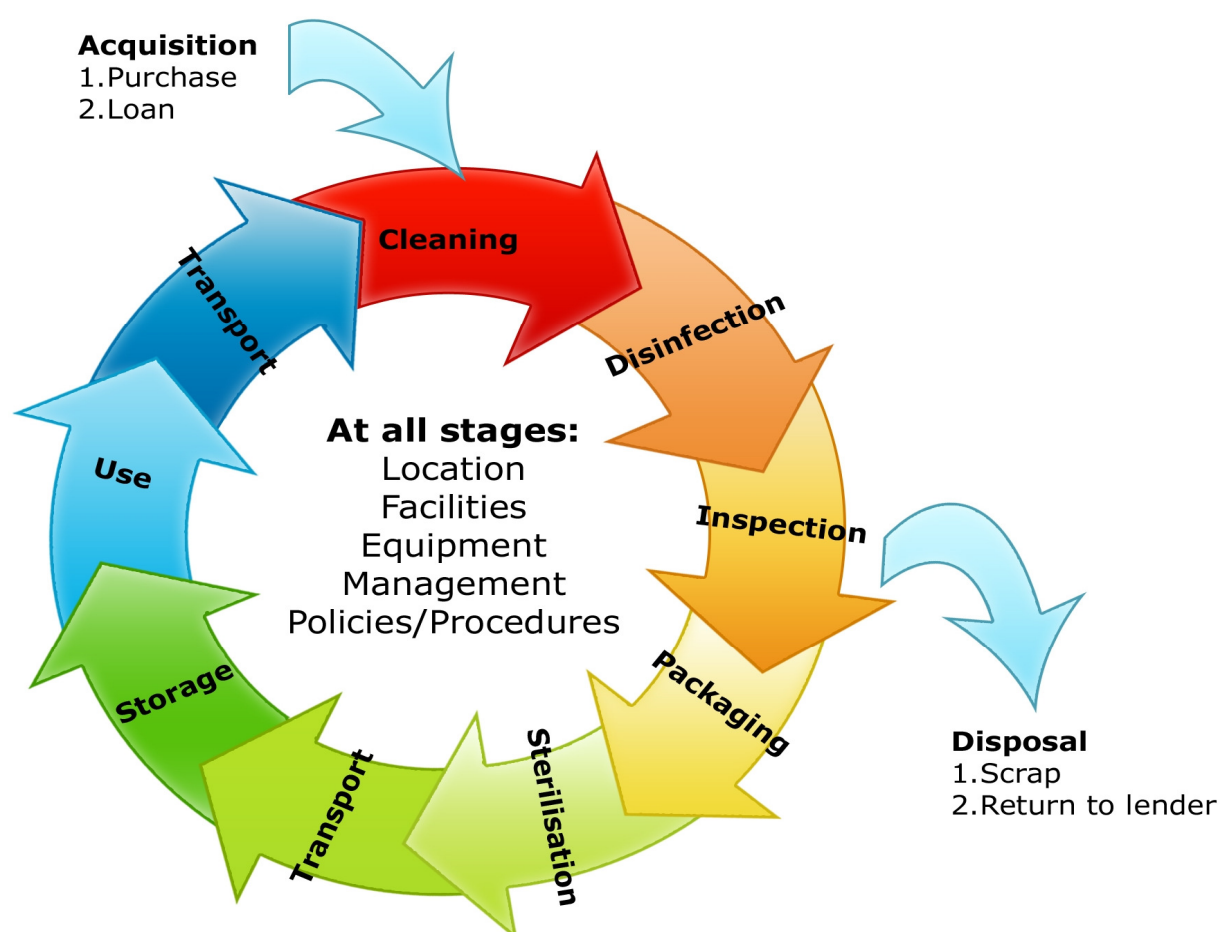


# Health Service Executive Standards and Recommended Practices for Dental Services in a Local Decontamination Unit (LDU)



**Reader Information**

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<b>Description:</b>	The Health Service Executive Standards and Recommended Practices for local decontamination units dental are the Standards required to ensure decontamination of dental reusable invasive medical devices (RIMD) for Dental Services in a Local Decontamination Unit (LDU) based on current legal requirements and professional best practice. A LDU is the dedicated area in a dental clinic that is used for decontamination of dental RIMD. These areas can be in the dental surgery or in a separate accommodation. The LDU may be present in a primary care dental setting which may include orthodontic and/or oral surgery unit.
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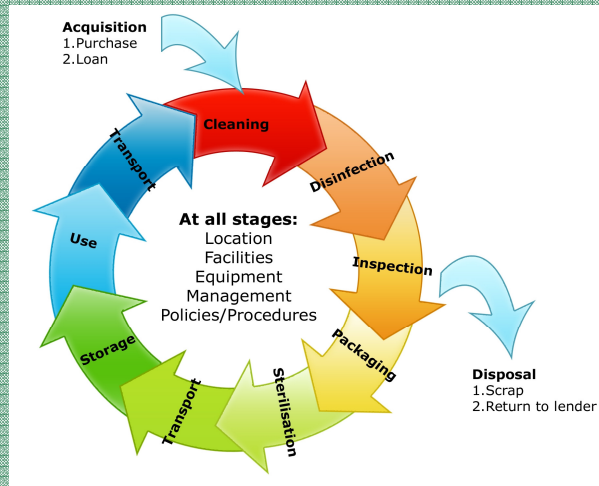
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# Standards and Recommended Practices for Local Dental Services (LDU)

## Part 1 Introduction

## Introduction

### 1. Introduction

#### 1.1 Prevention and control of healthcare associated infection

The Health Information and Quality Authority (HIQA) has developed the National Standards for Safer, Better Care to describe what a high quality, safe service looks like. Improving the quality of care and providing a safe working environment are thus fundamental activities for the Health Service Executive. Prevention and control of healthcare associated infection (HCAI) is central to these activities. Senior managers must ensure that they have effective systems in place in their healthcare facilities to minimise the risks of infection to service users and staff.

#### 1.2 Decontamination process

Decontamination is the combination of processes (including cleaning, disinfection and sterilisation) used to render RIMD safe for handling by staff and for use on service users. Effective decontamination of RIMD is an essential component in the prevention of healthcare associated infection.

*Cleaning* is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.

*Disinfection* describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores.

*Sterilisation* refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. Sterility is an absolute condition - an item is either sterile or not sterile.

When describing a sterilisation process, it is impossible to say that the chance of an organism surviving a process is zero. For medical equipment, it is acceptable to achieve a sterility assurance level of one in a million chances of a single organism surviving the process.



### 1.3 Effectiveness of decontamination

The effectiveness of decontamination is determined by all elements of the RIMD life cycle, which includes selection, specification, purchase, transport, storage and eventual disposal of RIMD and purchase, validation, maintenance and testing of associated decontamination equipment and processes. All aspects of the life cycle need to be controlled and managed if decontamination is to be fully effective.

This involves a multidisciplinary approach to the prevention and control of infection, including (in no particular order of priority):

- Standards, policies, procedures, protocols and guidelines in relation to decontamination.
- Maintaining a controlled environment.
- Investigation of incidents.
- Education and training of staff.
- Validation, maintenance and periodic testing of decontamination equipment.

## Introduction

## 2. Development of standards and recommended practices for decontamination of reusable invasive medical devices

### 2.1 Introduction

The standards and recommended practices for decontamination were developed as follows:

- Extensive literature search.
- Consideration of the opinion of experts knowledgeable in the subject.
- Consideration of the available current best practice, both in Ireland and internationally, that may impact on decontamination of RIMD.
- National workshops held with key stakeholder groups to provide an opportunity for input into draft documents.
- Development of draft Standards and recommended practices for distribution to key stakeholders for consultation.
- Feedback considered and where appropriate, incorporated into the current version of the standards and recommended practices.

### 2.2 Definition

**Standards** = Organisational structures and processes needed to identify, assess and manage specified risks in relation to the decontamination process.

- Each Standard has a **title**, which summarises the area on which that Standard focuses.
- This is followed by the Standard **statement**, which explains the level of performance to be achieved.
- The **rationale** section provides the reasons why the Standard is considered to be important.
- The Standard statement is expanded in the section headed **criteria**, where it states what needs to be achieved for the Standard to be reached.

## Introduction

### Part 1 Introduction

The Standards reflect the values and priorities of the Health Service Executive and will be used to direct and evaluate decontamination services in healthcare facilities.

**Recommended Practices** = recommendations concerning best practice in relation to the decontamination process.

The recommended practices are intended to define correct decontamination practice and to promote service user safety. They are also intended to serve as the basis for policy and procedure development in decontamination services in the Health Service Executive.

- Each recommended practice has an **introduction**, which summarises the area on which the recommended practice focuses.
- This is followed by the recommended practice **scope**, which explains the objective of the recommended practice and why it is considered to be important.
- The contents section outlines the **contents** of the recommended practice.
- This is expanded in the section headed **procedure**, where it states how each recommended practice can be achieved.

## Introduction

### 3. Devices Directive (93/42/EEC)

#### 3.1 Medical Devices Directives

There are three Medical Device Directives, covering Active Implantable Medical Devices (90/385/EEC) to In Vitro Diagnostic Medical Devices (98/79/EEC). Medical Devices in general are covered by the European Directive 93/42/EEC which came into force on 14th June 1993, and as amended by Directive 2007/47/EC which came into force on 21 March 2010. This Directive was transposed into Irish law by the European Communities (Medical Devices) Regulations Statutory Instrument 1994 No. 252 and the European Communities (Medical devices) (Amendment) Regulations 2001 No. 444 and 2002 No. 576, and the European Communities (Medical devices) (Amendment) Regulations 2009 No.110.

The Medical Devices Directive (93/42/EEC) applies to manufacturers placing medical devices on the market. In doing so, it specifies the essential requirements to be met by any medical device.

**These essential requirements should be regarded as the minimum acceptable Standard whether or not the decontamination unit qualifies as a ‘manufacturer’ within the terms of the Directive.**

A **Medical Device** is defined in the Medical Device Directive (93/42/EEC) & (2007/47/EC) as “an instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by its manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception, and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.

**Annex IX of the Medical Devices Directive 93/42/EEC** sets out the classification rules which manufacturers should use to determine which class a general medical device belongs to according to its properties, function and intended purpose. The level of control applied to the device is designed to reflect the perceived risk associated with the device. Thus the strictest controls are applied to those devices that present the greatest risk to health or safety.

There are four classes of general medical devices as follows:

- Class I - Generally regarded as low risk.
- Class IIa - Generally regarded as medium risk.
- Class IIb - Generally regarded as medium risk.
- Class III - Generally regarded as high risk.

Medical Devices Regulations also apply to accessories necessary for the correct functioning of the medical device. Washer-disinfectors and sterilisers for use in healthcare facilities are classified as medical devices. Packaging materials used when re-sterilising RIMD have been also cited as accessories.

**Annex IX of the Medical Devices Directive (93/42/EEC) defines an invasive device as:**

A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

A body orifice is defined as any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

The Directive also distinguishes a surgically invasive device as an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, are treated as surgically invasive devices.

## Introduction

### 3.2 Essential requirements of the Medical Devices Directive (93/42/EEC)

The Medical Devices Directive (93/42/EEC) specifies the **minimum Standards** (essential requirements) in relation to decontamination of medical devices the essential requirements of this Directive which are of particular relevance to sterile products include:

- That devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient/service, user and third parties (Annex 1, paragraph 8.1).
- That devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down.
- Devices should remain sterile unless the protective packaging is damaged or opened. (Annex 1 paragraph 8.3.).
- That devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. (Annex 1 paragraph 8.4.).
- That devices intended to be sterilised must be manufactured in appropriately controlled (e. g. environmental) conditions. (Annex 1 paragraph 8.5.).
- That packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. (Annex 1 paragraph 8.6.).
- That the packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. (Annex 1 paragraph 8.7.).
- That devices be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients/service users (Annex 1, paragraph 7.2).

All devices placed on the market must meet the essential requirements of the medical devices legislation and in doing so must not compromise the clinical condition or safety of service users, or the safety and health of users or where applicable other persons. The devices must also perform as intended by the manufacturer.

### 3.3 Placing on the market

‘Placing on the market’ implies the transfer of ownership from one legal entity to another of a device, either in return for payment or free of charge. This type of transaction is covered by the Medical Devices Directive (93/42/EEC). Thus if a central decontamination unit supplies a private hospital, this would constitute placing goods on the market and so the Medical Device Directive Standards would apply.

### 3.4 In-house manufacture

If a central decontamination unit supplies another healthcare facility within the Health Service Executive (i.e. for use by one legal entity for use within the same legal entity), this does not constitute placing goods on the market. However, there should not be one Standard for industry to meet and a different lower Standard for healthcare facilities. Accordingly, although activities undertaken solely within a legal entity are not covered by the regulations, the Health Service Executive requires all reprocessing units to meet the essential requirements of the Directive.

### 3.5 Particular procedure for systems and procedure packs and Procedures for sterilisation—Article 12

The decontamination of RIMD in central decontamination units almost invariably requires the assembly of devices into sets or packs intended for a specific purpose. The provisions of Article 12 of the Medical Device Directive apply to these circumstances. This includes the requirement that a system or procedure pack made up of devices bearing the CE marking shall not bear an additional CE marking. Article 12 provides exemption from a number of the regulations’ assessment requirements but not from the essential requirements. It imposes obligations on the manufacturer to declare:

## Introduction

- That he has confirmed mutual compatibility of the devices in accordance with the manufacturers' instructions, and has indicated that the devices have been processed together in accordance with the manufacturers' instructions.
- That he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers.
- That appropriate methods of internal controls and inspection have been applied.

Article 12 also requires a third-party assessment of the sterilisation process for sterile packs. This is undertaken by a notified body registered with a competent authority which, for the Republic of Ireland is the Irish Medicines Board (IMB).

### 3.6 CE marking

CE stands for: La Conformité Européenne or European Conformity. The CE mark is not a mark indicating conformity to a Standard but rather a mark indicating conformity to the legal requirements of European Union (EU) Directives. When a product has the CE mark, it can be traded freely in any country within the European economic area.

#### CE symbol

The CE marking symbolises the following:

- That the product can be freely marketed throughout all the member states of the EC without further control.
- The manufacturer is declaring that the product meets all the relevant provisions of the Directives that apply to it and that it has been assessed in accordance with them.
- The manufacturer claims its product meets the requirements laid down as essential for it to be considered safe and fit for its intended purpose.

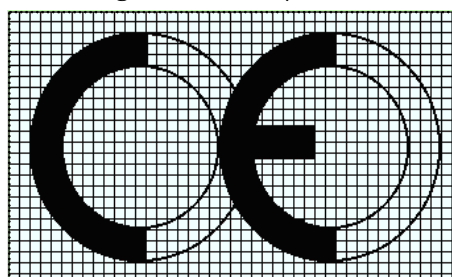
Before the CE mark can be placed on the label or packaging of a RIMD, the RIMD must conform to the requirements of the legislation. For low risk RIMD the manufacturer declares he is in conformance and for medium to high-risk RIMD the manufacturer declares conformance which is then verified by a Notified Body with the issue of a certificate of conformance.



The Medical Devices Directive (93/42/EEC) clarifies the rules and procedures for affixing the CE mark. A summary of these is given below:

- The CE marking of conformity must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use.
- Where applicable, the CE marking must also appear on the sales packaging.
- It shall be accompanied by the identification number of the Notified Body responsible for the implementation of the procedures, etc.
- It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking.
- Any other marking may be affixed to the RIMD, to the packaging or to the instruction leaflet accompanying the RIMD provided that the visibility and legibility of the CE marking is not thereby reduced.
- The CE marking should be affixed by the manufacturer or its agent within the community.
- The CE marking should be affixed at the end of the production control phase.

Figure 3.1: CE symbol



## Introduction

### 3.7 Notified Body

A Notified Body is the organisation which checks whether the appropriate conformity assessment procedures for the particular device have been followed. It is a certification organisation, which the Competent Authority, of a Member State designates to carry out one or more of the conformity assessment procedures described in the annexes of the legislation. In Ireland the Irish Medicines Board (IMB) has designated the National Standards Authority of Ireland (NSAI) to act as Notified Body for the medical devices legislation. There are more than 60 such bodies designated by Member States in the European Union (EU) and a manufacturer can choose to work with any one of these.

## 4. Guide to classification of infection risk

### 4.1 Classification of infection risk

Failure to adequately decontaminate RIMD will increase the risk of transmission of cross-infection between patients. Effective decontamination of RIMD is necessary to maintain the functionality of RIMD, maintain integrity of biopsy specimens and protect the patient from the adverse consequences of non-sterile contaminants.

RIMD are required to be accompanied by their manufacturers' *Instructions for Decontamination and Reprocessing*. These must be strictly followed to ensure appropriate decontamination.

To assess whether RIMD/Medical Devices, reprocessed accordingly, are safe for the level of risk involved in particular cases of re-use, guidance is provided in the following Risk Categorisation Table following a model (proposed in 1939, refined in 1968) by Prof. Earle Spaulding. This defines three broad risk categories and the required decontamination level for each. (It should be noted that some devices may not withstand sterilisation processes)

## Introduction

Table 4-1: Guide to classification of infection risk associated with the decontamination of RIMD

Risk	Application	Recommendation	<i>Examples *</i>
<b>Critical</b>	Items that enter sterile tissues/sterile body areas or the vascular system	Requires sterilisation	<i>Surgical reusable invasive medical devices, biopsy forceps, laparoscopes, arthroscopes,</i>  <i>Surgical dental RIMDs, e.g. forceps, elevators, luxators, scalers, surgical burs</i>
<b>Semi-critical</b> <i>(Not applicable to local dental decontamination services)</i>	Items in contact with mucous membranes or non-intact skin.	Sterilisation preferred but at a minimum, requires high level disinfection	<i>Flexible endoscopes,</i>  <i>Specula,</i>  <i>Respiratory therapy equipment</i>
<b>Non-critical</b>	Items in contact with intact skin but not mucous membranes or not in contact with the patient	Can be processed by cleaning (and low level disinfection where necessary)	<i>Blood pressure cuffs, oximeters, ECG leads, denture fabrication equipment, apex locators, impression material dispensers</i>

**\*Examples are for illustrative purposes only; the manufacturers' recommendations for reprocessing must be followed**

**High-level disinfection** – Refers to complete inactivation of all infectious microorganisms (vegetative bacteria, mycobacteria, enveloped and non-enveloped viruses) in or on a device, but not necessarily bacterial spores. High level disinfection requires the use of specific disinfectants, specialist equipment and trained staff (e.g., endoscope reprocessing units).

*Important Note: 'Specific procedures apply to RIMD used in high or medium risk procedures on patients with, or "at increased risk" of, Creutzfeldt - Jakob disease or other transmissible spongiform encephalopathies. Ref to [www.hse.ie](http://www.hse.ie)*

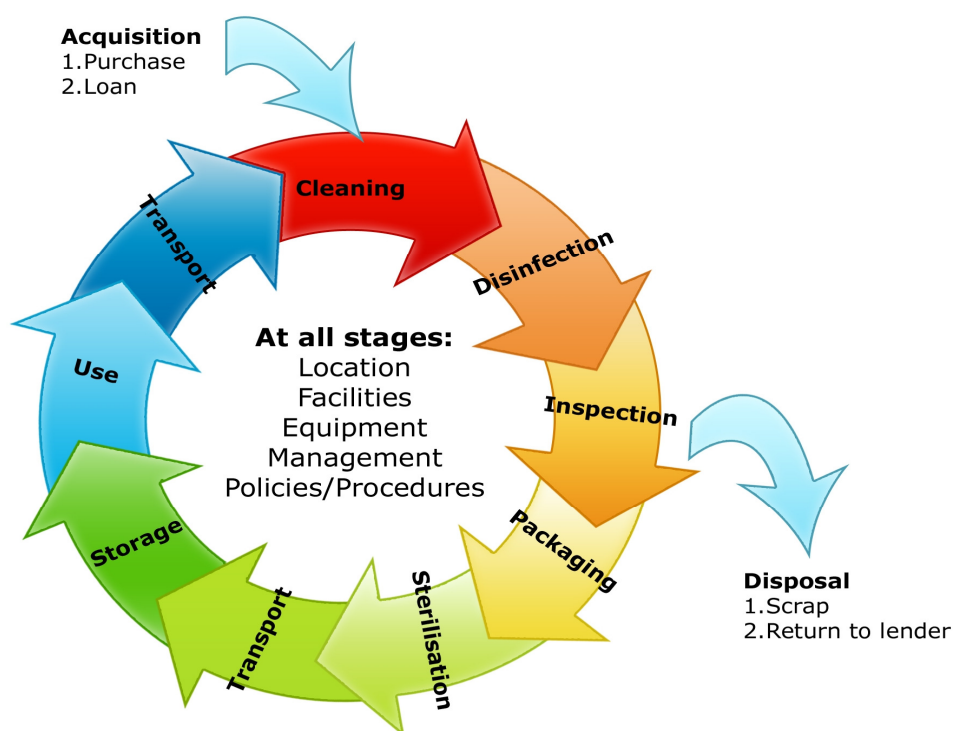
## Introduction

# 5. Life cycle for reusable invasive medical devices

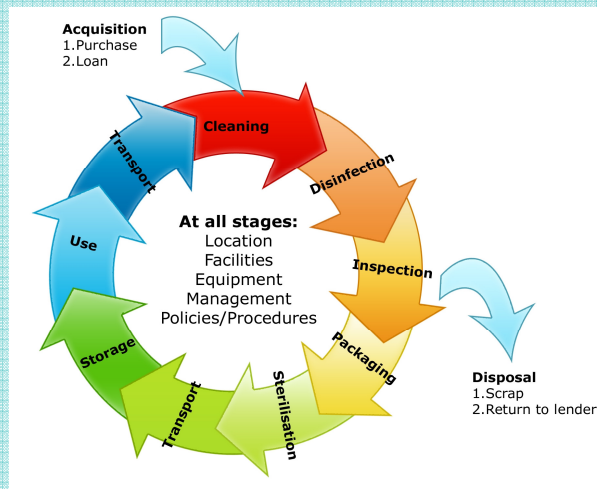
## 5.1 Introduction

The decontamination life cycle highlights the extent to which decontamination effects the whole organisation and not just areas processing RIMD. Figure 5-1 highlights each stage of the decontamination process through which RIMD must pass prior to every use. Effective decontamination requires the attainment of acceptable Standards at all stages of the life cycle. Failure at any stage may result in inadequate decontamination.

Figure 5.1: Decontamination life cycle







# Standards and Recommended Practices for Local Dental Services (LDU)

## Part 2 Standards

## Suitability of decontamination facilities

### 1. Suitability of decontamination facilities

#### 1.1 Statement

Dental clinics have dedicated non-clinical space provided for decontamination of dental reusable invasive medical devices (hereafter referred to in this document as dental RIMD), to minimise opportunities for cross-infection of service users, clinical staff and cross-contamination of the working environment. For guidance see *PD CEN ISO/ TR 14969:2005 and Safety, Health and Welfare at Work Act 2005*.

#### 1.2 Rationale

It is essential that decontamination facilities are appropriately designed, maintained and controlled. This is important in order to reduce the risk of cross-contamination and to provide a safe place of work.

#### 1.3 Criteria

##### *Unit design*

- 1.3.1 The local decontamination unit (LDU) is designed so that it is physically separated from the service user treatment area and administration areas.

*Note: Best practice dictates that the LDU is a separate room to both of these areas.*

- 1.3.2 The LDU is designed to prevent cross-contamination between 'dirty' and 'clean' activities.

- 1.3.3 The LDU is designed to facilitate a unidirectional flow from the 'dirty' area to the 'clean' area.

- 1.3.4 The LDU is not used for any other purpose.

- 1.3.5 The LDU is not used as a thoroughfare.

- 1.3.6 There is a designated changing area for donning clinical wear.

*Note: Best practice dictates that this is a separate area to the service user/patient treatment area.*



## Suitability of decontamination facilities

1.3.7 The LDU is free from ‘opening’ windows, ledges, and is designed to be easily cleanable.

1.3.8 The LDU is designed to minimise the ambient sound levels.

*Note: This will require attention to the installation of equipment, building finish, etc.*

### *Lighting and electrical power supply*

1.3.9 There is adequate lighting available to permit good working practices and visual examination of dental RIMD.

1.3.10 Task lighting and magnification is installed.

1.3.11 There are sufficient electricity supply points, computer terminal points and work stations in the department.

### *Ventilation and temperature*

1.3.12 All rooms in the department are mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures are controlled between 18-22°Celsius and relative humidity is controlled within the range 35-60%).

1.3.13 All ventilation equipment installed is in compliance with requirements for reprocessing of dental RIMD.

1.3.14 All ventilation equipment installed is in compliance with requirements for comfortable working environment for staff involved in the reprocessing of dental RIMD.

### *Walls, floors and ceilings*

1.3.15 The finishes on the walls and other surfaces are flush, smooth, non-linting, water resistant and able to withstand frequent cleaning and/or disinfection.

1.3.16 The junctions between the walls and floors are coved and flush.

**Suitability of decontamination facilities**

- 1.3.17 The fitments (where possible) are flush with wall surfaces.
- 1.3.18 Floors are covered in a washable non-slip material which is securely sealed.

***Workstations, furniture, shelving and equipment***

- 1.3.19 All work surfaces, fittings, fixtures and furniture are made of easily cleanable and robust material and maintained in good condition.
- 1.3.20 The workstations are equipped for the preparation of packs. They are of adequate size to accommodate the wrapping material to be used and are height adjustable.
- 1.3.21 There is adequate space between workstations for equipment and staff movement.
- 1.3.22 The shelving is manufactured from non-shedding material, easily cleanable and with a smooth surface that will not damage packaging.
- 1.3.23 The shelving is of sufficient depth for all the materials to be held and is not more than two metres high, unless special provision is made for loading and un-loading higher shelves.

***Restricted entry and movement between areas***

- 1.3.24 The unit is managed by appropriately trained staff who have a qualification which is recognised by the Dental Council (e.g. dental nurse) or a higher relevant qualification (e.g. degree in sterile services management or microbiology).
- 1.3.25 Entry to the decontamination unit is restricted to authorised personnel only.

## Suitability of decontamination facilities

### *Storage facilities*

- 1.3.26 Safe storage facilities are provided for process chemicals used in decontamination.
- 1.3.27 Storage facilities for consumable supplies are provided external to the designated decontamination unit.
- 1.3.28 Required personal protective equipment is easily accessible in each of the work areas.

### *Environmental control*

- 1.3.29 The control and quality of the environment does not undermine the reprocessing of dental RIMD.

### *Cleaning*

- 1.3.30 The environment in which decontamination of dental (RIMD) takes place is cleaned in accordance with policies, procedures, protocols, and guidelines as agreed at local level.

## Decontamination equipment

## 2. Decontamination equipment

### 2.1 Statement

All decontamination equipment that does not meet the requirements of current Standards is identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment is procured in conformance with existing European Standards.

All decontamination equipment is validated, maintained, periodically tested and monitored to current Standards.

### 2.2 Rationale

Decontamination equipment that does not meet current Standards cannot be relied upon to meet current requirements for decontamination or to provide the required level of assurance. Healthcare facilities should seek advice from/set up an advisory user group to consider the full implications of procurement of decontamination equipment. Validation, maintenance, periodic testing and monitoring are required to demonstrate compliance of installed equipment with current Standards.

### 2.3 Criteria

#### *Advisory user group (or relevant committee)*

Each healthcare facility seeks advice from a relevant committee who can provide expert advice/sets up an advisory user group to consider the decontamination equipment in the organisation with regard to the following:

- 2.3.1 Ability to meet current Standards.
- 2.3.2 Age and condition of equipment and availability of replacement parts.
- 2.3.3 Cost of maintaining and repairing the equipment.
- 2.3.4 Ability to interface with other equipment in the dental facility.
- 2.3.5 Ability to interface with user requirements.
- 2.3.6 Ability to meet the requirements of current test methods.

## Decontamination equipment

- 2.3.7 Ability to be validated and perform to intended purpose.
- 2.3.8 Energy and water conservation in line with current EU policy.
- 2.3.9 Ability for self-disinfection for washer-disinfectors.

### *Key representatives on the specialist group include: (where available)*

- 2.3.10 Dental staff.
- 2.3.11 Competent Infection Prevention and Control Advisor.

### *The group may also include as required:*

- 2.3.12 Procurement.
- 2.3.13 Technical services.
- 2.3.14 Other relevant experts (authorised person sterility nurse etc.).
- 2.3.15 The group identifies all decontamination equipment which needs to be replaced.
- 2.3.16 The group formulates a plan to replace or upgrade this equipment.
- 2.3.17 The plan is submitted to the senior management team and is revised annually as appropriate.
- 2.3.18 The group ensures that the decontamination equipment procured is compatible with the current stock of dental RIMD.
- 2.3.19 There is sufficient decontamination equipment available to meet the needs of the dental unit(s) and service user throughput.
- 2.3.20 Management ensures that there are clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and the day to day operation of decontamination equipment.
- 2.3.21 Validation and periodic testing is carried out by qualified personnel.

**Decontamination equipment**

- 2.3.22 The validation and periodic testing data is adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive.
- 2.3.23 The department has a permanent record of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

***Ultrasonic cleaning***

- 2.3.24 A stand-alone ultrasonic cleaner is provided for pre-treatment of those dental RIMD which are required to be cleaned by this method according to the manufacturers' instructions/recommendations. Ultrasonic cleaning is preferably only used as a pre-treatment for dental RIMD prior to further processing through a washer-disinfector. However, it is unsuitable for use with heat sensitive items.
- 2.3.25 The ultrasonic cleaner is fitted with a lid which is (preferably) interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- 2.3.26 The dental RIMD manufacturer is consulted to ensure that the enzymatic/detergent preparation is suitable for cleaning the dental RIMD they manufacture.
- 2.3.27 Concentration of detergent should comply with manufacturer's instructions.
- 2.3.28 The ultrasonic cleaner is used in accordance with the manufacturers' instructions.

***Washer-disinfectors***

- 2.3.29 All washer-disinfectors used for decontamination of dental RIMD should conform to EN15883 Parts 1 and 2.
- 2.3.30 The water for the final rinse stage should be compliant with the manufacturers' instructions/recommendations.
- 2.3.31 All washer-disinfectors purchased should conform to MES NHS small washer disinfectors (dental) 2007 with reference to EN15883 Parts 1 and 2.

## Decontamination equipment

- 2.3.32 Each washer-disinfector should be fitted with a process monitoring system.
- 2.3.33 When lumened devices are being reprocessed, the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- 2.3.34 The washer-disinfector should be subject to planned preventative maintenance.

### *Steam sterilisers*

- 2.3.35 Sterilisers and accessories are specified, installed, commissioned, tested and operated in accordance with the current standard EN 13060.
- 2.3.36 The sterilisation hold period is at 134-137°C for not less than 3 minutes.
- 2.3.37 The steriliser is subject to planned preventative maintenance.
- 2.3.38 Downward displacement sterilisers are not appropriate for sterilising wrapped loads of RIMD or for items that contain a lumen (e.g. dental handpieces), and are not used for these purposes under any circumstances.
- 2.3.39 All dental RIMD, items and equipment for use on service user are packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- 2.3.40 Boiling water sterilisers, hot air ovens, ultra violet light treatment, hot bead sterilisers and chemoclaves are not appropriate for sterilising dental RIMD and are not used.

### *Heat sealer (where applicable)*

- 2.3.41 Where heat seal packaging is to be used, a rotary heat sealer is provided.
- 2.3.42 Heat-sealing equipment used as part of the terminal packaging process is maintained and tested to manufacturer's performance criteria.
- 2.3.43 The heat sealer is validated and tested daily to verify the efficacy of the seal.
- 2.3.44 The heat sealer is subject to planned preventative maintenance.

## Choice of decontamination process

### 3. Choice of decontamination process

#### 3.1 Statement

To prevent infection, all dental RIMD that come into contact with the service user are systematically decontaminated after each procedure and attention is given to all potential sources of contamination. All decontamination processes are validated

#### 3.2 Rationale

RIMD must be decontaminated thoroughly to render them safe for further use. Effective sterilisation depends on thorough cleaning, thus minimising the amount of contamination present on RIMD before sterilisation.

#### 3.3 Criteria

- 3.3.1 Decontamination processes are chosen to be compatible with the dental RIMD to be processed.
- 3.3.2 Decontamination processes are chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- 3.3.3 Decontamination processes are chosen to be amenable to independent verification of the decontamination Standards achieved.
- 3.3.4 The decontamination methods selected are economical and effective.
- 3.3.5 The decontamination methods used are compliant with recommended methods of validation.



## Procedures relating to transmissible spongiform encephalopathies (TSEs)

### 4. Procedures relating to transmissible spongiform encephalopathies (TSEs)

#### 4.1 Statement

The organisation has processes in place to minimise the exposure of service users and employees to TSE agents.

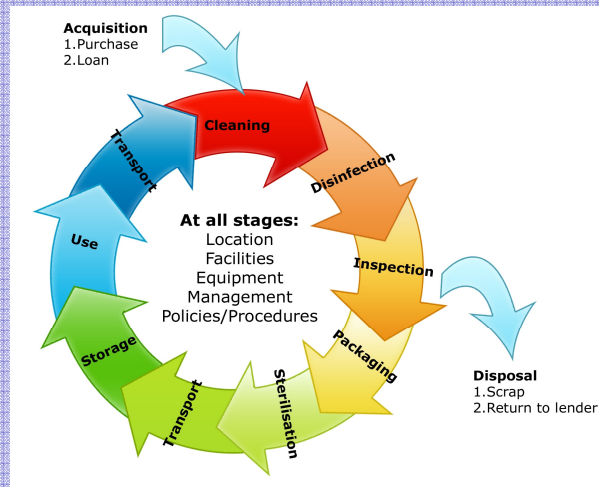
#### 4.2 Rationale

RIMDs contaminated with specific tissues from service users who have been diagnosed as having, or who are at risk of developing, a TSE require additional control measures to prevent iatrogenic transmission of TSE's.

#### 4.3 Criteria

- 4.3.1 The organisation has written policies, procedures, protocols and guidelines for the identification of service users at increased risk of developing a TSE's.
- 4.3.2 The organisation has written policies, procedures, protocols and guidelines to manage RIMD (or where possible, use single use equipment) currently based on the *Guidelines on Minimising the Risk of Transmission TSEs in Healthcare Settings in Ireland; 2004 (DoHC)* and reviewed when the guidance is updated.
- 4.3.3 The organisation regularly evaluates the implementation of the policies, procedures, protocols and guidelines to minimise the risk of iatrogenic transmission of TSEs and develop quality improvement plans to address any deficiencies.





# Standards and Recommended Practices for Local Dental Services (LDU)

## Part 3

### Recommended Practices

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## Design of dedicated area for decontamination of dental RIMD in a LDU

### 1. Design of dedicated area for decontamination of dental RIMD in a LDU

#### 1.1 Introduction

Dental clinics should have dedicated non-clinical space provided for decontamination of dental reusable invasive medical devices (hereafter referred to in this document as dental RIMD), to minimise opportunities for cross-infection of patients/service users, clinical staff and cross-contamination of the working environment. For guidance see PD CEN ISO/TR 14969:2005 and Safety, Health and Welfare at Work Act 2005.

#### 1.2 Scope

The objective of this recommended practice is to outline the principles of a safe working environment for decontamination of dental RIMD in a LDU. A LDU is the dedicated area in a dental clinic that is used for decontamination of dental RIMD. These areas can be in the dental surgery or in a separate accommodation. The LDU may be present in a primary care dental setting which may include orthodontic and/or oral surgery unit.

#### 1.3 Contents

- Section One: Local decontamination unit design
- Section Two: Lighting and electrical power supply
- Section Three: Ventilation and temperature
- Section Four: Walls, floors and ceilings
- Section Five: Workstations, furniture, shelving and equipment
- Section Six: Restricted entry and movement between areas
- Section Seven: Storage facilities
- Section Eight: Environmental control
- Section Nine: Cleaning

## Design of dedicated area for decontamination of dental RIMD in a LDU

### 1.4 Procedure

#### Section One: Local decontamination unit design

- 1.4.1 The local decontamination unit (LDU) should be designed so that it is physically separated from the patient/service user treatment area and administration areas.  
*(Note: Best practice dictates that the LDU should be a separate room to both of these areas.)*
- 1.4.2 The LDU should be designed to prevent cross-contamination between 'dirty' and 'clean' activities.
- 1.4.3 The LDU should be designed to facilitate an unidirectional flow from the 'dirty' area to the 'clean' area.
- 1.4.4 The LDU should not be used for any other purpose.
- 1.4.5 The LDU should not be used as a thoroughfare.
- 1.4.6 There should be a designated changing area for donning clinical wear.  
*(Note: Best practice dictates that this should be a separate area to the patient/service user treatment area.)*
- 1.4.7 The LDU should be free from 'opening' windows, ledges, and should be designed to be easily cleanable.
- 1.4.8 The LDU should be designed to minimise the ambient sound levels.  
*(Note: This will require attention to the installation of equipment, building finish, etc.)*

#### Section Two: Lighting and electrical power supply

- 1.4.9 There should be adequate lighting available to permit good working practices and visual examination of dental RIMD.
- 1.4.10 Task lighting and magnification should be installed.
- 1.4.11 There should be sufficient electricity supply points, computer terminal points and work stations in the department.

## Design of dedicated area for decontamination of dental RIMD in a LDU

### Section Three: Ventilation and temperature

- 1.4.12 All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures should be controlled between 18-22°Celsius and relative humidity should be controlled within the range 35-60%).
- 1.4.13 All ventilation equipment installed should be in compliance with requirements for reprocessing of dental RIMD.
- 1.4.14 All ventilation equipment installed should be in compliance with requirements for comfortable working environment for staff involved in the reprocessing of dental RIMD.

### Section Four: Walls, floors and ceilings

- 1.4.15 The finishes on the walls and other surfaces should be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning and/or disinfection.
- 1.4.16 The junctions between the walls and floors should be coved and flush.
- 1.4.17 The fitments (where possible) should be flush with wall surfaces.
- 1.4.18 Floors should be covered in a washable non-slip material which is securely sealed.

### Section Five: Workstations, furniture, shelving and equipment

- 1.4.19 All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- 1.4.20 The workstations should be equipped for the preparation of packs. They should be of adequate size to accommodate the wrapping material to be used and should be height adjustable.
- 1.4.21 There should be adequate space between workstations for equipment and staff movement.
- 1.4.22 The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- 1.4.23 The shelving should be of sufficient depth for all the materials to be held and should not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.

## Design of dedicated area for decontamination of dental RIMD in a LDU

### Section Six: Restricted entry and movement between areas

- 1.4.24 The unit should be managed by appropriately trained staff who have a qualification which is recognised by the Dental Council (e.g. dental nurse) or a higher relevant qualification (e.g. degree in sterile services management or microbiology).
- 1.4.25 Entry to the decontamination unit should be restricted to authorised personnel only.

### Section Seven: Storage facilities

- 1.4.26 Safe storage facilities should be provided for process chemicals used in decontamination.
- 1.4.27 Storage facilities for consumable supplies should be provided external to the designated decontamination unit.
- 1.4.28 Required personal protective equipment should be easily accessible in each of the work areas.

### Section Eight: Environmental control

- 1.4.29 The control and quality of the environment should not undermine the reprocessing of dental RIMD.

### Section Nine: Cleaning

- 1.4.30 The environment in which decontamination of dental RIMD takes place should be cleaned in accordance with policies, procedures protocols and guidelines as agreed.

## Environmental cleaning

## 2. Environmental cleaning

### 2.1 Introduction

Regular cleaning of all work areas is essential for decontamination to be effective. Environmental cleaning procedures and schedules adopted must ensure that contamination from dirty areas does not contaminate the clean areas.

### 2.2 Scope

The objective of this recommended practice is to provide guidelines in relation to environmental cleaning in decontamination facilities.

### 2.3 Contents

- Section One: Cleaning equipment
- Section Two: Cleaning frequency and cleaning efficacy
- Section Three: Floor cleaning equipment and method
- Section Four: Floor cleaning agents
- Section Five: Records

### 2.4 Procedure

#### Section One: Cleaning equipment

- 2.4.1 Separate cleaning equipment should be used for the clean and dirty areas.
- 2.4.2 Cleaning equipment should be regularly cleaned and maintained.



## Environmental cleaning

### Section Two: Cleaning frequency and cleaning efficacy

- 2.4.3 Work surfaces should be cleaned daily and whenever necessary.
- 2.4.4 Air vents and filters should be inspected, cleaned and serviced regularly.
- 2.4.5 There should be documented cleaning procedures for fixtures and fittings.
- 2.4.6 There should be documented cleaning procedures for process equipment.

### Section Three: Floor cleaning equipment and method

- 2.4.7 Floors should be cleaned daily and also cleaned when visibly soiled.

### Section Four: Floor cleaning agents

- 2.4.8 Floors should be cleaned using a neutral detergent (pH=7.0).
- 2.4.9 If visible blood/body fluids are present they should be neutralised using a chlorine based disinfectant, and then thorough cleaning should be completed.
- 2.4.10 Disinfectants should be prepared according to the manufacturers' instructions.

### Section Five: Records

- 2.4.11 Records should be kept of the following:
  - a. training of the personnel carrying out the cleaning.
  - b. periodic inspection of cleanliness.
  - c. vaccination status of the cleaning staff.
- 2.4.12 It is the responsibility of management to ensure that cleaning staff (in-house and contracted) are appropriately trained.

## Decontamination equipment

### 3. Decontamination equipment

#### 3.1 Introduction

All decontamination equipment that does not meet the requirements of current Standards is identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment must be procured in conformance with existing European Standards.

All decontamination equipment must be validated, maintained, periodically tested and monitored to current Standards.

#### 3.2 Scope

Decontamination equipment that does not meet current Standards cannot be relied upon to meet current requirements for decontamination or to provide the required level of assurance.

Healthcare facilities should seek advice from/set up an advisory user group to consider the full implications of procurement of decontamination equipment.

Validation, maintenance, periodic testing and monitoring are required to demonstrate compliance of installed equipment with current Standards.

#### 3.3 Contents

Section One: Advisory user group (or relevant committee)

Section Two: Ultrasonic cleaning

Section Three: Washer-disinfectors

Section Four: Steam sterilisers

Section Five: Heat sealers (where applicable)

## Decontamination equipment

### 3.4 Procedure

#### Section One: Advisory user group (or relevant committee)

- 3.4.1 Each healthcare facility should seek advice from a relevant committee who can provide expert advice/set up an advisory user group to consider the decontamination equipment in the organisation with regard to the following:
- a. ability to meet current Standards.
  - b. age and condition of equipment and availability of replacement parts.
  - c. cost of maintaining and repairing the equipment.
  - d. ability to interface with other equipment in the dental facility.
  - e. ability to interface with user requirements.
  - f. ability to meet the requirements of current test methods.
  - g. ability to be validated and perform to intended purpose.
  - h. energy and water conservation in line with current EU policy.
  - i. ability for self-disinfection for washer-disinfectors.
- 3.4.2 Key representatives on the group should include (where available):
- a. dental staff.
  - b. competent Infection Control and Prevention Advisor.
- 3.4.3 The group may also include as required:
- a. procurement.
  - b. technical services.
  - c. other relevant experts (authorised person/sterivigilance nurse, etc).
- 3.4.4 The group should identify all decontamination equipment which needs to be replaced.
- 3.4.5 The group should formulate a plan to replace or upgrade this equipment.
- 3.4.6 The plan should be submitted to the senior management team and revised annually as appropriate.

## Decontamination equipment

- 3.4.7 The group should ensure that the decontamination equipment procured is compatible with the current stock of dental RIMD.
- 3.4.8 There should be sufficient decontamination equipment available to meet the needs of the dental unit(s) and patient/service user throughput.
- 3.4.9 Management should ensure that there are clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and day to day operation of decontamination equipment.
- 3.4.10 Validation and periodic testing should be carried out by qualified personnel.
- 3.4.11 The validation and periodic testing data should be adequately audited annually by a qualified person (decontamination) registered with the Health Service Executive.
- 3.4.12 The department should have a permanent record of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

## Section Two: Ultrasonic cleaning

- 3.4.13 A stand-alone ultrasonic cleaner should be provided for pre-treatment of those dental RIMD which are required to be cleaned by this method according to the manufacturers' instructions/recommendations. Ultrasonic cleaning should preferably only be used as a pre-treatment for dental RIMD prior to further processing through a washer-disinfector. However, they are unsuitable for use with heat sensitive items.
- 3.4.14 The ultrasonic cleaner should be fitted with a lid which is (preferably) interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- 3.4.15 The dental RIMD manufacturer should be consulted to ensure that the enzymatic/detergent preparation is suitable for cleaning the dental RIMD they manufacture.
- 3.4.16 Concentration of detergent should comply with manufacturer's instructions. The ultrasonic cleaner should be used in accordance with the manufacturers' instructions.

## Decontamination equipment

### Section Three: Washer-disinfectors

- 3.4.17 All washer-disinfectors used for decontamination of dental RIMD should conform to EN15883 Parts 1 and 2.
- 3.4.18 The water for the final rinse stage should be compliant with the manufacturers' instructions/recommendations.
- 3.4.19 All washer-disinfectors purchased should conform to MES NHS small washer disinfectors (dental) 2007 with reference to EN15883 Parts 1 and 2.
- 3.4.20 Each washer-disinfector should be fitted with a process monitoring system.
- 3.4.21 When lumened devices are being reprocessed, the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- 3.4.22 The washer-disinfector should be subject to planned preventative maintenance.

### Section Four: Steam sterilisers

- 3.4.23 Sterilisers and accessories should be specified, installed, commissioned, tested and operated in accordance with the current standard EN 13060.
- 3.4.24 The sterilisation hold period should be at 134-137°C for not less than 3 minutes.
- 3.4.25 The sterilisers should be subject to planned preventative maintenance.
- 3.4.26 Downward displacement sterilisers are not appropriate for sterilising wrapped loads of RIMD or for items that contain a lumen (e.g. dental handpieces), and should not be used for these purposes under any circumstances.
- 3.4.27 All dental RIMD, items and equipment for use on patients/service users should be packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- 3.4.28 Boiling water sterilisers, hot air ovens, ultra violet light treatment, hot bead sterilisers and chemiclaves are not appropriate for sterilising dental RIMD and should not be used.

## Decontamination equipment

### Section Five: Heat sealers (where applicable)

- 3.4.29 Where heat seal packaging is to be used, a rotary heat sealer should be provided.
- 3.4.30 Heat-sealing equipment used as part of the terminal packaging process should be maintained and tested to manufacturer's performance criteria.
- 3.4.31 The heat sealer should be validated and tested daily to verify the efficacy of the seal.
- 3.4.32 The heat sealer should be subject to planned preventative maintenance.

**Procurement of dental RIMD****4. Procurement of dental RIMD****4.1 Introduction**

Procurement includes all activities from requisition, through payment to disposal and is the responsibility of all staff involved in the process. All staff engaged in procurement related activities are required to familiarise themselves with all relevant regulations. Any procurement undertaken must meet the terms of the Health Service Executive procurement policy.

**4.2 Scope**

The objective of this recommended practice is to provide guidelines on the procurement of dental RIMD and ancillary materials.

**4.3 Contents**

Section One: Advisory user group (or relevant committee)

Section Two: General principles

**4.4 Procedure****Section One: Advisory user group (or relevant committee)**

- 4.4.1 Each organisation should have an advisory user group (or relevant committee) in place to consider the procurement of dental RIMD.
- 4.4.2 Key representatives on the group should include (where available):
  - a. dental staff.
  - b. competent infection prevention and control advisor.

## Procurement of dental RIMD

### Section Two: General principles

- 4.4.3 Sufficient dental RIMD and accessories should be purchased to allow adequate time for reprocessing without adversely affecting throughput.
- 4.4.4 A decontamination assessment should be undertaken prior to the purchase of dental RIMD to ensure that the organisation has the facilities to reprocess the dental RIMD in accordance with the manufacturers' instructions.

#### *Any RIMD on trial should comply with these standards:*

- 4.4.5 Value for money issues should be considered when purchasing dental RIMD.
- 4.4.6 All dental RIMD and accessories should be CE marked as this will constitute the manufacturer's assurance that a device will be safe and will perform as intended.
- 4.4.7 Suppliers should be selected based on their ability to supply dental RIMD in accordance with the specified requirements and ability to provide service support over the lifetime of the dental RIMD, where applicable.
- 4.4.8 Where parts are single-use or have restricted use, this information should be provided prior to purchasing.



## Manufacturers' instructions

### 5. Manufacturers' instructions

#### 5.1 Introduction

Each dental RIMD must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the dental RIMD safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sale packaging. If individual packaging of each unit is not practicable, the information should be set out in the leaflet supplied with one or more devices.

#### 5.2 Scope

The objective of this recommended practice is to outline the information that should accompany each dental RIMD to ensure the safe use of the device.

#### 5.3 Contents

##### *Manufacturer*

Section One: Requirements to be met by the dental RIMD manufacturer

Section Two: Label

Section Three: The instructions for use

Section Four: Precautions and contraindications

Section Five: Information supplied on request

##### *Procedure for packs or sets processed in the local decontamination unit*

Section Six: Label

Section Seven: Instructions for use

## Manufacturers' instructions

### 5.4 Procedure

#### *Manufacturer*

##### Section One: Requirements to be met by the dental RIMD manufacturer

- 5.4.1 If the dental RIMD is intended by the manufacturer to be reused, the following information should be provided:
  - a. appropriate processes to allow reuse, including cleaning, disinfection, packaging and (if appropriate), the methods of sterilisation of the dental RIMD to be resterilised.
  - b. the number of reuses.
  - c. any restriction to the reuse.
- 5.4.2 If the dental RIMD is supplied with the intention that it can be sterilised before use, instructions for sterilisation methods should be provided.
- 5.4.3 If the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas should be provided.
- 5.4.4 Instructions for use should be included in the packaging of every dental RIMD. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to the harmonised European Standards. In areas for which no Standards exist, the symbols and colours should be described in the documentation supplied with the dental RIMD.
- 5.4.5 The degree of accuracy claimed for dental RIMD with a measuring function should be provided.
- 5.4.6 If the intended purpose of the dental RIMD is not obvious to the user, the manufacturer should clearly state the intended purpose on the label and in the instructions/recommendations for use.
- 5.4.7 Detachable components of the dental RIMD should be identified.
- 5.4.8 Action to detect any potential risk posed by the dental RIMD and detachable components should be provided.

**Manufacturers' instructions****Section Two: Label**

*The label should contain the following details:*

- 5.4.9 The name or trade name and address of the manufacturer.
- 5.4.10 The details strictly necessary for the user to identify the dental RIMD and the contents of the packaging.
- 5.4.11 Where appropriate (in the case of a single-use medical device), the method of sterilisation and the word 'STERILE'.
- 5.4.12 Where appropriate, the batch code preceded by the word 'LOT', or the serial number.
- 5.4.13 Where appropriate, an indication of the date by which the dental RIMD should be used, in safety, stating the month and the year.
- 5.4.14 Where appropriate, an indication that the dental RIMD is for single use.
- 5.4.15 If the dental RIMD is custom-made, the words 'custom-made dental RIMD'.
- 5.4.16 If the dental RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- 5.4.17 Any special storage and/or handling conditions.
- 5.4.18 Any special operating instructions.
- 5.4.19 Any warnings and/or precautions to be taken.
- 5.4.20 Year of manufacture.
- 5.4.21 Batch or serial number.
- 5.4.22 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

## Manufacturers' instructions

### Section Three: The instructions for use:

*The instructions for use should contain the following particulars:*

- 5.4.23 If the dental RIMD must be installed with, or connected to, other dental RIMD or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct dental RIMD or equipment to use in order to obtain a safe combination should be provided.
- 5.4.24 All the information needed to verify whether the dental RIMD is properly installed and can be operated correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the dental RIMD operates properly and safely at all times should be provided.
- 5.4.25 Where appropriate, information to avoid certain risks in connection with the implantation of the dental RIMD should be provided.
- 5.4.26 The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of re-sterilisation.
- 5.4.27 If the dental RIMD is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the dental RIMD to be re-sterilised, and any restriction on the number of reuses.
- 5.4.28 Details of any further treatment or handling needed before the dental RIMD can be used (for example, sterilisation, final assembly, etc).

### Section Four: Precautions and contraindications

*The instructions for use should contain the following precautions and contraindications:*

- 5.4.29 Precautions to be taken in the event of changes in the performance of the dental RIMD.
- 5.4.30 Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions; to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.

**Manufacturers' instructions**

- 5.4.31 Adequate information regarding the medicinal product or products which the dental RIMD in question is designed to administer, including any limitations in the choice of substances to be delivered.
- 5.4.32 Precautions to be taken against any special, unusual risks related to the disposal of the dental RIMD.

**Section Five: Information supplied on request**

- 5.4.33 The identity or information on the test methods used.
- 5.4.34 If the manufacturer differentiates between critical and less critical areas of the product, the rationale for this distinction.

*Procedures for packs or sets in the local decontamination unit***Section Six: Label***The label should contain the following details:*

- 5.4.35 The details strictly necessary for the user to identify the contents of the packaging.
- 5.4.36 Date of sterilisation.
- 5.4.37 Cycle number.

**Section Seven: Instructions for use**

- 5.4.38 In general, Class I and Class IIa devices which comprise most of the dental RIMD processed by the local decontamination, do not require specific instructions for use. Exceptionally where these are required, copies should be retained by the clinical user and should be referenced on the label on the dental RIMD.

## Personal protective equipment

### 6. Personal protective equipment

#### 6.1 Introduction

Personal protective equipment (PPE) must be worn by personnel when decontaminating dental RIMD to reduce the risk of exposure to potentially infectious material. Managers must ensure that PPE is made available, that staff are trained in the use of PPE and all personnel are responsible for ensuring the correct use and disposal of same.

PPE involves use of protective barriers such as gloves, gowns, aprons, masks or protective eyewear when required. PPE also provides protection against other hazards in the healthcare facility such as chemicals and physical injury. Standard precautions and safe work practices are required to minimise the risk of infection to both patients/service users and healthcare workers. They include, but are not limited to, good hygiene practices, particularly hand-washing, the use of PPE and the appropriate handling and disposal of waste. The provision of PPE is based on a risk assessment in accordance with Part V of the Safety, Health and Welfare at Work Act 2005 and (General Application) Regulations, 1993.

#### 6.2 Scope

The objective of this recommended practice is to outline the PPE that should be worn by staff to reduce risk of exposure to potentially infectious material.

#### 6.3 Contents

Section One: Head/hair cover

Section Two: Protective eyewear and face-shields

Section Three: Masks

Section Four: Gloves

Section Five:: Footwear

## Personal protective equipment

### 6.4 Procedure

#### Section One: Head/hair cover

- 6.4.1 All hair should be confined so that microbial dispersal is minimised.
- 6.4.2 Stud earrings should not be worn.

#### Section Two: Protective eyewear and face-shields

- 6.4.3 Healthcare workers (HCWs) should wear protective eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- 6.4.4 Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the top and side and should be worn with a face mask.
- 6.4.5 Protective eyewear or face shield should be single operator use. Single operator use protective eyewear or face shields should be decontaminated as appropriate.
- 6.4.6 Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- 6.4.7 Face shields should cover the eyes, nose, mouth and chin.

#### Section Three: Masks

- 6.4.8 HCWs should wear fluid repellent masks and/or face-shields to reduce the risk of pathogenic organisms being transferred to the nose or mouth.
- 6.4.9 Fluid repellent masks and/or face-shields should be fitted and worn according to the manufacturers' instructions.
- 6.4.10 Fluid repellent masks and/or face-shields should not be handled.
- 6.4.11 Fluid repellent masks and/or face-shields should cover both mouth and nose while being worn.
- 6.4.12 Fluid repellent masks and/or face-shields should be removed immediately if they become moist or visibly soiled and should be discarded in the appropriate healthcare waste stream.
- 6.4.13 Fluid repellent masks and /or face shields should not be worn loosely around the neck.

## Personal protective equipment

### Section Four: Gloves

*(Note: hand wrist or arm jewellery should not be worn in the decontamination unit).*

- 6.4.14 Appropriate wash-room gloves should be used for handling contaminated dental RIMD and waste and for performing environmental cleaning activities.
- 6.4.15 Gloves should be selected and worn according to the task to be performed.
- 6.4.16 Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- 6.4.17 When removing gloves, the outer surface of the gloves should not come into contact with skin.
- 6.4.18 Avoid letting the gloves snap, as this may cause contaminants to splash into eyes or mouth or onto skin or other personnel in the area.
- 6.4.19 It is important to remove used gloves and perform hand hygiene before touching anything that can become contaminated through contact, such as surfaces or pens.
- 6.4.20 HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves does not replace the need for hand decontamination, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- 6.4.21 After use, gloves should be discarded in the appropriate healthcare waste stream.

### Section Five: Footwear

- 6.4.22 HCWs should wear non-slip enclosed footwear that are sufficiently robust to protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally).

*(Note: Shoes that are made from canvas or cloth material or open-toed are unsuitable and should not be worn.)*

- 6.4.23 Footwear should be inspected and regularly cleaned as appropriate.



**Process chemicals**

## 7. Process chemicals

### 7.1 Introduction

Chemicals such as detergents and disinfectants may have hazardous properties associated with them (may be irritant, corrosive, flammable).

Process chemicals are potentially hazardous as they may cause irritation to the skin, eye, respiratory tract and mucous membranes.

(Reference: *The Safety, Health and Welfare at Work Act, (2005) (no. 10 of 2005). The Safety, Health and Welfare at Work (General Application) Regulations (1993), (S.I. no. 44 of 1993) as amended. The Safety, Health and Welfare at Work (Chemical Agents) Regulations, (2001) (S.I. no. 619 of 2001.)*

### 7.2 Scope

The objective of this recommended practice is to provide guidelines for staff in relation to the handling of chemicals.

### 7.3 Contents

- Section One: Choice of process chemicals
- Section Two: Control of process chemicals
- Section Three: Material Safety Data Sheets (MSDS) and labels
- Section Four: Training
- Section Five: Spillage kit

## Process chemicals

### 7.4 Procedure

#### Section One: Choice of process chemicals

- 7.4.1 Process chemicals should be chosen to be compatible with:
- the dental RIMD to be processed.
  - the decontamination equipment to be used and the intended use of the dental RIMD.
- 7.4.2 The least hazardous chemical that will fulfil a process requirement should be chosen.

#### Section Two: Control of process chemicals

- 7.4.3 Management should ensure that the methods to be used for handling and storage of process chemicals are defined in written procedures.
- 7.4.4 Chemicals that should not be stored together should be clearly identified.
- 7.4.5 Chemicals should not be stored above shoulder height.
- 7.4.6 Chemicals should be stored in locked cabinet.

#### Section Three: Material Safety Data Sheets (MSDS) and labels

- 7.4.7 Suppliers of chemical agents should provide MSDS for all chemical agents (including cleaning agents and disinfectants).
- 7.4.8 Copies of all MSDS should be available to all employees in a designated area at all times, so that appropriate action can be taken in case of exposure to a hazardous substance.
- 7.4.9 If information is incorporated into policies, procedures, protocols and guidelines, the original wording should be used and the MSDS referred to.
- 7.4.10 Personnel should read and follow the precautions and instructions given on the MSDS and on the label prior to handling and use.

**Process chemicals****Section Four: Training**

- 7.4.11 All personnel who handle chemicals e.g. rinse aid, disinfectants; etc should be trained in following:
- a. safe handling of chemicals.
  - b. method of cleaning process chemical spillages.
  - c. first aid required in the event of personal exposure.
  - d. correct disposal of material used.

**Section Five: Spillage kit**

- 7.4.12 In each area where chemicals are used, a spillage kit should be available to allow safe and easy removal of spills.
- 7.4.13 A first aid eye wash station should be available nearby or on hand.

## Traceability

## 8. Traceability

### 8.1 Introduction

Systems should be in place to record the decontamination process used on dental RIMD/packs (tracking) and link them with patients/service users on which they have been used (tracing).

The tracking system should record the progress of sets of dental RIMD, or individual supplementary dental RIMD, prior to sterilisation and allow retrospective demonstration that a particular set or supplementary dental RIMD has been correctly decontaminated.

### 8.2 Scope

The objective of this recommended practice is to provide guidelines for the effective tracking and traceability of dental RIMD through the decontamination process.

### 8.3 Contents

Section One: Processing

Section Two: Tracing

### 8.4 Procedure

#### Section One: Processing

- 8.4.1 Systems should be in place to allow the methods and operational cycles involved in the processing of a particular dental RIMD/dental RIMD set to be tracked through the decontamination processes in order to permit retrospective verification that the processes were carried out effectively.
- 8.4.2 Records should be maintained of:
  - a. the terminal sterilisation cycle used.
  - b. date, time and test result.

## Traceability

- 8.4.3 As a minimum, sets of dental RIMD should be individually identifiable .
- (Note: RIMD should not be labelled with tape.)*
- 8.4.4 IT based systems are preferred. Manually based systems should only be used for small areas with a very low turn-over or for back-up in the event of IT failure.
- 8.4.5 Records relating to decontamination processes should be maintained for the lifetime of the dental RIMD/decontamination equipment (approximately 25,000 cycles) plus eleven years.

### Section Two: Tracing

- 8.4.6 Systems should be implemented to enable the identification of service users on whom the dental RIMD/dental RIMD set has been used. This is important so that the relevant service users can be identified in the event exposure to potential risk.

## Choice of decontamination process

### 9. Choice of decontamination process

#### 9.1 Introduction

To prevent infection, all dental RIMD that come into contact with the patient/service user should be systematically decontaminated after each procedure and attention must be given to all potential sources of contamination. All decontamination processes must be validated.

#### 9.2 Scope

The objective of this recommended practice is to provide guidelines on the choice of decontamination processes.

#### 9.3 Contents

Section One: General principles

Section Two: Choice of process

#### 9.4 Procedure

##### Section One: General principles

- 9.4.1 Decontamination processes should be chosen to be compatible with the dental RIMD to be processed.
- 9.4.2 Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- 9.4.3 Decontamination processes should be chosen to be amenable to independent verification of the decontamination Standards achieved.
- 9.4.4 The decontamination methods selected should be economical and effective.
- 9.4.5 The decontamination methods used should be compliant with recommended methods of validation.

## Choice of decontamination process

### Section Two: Choice of process

- 9.4.6 In general, dental RIMD and equipment may be divided into three risk categories: high, medium-and low-risk, according to the risk of infection associated with the subsequent use of each item of equipment.
- high-risk RIMD** (i.e. RIMD that become contaminated with blood, other body fluids, secretions or excretions (excluding sweat)), cleaning followed by heat sterilisation is the method of choice. In certain circumstances, it may be necessary to use chemical disinfection for heat-sensitive items. For dental procedures it is best to use only RIMD that will endure sterilisation by the moist heat method (i.e. autoclaving), as this is one of the safest, most effective and easiest to monitor and validate.
  - medium risk items** consist of RIMD or equipment used in contact with mucous membranes in the oral cavity (e.g. light-curing units) that are not suitable for heat sterilisation and should be barrier protected prior to use. For reusable medium-risk items, the appropriate means of decontamination is cleaning followed by high-level disinfection or sterilisation.
  - low-risk items** include RIMD, equipment or other items/surfaces in the dental clinic that come into contact with a patient's/service user's healthy intact skin, and equipment that does not have close contact with the patient/service user. For these items, cleaning is sufficient. However, disinfection may be necessary if there is a known infection risk. Examples of low-risk items include surfaces, floors, walls and sinks.

*(Note: Most RIMD and equipment used in dentistry come into direct contact with the patients/service users oral cavity, so decontamination followed by sterilisation is the method of choice.)*

## Transportation – return of used items for reprocessing

### 10. Transportation – return of used items for reprocessing

#### 10.1 Introduction

After use, contaminated dental RIMD have to be removed from the dental surgery or dental clinical area, and transported to the dedicated processing unit for cleaning, decontamination and sterilisation.

#### 10.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the transportation of contaminated dental RIMD.

#### 10.3 Contents

Section One: General principles

#### 10.4 Procedure

##### Section One: General principles

- 10.4.1 RIMD should be removed from the surgery or clinical environment using a defined process.
- 10.4.2 Where cassettes are used, RIMD should be arranged in kits or cassettes for set procedures, (e.g. examination kit, scaling kit etc.) to prevent injuries during transportation and during decontamination.
- 10.4.3 Contaminated dental RIMD should preferably be transported to the decontamination unit in a covered container, as there is potential for dropping the RIMD en-route or indeed colliding with patients/service users or staff resulting in injury. This will also prevent contact between contaminated and sterilised/disinfected RIMD which should always be transported separately.
- 10.4.4 Depending on how long the RIMD are stored before cleaning, it may be necessary to store them in a disinfectant solution.



**Transportation – return of used items for reprocessing**

- 10.4.5 Some commercial disinfectant products recommended for this purpose result in corrosion if in contact with RIMD for extended periods.
- 10.4.6 Preferably, RIMD should be cleaned and disinfected immediately or shortly after use.
- 10.4.7 In the case of instruments or implements used for mixing dental materials it is best to remove as much of the residual material before it dries on to the instrument or implement.
- 10.4.8 All disposable items should be removed from the kit prior to transportation, e.g. disposable needles, cartridges etc.
- 10.4.9 Broken RIMD or RIMD that require repair should be decontaminated and sterilised prior to disposal or repair.
- 10.4.10 Policies, procedures, protocols and guidelines for transportation (return of used items for reprocessing) of contaminated dental RIMD should be developed, reviewed periodically, and readily available within the practice setting.

## Sorting and disassembly of contaminated dental RIMD

### 11. Sorting and disassembly of contaminated dental RIMD

#### 11.1 Introduction

Effective and timely decontamination of dental RIMD should be performed where feasible. Sorting, disassembly and cleaning should be performed in a manner that minimises risk to those performing the task.

#### 11.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the sorting and disassembly of contaminated dental RIMD.

#### 11.3 Contents

Section One: Sorting of items in the decontamination unit prior to cleaning

Section Two: Disassembly of dental RIMD

#### 11.4 Procedure

##### Section One: Sorting of items in the decontamination unit prior to cleaning

- 11.4.1 On receipt at the decontamination unit, dental RIMD should be sorted according to the selected method of cleaning. The manufacturers' instructions for cleaning should be followed in order to ensure the dental RIMD is not damaged and is cleaned adequately.
- 11.4.2 Policies, procedures, protocols and guidelines should be developed for the handling, sorting and disassembly of dental RIMD.
- 11.4.3 There should be written policies, procedures, protocols and guidelines for handling specialised items.
- 11.4.4 Care and handling of dental RIMD should be in accordance with manufacturers' instructions/recommendations and healthcare organisation policies, procedures, protocols and guidelines.

## Sorting and disassembly of contaminated dental RIMD

### Section Two: Disassembly of dental RIMD

*To facilitate effective cleaning, the following activities should be completed:*

- 11.4.5 Place dental RIMD in a mesh basket in a manner which ensures effective cleaning of RIMD. Do not place dental RIMD one on top of the other. Overloaded baskets will result in ineffective cleaning due to masking.
- 11.4.6 Arrange dental RIMD in an orderly fashion in mesh trays so that all surfaces are exposed to the action of an automated cleaner, if used.
- 11.4.7 Place each jointed dental RIMD in the open position in the mesh basket.
- 11.4.8 If extra mesh baskets are required for cleaning purposes of a dental RIMD set, a marker should be placed in the extra baskets to identify the set name and number.
- 11.4.9 Place heavy dental RIMD on the bottom or in a separate tray.
- 11.4.10 Secure small and light items with a hold down screen or by other means, to ensure they are not free to move around during the cleaning process. Place scissors, light-weight dental RIMD, and microsurgical RIMD next.
- 11.4.11 Separate all sharp dental RIMD from general dental RIMD. This is to ensure ease of identification for personnel assembling the dental RIMD after cleaning, in order to prevent sharps injury.

## Cleaning (including pre-cleaning)

## 12. Cleaning (including pre-cleaning)

### 12.1 Introduction

Cleaning is an essential prerequisite for all effective disinfection and sterilisation processes, as organic residue may prevent the disinfectant or sterilant from contacting the item being processed and may also bind and inactivate chemical disinfectants (Muscarella, 1998).

*If the item cannot be cleaned, it cannot be disinfected or sterilised. This process must not be used for items intended for single-use only.*

### 12.2 Scope

The objective of this recommended practice is to provide guidelines in relation to cleaning of contaminated dental RIMD. Cleaning is the initial and most crucial step in breaking the chain of disease transmission. Cleaning should remove all visible soil, dirt, dust or other foreign material.

### 12.3 Contents

- Section One: Manufacturers' instructions
- Section Two: Automated versus manual cleaning
- Section Three: Automated cleaning
- Section Four: Manual cleaning
- Section Five: Dental handpieces

### 12.4 Procedure

#### Section One: Manufacturers' instructions

- 12.4.1 The manufacturers' instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the dental RIMD will tolerate immersion.

## Cleaning (including pre-cleaning)

- 12.4.2 Dental RIMD should be cleaned, handled and inspected according to manufacturers' instructions/recommendations. Manufacturers' instructions/recommendations provide direction for care, cleaning and handling of dental RIMD. The instructions for cleaning and sterilisation should be such that if correctly followed the dental RIMD can be reused, without causing injury or harm to the patient/service user or personnel using the dental RIMD.

### Section Two: Automated versus manual cleaning

- 12.4.3 The use of mechanical cleaners such as washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.
- 12.4.4 The advantage of using automated cleaning equipment is that it provides an efficient, validated, reproducible process which can be more easily controlled than manual methods.
- 12.4.5 Automated processes are generally more convenient and also provide protection for the user in reducing exposure to contaminated dental RIMD and chemicals.

### Section Three: Automated cleaning

- 12.4.6 Automated washer disinfectors can significantly reduce the risks of transmission of infectious agents from contaminated dental RIMD.
- 12.4.7 A washer disinfectant is an automated piece of equipment similar to a domestic dishwasher that is specially designed to clean, decontaminate and thermally disinfect RIMD and equipment.
- 12.4.8 The washer disinfectant runs a washing cycle with detergent followed by a disinfection cycle and a drying cycle.
- 12.4.9 Disinfection is performed by flushing with hot water of approximately 90°C for one minute.
- 12.4.10 The machine renders equipment clean, disinfected, dry and safe for further handling.

### Cleaning (including pre-cleaning)

- 12.4.11 Washer disinfectors are fast and are easy to operate. They usually have set programmes for different types of loads and allow for minimum RIMD handling, however, they are unsuitable for use with heat-sensitive items.
- 12.4.12 Care should be taken not to over-load the washer disinfectant as this can result in some RIMD being shielded and not being properly cleaned or disinfected.

#### *Washer-disinfectors*

- 12.4.13 All washer-disinfectors used for decontamination of dental RIMD should conform to EN 15883, parts 1 and 2. The water for the final rinse stage should be compliant with the manufacturers' instructions/recommendations.
- 12.4.14 All washer-disinfectors purchased should conform to MES NHS small washer disinfectors (dental) 2007 with reference to EN15883 Parts 1 and 2.
- 12.4.15 Factors to be considered when determining if the RIMD is compatible with the washer-disinfectant:
- manufacturers' instructions/recommendations.
  - if the dental RIMD can be immersed in water.
  - maximum operating temperature. (In general if an RIMD is suitable for autoclaving it is suitable for decontamination in a washer/disinfectant).
  - mechanical damage which may occur from the impact of the water jets or other items in the load.
  - the compatibility of the process chemicals.

#### *Equipment*

- 12.4.16 See decontamination equipment section, page 40

#### *Procedure*

- 12.4.17 Ensure the washer-disinfectant and all services are operational. The washer-disinfectant should not start if any anomalies are present.
- 12.4.18 Wearing protective clothing, load the carrier/rack ensuring that the loading configuration does not impede the cleansing process and the rotary spray arms can rotate.

**Cleaning (including pre-cleaning)**

- 12.4.19 Only use load carrier/racks with the items for which they were intended.
- 12.4.20 Insert the load carrier into the washer-disinfector.
- 12.4.21 Secure the door, select and start the cycle.
- 12.4.22 On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the dental RIMD processed should be inspected.
- 12.4.23 A typical cycle comprises the following phases:
  - a. cold rinse.
  - b. warm wash.
  - c. rinse.
  - d. disinfection rinse.
  - e. drying.
- 12.4.24 Information should be recorded for each washer-disinfector cycle. This may be recorded using a log-book. Documentation is required for every washer-disinfector cycle and should contain the following:
  - a. washer-disinfector identification number.
  - b. cycle number.
  - c. type of washer-disinfector.
  - d. type of cycle used.
  - e. date and time of start of cycle.
  - f. critical parameters for the specific washer-disinfector cycle.
  - g. results of washer-disinfector process.
  - h. signature of designated, appropriate personnel who have been trained in decontamination practices, confirming whether or not the process cycle was within recommended parameters.
  - i. any notes or observation for the process cycle.
- 12.4.25 All records should be maintained for a period of 10 years.

## Cleaning (including pre-cleaning)

12.4.26 Cycles which were aborted should be documented with the action taken in a log book.

12.4.27 Where washer-disinfectors are used, segregation of unprocessed goods from processed goods should take place.

### Validation

12.4.28 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the washer-disinfector is functioning correctly and that it will produce cleaned and disinfected loads consistently.

12.4.29 The effectiveness of the disinfection process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if correct conditions are created throughout the washer-disinfector chamber and the load during every cycle.

12.4.30 Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is considered as a process which comprises:

- a. commissioning (installation qualification and operational qualification).
- b. performance qualification.
- c. periodic testing.
- d. annual and revalidation tests.

### Commissioning

12.4.31 This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier*, that it is safe to operate (installation qualification) and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions (operational qualification).

*It consists of:*

### Installation qualification

12.4.32 Verification of calibration, automatic control test, water quality tests, water supply temperature, water supply pressure.



## Cleaning (including pre-cleaning)

### *Operational qualification*

- 12.4.33 Weekly safety checks, automatic control test, verification of calibration of washer disinfectant RIMD, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical additive dosing tests, load carriers, test for air quality, cleaning efficacy test, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric tests for thermal disinfection, and load dryness test..
- 12.4.34 These tests should be carried out when a new washer-disinfectant is purchased or when a used washer-disinfectant has been relocated to other premises or following repairs that may affect the key performance indicators of the washing process.
- 12.4.35 The tests should be carried out before the washer-disinfectant is used for the first time. Installation and commissioning checks and tests should be performed by an appropriately qualified test person or suitably qualified person (decontamination). Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the washer-disinfectant is functioning correctly.
- 12.4.36 Even though the manufacturer should have tested a washer-disinfectant before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is **operating correctly**.

### *Performance qualification*

- 12.4.37 Performance qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean/disinfect. Performance qualification is indicated for initial use of a new/relocated washer-disinfectant. It should be carried out by a test person (or suitably qualified person decontamination).

### *These tests consist of:*

- 12.4.38 Thermometric tests of all dental RIMD/loading equipment to be processed, load dryness test (of RIMD requiring reprocessing); cleaning efficacy test, water/detergent penetration/contact times of all test loads and process residues.

### *Periodic testing*

- 12.4.39 After validation and when the washer-disinfectant has been passed for use, it is subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals.

## Cleaning (including pre-cleaning)

- 12.4.40 Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.

*Periodic tests consist of the following:*

- a. **Daily:** Spray arm rotation, spray nozzles, removes and clean strainers and filters and as advised by the manufacturers' instructions.
- b. **Weekly:** Cleaning efficacy test ( soil test).
- c. **Quarterly tests (user):** Weekly safety checks and tests, automatic control test.
- d. **Annual tests:** Daily and weekly tests, yearly safety checks, automatic control test, verification of calibration of RIMD, chemical additive dosing, cleaning efficacy, and thermometric tests.

*Monitoring and control*

- 12.4.41 Cycle variables should be inspected at the end of each cycle to ensure that the specified parameters are obtained for each cycle. The critical cycle variables are temperature, time and enzymatic detergent concentration.
- 12.4.42 Validation, routine monitoring and control should be carried out in accordance with EN 15883, parts 1 and 2 with reference to MES NHS small washer disinfectors (dental) 2007.

*Maintenance*

- 12.4.43 Preventative maintenance (as per manufacturers' instructions) should be planned and performed in accordance with International Standards ISO 15883 Part1 and ISO 15883 Part 2 and manufacturers' instructions. The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 12.4.44 The washer-disinfector should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily (i.e. the equipment is functioning so that all of the required parameters are achieved) and recorded.
- 12.4.45 A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically
- 12.4.46 Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.

**Cleaning (including pre-cleaning)**

- 12.4.47 Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policy, procedure, protocol and guideline, including:
- a. inspecting and cleaning all filters.
  - b. dismantling and cleaning spray arms and nozzles.
  - c. efficacy tests during operational conditions.

## Cleaning (including pre-cleaning)

Table 12.1: Minimum set of washer-disinfector tests.

Test	ENO ISO 15883
<b>Daily checks (user)</b>	
1. Check spray arm rotation for free movement and remove and clean strainers and filters etc.	N/A
2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages for instruments)	N/A
<b>Weekly tests (user)</b>	
1. Carry out daily checks	N/A
2. Cleaning efficacy test by residual soil detection	6.10.3
<b>Quarterly tests (user)</b>	
1. Weekly safety checks and tests	N/A
2. Automatic control tests	6.13
<b>Yearly and revalidation tests (re-qualification in EN 15883 terminology)</b>	
1. Yearly safety checks	N/A
2. Automatic control test	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Chemical additive dosing tests for reproducibility and low level detection	6.9.1 and 6.9.2
5. Cleaning efficacy test	6.10.2, 6.10.3
6. Thermometric test for thermal disinfection	6.8

(Note: This is the minimum set of tests required to enable compliance with the purchase specification "MES Small Washer-disinfectors Nov\_2007". This series of tests in itself is not sufficient to demonstrate compliance with ISO EN 15883 Part 1 and Part 2 and if users wish to demonstrate compliance with the International Standard further tests are required. These are identified within the HSE Decontamination of RIMD Standards and Recommended Practices for Dental CDUs. Version 2.0. June 2011.)

(Note: Validation of decontamination reprocessing equipment must be independently measured using data loggers equipment that has been calibrated and measured to source documents.)

## Cleaning (including pre-cleaning)

### *Ultrasonic cleaners*

- 12.4.48 Ultrasonic cleaners should be used for the pre-cleaning of RIMD prior to further processing in a washer disinfectant. Ultrasonic cleaners work by the use of high intensity, high frequency sound waves which cause soil to be dislodged from the dental RIMD, or to be sufficiently loosened to be removed during the rinsing process. Plastics and other similar materials cannot be successfully processed by this method. The manufacturers' instructions should be considered in relation to the suitability of dental RIMD for ultrasonic cleaning.

### *Equipment*

- 12.4.49 See decontamination equipment, page 40.

### *Procedure*

- 12.4.50 Staff should be trained in the correct use of the ultrasonic cleaning equipment.
- 12.4.51 Staff should wear personal protective equipment at all times while handling contaminated dental RIMD and working with the ultrasonic cleaner.
- 12.4.52 Fill the tank with potable water (drinking quality) to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- 12.4.53 Bring the solution up to the operating temperature manufacturers' instructions/recommendation.
- 12.4.54 De-gas the water as recommended by the manufacturer.
- 12.4.55 Place the opened/dismantled dental RIMD into the basket.
- 12.4.56 Ensure all dental RIMD are fully immersed.
- 12.4.57 Place the basket of dental RIMD into the tank. Never put dental RIMD directly onto the base of an ultrasonic washer.
- 12.4.58 Close the lid and initiate the cleaning cycle.
- 12.4.59 After the cycle has been completed, remove the basket from the tank and rinse the items with clean, potable water – unless the machine has an automatic rinse stage, or the load is to be transferred directly into a washer-disinfectant for further processing.
- 12.4.60 The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.

### Cleaning (including pre-cleaning)

- 12.4.61 It is recommended that the tank is emptied regularly. This should be at intervals not exceeding four hours, or when the water is visibly soiled.
- 12.4.62 Combine only dental RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in dental RIMD etching and pitting.
- 12.4.63 Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.

#### *Performance testing*

- 12.4.64 Performance testing should be carried out routinely to ensure that the ultrasonic cleaner conforms to process requirements.

#### *Maintenance*

- 12.4.65 Preventative maintenance should be planned and performed in accordance with documented procedures as recommended by the manufacturers' instructions/ recommendations.
- 12.4.66 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 12.4.67 The ultrasonic cleaner should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 12.4.68 A suitably qualified person (decontamination) should review the maintenance plan, main procedures and maintenance records periodically.

**Cleaning (including pre-cleaning)****Table 12.2: Minimum set for stand-alone ultrasonic baths**

Test	EN ISO 15883 Reference
<b>Daily checks (user)</b>	
1. Remove and clean strainers and filters etc.	N/A
<b>Weekly tests (user)</b>	
1. Carry out daily checks	N/A
<b>Quarterly tests (user)</b>	
1. Weekly safety checks and tests	N/A
2. Automatic control tests (if an automatic cycle control is fitted)	6.13
<b>Yearly and revalidation tests (re-qualification in EN 15883 terminology)</b>	
1. Yearly safety checks	N/A
2. Automatic control tests (if an automatic cycle control is fitted)	6.13
3. Cleaning efficacy test	6.10.2, 6.10.3
4. Test for ultrasonic activity	6.8

*(Note :This is the minimum set of tests required to enable compliance with the purchase specification "MES Small Washer-disinfectors Nov\_2007". This series of tests in itself is not sufficient to demonstrate compliance with ISO EN 15883 Part 1 and Part 2 and if users wish to demonstrate compliance with the International Standard further tests are required. These are identified within the HSE Decontamination of RIMD Standards and Recommended Practices for Dental CDUs. Version 2.0. June 2011.)*

*(Note: Validation of decontamination reprocessing equipment must be independently measured using data loggers equipment that has been calibrated and measured to source documents.)*

## Cleaning (including pre-cleaning)

### Section Four: Manual Cleaning

12.4.69 This is the least preferred method of RIMD decontamination and should be **strongly discouraged** due to the extremely high risk of percutaneous injury and splashing with infectious material during cleaning. **Unfortunately this hazardous and clearly dangerous procedure is still widely practiced in dental clinics.** Manual cleaning of RIMD is also inefficient, laborious and time consuming (and thus expensive). It is also impossible to validate such manual processes. Hand washing of dental RIMD should only be undertaken following pre-treatment in an ultrasonic cleaner.

#### *Monitoring and control*

12.4.70 Validated process control requires that the process can be replicated precisely; this is only possible with an automated process. Where a non-automated process is used, every effort should be made to control all the variables that affect the process.

*For manual washing, these include:*

- a. staff training/competence.
- b. water temperature.
- c. detergent concentration.
- d. nature of soil.
- e. method of soil removal.
- f. accessibility of fluid to item.

12.4.71 If either the cleaning solution or rinse water becomes visibly soiled or contaminated, it should be changed and the process repeated.

#### *Maintenance*

12.4.72 Regularly inspect all receptacles, sinks, surfaces including water supply and drains, for damage. Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions/recommendations.



## Cleaning (including pre-cleaning)

### Section Five: Dental handpieces

- 12.4.73 After each patient/service user use, dental handpieces that are connected to the dental chair unit (DCU) air/water system should be operated for a minimum of 30 seconds to discharge water and/or air, taking care not to inhale the aerosol.
- 12.4.74 This procedure is designed to dislodge any patient/service user-derived material that may have been retracted into the air and/or water lines due to failure of antiretraction valves.
- (Note: These valves are designed to prevent material or fluids from being retracted or siphoned back into air and/or waterlines but studies have shown that failure of antiretraction valves is not uncommon.)*
- 12.4.75 Following air and waterline purging, handpieces should be detached from the DCU RIMD line, cleaned, decontaminated and sterilised according to the manufacturer's instructions/recommendations and local policy, procedure, protocol and guidelines.
- 12.4.76 Automated pre-sterilisation cleaning of handpieces is the preferred method of handpiece decontamination.
- 12.4.77 However, manual cleaning is still widely practiced. If carrying out manual cleaning, the outside of the handpiece should be cleaned with detergent and warm water (follow the manufacturers' instructions/recommendations with regard to type of detergent recommended).
- 12.4.78 If recommended by the manufacturer, lubricate the handpiece with pressurised oil until clean oil appears from the chuck or use automated oiler (wear protective clothing including gloves, glasses and a face-mask).
- 12.4.79 Cover the working end of the handpiece with disposable paper towel to absorb the residual oil and clean away any excess oil.
- 12.4.80 Following cleaning, package appropriately and sterilise in a steriliser with a pre-sterilisation vacuum phase.
- 12.4.81 Dental handpieces should preferably be processed through a washer-disinfector equipped with lumen attachments.

## Disinfection

### 13. Disinfection

#### 13.1 Introduction

Disinfection is a process that inactivates infectious agents, using either thermal (moist or dry heat) or chemical means. The level of disinfection achieved depends on the temperature, exposure time and/or type of chemical disinfectant used.

#### 13.2 Scope

The objective of this recommended practice is to provide guidelines in relation to disinfection of dental RIMD.

#### 13.3 Contents

Section One: Disinfection process

#### 13.4 Procedure

##### Section One: Disinfection process

- 13.4.1 **Thermal disinfection** can be achieved in a thermal washer-disinfector by choosing the appropriate cycle.
- 13.4.2 **Chemical disinfection** can be achieved with a compatible RIMD-grade disinfectant of the required level, used alone or in conjunction with a chemical washer-disinfector. This is the minimum treatment recommended for reprocessing dental RIMD that cannot be sterilised.

##### *Thermal Disinfection*

- 13.4.3 If items can withstand heat and moisture and do not require sterilisation (non-critical items such as disinfectant bottles), then thermal disinfection in a washer-disinfector is the simplest, most efficient and cost-effective method of disinfection. Please note that low level thermal disinfection of dental RIMD is not recommended. RIMD that can tolerate sterilisation should be used wherever possible.

## Disinfection

### *Chemical Disinfection*

- 13.4.4 The ability of chemical disinfectants to effectively inactivate contaminating infectious agents depends on a number of factors, including the density of agents present, temperature, pH and concentration (*Chiba, 1994*). Only dental RIMD disinfectants or sterilants are suitable for use with dental RIMD. Healthcare facility or household/commercial-grade disinfectants should not be used on dental RIMD; they are suitable only for use on environmental surfaces (e.g. walls, floors, cupboards).

### *Equipment*

- 13.4.5 Dental RIMD disinfectant or sterilant.
- 13.4.6 Automated equipment.

### *Monitoring and control*

- 13.4.7 Chemical disinfection processes should provide adequate assurance of the required microbial lethality.
- 13.4.8 Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.
- 13.4.9 Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- 13.4.10 All surfaces should be immersed and channels flushed whether manually or automatically to ensure the solution is present within the channels therefore ensuring the decontamination process.
- 13.4.11 Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.
- 13.4.12 After chemical disinfection, dental RIMD should be free from toxic residues and should be rinsed free from disinfectant with purified water free from microbial contamination. The quality of water used should be appropriate to the clinical procedures being undertaken.
- 13.4.13 When rinsing, channels should be flushed thoroughly if performed manually.

## Drying

# 14. Drying

## 14.1 Introduction

Drying minimises rusting, staining and reduces the risk of recontamination during inspection and assembly of dental RIMD. Residual moisture interferes with the sterilisation process, and can damage dental RIMD.

## 14.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the drying of dental RIMD.

## 14.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Monitoring and control

Section Four: Maintenance

## 14.4 Procedure

### Section One: Equipment

14.4.1 See decontamination equipment, page 40

### Section Two: Procedure

14.4.2 The preferred method of drying is to use a washer-disinfector with a validated drying cycle. Alternatively a clean single-use lint-free, absorbent cloth should be used, taking care to prevent percutaneous injury.

## Drying

- 14.4.3 Care should be taken not to exceed the temperature tolerances advised by the manufacturer.
- 14.4.4 Dry the dental RIMD in a sloping position to facilitate drainage.

### Section Three: Monitoring and control

- 14.4.5 Manual drying should be avoided unless a single-use lint free cloth is used.
- 14.4.6 Items should not be left to dry in ambient air.
- 14.4.7 Alcohol or other flammable liquids should not be used as drying agents, other than in automated equipment designed for this purpose.

### Section Four: Maintenance

- 14.4.8 Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions/recommendations.
- 14.4.9 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 14.4.10 A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.

## Post cleaning inspection and function testing

# 15. Post cleaning inspection and function testing

## 15.1 Introduction

Inspection, maintenance and testing of dental RIMD should be carried out by trained persons in accordance with the manufacturers' instructions. All dental RIMD should be inspected to ensure that they are intact and that there are no chips, worn spots, flaking or other damage. The functionality of all dental RIMD should be tested or checked before being packaged for further processing or storage. The unit where inspection takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the dental RIMD/dental RIMD sets.

## 15.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the post cleaning inspection and function testing of dental RIMD.

## 15.3 Contents

- Section One: Equipment
- Section Two: Procedure
- Section Three: Documentation post automated cleaning
- Section Four: Inspection and function testing
- Section Five: Monitoring and control

## 15.4 Procedure

### Section One: Equipment

- 15.4.1 Work bench.
- 15.4.2 Magnifying glass.
- 15.4.3 Light source.

## Post cleaning inspection and function testing

### Section Two: Procedure

*When the automated cleaning process is complete, the following should be carried out:*

- 15.4.4 Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted.
- 15.4.5 Check that the operating cycle is in accordance with the specification for the load used.
- 15.4.6 Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- 15.4.7 If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the dental RIMD or dental RIMD may not be compatible with automated washing.
- 15.4.8 If staining and/or residue are present, this may be due to the configuration of the load, overloaded cart or malfunction in the washing cycle.
- 15.4.9 Make a visual inspection of the load for dryness.
- 15.4.10 Where a load may not be properly cleaned, the entire load is rejected and returned for re-cleaning.
- 15.4.11 Any load or items rejected should be documented as a non conformance; this non conformance should also be documented for further investigation.

### Section Three: Documentation post automated cleaning

- 15.4.12 All documentation for automated cleaning should contain the following information:
  - a. washer-disinfector identification number.
  - b. cycle number.
  - c. type of washer-disinfector.
  - d. type of cycle used.
  - e. date and time of start of cycle.

## Post cleaning inspection and function testing

- f. critical parameters for the specific washer-disinfector cycle.
  - g. results of washer-disinfector process.
  - h. any notes or observation for the process cycle.
- 15.4.13 All records should be maintained for a period of 10 years.
- 15.4.14 Before commencing inspection the person carrying out inspection should ensure that:
- a. the dental RIMD/dental RIMD set has been recorded as being through the specific cleaning process.
  - b. if there is no record of cleaning, the dental RIMD/dental RIMD set is rejected and returned for re-cleaning. Items which have been manually cleaned should also be recorded as being cleaned through the manual cleaning process.
  - c. the signature of identified responsible person confirming that the cycle has passed.

## Section Four: Inspection and function testing

- 15.4.15 Each dental RIMD/dental RIMD set should be inspected separately.
- 15.4.16 Box joints, serrations and crevices, should be critically inspected for cleanliness.
- 15.4.17 Hinges should be checked for ease of movement.
- 15.4.18 Jaws and teeth should be checked for alignment.
- 15.4.19 Ratchets should be checked for security.
- 15.4.20 Ratchets should close easily and hold firmly.
- 15.4.21 Any damaged, incomplete or malfunctioning dental RIMD should be reported immediately.
- 15.4.22 Each dental RIMD set should be checked for completeness and defects.
- 15.4.23 Each dental RIMD should be checked within an agreed period that there is free movement of all parts and that joints do not stick.



### Post cleaning inspection and function testing

- 15.4.24 Each dental RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.
- 15.4.25 Each dental RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.

### Section Five: Monitoring and control

- 15.4.26 The user should be aware of the factors that may alter the efficacy of the method:
- a. staff training/competence.
  - b. age of the dental RIMD.
- 15.4.27 A record of service, maintenance, validation schedules should be pre determined and agreed.

## Packaging

### 16. Packaging

#### 16.1 Introduction

After cleaning and decontamination, dental RIMD have to be appropriately packaged prior to sterilisation by autoclaving. RIMD should be packed before sterilisation, because otherwise they become recontaminated with dust and microorganisms from the environment as soon as they are removed from the steriliser. Packaging allows the dental RIMD to be safely stored and transported within the clinical environment following sterilisation.

#### 16.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the packaging of dental RIMD.

#### 16.3 Contents

- Section One: General principles
- Section Two: Packaging systems
- Section Three: Packaging materials
- Section Four: Single use packaging
- Section Five: Types of packaging
- Section Six: Packaging techniques
- Section Seven: Sealing of packs and bags
- Section Eight: Labelling
- Section Nine: Monitoring and control
- Section Ten: Maintenance

## Packaging

## 16.4 Procedure

## Section One: General principles

- 16.4.1 The choice and type of wrapping material will depend on the type of sterilisation process used.
- 16.4.2 Materials used should comply with EN ISO 11607-1 and EN ISO 11607-2, 2006 and EN 868 parts 2-10, inclusive. Dental RIMD may be packaged in any of the following products: papers/non-wovens, polypropylene, containers, and plastic/paper pouches.
- 16.4.3 When selecting a packaging system each specific products capability to meet predetermined requirements and criteria should be evaluated.
- 16.4.4 The appropriate size of wrapping material should be chosen to attain adequate coverage of the item being packaged.
- 16.4.5 Hollowware, (e.g. dappen dish) RIMD or dressings should not be placed in textile (linen) packs as difficulty may be experienced in drying the combined pack materials and sterilisation may be compromised as the temperature increases in these materials at different rates.
- 16.4.6 Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.
- 16.4.7 Dental RIMD packs should be packed in a manner that prevents damage to delicate items.
- 16.4.8 Trays used for packaging RIMD should be perforated to allow for penetration of the sterilant.
- 16.4.9 Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.
- 16.4.10 Hollowware should be packaged so that all openings face the same direction.
- 16.4.11 Only raw materials commensurate with daily production should be held within the clean room.
- 16.4.12 Compatibility of the packaging material with the sterilisation process should be established.

## Packaging

- 16.4.13 If chemical indicators are used inside the pack, they should conform to European Standard EN ISO 11140-1 and should be compatible with the pack.
- 16.4.14 All RIMD should be cleaned and thoroughly dry before packaging and sterilisation.
- 16.4.15 The packaging material should be compatible with the sterilisation process (i.e. allow passage of air and steam) and should provide an effective barrier against recontamination by microorganisms (i.e. the packaging should be robust and allow handling and transportation while maintaining the sterility of the packaged RIMD).
- 16.4.16 Primary packaging consisting of sterilisation pouches or bags is generally sufficient for the dental clinic environment.
- 16.4.17 Alternatively, RIMD in kits or cassettes may be packaged prior to sterilisation as they are frequently perforated.
- 16.4.18 Packaging should also contain clearly visible chemical indicator strips that give a colour change when sterilising conditions have been achieved during autoclaving.
- 16.4.19 Finally, packaging should be appropriately labelled so that the packaged RIMD is clearly identified.

## Section Two: Packaging systems

*Packaging systems should:*

- 16.4.20 **Be appropriate to the items being sterilised, i.e.**
  - a. permit identification of contents.
  - b. permit complete and secured enclosure of items.
  - c. protect package contents from physical damage.
  - d. permit delivery of contents without contamination.
  - e. maintain sterility of package contents until opened.
- 16.4.21 **Be appropriate to the method of sterilisation, i.e.**
  - a. provide adequate seal integrity.
  - b. provide an adequate barrier to particulate matter and fluids.
  - c. be compatible with and able to withstand physical conditions of the sterilisation process.

## Packaging

- d. allow penetration and removal of sterilant.
- e. maintain integrity of the pack.
- f. permit use of material compatible (i.e. non-degradable) with the sterilisation process.

**16.4.22 Be used according to the manufacturers' instructions.**

*Be of the following:*

- a. resistant to punctures, tears and other damage which may break the barrier and cause contamination.
- b. resistant to penetration by microorganisms from the surrounding environment.
- c. free of holes.
- d. free of toxic ingredients.
- e. low-linting.
- f. tamper proof and able to seal only once.
- g. provide an adequate barrier to particulate matter and fluids.

**Section Three: Packaging materials**

*Packaging materials should:*

- 16.4.23 Be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity equilibrium of packaging material is important to maintain the integrity of the product.
- 16.4.24 Not be stored adjacent to external walls or other surfaces which may be at a lower temperature or a higher temperature than the ambient temperature of the store room.
- 16.4.25 Be stored on shelves and clear of the floor.
- 16.4.26 Be rotated to ensure it does not exceed its shelf life.

## Packaging

### Section Four: Single use packaging

- 16.4.27 The medical device regulations include a requirement that sterile dental RIMD should be designed manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile. There is thus a clearly stated preference for single-use packaging as the primary packaging for sterile dental RIMD.

### Section Five: Types of packaging

#### *Papers and non-wovens*

- 16.4.28 Both papers, which are made from cellulose fibres, and non-wovens made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilisation and most gas processes because they are permeable to air, steam and other gases.
- 16.4.29 Appropriate plain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gusseted to accommodate bulky items.
- 16.4.30 Non-wovens are generally less effective as a microbial barrier and may need to be used in, or as one of, two layers; they are however generally softer with better handling and drape characteristics.

#### *Containers*

##### *Rigid reusable containers:*

- 16.4.31 Should be easily disassembled for cleaning, drying and storage.
- 16.4.32 Should be suitable for the method of sterilisation being used.
- 16.4.33 Should be compatible to the cleaning method and cleaning agent being used.
- 16.4.34 Should be suitable to the storage configuration.
- 16.4.35 Should have locking devices which are tamperproof and non resealable.
- 16.4.36 Should be packed in a manner which allows for penetration of the sterilising agent.
- 16.4.37 Lid and contents should be removable without the risk of contamination of the contents.

## Packaging

- 16.4.38 Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.
- 16.4.39 The filter plate should be examined for integrity both before installation and after the sterilisation process.
- 16.4.40 If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system should be used in the practice setting.
- 16.4.41 The integrity of the rigid container system is essential to permit sterilisation of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination.
- 16.4.42 Loosened rivets, improperly maintained valves, worn gaskets or dents compromises to the integrity of the container system, will compromise the sterilisation process and may not permit the contents to remain sterile or be delivered aseptically.
- 16.4.43 When re-usable containers are being evaluated it is important that the sterilisation, cleaning, inspection, maintenance and storage procedures and methods are also evaluated for their ability to be consistently re-used and for their compatibility with the process being used.
- 16.4.44 Containers should be cleaned between each use; automated cleaning is the preferred method of cleaning.

### Section Six: Packaging techniques

- 16.4.45 Dental RIMD may be packaged in any combination of **flat wrapping material** (sheets, bags, pouches, or reels) or **containers** to maintain the integrity of the product. Devices wrapped with sheet material using either the **envelope** or **parcel fold** technique.
- 16.4.46 Dental RIMD should be wrapped in a manner which minimises the risk of contamination during opening and removal of contents.

### *Self-seal pouches*

- 16.4.47 When closing self seal bags follow manufacturers' instructions/recommendations for sealing.

*(Note : Ensure the bag (pouch) is folded properly so as to form a seal that is airtight.)*

## Packaging

*Figure 16.1: A sealed pouch containing a RIMD*



### *Paper and paper/plastic pouches using heat seal*

- 16.4.48 The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above or below those specified by the packaging manufacturer.
- 16.4.49 Packaging intended for heat sealing may be film coated; grid lacquered, or have an adhesive band.
- 16.4.50 Heat seal pouches should be sealed using suitable heat sealing equipment.
- 16.4.51 Heat seal pouches should be hermetically sealed.
- 16.4.52 Heat seal pouches should provide a seal of proven integrity and not allow resealing.
- 16.4.53 Before commencing wrapping procedure ensure that work area and packaging equipment are clean.
- 16.4.54 Check size of edges for easy aseptic opening by user.

### *Equipment*

- 16.4.55 Heat-seal pouches.
- 16.4.56 Heat sealer.
- 16.4.57 Indelible marking pen.
- 16.4.58 Label (where applicable).



## Packaging

*Procedure*

- 16.4.59 Select appropriate size heat seal pouch.
- 16.4.60 Place dental RIMD into pouch.
- 16.4.61 Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.
- 16.4.62 As much air as possible should be removed from the pouches before sealing. Air acts as a barrier to heat and moisture. Expansion of air during the sterilisation process may cause the bag to rupture during the sterilisation process.
- 16.4.63 Place open end of pouch in heat sealer.
- 16.4.64 Apply heat and pressure to the surface of the open end of the heat seal pouch.
- 16.4.65 Check should be made that the seal is complete, especially over the gusset folds of the pouches.
- 16.4.66 A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.
- 16.4.67 The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- 16.4.68 When double wrapping using heat seal pouches the packages should be used in such a way as to avoid folding the inner package to fit into the outer package.
- 16.4.69 Edges of inner heat seal pouches should not be folded as air may be trapped in the folds and inhibit sterilisation.
- 16.4.70 When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the dental RIMD to be viewed.
- 16.4.71 When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the sterilant into and out of the package.
- 16.4.72 If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.

## Packaging

- 16.4.73 It is important to wrap the dental RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- 16.4.74 Use adhesive dental RIMD identification label, do not write on the paper side of the pouch.
- 16.4.75 The dental RIMD identification label is placed on the outside packaging.

### *Flat wrapping material*

#### *Equipment required*

- 16.4.76 Packaging material.
- 16.4.77 Sterilisation chemical indicator tape.
- 16.4.78 Indelible marking pen.
- 16.4.79 Label (where applicable).
- 16.4.80 Tray liners.

#### *Procedure (parcel-fold wrapping method)*

- 16.4.81 Select appropriate packaging material and place on work top.
- 16.4.82 The dental RIMD set is placed on the wrap, approximately in the centre of the packaging material. .
- 16.4.83 Verify the accuracy of the dental RIMD identification label with the dental RIMD/ dental RIMD set, (i.e. corresponds to dental RIMD list, internal tray label, etc).
- 16.4.84 The long edge of the tray should be aligned parallel to the long edge of the wrap.
- 16.4.85 One of the long edges of the wrap is folded over the pack contents to the base of the tray, and the edge of the wrap is turned back on itself. The fold made by the turning back of the wrap should overlap the centre line of the contents.
- 16.4.86 The opposite side of the wrap is then folded over the pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself.
- 16.4.87 The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- 16.4.88 Where outer wraps are used, the same procedure may then be repeated for an outer wrap(s).

## Packaging

- 16.4.89 The wrap is secured in position using sterilisation indicator tape.
- 16.4.90 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- 16.4.91 Dental RIMD identification label is placed on outside wrap.

### *Procedure (envelope wrapping method)*

- 16.4.92 Select appropriate packaging material and place on work top.
- 16.4.93 The dental RIMD set is placed on the wrap diagonally and slightly off the centre line.
- 16.4.94 Verify the accuracy of the dental RIMD identification label with the dental RIMD/ dental RIMD set (i.e. corresponds to the dental RIMD list, tray internal label, etc).
- 16.4.95 The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.
- 16.4.96 This is repeated with the corners to the right and left of the first folded corner.
- 16.4.97 In each case the corner is turned back to provide a flap for opening.
- 16.4.98 Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.
- 16.4.99 The same procedure may then be repeated for an outer wrap(s).
- 16.4.100 The wrap is secured in position using sterilisation chemical indicator tape.
- 16.4.101 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- 16.4.102 The dental RIMD identification label is placed on the outside wrap.

## Packaging

### *Pouches and bags (requiring folding)*

16.4.103 Folding is the simplest method to obtain a satisfactory closure for both pouches and bags, although it may not be a convenient method for high volume production.

### *Equipment*

16.4.104 Pouches and/or bags.

16.4.105 Sterilisation chemical indicator tape.

16.4.106 Indelible marking pen.

16.4.107 Label (where applicable).

### *Procedure*

16.4.108 The corners at the open end of the pouch are folded diagonally to give mitred corners.

16.4.109 The top of the pouch is then folded over three times in succession.

16.4.110 The same procedure may then be repeated for an outer wrap(s).

16.4.111 The pouch is secured in place with sterilisation chemical indicator tape. It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.

16.4.112 When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the dental RIMD to be viewed.

16.4.113 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.

16.4.114 The dental RIMD identification label is placed on the outside wrap.

## Packaging

### Section Seven: Sealing of packs and bags

16.4.115 The purpose of sealing is to maintain pack integrity, this can be achieved by the use of heat sealers, sterilising chemical indicator tape and seal secures. The indicator tape should meet European Standard EN ISO 11140 Part 1.

*Accessories used to close or secure packages should be able to perform the following:*

16.4.116 Allow sterilisation.

16.4.117 Avoid constriction of the package.

16.4.118 Maintain package integrity.

16.4.119 The accessories should also be recommended by the manufacturer.

*The following accessories should not be used:*

16.4.120 Tape (other than sterilisation chemical indicator tape).

16.4.121 Safety pins.

16.4.122 Paper clips.

16.4.123 Staples.

### *Sterilising indicator tape*

*Sterilising indicator should be:*

16.4.124 Specific to the method of sterilisation being used and which will change colour when exposed to the relevant sterilisation agent.

16.4.125 Pressure sensitive.

16.4.126 Non toxic, adhere to clean surfaces and leave no adhesive residue on removal.

16.4.127 Compatible with the wrapping material used.

16.4.128 Heat stable.

16.4.129 Moisture-stable and permeable to the sterilising agent.

## Packaging

### Section Eight: Labelling

- 16.4.130 Packages to be sterilised should be labelled before sterilisation.
- 16.4.131 The information of the label should include the following:
- a. name of product.
  - b. sterilisation date.
- 16.4.132 Label information should be documented on sterilisation chemical indicator tape or label and not on the packaging material. Plastic/paper pouches can be labelled on the plastic portion.
- 16.4.133 Marking pen used to label the pack should be indelible, non-bleeding, and non-toxic. Sharp tipped water based or ball type pens should not be used as these may compromise the integrity of the pack.
- 16.4.134 Label fixed to the surface of the packaging should be able to withstand exposure to the sterilisation process.
- 16.4.135 Policies, procedures, protocols and guidelines for wrapping and labelling and sealing of dental RIMD to be sterilised should be developed, reviewed periodically, and readily available within the practice setting.

### Section Nine: Monitoring and control

*The following should be monitored during labelling:*

- 16.4.136 General appearance of the packaging material.
- 16.4.137 Whether packages are complete.
- 16.4.138 Whether the correct products and packaging material are used.
- 16.4.139 Whether the labelling is correct on the product.
- 16.4.140 Whether the sealing is correct.
- 16.4.141 Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.
- 16.4.142 Material should be checked for tears, flaws and holes.

## Packaging

- 16.4.143 Containers seals and filters should be checked.
- 16.4.144 Containers should be checked for dints which may interfere with maintaining sterility.

**Section Ten: Maintenance**

- 16.4.145 Reusable containers should be subject to thermometric performance tests.
- 16.4.146 Containers should be validated periodically for reuse according to manufacturers' instructions/recommendations.
- 16.4.147 Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policies, procedures, protocols and guidelines.
- 16.4.148 Heat seal efficiency, integrity and strength test should be preformed on each heat sealer daily.
- 16.4.149 Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.
- 16.4.150 Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.
- 16.4.151 Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers' instructions/recommendations.
- 16.4.152 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 16.4.153 The heat sealer should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 16.4.154 Records of all maintenance, validation and servicing should be maintained for a period of time equivalent to the life-time of the equipment (approximately 25,000 cycles) plus eleven years.
- 16.4.155 A nominated suitably qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

## Sterilisation

### 17. Sterilisation

#### 17.1 Introduction

Steam sterilisation is the most practical method for sterilising reusable medical devices in dental clinics. It is rapid, non-toxic and can effectively destroy microorganisms and thus is the method of choice for sterilising dental RIMD.

#### 17.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the sterilisation of dental RIMD.

#### 17.3 Contents

- Section One: Types of sterilisers
- Section Two: Choice of sterilisation process
- Section Three: Steam sterilisation
- Section Four: Loading the steriliser
- Section Five: Steam sterilisation of dental RIMD
- Section Six: Criteria for release of processed dental RIMD
- Section Seven: Sterilisation records
- Section Eight: Validation
- Section Nine: Monitoring and control
- Section Ten: Maintenance
- Section Eleven: Chemical and biological indicators



## Sterilisation

### 17.4 Procedure

#### Section One: Types of sterilisers

- 17.4.1 Sterilisers can be divided into those based on exposure to elevated temperature (thermal processes) and those based on exposure to microbicidal chemical agents. (Low temperature processes.)
- 17.4.2 Thermal processes include dry heat (not covered in this document) and high temperature steam sterilisation. The steam sterilisers intended to be used for sterilisation of wrapped dental RIMD are referred to as porous load sterilisers.
- 17.4.3 Sterilisers that have a pre-vacuum stage are the most appropriate for sterilisation for heat-tolerant dental RIMD and other items and should conform to current European Union Standards (e.g. EN285, and EN13060 (for bench top sterilisers)).
- 17.4.4 The manufacturer's instructions for correct use of equipment should always be followed and the equipment should be used by trained and competent personnel.
- 17.4.5 Many dental practices use sterilisers without a pre-sterilisation vacuum phase in which air is removed from the steriliser chamber by steam displacement (i.e. downward displacement sterilisers).
- 17.4.6 Downward displacement sterilisers are not appropriate for sterilising wrapped loads of RIMD or for items that contain a lumen (e.g. dental handpieces), and **should not be used for these purposes under any circumstances**.
- 17.4.7 All dental RIMD, items and equipment for use on patients/service users should be packaged or wrapped and labelled prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- 17.4.8 Flash sterilisers rely on natural air displacement and should not be used for wrapped goods, hollow devices or tubing.
- 17.4.9 Boiling water sterilisers, hot air ovens, ultra violet light treatment, hot bead sterilisers and chemiclaves are not appropriate for sterilising dental RIMD and should not be used.

## Sterilisation

### Section Two: Choice of sterilisation process

- 17.4.10 Steam sterilisation is the most practical method for sterilising RIMD in dental clinics. It is rapid; non-toxic can effectively destroy microorganisms and thus is the method of choice for sterilising dental RIMD.
- 17.4.11 Steam sterilisation requires direct contact between saturated steam and all surfaces of the load at one of the pressure, time, and temperature relationships shown in table 17-1. The highest temperature compatible with the RIMD/equipment to be sterilised (as recommended by the manufacturer) should be used.

### Section Three: Steam sterilisation

- 17.4.12 Effective steam sterilisation requires the removal of air from all parts of the chamber and load so that steam can reach all of the surfaces to be sterilised.
- 17.4.13 For hollow devices, tubing, fabrics and wrapped goods, natural displacement of air by steam cannot be relied upon to remove the air effectively and a forced air removal system is required.
- 17.4.14 Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.
- 17.4.15 These sterilisers have a vacuum pump to remove air from the steriliser chamber and load. When loading the steriliser, RIMD and other items to be sterilised should be arranged to facilitate free circulation of steam and care should be taken not to over-fill the steriliser chamber.
- 17.4.16 Sterilised RIMD packs should be allowed to dry inside the steriliser before removing and handling.
- 17.4.17 Many modern vacuum sterilisers have a post-sterilisation drying cycle that facilitates drying of RIMD packs.
- 17.4.18 The operating cycle of a porous load steriliser generally has five stages:
  - a. air removal.
  - b. steam admission.
  - c. sterilisation holding time.

## Sterilisation

- d. vacuum drying.
- e. filtered air admission.

### Section Four: Loading the steriliser

- 17.4.19 Healthcare Workers (HCWs) should never let the dental RIMD touch the chamber walls since it may cause the dental RIMD to become wet.
- 17.4.20 Doors should be open only when loading and unloading. An open door will cause the chamber to cool down and may cause condensation during the subsequent process.
- 17.4.21 Manufacturers' instructions/recommendations and protocols agreed during validation should be followed for loading.
- 17.4.22 Overloading of sterilisers may compromise the process.

### Section Five: Steam sterilisation of dental RIMD

- 17.4.23 HCWs should wear personal protective equipment.
- 17.4.24 HCWs should ensure that all necessary tests and maintenance have been carried out satisfactorily before using the steriliser.
- 17.4.25 HCWs should ensure that the cycle recorder(s) has sufficient paper and ink to record the cycle.
- 17.4.26 HCWs should ensure that the correct operating cycle has been selected.  
  
(Note: test cycles such as a Bowie and Dick test and leak rate test cannot be used for sterilising product.)
- 17.4.27 Healthcare Workers (HCWs) should initiate the cycle in accordance with the steriliser manufacturers' instructions/recommendations.
- 17.4.28 When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.
- 17.4.29 The fail cycle will require a special key to open the steriliser door.
- 17.4.30 On a pass cycle, the load should be removed and held in the cooling area until the sterile produce release procedure has been completed.

## Sterilisation

### Section Six: Criteria for release of processed dental RIMD

- 17.4.31 In order to release processed dental RIMD evidence is required that the sterilisation cycle was satisfactory, i.e. within the limits established during validation, and that the load items are undamaged and fit for use. There is a documented procedure specifying the actions to be taken and the criteria to be met in accepting the sterilisation cycle and releasing product as sterile. The sterilisation release procedure is only carried out by staff who have been trained to undertake this task.

#### *Sterilisation cycle verification*

- 17.4.32 The cycle records should be examined to confirm that the cycle variables were within the limits established as satisfactory during validation.

*This should include:*

- a. the number and extent of air removal pulses.
  - b. the temperature and duration of the sterilisation plateau period.
  - c. the depth and duration of the drying vacuum.
  - d. the data should be read from the automatic controller record or from an independent recorder if available.
- 17.4.33 Any cycle not meeting the criteria, although indicated as a pass by the automatic controller, should be rejected. The load should be repacked and sterilised and the steriliser removed from service until the cause of the fault has been established and remedied.
- 17.4.34 A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

## Sterilisation

### *Inspection of sterilised load*

- 17.4.35 Each item sterilised should be inspected to ensure that:
- chemical process indicators have changed colour as described in the indicator manufacturers' instructions/recommendations. (Chemical process indicators, e.g. autoclave tape, do not indicate sterilisation; they are evidence only that the load has been exposed to the sterilising process.)
  - the packaging is in place and undamaged (i.e. seals, taped joints have not come undone, packs are not torn).
  - the packaging is dry and free from visible dampness.
  - all labels are intact and legible (if placed on packaging before sterilisation).
- 17.4.36 Any load dental RIMD not meeting these criteria should be rejected and quarantined, non conformance must be recorded and the dental RIMD returned to the clean room for repacking and sterilisation.

### Section Seven: Sterilisation records

- 17.4.37 Sterilisation cycle records should contain the following information for each sterilisation cycle:
- steriliser identification.
  - the cycle number and (batch number if applicable).
  - type of cycle used.
  - date and time of start of cycle.
  - print-out from steriliser cycle.
  - any notes or observation for the process cycle.
  - read out results of physical, chemical or biological indicators that are used.
  - all records should be retained for 10 years.
- 17.4.38 Many modern sterilisers are supplied with integral recording equipment that print out sterilisation cycle details or electronically stored cycle data—e.g. cycle time, temperature and pressure.

## Sterilisation

### Section Eight: Validation:

- 17.4.39 Sterilisation cannot be confirmed by inspection and testing of the product. In order to ensure that a steriliser is functioning properly and will consistently produce sterile loads, validation, maintenance, periodic testing and record keeping are necessary.
- 17.4.40 Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications.

*It is comprised of:*

- a. commissioning (installation qualification and operational qualification).
- b. performance qualification.
- c. periodic testing.
- d. revalidation.

*Confirmation that the steriliser continues to function correctly is provided by periodic testing and revalidation.*

### *Commissioning*

- 17.4.41 Commissioning is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications by the manufacturer, that it is safe to operate and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions.
- 17.4.42 **Installation qualification** is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier* and that it is safe to operate.

### *Installation checks and tests*

- a. preliminary checks.
- b. electrical checks.
- c. functional checks.
- d. response to faults.

## Sterilisation

### *Operational qualification*

17.4.43 The process of obtaining and documenting evidence that the equipment functions within predetermined limits when operated in accordance with the manufacturer's operating instructions/recommendations.

*It consists of:*

- a. air leakage test.
- b. thermometric test.
- c. calibration.
- d. steam penetration test.

17.4.44 These tests should be carried out when a new steriliser is purchased, when a used steriliser has been relocated to other premises or following repairs that may affect the key performance indicators of the washing process.

17.4.45 The tests should be carried out before the steriliser is used for the first time.

17.4.46 Installation and operational checks and tests should be performed by a person with specialist technical training in testing of sterilisers.

17.4.47 Data from the installation and operational tests provide evidence that the steriliser is functioning correctly.

## Sterilisation

### *Performance qualification*

- 17.4.48 Performance qualification is required to show that sterilising conditions are attained for typical loads and also test loads that are difficult to sterilise. Performance qualification is indicated for initial use of a new steriliser or when the load profile changes (e.g. new types of RIMD or packaging). It should be carried out by a test person or suitably qualified person (decontamination).

*These tests consist of:*

- a. air leakage tests (automatic).
  - b. thermometric tests of all dental RIMD to be processed.
  - c. steam penetration test (e.g. Bowie and Dick).
  - d. load dryness test (only required for sterilisers with drying cycles).
- 17.4.49 The performance qualification test protocol and data should be audited by the qualified person (decontamination).

### *Periodic testing*

- 17.4.50 Periodic testing consists of a programme of tests that are intended to show that the steriliser's performance is continually satisfactory. The appropriate tests should be carried out at daily, weekly and annual intervals. It is the responsibility of the practice manager to ensure that these tests are performed.
- 17.4.51 After appropriate training the user should perform the daily tests. Many modern sterilisers have an integrated automated test facility that enables the steriliser to perform some of the specialised weekly tests itself. These can be undertaken by the user after appropriate training. Older sterilisers may require the services of a test person or suitably qualified person (decontamination) to undertake weekly tests. Annual tests should be performed by a test person or suitably qualified person (decontamination). Each cycle available to the user should be tested. If the steriliser is not tested periodically it will not be possible to know if it is working correctly. Failure of a test implies that the steriliser is not working to specification.
- 17.4.52 The user should have a written procedure for handling test failures but, in all cases, the steriliser must be withdrawn from service, the failure investigated, the cause rectified, and the steriliser re-tested successfully before being used. The user has the ultimate responsibility for certifying that the steriliser is fit for use.



## Sterilisation

### *Daily Test—Bowie and Dick/Helix*

- 17.4.53 These tests are intended to show that steam will penetrate rapidly and evenly into a test device as outlined in the manufacturers' instructions. The test device contains an indicator that sits inside a process challenge device, (PCD) that responds (usually it changes colour – and should do so completely) only when steam penetration is adequate. If a cycle is provided specifically to test the effectiveness of steam penetration, it should have the same air removal stage as used during routine sterilisation cycles. A Bowie and Dick test pack is an example of a process challenge device as is a Helix.

### *Test procedure*

- 17.4.54 A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.
- 17.4.55 At the end of the process the test device is removed from the chamber.
- 17.4.56 The test device is checked for a pass or fail in accordance with the manufacturers' instructions/recommendations. The test results should be recorded.
- 17.4.57 If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results.
- 17.4.58 The sterilisation temperature for the operating cycle to be tested should be selected this should be the highest temperature compatible with the load. The cycle should be commenced.
- 17.4.59 A batch (cycle) process record should be made in the steriliser log book.

## Sterilisation

### Weekly tests

- 17.4.60 The user should perform safety checks before starting the sequence of weekly tests.  
The schedule of weekly tests is summarised in Table 17-2 below

**Table 17-1: Sterilisation temperature, steam pressure and hold time**

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilisation Hold time
134 <sup>0</sup> c	2.30 bar gauge	137 <sup>0</sup> c	3 minutes

**Table 17-2: Summary of Weekly Tests for Steam Sterilisers**

Weekly Checks/Tests	D.D.A.(N) Autoclave	V.A.(S) Autoclave
1. Air leakage test	N.A.	134 <sup>0</sup> c
2. Automatic air detection system function test (if fitted)	N.A.	Yes
3. Automatic Control test	N.A.	Yes
4. Steam penetration test	Yes	Yes

*(Note: All tests can be combined into one test.)*

- 17.4.61 Plus any other tests recommended by the steriliser manufacturer for proving that the air detection system functions correctly.

*(Note: Validation of decontamination reprocessing equipment must be independently measured using data loggers equipment that has been calibrated and measured to source documents.)*

- 17.4.62 Safety checks
- 17.4.63 Vacuum leak test (automatic)
- 17.4.64 Automatic control test
- 17.4.65 Bowie-Dick / Helix Test for steam penetration (134<sup>0</sup>c cycles)

## Sterilisation

### *Safety checks*

17.4.66 These tests are intended to ensure the steriliser is both safe to use and to test.

*They consist of:*

- a. examining the door seal for signs of deterioration or leaks.
- b. checking the security and performance of door safety devices.

No attempt should be made to open the door while the chamber is pressurised.

Any defects should be corrected before attempting to perform the weekly tests or before using the steriliser.

### *Vacuum leak test*

17.4.67 The air leakage test is intended to check that air does not leak into the steriliser during periods of vacuum, at a rate that is greater than that specified by the steriliser manufacturer.

17.4.68 Air leaking into the chamber can impair steam penetration into the load and prevent sterilisation and/or recontaminate the damp load during the drying phase.

17.4.69 Air is first removed from the chamber until the pressure is the lowest achieved in all of the cycles available on the steriliser and then the vacuum source is isolated and all valves connected to the chamber are closed.

17.4.70 The absolute pressure is measured at the end of the vacuum stage. Any subsequent rise in the chamber pressure will be caused by air leaking into it - and the rate of pressure rise in the chamber is measured.

17.4.71 Ideally the steriliser should be equipped with an automated test cycle so that the user can do the test. If there is not an automatic test facility, a test person or suitably qualified person (decontamination) should do the test using special, calibrated RIMD.

*The pass/fail criteria are:*

17.4.72 The absolute pressure at the end of the air removal stage should be within the limits specified by the manufacturer. After an initial 5 minute equilibration period the rate of pressure rise should not be greater than 1.3 mbar per minute over a 10 minute period.

17.4.73 A machine that fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.

## Sterilisation

### *Automatic control test*

- 17.4.74 The purpose of this test is to verify that all the operational components of the steam steriliser are satisfactory and that no anomalies are observed.
- 17.4.75 The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the steriliser was validated to be working correctly, e.g. immediately after the test person had tested it using calibrated RIMD.
- 17.4.76 The test should be performed using the sterilising cycle with the highest temperature compatible with the load. The following parameters should be noted during the sterilising (holding) stage of the cycle:
- a. chamber temperatures and pressures, their maximum values and duration in minutes and seconds.
  - b. the values on the cycle record should be compared with those on the master process record.
  - c. the test can be considered satisfactory if at the end of the cycle if:
    - i. the chamber temperature and pressure is within the limits of the appropriate band, for the duration of the holding time, as specified in table 17-1.
    - ii. a visual display of 'cycle complete' is indicated.
    - iii. no mechanical or other anomaly is observed.
- 17.4.77 For vacuum sterilisers the test can be done at the same time as the steam penetration test but the steam penetration test must be performed with the chamber empty except for the test device. The test is not required if the steriliser is equipped with a recorder that provides a permanent record of the temperature, pressure and elapsed time during all sterilising cycles. Verification should be sought from the manufacturer as to whether it is necessary to pre-heat the steriliser chamber before performing these tests, as this can extend the test time.

## Sterilisation

### *Test procedure for automatic control test of a steriliser without a cycle recorder*

- 17.4.78 The elapsed time, and indicated chamber temperatures and pressures at all significant points of the operating cycle, e.g. the beginning and end of each stage or sub-stage, and the maximum values during the holding time should be observed and recorded.
- 17.4.79 The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be recorded.
- 17.4.80 All parameters recorded should be compared with the parameter results obtained during commissioning qualification.

### *Test procedure for automatic control test of a steriliser with a cycle recorder*

- 17.4.81 The recorder should make a batch process printout. The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be noted.
- 17.4.82 All the parameters recorded should be compared with the parameter results obtained during validation.
- 17.4.83 These require specialised test equipment and only a test person or suitably qualified person (decontamination) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate.

### *Annual tests*

- 17.4.84 These require specialised test equipment and only a a test person or suitably qualified person (decontamination) who has the necessary training, experience, skills and equipment should perform them. Annual tests for porous load sterilisers are summarised in table 17-3.

## Sterilisation

### *Sterilisation*

Table 17.3: Summary of annual tests for vacuum and non vacuum sterilisers

Annual Tests	D.D.A. (N) Autoclave	V.A. (B or S) Autoclave
1. Air leakage test (automatic)	N.A	Yes
2. Air leakage test (manual) (temperature and pressure sensors	N.A	Yes
3. Automatic control test	Yes	Yes
4. Verification of calibration of steriliser instruments	Yes	Yes
5. Thermometric test for a full load	Yes	Yes
6. Porous load dryness test	N.A	Yes
7. Test for performance re-qualification as required by the user	Yes	Yes
8. Air leakage test (automatic) (sensors removed)	N.A	Yes
9. Steam penetration test	N.A	Yes

- 17.4.85 Plus any other tests recommended by the steriliser manufacturer for proving that the air detection system functions correctly.

*(Note: Validation of decontamination reprocessing equipment must be independently measured using data loggers equipment that has been calibrated and measured to source documents.)*

### Section Nine: Monitoring and control

- 17.4.86 134°C is the preferred sterilisation temperature.
- 17.4.87 Routine monitoring and testing should be carried out in accordance with documented procedures in line with EN 13060.

## Sterilisation

## Section Ten: Maintenance

- 17.4.88 Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' instructions.
- 17.4.89 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 17.4.90 The steriliser should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 17.4.91 Records of all tests, checks and maintenance should be retained as specified in EN 13060.
- 17.4.92 A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- 17.4.93 A record of mechanical testing, repairs and preventative maintenance should be recorded in a logbook for each steriliser. Records should be maintained in a designated storage area for the lifetime of the steriliser plus eleven years.
- 17.4.94 Revalidation may be required after steriliser relocation, engineering work, repair work, software control function modifications and when required by the user.

*Some examples of requirement for revalidation are:*

- a. adjustment to steam controls.
- b. adjustment to microprocessor controls.
- c. adjustment to control parts.

## Section Eleven: Chemical and biological indicators

*Chemical indicators (Process challenge devices—PCD)*

- 17.4.95 Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- 17.4.96 Chemical indicators should meet the requirements of relevant Standards (e.g. EN ISO 11140).
- 17.4.97 The type used should be in accordance with the steriliser manufacturers' recommendations.

## Sterilisation

- 17.4.98 The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- 17.4.99 The use of an inappropriate indicator may give dangerously misleading results; indicator performance can be adversely affected by the storage conditions and methods of use.
- 17.4.100 Indicators should not be used beyond their expiry date.
- 17.4.101 Spore tests provide the only absolute evidence of the sterilisation capability of a steriliser cycle.
- 17.4.102 One disadvantage of spore tests is that test results usually take 24 to 48 hours. If spore testing is used as the principal parameter for assessing the sterility of a sterilised load of dental RIMD, the sterilised RIMD packs should be withheld from use until the results of the spore test are available.

*Two types of chemical indicator are commonly used:*

- 17.4.103 **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
- 17.4.104 **Integrating indicators and/or emulating indicators:** These indicators are intended to monitor the attainment of two or more critical variables in the sterilisation process, either by a graduated response or a defined end point reaction. These types of indicators are not currently available for hydrogen peroxide processes.



## 18. Storage

### 18.1 Introduction

All decontaminated RIMD must be stored in such a way that their integrity and microbial state is maintained (e.g. sterile, high-level disinfected). Dental RIMD packs should be stored in a clean, dry environment and protected from sharp objects that may damage the packaging.

### 18.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the storage of dental RIMD.

### 18.3 Contents

- Section One: Storage areas
- Section Two: Storage equipment in storage area
- Section Three: Shelf life/rotation of stock
- Section Four: Non-conforming stock

### 18.4 Procedure

#### Section One: Storage areas

- 18.4.1 The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stocks. The design should be conducive to good inventory management. All materials and processed goods should be stored in designated purpose built storage areas enabling different classifications of stored goods to be segregated and maintained in appropriate environmental conditions.

*There are two types of storage area:*

- a. the processed goods storage area.
- b. the raw materials storage area.

## Storage

### *Processed goods storage area*

- 18.4.2 The processed goods storage area is for dental RIMD produced by the department and dental RIMD which have been commercially manufactured and sterilised.
- 18.4.3 The outer packaging (shipper carton) should be removed from RIMD which have been commercially manufactured and sterilised – if stored in the same store as those dental RIMD which have been produced by the department.
- 18.4.4 Sterile and non-sterile goods should be stored separately. Storage areas should be kept secure and access should be restricted to authorised personnel.
- 18.4.5 Sterile materials should be stored at least 20 to 80 centimetres from the floor, at least 45 centimetres from the ceiling, and at least 5 centimetres from outside walls.
- 18.4.6 The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.
- 18.4.7 Medical and surgical process goods should not to be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.
- 18.4.8 Processed goods should be stored on appropriate designated shelving.

### Section Two: Storage equipment in storage area

#### *General principles*

- 18.4.9 Sterile items should not be stored anywhere but on, or in, designated shelving, counters, or containers, because other areas may not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside.
- 18.4.10 Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that may form on the interior surfaces of outside walls.
- 18.4.11 Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it micro organisms from the air and surfaces.

**Storage**

- 18.4.12 Dental RIMD made of polymeric materials (especially latex) should not be stored adjacent to electric switch gear, laser printers, photocopiers or other sources of ozone. (Ozone can cause rapid degradation of these materials.)

***Shelving and drawers***

- 18.4.13 Shelves and drawers should afford sufficient space to store the required stock to protect the sterile status of packs in line with local supply policy and production demands.
- 18.4.14 Shelving and drawers should be purpose built, easily cleaned and maintained.
- 18.4.15 There should be enough space between shelves and racking to allow an adequate passageway between fixtures.
- 18.4.16 Shelving or drawers should enable items to be clearly labelled.

**Figure 18-1: Storage of sterile items**



## Storage

### *Closed or covered cabinets*

- 18.4.17 Closed or covered cabinets are recommended for the storage of seldom-used sterile supplies.
- 18.4.18 Closed cabinets limit dust accumulation, discourage handling, and minimise inadvertent contact with sterile items.

### Section Three: Shelf life/rotation of stock

- 18.4.19 General factors which influence shelf life are event related and include the following:
- a. packaging materials.
  - b. storage and handling conditions.
  - c. likelihood of product material deterioration.
  - d. package design.
- 18.4.20 Each designated dental decontamination unit should develop a system of stock rotation based on the date of sterilisation. Good management practices demand that stock be maintained at adequate levels.
- 18.4.21 Best practice dictates that product which has remained unused for more than six months should be deemed to be a product of over-stocking and an assessment undertaken as to its future need.
- 18.4.22 There are occasions where devices must form part of emergency stocks and as a result may not be used within this time frame. Procedures should be put in place to ensure that these products are subject to a reprocessing regime over time.

### Section Four: Non-conforming stock

- 18.4.23 A package should be considered non-conforming, i.e. non-sterile and not suitable for use when:
- a. it is incorrectly wrapped.
  - b. it is damaged, opened or has been dropped. The sterilisation process indicator does not confirm that the pack has been subject to an appropriate sterilisation process.

**Transportation – of sterile items****19. Transportation – of sterile items****19.1 Introduction**

Sterile dental RIMD should be transported in a manner that will not compromise their status. Loss of sterility is event related and depends on the extent and nature of handling, environmental conditions during transportation and storage, and the quality of the packaging material.

**19.2 Scope**

The objective of this recommended practice is to provide guidelines in relation to the transportation of sterile dental RIMD.

**19.3 Contents**

Section One: General principles

Section Two: External transportation

**19.4 Procedure****Section One: General principles**

- 19.4.1 Sterile dental RIMD should be transported in clean dry conditions in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage to devices and flexible packaging.
- 19.4.2 Sterile dental RIMD should be cooled before they can be transported.
- 19.4.3 Sterile dental RIMD should be transported in closed solid walled containers, or in covered or enclosed carts with solid-bottom shelves to protect them from exposure to environmental contaminants along the transportation route.

## Transportation – of sterile items

### Section Two: External transportation

- 19.4.4 Where sterile dental RIMD are transported in vehicles, the vehicles should be dedicated to the purpose, should provide appropriate segregation for the transport of sterile and used dental RIMD and the loading area should be constructed so that it is easily cleanable.
- 19.4.5 Where small quantities of sterile dental RIMD are to be transferred (e.g. school/ domiciliary visits) or where it is only occasionally required, they may be transported in a socially clean general purpose vehicle provided they are contained within a closed solid walled container.

## Water supply for washer-disinfectors and sterilisers

## 20. Water supply for washer-disinfectors and sterilisers

### 20.1 Introduction

The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process. Prior to initial installation of a **small porous steam steriliser** a survey should be carried out on the supply mains water to establish the quality of the water intended for clean steam. The quality of the water required for steam supply will be determined by the Ph, conductivity, hardness, microbial content will of the water surveyed.

### 20.2 Scope

The objective of this recommended practice is to provide guidelines in relation to provision of water of optimum quality for each stage of the cleaning process.

### 20.3 Contents

Section One: General requirements

Section Two: Water quality for washer-disinfectors

Section Three: Water treatment, water treatment options

### 20.4 Procedure

#### Section One: General requirements

20.4.1 At each stage in the cleaning process the water quality should be compatible with:

- a. the components of the steriliser.
- b. the dental RIMD to be processed.
- c. the process chemical to be used.
- d. the process requirements of that particular stage.

## Water supply for washer-disinfectors and sterilisers

- 20.4.2 The key quality elements to be considered are:
- hardness.
  - temperature.
  - ionic contaminants (e.g. heavy metals, halides, phosphates, and silicates).
  - microbial population.
- 20.4.3 The water supply for the decontamination equipment should be controlled to meet with the manufacturers' instructions and the European Standard EN 13060.
- 20.4.4 If the water supply for the steriliser is coming from a tank, the water must be audited (the steriliser should be supplied with a one shot water supply, no recycling) to ensure that it meets the European Standard EN 13060.

### Section Two: Water quality for washer-disinfectors

- 20.4.5 The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process. Prior to initial installation of a **small washer-disinfector** a survey should be carried out on the supply mains water to establish the quality of the water intended for clean water supply. The quality of the water required for water supply will be determined by the Ph, conductivity, hardness, microbial content will of the water surveyed.

#### *Other reasons effecting steam and rinse water efficacy*

##### *Hardness*

- 20.4.6 Water hardness is caused by the presence of dissolved salts of the alkaline earths (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (lime-scale) when water is heated or evaporated.
- 20.4.7 The deposition of lime-scale on electrical heating elements or heat exchange components or within pipes will seriously impair the performance of a steriliser.
- 20.4.8 Using hard water in the steriliser is one of the major causes of white powdery deposits on load items. These are unsightly and act as a focus for soiling and recontamination of the item in use. In some applications (e.g. with optical systems) such deposits may seriously impair the utility of the item.



## Water supply for washer-disinfectors and sterilisers

### *Temperature*

- 20.4.9 The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.
- 20.4.10 Water at too high a temperature may lead to the coagulation of proteins and thus serve to 'fix' proteinaceous soil to the surface of the load items.
- 20.4.11 When enzymatic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.
- 20.4.12 The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

### *Ionic contaminants*

- 20.4.13 Ionic contaminants in the water may react with materials such as stainless steel.
- 20.4.14 Water used for stainless steel RIMD should have a chloride concentration less than 120 mg/l Cl<sup>-</sup> to minimise the risk of corrosion.
- 20.4.15 Tarnishing of stainless steel RIMD, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discoloration.
- 20.4.16 Total dissolved solids should be checked with conductivity meter according to the manufacturers' instructions and at periods agreed during commissioning.

### *Microbial population*

- 20.4.17 The microbial population in the water used in the washer-disinfector (WD), particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.
- 20.4.18 Suitable potable water with < 100 cfu/100ml\* (\* aerobic heterotrophic bacteria).

## Water supply for washer-disinfectors and sterilisers

### *Bacterial endotoxins*

- 20.4.19 Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse effects. They are not readily inactivated at the temperatures used for disinfection or sterilisation.

### Section Three: Water treatment, water treatment options

- 20.4.20 There are three methods of water treatment generally used on water supplies for sterilisers.

(Note: Distilled water is not suitable.)

- a. “base-exchange” softeners.
- b. de-ionisers.
- c. reverse osmosis.

### *“Base-exchange” softeners*

- 20.4.21 Base-exchange softeners, consist of an ion exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride).
- 20.4.22 After regeneration high levels of chloride ions may be present in the initial output from the softener which should be configured to automatically run an initial volume to waste.

### *Deionisers*

- 20.4.23 De-ionisation (demineralisation) systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in separate columns.
- 20.4.24 Regeneration requires the use of strong acid (hydrochloric acid) and strong alkaline (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers.

## Water supply for washer-disinfectors and sterilisers

- 20.4.25 De-ionised (DI) water may be heavily contaminated with microorganisms and DI water stored at ambient temperatures will be colonised rapidly. (The chloride ions normally present in drinking water to control microbial growth have been removed).
- 20.4.26 DI water should not be used for the final rinse of products intended for invasive use without further decontamination processing.

### *Reverse osmosis*

- 20.4.27 Reverse osmosis (RO) treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and microorganisms, as well as ionic species.
- 20.4.28 When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.

#### *Appropriate measures include:*

- a. continuous recirculation system water.
  - b. filtration, e.g. through a 0.22 µm filter to remove microbial contaminants.
  - c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J. m<sup>-2</sup>)).
- 20.4.29 The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Good quality stainless steel pipes are preferred for all qualities of purified water.
- 20.4.30 All pipe work should be run with a continuous fall to the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.

## Single use invasive medical devices

### 21. Single use invasive medical devices

#### 21.1 Introduction

A single use invasive medical device (SIMD) is defined as a device intended by the manufacturer to be used on one patient/service user during one procedure. The device is **not intended for reprocessing** and/or use on another patient/service user or on the same patient/service user at another time.

#### 21.2 Scope

The objective of this recommended practice is to provide guidelines in relation to SIMD.

#### 21.3 Contents

Section One: General principles

#### 21.4 Procedure

##### Section One: General principles

- 21.4.1 If an item is marked single-use, it should only be used on a single occasion and then it should be discarded into healthcare risk waste or a sharps box, as appropriate.
- 21.4.2 A single-use item or device should not be used on multiple occasions either on an individual patient/service user or on a different patient/service user. Examples of single-use items include plastic syringes used for irrigation, suction tips, endodontic files, matrix bands and polishing cups.
- 21.4.3 Before using a pre-packed sterile single-use or single-patient/service user-use item, check that the packaging is intact and the product is within its use-by date.
- 21.4.4 These devices should be stored in clean, designated areas where there is no risk of moisture, droplet and aerosol contamination.

## Single use invasive medical devices

- 21.4.5 To avoid cross-contamination between patients/service users, SIMD should be used wherever this is practical.
- 21.4.6 Single-use items should be used for a single patient/service user and not reused on subsequent patients/service users. Patient/service user care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- 21.4.7 RIMD intended for single-use and labelled 'single-use' by the manufacturer should be immediately disposed of after use.
- 21.4.8 Users who disregard this information and prepare single use products for further use, are transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them and have become the manufacturer of the device.
- 21.4.9 The symbol for single use RIMD is as given in ISO EN 980:2003.
- 21.4.10 Synonyms for 'do not reuse' are 'single use', 'use only once'.
- 21.4.11 See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).
- 21.4.12 Organisations should have well established criteria for their choice of SIMD or dental RIMD where both are available.

**Figure 22-1: Do not reprocess symbol**



## Action on non-conforming product

## 22. Action on non-conforming product

### 22.1 Introduction

To ensure patient/service user safety and compliance with the *Safety, Health and Welfare at Work Act, 2005 and S.I. 252 of 1994*, the service provider must establish procedures to expedite the retrieval of reprocessed items that are suspected to be non-sterile, contaminated or otherwise defective and to ensure appropriate follow-up actions. Follow-up actions may include quarantine of the dental RIMD, notification of clinicians and surveillance of patients/service users as well as remedial action to prevent any recurrence .

### 22.2 Scope

The objective of this recommended practice is to provide guidelines in relation to action on nonconforming product

### 22.3 Contents

Section One: Policies and procedures

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

### 22.4 Procedure

#### Section One: Policies and procedures

22.4.1 Service providers should ensure that written policies and procedures for the recall of non-conforming product are developed, available and implemented in the healthcare facility.

22.4.2 Where any occurrence gives cause for concern that the required assurance of sterility, functionality and freedom from contamination has not been met, the senior manager (or designated person) should be notified immediately so that follow-up surveillance of patients/service users can be conducted.

**Action on non-conforming product****Section Two: Recall procedure**

22.4.3 A recall procedure should:

- a. be written.
- b. outline the circumstances for issuing a recall order.
- c. designate the person(s) authorised to issue a recall order.
- d. designate the person(s) responsible for reporting on the execution of a recall order.

**Section Three: Recall order**

22.4.4 A recall order should:

- a. be written.
- b. identify by sterilisation lot number the products to be recalled.
- c. identify the persons or departments to whom the order is addressed.
- d. require the recording in terms of kind and quantity of the products obtained in the recall.
- e. specify the action to be taken by the person or persons receiving the order (e.g. destruction or return of product).

**Section Four: Recall report**

22.4.5 A report of a recall order should:

- a. identify the circumstances that prompted the recall or order.
- b. specify the corrective action(s) taken to prevent a recurrence.
- c. state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall.

*(Note: Non conforming products may include RIMD, RIMD reprocessor or other equipment used in the decontamination unit.)*

## Records Management

### 23. Records Management

#### 23.1 Introduction

Records of maintenance, testing and operating cycles provide evidence that the process delivered sterile products consistently.

#### 23.2 Scope

The objective of this recommended practice is to provide recommended practices in relation to records management in dental facilities.

#### 23.3 Contents

Section One: Steriliser logbook

Section Two: Master process record

Section Three: Traceability

#### 23.4 Procedure

##### Section One: Steriliser logbook

- 23.4.1 A permanent record should be kept for each steriliser to provide evidence that it was/is functioning correctly and achieving sterilising conditions consistently.
- 23.4.2 This permanent record can take any convenient form e.g. a book, a loose-leaf folder, or an electronic device (provided that it will give a printout on demand).
- 23.4.3 The record should be kept close to the steriliser so that it can easily be updated. It should provide a complete history of the steriliser and should include records of:
  - a. commissioning and validation tests and checks. A master process record (see below) should be provided by the company that installed the steriliser.
  - b. routine monitoring of every sterilisation cycle – load type, cycle selected and whether or not the cycle was satisfactory.



## Records Management

- c. actions taken to correct any cycle failure and details of what happened to the unsatisfactory load.
- d. results of all tests should be audited and records kept.
- e. maintenance, repair, or any modifications.
- f. operator training should include name of trainee, name of trainer, date of competency achieved in parameters as detailed in the staff training section.

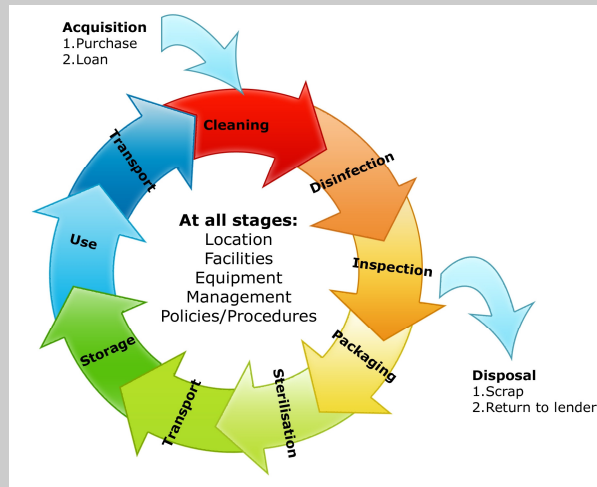
### Section Two: Master process record

- 23.4.4 The master process record contains the information gathered during commissioning by the manufacturer. It includes details of the values and permitted tolerances of the cycle variables for each correctly functioning operating cycle, and for each load type that is to be processed.
- 23.4.5 This is the record against which:
- a. production cycle records can be compared to verify that sterilising conditions have been achieved for each load.
  - b. results of weekly tests should be compared to establish whether the steriliser is functioning correctly and achieving sterilising conditions.
  - c. results of periodic tests and performance re-qualification tests can be compared.

### Section Three: Traceability

- 23.4.6 A record of every load should be kept which should include the load number (unique identifier cycle number), date, time, and type of load, test result and identity of the operator.
- 24.3.7 An adhesive load label bearing the load number and date should be created and manually placed on each RIMD pouch after sterilisation, and a duplicate should be placed in the patient's/service user's clinical chart when the RIMD is used.
- (Note: Where external guidance is sought to review documentation, this should be conducted by a suitably qualified person (decontamination).)*





# Standards and Recommended Practices for Local Dental Services (LDU)

## Part 4

### Additional Resources and Appendices

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## Resources

### 1. Resources

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## Resources

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## Abbreviations

## 2. Abbreviations

CE	Conformité Européenne
CDU	Central Decontamination Unit
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
EEC	European Economic Community
EN	European Norm
EU	European Union
HAS (H&S)	Health and Safety
HBN	Health Building Note
HCAI	Healthcare Associated Infection
HCW	Health Care Worker
HIQA	Health Information Quality Authority
HSE	Health Service Executive
IMB	Irish Medicines Board
ISO	International Standards Organisation
LDU	Local Decontamination Unit
MSDS	Material Safety Data Sheets
NSAI	National Standards Authority of Ireland
PPE	Personal Protective Equipment
PPPG	Policy, procedure, protocol and guideline
RIMD	Reusable Invasive Medical Devices
TSE	Transmissible Spongiform Encephalopathies
WD	Washer-disinfector

## Glossary

### 3. Glossary

#### Adverse event

An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.

#### Cleaning

The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning removes microorganisms and the organic material on which they thrive. It is a necessary pre-requisite of effective disinfection or sterilisation.

#### Clinical governance

Corporate accountability for clinical performance.

#### Decontamination

The removal of microorganisms or foreign matter (or both) from contaminated materials or living tissue. Three processes for decontamination are commonly used; cleaning, disinfection and sterilisation.

#### Disinfectant

A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms; and that is not represented by the manufacturer to be suitable for internal use.

#### Disinfection

The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation.

#### Hazard

A source of potential harm or a situation with a potential to cause loss.

#### Healthcare associated infection

Infection contracted as a result of health care. Includes iatrogenic infections resulting from medical procedures and nosocomial infections resulting from the patient's presence in a health care establishment.



## Glossary

### Healthcare workers

Refers to all health care professionals, including students and trainees, and employees of health care establishments, who have contact with patients or with blood or body substances from patients.

### Incidence (of infection)

Rate at which new cases occur.

### Invasive procedure

Any procedure that pierces skin or mucous membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities or organs, or repair of traumatic injuries.

### Local Decontamination Unit

A LDU is the dedicated area in a dental clinic that is used for decontamination of dental RIMD. These areas can be in the dental surgery or in a separate accommodation. The LDU may be present in a primary care dental setting which may include orthodontic and/or oral surgery unit.

### Medical device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap;
  - investigation, replacement or modification of the anatomy or of a physiological process;
- or**
- control of conception and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

### Monitor

To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change.

### Prion

The small proteinaceous infectious unit that appears.

## Glossary

### Primary care

HSE healthcare provision outwith hospitals, for example, general medical practitioner and general dental practitioner services.

### Risk

The chance of something happening that will have an impact upon objectives. It is measured in terms of the severity of the consequence and frequency.

### Risk assessment

The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria.

### Risk management

The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects.

### Risk management process

The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk.

### Risk reduction

A selective application of appropriate techniques and management principles to reduce either likelihood or an occurrence or its consequences, or both.

### Reprocessing

All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation.

### Reusable item

An item designated or intended by the manufacturer to be suitable for reprocessing and reuse.

### Sharps

Any object capable of inflicting penetrating injury, including needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.

### Stakeholders

Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.

## Glossary

### Standard

Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

### Statutory

Required by law.

### Sterilisation

A process used to render an object free from viable microorganisms including viruses and bacterial spores.

### TSEs

TSEs are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans.

### Validation

Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications. Validation broadly encompasses three activities – commissioning, verification of a process specification and performance qualification.

### Verification

Checking or confirmation of the truth or accuracy of something (e.g., self-assessment).

### Suitably qualified person

A suitably qualified person (decontamination) is (decontamination) defined as a (person designated by Management to provide testing, advice and review/witness documentation. Be qualified to graduate level in an appropriate discipline.

The suitably qualified person (decontamination) should demonstrate extensive relevant experience on decontamination equipment testing and the subject of decontamination and a lower level qualification should also be considered. Each case should be considered on its merits.

## Appendices

### Appendix I: Membership of National Decontamination Advisory Group

Name	Title	Organisation
Ronnie Russell	Senior Lecturer and Microbiologist	Trinity College, Dublin
Winifred Ryan	Head of Standards and Guidance	Quality & Patient Safety Directorate, HSE
Anne Gilleece	Consultant Microbiologist, Connolly Hospital, Blanchardstown, Dublin	Irish Society of Clinical Microbiologists
David C. Coleman	Professor of Oral & Applied Microbiology, Head of Division of Oral Biosciences	Trinity College, Dublin
Fiona Kennedy	Technical Advisor	Applied Management Systems Ltd.
Nick Armstrong replaced by Jane Renehan	Principal Dental Surgeon  Principal Dental Surgeon	HSE, (Dental Representative)
Jim Murphy	Engineering Advisor	HSE, Technical Services/ Estates
Joy Markey	National Decontamination Programme Lead	Quality & Patient Safety Directorate, HSE
Mary Owens	Director of Nursing	Irish Association of Directors of Nursing and
Monica Griffin	Theatre Manager	Irish Theatre Managers Association
Paschal Kent	Decontamination Coordinator, CUH Group	HSE, South
Sheila Donlan	Infection Control Nurse Manager	Health Protection Surveillance Centre
Sinead Horgan	Endoscopy Manager	Chair of Irish Endoscopy Association
Tom Finn	Assistant National Director	Commercial Services, HSE
Tony Mc Loughlin	SSD Manager	Irish Association of Sterile Services Managers
Wayne Spencer	Technical Advisor	Spencer Nickson Ltd
Wilf Higgins	Chairman, Advisory Committee for Medical Devices	Irish Medicines Board

## Appendices

### Appendix II: National Dental IPC Committee Members

Name	Title	Organisation
Nick Armstrong, Chair until retirement, October 2011	Principal Dental Surgeon	HSE, Mid-Leinster
Jane Renahan, Chair since November 2011	Principal Dental Surgeon	HSE, Dublin North-East
Dympna Kavanagh	National Oral Health Lead	HSE, Corporate
Hugh O'Connor	Principal Clinical Engineer	HSE, Dublin
Dorothy Halpin	Dental Hygienist	HSE, Dublin North-East
Joe O'Connor	Principal Dental Surgeon	HSE, West
Marion Jones	Senior Dental Nurse	HSE, West
Mary Fitzpatrick	Manager, Orthodontic Service	HSE, Dublin Mid-Leinster
Niamh Galvin*	Principal Dental Surgeon	HSE South
Pádraig Creedon*	Principal Dental Surgeon	HSE, South
Sheila Donlon	IPC Manager	HPSC
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### Appendix III: Standards and Guidance on which the HSE standards and recommended standards are based

There are a number of European and International standards which are of direct relevance to the decontamination of RIMD. Where these can provide a presumption of conformity under Article 5 of the Medical Device Directive (93/42/EEC) they have been published in the Official Journal of the European Union as harmonised standards. In addition, the Health Departments of a number of countries and various professional bodies and trade associations have published guidance on best practice for decontamination of RIMD. The list below is not exhaustive but includes the key documents that may be used to inform the management of decontamination of RIMD within a health service environment.

#### Legislation

Directive 93/42/EEC.

#### European and International Standards

##### i. Cleanroom Standards

EN ISO 14644-2:2000 Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.

EN ISO 14644-4:2001 Cleanrooms and associated controlled environments. Design, construction and start-up.

EN ISO 14644-5:2004 Cleanrooms and associated controlled environments. Operations.

EN ISO 14644-7:2004 Cleanrooms and associated controlled environments. Separative devices (clean air hoods, gloveboxes, isolators and mini-environments).

EN ISO 14698-1:2003 Cleanrooms and associated controlled environments. Biocontamination control. General principles and methods.

EN ISO 14698-2:2003 Cleanrooms and associated controlled environments. Biocontamination control. Evaluation and interpretation of biocontamination data.

## ii. Disinfectant Standards

EN 13624:2003 Chemical disinfectant and antiseptics. Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area. Test method and requirements (phase 2, step 1).

EN 13727:2003 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area. Test method and requirements (phase 2/Step 1).

EN 14348:2005 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants for instruments used in the medical area including instrument disinfectants. Test method and requirements (phase 2, step 1).

## iii. Equipment Standards

### Sterilizers

EN 285:2006 + A2:2009 Sterilization. Steam sterilizers. Large sterilizers.

EN ISO 13060: 2004 + A2:2010 Small steam sterilizers.

EN 1422:1998 + A1:2009 Sterilisation of medical device. Ethylene oxide sterilizers. Requirements and test methods.

**EN 14180:2003 + A2:2009 Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers. Requirements and testing.**

### Washer-disinfectors

EN ISO 15883-1: 2009 Washer-disinfectors – Part 1: General requirements, definitions and tests.

EN ISO 15883-2: 2009 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.

EN ISO 15883-4: 2009 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

ISO TS 15883-5: 2005 Washer-disinfectors – Part 5 Test soils

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### iv. Management

EN ISO 13485:2003 Quality managements systems – Regulatory compliance for medical devices.

PD CEN ISO/TR 14969:2005 Medical devices - - Quality management systems - Guidance on the application of EN ISO 13485:2003.

### v. Materials

#### Biological indicators

EN ISO 11138 series Biological systems for testing sterilizers and sterilisation processes.

EN ISO 14161:2009 Sterilisation of health care products. Biological indicators. Guidance for the selection, use and interpretation of results.

#### Chemical indicators

EN ISO 11140 series Non-biological systems for use in sterilizers.

EN 867-5:2001 Non-biological systems for use in sterilizers. Specification for indicators systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S.

EN ISO 15882:2008 Sterilisation of health care products. Chemical indicators. Guidance for selection, use and interpretation of results .

#### Packaging

EN ISO 11607-1: 2009 Packaging for terminally sterilized Medical Devices – Part 1 Requirements for materials, sterile barrier systems and packaging systems.

EN 868-2:2009 Packaging materials and systems for medical devices which are to be sterilized. Sterilisation wrap. Requirements and test methods.

EN 868-3:2009 Packaging materials and systems for medical devices which are to be sterilized. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5). Requirements and test methods.

EN 868-4:2009 Packaging materials and systems for medical devices which are to be sterilized. Paper bags. Requirements and test methods.



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EN 868-5:2009 Packaging materials and systems for medical devices which are to be sterilized. Heat and self-sealable pouches and reels of paper and plastic film construction. Requirements and test methods.

EN 868-6:2009 Packaging materials and systems for medical devices which are to be sterilized. Paper for the manufacture of packs for medical use for sterilisation by ethylene oxide or irradiation. Requirements and test methods.

EN 868-7:2009 Packaging materials and systems for medical devices which are to be sterilized. Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilisation by ethylene oxide or irradiation. Requirements and test methods.

EN 868-8:2009 Packaging materials and systems for medical devices which are to be sterilized. Re-usable sterilisation containers for steam sterilizers conforming to EN 285. Requirements and test methods.

EN 868-9:2009 Packaging materials and systems for medical devices which are to be sterilized. Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids. Requirements and test methods.

EN 868-10:2009 Packaging materials and systems for medical devices which are to be sterilized. Adhesive coated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids. Requirements and test methods.

### vi. Medical devices

EN 556-1:2001 Sterilisation of medical devices. Requirements for medical devices to be designated 'STERILE'. Requirements for terminally sterilized medical devices.

EN 556-2:2003 Sterilisation of medical devices. Requirements for medical devices to be designated 'STERILE'. Requirements for aseptically processed medical devices.

EN 1041:2008 Information supplied by the manufacturer with medical devices.

EN ISO 17664:2004 Sterilisation of medical devices. Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

BS EN 980:2008 Symbols for use in the labelling of medical devices.

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### vii. Processes

#### Sterilisation

EN ISO 17665-1:2006 Sterilisation of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilisation process for medical devices.

DD CEN ISO/TS 17665-2:2009 Sterilisation of health care products - Moist heat. Guidance on the application of ISO 17665-1

EN ISO 11737-1:2006 Sterilisation of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products.

EN ISO 11737-2:2009 Sterilisation of medical devices - Microbiological methods. Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process

EN ISO 14937:2009 Sterilisation of health care products. General requirements for characterisation of a sterilizing agent and the development, validation and routine control of a sterilisation process for medical devices.

### viii. Safety

EN 61010-2-040:2005 (Dual no: IEC 61010-2-040:2005 ) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

## UK Guidance Documents

HBN13 Sterile service departments.

HTM 201-01 Part A: Decontamination of Reusable Medical Devices

HTM 2010 Sterilisers.

HTM 2030 Washer-disinfectors.

HTM 2031 Steam for sterilisation.

MAC Manual 2010.

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MDA SN 1999 (32) Storage of sterile medical devices.

MDA SN 2001 (28) Compatibility of medical devices and reprocessing units with decontamination agents.

MHRA DB 2010(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts.

MDB 2006 (05) Managing medical devices

MDB 2002(06) Purchasing, etc of benchtop B&I sterilizers.

MDB 2000(05) Purchasing, etc of benchtop vacuum sterilizers.

MDB 2006(04) Single-use medical devices: implications and consequences of reuse.

**The Joint Transmissible Spongiform Encephalopathy (TSE) Working Group of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee Joint Working Group** <http://www.dh.gov.uk/ab/ACDP/TSEguidance>.

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### Appendix IV: Regulations and Guidance

#### Medical Device

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) concerning medical devices defines a ‘medical device’ as: any instruments, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological means, but which may be assisted in its function by such means.

#### Medical Devices Directive

Medical Devices are regulated by three main Directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990).
- The Council Directive 93/42/EEC on Medical Devices (MDD)(1992).
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998).

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These three Directives:

- Specify essential requirements which must be met before any device can be placed on the market or put into service.
- Introduce controls covering the safety, performance, specification, design, manufacture and packaging of devices.
- Specify requirements for assessment of clinical investigation protocols, and the evaluation of any adverse incidents that occur.
- Introduce a system of classifying devices, and applies a level of control which is matched to the degree of risk inherent in the device.
- Empower a Competent Authority to identify and designate Notified Bodies who check and verify that devices meet the relevant essential requirements.

The Directives are intended to ensure the safety and performance of medical devices and to prohibit the marketing of devices, which may compromise the health and safety of patients and users.

### Irish Medicines Board

The Irish Medicines Board (IMB) is the Competent Authority for general medical devices, active implantable medical devices and in-vitro diagnostic medical devices in Ireland. The IMB has responsibility under the legislation to ensure that manufacturers of medical devices and the medical devices they place on the market meet the requirements of the legislation in the interest of protection of the patient, user and others involved in the use of medical devices.

### Legislation

There are six EU Directives concerning medical devices all of which are transposed into Irish Law by way of Statutory Instrument. This legislation places explicit obligations on manufacturers who intend to place their products on the market in Ireland or elsewhere in the European Union. The following is a list of the main Irish Statutory Instruments, which apply to medical devices placed on the Irish Market.

- SI No 110 of 2009 European Communities (Medical Devices) (Amendment) Regulations, 2009, which became mandatory on 21<sup>st</sup> March 2010

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- S.I. No. 253 of 1994 European Communities (Active Implantable Medical Devices) Regulations, 1994 which became mandatory on 1<sup>st</sup> January 1995.
- S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994 which became mandatory on 14<sup>th</sup> June 1998.
- S.I. No. 304 of 2001 European Communities (In-vitro Diagnostic Medical Devices) Regulations, 2001 which came into force on 29<sup>th</sup> June 2001 and becomes mandatory on the 7<sup>th</sup> December 2003.

## Vigilance

The vigilance system is the name given to the process of notification and evaluation of adverse incidents. The Medical Devices Directive (MDD) includes requirements for medical devices manufacturers to report certain types of incidents to the Competent Authority (CA). The Directives also outline the obligations on CA's to share details of certain incidents reported to them, between each other and with the European Commission.

Under the terms of the Irish Medical Devices Regulations, the Irish Medicines Board (IMB) as the CA is obliged to institute and co-ordinate a reporting system for adverse incidents associated with the use of medical devices in Ireland. The system is intended to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in the European Economic Area (EEA) and to correct product problems.

## Manufacturer of Medical Devices

A manufacturer of a medical device has responsibility for the design, packaging and labelling of a medical device before the device is available on the market place for payment or free of charge with his own name on the label. Under the legislation, the obligations of a manufacturer may also apply to those persons who refurbish, sterilise or significantly modify medical devices as well as system & procedure pack assemblers and 'off-label' users.

### Legal Entity

A legal entity is defined as a body other than a natural person that can function legally i.e. sue or be sued and can make decision through agents. Typically a legal entity is a company/corporation or a corporation sole such as a Minister or a statutory body, e.g. clinics, GP practices, private hospital, public hospital, health board, etc.

Medical devices when manufactured by a healthcare institution will either remain within the legal entity, i.e. the medical devices are for use in or by patients of that same entity, or will transfer to a different legal entity, i.e. the medical devices have been placed on the market.

### Safety, Health and Welfare at Work Act, 2005

The Safety, Health and Welfare at Work Act, 2005 came into effect on 1<sup>st</sup> September 2005 and places obligations in regard to health and safety at work on employers and employees. This Act replaces the 1989 Act and ensures Ireland's compliance with European Union law in this area.

The 2004 Act sets out:

- The requirements for the control of safety and health at work.
- The management, organisation and the systems of work necessary to achieve those goals.
- The responsibilities and roles of employers, the self-employed, employees and others.
- The enforcement procedures needed to ensure that the goals are met.

The Safety, Health and Welfare at Work Act, 2005 takes a preventative approach to reducing accidents and ill health at work. The main effects on each party involved are set out in this document. The 2005 Act introduces some significant changes in relation to risk assessment and safety statements where there are less than three employees. It also deals with the use of intoxicants, employees medical fitness for work, penalties upon conviction and the introduction of 'on the spot fines'.

