaning dental instruments and made up at the concentration specified by the manufacturer should be used. Alkaline detergents are much more effective than a neutral pH detergent in removing blood and fatty substances. Adequate amounts of disinfectants must be available on the premises.

1.1d) Common household detergents must not be used due to their high foaming properties and the difficulties in rinsing items free of detergent residue which can interfere with the sterilising/disinfecting process. In addition, too much foam prevents the operator from seeing instruments under the water in the sink and thereby greatly increases the risk of cuts and penetrating injuries from sharp instruments.

1.1e) The water level in the sink must be deep enough to allow all instruments to be fully submerged during washing to minimise splashes and aerosols.

1.1f) Instruments should be scrubbed with a long handled, soft plastic bristled brush.

1.1g) The instruments should then be placed on a perforated tray/rack and rinsed with water to remove all traces of detergent.

1.1h) They should then be allowed to air dry.

1.1i) Abrasive cleaners such as steel wool and abrasive cleaning powders should not be used as they can damage instruments and residues may be left.

1.1j) Cleaning brushes must be washed, rinsed and stored dry. A bur brush maintained in good condition is also necessary for cleaning tungsten carbide and diamond burs.

STANDARD STATEMENT 1.2 – Mechanical Cleaning

Rationale

Automated mechanical cleaning is preferred to manual cleaning as it is more efficient, reduces the risk of exposure to blood and reduces the risk of penetrating skin injuries from sharp or pointed instruments.

Essential criteria

1.2a) Mechanical cleaning of instruments should be carried out in thermal washer disinfectors or ultrasonic cleaners.

1.2b) Washers and ultrasonic cleaners must be well maintained and cleaned regularly to prevent formation of biofilms which could contaminate the instruments being processed.

1.2c) Mechanical cleaning is particularly useful for cleaning jointed instruments such as scissors, stainless steel syringes or those with serrated beaks such as artery and extraction forceps.

1.2d) Items must be rinsed free of visible soil before being placed in an ultrasonic cleaner.

1.2e) Instruments cleaned in an ultrasonic bath still need to be rinsed and dried as per Standard 1.1f and 1.1g above.

In addition:

- Lids, tanks, gaskets and strainers must be cleaned daily;
- Cleaning fluid must be changed when it becomes heavily contaminated or according to the manufacturer's instructions (whichever comes first), because the build-up of debris will reduce the effectiveness of cleaning;
- The lid must be closed during operation (to avoid dispersal of aerosols);
- Instruments must be completely submerged in fluid; and
- No part of the operator's fingers or hands is permitted to be immersed in the fluid during operation of the cleaner.

1.2f) At the end of each day, the ultrasonic cleaner tank must be emptied, cleaned and left dry.

STANDARD 2 - Instruments to be sterilised by steam should be dried.

Rationale

Residual moisture and salts in water may impede the sterilisation process.

Essential Criteria

2a) Suitable methods for drying instruments include using a drying cabinet or alternatively, instruments can be allowed to air dry.

2b) If instrument washers are being used, these have a drying cycle which eliminates the need for a separate drying step.

STANDARD 3 – Packing of Instruments prior to sterilisation.

Rationale

Packaging and wrapping materials must permit the penetration of steam into the pack and the removal of steam and water vapour after sterilisation.

Critical instruments which breach oral mucosa and penetrate normally sterile tissue need to be sterile at the time of use. Critical items confer a high risk for infection if they are contaminated with any microorganism. These instruments which penetrate sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes all instruments used for surgical procedures such as forceps, scalpels, bone chisels and surgical burs. Sterility can only be ensured if the instrument is packed prior to being sterilised, and is then sterilised using a vacuum cycle.

Semi-critical instruments are those instruments that are not intended to breach the oral mucosa but contact mucous membranes or non-intact skin, such as mirrors, anaesthetic syringes, reusable impression trays and instruments used for routine conservative procedures such as hand pieces, excavators, condensers, burnishers, carvers, flat plastic instruments, matrix band retainers and chisels. These devices need not be packed but must be sterilised after each use to prevent cross contamination between patients.

Non-critical instruments are those that come into contact only with intact skin such as external components of x-ray heads, blood pressure cuffs and pulse oximeters. Such devices have a relatively low risk of transmitting infection; and, therefore, may be barrier-protected or reprocessed between patients by intermediate-level or low-level disinfection.

Semi-critical and non-critical instruments should be stored in such a way as to protect against contamination.

Single-use/disposable items such as saliva ejectors, prophy brushes, matrix strips and polishing strips should be discarded after one use. Single use devices and items used during surgical procedures should be sterile at time of use.

Essential Criteria

3a) Critical instruments must be bagged or wrapped prior to sterilisation and must remain bagged or wrapped until use.
3b) Critical instruments may be processed in an open tray and transported to the treatment zone in a sterile container for immediate use.
3c) For a B class cycle of sterilisation, packs which allow air removal prior to the introduction of steam into the chamber of the steriliser must be used. Paper bags/wraps and textile linen wraps are suitable for steam sterilisation. Paper and synthetic packaging is single use.
3d) Trays or cassettes used for packaging instrument sets must be perforated to allow for penetration of steam and efficient drying.
3e) Instruments with hinges or ratchets must remain open and unlocked while sharp instruments should be packaged in such a way as to prevent perforation of the pack.
3f) Packs or bags must be sealed prior to processing. This can be done by using a heat sealing machine or by using bags which are self-sealing. String, adhesive tape, staples and elastic bands are not to be used.
3g) Sterilised packs should be marked with a date 1 year from the date of sterilisation. If the instrument is not used by this date, it should be reprocessed, repacked and resterilised. Felt tipped non-toxic marking pens, rubber stamps or labels using water-resistant ink may be used for the labelling of packs and bags on the laminated side of packs prior to sterilisation.

STANDARD 4 – Loading of instruments has to allow steam to circulate and reach the instruments.

Rationale

The steam steriliser can only work effectively if steam can circulate freely and touch every surface of every instrument. Correct loading also reduces damage to packs and their contents and maximizes the efficient use of the steam steriliser.

Essential Criteria

4a) Items waiting to be sterilized must be stored in a dedicated 'pre-sterilisation' area, not in the steam steriliser. This will minimize the risk that they might be recirculated as already sterilised instruments.

4b) The steam steriliser trays should not be crowded and items must not be packed on top of each other.

4c) To ensure air removal, hollow items should be loaded according to autoclave manufacturer's instructions.

4d) Packs of drapes must be loaded with the drape layers in a vertical direction.

4e) Packaging materials must be loaded flat with paper surface downwards.

4f) Only a single layer of packs must be placed on each tray.

4g) In a mixed load of wrapped and unwrapped items, unwrapped items should be loaded on the bottom racks of the autoclave so as to prevent condensation dripping onto wrapped/bagged items, and thus compromising their drying.

STANDARD 5 – The type B steam steriliser has to be properly operated in order to ensure that the instruments have been sterilised.

Rationale

The key consideration when determining sterilisation operating procedures is the type of object being sterilised because this dictates which autoclave cycle needs to be used. As with all infection control procedures, dental health care professionals must be trained in the correct operation of the steam steriliser.

Essential Criteria

5a) An operator's manual must be available on site and the unit must be used according to the manufacturer's instructions.

5b) Written sterilisation procedures that are based on the manufacturer's instructions and that include loading, choice of sterilisation cycle, and procedure after sterilisation and record keeping have to be in place. All staff members have to follow these written procedures.

5c) Before steam sterilising an instrument, the operator must verify that the item is suitable for the process (some instruments made of plastic cannot withstand the process).

5d) Each day the steriliser is used daily housekeeping checks and daily tests have to be carried out. (Standard 5.2)

5e) Maintenance and testing records for all sterilisers in use are to be satisfactory and up-to-date.

Standard 5.1 – The sterilisation process must be validated.

Rationale

In order to ensure appropriate sterilisation of dental instruments a concept known as validation of the sterilisation process is undertaken.

Essential Criteria

5.1a) The Validation Report has to summarise satisfactory completion of commissioning and performance qualification.

5.1b) Commissioning - All steam sterilisers must be commissioned on installation. Commissioning reports have to include installation documents and operation verification. This has to be performed by the service technician when new or repaired sterilisers are installed in the clinic.

5.1c) Performance qualification – demonstrated by means of a physical qualification which has to be done by a qualified instrument technician or manufacturer's technician and it has to include:

- A validation report – the frequency of which needs to be according to the manufacturer's instructions, or if not specified in the manufacturer's instructions, every 12 months- which should include:
  - Thermometric tests for small and large loads
  - Load dryness tests for small and large loads
  - Chamber overheat cut out test
- A Calibration report whereby the autoclave's sensor response is compared to a previously calibrated device (certificate of calibration of the device to be included in the report).

Standard 5.2 - The steam steriliser's performance must also be monitored by periodic testing.

Rationale

It is necessary to regularly monitor the sterilisation process to ensure the process has met all parameters and that consequently the reprocessed instruments can be assumed to be sterile. Satisfactory periodic testing is necessary to provide ongoing reassurance that the steriliser is performing consistently as specified at validation.

Essential Criteria

A daily (each day the steriliser is used) automatic control test should be performed every day to verify that:

- A visual display of "cycle complete" occurs.
- Values of the cycle parameters as indicated on the process-data record (or observed) are within the limits established by the manufacturer.
- Disinfection/cleaning/sterilising temperatures are within an appropriate temperature band.
- The time for which the temperatures are maintained is not less than that established by the manufacturer.

5.2a) In the absence of an automatic air leak detection test, an air leak detection test should be run every working day, prior to commencing the first sterilising cycle.

5.2b) Weekly safety checks of the door seal and lock have to be carried out by clinic personnel.

5.2c) A Helix Test needs to be carried out each day the steriliser is used. The Helix Test should be placed in a standard pack or pouch prior to being placed in the loaded autoclave for testing.

5.2d) Yearly (also known as annual revalidation) tests require specialist equipment and are performed by external personnel (a Test Person/Sterilisers).

5.2e) Autoclave logs are important documentation to be retained to provide the maintenance and performance history of the steriliser. An organised record of autoclave logs and relevant autoclave testing (all those mentioned in Standard 5) should be kept. These logs need to be kept for a minimum of 5 years.

Standard 5.3 – The built-in drying process of the steam steriliser should be used to dry sterilised instruments.

Rationale

This process results in a faster, more effective cycle and prevents the formation of condensate and guarantees that even the most difficult loads such as textiles, porous loads, and hollow instruments will dry.

Essential Criteria

5.3a) Forced cooling of items by external fans or boosted air conditioning must NOT be used.

5.3b) Cooling items must not be placed on solid surfaces since condensation of vapour inside the pack may result. Leave the instruments to cool in the autoclave.

5.3c) Packaged or unpackaged items must never be dried by opening the door of the steam steriliser before the drying cycle is completed.

Standard 5.4 – Once a load is completed the cycle parameters must be checked.

Rationale

It cannot be assumed that sterilisation has been achieved without the appropriate testing and load checking. Time, temperature and pressure must be measured with continuous, automatic, permanent monitoring (e.g., process recorder, printer or data logger).

Essential Criteria

5.4a) Pressure, temperature and holding time readings have to be checked and compared to the recommended values.

5.4b) If any reading is outside its specified limits, the sterilisation cycle must be regarded as unsatisfactory (regardless of results obtained from chemical indicators) and the sterilising cycle repeated.

5.4c) If the second cycle is unsatisfactory, the steam steriliser must not be used until the problem has been rectified by an instrument technician.

5.4d) Logs and print-outs must be retained for inspection and monitoring.

5.4e) For dental instruments and equipment, vacuum steam sterilisers must reach a temperature of 121°C for not less than 15 minutes or 134°C for not less than 3 minutes.

Standard 6 - The completed load has to be checked.

Rationale

Once the sterilising process (including the drying cycle) is complete, a number of checks need to be carried out on the instruments to ensure satisfactory completion of the process.

Essential Criteria

6.1a) The process documentation print out/log verifies that the correct sterilization parameters of temperature, pressure and time have been achieved.

6.1b) Each bag must be checked to ensure that both the bag and its contents are dry and the bag is undamaged and properly sealed. The integrity of the packaging needs to be checked again immediately prior to use of the item.

6.1c) If the bag/packaging is compressed, torn, unsealed or wet or if items have been dropped on the floor or placed on dirty surfaces, the affected instruments must be considered contaminated and must be repackaged and reprocessed.

6.1d) Unpacked instruments need to be dry. They then need to be stored appropriately in drawers which are easy to clean and, where necessary, disinfect. All clean surfaces and stored instruments should not be touched when wearing contaminated gloves.

Standard 7 – The licensee is responsible to ensure appropriate disinfection and/or sterilisation of all dental devices used in the clinic.

Rationale

The licensee is the person responsible of ensuring that these standards for **appropriate disinfection and sterilisation of all dental devices used in the clinic** are adhered to.

Essential Criteria

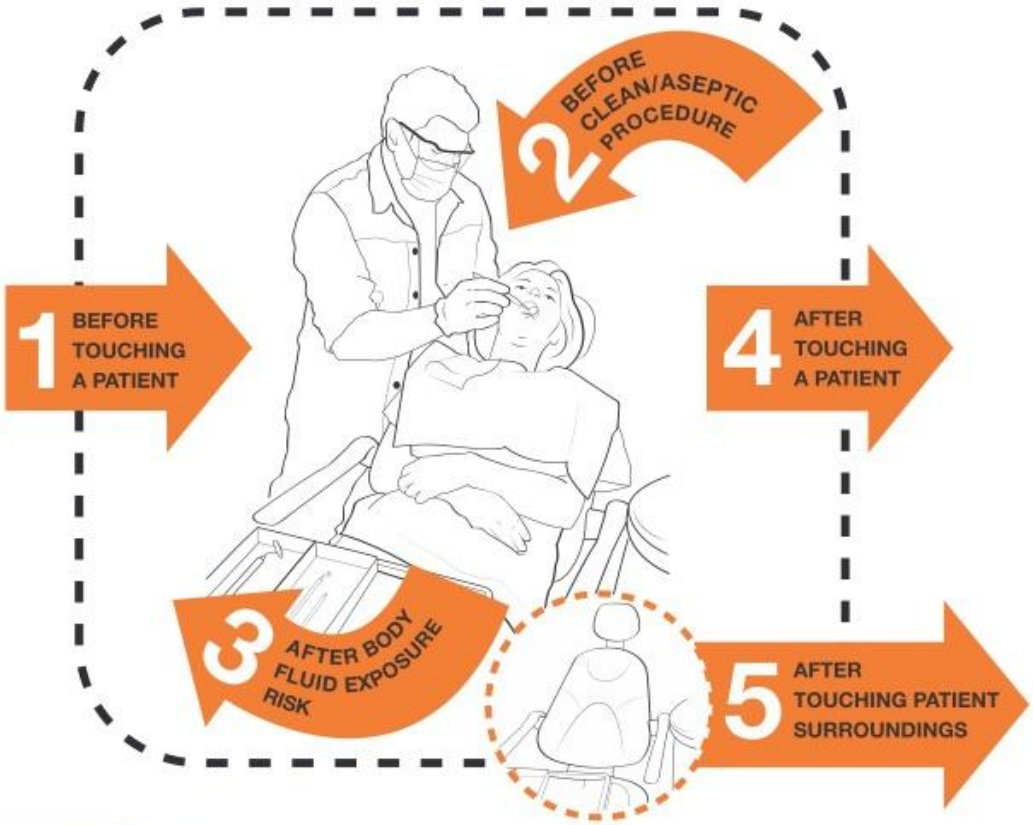
7a) Licensee has to set up Decontamination Operating Procedures based on these standards and the vacuum steam steriliser's manufacturer instructions (**email on contact details on page 2 for an editable soft copy**). This document has to be signed by the licensee since he/she will be responsible to follow the plan described in this document. If sterilisation is subcontracted, this needs to be done through a licensed service provider.

7b) As part of their inspection, Health Inspectors will check that the Decontamination Operating Procedure is being followed, by inspecting the logs (printed or soft copies) and tests specified above.

Appendix 1: WHO 5 moments for Hand Hygiene

Your 5 Moments for Hand Hygiene

Dental Care



1	BEFORE TOUCHING A PATIENT	WHEN?	Clean your hands before touching a patient.
		WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ ASEPTIC PROCEDURE	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
		WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID EXPOSURE RISK	WHEN?	Clean your hands immediately after a procedure involving exposure risk to body fluids (and after glove removal).
		WHY?	To protect yourself and the environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	WHEN?	Clean your hands after touching the patient at the end of the encounter or when the encounter is interrupted.
		WHY?	To protect yourself and the environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	WHEN?	Clean your hands after touching any object or furniture in the patient surroundings when a specific *zone* is temporarily and exclusively dedicated to a patient - even if the patient has not been touched.
		WHY?	To protect yourself and the environment from harmful patient germs.

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WHO acknowledges the Ministry of Health of Spain and the Hôpitaux Universitaires de Genève (Infection Control programme) for their active participation in developing this material.

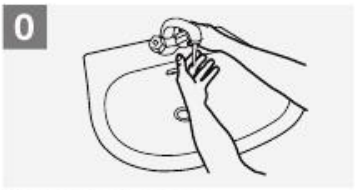
March 2012

Appendix 2: How to Handwash

How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

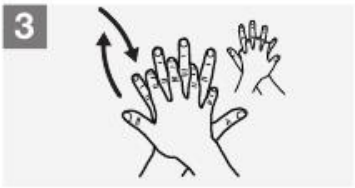
Duration of the entire procedure: 40-60 seconds



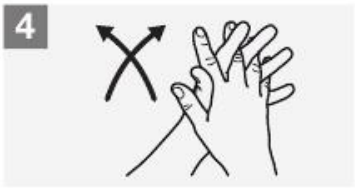
Wet hands with water;

Apply enough soap to cover all hand surfaces;

Rub hands palm to palm;



Right palm over left dorsum with interlaced fingers and vice versa;



Palm to palm with fingers interlaced;

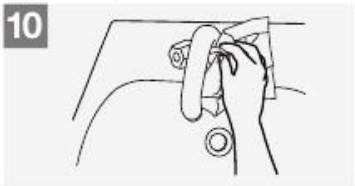
Backs of fingers to opposing palms with fingers interlocked;

Rotational rubbing of left thumb clasped in right palm and vice versa;

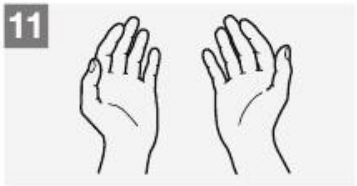
Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;

Rinse hands with water;

Dry hands thoroughly with a single use towel;



Use towel to turn off faucet;



Your hands are now safe.

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WHO acknowledges the Hôpitaux Universitaires de Geneve (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

May 2009

Appendix 3: WHO How to Handrub

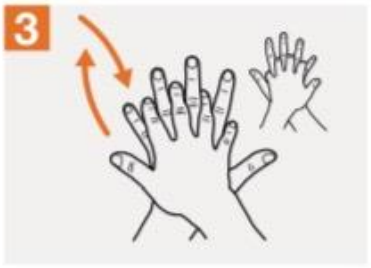
How to Handrub?

RUB HANDS FOR HAND HYGIENE! WASH HANDS WHEN VISIBLY SOILED

Duration of the entire procedure: 20-30 seconds

Apply a palmful of the product in a cupped hand, covering all surfaces;

Rub hands palm to palm;



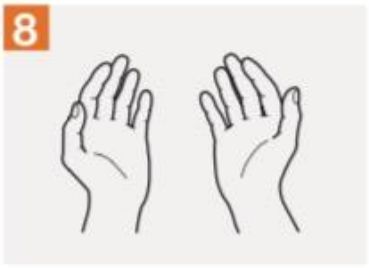
Right palm over left dorsum with interlaced fingers and vice versa;

Palm to palm with fingers interlaced;

Backs of fingers to opposing palms with fingers interlocked;

Rotational rubbing of left thumb clasped in right palm and vice versa;

Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



Once dry, your hands are safe.

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Bibliography

1. *ADA guidelines for infection control*, Australian Dental Association Incorporated, August 2008.
2. *Sterilization of Dental Instruments - Dental Clinical Guidance*, Scottish Dental Clinical Effectiveness Programme, December 2011 (reviewed January 2016).
3. *Health Technical Memorandum 01-05: Decontamination in primary care dental practices*, Department of Health, Leeds, 2013.
4. *Health Technical Memorandum 2010 Part 3 (Including Amendment 1): Validation and Verification – Sterilization,* NHS Estates, London, 2010.
5. *Decontamination - Health Technical Memorandum 01-05: Decontamination in primary care dental practices*, UK Health Department, November 2013.
6. *Guideline for Disinfection and Sterilization in Healthcare Facilities* – Centre for Disease Control, November 2008.
7. *Guidelines for infection control in dental health care settings: Basic Expectations for Safe Care*— Centers for Disease Control and Prevention. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, 2016.
8. *EN 285:2015 Sterilization — Steam sterilizer's Large sterilizers* European Committee for Standardization (CEN). 2015.
9. *Guidelines for Environmental Infection Control in Health-Care Facilities*— Centers for Disease Control and Prevention. 2003. MMWR 2003; 52(No. RR-10); 1-42.
10. *WHO 5 moments of Hand Hygiene for Dental Care,* 2012
11. *WHO How to Handwash, 2009*
12. *WHO How to Handrub,* 2012