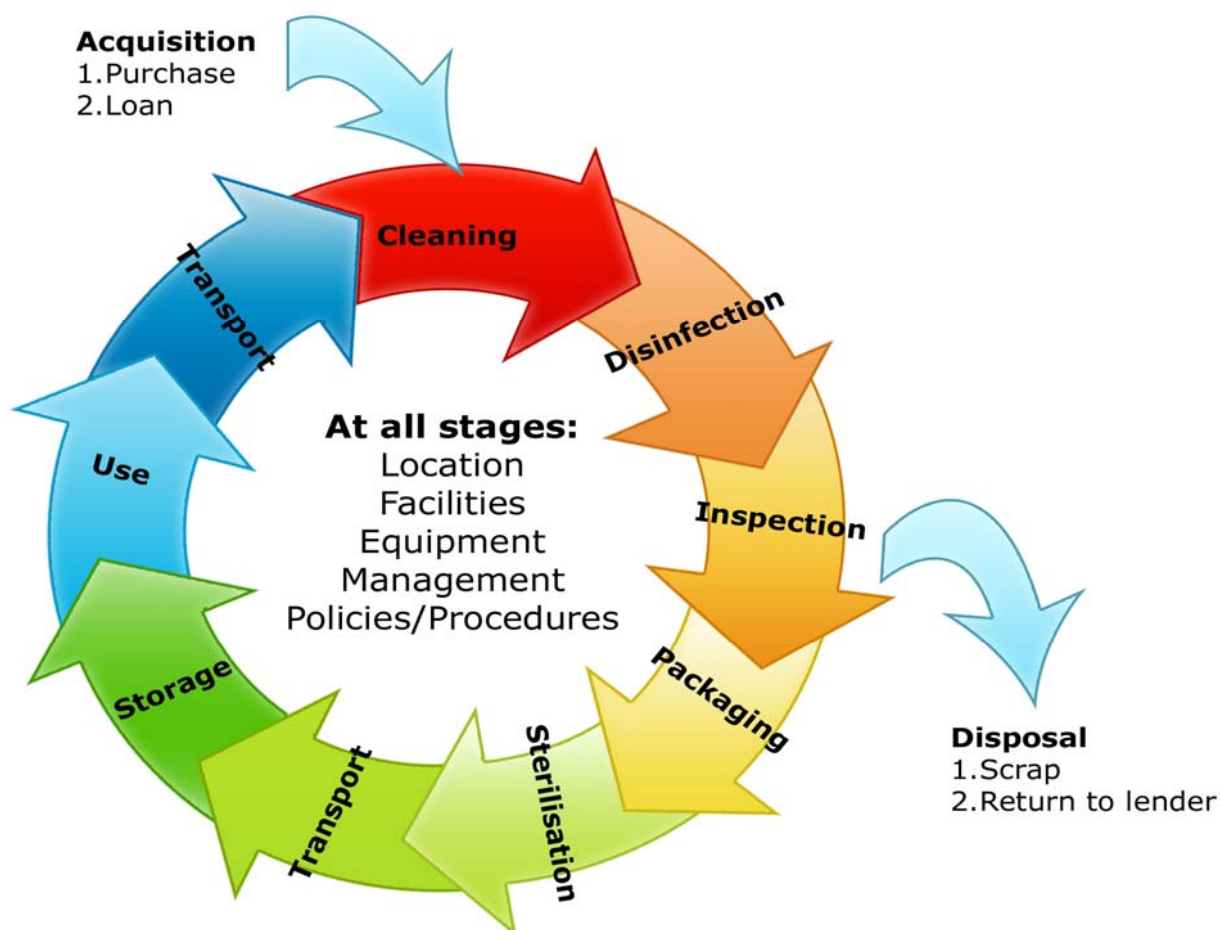


# Health Service Executive Standards and Recommended Practices for Dental Services (Central Decontamination Units)



## Reader Information

<b>Directorate:</b>	Quality & Patient Safety
<b>Title:</b>	HSE Standards and Recommended Practices for Central Decontamination Units (CDUs)
<b>Document Reference Number:</b>	QPSD-D-004-2
<b>Version Number:</b>	2.0
<b>Document Purpose:</b>	Standards & Recommended Practices
<b>Author:</b>	HSE National Decontamination of Reusable Invasive Medical Devices Advisory Group
<b>Approval Date:</b>	July 2011
<b>Target Audience:</b>	All relevant staff in the public health service who work in Central Decontamination units, and other relevant staff with responsibility for decontamination of reusable invasive medi-
<b>Description:</b>	The Standards and Recommended Practices are a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central decontamination Units, based on current legal requirements and professional
<b>Superseded Docs:</b>	HSE Code of Practice for Decontamination of RIMD V 1.0, 2007
<b>Revision Date:</b>	July 2014
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# Standards and Recommended Practices for Dental Services (CDUs)

## Part 1

### Introduction

## Introduction

## 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 patients 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, including service users 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.

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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, 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 (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.

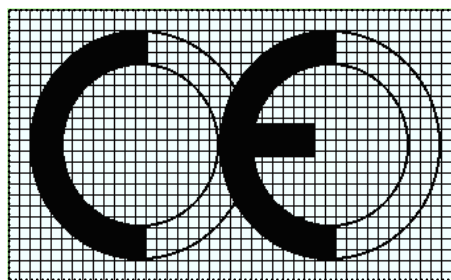
Before the CE mark can be placed on the label or packaging of a RIMD, the RIMD must conform to the requirements of the legislation. For low risk RIMD the manufacturer declares he is in conformance and for medium to high-risk RIMD the manufacturer declares conformance which is then verified by a Notified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

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.

In 1968 Earle Spaulding devised a classification system for infection risk associated with the decontamination of RIMD. Spaulding believed that RIMD and equipment should be cleaned and reprocessed according to the level of risk associated with their intended use. The three categories he described were critical, semicritical and noncritical. The appropriate level of decontamination will depend on the procedure for which the RIMD is used.

Table 4-1: Classification of infection risk associated with the decontamination of RIMD

Risk	Application	Recommendation
Critical	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area, e.g. theatre surgical instrument set	Requires Sterilisation
Semi-critical	Items in close contact with intact skin, mucous membranes or body fluids, particularly after use on infected patients or prior to use on immunocompromised patients, e.g. endoscopes	Requires high level disinfection* (Sterilisation preferred where practicable)
Non-critical	Items in contact with healthy skin or mucous membranes or not in contact with patient, e.g. blood pressure cuff	Can be processed by cleaning (and low level disinfection where necessary)

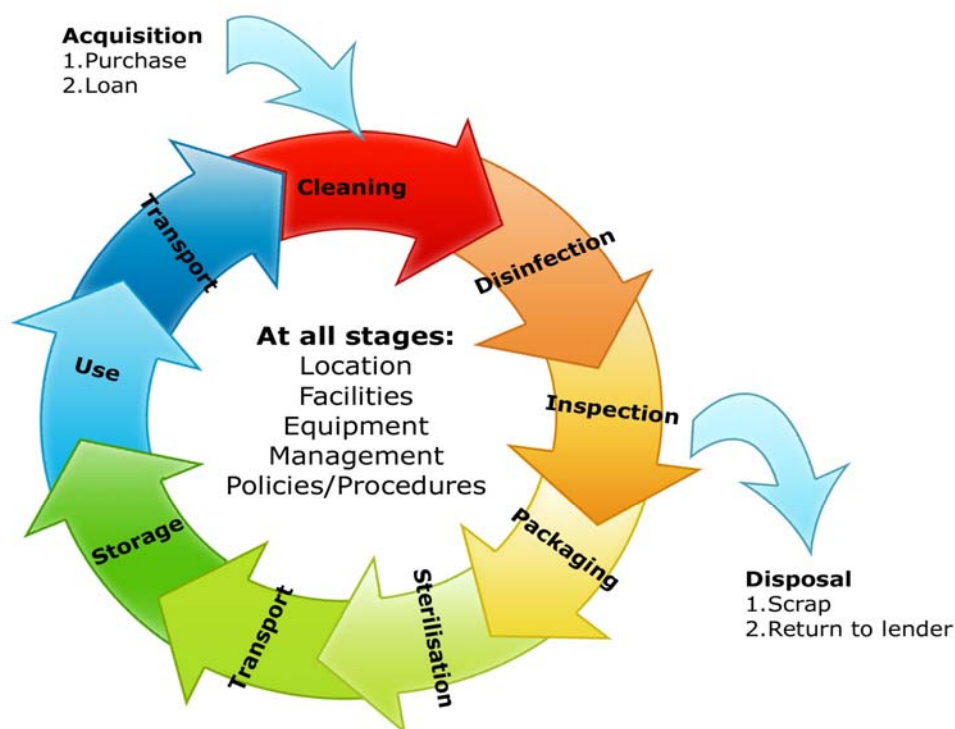
## Introduction

### 5. Life cycle for reusable invasive medical devices

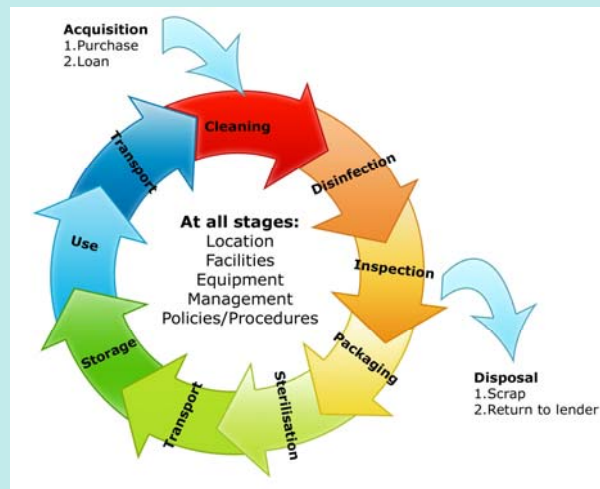
#### 5.1 Introduction

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



Note: Variants of this life-cycle apply for example to the endoscope reprocessing unit



# Standards and Recommended Practices for Dental Services (CDUs)

## Part 2 Standards

**Suitability of decontamination facilities****1. Suitability of decontamination facilities****1.1 Statement**

Decontamination facilities are designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimises adventitious contamination of clean and disinfected reusable invasive medical devices (RIMD) including flexible scopes. For guidance see PD CEN ISO/TR 14969:2005. Additional detailed guidance is available in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities).

**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 department is designed so that it is physically separated from all other work areas.
- 1.3.2 The department is designed to allow segregation of 'dirty' and 'clean' activities.
- 1.3.3 The department is designed to facilitate a unidirectional work flow from the 'dirty' area to the 'clean' area (clean room and inspection, assembly and packaging (IAP) room).
- 1.3.4 The department is not used for any other purpose.
- 1.3.5 The department is not used as a thoroughfare.
- 1.3.6 The department is not part of any service user treatment area.

**Suitability of decontamination facilities**

- 1.3.7 There is a changing area for donning work wear which includes shower facilities, toilet facilities and lockers in proximity to the decontamination area.
- 1.3.8 Access to the wash room, clean room and to the inspection, assembly and packaging (IAP) room is through separate dedicated gowning rooms provided with hand hygiene facilities.
- 1.3.9 The wash room, clean room, inspection, assembly and packaging (IAP) room and steriliser unloading area are free from 'opening' windows, ledges, and uncleanable areas.
- 1.3.10 The wash area, clean room and inspection, assembly and packaging (IAP) room are designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).

***Lighting and electricity***

- 1.3.11 There is adequate lighting available to permit good working practices and visual examination of RIMD.
- 1.3.12 Task lighting and magnification are in situ.
- 1.3.13 There is sufficient electricity supply, computer terminal points and work stations in the department.

***Ventilation and temperature***

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

***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.

**Suitability of decontamination facilities**

- 1.3.16 The junction between the walls and floors is coved and flush.
- 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 are maintained in good condition.
- 1.3.20 The workstations are equipped for the preparation of single or composite 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 in storage facilities 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 meters high, unless special provision is made for loading and un-loading higher shelves.

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

- 1.3.24 The area is managed by trained staff whose sole or primary responsibility is management of the decontamination unit.
- 1.3.25 Entry to the decontamination unit is restricted to authorised personnel only.
- 1.3.26 Staff movement, between dirty and clean areas is not possible without passing through a clothing change and hand-wash area.

***Storage facilities***

- 1.3.27 Safe storage facilities are provided for process chemicals used in decontamination.



**Suitability of decontamination facilities**

- 1.3.28 Storage facilities for bulk items are provided external to the wash room, clean room and inspection, assembly and packaging (IAP) room.
- 1.3.29 Storage facilities are provided for sterile product prior to dispatch.
- 1.3.30 Adequate storage is provided for required personal protective equipment (PPE) is easily accessible in each of the work areas.

***Environmental control***

- 1.3.31 The environment in which clean non-sterile RIMD are inspected, assembled and packed are controlled as a clean room to ISO 14644-1: 1999 Class 8 (manned/unmanned).
- 1.3.32 The inspection, assembly and packaging area (IAP) is monitored microbiologically. (Reference EN ISO 14698: Part 1:2003 and EN ISO 14698 Part 2:2003).

***Cleaning***

- 1.3.33 The environment in which decontamination of (RIMD) takes place is cleaned in accordance with policies, procedures, protocols, guidelines and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse).
- 1.3.34 Dedicated cleaning provision (both equipment and storage) is provided for the wash room, clean room and the inspection, assembly and packaging (IAP) room.

***Other***

- 1.3.35 Further detailed guidance is given in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities).

*Note: The Health Service Executive is currently drafting a HSE health building/design specification for the following decontamination facilities central decontamination unit, endoscope reprocessing unit and local decontamination unit.*

## Decontamination equipment

## 2. Decontamination equipment

### 2.1 Statement

All decontamination equipment that does not meet current Standards is identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment is procured in conformance with extant harmonised 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. Organisations must have a specialist group in place 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

#### *Specialist group*

The organisation has a specialist group in place to consider the decontamination equipment in the organisation as follows:

- 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 decontamination facility.
- 2.3.5 Ability to interface with user requirements.
- 2.3.6 Ability to meet the requirements of current test methods.
- 2.3.7 Ability to be validated and perform to intended purpose.

## Decontamination equipment

- 2.3.8 Energy and water conservation.
- 2.3.9 Ability for self-disinfection for washer-disinfectors and endoscope washer-disinfectors.

Key representatives on the specialist group include:

- 2.3.10 Decontamination Co-ordinator.
- 2.3.11 Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/Endoscopy Manager.
- 2.3.12 Clinical Unit Manager, e.g. Theatre Manager.
- 2.3.13 Infection Prevention and Control.
- 2.3.14 Bio-medical Engineering/Clinical Engineering/Medical Physics.
- 2.3.15 Procurement.

The group may also include as required:

- 2.3.16 Technical Services.
- 2.3.17 Materials Management.
- 2.3.18 Finance Manager/Budget Holder/Business Manager.
- 2.3.19 Other relevant experts (Qualified Person (decontamination)/Sterivigilance Nurse/Microbiologist).
- 2.3.20 The specialist group identifies all decontamination equipment that needs to be replaced.
- 2.3.21 The specialist group formulates a plan to replace or upgrade this equipment.
- 2.3.22 The plan is submitted to the senior management team and is revised annually by the decontamination coordinator (or designated officer).
- 2.3.23 There are sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
- 2.3.24 There are clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and the day to day operation of decontamination equipment.

## Decontamination equipment

- 2.3.25 The operational management of each item of decontamination equipment is the defined responsibility of a named person (usually the decontamination unit manager).
- 2.3.26 The validation and periodic testing is carried out by qualified personnel.
- 2.3.27 The validation and periodic testing data is adequately audited quarterly by a qualified person (decontamination).
- 2.3.28 The department has a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

### *Manual washing*

- 2.3.29 Manual washing is used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a washer-disinfector (WD).

*Note for Endoscope Reprocessing Units: Whichever type of automated endoscope reprocessor is used manual cleaning is done first in accordance with endoscope manufacturers' instruction.*

- 2.3.30 Dedicated manual cleaning equipment and accessories are available for specified RIMD that cannot be cleaned in an automated cleaning process.
- 2.3.31 Separate sinks for washing and rinsing are provided.
- 2.3.32 The detergent used is one specified by the manufacturer for the manual cleaning of RIMD.
- 2.3.33 Means are provided to control the concentration of detergent.
- 2.3.34 A pass-through drying cabinet with inter-locking doors is provided for hot-air drying of manually washed RIMD that cannot be processed through a washer-disinfector.

### *Ultrasonic cleaning*

- 2.3.35 A stand-alone ultrasonic cleaner is provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers' instructions or as a pre-treatment for RIMD prior to processing through a washer-disinfector.
- 2.3.36 The ultrasonic cleaner is equipped with the facility for automatic filling and emptying directly to the drain.

## Decontamination equipment

- 2.3.37 The ultrasonic cleaner is fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- 2.3.38 The detergent used is one specified by the manufacturer for the ultrasonic cleaning of reusable invasive medical devices (RIMD).
- 2.3.39 Means are provided to control the concentration of detergent.
- 2.3.40 The ultrasonic cleaner is used in accordance with the manufacturers' instructions.
- 2.3.41 The ultrasonic cleaner is validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1.
- 2.3.42 The temperature of the cleaning solution in the ultrasonic cleaner is thermostatically controlled.

### *Washer-disinfectors*

- 2.3.43 The specification of the washer-disinfector complies with the requirements of EN ISO 15883, parts 1 & 2 (washer-disinfectors), part 3 (thermal washer-disinfector), part 4 (endoscope washer-disinfector).
- 2.3.44 Washer-disinfectors are double ended with the clean side discharging into the inspection area of the clean room and the inspection, assembly and packaging (IAP) room.
- 2.3.45 Each washer-disinfector is fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
- 2.3.46 When lumened devices are being reprocessed, the washer-disinfector is provided with load carriers that permit the irrigation of the lumened device.
- 2.3.47 Washer-disinfectors and accessories are specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1, 2 & 5.
- 2.3.48 The washer-disinfector is subject to planned preventative maintenance.

**Decontamination equipment***Steam steriliser*

2.3.49 The specification of each steam steriliser complies with requirements of EN 285 and the steriliser is fitted with an air-detector.

*Note: Where it is not possible to fit an air detector to an existing steriliser an alternative method of assuring steam penetration during each cycle run (such as a suitable process challenge device verified as valid for the product being processed in the steriliser ) is used. Further Guidance is available in DD CEN ISO/TS 17665-2.*

2.3.50 Each steam steriliser is fitted with a process monitoring system independent of the automatic controller.

2.3.51 The sterilisation hold period is at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.

2.3.52 Steam sterilisers are double ended with the loading side in the clean room and the inspection and packaging room.

*Low temperature sterilisers*

2.3.53 Low temperature sterilisation methods are used when recommended by and in accordance with the RIMD (including flexible/rigid scopes) manufacturers' instructions.

2.3.54 Low temperature sterilisation is carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Gas Plasma processes.

2.3.55 Low temperature sterilisation methods are validated and are subject to periodic testing in accordance with ISO 14937. Where ISO 14937 does not detail specific periodic tests these should be undertaken in accordance with manufacturers' recommendations.

2.3.56 Low temperature sterilisers are subject to planned preventative maintenance in accordance with manufacturers' instructions and at the manufacturers' recommended frequencies.

## Decontamination equipment

### *Drying cabinet*

- 2.3.57 Where a pass through washer-disinfector is not available, a pass-through drying cabinet between the wash-room, clean room and the inspection, assembly and packaging (IAP) room is provided. The doors of the drying cabinet are interlocked to prevent direct connection between the wash room, clean room and the inspection and packaging (IAP) room.
- 2.3.58 The drying cabinet is fitted with a temperature indicator and/or recorder independent of the controller.
- 2.3.59 The drying temperature throughout the cabinet is within  $\pm 5^{\circ}$  Celsius of the set temperature. Or in accordance with drying cabinet /flexible scope manufacturer's recommendation.
- 2.3.60 The drying cabinet is fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than  $10^{\circ}$  Celsius the heating source is isolated.
- 2.3.61 The air in the cabinet is mechanically circulated and items placed throughout the cabinet is dried uniformly.
- 2.3.62 The drying cabinet is subject to planned preventative maintenance.

### *Heat sealer*

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

## Decontamination process

### 3. Decontamination process

#### 3.1 Statement

Reusable invasive medical devices (RIMD) e.g. surgical instruments, powered devices, rigid and flexible endoscopes, etc. are decontaminated in accordance with the recommendations of the manufacturers validated instructions for decontamination (Ref. EN ISO 17664:2004), current legislation and quality system Standards.

#### 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 All stages of the decontamination process are clearly defined, documented, controlled and recorded.
- 3.3.2 All processes are carried out in accordance with documented policies, procedures, protocols and guidelines.
- 3.3.3 All RIMD sets (including flexible scopes) are traced through the decontamination process to the service user.
- 3.3.4 Processing data are retained for the lifetime of the equipment plus eleven years.
- 3.3.5 There is a regular review of all procedures and any necessary changes are implemented by a documented change in procedures.
- 3.3.6 RIMD are checked and reprocessed in accordance with the manufacturers' instructions.
- 3.3.7 All RIMD are visually inspected for cleanliness prior to release and transportation.
- 3.3.8 All RIMD are inspected and/or tested for functionality prior to release and transportation.



**Decontamination process**

- 3.3.9 There is a formal release procedure for sterile product to ensure that only RIMD that have been subjected to a satisfactory sterilisation cycle are released for use.
- 3.3.10 All product released from the decontamination unit is labelled with a clear indication of the pack contents, the review date and a unique number which is used to trace the decontamination processes to which the RIMD/flexible scope was subjected.
- 3.3.11 Single use devices are not reprocessed. Any device with the following symbol is deemed single use only.

*Note: Single patient interrupted use in accordance with the manufacturers' instructions for use is not considered to breach this criterion.*

**Procedures relating to transmissible spongiform encephalopathies (TSEs)****4. Procedures relating to transmissible spongiform encephalopathies (TSEs)****4.1 Statement**

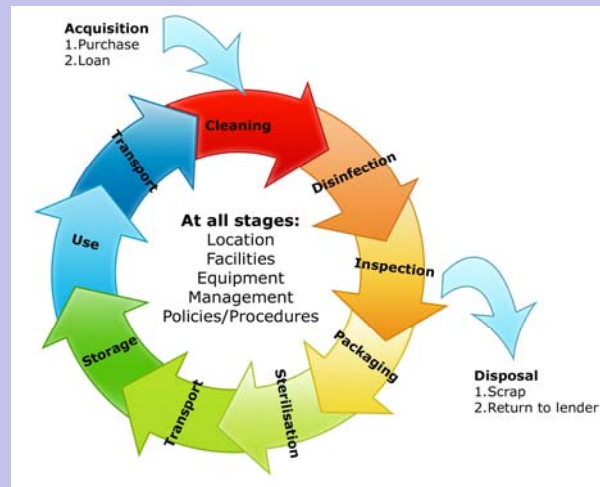
The organisation has processes in place to minimize the exposure of service users and employees to TSE agents.

**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 patients 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 Health-care Settings in Ireland; 2004 (DoHC) and reviewed when the guidance is updated.
- 4.3.3 The organisation will regularly evaluate 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 Dental Services (CDUs)

## Part 3

### Recommended Practices

## **Design of designated area for decontamination of dental reusable invasive medical devices (RIMD) in a central decontamination unit (CDU)**

### **1. Design of designated area for decontamination of dental reusable invasive medical devices (RIMD) in a central decontamination unit (CDU)**

#### **1.1 Introduction**

Dental clinics should have designated non-clinical space provided for dental reusable invasive medical devices (hereafter referred to in this document as dental RIMD), decontamination to minimise opportunities for cross-infection of service users clinical staff and cross-contamination of the working environment.

#### **1.2 Scope**

The objective of this recommended practice is to outline the principles of a safe working environment for decontamination of dental RIMD.

#### **1.3 Contents**

Section One: 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 designated area for decontamination of dental reusable invasive medical devices (RIMD) in a central decontamination unit (CDU)

### 1.4 Procedure

#### Section One: Unit design

- 1.4.1 The Central Decontamination Unit (CDU) should be designed so that it is physically separated from all other work areas.
- 1.4.2 The CDU should be designed to allow segregation of 'dirty' and 'clean' activities.
- 1.4.3 The CDU should be designed to facilitate a unidirectional work flow from the 'dirty' area to the 'clean' area (clean room, inspection, assembly and packaging room).
- 1.4.4 The CDU should not be used for any other purpose.
- 1.4.5 The CDU should not be used as a thoroughfare.
- 1.4.6 The CDU should not be part of any service user area.
- 1.4.7 There should be a designated changing area for donning work wear.
- 1.4.8 The decontamination room/wash room, clean room, inspection, assembly and packaging room (IAP) and steriliser unloading area should be free from 'opening' windows, ledges, and uncleanable areas.
- 1.4.9 The decontamination room/wash room and clean room, inspection, assembly and packaging room (IAP) should be designed to minimise the ambient sound levels. (This will require attention to the installation of equipment, building finish, etc.).

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

- 1.4.10 There should be adequate lighting available to permit good working practices and visual examination of dental RIMD.

*(Note: Full spectrum lighting is desirable to reduce fatigue and facilitate inspections relying on colour balance e.g. corrosion.)*

- 1.4.11 Task lighting and magnification should be in situ.
- 1.4.12 There should be sufficient electricity supply points, computer terminal points and work stations in the department.

## **Design of designated area for decontamination of dental reusable invasive medical devices (RIMD) in a central decontamination unit (CDU)**

### **Section Three: Ventilation and temperature**

- 1.4.13 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%).

### **Section Four: Walls, floors and ceilings**

- 1.4.14 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.
- 1.4.15 The junctions between the walls and floors should be coved and flush.
- 1.4.16 The fitments (where possible) should be flush with wall surfaces.
- 1.4.17 Floors should be covered in a washable non-slip material which is securely sealed.

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

- 1.4.18 All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- 1.4.19 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.
- 1.4.20 There should be adequate space between workstations for equipment and staff movement.
- 1.4.21 The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- 1.4.22 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 designated area for decontamination of dental reusable invasive medical devices (RIMD) in a central decontamination unit (CDU)**

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

- 1.4.23 The area should be managed by trained staff.
- 1.4.24 Entry to the decontamination unit should be restricted to authorised personnel only.
- 1.4.25 Staff movement between dirty and clean areas should not be possible without passing through a clothing change and hand wash area.

### **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 bulk items should be provided external to the designated decontamination area.
- 1.4.28 Adequate storage should be provided for required personal protective equipment and should be easily accessible in each of the work areas.
- 1.4.29 Appropriate storage facilities should be provided for sterile products prior to dispatch.

### **Section Eight: Environmental control**

- 1.4.30 The inspection, assembly and packaging room (IAP) in which clean non-sterile dental RIMD are inspected, assembled and packed is monitored microbiologically. (Reference EN ISO 14698: Part 1:2003 and EN ISO 14698 Part 2:2003).

### **Section Nine: Cleaning**

- 1.4.31 The environment in which decontamination of dental RIMD takes place should be cleaned in accordance with methods, procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Team).
- 1.4.32 Dedicated cleaning provision (both equipment and storage) should be provided for inspection, assembly and packaging area and the wash room.

## Environmental cleaning

## 2. Environmental cleaning

### 2.1 Introduction

Adequate regular cleaning of all work areas is essential for the decontamination cycle to be effective. Environmental cleaning schedules based on policies, procedures, protocols and guidelines must ensure that contamination from dirty areas does not contaminate the clean areas. The cleaning should be monitored by regular documented inspection and testing of the cleanliness of the environment and the cleaning equipment. Written cleaning policy, procedures, protocols and guidelines should include methods and frequency of cleaning and should be approved by the appropriate local committee.

### 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: Spillage kits

Section Six: Records

Section Seven: Environmental monitoring



## Environmental cleaning

## 2.4 Procedure

## Section One: Cleaning equipment

- 2.4.1 There should be a separate cleaner's utility room for the clean and dirty areas.
- 2.4.2 Separate colour coded cleaning equipment should be used for the clean room inspection, assembly and packaging area and wash areas.
- 2.4.3 Cleaning equipment should be regularly cleaned and maintained.

## Section Two: Cleaning frequency and cleaning efficacy

- 2.4.4 Work surfaces should be cleaned at the start of the working day, periodically during the working day and whenever necessary.
- 2.4.5 Entire rooms should be deep cleansed annually. Air vents and filters should be serviced regularly.
- 2.4.6 There should be documented cleaning procedures for fixtures and fittings.
- 2.4.7 There should be documented cleaning procedures for process equipment.
- 2.4.8 There should be microbial settlement monitoring by passive sampling.
- 2.4.9 Efficacy of cleaning should be monitored microbiologically using contact media containing neutralisers.
- 2.4.10 Warning/action limits should be set for microbial contamination in each area after a period baseline monitoring.

## Section Three: Floor cleaning equipment and method

*The following floor cleaning equipment and method should be used:*

- 2.4.11 Mop and bucket using 'two bucket' system and a free rinsing detergent.
- 2.4.12 Vacuum fitted with HEPA filtered exhaust.

## Environmental cleaning

- 2.4.13 Rotary scrubbers and polishers should not be used (unless all devices are first removed from the area, or covered, and all horizontal work surfaces are cleaned after the floors).
- 2.4.14 Floors should be cleaned daily and also cleaned when visibly soiled.

### Section Four: Floor cleaning agents

- 2.4.15 Suitably approved detergent/chemical should be used routinely to ensure infection prevention and control and to ensure that cleaning equipment does not spread microbial load. Therefore monitoring efficacy is essential.
- 2.4.16 Cleaning efficacy should be monitored routinely.
- 2.4.17 If visible blood/body fluids are present, disinfectants should be used following thorough cleaning.
- 2.4.18 Disinfectants should be made up according to the manufacturers' instructions/healthcare organisations policies, procedures, protocols and guidelines.
- 2.4.19 Where disinfectant containers are reused they should not be 'topped up' but should be cleaned and thoroughly rinsed with clean water prior to refilling with disinfectant solution at its working concentration.

### Section Five: Spillage kits

- 2.4.20 The areas where used RIMD are received and handled should have a chlorine based disinfectant to decontaminate blood spills.
- 2.4.21 The wash area should be equipped with spillage kits to contain, neutralise if necessary and remove spillages of process chemicals (guidance on the specific requirements should be found in the Material Safety Data Sheet (MSDS) supplied by the process chemical manufacturer).

## Environmental cleaning

## Section Six: Records

*Records should be kept of the following:*

- 2.4.22 Training of the personnel carrying out the cleaning.
- 2.4.23 All cleaning carried out and by whom.
- 2.4.24 Cleaning of the cleaning equipment.
- 2.4.25 Periodic inspection and testing of cleanliness.
- 2.4.26 Any non-conformances found and the remedial action taken.
- 2.4.27 Vaccination Status of the cleaning staff.

*(Note: The scope of responsibility shall include the competence of contractors where the healthcare organisation buys in services.)*

- 2.4.28 Written instructions/manuals agreed with the infection prevention and control committee.

## Section Seven: Environmental monitoring

- 2.4.29 Regular audits carried out by appropriately trained staff should form part of the management of environmental cleaning. Audit frequency should be agreed locally. Microbiological or biocontamination monitoring of the environment within a controlled area should include the air, contact surfaces and if present, water and compressed air or gases. Also monitor staff and personal protective equipment in the course of routine activity by using contact plates.

- 2.4.30 Microbiological sampling methods suited to locations and purpose should be chosen.

*(Note: Warning action limits should be set for microbial contamination in each area, after a period of baseline monitoring.)*

- 2.4.31 Air may be sampled in two ways:
  - a. by passive settling of microbes using 90mm diameter 'settle' plates which contain either Tryptone Soya Agar (TSA) or Sabaround Dextrose Agar (SDA).

## Environmental cleaning

Table 2.1: Parameters for assessment of microbiological air quality by ‘Settle Plate’ method

Settle Plates	Tryptose soya agar (TSA)	Sabaroud dextrose agar (SDA)
Target Microbes	Broad range of bacteria, some yeasts and moulds	Mainly yeasts and moulds
Exposure time	1– 4 hours	1– 4 hours
Incubation temperature	30–35°C	20–25°C
Incubation Time	3days (5 days to show moulds)	5 days
Results reported as:	Colony-forming units/plate	Colony-forming units/plate

- b. by active sampling using a microbiological air sampler to physically draw a known volume of air over an agar plate at a standard speed and capture the microbes present on the agar.

Table 2.2: Parameters for assessment of microbiological air quality using an ‘Active Sampling’ device

	Tryptose soya agar (TSA)	Sabaroud dextrose agar (SDA)
Target Microbes	Broad range of bacteria, some yeasts and moulds	Mainly yeasts and moulds
Exposure volume	200–1000 litres	200–1000 litres
Incubation temperature	30–35°C	20–25°C
Incubation Time	3days (5 days to show moulds)	5 days
Results reported as:	Colony-forming units/m <sup>3</sup> or 1000 per litres	Colony-forming units/m <sup>3</sup> or per 1000 litres

## Environmental cleaning

2.4.32 Contact surfaces may also be sampled microbiologically in a number of ways.

*Flat surfaces*

- a. where surfaces to be sampled are flat, small petri dishes (c.50mm diameter) with protruding agar referred to as 'contact plates' can be used to directly sample the surface by pressing firmly against it. Alternatively, small 'paddle' like devices coated with agar, can be used in a similar fashion. When incubated, the colony count is indicative of the biocontamination load of the exact area sampled (colony forming units per sq cm). The agar can again be TSA or SDA but they should additionally contain disinfectant neutralisers. These are available commercially. Incubation details are identical to those for contact plates or settle plates.

*(Note: Complete neutralisation of disinfectants is very important because disinfectant carryover onto contact plates may cause a false negative result.)*

*Irregular surfaces*

- a. where surfaces are not flat, and contact plates cannot be used, sterile sampling swabs can be used. These are pre-moistened with neutralising buffer prior to use enabling it to pick up organisms easily. Carefully remove the swab from its tube, allowing any excess moisture to remain in the tube. Then rub the swab against the sample surface using a twisting motion, and replace it in the tube. The swab can later be rubbed on the surface of a TSA or SDA agar plate to transfer the sample and the plate incubated as for the settle plates and contact plates.

*(Note: Swabs for environmental sampling are commercially available and these types should be used rather than swabs designed for clinical sampling. The swab comes as a sealed pack containing a sealed plastic tube with neutralising buffer and a capped swab.)*

*Alternative sampling procedure*

*(Note: Rapid screening of surfaces for microbial contamination following cleaning can be undertaken using commercially available adenosine triphosphate (ATP) detection or nicotinamide adenine dinucleotide (NAD) detection tests. These tests identify where there has been a failure of cleaning and disinfection procedures designed to minimise microbial contamination on surfaces. Samples from surfaces are collected using swabs moistened with treatment agents that release ATP or NAD from intact microorganisms. ATP release is detected by bioluminescence. The more light released, the greater the number of viable microorganisms on the surface sampled. NAD release is measured by a color change rather than light output. These tests are useful for monitoring the efficacy of cleaning and disinfection.)*

## Environmental cleaning

- 2.4.33 A monitoring plan (locations) of the sampling sites should be prepared.
- a. environmental monitoring should be capable of detecting, in a timely manner, an adverse trend in microbial populations, and facilitate the identification of that trends source(s), such as equipment failure, sanitisation practices, personnel habits, or training deficiencies, so that they may be promptly corrected. If the critical elements of a robust environmental-monitoring system are performed and documented regularly, environmental control can be easily demonstrated and monitored.

### *Air flows*

- b. a scale drawing of the decontamination unit should be obtained. On this should be marked all points of air intake and extract. The path that airflow takes during normal working conditions should be mapped using a small smoke generator. This can show anomalies e.g. during filter malfunction or can aid in choosing sampling sites for air quality.

### *Sampling sites*

- c. drawings of rooms should be prepared and sampling sites marked clearly on them using a simple numbering system such as S Series (S1, S2, S3 etc.) for settle plate locations, C Series for contact sample locations, A Series for active air sampling, W Series for water samples etc. The number of sites will vary with the size of the facility. Settle plates sampling locations should be close to areas where medical devices are handled and stored or at points of air inflow but should not interfere with normal work flow. Active air sampling locations should be in front of air inflows or areas of high activity. Contact sampling locations should be critical areas such as worksurfaces, control panels and personal protective equipment.
  - d. a number of sampling locations may be chosen and identified on the plan but not all of these will need to be sampled regularly. Just a limited core number sampled regularly to obtain baseline values whilst some may be sampled on a rotating programme.
- 2.4.34 A monitoring programme (frequency and timing sampling) should be prepared. This will define when the samples are to be taken. A typical programme for a Class 8 facility are as follows:
- a. settle plates carried out every month.

## Environmental cleaning

- b. contact plates carried out weekly.
  - c. active air sampling ideally should be carried out monthly (where a sampler is available).
  - d. additional sampling rounds may occur in response to unusual circumstances e.g. breakdown in air supply, maintenance of ventilation system.
  - e. part of the sampling programme should be carried out when the facility is unoccupied to achieve a baseline contamination level prior to active sampling.
- 2.4.35 Monitoring results should be used to plot simple graphs to determine baselines and trends (these should cover a 12 month period).
- 2.4.36 'Alert' limits and 'action' limits should be adopted for the respective sampling sites.
- a. environmental monitoring should be used as an early warning system to alert staff when environmental quality is drifting out of control. Any formal environmental-monitoring system requires the establishment of alert and action levels (threshold numbers of viable microbial colony- forming units (CFUs) that indicate a facility's loss of control). The absolute CFU value has limited scientific meaning but is used to identify adverse trends and deviations from a known baseline of microorganisms within a controlled environment. Each healthcare organisation should have its own unique baseline patterns.
  - b. the limit values chosen should be based on averaged values achieved over at least a six month or twelve month period.
  - c. **Alert level** – CFU levels that, when exceeded, signal a possible deviation from normal operating conditions and may not require action, but may need to be monitored more closely.
  - d. **Action level** – CFU levels that, that when exceeded, indicate a deviation from normal operating conditions and require immediate action.

## Environmental cleaning

Table 2.3: Typical microbial ‘Action’ limit values used in Class 7 or Class 8 clean rooms

	Contact plate CFU/plate	Settle plate CFU/plate
Class 8 Alert	5	5
Class 8 Action	30 (floor counts)	20
Class 7 Alert	4	3
Class 7 Action	5 (10 floor ) (20 floor, dirty side)	5

- 2.4.37 Investigation procedures and corrective actions should be prepared for response to breaches of action limits. Guidance may be sought from a microbiologist concerning the type of microorganisms present on the plates which may help assess risk or may point to a contamination source. It is also important to know if disinfectants in use are effective against these and at what concentration.
- 2.4.38 Investigation should include the following checks:
- that all control samples gave appropriate results. This could include checking that plate media were within expiry date, were not excessively wet or dry or contaminated prior to use.
  - do counts when area is unmanned show similar patterns?
  - any unusual activity or circumstances prior to and including sampling time.
  - any possibility of abuse of samples in transit (not inverted, open lids, damaged etc).
  - any maintenance work undertaken e.g. changing or adjusting air filters.
  - any malfunction of the air handling system.
  - any problems with water quality.
  - any problems with cleaning equipment.
  - are disinfectants or detergents free from contamination?
  - have shoes and PPE been checked for contamination?



## 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 extant harmonised standards.

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

#### 3.2 Scope

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

#### 3.3 Contents

Section One: Specialist group

Section Two: Manual washing

Section Three: Ultrasonic cleaning

Section Four: Washer-disinfectors

Section Five: Steam sterilisers

Section Six: Low temperature sterilisers

Section Seven: Drying cabinets

Section Eight: Heat sealers

## Decontamination Equipment

### 3.4 Procedure

#### Section One: Specialist group

- 3.4.1 Each organisation should have a specialist group in place to consider the decontamination equipment in the healthcare 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, repairing and replacing the equipment.
  - d. ability to interface with other equipment in the decontamination 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.
  - i. ability for self-disinfection for washer-disinfectors and endoscope washer disinfectors.
- 3.4.2 Key representatives on the specialist group should include:
- a. Decontamination Coordinator.
  - b. Decontamination Unit Manager, e.g. dental reprocessing (decontamination) Unit Manager.
  - c. Clinical Unit Manager.
  - d. Infection Prevention and Control.
  - e. Bio-medical Engineering/Clinical Engineering/Medical Physics.
  - f. Procurement.

## Decontamination Equipment

### *Procurement*

- 3.4.3 The group may also include as required:
  - a. Technical Services.
  - b. Materials Management.
  - c. Finance Manager/Budget Holder/Business Manager.
  - d. Other relevant experts (Qualified Person (decontamination)/Sterivigilance personnel/Microbiologist).
- 3.4.4 The specialist group should identify all decontamination equipment which needs to be replaced.
- 3.4.5 The specialist 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 by the decontamination coordinator (or designated officer).
- 3.4.7 There should be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
- 3.4.8 There should be clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and day to day operation of decontamination equipment.
- 3.4.9 The operational management of each item of decontamination equipment should be the defined responsibility of a named person (usually the decontamination unit manager).
- 3.4.10 Validation and periodic testing should be carried out by qualified personnel (decontamination).
- 3.4.11 The validation and periodic testing data should be adequately audited quarterly by a qualified person (decontamination).
- 3.4.12 The department should have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

## Decontamination Equipment

### Section Two: Manual washing

- 3.4.13 Manual washing should be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a washer-disinfector.
- 3.4.14 Dedicated manual cleaning equipment and accessories should be available for specified RIMD that cannot be cleaned in an automated cleaning process.
- 3.4.15 Separate sinks for washing and rinsing should be provided.
- 3.4.16 The detergent used should be one specified by the manufacturer as being suitable for manual cleaning of RIMD and compatible with the manufacturers' instructions for the RIMD being cleaned.
- 3.4.17 Means should be provided to control the concentration of detergent.  
*(Note: An automated dispenser is preferable.)*
- 3.4.18 A pass-through drying cabinet with inter-locking doors should be provided for hot-air drying of manually washed RIMD that cannot be processed through a washer-disinfector.

### Section Three: Ultrasonic cleaning

- 3.4.19 A stand-alone ultrasonic cleaner should be provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers' instructions or as a pre-treatment for RIMD prior to processing through a washer-disinfector.
- 3.4.20 The ultrasonic cleaner should be equipped with the facility for automatic filling and emptying directly to the drain.
- 3.4.21 The ultrasonic cleaner should be fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- 3.4.22 The detergent used should be one specified by the manufacturer as being suitable for the ultrasonic cleaning of RIMD.
- 3.4.23 Means should be provided to control the concentration of detergent.
- 3.4.24 The ultrasonic cleaner should be used in accordance with the manufacturers' instructions.

## Decontamination Equipment

- 3.4.25 The ultrasonic cleaner and accessories should be specified, installed, validated, commissioned and operated in accordance with EN ISO 15883, parts 1,2 & 5.
- 3.4.26 The ultrasonic cleaner shall be subject to periodic testing in accordance with EN ISO 15833, parts 1, 2, & 5.
- 3.4.27 The ultrasonic cleaner should be subject to a planned preventative maintenance programme in accordance with the manufacturers' recommendations.

*(Note: The only effective means for cleaning the lumen of a dental handpiece is to process it through a washer-disinfector with each lumen connected to a flushing system.)*

### Section Four: Washer-disinfectors

- 3.4.28 The specification of the washer-disinfector should comply with requirements of EN ISO 15883, parts 1&2.
- 3.4.29 Washer-disinfectors should be double ended with the clean side discharging into a designated area of the clean room, inspection, assembly and packaging room (IAP).
- 3.4.30 Each washer-disinfector should be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
- 3.4.31 When lumened devices are being reprocessed, the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- 3.4.32 Washer-disinfectors and accessories should be specified, installed, validated, commissioned, and operated in accordance with EN ISO 15883, parts 1, 2 & 5.
- 3.4.33 The washer-disinfector should be subject to periodic testing in accordance with EN ISO 15883, parts 1, 2 & 5.
- 3.4.34 The washer-disinfector should be subject to a planned preventative maintenance programme in accordance with the manufacturers' recommendations.

## Decontamination Equipment

### Section Five: Steam sterilisers

- 3.4.35 Sterilisers and accessories should be specified, installed, commissioned, tested and operated in accordance with the current standard EN 285 where relevant /EN 13060 and EN ISO 17665, part 1.
- 3.4.36 The sterilisation hold period should be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
- 3.4.37 The sterilisers should be subject to planned preventative maintenance.
- 3.4.38 Downward displacement sterilisers are not appropriate for sterilising wrapped loads of dental RIMD or for items that contain a lumen (e.g. dental handpieces), and **should not be used for these purposes under any circumstances.**
- 3.4.39 All dental RIMD, items and equipment for use on service users should be packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee sterilisation.
- 3.4.40 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.

### Section Six: Low temperature sterilisers

- 3.4.41 Low temperature sterilisation may be required for sterilisation of RIMD (including flexible/rigid scopes in accordance with manufacturers' instruction ).
- 3.4.42 Low temperature sterilisation should be carried out using vapour Phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma processes.  
  
*(Note: The low temperature sterilisation process must be compatible with the device for processing.)*
- 3.4.43 Low temperature sterilisation methods should be validated and subject to periodic testing in accordance with EN ISO 14937. Where EN ISO 14937 does not detail specific periodic tests these should be undertaken in accordance with manufacturers' recommendations.
- 3.4.44 Low temperature sterilisers should be subject to planned preventative maintenance in accordance with manufacturers' instructions and at the manufacturers' recommended frequencies.

## Decontamination Equipment

### Section Seven: Drying cabinets

- 3.4.45 Where a pass through washer-disinfector is not available, a pass-through drying cabinet between the wash-room and the clean room, inspection, assembly and packaging (IAP) room should be provided. The doors of the drying cabinet should be interlocked to prevent direct connection between the wash room and the clean room, inspection, assembly and packaging room.
- 3.4.46 The drying cabinet should be fitted with a temperature indicator and/or recorder independent of the controller.
- 3.4.47 The drying temperature throughout the cabinet should be within  $\pm 5^{\circ}$  Celsius of the set temperature. Or in accordance with drying cabinet /flexible scope manufacturers recommendation.
- 3.4.48 The drying cabinet should be fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than  $10^{\circ}$  Celsius the heating source is isolated.
- 3.4.49 The air in the cabinet should be mechanically circulated and items placed throughout the cabinet should be dried uniformly.
- 3.4.50 The drying cabinet should be subject to a planned preventative maintenance programme in accordance with the manufacturers' recommendations.
- 3.4.51 The drying cabinet should be subject to annual validation in accordance with manufacturers' recommendations.

### Section Eight: Heat sealers

- 3.4.52 Where heat seal packaging is to be used, a rotary heat sealer should be provided.
- 3.4.53 Heat-sealing equipment used as part of the terminal packaging process should be maintained and tested to manufacturer's performance criteria.
- 3.4.54 The heat sealer should be validated and tested daily to verify the efficacy of the seal.
- 3.4.55 The heat sealer should be subject to a planned preventative maintenance programme in accordance with manufacturers' recommendations.

## Procurement of reusable invasive medical devices (RIMD)

### 4. Procurement of reusable invasive medical devices (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 RIMD and ancillary materials.

#### 4.3 Contents

Section One: Specialist group

Section Two: Procurement policy

Section Three: Specification

Section Four: General principles

#### 4.4 Procedure

##### Section One: Specialist group

- 4.4.1 Each healthcare organisation should have a specialist group in place to consider medical devices and equipment in accordance with the recommendations of the Irish Medicines Board (IMB) safety notice SN2006(03).



## Procurement of reusable invasive medical devices (RIMD)

### Section Two: Procurement policy

- 4.4.2 All medical devices and equipment are selected and acquired in accordance with the Health Service Executive's Procurement Policy.

### Section Three: Specification

- 4.4.3 There should be a detailed specification for each RIMD which complies with current standards.

### Section Four: General principles

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

*(Note: The procurement group should carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the reprocessing procedure. Hence it is essential to consult the decontamination unit management before making a decision. This will require that the manufacturers' validated instructions for the reprocessing of RIMD are available prior to purchase and comply with local policies, procedures, protocols and guidelines.)*

- 4.4.6 Value for money issues should be considered when purchasing RIMD.
- 4.4.7 All 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.
- 4.4.8 Suppliers should be selected based on their ability to supply RIMD in accordance with the specified requirements and ability to provide service support over the lifetime of the RIMD, where applicable.
- 4.4.9 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 should 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 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 in the central decontamination unit*

Section Six: Label

Section Seven: Instructions for use

## 5.4 Procedure

### *Manufacturer*

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

- 5.4.1 If the RIMD is intended by the manufacturer to be reused, the following information should be provided in English:
  - a. appropriate processes to allow reuse, including cleaning, disinfection, packaging and (if appropriate), the methods of sterilisation of the RIMD to be resterilised.
  - b. the number of reuses.
  - c. any restriction to the reuse.
- 5.4.2 If the 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 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 RIMD.
- 5.4.5 The degree of accuracy claimed for RIMD with a measuring function should be provided.
- 5.4.6 If the intended purpose of the RIMD is not obvious to the user, the manufacturer should clearly state the intended purpose on the label and in the instructions for use.
- 5.4.7 Detachable components of the RIMD should be identified.
- 5.4.8 Action to detect any potential risk posed by the RIMD and detachable components should be provided.

## Manufacturers' instructions

- 5.4.9 Where parts are single use or have restricted use, this information should be provided.
- 5.4.10 Technical/User training should be provided by the manufacturer and training records maintained.

### Section Two: Label

*The label should contain the following details:*

- 5.4.11 The name or trade name and address of the manufacturer.
- 5.4.12 The details strictly necessary for the user to identify the RIMD and the contents of the packaging.
- 5.4.13 Where appropriate, the word 'STERILE'.
- 5.4.14 Where appropriate, the batch code preceded by the word 'LOT', or the serial number.
- 5.4.15 Where appropriate, an indication of the date by which the RIMD should be used, in safety, stating the month and the year.
- 5.4.16 Where appropriate, an indication that the medical device is for single use.
- 5.4.17 If the RIMD is custom-made, the words 'custom-made RIMD'.
- 5.4.18 If the RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- 5.4.19 Any special storage and/or handling conditions.
- 5.4.20 Any special operating instructions.
- 5.4.21 Any warnings and/or precautions to be taken.
- 5.4.22 Year of manufacture.
- 5.4.23 Batch or serial number.
- 5.4.24 Where applicable, method of sterilisation.
- 5.4.25 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:*

- 5.4.26 If the RIMD must be installed with, or connected to, other medical RIMD or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct RIMD or equipment to use in order to obtain a safe combination should be provided.
- 5.4.27 All the information needed to verify whether the 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 RIMD operate properly and safely at all times should be provided.
- 5.4.28 Where appropriate, information to avoid certain risks in connection with the implantation of the RIMD should be provided.
- 5.4.29 Information regarding the risks of reciprocal interference posed by the presence of the RIMD during specific investigations or treatment.
- 5.4.30 The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of resterilisation.
- 5.4.31 If the medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the RIMD to be resterilised, and any restriction on the number of reuses.
- 5.4.32 Details of any further treatment or handling needed before the RIMD can be used (for example, sterilisation, final assembly, etc).
- 5.4.33 In the case of RIMDs emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

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

- 5.4.34 Precautions should be taken in the event of changes in the performance of the RIMD.

**Manufacturers' instructions**

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

**Section Five: Information supplied on request**

- 5.3.38 The identity or information on the test methods used.
- 5.3.39 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 central decontamination unit*****Section Six: Label*****The label should contain the following details:***

- 5.4.40 The name or trade name and address of the central decontamination unit.
- 5.4.41 The details strictly necessary for the user to identify the contents of the packaging.
- 5.4.42 Where appropriate, the word 'STERILE'.
- 5.4.43 An indication of the date by which the RIMD should be used, in safety, stating the month and the year.
- 5.4.44 Any special storage and/or handling conditions.
- 5.4.45 Reference to any special operating instructions, warnings and/or precautions to be taken.
- 5.4.46 Year of manufacture.
- 5.4.47 Batch or serial number.

**Manufacturers' instructions**

5.4.48 Where applicable, method of sterilisation.

**Section Seven: Instructions for use**

5.4.49 In general, Class I and Class IIa devices (see introduction) which comprise most of the RIMD processed by a decontamination unit, do not require specific instructions for use. Exceptionally where these are required, copies should be retained by the clinical user and the central decontamination unit and should be referenced on the label on the RIMD.

## Personal protective equipment

## 6. Personal protective equipment

### 6.1 Introduction

Standard precautions and safe work practices are required to minimise the risk of infection to both 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. PPE involves use of protective barriers such as gloves, gowns, aprons, masks or protective eyewear. PPE also provides protection against other hazards in the healthcare facility such as chemicals and physical injury. The provision of PPE is based on a risk assessment in accordance with Part V of the Safety, Health and Welfare at Work Act (General Application) Regulations, 1993.

Personal protective equipment (PPE) should be worn by personnel when decontaminating RIMD to reduce the risk of exposure to potentially infectious material. Managers should ensure that PPE is made available and all personnel including engineering contractors and personnel responsible for ensuring the correct use and disposal of same.

### 6.2 Scope

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

### 6.3 Contents

#### *Decontamination unit*

Section One: Attire

#### *Gowning for entry to the wash area*

Section Two: Head/hair cover

Section Three: Protection for eyes /nose and mouth

Section Four: Protection for skin and clothing



## Personal protective equipment

Section Five: Gloves

Section Six: Footwear

Section Seven: Clean room, inspection, assembly and packaging room (IAP) attire

### 6.4 Procedure

#### *Decontamination unit*

##### Section One: Attire

- 6.4.1 All personnel working in the decontamination unit should wear freshly laundered low linting attire. (Low linting attire minimises bacterial shedding and provides comfort and professional appearance should be selected).
- 6.4.2 Freshly laundered attire should be changed daily or whenever it becomes visibly soiled or wet.
- 6.4.3 Staff who are involved in the maintenance of decontamination equipment should be required to wear the same type of clothing as other personnel working in the department.
- 6.4.4 On leaving the decontamination unit, staff should change into their normal day wear.
- 6.4.5 After use, the attire should be discarded appropriately in a designated post use container/bag.
- 6.4.6 Hands should be decontaminated before leaving the changing area.
- 6.4.7 Work attire should never be worn outside the decontamination unit.

#### *Gowning for entry to the wash room*

##### Section Two: Head/hair cover

- 6.4.8 The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.

## Personal protective equipment

- 6.4.9 The hat or hood should be designed so that microbial dispersal is minimised.
- 6.4.10 All hair should be confined as well as covered.
- 6.4.11 After use, headgear should be discarded in the appropriate healthcare waste stream.
- 6.4.12 Stud earrings may be worn and should be totally confined within the head cover.

*(Note: Make-up or jewellery should not be worn in the decontamination unit.)*

### Section Three: Protection for eyes /nose and mouth

- 6.4.13 Healthcare workers should wear single use PPE to reduce the risk of body fluid exposure from splashing and spraying of blood or body fluids, protection for eyes/nose and mouth should include the following:
  - a. a face shield that covers the eyes, nose, mouth and chin.
  - b. fluid repellent mask and separate goggles.
  - c. fluid repellent mask with integrated eye shield.
- 6.4.14 Goggles, masks and face shields should be:
  - a. single-use.
  - b. fitted and worn according to the manufacturers' instructions.
  - c. removed immediately if moist or visibly soiled and discarded in the appropriate healthcare waste stream.
- 6.4.15 Goggles, masks and face shields with integrated eye protection should be:
  - a. optically clear, antifog, distortion free, close fitting and shielded at the side.

*(Note: Fluid repellent masks, goggles and face shields should not be touched by hands while being worn or worn loosely around the neck.)*

*(Note: All PPE should be discarded in the appropriate healthcare waste stream.)*

## Personal protective equipment

### Section Four: Protection for skin and clothing

- 6.4.16 Healthcare workers should wear plastic aprons or impermeable gowns with long cuffed sleeves and tuck-ins gloves during procedures that are likely to generate splashes of blood or body fluids or during activities that may contaminate clothing, uniforms and/or personnel with microorganisms or infectious material.
- 6.4.17 Fluid repellent attire and aprons should be changed whenever they become visibly soiled or wet.
- 6.4.18 After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

*(Note: A risk assessment should be undertaken to determine whether a plastic apron or gown should be worn).*

### Section Five: Gloves

- 6.4.19 Healthcare workers should decontaminate their hands before and after removing gloves by:
  - a. handwashing.
  - b. using alcohol gel.

*(Note: Alcohol gel should not be used on visibly soiled hands .)*
- 6.4.20 Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- 6.4.21 Gloves should be:
  - a. used for handling contaminated RIMD, waste and when performing environmental cleaning activities.
  - b. selected and worn according to the task and if torn or perforated.
- 6.4.22 When removing gloves:
  - a. the outer surface of the gloves should not come into contact with skin.
  - b. 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.

## Personal protective equipment

- 6.4.23 After use, gloves should be discarded in the appropriate healthcare waste stream.
- 6.4.24 It is important to remove used gloves and decontaminate hands before touching a clean surface such as worktops, or pens.

### Section Six: Footwear

- 6.4.25 Healthcare workers should wear non-slip enclosed footwear that can protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally).
- 6.4.26 Footwear should be regularly cleaned and disinfected.
- 6.4.27 Footwear should be appropriate to the area in which HCWs are designated.

**Figure 6-1: Personal Protective Equipment (Decontamination Unit)**



## Personal protective equipment

### Section Seven: Clean room, inspection, assembly and packaging room (IAP) attire

#### *Attire*

- 6.4.28 Healthcare workers working in the clean room, inspection, assembly and packaging (IAP) room should wear a freshly laundered scrub suit.
- 6.4.29 Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- 6.4.30 Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet.
- 6.4.31 Appropriate clothing should be used by staff who are involved in the maintenance of reprocessing equipment.
- 6.4.32 When working outside the decontamination area suitable cover attire should be worn.

#### *Head/hair cover*

- 6.4.33 The first item to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- 6.4.34 The hat or hood should be designed so that microbial dispersal is minimised.
- 6.4.35 All hair should be confined as well as covered.
- 6.4.36 After use, headgear should be discarded in the appropriate healthcare waste stream.
- 6.4.37 Stud earrings may be worn and should be totally confined within the head cover.

## Personal protective equipment

Figure 6-2: Personal Protective Equipment (Clean room, inspection, assembly and packaging room)



## 7. Process chemicals

### 7.1 Introduction

Chemicals such as detergents and disinfectants may have hazardous properties associated with them (may be irritant, corrosive, flammable), e.g. bleach and ammonia if mixed will release lethal chlorine gas. 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 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.
  - the least hazardous chemical that will fulfil a process requirement should be chosen.

#### Section Two: Control of process chemicals

- 7.4.2 The methods to be used for handling and storage of process chemicals should be defined in written policies, procedures protocols and guidelines.
- 7.4.3 Chemicals that should not be stored together should be clearly identified.
- 7.4.4 Chemicals should not be stored above shoulder height.
- 7.4.5 Chemicals should be stored in locked cabinet.

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

- 7.4.6 Suppliers of chemical agents should provide MSDS for all chemical agents (including cleaning agents and disinfectants).
- 7.4.7 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.
- 7.4.8 If information is incorporated into policies, procedures, protocols and guidelines, the original wording should be used and the MSDS referred to.
- 7.4.9 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**

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

**Section Five: Spillage kit**

- 7.4.11 In each area where chemicals are used, a spillage kit should be available to allow safe and easy removal of spills.
- 7.4.12 A first aid eye wash station should be available nearby or on hand.
- 7.4.13 Where chemicals may contact eyes/skin, consideration should be given to the availability of chemical neutralisation within the department. (e.g. the hypertonic, polyvalent, amphoteric compound Diphoterine can be used to neutralise and inactivate up to 600 chemicals, including spills on environmental surfaces and inadvertent chemical contact with skin, eyes or mucous membranes).

## Traceability

# 8. Traceability

## 8.1 Introduction

Systems should be in place to record the decontamination process used on dental RIMD (tracking) and link them with 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, through each stage of the decontamination process and allow retrospective demonstration that a particular set and the set contents or supplementary dental RIMD has been correctly decontaminated.

The tracing system should permit retrospective tracing of the dental RIMD history including the service user on which the dental RIMD was used.

As a minimum, records should be kept that permit the tracking of dental RIMD to the cleaning process used and the steriliser cycle in which they were sterilised.

## 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 cycle ensuring that an effective audit trail can be created to service user use.

## 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, operational cycles and personnel involved in the processing of a particular dental RIMD/supplementary RIMD 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:
- the cleaning, disinfection and sterilisation process cycle used.
  - the name of the person undertaking each stage of the decontamination process.
  - the date, time and test result.
  - details of the dental RIMD and accessories being processed.
- 8.4.3 As a minimum, sets of dental RIMD should be individually identified with a Global Standard 1 (GS1) Global Individual Asset Identifier (GIAI) code.
- 8.4.4 Identification of all individual dental RIMD may not be required. (The technology required for efficient and economical identification of individual RIMD is not sufficiently developed to recommend this as a requirement, although it is desirable).
- (Note: Sites reprocessing of dental RIMD used in identified high risk procedures single use instrument tracking at set and supplementary level is required.)*
- 8.4.5 IT based systems are preferred. Manually based systems should only be used for small units with a very low turn-over or for back-up in the event of IT failure. The IT systems selected to track dental RIMD should be capable of maintaining traceability for items that have been loaned from commercial organisations of other healthcare organisations utilising the unique coding of that item.
- 8.4.6 Records relating to decontamination processes should be maintained for the lifetime of the dental RIMD/decontamination equipment plus eleven years.

### Section Two: Tracing

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

## Choice of decontamination process

### 9. Choice of decontamination process

#### 9.1 Introduction

To prevent infection, all RIMD that come into contact with the service user or surgical field 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

#### 9.4 Procedure

##### Section One: General principles

- 9.4.1 RIMD should be reprocessed to a level appropriate for their intended use. The appropriate level depends on the body sites where the RIMD will be used and the risk associated with a particular procedure.
- 9.4.2 The minimum levels of processing and storage requirements for RIMD, based on three risk categories of use, are shown in the Spaulding Classification (see below). In brief, the minimum levels of reprocessing are as follows for different types of site:
  - a. **Critical site** – dental RIMD should be sterile at the time of use. This means dental RIMD should be single use, should be steam sterilised (for dental RIMD that are capable of withstanding heat), or should have undergone low temperature sterilisation.

## Choice of decontamination process

- b. **Semicritical site** – dental RIMDs should be single use or sterilised after each use. If this is not possible, high-level disinfection is the minimum level of reprocessing that is acceptable.
  - c. **Noncritical site** – cleaning alone is generally sufficient for all noncritical items after every individual use, although either intermediate or low-level disinfection may be appropriate in specific circumstances.
- 9.4.3 Decontamination processes should be chosen to be compatible with the dental RIMD to be processed.
- 9.4.4 Decontamination processes should be chosen to be capable of providing not less than the standard of decontamination required for the clinical procedures to be undertaken.
- 9.4.5 Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- 9.4.6 Decontamination processes should be chosen to be amenable to independent verification of the decontamination standards achieved.
- 9.4.7 The decontamination methods selected should be economical and effective.
- 9.4.8 The decontamination methods used should be compatible with recommended methods of validation.

*(Note: Most RIMD and equipment used in dentistry come into direct contact with the 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 area 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: Agreement on Dangerous Goods by Road (ADR) Compliance

Section Two: General principles

Section Three: Staff

#### 10.4 Procedure

##### Section One: Agreement on Dangerous Goods by Road (ADR) Compliance

- 10.4.1 Recommendations regarding the transport of contaminated surgical dental RIMDs with reference to the '*Agreement on Dangerous Goods by Road European Agreement Concerning the International Carriage of Dangerous Goods by road regulations 2009*'. Therefore the following advice should be adhered to when transporting contaminated RIMD for reprocessing.

**Transportation – return of used items for reprocessing**Scenario 1:

- 10.4.2 If the dental RIMD are unlikely to cause disease in humans or animals they are not subject to the provisions of the ‘*Agreement on Dangerous Goods by Road*’, (road transport regulations) and there are no further requirements when transporting the dental RIMD by road, e.g. contaminated dental RIMD used during pregnancy where the mother has no known infection.

ADR 2.2.62.1.5.1

“Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to the provisions of the *Agreement on Dangerous Goods by Road*”.

Scenario 2:

- 10.4.3 If the contaminated dental RIMD have been washed or the infectious hazard has been nullified then the dental RIMD are not subject to the provisions of the *Agreement on ‘Dangerous Goods by Road’*, (road transport regulations) and there are no further requirements when transporting the dental RIMD by road.

ADR 2.2.62.1.5.3

“Substances in a form that any present pathogens have been neutralised or inactivated such that they no longer pose a health risk are not subject to ‘*Agreement on Dangerous Goods by Road*’ .

Scenario 3:

- 10.4.4 If the dental RIMD have not been washed or disinfected and contain infectious substances or poses a risk to the health of personnel involved in the carriage of such dental RIMD then the dental RIMD must be transported in the same packaging used to transport service user specimens. The packaging must meet the requirements according to packing instruction P650 of the “*Agreement on Dangerous Goods by Road*” (ADR) (road transport regulations). These instructions will be transported as “UN3373, Biological Substances, Category B”.

## Transportation – return of used items for reprocessing

### Section Two : General principles

- 10.4.5 Contaminated dental RIMD should be placed in closed, sealed secure containers/trolleys and transported to the wash area as soon as possible after use.
- 10.4.6 Dental 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.
- 10.4.7 Contaminated dental RIMD should preferably be transported to the decontamination area in a covered container, as there is potential for dropping the dental RIMD en-route or indeed colliding with service users or staff resulting in injury. This will also prevent contact between contaminated and sterilised/disinfected dental RIMD which should always be transported separately.
- 10.4.8 Depending on how long the dental RIMD are stored before cleaning, it may be necessary to store them in a disinfectant solution.
- 10.4.9 Some commercial disinfectant products recommended for this purpose result in corrosion if in contact with dental RIMD for extended periods.
- 10.4.10 Preferably, dental RIMD should be cleaned and disinfected immediately or shortly after use.
- 10.4.11 All disposable items should be removed from the kit prior to transportation, e.g. disposable needles, cartridges etc.
- 10.4.12 Broken dental RIMD or dental RIMD that require repair should be decontaminated and sterilised prior to disposal or repair.
- 10.4.13 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.

### Section Three: Staff

- 10.4.14 Personnel should be trained to handle, collect and transport contaminated RIMD/RIMD sets and should wear personal protective equipment (PPE) in accordance with local safety policies, procedures and guidelines.
- 10.4.15 Policies, procedures, protocols and guidelines for transportation (return of used items for reprocessing) of contaminated RIMD/RIMD sets should be developed, reviewed periodically, and readily available within the department.



## 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 area prior to cleaning

Section Two: Disassembly of dental RIMD

## 11.4 Procedure

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

- 11.4.1 On receipt at the decontamination area, 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 and 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 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. Manufacturers' instructions 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 to the 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 dental 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 1-10 minutes.
- 12.4.10 The machine renders equipment clean, disinfected, dry and safe for further handling.
- 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 dental RIMD handling, however, they are unsuitable for use with heat-sensitive items.

**Cleaning (including pre-cleaning)**

- 12.4.12 Care should be taken not to over-load the washer disinfectant as this can result in some dental 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 ISO 15883 parts 1, 2 and 5. The water for the final rinse stage should be purified water (prepared by reverse osmosis or deionisation) as this gives the lowest levels of process residuals.
- 12.4.14 Factors to be considered when determining if the RIMD is compatible with the washer-disinfectant.
- a. manufacturers' instructions.
  - b. if the dental RIMD can be immersed in water or subject to a high pressure water spray as appropriate for the type of washer- disinfectant being used.
  - c. maximum operating temperature. (In general if a dental RIMD is suitable for autoclaving it is suitable for decontamination in a washer-disinfectant).
  - d. mechanical damage which may occur from the impact of the water jets or other items in the load.
  - e. the compatibility of the process chemicals.

***Equipment***

- 12.4.15 See decontamination equipment section, page 49.

***Procedure***

- 12.4.16 Ensure the washer-disinfectant and all services are operational. The washer-disinfectant should not start if any anomalies are present.
- 12.4.17 Wearing protective clothing, load the rack/machine ensuring that the loading configuration does not impede the cleansing process and that the rotary spray arms can rotate.
- 12.4.18 Only use load carrier and racks with the items for which they were intended.
- 12.4.19 Keep a record of each dental RIMD/RIMD set processed in each washer-disinfectant and each cycle in order to trace the dental RIMD/RIMD set through the decontamination process.

**Cleaning (including pre-cleaning)**

- 12.4.20 Load the load carrier into the washer-disinfector.
- 12.4.21 Secure the door (if fitted), 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. 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 a qualified person (decontamination) 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 time equivalent to the life-time of the equipment plus eleven years.
- 12.4.26 Cycles which were aborted should be documented with the action taken in a log book.
- 12.4.27 Where single-ended washer-disinfectors are used adequate segregation of unprocessed goods from processed goods should take place.

**Cleaning (including pre-cleaning)**

- 12.4.28 Thermal disinfection conditions are defined as  $A_0$  values (see ISO 15883-1, Annex B).
- for thermal disinfection of RIMD an  $A_0$  of not less than 60 is required.
  - all washer-disinfectors complying with EN ISO 15883-2 are required to be capable of providing for disinfection times and temperatures to give an  $A_0$  value up to a maximum value of not less than 3000.
  - typical time-temperature relationships providing these values are shown in table 12-1 below.
- 12.4.29 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.
- 12.4.30 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.
- 12.4.31 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 of:*
- commissioning (installation qualification and operational qualification).
  - performance qualification.
  - periodic testing.
  - annual and revalidation tests.

***Commissioning***

- 12.4.32 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).

## Cleaning (including pre-cleaning)

It consists of:

### *Installation qualification*

- 12.4.33 Verification of calibration of washer-disinfector dental RIMD, automatic control test, water quality tests, water supply temperature, water supply pressure.

### *Operational Qualification*

- 12.4.34 Safety checks, automatic control test, verification of calibration of washer-disinfector RIMD, water system, drainage, venting system, doors and door interlocks, fault interlock, water vapour discharge test, aerosol discharge test, 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, load dryness test and sound pressure.
- 12.4.35 These tests should be carried out when a new washer-disinfector is purchased or when a used washer-disinfector has been relocated to another premises or following critical repairs.
- 12.4.36 The tests should be carried out before the washer-disinfector is used for the first time. Installation and commissioning checks and tests should be performed by a qualified person (decontamination) or other person with specialist technical training in commissioning of washer-disinfector. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the washer-disinfector is functioning correctly.
- 12.4.37 Even though the manufacturer should have tested a washer-disinfector 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 working correctly and is performing correctly to specification.

### *Performance qualification*

- 12.4.38 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-disinfector or when the load profile changes (e.g. new dental RIMD). It should be carried out by a Test Person (or suitably qualified person decontamination).



## Cleaning (including pre-cleaning)

*These tests consist of:*

- a. thermometric tests for a full load of items not previously represented by the reference load.
- b. load dryness test (of dental RIMD requiring reprocessing).
- c. cleaning efficacy test.
- d. process residue test.

### *Periodic testing*

- 12.4.39 After validation and when the washer-disinfector has been passed for use, it is subject to a schedule of periodic tests at daily, weekly quarterly and yearly intervals.
- 12.4.40 The daily, weekly and quarterly tests supply evidence that the washer-disinfector is still operating within the limits established during commissioning.
- 12.4.41 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.
- 12.4.42 Periodic tests consist of the following:
  - a. **Daily:** Spray arm rotation, spray nozzles, removes and clean strainers and filters.
  - b. **Weekly:** Automatic control test, safety checks, daily tests, water hardness, water conductivity and cleaning efficacy test (residual soil detection).
  - c. **Quarterly tests:** Weekly safety checks, automatic control test, verification of calibration of dental RIMD, thermometric test for thermal disinfection and cleaning
  - d. **Annual tests:** Yearly safety checks, automatic control test, verification of calibration of dental RIMD, water system, drainage, doors, door interlocks, fault interlocks, water vapour discharge, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, over-temperature cut-out, thermometric tests for thermal disinfection, load dryness test and process residues.

**Cleaning (including pre-cleaning)****Table 12.1** The following table identifies the minimum level of periodic testing that should be undertaken for washer-disinfector:

Test	EN ISO 15883 Reference
<b>Daily tests</b>	
1. Check spray arm rotation for free movement	N/A
2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages for dental RIMD)	N/A
3. Remove and clean strainers and filters etc	N/A
<b>Weekly tests</b>	
1. Weekly safety checks	N/A
2. Carry out daily tests	N/A
3. Water hardness (all process stages)	6.4.2.2
4. Water conductivity (final rinse stage)	6.4.2.2
5. Automatic control test	6.13
6. Cleaning efficacy test by residual soil detection	6.10.3
<b>Quarterly tests</b>	
1. Weekly safety checks	N/A
2. Automatic control tests	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Thermometric test for thermal disinfection	6.8
5. Cleaning efficacy test	6.10.2, 6.10.3
<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. Water system	6.4

## Cleaning (including pre-cleaning)

-chemical purity	6.4.2.2
-bacterial endotoxins	6.4.2.3
5. Drainage	
-free draining	6.5.2. 6.5.4
-efficacy of discharge	6.5.4
6. Doors and door interlocks	
-cycle start	6.3.1
-in-cycle	6.3.2, 6.3.3
-failed cycle	6.3.7
7. Fault interlock	6.3.5 6.3.6
8. Water vapour discharge test (fluid emission)	6.5.3
9. Chemical additive dosage dosing tests	
-reproducibility	6.9.1
-low level detection	6.9.2
11 Test air for quality	6.11
12. Cleaning efficacy test	6.10.2, 6.10.3
13. Over temperature cut-out test	6.8.5
14. Thermometric test for thermal disinfection	6.8
15. Load dryness test	6.12
16. Process residues – chemical additives (for performance re-qualification only if required)	6.10.4

- 12.4.43 Monitoring and control, cycle variables should be monitored to ensure that the specified parameters are obtained for each cycle. The critical cycle variables are temperature, time, detergent concentration and water pressure or flow rate.

**Cleaning (including pre-cleaning)**

- 12.4.44 Validation, routine monitoring and control should be carried out in accordance with documented procedures in accordance with European standard EN ISO 15883, part 2, 2009.
- 12.4.45 Preventative maintenance should be planned and performed in accordance with International Standards EN ISO 15883-1 and EN ISO 15883-2 and the manufacturers' recommendations.
- 12.4.46 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 12.4.47 The washer-disinfector should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 12.4.48 A qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- 12.4.49 Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.
- 12.4.50 Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers' instructions and/or local policy, procedure, protocol and guidelines, including:
  - a. inspecting and cleaning all filters.
  - b. dismantling and cleaning spray arms and nozzles.
  - c. efficacy tests during operational conditions.

***Ultrasonic Cleaners***

- 12.4.51 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. Cemented glass syringes and lenses will be damaged if repeatedly subjected to this process. The manufacturers' instructions should be considered in relation to the suitability of dental RIMD for ultrasonic cleaning.

***Equipment Required***

- 12.4.52 See decontamination equipment, page 49.

**Cleaning (including pre-cleaning)***Procedure*

- 12.4.53 Staff should wear personal protective equipment at all times while handling contaminated RIMD and working with the ultrasonic cleaner.
- 12.4.54 Fill the tank with potable water (drinking quality) to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- 12.4.55 Bring the solution up to the operating temperature.
- 12.4.56 De-gas the water as recommended by the manufacturer.
- 12.4.57 Place the opened/dismantled RIMD into the basket.
- 12.4.58 Ensure all RIMD are fully immersed.
- 12.4.59 If the RIMD is not for further cleaning, e.g. automated cleaning, record the following:
  - a. method used.
  - b. solution dilution and temperature.
  - c. healthcare worker carrying out procedure.
  - d. date.
  - e. ultrasonic cleaner identification or serial number.
- 12.4.60 Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.
- 12.4.61 Close the lid and initiate the cleaning cycle.
- 12.4.62 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-disinfector for further processing.
- 12.4.63 The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.
- 12.4.64 Combine only RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.
- 12.4.65 Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.
- 12.4.66 It is recommended that the tank be emptied regularly. This should be at intervals not exceeding four hours, or when the water is visibly soiled.

**Cleaning (including pre-cleaning)*****Validation***

- 12.4.67 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.
- 12.4.68 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:
- commissioning (installation qualification and operational qualification).
  - performance qualification.
  - periodic testing.
  - annual and revalidation tests.

***Commissioning***

- 12.4.69 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 tests***

- 12.4.70 Verification of calibration, automatic control test, water quality tests—hardness, and water supply temperature.

***Operational qualification tests***

- 12.4.71 Weekly safety checks, verification of calibration, automatic control test, cleaning efficacy test, water system, drainage, doors and door interlocks, fault interlock, aerosol discharge, chemical additive dosing, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasound activity and sound pressure.
- 12.4.72 These tests should be carried out when a new ultrasonic cleaner is purchased or when a used ultrasonic cleaner is has been relocated to another premises.
- 12.4.73 Installation and commissioning checks and tests should be performed by a qualified person (decontamination) or other person with specialist technical training in commissioning of ultrasonic cleaner.

## Cleaning (including pre-cleaning)

- 12.4.74 Even though the manufacturer should have tested the ultrasonic cleaner 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 working correctly.

### *Performance qualification*

- 12.4.75 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. Performance qualification is indicated for initial use of a new/relocated ultrasonic cleaner or when there is a requirement to process a new type of product. It should be carried out by a Test Person (or other suitably qualified person).

*These tests consist of:*

- a. cleaning efficacy test, load dryness test and process residues test.
- b. load dryness test.
- c. process residue test.

### *Periodic testing*

- 12.4.76 After validation and when the ultrasonic cleaner has been passed for use, it is subject to a schedule of periodic tests and daily, weekly, quarterly and yearly intervals.
- 12.4.77 The daily, weekly and quarterly tests supply evidence that the ultrasonic cleaner is still operating within the limits established during commissioning.
- 12.4.78 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.

*These tests consist of:*

- a. **Daily:** Remove and clean strainers and filters.
- b. **Weekly:** Daily tests, automatic control test (if using an automated ultrasonic cleaner) safety checks, and cleaning efficacy test (residual soil detection).
- c. **Quarterly tests:** Weekly safety checks, automatic control test, verification of calibration of dental RIMD, test for ultrasonic activity and cleaning efficacy test.

**Cleaning (including pre-cleaning)**

- d. **Annual tests:** Weekly safety checks, automatic control test, verification of calibration of dental RIMD, water system, drainage, doors and door interlocks, fault interlock, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, chamber wall and load carrier temperature test, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasonic activity and sound pressure test.

**Table 12.2:** The following table identifies the minimum level of periodic testing that should be undertaken for automated ultrasonic cleaner:

Test	EN ISO 15883 Reference
<b>Daily tests</b>	
1. If fitted check spray arm rotation for free movement	N/A
2. If fitted check spray nozzles for blockage (paying particular attention to those fitted to carriages for dental RIMD)	N/A
3. Remove and clean strainers and filters etc	N/A
<b>Weekly tests</b>	
1. Weekly safety checks	N/A
2. Carry out daily tests	N/A
3. Automatic control test (if using an automated ultrasonic cleaner)	6.13
4. Cleaning efficacy test by residual soil detection	6.10.3
<b>Quarterly tests</b>	
1. Weekly safety checks	N/A
2. Automatic control tests (if using an automated ultrasonic cleaner)	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Test for ultrasonic activity*	6
5. Cleaning efficacy test	6.10.2, 6.10.3



## Cleaning (including pre-cleaning)

Yearly and revalidation tests (requalification in EN 15883 terminology)	
1. Yearly safety checks	N/A
2. Automatic control test (if using an automated ultrasonic cleaner)	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Water system	6.4
-chemical purity	6.4.2.2
-bacterial endotoxins	6.4.2.3
5. Drainage	
-free draining	6.5.2, 6.5.4
-efficacy of discharge	6.5.4
6. Doors and door interlocks	
-cycle start	6.3.1
-in-cycle	6.3.2, 6.3.3
-failed cycle	6.3.7
7. Fault interlock	6.3.5, 6.3.6
8. Water vapour discharge test (fluid emission)	6.5.3
9. Chemical additive dosing tests (if using an automated ultrasonic cleaner)	
-reproducibility	6.9.1
-low level detection	6.9.2
10. Load carriers-alignment (if load carriers used)	6.7.1
11. Test for air quality (if a ventilation system is fitted)	6.11
12. Cleaning efficacy test	6.10.2, 6.10.3
13. Over temperature cut-out test (if using an automated ultrasonic cleaner)	6.8.5
14. Thermometric test for thermal disinfection (if a disinfection stage is fitted)	6.8
15. Load dryness test (if a drying stage is fitted)	6.12
16. Test for ultrasonic activity	N/A

**Cleaning (including pre-cleaning)**

*(Note: EN ISO 15883 does not contain a test for ultrasonic activity. A test method is provided within this document.)*

**Monitoring and control**

- 12.4.79 Validation, routine monitoring and control should be carried out in accordance with documented procedures as recommended by the manufacturers' instructions. It is recommended that a soil test and a residual protein test should be performed as part of the weekly tests to establish the efficacy of the washers' cleaning process. The following simple test may be undertaken to establish that there is ultrasonic action in the tank.

**Maintenance**

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

**Test for Ultrasonic Activity (reference HTM 2030)**

- 12.4.84 The activity of an ultrasonic cleaner may be tested by the erosion pattern which is created on aluminium foil exposed in a bath for a short period. Note: the activity will not be uniform throughout the bath. The exposure time will depend on the thickness of the foil, the hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.

**Equipment**

- 12.4.85 Aluminium foil (sold as aluminium foil wrap for cooking).
- 12.4.86 Steriliser indicator tape.
- 12.4.87 Stopwatch.
- 12.4.88 Ruler/tape measure graduated in mm.

**Cleaning (including pre-cleaning)*****Method***

- 12.4.89 Measure the depth of the bath from the level of the lid to the bottom of the bath.
- 12.4.90 Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.
- 12.4.91 Carry out the manufacturer's recommended start-up procedure.
- 12.4.92 Ensure that the water in the tank is at the required level, that the amount of chemical additive specified by the manufacturer has been added and that the water in the tank is at the specified operating temperature.
- 12.4.93 Using strips of steriliser indicator tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3 x 3 grid.
- 12.4.94 The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should not be more than 10mm above, but not touching the bottom of the bath.
- 12.4.95 Operate the bath for the predetermined exposure time.
- 12.4.96 Remove the strips from the bath, blot dry and examine.
- 12.4.97 The zones of maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent (on visual inspection).
- 12.4.98 On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

**Section Four: Manual cleaning*****Immersion***

- 12.4.99 The use of automated cleaning methods may be contra-indicated for washing certain delicate or complex dental RIMD. These dental RIMD should be carefully hand-washed and rinsed according to the manufacturers' instructions.

***Equipment required***

- 12.4.100 A sink (not a hand hygiene sink), or a receptacle which will hold sufficient volume of water/detergent so that the item of equipment to be cleaned can be fully immersed.

### Cleaning (including pre-cleaning)

- 12.4.101 Dirty put-down area adjacent to the wash sink adjacent to a washed dental RIMD put-down area, adjacent to the rinse sink adjacent to the rinsed dental RIMD out-down area

Figure 12-3: Sink required for manual cleaning



- 12.4.102 A validated method of dispensing a measured quantity of detergent.
- 12.4.103 A method of controlling temperature of the water in the wash and rinse sinks: thermostatic mixer taps are preferred.
- 12.4.104 A warm detergent solution. (Follow manufacturers' instructions for dilution and temperature).
- 12.4.105 A selection of brushes in a range of diameters and lengths for cleaning both the external surfaces and the internal surfaces of RIMD.
- 12.4.106 After cleaning, manually washed RIMD that are not to be further processed through the washer-disinfector should be dried.
- 12.4.107 RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free, absorbent wipe should be use

#### *Procedure*

- 12.4.108 Healthcare workers should wear personal protective equipment at all times while handling contaminated RIMD.

## Cleaning (including pre-cleaning)

- 12.4.109 The sink should be filled with potable water to a predetermined level, at the specified temperature and with the appropriate amount of detergent (as per manufacturers' instructions). The sink should be solely dedicated for the cleaning of dental RIMD and not for any other purpose.
- 12.4.110 Detergents used should be specifically designed to clean RIMD: **washing up liquid must not be used**. A mild detergent is preferred for manual cleaning of RIMD (pH range 8.0–11.5).
- 12.4.111 Detergent dilution and water temperature should be in accordance with the manufacturers' instructions and local policies, procedures, protocols and guidelines.
- 12.4.112 Consideration should be given to the use of an enzymatic detergent to facilitate the cleaning of RIMD with channels or complex parts.
- 12.4.113 Carefully immerse the item in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reaches all surfaces including those of lumened RIMD.
- 12.4.114 Remove all visible soiling from the RIMD, including lumens and valves. Remove stubborn staining by using a non-abrasive scouring pad or soaking in an approved stain-removing solution.
- 12.4.115 Flush all lumened RIMD with a jet-gun (discharge under water).
- 12.4.116 Rinse the item finally in warm-to-hot water (unless contra-indicated).
- 12.4.117 Dry mechanically in a drying cabinet or hand dry with a clean, lint-free cloth.
- (Note: Items should not be left to dry in ambient air.)*
- 12.4.118 Inspect RIMD and equipment to establish that they are clean before further processing or storage.
- 12.4.119 Thoroughly wash and dry receptacles before storing and re-use.
- 12.4.120 Cleaning brushes should be identified for cleaning only and should be washed, thermally disinfected, and stored dry.
- 12.4.121 A record should be kept of each RIMD/RIMD set that has been manually cleaned.
- 12.4.122 The records should contain:
- name of RIMD/RIMD set.
  - name of processor.

**Cleaning (including pre-cleaning)**

- c. date.
- d. type of cleaning.
- e. type of detergent and detergent dilution used.

***Monitoring and control***

12.4.123 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.

12.4.124 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.

*(Note: If either the cleaning solution or rinse water becomes visibly soiled or contaminated, it should be changed and the process repeated.)*

***Maintenance***

12.4.125 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.

***Non-Immersion***

12.4.126 Non-immersion manual cleaning methods are appropriate for certain RIMD as some RIMD may become compromised by soaking in aqueous solutions, e.g. electrical, powered RIMD. Cleaning information about the methods to be used for specific devices should be sought from individual RIMD manufacturers.

***Equipment required***

12.4.127 A warm detergent solution. Follow manufacturers' instructions for dilution and temperature.

12.4.128 RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free, absorbent wipe should be used.

**Cleaning (including pre-cleaning)*****Procedure***

- 12.4.129 If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- 12.4.130 Wearing protective clothing immerse the cleaning cloth in the detergent solution and wring thoroughly.
- 12.4.131 Commencing with the upper surface of the RIMD, wipe thoroughly ensuring that the detergent solution does not enter electrical components.
- 12.4.132 Periodically rinse the cloth in clean water and repeat the previous two steps.
- 12.4.133 Remove detergent solution using clean, damp, non-linting cloth.
- 12.4.134 Dental RIMD should be placed in a drying cabinet. Where a drying cabinet is not available, a clean disposable lint free absorbent wipe should be used.

***Monitoring and control***

- 12.4.135 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.

**Section Five: Dental hand-pieces**

- 12.4.136 After each 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. This procedure is designed to dislodge any service user-derived material that may have been retracted into the air and/or water lines due to failure of antiretraction valves.
- 12.4.137 These valves are designed to prevent material or fluids from being retracted or siphoned back into air and/or waterlines but studies have show that failure of antiretraction valves is not uncommon.

**Cleaning (including pre-cleaning)**

- 12.4.138 Following air and waterline purging, handpieces should be detached from the DCU RIMD line, cleaned, decontaminated and sterilised according to the manufacturer's instructions and local policy.
- 12.4.139 Automated pre-sterilisation cleaning of handpieces is the preferred method of handpiece decontamination.
- 12.4.140 However, manual cleaning is still widely practiced. The outside of the handpiece should be cleaned with detergent and warm water (follow the manufacturers' instructions with regard to type of detergent recommended).
- 12.4.141 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).
- 12.4.142 Cover the working end of the handpiece with disposable paper towel to absorb the residual oil and clean away any excess oil.
- 12.4.143 Following cleaning, package appropriately and sterilise in a steriliser with a pre-sterilisation vacuum phase.
- 12.4.144 Dental handpieces should preferably be processed through a washer-disinfector equipped with lumen attachments.

**Figure 12-1: Dental handpieces**





## 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 RIMD.

### 13.3 Contents

Section One: Level of disinfection

Section Two: Disinfection process

### 13.4 Procedure

#### Section One: Level of disinfection

- 13.4.1 **High-level disinfection** – this is the minimum treatment recommended for reprocessing RIMD that cannot be sterilised, for use in semi-critical sites or when there are specific concerns regarding contamination of surfaces with species of mycobacteria, for example, mycobacterium tuberculosis.
- 13.4.2 **Low-level disinfection** – this is the minimum treatment recommended for reprocessing RIMD for use in noncritical sites.

#### Section Two: Disinfection process

- 13.4.3 **Thermal disinfection** can be achieved in a thermal washer-disinfector by choosing the appropriate cycle.

## Disinfection

- 13.4.4 **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.
- 13.4.5 Disinfection should be carried out using a thermal disinfection process whenever practicable. Chemical disinfection should be employed only when required by the RIMD manufacturers' instructions.

### *Thermal Disinfection*

- 13.4.6 If items can withstand heat and moisture and do not require sterilisation, then thermal disinfection using moist heat at temperatures and times that destroy pathogenic agents, is the simplest, most efficient and cost-effective method of disinfection.

### *Equipment required*

- 13.4.7 Automated equipment, such as washer-disinfectors are recommended for use in thermal disinfection processes.
- 13.4.8 The level of disinfection depends on the water temperature and the exposure time. Thermal washer-disinfectors can be programmed to deliver a range of disinfection levels, depending on the cycle selected (i.e. set temperature and exposure times).
- 13.4.9 The manufacturers' instructions should be followed to achieve the required level of disinfection.

### *Monitoring and control*

- 13.4.10 Whenever practicable, disinfection should be carried out using a validated disinfection process using automated equipment (e.g. washer-disinfector).
- 13.4.11 Thermal disinfection equipment should be provided with means to independently monitor and/or record the time for which the load was exposed to the required temperature.
- 13.4.12 The thermal disinfection process should provide adequate assurance of the required microbial lethality.

**Disinfection***Chemical Disinfection*

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

*Equipment required*

- 13.4.14 RIMD disinfectant or sterilant.
- 13.4.15 Automated equipment.

*Monitoring and control*

- 13.4.16 Chemical disinfection processes should provide adequate assurance of the required microbial lethality.
- 13.4.17 Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.
- 13.4.18 Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- 13.4.19 All surfaces should be immersed and channels flushed whether manually or automatically to ensure the solution is present within the channels during ensuring the decontamination process.
- 13.4.20 Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.
- 13.4.21 After chemical disinfection 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.
- 13.4.22 When rinsing, channels should be flushed thoroughly if rinsing is 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 49.

##### Section Two: Procedure

14.4.2 RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free, absorbent wipe should be used.

14.4.3 Care should be taken not to exceed the temperature tolerances advised by the manufacturer.

14.4.4 Dry the 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, e.g. some endoscope washer-disinfectors.

**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.
- 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.
- 14.4.11 Drying cabinet maintenance and repair log book should be maintained for each dryer.
- 14.4.12 The dryer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 14.4.13 Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485: 2003(E).

## 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 area 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

Section Six: Maintenance

## Post cleaning inspection and function testing

### 15.4 Procedure

#### Section One: Equipment

- 15.4.1 Work bench.
- 15.4.2 Magnifying glass and oblique of stereo-microscope.
- 15.4.3 Light source.
- 15.4.4 Diathermy pin hole detector

#### Section Two: Procedure

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

- 15.4.5 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.
- 15.4.6 Check that the operating cycle is in accordance with the specification for the load used, (e.g. laryngeal masks do not require rinse aid).
- 15.4.7 Check that arms rotate. If arms do not rotate, loads should be rejected as the load has not been exposed to the water spray effectively.
- 15.4.8 Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- 15.4.9 If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the RIMD or RIMD may not be compatible with automated washing.
- 15.4.10 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.
- 15.4.11 Make a visual inspection of the load for dryness.
- 15.4.12 Where a load may not be properly cleaned the load is rejected and returned for re-cleaning.

### Post cleaning inspection and function testing

- 15.4.13 Unless there is clear indication why a small percentage of RIMD in a load were not cleaned and/or dried effectively, the entire load should be returned for re-processing.
- 15.4.14 Where a small percentage of the load is suspect the items are rejected and returned for re-cleaning.
- 15.4.15 Any load or items rejected should be documented as a non conformance; this non conformance should also be documented into the washer-disinfector log book for further investigation.

### Section Three: Documentation post automated cleaning

- 15.4.16 All documentation for automated cleaning should contain the following information:
  - a. washer-disinfector serial or identification number.
  - b. cycle number.
  - c. type of washer-disinfector.
  - d. type of cycle used.
  - e. date and time of start of cycle.
  - f. load content, e.g. general RIMD, stitch set, mayo scissors.
  - g. critical parameters for the specific washer-disinfector cycle.
  - h. operators name.
  - i. results of washer-disinfector process.
  - j. signature of an authorised qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters.
  - k. any notes or observation for the process cycle.
- 15.4.17 All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.



## Post cleaning inspection and function testing

- 15.4.18 Before commencing inspection the person carrying out inspection should ensure that:
- RIMD/RIMD set has been recorded as being through the specific cleaning process.
  - if there is no record of cleaning the RIMD/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.
  - the signature of identified responsible person confirming that the cycle has passed.

### Section Four: Inspection and function testing

- 15.4.19 Each RIMD set should be inspected separately.
- 15.4.20 Box joints, serrations and crevices, should be critically inspected for cleanliness.
- 15.4.21 Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.
- 15.4.22 Jaws and teeth should be checked for alignment.
- 15.4.23 Ratchets should be checked for security.
- 15.4.24 Ratchets should close easily and hold firmly.
- 15.4.25 Any damaged, incomplete or malfunctioning RIMD should be reported immediately to the supervisor.
- 15.4.26 Cannulated RIMD should be checked to ensure channel is patent.
- 15.4.27 Telescopes and light cables should be function checked as per manufacturers' instructions.
- 15.4.28 Each RIMD set should be checked for completeness and defects.
- 15.4.29 Cutting edges (on RIMD such as scissors, rongeurs, chisels, curettes) should be checked for sharpness.
- 15.4.30 Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.

**Post cleaning inspection and function testing**

- 15.4.31 RIMD that have an outer insulation coating, for example diathermy forceps etc., require close inspection to ensure that the insulation remains intact. Insulated RIMD should be checked using a diathermy pin point tester. Damaged surfaces not only will allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and service users.
- 15.4.32 Each RIMD should be checked that there is free movement of all parts and that joints do not stick. A water based lubricant may be used if required.
- 15.4.33 Each RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.
- 15.4.34 Each RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.
- 15.4.35 The diathermy pin hole detector should be used in accordance with the manufacturers' instructions to ensure safe use of equipment.

**Section Five: Monitoring and control**

- 15.4.36 The user should be aware of the factors that may alter the efficacy of the method:
  - a. staff training/competence.
  - b. age of the RIMD.

**Section Six: Maintenance**

- 15.4.37 Preventative maintenance is to be planned and performed for all equipment, (e.g. light source and pin hole detector) in accordance with documented procedures as recommended by the manufacturers' recommendations.
- 15.4.38 Records of all maintenance, validation and servicing should be maintained in accordance with EN ISO 13485:2003(E).

## Post cleaning inspection and function testing

Figure 15-1: Post cleaning inspection



## Packaging

### 16. Packaging

#### 16.1 Introduction

After cleaning and decontamination, dental RIMD have to be appropriately packaged prior to sterilisation by autoclaving. Dental 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

## 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. 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, 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 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 the minimum of 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 Sequential wrapping using two barrier-type wrappers is recommended as it provides a torturous pathway to impede microbial migration.

### Section Two: Packaging systems

*Packaging systems should:*

- 16.4.15 **Be appropriate to the items being sterilised, i.e.**
- permit identification of contents.
  - permit complete and secured enclosure of items.
  - protect package contents from physical damage.
  - permit delivery of contents without contamination.
  - maintain sterility of package contents until opened.
  - should facilitate aseptic technique at all times including opening of package.
- 16.4.16 **Be appropriate to the method of sterilisation, i.e.**
- provide adequate seal integrity.
  - provide an adequate barrier to particulate matter and fluids.
  - be compatible with and able to withstand physical conditions of the sterilisation process.
  - allow penetration and removal of sterilant.
  - maintain integrity of the pack.
  - permit use of material compatible (i.e. non-degradable) with the sterilisation process.
- 16.4.17 **Be used according to the manufacturers' instructions**
- Be of the following:*
- resistant to punctures, tears and other damage which may break the barrier and cause contamination.

- b. resistant to penetration by micro-organisms from the surrounding environment.
- c. free of holes.
- d. be 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:*

- 16.4.18 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.
- 16.4.19 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.
- 16.4.20 Be stored on shelves and clear of the floor.
- 16.4.21 Be rotated to ensure it does not exceed its shelf life.

### Section Four: Single use packaging

- 16.4.22 The medical device regulations include a requirement that sterile 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 RIMD.

### Section Five: Types of packaging

*Papers and non-wovens*

- 16.4.23 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.

## Packaging

- 16.4.24 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.
- 16.4.25 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:*

- 16.4.26 Should be easily disassembled for cleaning, drying and storage.
- 16.4.27 Should be suitable for the method of sterilisation being used.
- 16.4.28 Should be compatible to the cleaning method and cleaning agent being used.
- 16.4.29 Should be suitable to the storage configuration.
- 16.4.30 Should have locking devices which are tamperproof and non resealable.
- 16.4.31 Should be packed in a manner which allows for penetration of the sterilising agent.
- 16.4.32 Lid and contents should be removable without the risk of contamination of the contents.
- 16.4.33 Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.
- 16.4.34 The filter plate should be examined for integrity both before installation and after the sterilisation process.
- 16.4.35 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.
- 16.4.36 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.
- 16.4.37 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.



## Packaging

- 16.4.38 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.
- 16.4.39 Containers should be cleaned between each use; automated cleaning is the preferred method of cleaning.

**Section Six: Packaging techniques**

- 16.4.40 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.
- 16.4.41 RIMD should be wrapped in a manner which minimises the risk of contamination during opening and removal of contents.

*Flat wrapping material**Equipment required*

- 16.4.42 Packaging material.
- 16.4.43 Sterilisation chemical indicator tape.
- 16.4.44 Marking pen.
- 16.4.45 Label (where applicable).
- 16.4.46 Tray liners.

*Procedure (parcel-fold wrapping method)*

- 16.4.47 Select appropriate packaging material and place on work top.
- 16.4.48 The RIMD set is placed on the wrap, approximately in the centre of the packaging material.
- 16.4.49 Verify the accuracy of the RIMD identification label with the RIMD/RIMD set, (i.e. corresponds to RIMD list, internal tray label, etc).
- 16.4.50 The long edge of the tray should be aligned parallel to the long edge of the wrap.
- 16.4.51 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.

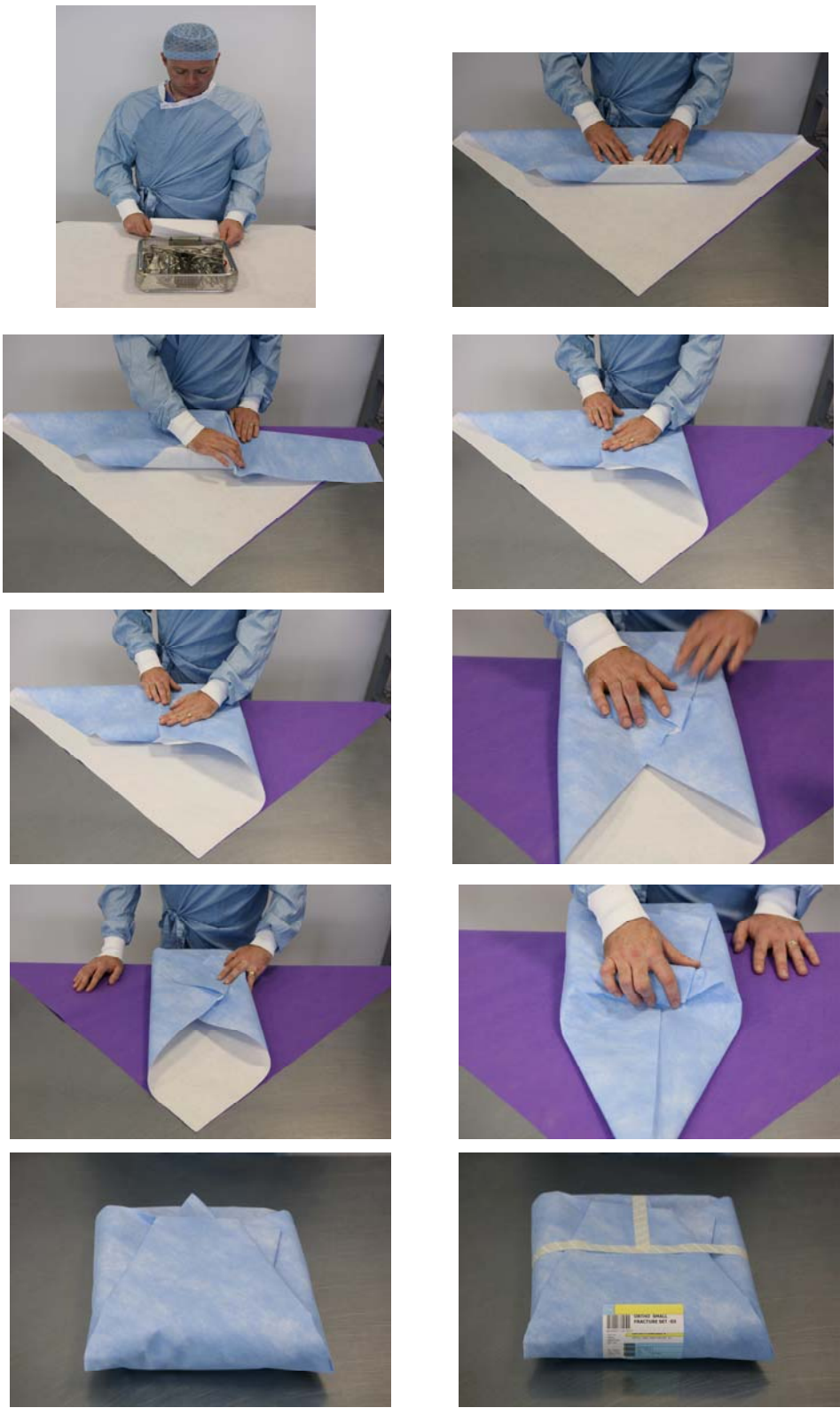
**Packaging**

- 16.4.52 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.
- 16.4.53 The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- 16.4.54 The same procedure may then be repeated for an outer wrap(s).
- 16.4.55 The wrap is secured in position using sterilisation indicator tape.
- 16.4.56 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- 16.4.57 RIMD identification label is placed on outside wrap.

***Procedure (envelope wrapping method)***

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

Figure 16-1: Envelope wrapping method



## Packaging

- 16.4.69 **Pouches and bags (requiring folding)** 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 required*

- 16.4.70 Pouches and/or bags.
- 16.4.71 Sterilisation chemical indicator tape.
- 16.4.72 Marking pen.
- 16.4.73 Label (where applicable).

### *Procedure*

- 16.4.74 The corners at the open end of the pouch are folded diagonally to give mitred corners.
- 16.4.75 The top of the pouch is then folded over three times in succession.
- 16.4.76 The same procedure may then be repeated for an outer wrap(s).
- 16.4.77 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.
- 16.4.78 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 RIMD to be viewed.
- 16.4.79 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- 16.4.80 RIMD identification label is placed on the outside wrap.

### *Self-seal pouches*

- 16.4.81 When closing self seal bags follow manufacturers' instructions for sealing.

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

#### *General principles*

- 16.4.82 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.

**Packaging**

- 16.4.83 Packaging intended for heat sealing may be film coated; grids lacquered, or have an adhesive band.
- 16.4.84 Heat seal pouches should be sealed using suitable heat sealing equipment.
- 16.4.85 Heat seal pouches should be hermetically sealed.
- 16.4.86 Heat seal pouches should provide a seal of proven integrity and not allow resealing.
- 16.4.87 Before commencing wrapping procedure ensure that work area and packaging equipment are clean.
- 16.4.88 Check size of edges for easy aseptic opening by user.

***Equipment required***

- 16.4.89 Heat-seal pouches.
- 16.4.90 Heat sealer.
- 16.4.91 Marking pen.
- 16.4.92 Label (where applicable).

***Procedure***

- 16.4.93 Select appropriate size heat seal pouch.
- 16.4.94 Place RIMD into pouch.
- 16.4.95 Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.
- 16.4.96 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.
- 16.4.97 Place open end of pouch in heat sealer.
- 16.4.98 Apply heat and pressure to the surface of the open end of the heat seal pouch.
- 16.4.99 Checks should be made that the seal is complete, especially over the gusset folds of the pouches.

## Packaging

- 16.4.100 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.
- 16.4.101 The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- 16.4.102 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.
- 16.4.103 Edges of inner heat seal pouches should not be folded as air maybe entrapped in the folds and inhibit sterilisation.
- 16.4.104 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 RIMD to be viewed.
- 16.4.105 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 steriliant into and out of the package.
- 16.4.106 If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.
- 16.4.107 It is important to wrap the RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- 16.4.108 Use adhesive RIMD identification label, do not write on the paper side of the pouch.
- 16.4.109 RIMD identification label is placed on the outside packaging.

## Packaging

Figure 16-2: Using the heat seal



Figure 16-3: Heat seal pouch



## Packaging

### Section Seven: Sealing of packs and bags

16.4.110 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:*

16.4.111 Allow sterilisation.

16.4.112 Avoid constriction of the package.

16.4.113 Maintain package integrity.

*(Note: The accessories should also be recommended by the manufacturer.)*

*The following accessories should not be used:*

16.4.114 Tape (other than sterilisation chemical indicator tape).

16.4.115 Safety pins.

16.4.116 Paper clips.

16.4.117 Staples.

### *Sterilising indicator tape*

*Sterilising indicator should be:*

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

16.4.119 Pressure sensitive.

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

16.4.121 Compatible with the wrapping material used.

16.4.122 Heat stable.

16.4.123 Moisture-stable and permeable to the sterilising agent.



**Section Eight: Labelling**

16.4.124 Packages to be sterilised should be labelled before sterilisation.

16.4.125 The information of the label should include the following:

- a. name of product.
- b. name of wrapper.
- c. use by date or/and sterilisation date.
- d. where appropriate the word sterile.

16.4.126 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.

16.4.127 Marking pen used to label the pack should be indelible, nonbleeding, and non-toxic. Sharp tipped water based or ball type pens should not be used as these may compromise the integrity of the pack.

16.4.128 Label fixed to the surface of the packaging should be able to withstand exposure to the sterilisation process.

16.4.129 Policies, procedures, protocols and guidelines for wrapping and labelling and sealing of RIMD to be sterilised should be developed, reviewed periodically, and readily available within the department.

**Section Nine: Monitoring and control**

*The following should be monitored during labelling:*

16.4.130 General appearance of the packaging material.

16.4.131 Whether packages are complete.

16.4.132 Whether the correct products and packaging material are used.

16.4.133 Whether the labelling is correct on the product.

16.4.134 Whether the sealing is correct.

## Packaging

- 16.4.135 Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.
- 16.4.136 Material should be checked for tears, flaws and holes.
- 16.4.137 Containers seals and filters should be checked.
- 16.4.138 Containers should be checked for dints which may interfere with maintaining sterility.

## Section Ten: Maintenance

- 16.4.139 Reusable containers should be subject to thermometric performance tests.
- 16.4.140 Containers should be validated periodically for reuse according to manufacturers' instructions.
- 16.4.141 Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policies, procedures, protocols and guidelines.
- 16.4.142 Heat seal efficiency, integrity and strength test should be preformed on each heat sealer daily.
- 16.4.143 Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.
- 16.4.144 Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.
- 16.4.145 Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.
- 16.4.146 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 16.4.147 The heat sealer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 16.4.148 Records of all maintenance, validation and servicing should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.

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- 16.4.149 A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

*(Note: 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.)*

**Figure 16-4: Labelling**



## Sterilisation

# 17. Sterilisation

## 17.1 Introduction

Sterilisation is a process including the use of a physical or chemical procedure to destroy all microbial life including high resistant bacterial spores. The function of sterilisation is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones. To be effective, cleaning must precede sterilisation.

Steam sterilisation is the most practical method for sterilising reusable medical devices in dental clinics.

## 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 loading trolley prior to sterilisation

Section Five: Loading the steriliser

Section Six: Steam sterilisation of dental RIMD

Section Seven: Criteria for release of processed dental RIMD

Section Eight: Sterilisation records

Section Nine: Validation

Section Ten: Monitoring and control

Section Eleven: Maintenance

## 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 RIMD are referred to as porous load sterilisers.
- 17.4.3 Low temperature processes include ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), and Hydrogen Peroxide Plasma.
- 17.4.4 The preferred method of low temperature sterilisation is vapour phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma.

*(Note: Downward displacement sterilisers are not appropriate for sterilising wrapped loads of dental RIMD or for items that contain a lumen (e.g. dental handpieces), and **should not be used for these purposes under any circumstances.**)*

- 17.4.5 Steam 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.

### Section Two: Choice of sterilisation process

- 17.4.6 High temperature steam sterilisation at 134-137°C for three minutes in a porous load steriliser is generally the method of sterilisation used for RIMD.
- 17.4.7 A lower temperature steam sterilisation process may be required for sterilisation of RIMD.
- 17.4.8 Low temperature vapour phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma sterilisation may be required for sterilisation of RIMD.
- 17.4.9 Hydrogen Peroxide Plasma, Hydrogen Peroxide Gas Plasma is the preferred low temperature sterilisation method because, compared with EO and LTSF, the installation and health and safety requirements are greatly reduced.

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(Note: The manufacturers instructions for RIMD purchased from the United States will often specify steam sterilisation cycles that are different from the standard cycle given above, e.g. 132oC for ten minutes. In most cases these RIMD can be processed through the standard cycle but confirmation should be obtained from the RIMD manufacturer.)

**Figure 17-1: Steriliser**



**Table 17-1: Sterilisation temperatures, steam pressures and hold times**

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilisation Hold time
121 <sup>o</sup> C	1.03 bar gauge	124 <sup>o</sup> C	15 minutes
134 <sup>o</sup> C	2.30 bar gauge	37 <sup>o</sup> C	3 minutes

**Section Three: Steam sterilisation**

- 17.4.10 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.
- 17.4.11 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.

**Sterilisation**

- 17.4.12 Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.
- 17.4.13 These sterilisers have a pump to remove air from the steriliser chamber and load. When loading the steriliser, dental 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.
- 17.4.14 Sterilised dental RIMD packs should be allowed to dry inside the steriliser before removing and handling.
- 17.4.15 Many modern vacuum sterilisers have a post-sterilisation drying cycle that facilitates drying of dental RIMD packs.
- 17.4.16 The operating cycle of a porous load steriliser generally has five stages:
  - a. air removal.
  - b. steam admission.
  - c. sterilisation holding time.
  - d. vacuum drying.
  - e. filtered air admission.

**Section Four: Loading the loading trolley prior to sterilisation*****Equipment***

- 17.4.17 See decontamination equipment, page 49.
- 17.4.18 Loading trolley.
- 17.4.19 IT based/manual tracking system and accessories, i.e. paper, pen, scanner.
- 17.4.20 Batch control labeller.
- 17.4.21 Personal protective equipment—(heat resistant gloves).

## Sterilisation

### *Procedure*

- 17.4.22 Healthcare workers should wear personal protective equipment.
- 17.4.23 Healthcare workers should ensure that all items within the load are compatible with the process to which they are to be exposed.
- 17.4.24 Loading should allow for free circulation of steam around each pack and each item.
- 17.4.25 RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
- 17.4.26 Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.
- 17.4.27 Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.
- 17.4.28 Hollowware should be placed upside-down or tilted, to prevent collection of condensate.
- 17.4.29 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 air and steam into and out of the package.
- 17.4.30 Containers should be loaded onto the trolley such that an air space is formed between each container layer.
- 17.4.31 When using the basket system healthcare workers should ensure that the appropriate size basket is used. Select the height of the basket so that there will always be a few centimetre air gap between the pack and the basket above.
- 17.4.32 When loading, healthcare workers should ensure that each RIMD is labelled.
- 17.4.33 When loading is complete, each item on the loading trolley should be recorded using the IT (or manual) tracking system.

### **Section Five: Loading the steriliser**

- 17.4.34 Healthcare workers should load the steriliser using the loading trolley.
- 17.4.35 Healthcare workers should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.



## Sterilisation

- 17.4.36 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.
- 17.4.37 Manufacturers' instructions and protocols agreed during validation should be followed for loading.
- 17.4.38 Overloading of sterilisers may compromise the process.

**Section Six: Steam sterilisation of dental RIMD**

- 17.4.39 Healthcare workers should wear personal protective equipment.
- 17.4.40 Healthcare workers should ensure that all necessary tests and maintenance have been carried out satisfactorily before using the steriliser. Healthcare workers should ensure that the cycle recorder(s) has sufficient paper and ink to record the cycle.
- 17.4.41 Healthcare workers 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 products.)*
- 17.4.42 Healthcare workers should initiate the cycle in accordance with the steriliser manufacturers' instructions.
- 17.4.43 Where single door steriliser is in use a system should be in place to ensure segregation of non sterile and sterile RIMD.
- 17.4.44 When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.
- 17.4.45 The fail cycle may require a special key to open the steriliser door.
- 17.4.46 On a pass cycle, the load should be removed and held in quarantine in the cooling area until the sterile produce release procedure has been completed.

## Sterilisation

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

- 17.4.47 In order to release processed 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 policy, procedure, protocol and guideline 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 healthcare workers who have been trained to undertake this task and have been authorised to do so by the decontamination unit manager.

#### *Sterilisation cycle verification*

- 17.4.48 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 independent recorder not from the automatic controller record.
- 17.4.49 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.
- 17.4.50 A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

Figure 17-2: Cycle records



### Inspection of sterilised load

17.4.51 Each item sterilised should be inspected to ensure that:

- chemical process indicators have changed colour as described in the indicator manufacturers' instructions. (Chemical process indicators 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 dampness.
- all labels are intact and legible.

17.4.52 Any load RIMD not meeting these criteria should be rejected and quarantined, non conformance must be recorded and the RIMD returned to the clean room for repackaging and sterilisation.

### Section Eight: Sterilisation records

17.4.53 Sterilisation cycle records should contain the following information for each sterilisation cycle:

- steriliser identification or serial number.
- the cycle number and batch number if applicable.

**Sterilisation**

- c. name of the loading operator and unloading operator.
  - d. type of cycle used.
  - e. date and time of start of cycle.
  - f. contents of the load.
  - g. chart record and/or print-out from steriliser cycle.
  - h. signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.
- 17.4.54 Any notes or observation for the process cycle.
- 17.4.55 Read out results of physical, chemical or biological indicators that are used.
- 17.4.56 All records should be retained for the lifetime of the steriliser plus eleven years.

**Section Nine: Validation**

- 17.4.57 Sterilisation cannot be confirmed by inspection and testing of the product. Thus the sterilisation processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained.
- 17.4.58 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that a steam steriliser is functioning correctly and that it will produce sterilised loads consistently. The purpose of routine monitoring and control is to demonstrate that a validated and specified sterilisation process has been completed successfully during every cycle.
- 17.4.59 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.

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

*Commissioning*

- 17.4.60 **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.

*Operational qualification*

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

*It consists of:*

- a. air leakage test.
  - b. thermometric test.
  - c. calibration.
  - d. steam penetration test.
- 17.4.62 These tests should be carried out when a new steriliser is purchased or when a used steriliser has been relocated to another premises.
- 17.4.63 The tests should be carried out before the steriliser is used for the first time.
- 17.4.64 Installation and operational checks and tests should be performed by a person with specialist technical training in testing of sterilisers.
- 17.4.65 Data from the installation and operational tests provide evidence that the steriliser is functioning correctly.

## Sterilisation

### *Performance Qualification*

- 17.4.66 Performance qualification is required to show that sterilising conditions are attained for loads and test loads that are assessed by the user to be difficult to sterilise. Performance qualification is required for initial use of a new/relocated steriliser or when the load profile changes (e.g. new dental RIMD). It should be carried out by a Test Person (or other suitably qualified person).

*These tests consist of:*

- a. air leakage tests (automatic).
- b. thermometric tests of all RIMD to be processed.
- c. steam penetration and complete sterilant contact of all test loads.
- d. load dryness test (of RIMD requiring reprocessing).
- e. microbiological tests.

- 17.4.67 The decontamination unit manager should identify all the types of load to be sterilised agree worst case loads to be tested. The performance qualification test protocol and data should be audited by the qualified person (decontamination).

### *Periodic testing*

- 17.4.68 Periodic testing consists of a programme of tests that are intended to demonstrate that the sterilisers' performance is satisfactory.
- 17.4.69 The appropriate tests should be carried out at daily, weekly, quarterly and annual intervals.
- 17.4.70 A Test Person or qualified person (decontamination) should draw up a schedule for periodic testing. It is the responsibility of the Test Person or qualified person (decontamination) and the decontamination unit manager to ensure that these tests are performed.

### *Daily Test—Steam Penetration Test /Bowie and Dick (EN ISO 11140)*

- 17.4.71 The steam penetration test is intended to show that steam will penetrate rapidly and evenly into a test device that is at least as difficult to sterilise as the intended load. The test device contains an indicator that responds only when steam penetration is adequate (usually it changes colour – and should do so completely). 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.

**Sterilisation***Test procedure*

- 17.4.72 A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.
- 17.4.73 At the end of the process the test device is removed from the chamber.
- 17.4.74 The test device is checked for a pass or fail in accordance with the manufacturers instructions. The test results should be recorded.
- 17.4.75 If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results.
- 17.4.76 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.
- 17.4.77 A batch (cycle) process record should be made in the steriliser log book.

**Figure 17-3: Bowie-Dick Test**

## Sterilisation

### *Weekly tests*

- 17.4.78 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 17-2: Summary of Weekly Tests for Steam Sterilisers (Note: All tests can be combined into one test).**

Weekly Checks/Tests
Safety Checks
Vacuum Leak Test (automatic)
Air Detector Function test
Automatic Control test
Bowie-Dick test for Steam penetration

### *Safety checks*

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

*They consist of:*

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

*(Note: 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*

- 17.4.80 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.
- 17.4.81 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.
- 17.4.82 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.



## Sterilisation

- 17.4.83 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.
- 17.4.84 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 qualified person (decontamination) should do the test using special, calibrated dental RIMD.

*The pass/fail criteria are:*

- 17.4.85 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.
- 17.4.86 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.

***Air detector function test***

- 17.4.87 The air detection system should be tested weekly to demonstrate that it is functioning correctly. There is such a wide variety of steam sterilisers that there is not a standard air detection system and each steriliser manufacturer should therefore specify the test method to demonstrate that the automatic air detection system is functioning correctly.

*(Note: Where it is not possible to fit an air detector to an existing steriliser an alternative method of assuring steam penetration during each cycle run (such as a suitable process challenge device verified as valid for the product being processed in the steriliser) shall be used. Further Guidance is available in DD CEN ISO/TS 17665-2:2009.)*

***Automatic control test***

- 17.4.88 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.
- 17.4.89 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 or qualified person (decontamination) had tested it using calibrated dental RIMD.

## Sterilisation

17.4.90 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.

17.4.91 The test can be considered satisfactory if at the end of the cycle:

- a. the chamber temperature and pressure is within the limits of the appropriate band, for the duration of the holding time, as specified in table 17-2.
- b. a visual display of 'cycle complete' is indicated.
- c. no mechanical or other anomaly is observed.

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

17.4.92 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.

17.4.93 All the parameters recorded should be compared with the parameter results obtained during validation.

### *Quarterly tests*

17.4.94 These require specialised test equipment and only a person e.g. a Test Person or qualified person (decontamination) who has the necessary training, experience, skills and equipment should perform them.

17.4.95 The tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate. Quarterly tests for steam sterilisers are summarised in table 17-3.

## Sterilisation

Table 17-3: Summary of Quarterly Tests for Steam Sterilisers.

Test Description
Safety Checks
Vacuum Leak Test
Vacuum leak Test (temperature and pressure sensors connected)
Automatic Control test
Verification of Calibration of Steriliser Instruments
Thermostatic Test for a Small Load
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function (automatic)
Bowie-Dick Test for Steam Penetration

*Annual Tests*

- 17.4.96 These require specialised test equipment and only a person e.g. a Test Person or qualified person (decontamination) who has the necessary training, experience, skills and equipment should perform them.
- 17.4.97 The annual tests are intended to confirm that the data generated during validation remain consistent and accurate. Annual tests for steam sterilisers are summarised in table 17-4.

## Sterilisation

Table 17-4: Summary of Annual Tests for Steam Sterilisers (EN285) .

Test description
Safety Checks
Vacuum Leak Test (automatic)
Vacuum leak test (temperature and pressure sensors connected)
Automatic Control Test
Verification of Calibration of Steriliser Instruments
Steam Non-condensable Gas Test
Steam Super-heat Test
Air Detector Performance Test for a Small Load
Air Detector Performance Test for a Full Load
Steam Dryness Test
Thermometric Test for a Small Load
Thermometric Test for a Full Load
Test Performance Requalification (as required)
Vacuum leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick test for Steam Penetration

### Section Ten: Monitoring and control

- 17.4.98 134°C is the preferred sterilisation temperature. For RIMD, which may be damaged at 134°C, any of the other lower temperature bands may be used.
- 17.4.99 There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
- 17.4.100 Routine monitoring and testing should be carried out in accordance with documented procedures in line with I.S. EN ISO 17665 part 1. and with consideration given to the further detail in EN ISO/TS 17665 part 2.

**Section Eleven: Maintenance**

- 17.4.101 Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' recommendations and standards.
- 17.4.102 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 17.4.103 The steriliser should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 17.4.104 Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665, 2006.
- 17.4.105 A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- 17.4.106 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.
- 17.4.107 Revalidation may be required after steriliser relocation, engineering work, repair work, software control function modifications and when required by the decontamination unit manager.

*Some examples of requirement for revalidation are:*

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

**Low temperature sterilisation****18. Low temperature sterilisation****18.1 Introduction**

Low temperature sterilisation may be required for sterilisation of RIMD (including flexible/rigid scopes in accordance with manufacturers' instruction)

**18.2 Scope**

The objective of this recommended practice is to provide guidance on the choice and use of low temperature sterilisation methods.

**18.3 Contents**

Section One: General principles

Section Two: Validation

Section Three: Periodic testing

Section Four: Chemical and Biological Indicators

Section Five: Sterilisation of RIMD including flexible/rigid scopes

Section Six: Sterile product release

Section Seven: Storage and use

**18.4 Procedure****Section One: General principles**

- 18.4.1 Four different methods of low temperature sterilisation are available for use in healthcare organisation; ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), vapour phase hydrogen peroxide (VHP) and hydrogen peroxide gas plasma.

**Low temperature sterilisation**

- 18.4.2 The hydrogen peroxide based methods are preferred. (The residuals from EO and LTSF are toxic and must be degassed from RIMD after sterilisation whereas the residuals from hydrogen peroxide are innocuous (water and oxygen); also, EO and LTSF are alkylating processes which are believed to stabilise prion proteins).
- 18.4.3 Low temperature sterilisation methods should only be used for:
- RIMD specifically identified by the RIMD manufacturer or steriliser manufacturer as suitable for processing in the steriliser.
  - RIMD made of materials of a size and configuration (e.g. length and diameter of lumen) within the criteria specified by the steriliser manufacturer.
- (Note: Documentation of items that can and cannot be processed should be obtained from the RIMD (scope) and steriliser manufacturers.)*
- 18.4.4 RIMD to be processed in a low temperature steriliser must be scrupulously clean and thoroughly dried prior to sterilisation. (The presence of residual soiling or droplets of water may seriously impair the sterilisation process.)
- 18.4.5 The packaging used to contain RIMD to be sterilised must be compatible with the process. Only products designed for use with the particular process should be used.

**Section Two: Validation**

- 18.4.6 The effectiveness of the sterilisation process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if sterilising conditions are created throughout the steriliser chamber and the load during every cycle.
- 18.4.7 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the steriliser is functioning correctly and that it will produce sterilised loads consistently.
- 18.4.8 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.

## Low temperature sterilisation

*It is comprised of:*

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

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

- 18.4.9 Revalidation is required annually and whenever any major change is made to the steriliser, sterilisation cycle or nature of the loads to be sterilised.
- 18.4.10 Validation and re-validation should be carried out in accordance with the requirements of EN ISO 14937.
- 18.4.11 A qualified person (decontamination) with specific training on the process to be validated should advise on the validation programme and audit the data obtained.

### Section Three: Periodic testing

- 18.4.12 Periodic testing consists of a programme of tests that are intended to demonstrate that the performance of the steriliser remains within the limits established during validation.
- 18.4.13 The tests and checks specified by the steriliser manufacturer should be carried out at the intervals specified by the steriliser manufacturer. (This will normally require detailed functional and calibration tests and checks at intervals of 3, 6, or 12 months).
- 18.4.14 A qualified person (decontamination) should review and approve the schedule for periodic testing.
- 18.4.15 It is the responsibility of the operational manager to ensure that these tests are performed and that the results were satisfactory before allowing the continued use of the steriliser.



## Low temperature sterilisation

## Section Four: Chemical and biological indicators

*Chemical indicators*

- 18.4.16 Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- 18.4.17 Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).
- 18.4.18 The type used should be in accordance with the steriliser manufacturers' recommendations.
- 18.4.19 The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- 18.4.20 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.
- 18.4.21 Indicators should not be used beyond their expiry date.
- 18.4.22 Two types of chemical indicator are commonly used:
- 18.4.23 **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
- 18.4.24 **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.

*Biological indicators*

- 18.4.25 Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained.
- 18.4.26 Biological indicators must meet the requirements of BS EN ISO 11138-1:2006.
- 18.4.27 They are of limited value in routine process control (because of the delay before the results are available) and are restricted to a few special applications e.g. in process validation.
- 18.4.28 When used for validation studies they should always be regarded as additional to the physical measurement of the critical control variables (e.g. temperature, pressure, sterilant concentration and time).

**Low temperature sterilisation****Section Five: Sterilisation of RIMD (including flexible/rigid scopes)**

- 18.4.29 Wear personal protective equipment.
- 18.4.30 Ensure that any checks and test that are to be carried out prior to sterilisation have been complete and were satisfactory.
- 18.4.31 Where single door steriliser is in use a system must be in place to ensure segregation of non-sterile and sterile RIMD (including flexible/rigid scopes).
- 18.4.32 The steriliser door/s should be kept closed when the steriliser is not in use.
- 18.4.33 Select the validated cycle programme suitable for the load being processed.
- 18.4.34 Ensure the load is suitable for the process to which it will be exposed.
- 18.4.35 Manufacturers written instructions for operating the steriliser should be followed.

**Section Six: Sterile product release**

In order to release processed RIMD (including flexible/rigid scopes) as sterile, evidence is required to ensure that the sterilisation cycle was completed satisfactorily.

***Parametric release***

- 18.4.36 When cycle is complete post sterilisation inspection is carried out to verify that the sterilisation cycle has completed with defined, validated critical parameters (VCP).
- 18.4.37 Parameter release should show evidence that the RIMD (including flexible/rigid scopes) were subjected to a process and have met all-processing variables achieved during performance qualification.

***Non-parametric release***

- 18.4.38 When it is not possible to measure the value of all the critical variables throughout the sterilisation cycle a non-parametric release method must be used. Non-parametric release involves verifying that the required values were met during the sterilisation cycle for those variables that can be measured and, in addition, using biological indicators. The load cannot be released until biological indicators that were placed in the load before sterilisation have been removed from the load at the end of the steriliser cycle and incubated under the conditions, and for the time, specified by the manufacturer of the biological indicator.

**Low temperature sterilisation**

- 18.4.39 In both parametric and non-parametric release post-sterilisation inspection is carried out to ensure that the values of the recorded cycle variables (e.g. temperature, pressure, time) are checked to ensure that they are within the limits determined as satisfactory during validation.
- 18.4.40 Failure of one or more of the cycle variables to meet the specified value(s) must lead to the steriliser load being transferred to the clean room to be repacked and sterilised.
- 18.4.41 The cause of failure should be investigated and documented.
- 18.4.42 A steriliser cycle in which there is no record from the automatic controller or from the independent recorder should be regarded as a sterilisation failure.
- 18.4.43 The chemical process indicator has undergone the expected colour change.
- 18.4.44 The integrity of the outer wrap and its seals has not been compromised, e.g. torn wrap, sealing tape undone).
- 18.4.45 The packed RIMD (including flexible/rigid scopes) are dry.
- 18.4.46 The labelling remains in place and legible.
- 18.4.47 If the integrity of the packaging or labelling is compromised the sterilised load is regarded as non-sterile. The RIMD (including flexible/rigid scopes) must be reprocessed and the cause of the failure investigated and documented.
- 18.4.48 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.

## Low temperature sterilisation

### Section Seven: Storage and use

- 18.4.49 Sterile RIMD should be stored in a clean, dry area, which is secure, dust free and above floor level.
- 18.4.50 Packs should be labeled with the contents, the word 'Sterile', the date of sterilisation and a unique identifier from which all stages of the decontamination process to which it was subjected may be traced.
- 18.4.51 Packs should be stored so that they are used in sequential order, i.e. the oldest first.
- 18.4.52 Packs should be inspected for damage before they are opened. If there is any sign of damage to the packaging, the contents should be returned to the decontamination unit to be re-sterilised before they are used.

## 19. Storage

### 19.1 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). RIMD packs should be stored in a clean, dry environment and protected from sharp objects that may damage the packaging.

### 19.2 Scope

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

### 19.3 Contents

Section One: Storage areas

Section Two: Storage equipment

Section Three: Shelf life/rotation of stock

Section Four: Non-conforming stock

### 19.4 Procedure

#### Section One: Storage areas

- 19.4.1 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 store.
- b. the raw materials store.

## Storage

### *Processed goods store*

- 19.4.2 The processed goods store should be located adjacent to the cooling bay in the sterilisation area and with access to the despatch area. This store is for RIMD produced by the department and RIMD which have been commercially manufactured and sterilised.
- 19.4.3 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 RIMD which have been produced by the department.
- 19.4.4 Raw materials should not be stored in the processed goods store.
- 19.4.5 Loose, processed RIMD should be stored separately from those packed in cases.
- 19.4.6 Storage areas should be kept secure and access should be restricted to authorised personnel.
- 19.4.7 Sterile materials should be stored at least 20 to 80 centimetres from the floor, at least 18 inches from the ceiling, and at least 5 centimetres from outside walls.
- 19.4.8 The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.
- 19.4.9 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.
- 19.4.10 Processed goods should be stored on appropriate designated shelving.

### *Raw materials store*

- 19.4.11 The storage area is for the reception, storage and supply of all non-sterile materials including textiles and where appropriate, bulk cased supplies of commercially sterilised RIMD.
- 19.4.12 The raw materials store should be located between the goods reception and the clean room inspection, assembly and packaging area.
- 19.4.13 Materials should be segregated and stored separately according to their specific requirements.
- 19.4.14 Sterile RIMD should not be stored in this area (unless supplies are bulk cased).
- 19.4.15 Single items should be stored separately from those in cases.
- 19.4.16 Storage areas should be kept secure and access restricted.

- 19.4.17 Accommodation should be designed in accordance with guidance in PD CEN ISO/TR 14969:2005.

## Section Two: Storage equipment

### *General principles*

- 19.4.18 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.
- 19.4.19 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.
- 19.4.20 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.
- 19.4.21 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 racking*

- 19.4.22 Shelves and racking should afford adequate space to store the required stock in line with local supply policy and production demands.
- 19.4.23 Shelving and racking should be purpose built, easily cleaned and maintained.
- 19.4.24 There should be enough space between shelves and racking to allow an adequate passageway between fixtures.
- 19.4.25 Shelving or racking should enable items to be clearly labelled.

### *Closed or covered cabinets*

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

## Storage

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

- 19.4.28 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.
- 19.4.29 Each central 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.
- 19.4.30 As a “rule of thumb”, 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.
- 19.4.31 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: Nonconforming stock

- 19.4.32 A package should be considered nonconforming, i.e. non sterile and not suitable for use when:
- a. it is incorrectly wrapped.
  - b. it is damaged or opened.
  - c. the product is outside the expiry date.
- 19.4.33 The sterilisation process indicator does not confirm that the pack has been subject to an appropriate sterilisation process.



## Storage

Figure 19-1: Storage



**Transportation – of sterile items****20. Transportation – of sterile items****20.1 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.

**20.2 Scope**

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

**20.3 Contents**

Section One: General principles

Section Two: External transportation

**20.4 Procedure****Section One: General principles**

- 20.4.1 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.
- 20.4.2 Sterile dental RIMD should be cooled before they can be transported.
- 20.4.3 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**

- 20.4.4 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.
- 20.4.5 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

### 21. Water supply for washer-disinfectors

#### 21.1 Introduction

The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process, as the water is the last product to make contact with the Dental RIMD prior to the procedure.

#### 21.2 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.

#### 21.3 Contents

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

#### 21.4 Procedure

##### Section One: General requirements

- 21.4.1 At each stage in the cleaning process the water quality should be compatible with:
- the materials of construction of the washer-disinfector (WD).
  - the RIMD to be processed.
  - the process chemical to be used.
  - the process requirements of that particular stage.

**Water supply for washer-disinfectors**

- 21.4.2 The key quality elements to be considered are:
- hardness.
  - temperature.
  - ionic contaminants (e.g. heavy metals, chlorides, phosphates, silicates, iron, total dissolved solids and collective conductivity).
  - microbial population. e.g. Total Viable Count TVC as cfu/100ml.
  - bacterial endotoxins.
  - pH.
- 21.4.3 The water supply should be controlled to ensure that it consistently meets the required quality.

**Section Two: Water quality*****Hardness***

- 21.4.4 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.
- 21.4.5 The deposition of lime-scale on electrical heating elements or heat exchange components, within pipes and around the edges of spray nozzles will seriously impair the performance of a washer-disinfector.
- 21.4.6 Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- 21.4.7 Using hard water in the thermal disinfection and final rinse stages of the WD cycle 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.
- 21.4.8 When hard water is used in the process of reverse osmosis (RO), it can cause the RO to reduce the quality and quantity of water required for the washer-disinfector (WD).
- 21.4.9 The hardness is normally removed by a water softner; this can then be used to pre treat the water prior to washer-disinfector system.

**Water supply for washer-disinfectors**

21.4.10 The water softener can also be used to supply water directly to WD when RO is not present, However RO water is preferable.

21.4.11 The hardness of water should be less than 5ppm.

***Temperature***

21.4.12 The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.

21.4.13 Water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to “fix” proteinaceous soil to the surface of the load items. EN ISO 15883 recommends that the initial temperature should not exceed 45°C. The initial flushing stage should be supplied with water from a cold supply.

21.4.14 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, too low and they may not activate.

21.4.15 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***

21.4.16 Ionic contaminants in the water may react with materials such as stainless steel.

21.4.17 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.

21.4.18 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.

21.4.19 Ionic contaminants conduct electricity, because pure water has a high resistance to electrical current, the measurement of electrical conductivity can provide an accurate assessment of ionic concentration. Conductivity is described in micro Siemens and is measured by a conductivity meter and probes. In washer-disinfector, the guideline limit for conductivity is no greater than 30 micro-siemens.

## Water supply for washer-disinfectors

### *Microbial population*

- 21.4.20 The microbial population in the water used in the washer-disinfector, particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.
- 21.4.21 For items which are intended to be used without further processing (e.g. flexible endoscopes processed in an endoscope washer-disinfector) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the service user, either through infection or by leading to a erroneous diagnosis. The guideline limits for microbial contamination are no greater than 10 CFU/100ml sample.

### *Bacterial endotoxins*

- 21.4.22 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.
- 21.4.23 Water used for the final stages of processing in a WD, where there is a significant risk of residual water remaining on the load items, should not contain more than 0.25 endotoxin units/ml when the WD is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.

### *pH*

- 21.4.24 The relative acidic or alkaline level of a solution is measured by pH. The pH is a measure of hydrogen ion concentration in the water. A pH of less than 7.0 is acidic and a pH of more than 7.0 is alkaline. The pH for a washer-disinfector should be between 5.5 & 8.0, any outlining values may indicate crossover of detergent or disinfectant.

*(Note: All of the above parameters should be tested for on a regular 3 month basis, to ensure the water quality does not breach the recommended guidelines.)*

## Water supply for washer-disinfectors

### Section Three: Water treatment

21.4.25 There are three methods of water treatment generally used on water supplies for washer-disinfectors:

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

#### *“Base-exchange” softeners*

21.4.26 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).

21.4.27 The concentration of total dissolved solids in the water is not reduced by this process. The sodium salts which remain do not readily form hard deposits to foul heat exchangers or spray nozzles but if used as the final rinse will leave white deposits on the load items as they dry.

21.4.28 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.

21.4.29 Water softeners are generally used as a pre treatment to reverse osmosis systems.

21.4.30 Water quality from water softeners can vary as only calcium and magnesium are removed by this type of water treatment.

21.4.31 Softened water should not be used for final rinse of products intended for invasive use without further water treatment decontamination processing.

21.4.32 Water softeners should be disinfected periodically and output water should be subject to periodic microbiological testing as microbial biofilms readily form on the resin matrix which can add considerable bioburden to treated water if the softener is not well maintained. Periodic planned preventive maintenance of all softener units is essential.



**Water supply for washer-disinfectors***Deionisers*

- 21.4.33 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.
- 21.4.34 Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers. Deionising columns are also subject to microbial biofilm contamination and require periodic preventive maintenance and microbiological testing of output water.
- 21.4.35 De-ionised (DI) water may be heavily contaminated with microorganisms and DI water stored at ambient temperatures will deteriorate rapidly due to proliferation of microorganisms, particularly bacterial species. Contamination of DI with skin bacteria is common. Containers used for DI should be cleaned regularly and should not be constantly topped up. Ideally, DI containers should be sterilised following cleaning. (The chloride ions normally present in drinking water to control microbial growth have been removed).
- 21.4.36 DI water should not be used for the final rinse of products intended for invasive use without further water treatment.
- 21.4.37 De-ionisers should be disinfected regularly.

*Reverse osmosis*

- 21.4.38 Reverse osmosis 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.
- 21.4.39 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. However, the microbiological quality of the water can deteriorate following storage due to proliferation of bacterial species.

*Appropriate measures include:*

- a. a continuous recirculation system water.
- b. filtration, e.g. through a 0.22 µm filter to remove microbial contaminants.

## Water supply for washer-disinfectors

- c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g.  $>60^{\circ}\text{C}$ ) or by the use of UV irradiation (wavelength  $260 \pm 10\text{nm}$ ;  $>2\text{J. m}^{-2}$ ) and by periodic disinfection (elevated water temperature e.g.  $>80^{\circ}\text{C}$ ).





### *Water Supply and distribution*

- 21.4.40 The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Orbitally welded stainless steel pipes or clean pex are preferred for all qualities of purified water.
- 21.4.41 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.
- 21.4.42 Regular disinfection of the storage and distribution system should be undertaken and the efficacy of such control procedures should be subject to microbiological testing.
- 21.4.43 It may be helpful if microbiological results from weekly tests are plotted on a graph to give a trend. This will allow the 'normal' and 'unusual' results to be distinguished for a particular situation.
- 21.4.44 Investigation of unusual, or unsatisfactory results are then undertaken if the results demand (e.g. if routine results are below 10cfu/100ml and some of the results are above 10cfu/100ml).
- 21.4.45 If a bacterial count is obtained from test water the identification of bacterial species is advised and the results presented to the Microbiologist or Infection Prevention and Control team for consideration.
- 21.4.46 This information may aid identification of the contamination source and assist with any subsequent advice.

*(Note: For washer-disinfectors in which the RIMD is rinsed after the disinfection stage (e.g. those using a chemical process for disinfection) the quality of the final rinse water should be as follows (table: 21-1).)*

## Water supply for washer-disinfectors

Table 21-1: Typical bacterial counts as indicators of process water quality

Microbiology		
Aerobic colony count in 100 mL at 35°C for 72 hr	Interpretation/action	Colour grade
Less than 1	Satisfactory	Green 
1-9 on a regular basis	Acceptable -indicates that bacterial numbers are under a reasonable level of control	Yellow 
10-100	Unsatisfactory - investigate potential problems and self-disinfect or super-chlorinate	Orange 
Over 100	Unacceptable - take AER out of service until water quality improved	Red 
(Note: <i>Mycobacterium</i> sp. not detected in 100 mL water satisfactory)		
Source: Willis C, Epidemiol. Infect. 134 (2):279-84, 2005		

(Note: For washer-disinfectors with no rinse after the disinfection stage (e.g. those with thermal disinfection) and for all other stages of the process, the water services supplied to the washer-disinfector should have less than 100cfu/100ml of water.)

## Water supply for washer-disinfectors

Table 21-2: Water quality for washer-disinfectors

Washer-disinfector Process stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Flush	Cold soft/mains	Cold mains
Wash	Reverse osmosis	Hot soft/mains
Rinse	Reverse osmosis	Reverse osmosis
Thermal disinfection	Reverse osmosis	Reverse osmosis
Chemical disinfection*	Reverse osmosis	Soft/mains
Post chemical disinfection rinse*	Reverse osmosis 0.22mm filtered	De-ionised 0.22mm filtered

\*Endoscope washer-disinfector only

Table 21-3: Water quality for cleaning RIMD

Washer-disinfector Process stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Manual wash	Reverse osmosis @ 35-45°C	Soft/mains @ 35-45°C
Manual rinse	Reverse osmosis	Soft/mains <sup>1</sup>
Ultrasonic wash	Reverse osmosis@ 35-55°C	Soft/mains @ 35-55°C
Ultrasonic rinse	Reverse osmosis	Soft/mains <sup>1</sup>

<sup>1</sup> When the manually/ultrasonically cleaned RIMD are to be further processed through an automated washer-disinfector

## Single use invasive medical devices

## 22. Single use invasive medical devices

## 22.1 Introduction

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

## 22.2 Scope

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

## 22.3 Contents

Section One: General principles

## 22.4 Procedure

## Section One: General principles

- 22.4.1 To avoid cross-contamination between service users, SIMD should be used wherever this is practical.
- 22.4.2 Single-use items should be used for a single service user and not reused on subsequent service users. Service user care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- 22.4.3 Devices intended for single-use and labelled 'single-use' by the manufacturer should be immediately disposed of after use.
- 22.4.4 Decontamination unit managers 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.
- 22.4.5 The symbol for single use instruments is as given in EN 980:2003.

### Single use invasive medical devices

- 22.4.6 Synonyms for “do not reuse” are “single use”, use only once”.
- 22.4.7 See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).
- 22.4.8 Healthcare organisations should have well established criteria for their choice of SIMD or RIMD where both are available.

Figure 22-1: Do not reprocess symbol



## Transfer of used reusable invasive medical devices (RIMD) to third parties

### 23. Transfer of used reusable invasive medical devices (RIMD) to third parties

#### 23.1 Introduction

Anyone who inspects, services, repairs or transports RIMD, either on healthcare organisation premises or elsewhere, has a right to expect that the RIMD have been appropriately treated so as to remove or minimise the risk of infection or other hazards.

#### 23.2 Scope

The objective of this recommended practice is to provide guidelines in relation to the transfer of RIMD to third parties for the inspection, service, repair, or disposal of RIMD.

#### 23.3 Contents

Section One: General principles

#### 23.4 Procedure

##### Section One: General principles

- 23.4.1 All RIMD intended for inspection, service, repair, or disposal must be decontaminated before despatch and must be accompanied by a certificate stating the method by which they were decontaminated.
- 23.4.2 All RIMD must be decontaminated in accordance with the manufacturers' instructions.
- 23.4.3 If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, the recipient may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.

**Transfer of used reusable invasive medical devices (RIMD) to third**

- 23.4.4 RIMD that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.
- 23.4.5 When RIMD are returned after being repaired, the RIMD must be decontaminated and, where relevant, replaced in the original RIMD set.
- 23.4.6 Each RIMD set should be checked or completeness as per healthcare organisation policy, procedure, protocol and guideline.



**Loan reusable invasive medical devices****24. Loan reusable invasive medical devices****24.1 Introduction**

Dental RIMD may be loaned to a healthcare organisation so that a particular procedure can be performed. The RIMD may be borrowed either from manufacturers or other healthcare organisation and are returned after use. This practice increases the risks associated with the decontamination and reprocessing of such devices because the organisation may not be familiar with the RIMD or the required decontamination process. Items on loan should be managed in line with HSE policy, procedure, protocol and guidelines. Loan RIMD should be tracked with the same level of detail as healthcare organisation owned RIMD. Required documentation stipulated by the IMB, and EN policy, procedure, protocol and guidelines should be made available at each point of need within the decontamination process.

**24.2 Scope**

The objective of this recommended practice is to provide guidelines in relation to the transfer of RIMD to third parties for the repair, loan and disposal of RIMD.

**24.3 Contents**

Section One: General principles

Section Two: Procedure for loaning and borrowing dental RIMD

**24.4 Procedure****Section One: General principles**

- 24.4.1 Borrowed RIMD must be accompanied by relevant reprocessing instructions (including disassemble and reassemble instructions where relevant) and a list of contents. The supporting documentation relating to the RIMD must be in a form that can accompany the set throughout the decontamination cycle. In addition each set of RIMD must be entered into the relevant tracking system to ensure that should an adverse incident occur, full traceability can be achieved.

### Loan reusable invasive medical devices

- 24.4.2 All borrowed RIMD must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly.
- 24.4.3 RIMD on loan must be registered, including ownership, service history, current location, service responsibility and instructions for use.
- 24.4.4 It is the responsibility of the user to ensure that a full record of use for the RIMD will be available from the loan organisation, and that the usage history is both available and complete.

### Section Two: Procedure for loaning and borrowing RIMD

#### *Requests*

- 24.4.5 All requests for the loan of RIMD must be made directly by clinical manager of the unit intending to use the RIMD.
- 24.4.6 When agreement has been reached that the RIMD may be borrowed, the manager of the central decontamination unit that will be responsible for decontamination must be informed.

#### *Documentation*

- 24.4.7 The owner of the RIMD being loaned is responsible for ensuring that the loaned RIMD are accompanied by the following documentation:
  - a. the tray of RIMD or single RIMD is tracked using a globally accepted Global Standards 1 (GS1 code).
  - b. contents list.
  - c. decontamination certificate.
  - d. reprocessing instructions, including disassembly and reassembly, where relevant.
  - e. instruction for use.
  - f. the above data is presented in an accessible and appropriate manor so that it can be used throughout the reprocessing cycle.

**Loan reusable invasive medical devices***Log book*

24.4.8 Details of all RIMD which are loaned to/borrowed from other institutions should be entered into a log book detailing:

- a. name and description of the RIMD.
- b. RIMD identification number(s).
- c. name of the person to whom the RIMD is being loaned to/borrowed from.
- d. identity of the institution providing/receiving the RIMD.
- e. identity of the person who is making the loan.
- f. date of loan.
- g. expected date of return.
- h. confirmation that the relevant supporting documentation required to track reprocess and use the RIMD have been received and are available to all person departments requirement that information.
- i. the unique identifier permitting traceability of the decontamination cycle(s) for the RIMD prior to use. Global Standard 1 (GS1) GIAI code.
- j. the unique identifier for the service users on which the RIMD was used.
- k. the unique identifier permitting traceability of the decontamination cycle(s) for the RIMD after use.
- l. confirmation that the owning institution has appropriate systems in place to maintain an effective loaning history for the RIMD.

*Arrangements for return of RIMD*

24.4.9 Arrangements for the return of RIMD must be made directly by the person who borrowed the RIMD within the defined time period agreed.

24.4.10 Responsibility for logging the safe and complete return of the RIMD rests with the designated person to whom the RIMD are returned.

24.4.11 The return date, the name of the institution and the person returning the RIMD should be recorded.

**Action on non-conforming product***Internal Tracking of Loan RIMD sets and singles*

- 24.4.12 The unique reference supplied by the loan organisation should be used to track the set/items through the decontamination cycle and subsequent use on a service user to ensure traceability.
- 24.4.13 The contents within the tray of RIMD or details relating to a supplementary item should be entered in full into the tracking system.
- 24.4.14 The required supporting documentation should be made available at all points of the decontamination process to ensure that the RIMD is dismantled, processed and reassembled in accordance with manufacturers' recommendations.

**Action on non-conforming product****25. Action on non-conforming product****25.1 Introduction**

To ensure service user safety and compliance with the Safety, Health and Welfare at Work Act, 2005 and S.I. 252 of 1994, the organisation 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 RIMD, notification of clinicians and surveillance of service users as well as remedial action to prevent any recurrence.

**25.2 Scope**

The objective of this recommended practice is to provide guidelines in relation to action on non-conforming product.

**25.3 Contents**

Section One: Policies, procedures, protocol and guidelines

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

**25.4 Procedure****Section One: Policies, procedures, protocols and guidelines**

- 25.4.1 Written policies, procedures, protocols and guidelines for the recall of non-conforming product should be developed, available and implemented in the healthcare organisation.
- 25.4.2 Where any occurrence gives cause for concern that the required assurance of sterility, functionality and freedom from contamination has not been met, the infection control nurse and risk manager should be notified so that follow-up surveillance of service users can be conducted.

**Action on non-conforming product**

- 25.4.3 The nature and seriousness of the fault and the risk category of the product will determine whether it will be necessary to issue an advisory notice or to institute a recall. These factors will also determine the speed and extent of the action. Ref: EN 724:1994.

**Section Two: Recall procedure**

- 25.4.4 A recall policy, procedure, protocol and guideline 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.

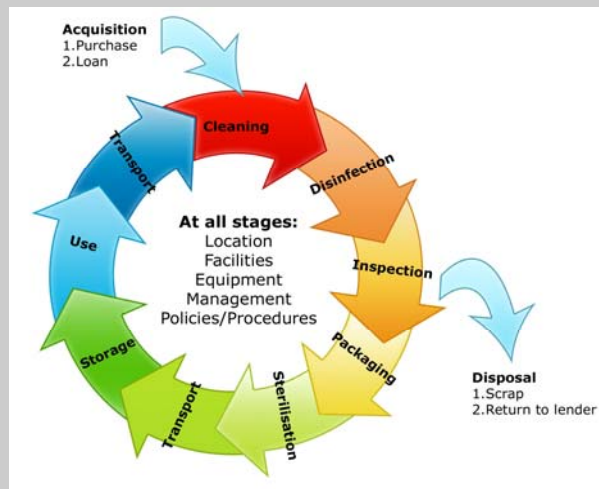
**Section Three: Recall order**

- 25.4.5 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).

**Action on non-conforming product****Section Four: Recall report**

25.4.6 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.



# Standards and Recommended Practices for CDUs

## Part 4

### Additional Resources and Appendices

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## 1. Resources

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**Abbreviations*****2. Abbreviations***

AORN	Association of Perioperative Registered Nurses
AER	Automated Endoscope Reprocessor
ATP	Adenosine Triphosphate
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
ERU	Endoscopy Reprocessing Unit
EWD	Endoscope Washer-Disinfector
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
LCD	Liquid Chemical Disinfector

**Abbreviations**

MSDS	Material Safety Data Sheets
NAD	Nicotinamide Adenine Dinucleotide
NSAI	National Standards Authority of Ireland
PPE	Personal Protective Equipment
PPPG	Policy, procedure, protocol and guideline
RIMD	Reusable Invasive Medical Devices
SDA	Sabaroud Dextrose Agar
TSA	Tryptose Soya Agar
TSE	Transmissible Spongiform Encephalopathies
WD	Washer-disinfector

### 3. Glossary

<b>Adverse event</b>	An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.
<b>Cleaning</b>	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.
<b>Clinical Governance</b>	Corporate accountability for clinical performance.
<b>Decontamination</b>	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.
<b>Disinfectant</b>	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.
<b>Disinfection</b>	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.
<b>Hazard</b>	A source of potential harm or a situation with a potential to cause loss.
<b>Healthcare associated infection</b>	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

<b>Health Care Workers</b>	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.
<b>Incidence (of infection)</b>	Rate at which new cases occur.
<b>Invasive procedure</b>	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.
<b>Medical device</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• diagnosis, prevention, monitoring, treatment or alleviation of disease;</li> <li>• diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap;</li> <li>• investigation, replacement or modification of the anatomy or of a physiological process; or</li> <li>• 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.</li> </ul>
<b>Monitor</b>	To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change.
<b>Prion</b>	The small proteinaceous infectious unit that appears to cause TSEs.

## Glossary

<b>Primary Care</b>	HSE healthcare provision outwith hospitals, for example, general medical practitioner and general dental practitioner services.
<b>Risk</b>	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.
<b>Risk Assessment</b>	The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria.
<b>Risk Management</b>	The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects.
<b>Risk Management Process</b>	The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk.
<b>Risk Reduction</b>	A selective application of appropriate techniques and management principles to reduce either likelihood or an occurrence or its consequences, or both.
<b>Reprocessing</b>	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.
<b>Reusable item</b>	An item designated or intended by the manufacturer to be suitable for reprocessing and reuse.
<b>Sharps</b>	Any object capable of inflicting penetrating injury, including needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.

## Glossary

<b>Stakeholders</b>	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.
<b>Standard</b>	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.
<b>Statutory</b>	Required by law.
<b>Sterilisation</b>	A process used to render an object free from viable microorganisms including viruses and bacterial spores.
<b>TSEs</b>	TSEs are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans.
<b>Validation</b>	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.
<b>Verification</b>	Checking or confirmation of the truth or accuracy of something (e.g., self-assessment).
<b>Suitably qualified person (decontamination)</b>	<p>A suitably qualified person (decontamination) is defined as a (person designated by Management to provide testing, advice and review/witness documentation. Be qualified to graduate level in an appropriate discipline.</p> <p>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.</p>



## Appendices

### Appendix 1: Membership of National Decontamination Advisory Group

Dr. Ronnie Russell	Chairperson National Decontamination Advisory Group
Ms. Winifred Ryan	Quality & Patient Safety Directorate, Health Service Executive
Ms. Joy Markey	Quality & Patient Safety Directorate, Health Service Executive
Mr. Tom Finn	Assistant National Director commercial unit, Health Service Executive
Ms. Fiona Kennedy	Decontamination advisor
Mr. Wayne Spencer	Decontamination technical advisor
Professor David Coleman	Professor of Oral & Applied Microbiology, Head of division of oral biosciences
Dr. Anne Gilleece	Consultant Microbiologist Connolly hospital
Ms. Sinead Horgan	Chairperson, Irish Endoscopy Nurses Association
Mr. Tony Mc Loughlin	Vice Chairperson, Irish Decontamination Institute
Ms. Paschal Kent	Decontamination coordinator, CUH Group
Ms. Monica Griffin	Irish Theatre Nurses Association
Ms. Sheila Donlan	Health Protection Surveillance Centre
Ms. Mary Owens	Chairperson, Irish Association Director of Nursing and Midwives
Mr. Jim Murphy	Health Service Executive, Estates
Mr. Wilf Higgins	Irish Medicines Board

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### Appendix 2: List of hospitals /stakeholders who participated in the consultation process

Bantry General Hospital
Beaumont Hospital
Cappagh National Orthopaedic Hospital
Cavan/Monaghan Hospital Group
Children's University Hospital Temple Street
Coombe Women's Hospital
Cork University Hospital
Galway University Hospital
Kerry General Hospital
Mallow General Hospital
Mater Hospital Dublin
Mid Western Regional Hospital Dooradoyle
Mid Western Regional Hospital Ennis
Mid Western Regional Hospital Maternity Hospital Limerick
Mid Western Regional Orthopaedic Hospital Croom Co. Limerick
Mid Western Regional Hospital Nenagh Co. Tipperary
Our Lady's of Lourdes Hospital Drogheda
Our Lady's Hospital Navan
Our Lady's Hospital Crumlin
Rotunda Hospital
Connolly Hospital Blanchardstown
Naas General Hospital
St. John's Hospital Limerick City
Midland Regional Hospital Portlaoise
St Columcille's Hospital Loughlinstown Co. Dublin
National Maternity Hospital Holles Street Dublin 2

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Royal Victoria eye & Ear Hospital
South Infirmary Victoria Hospital Cork
South Tipperary General Hospital
St James Hospital Dublin
St. Luke's General Hospital Kilkenny
St Luke's Hospital Rathgar
St. Michaels Dunlaoghaire
St Vincent's Hospital Dublin
Waterford Regional Hospital
Wexford General Hospital
Dublin Dental School and Hospital University of Dublin Trinity College
Cork University Maternity Hospital
St. Finbarr's Hospital Douglas Road Cork
Monaghan General Hospital
Sligo General Hospital
Mayo general Hospital
Roscommon County Hospital
Portiuncula Hospital Ballinasloe Co. Galway
Letterkenny Hospital Co. Donegal
Midland regional Hospital Mullingar Co. Westmeath
Midland regional Hospital Tullamore Co. Offaly
Adelaide & Meath Incorp. National Children's Hospital Tallaght Dublin 24
Lourdes Orthopaedic Hospital Kilcreene Co. Kilkenny
St Mary's Orthopaedic Hospital Gurranbaher Cork

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Mercy University Hospital Grenville Place Cork
Louth County Hospital Dundalk Co Louth
<b>Consultees (External)</b>
Department of Health and Children
RCPI Faculty of Occupational health
Royal College of Surgeons Ireland
Royal College of Physicians Ireland RCPI
Faculty of Public Health
Irish Society of Clinical Microbiologists
Irish Directors of Nursing and Midwifery Association
Irish Association of Sterile Services Managers
SARI National Committee
Maintenance Management Association
Health Care Risk Managers Forum
DATHs Risk Management Forum
Clinical Indemnity Scheme
Association of Occupational therapists Ireland
Irish Society of Chartered Physiotherapists
Irish Speech and Language Therapist Association
Irish Medicines Board
Association of Physical Scientists in Medicine
Infection Control Nurses Association
Irish Society of Endoscopy Nurses
Irish Association of Theatre Managers
Irish Patients Association

### *Appendix 3: 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.

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### 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 Sterilisation. 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

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.



**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>.

## *Appendix 4: 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

- 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.

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### 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'.

