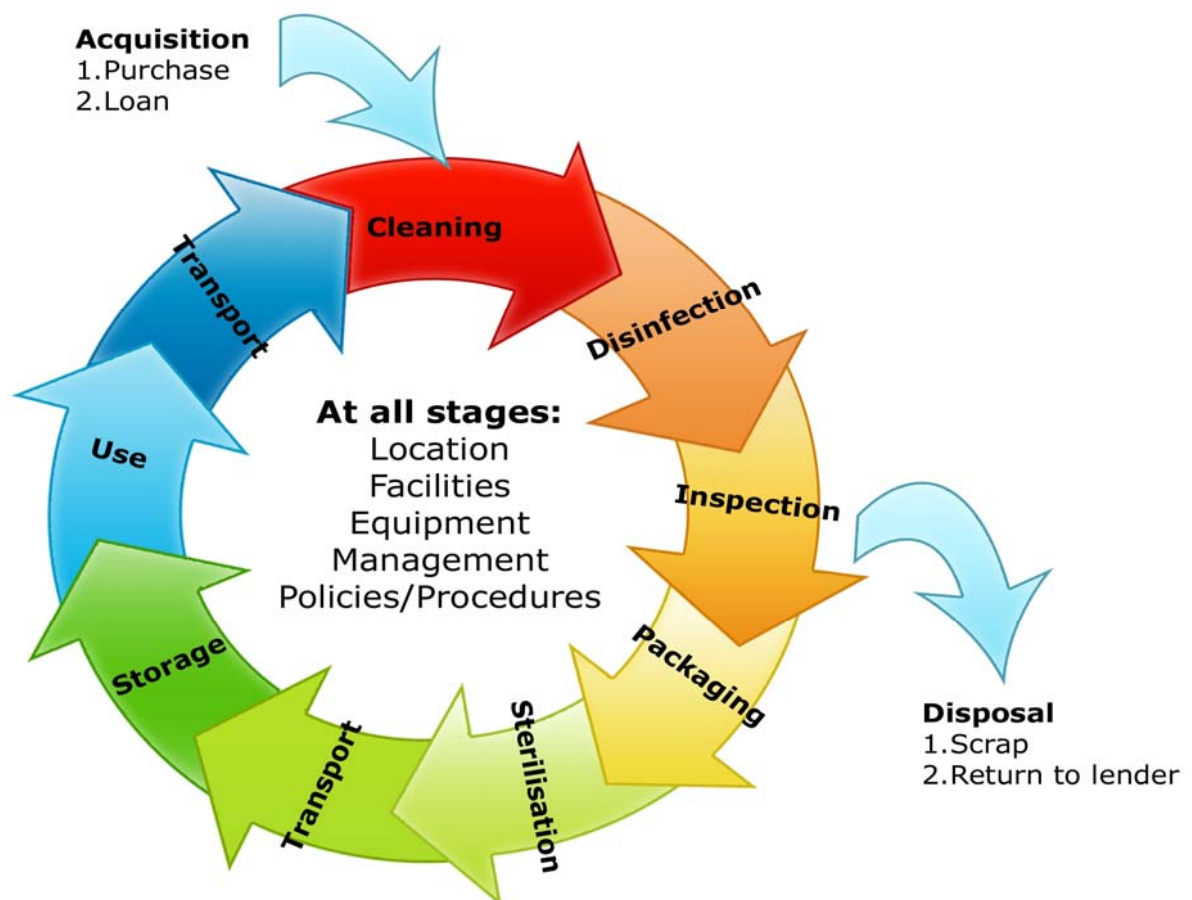


## PART 1: BACKGROUND

# Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices



## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 1
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All relevant staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2008
<b>Contact Details:</b>	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p><b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a></p> <p><b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a></p>

## Foreword

### Foreword

The Health Service Executive (HSE) is delighted to present the *HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices (hereafter referred to in this document as RIMD)*. The HSE is publishing this Code of Practice as it's guide to Standards and recommended practices for decontamination of RIMD required in the Irish public health service.

The Code of Practice is the result of many months of hard work by the Decontamination Steering Committee, the Standards sub-group and many others with an interest in decontamination. It would not have been possible to complete this work without the excellent contributions from individuals, staff members and key stakeholder groups who participated in the national consultation process on the Standards and recommended practices. Work on the Code also benefited greatly from the input of David J Hurrell MSc FIHEEM AP(S) Managing Director, Healthcare Science Ltd.

Sincere thanks are offered to the members of the Steering Committee who led the development of the Code of Practice and the Standards sub-group who drafted the document.

The Code provides:

1. A framework for management of decontamination in the Health Service Executive.
2. A reference point against which continuous quality improvement in decontamination services can take place.

The Code applies to all relevant staff in the public health service. This is an evolving document because Standards and practices in relation to decontamination will change over time. It will therefore be subject to regular review and updated as necessary. We welcome and commend the Code of Practice as a means of helping staff to improve their performance in relation to decontamination of RIMD.

**Mr. John O'Brien, National Director, National Hospitals Office**

**Ms Laverne McGuinness, National Director, Primary, Community and Continuing Care**

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The document has been prepared in seven main parts. There is an overall table of contents following the foreword. Each part of the document also has its own contents page, which provides a detailed breakdown of all the sections and subsections in that part of the document

Part 1	Background	This part provides the foundation for all Standards and recommended practices detailed in the remainder of the document.
Part 2	Standards	The Standards for decontamination of RIMD are described in this section.
Part 3	Recommended Practices for CDUs	This part identifies the recommended practices that are intended to define correct decontamination practices for staff who work in Central Decontamination Units (CDUs).
Part 4	Recommended Practices for Endoscopy Units	This part identifies the recommended practices that are intended to define correct decontamination practices for staff who work in Endoscopy Units.
Parts 5 a & 5b	Recommended Practices for Dental Services	These parts identifies the recommended practices that are intended to define correct decontamination practices for staff who work in Dental Services. (CDU & LDU)
Part 6	Audit Tool	The audit tool provides a method for assessment of processes for decontamination of RIMD in the Irish public health service.
Part 7	Additional Resources & Appendices	This part includes a glossary, list of abbreviations and a reference list. Appendices include the membership of the Decontamination Steering Committee and suggested membership for a decontamination advisory group.

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**Part 1**

*Part 1*  
*Background*

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## Introduction

# 1 Introduction

## 1.1 Prevention and control of healthcare associated infection

Improving the quality of care and providing a safe working environment are fundamental activities for the Health Service Executive. Prevention and control of healthcare associated infection (HAI) is central to these activities. Senior managers must ensure that they have effective systems in place in their healthcare facilities to minimize the risks of infection to patients and staff.

## 1.2 Steering committee

Following concern about the risk of healthcare associated infection and review of a report on reprocessing of medical devices in hospital central decontamination units (*Irish Association of Sterile Services Managers, 2003*), Dr Mary Hynes, Assistant Director of Quality, Risk and Customer Care in the National Hospitals Office (NHO) set up a Steering Committee to provide guidance on decontamination services. The development of Standards and recommended practices on the decontamination process was an important part of the Steering Committees remit.

## 1.3 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 patients. 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 micro-organisms 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.

## Introduction

When describing a sterilization 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.

### 1.4 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 and procedures 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.

## Development of decontamination code of practice

## 2 Development of decontamination code of practice

### 2.1 Introduction

The Code of Practice was 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.
- Development of draft Standards and recommended practices for distribution for consultation to key stakeholders.
- Incorporation of feedback, where appropriate into the final version of the Code.

### 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.

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.

## Development of decontamination code of practice

**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 patient 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.

## Medical Devices Directive (93/42/EEC)

### 3 Medical 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. 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.

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) as “an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with the software necessary for its proper application, which is 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

...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”.



## Medical Devices Directive (93/42/EEC)

**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 XI** 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.

## Medical Devices Directive (93/42/EEC)

### 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, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization 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 patients, or the safety and health of users or where applicable other persons. The devices must also perform as intended by the manufacturer.

## **Medical Devices Directive (93/42/EEC)**

### **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—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:

- 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 sterilization 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).

## Medical Devices Directive (93/42/EEC)

### 3.6 CE marking

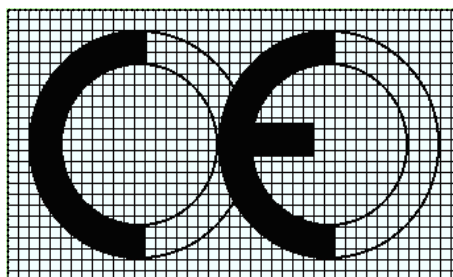
CE stands for: La Conformité Européenne or European Conformity. The CE mark is not a mark indicating conformity to a Standard but rather a mark indicating conformity to the legal requirements of European Union (EU) Directives. When a product has the CE mark, it can be traded freely in any country within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

### 3.7 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 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.

Figure 3-1 CE symbol



## **Medical Devices Directive (93/42/EEC)**

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.

### **3.8 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.

## Spaulding classification

### 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 instruments 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 device is used (see Table 4-1 below).

**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 surgi-	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* (Sterilization 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)

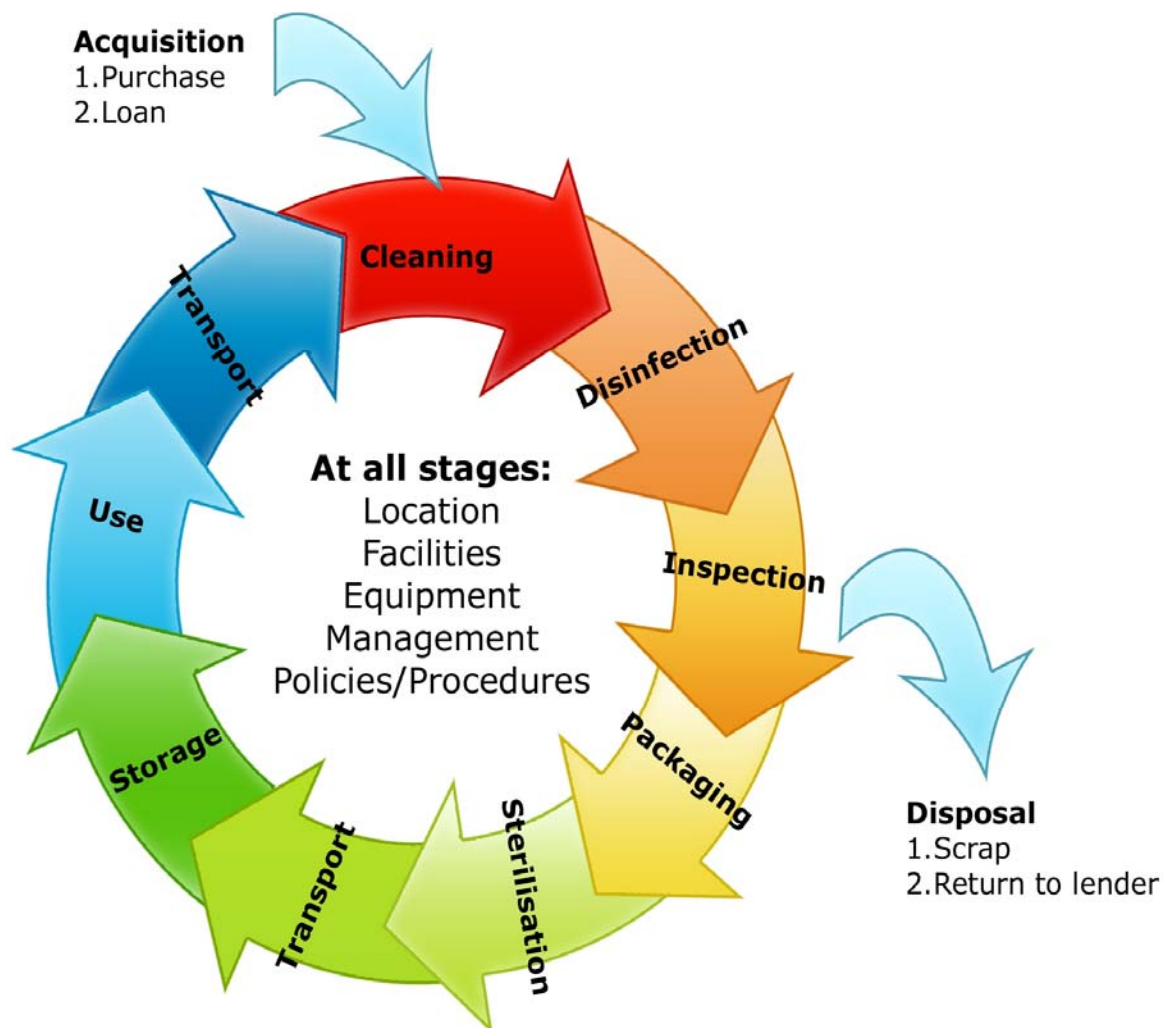
## Life cycle for reusable invasive medical devices

### 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.

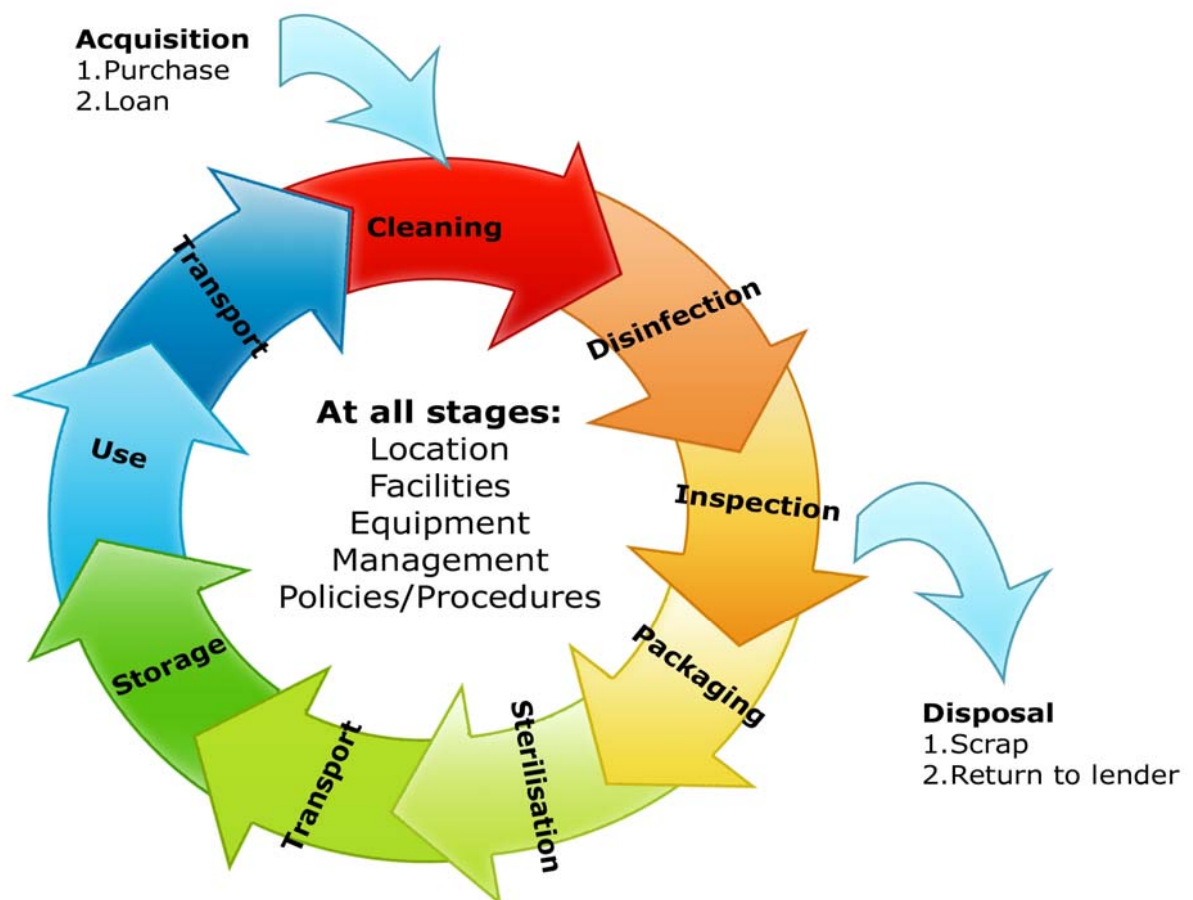
Figure 5.1 Decontamination life cycle



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

## PART 2: STANDARDS

# Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices





## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 2
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2009
<b>Contact Details:</b>	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p><b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a></p> <p><b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a></p>

## Part 2

# *Part 2* *Standards*

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## **Communication and consultation**

# **1 Communication and consultation**

## **1.1 Statement**

Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD), with key stakeholders within and outside the organisation.

## **1.2 Rationale**

Interactive exchange of information with key stakeholders creates an empowering infrastructure and environment. These are important factors for increasing the level of compliance with the decontamination programme and for continually improving performance.

## **1.3 Criteria**

1. The organisation shall develop a set of shared values, behavioural guidelines and quality principles in support of the Health Service Executive Code of Practice for Decontamination of RIMD that are reflected in job descriptions and vision statements.
2. Healthcare Workers shall be given an opportunity to provide feedback on these values, guidelines and quality principles.
3. These values, guidelines and quality principles shall be reflected in each departments business plans.
4. Regular reviews shall be undertaken to ensure that business plans are translated into action.
5. The organisation shall develop and implement a practical methodology for sharing best practice both internally and with key stakeholders in relation to decontamination of RIMD.
6. The organisation shall inform their staff and patients about the Health Service Executive Code of Practice for Decontamination of RIMD.

## **Communication and consultation**

7. Educational material shall be provided using a variety of different media as required.
8. Staff and key stakeholders shall be encouraged to use feedback procedures to the organisation for any concerns they have in relation to decontamination of RIMD.
9. The decontamination unit and clinical units which it supplies shall have a service level agreement.
10. The decontamination unit shall have in place a formal system for recording and analysing customer complaints.
11. The decontamination unit shall have in place a programme to reduce customer complaints.

## **Organisational structure and accountability**

## **2 Organisational structure and accountability**

### **2.1 Standard Statement**

Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.

### **2.2 Rationale**

The CEO/Manager through the senior management team is responsible for ensuring that there are effective arrangements for the decontamination of RIMD.

### **2.3 Criteria**

1. Individual responsibility for decontamination of RIMD shall be clearly defined throughout the organization and there shall be clear lines of accountability leading up to the most senior manager or director.
2. The scope of responsibility shall include the competence of contractors where the organisation buys in services and professional liability where the organisation sells services to other organisations.
3. Decontamination of RIMD shall be a standard item on the agenda of the quality and risk management committee (or appropriate committee) in the organisation. The Decontamination Coordinator shall submit regular reports on management of decontamination to the committee.
4. A twice yearly report on the conformity of the decontamination process within the organisation shall be submitted to the quality and risk committee (or appropriate committee) for review. This committee, which shall include in its membership the CEO/Manager or CEO/Manager nominee, shall present the report to the management team.
5. Each organisation shall identify a Decontamination Co-ordinator. The duties of the co-ordinator shall not be confined to any one aspect or decontamination function but shall encompass all decontamination processes wherever they occur within the organisation.



## Organisational structure and accountability

6. The Decontamination Coordinator shall have responsibility and authority for developing and monitoring policies, continuous quality improvement and/or strategies for decontamination of RIMD for approval by the quality and risk committee (or appropriate committee).
7. The Decontamination Coordinator shall attend appropriate meetings and conferences local and national, relevant to decontamination of RIMD, which will increase their knowledge and improve their ability to undertake the role.
8. The Decontamination Coordinator shall undertake the dissemination of all information, received from the National Hospitals Office and/or PCCC Directorates/relevant agencies relating to decontamination of RIMD within the organisation.
9. The Decontamination Coordinator shall work with clinicians and decontamination unit managers to develop and improve the systematic approach to decontamination of RIMD.
10. The Decontamination Coordinator shall be responsible for ensuring that the audit activity for decontamination of RIMD, under the responsibility of each decontamination unit manager has been completed.
11. The quality and risk committee (or appropriate committee) shall be responsible for the implementation and monitoring of a decontamination of RIMD audit and monitoring programme in each organisation.
12. Each relevant member of staff shall be made aware of their responsibility in relation to the decontamination process.
13. Each organisation shall have a specific resource provision for decontamination of RIMD related at least in part, to throughput.

**Note:** Smaller healthcare facilities may decide that the role of the Decontamination Coordinator is best performed as part of the duties of a Coordinator in a larger healthcare facility in the network/PCCC region or as part of the responsibilities of another role. What is important is that:

- The CEO/Manager takes active responsibility for management of decontamination.
- The resources devoted to decontamination of RIMD are adequate.

## **Suitability of decontamination facilities**

### **3 Suitability of decontamination facilities**

#### **3.1 Standard Statement**

Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD. 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) and Health Building Note 52 (Endoscopy Units).

#### **3.2 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.

#### **3.3 Criteria**

1. The department shall be designed so that it is physically separated from all other work areas.
2. The department shall be designed to allow segregation of 'dirty' and 'clean' activities.
3. The department shall be designed to facilitate a unidirectional work flow from the 'dirty' area to the 'clean' area.
4. The department shall not be used for any other purpose.
5. The department shall not be used as a thoroughfare.
6. The department shall not be part of any patient treatment area.
7. All rooms in the department shall be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures shall be controlled between 18-22 degrees Celsius and relative humidity shall be controlled within the range 35-60%).

### **Suitability of decontamination facilities**

8. The environment in which clean non-sterile RIMD are inspected, assembled and packed shall be controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8.
9. The clean area shall be micro-biologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003).
10. Safe storage facilities shall be provided for process chemicals used in decontamination.
11. Storage facilities for bulk items shall be provided external to the clean room and the wash room.
12. Storage facilities shall be provided for sterile product prior to despatch.
13. The shelving in storage facilities shall be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
14. Required personal protective equipment shall be easily accessible in each of the work areas.
15. Entry to the decontamination unit shall be restricted to authorised personnel only.
16. There shall be a changing area for donning work wear which shall include shower facilities, toilet facilities and lockers in proximity to the decontamination area.
17. Access to the wash room and to the clean room shall be through separate dedicated gowning rooms provided with hand hygiene facilities.
18. The area shall be managed by trained staff whose sole or primary responsibility is management of the decontamination unit.
19. The environment in which decontamination of RIMD takes place shall be cleaned in accordance with procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse).
20. Dedicated cleaning provision (both equipment and storage) shall be provided for the clean room and the wash room.
21. There shall be sufficient electricity supply, computer terminal points and work stations in the department.
22. The finishes on the walls and other surfaces shall be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning.
23. The junctions between the walls and floors shall be coved and flush.
24. The fitments (where possible) shall be flush with wall surfaces.

### **Suitability of decontamination facilities**

25. Floors shall be covered in a washable non-slip material which is securely sealed.
26. There shall be adequate lighting available to permit good working practices and visual examination of RIMD.
27. Task lighting and magnification shall be in situ.
28. All work surfaces, fittings, fixtures and furniture shall be made of easily cleanable and robust material and shall be maintained in good condition.
29. The workstations shall be equipped for the preparation of single or composite packs. They shall be of adequate size to accommodate the wrapping material to be used and shall be height adjustable.
30. There shall be adequate space between workstations for equipment and staff movement.
31. The shelving shall be of sufficient depth for all the materials to be held and shall not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.
32. The wash room, clean room and steriliser unloading area shall be free from 'opening' windows, ledges, and uncleanable areas.
33. The wash area and clean room shall be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).
34. Further detailed guidance is given in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities) and Health Building Note 52 (Endoscopy Units).

## **Decontamination equipment**

### **4 Decontamination equipment**

#### **4.1 Standard Statement**

All decontamination equipment that does not meet the requirements of current Standards shall be identified and upgraded or replaced in accordance with a planned replacement programme.

All new decontamination equipment shall be procured in conformance with extant harmonized Standards.

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

#### **4.2 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.

#### **4.3 Criteria**

1. The organisation shall have a specialist group in place to consider the decontamination equipment in the organisation as follows:
  - Ability to meet current Standards.
  - Age and condition of equipment and availability of replacement parts.
  - Cost of maintaining and repairing the equipment.
  - Ability to interface with other equipment in the decontamination facility.
  - Ability to interface with user requirements.

## Decontamination equipment

- Ability to meet the requirements of current test methods.
  - Ability to be validated and perform to intended purpose.
  - Energy and water conservation.
  - Ability for self-disinfection for washer-disinfectors and endoscope washer-disinfectors.
2. Key representatives on the specialist group shall include:
- Decontamination Coordinator.
  - Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/Endoscopy Manager.
  - Clinical Unit Manager, e.g. Theatre Manager.
  - Infection Prevention and Control.
  - Bio-medical Engineering/Clinical Engineering/Medical Physics.
  - Procurement.

The group may also include as required:

- Technical Services.
  - Materials Management.
  - Finance Manager/Budget Holder/Business Manager.
  - Other relevant experts (Authorised Person/Sterivigilance Nurse/Microbiologist).
3. The specialist group shall identify all decontamination equipment that needs to be replaced.
4. The specialist group shall formulate a plan to replace or upgrade this equipment.
5. The plan shall be submitted to the senior management team and shall be revised annually by the decontamination coordinator (or designated officer).
6. There shall be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
7. There shall be clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment.
8. The operational management of each item of decontamination equipment shall be the defined responsibility of a named person (usually the decontamination unit manager).

## Decontamination equipment

9. The validation and periodic testing data shall be carried out by qualified personnel.
10. The validation and periodic testing data shall be adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive.
11. The department shall have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

### *Manual washing*

12. Manual washing shall be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector (WD).
13. Dedicated manual cleaning equipment and accessories shall be available for specified RIMD that cannot be cleaned in an automated cleaning process.
14. Separate sinks for washing and rinsing shall be provided.
15. The detergent used shall be one specified by the manufacturer for the manual cleaning of RIMD.
16. Means shall be provided to control the concentration of detergent.
17. A pass-through drying cabinet with inter-locking doors shall be provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector.

### *Ultrasonic Cleaning*

18. A stand-alone ultrasonic cleaner shall 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.
19. The ultrasonic cleaner shall be equipped with the facility for automatic filling and emptying directly to the drain.
20. The ultrasonic cleaner shall be fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
21. The detergent used shall be one specified by the manufacturer for the ultrasonic cleaning of RIMD.
22. Means shall be provided to control the concentration of detergent.
23. The ultrasonic cleaner shall be used in accordance with the manufacturers' instructions.
24. The ultrasonic cleaner shall be validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006.

## **Decontamination equipment**

25. The temperature of the cleaning solution in the ultrasonic cleaner shall be thermostatically controlled.

### ***Washer-Disinfectors***

26. The specification of the washer-disinfector shall comply with requirements of EN ISO 15883, parts 1 & 2.
27. Washer-Disinfectors shall be double ended with the clean side discharging into the inspection area of the clean room.
28. Each washer-disinfector shall be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
29. When lumened devices are being reprocessed, the washer-disinfector shall be provided with load carriers that permit the irrigation of the lumened device.
30. Washer-disinfectors and accessories shall be specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1,2 & 5.
31. The Washer-Disinfector shall be subject to planned preventative maintenance.

### ***Steam Steriliser***

32. The specification of each steam steriliser shall comply with requirements of EN 285 and the steriliser shall be fitted with an air-detector.
33. Each steam steriliser shall be fitted with a process monitoring system independent of the automatic controller.
34. The sterilisation hold period shall be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
35. Steam Sterilisers shall be double ended with the loading side in the clean room.
36. Sterilisers and accessories shall be specified, installed, commissioned, tested and operated in accordance with the current Standard EN 285 and EN ISO 17665, part 1.
37. The steam sterilisers shall be subject to planned preventative maintenance.

### ***Low temperature sterilisers***

38. Low temperature sterilisation methods shall only be used where the manufacturers' instructions do not permit steam sterilisation.
39. Low temperature sterilisation shall be carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes.



## **Decontamination equipment**

- 40. Low temperature sterilisation methods shall be validated and shall be subject to periodic testing in accordance with ISO 14937.
- 41. Low temperature sterilisers shall be subject to planned preventative maintenance.

### ***Drying cabinet***

- 42. A pass-through drying cabinet between the wash-room and the clean room shall be provided. The doors of the drying cabinet shall be interlocked to prevent direct connection between the wash room and the clean room.
- 43. The drying cabinet shall be fitted with a temperature indicator and/or recorder independent of the controller.
- 44. The drying temperature throughout the cabinet shall be within  $\pm 5^{\circ}$  Celsius of the set temperature.
- 45. The drying cabinet shall 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.
- 46. The air in the cabinet shall be mechanically circulated and items placed throughout the cabinet shall be dried uniformly.
- 47. The drying cabinet shall be subject to planned preventative maintenance.

### ***Heat sealer***

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

## **Procurement of reusable invasive medical devices**

# **5 Procurement of reusable invasive medical devices**

## **5.1 Standard Statement**

Decontamination issues shall be considered prior to the acquisition of RIMD.

## **5.2 Rationale**

The type of RIMD, its design and construction determine the processes required for effective decontamination. This needs to be considered prior to purchase to ensure that the RIMD can be decontaminated within the available facilities.

## **5.3 Criteria**

1. The organisation shall have a specialist group in place to consider the procurement of RIMD.
2. Key representatives on the specialist group shall include:
  - Decontamination Coordinator.
  - Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/Endoscopy Manager.
  - Clinical Unit Manager, e.g. Theatre Manager.
  - Infection Prevention and Control.

The group may also include as required:

- Technical Services.
- Procurement.
- Bio-medical Engineering/Clinical Engineering/Medical Physics.
- Materials Management.
- Finance Manager/Budget Holder/Business Manager.
- Other relevant experts (Authorised person/Sterivigilance Nurse/Microbiologist).
- Health and Social Care Professional representative.

### Procurement of reusable invasive medical devices

3. The organisation shall have a documented procurement policy.
4. The procurement policy shall comply with the Irish Medicines Board (IMB) recommendations on the procurement of RIMD. SN2006(03)
5. The procurement of RIMD shall be based on agreed specifications and shall comply with the documented procurement policy.
6. There shall be a detailed specification for each RIMD which shall comply with current Standards.
7. Sufficient RIMD and accessories shall be purchased to allow adequate time for reprocessing in the decontamination unit(s) without adversely affecting throughput.
8. A decontamination assessment shall be undertaken prior to the purchase of RIMD to ensure that the organisation has the facilities to reprocess the RIMD in accordance with the manufacturers' instructions.

**Note:** The procurement group shall carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the processing procedure. This shall require that the manufacturers' validated instructions for the reprocessing of RIMD are available prior to purchase and comply with local policies and procedures.

9. Value for money issues shall be considered when purchasing RIMD.
10. Goods and services shall be purchased from the suppliers in line with the HSE procurement policy.
11. All RIMD and accessories shall be CE marked as this will constitute the manufacturers assurance that a device will be safe and will perform as intended.
12. Suppliers shall be selected based on their ability to supply RIMD in accordance with the specified requirements and provide service support over the lifetime of the RIMD, where applicable.
13. Where parts are single-use or have restricted use this information shall be provided prior to purchasing.

## Decontamination process

# 6 Decontamination process

## 6.1 Standard Statement

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

## 6.2 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.

## 6.3 Criteria

1. All stages of the decontamination process shall be clearly defined, documented, controlled and recorded.
2. All processes shall be carried out in accordance with documented procedures.
3. All RIMD sets shall be traced through the decontamination process to the patient.
4. Processing data shall be retained for the lifetime of the equipment plus eleven years.
5. There shall be a regular review of all procedures and any necessary changes shall be implemented by a documented change in procedures.
6. RIMD shall be checked and reprocessed in accordance with the manufacturers' instructions.
7. All RIMD shall be visually inspected for cleanliness prior to packaging.
8. All RIMD shall be inspected and/or tested for functionality prior to packaging.
9. There shall be 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.
10. All product released from the decontamination unit shall be labelled with a clear indication of the pack contents, the expiry date and a unique number which shall be used to trace the decontamination processes to which the RIMD was subjected.

## Decontamination process

11. Single use devices shall not be reprocessed. Any device with the following symbol shall be deemed single use only.

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

Figure 6-1      Do not reprocess symbol



## Management and key personnel

# 7 Management and key personnel

## 7.1 Standard Statement

Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.

## 7.2 Rationale

To ensure a high quality and safe decontamination of RIMD service.

## 7.3 Criteria

Key persons and responsibilities shall be as follows:

1. The *CEO/Manager* shall put in place arrangements to ensure effective decontamination of RIMD.
2. A *Decontamination Coordinator* shall be appointed, shall have formally defined responsibilities in accordance with these Standards and shall be provided with the necessary resource to discharge these responsibilities.
3. Each *Decontamination Unit* shall have a person appointed with responsibility for operational management of the unit, which may be in addition to other duties.
4. *Maintenance Personnel* (in-house or sub-contracted) shall be available and shall have documentary evidence to demonstrate competence in the maintenance of the decontamination equipment they will be dealing with.
5. *Test Personnel* (in-house or sub-contracted) shall be available and shall have documentary evidence to demonstrate competence in periodic testing of the decontamination equipment which they will be dealing with.
6. A *Microbiologist* shall be available to advise on microbiological aspects of decontamination.
7. An *Infection Prevention and Control Nurse* shall be available to advise on all aspects of infection surveillance, prevention and control.
8. The Decontamination Unit Manager shall have designated *Operatives* to be responsible for each aspect of the decontamination process and shall ensure that these personnel have been trained to the necessary standard of competence.

## Management and key personnel

9. A *Biomedical Engineer/Clinical Engineer* shall be available and designated by management for the testing and validation of decontamination equipment.
10. The *Qualified Person (decontamination)* used by the organisation shall be a person registered as an Authorised Person (Sterilisers) with the Institute of Healthcare Engineering and Estates management and shall be registered with the Health Service Executive as competent to discharge the duties of a Qualified Person (decontamination) in Ireland.

## Education and training

# 8 Education and training

## 8.1 Standard Statement

Education and Training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.

## 8.2 Rationale

All clinical and relevant support staff should have a clear understanding of the principles of the decontamination process and the part it plays in the control of infection. Staff who are well trained are more likely to provide a high quality, safe service.

## 8.3 Criteria

### 1. *General induction training shall include:*

- i. Departmental policies, procedures and Standards, including:
  - Infection Prevention and Control.
  - Safety, Health and Welfare at Work Act, 2005.
  - Occupational Health and Safety.
- ii. Safe operation of equipment.
- iii. Safety Statements (Corporate /Organisation/Departmental) to include specific risk assessments on the physical/chemical/biological hazards and associated protective and preventative measures.
- iv. Fire hazards and regulations.
- v. Moving and Handling.
- vi. First Aid.
- vii. Communications within the Health Service Executive.



## Education and training

### *2. In particular, the following issues shall be addressed in the training of clinical staff*

- i. An appreciation of the decontamination process.
- ii. Why processes and procedures take time to give an understanding of the issues faced by decontamination staff.
- iii. Standard Precautions for Infection Prevention and Control.
- iv. Transportation of contaminated equipment/RIMD.
- v. Principles of Cleaning, Disinfection, Inspection, Assembly, Packaging, Sterilisation and Despatch.
- vi. Transportation of sterile RIMD.
- vii. Storage of sterile RIMD.
- viii. Manufacturers' instructions for use of RIMD.
- ix. Identification of RIMD anomalies.
- x. Procurement.
- xi. Quality Management System.
- xii. Risk Management System.
- xiii. Repair/loan equipment.
- xiv. Labelling and single use items and their disposal.
- xv. Symbols associated with sterile RIMD.
- xvi. Roles and responsibilities of management and staff in relation to decontamination of RIMD.
- xvii. Procedures for dealing with contaminated equipment (Transmissible Spongiform Encephalopathies—TSEs).
- xviii. Audit and Monitoring.
- xix. Maintaining environmental cleanliness.

## Education and training

### *3. In particular, the following issues shall be addressed in the training of staff who work in decontamination units*

A detailed knowledge of the following processes, their control and monitoring and any necessary safety precautions:

- i. Standard Precautions for Infection Prevention and Control.
- ii. Transportation of contaminated equipment/RIMD.
- iii. Sorting and Disassembly of contaminated RIMD.
- iv. Cleaning.
- v. Disinfection.
- vi. Drying.
- vii. Post Cleaning Inspection and Function Testing.
- viii. Assembly.
- ix. Packaging.
- x. Sterilisation.
- xi. Storage.
- xii. Transportation of sterile equipment and RIMD.
- xiii. Manufacturers instructions for decontamination of RIMD.
- xiv. Identification of RIMD anomalies.
- xv. Clean room technology.
- xvi. Procurement.
- xvii. Testing, maintenance and validation of decontamination equipment.
- xviii. Personal Protective Equipment specific to decontamination of RIMD.
- xix. Quality Management System.
- xx. Risk Management System.
- xxi. Standards and legislation.
- xxii. The build environment (Health Building Notes).
- xxiii. Repair/loan equipment.

## Education and training

- xxiv. Labelling and single use items and their disposal.
  - xxv. Roles and responsibilities of management and staff in relation to decontamination of RIMD.
  - xxvi. Procedures for dealing with contaminated equipment (Transmissible Spongiform Encephalopathies—TSEs).
  - xxvii. Audit and Monitoring.
  - xxviii. Maintaining environmental cleanliness.
- 
- 4. *Induction training (see above) shall be provided and recorded in the relevant individuals training record.*
  - 5. *There shall be a continuing programme of training and education for staff.*
  - 6. *Training shall be supported with adequate resources and facilities.*
  - 7. *Individual competencies shall be assessed and records shall be kept in the unit.*
  - 8. *A formal appraisal system shall be in place to monitor staff performance and to identify individual training needs.*

## Quality management system

# 9 Quality management system

## 9.1 Standard Statement

Central decontamination units shall operate a quality management system in accordance with EN ISO 13485.

Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.

## 9.2 Rationale

Formal documented control of decontamination within a quality management system is necessary to monitor each aspect of the decontamination process in order to demonstrate compliance with current legislation and guidance. This reduces risks to patients, staff and to the Health Service Executive.

## 9.3 Criteria

1. Central Decontamination Units in the organisation shall operate a quality management system in accordance with EN ISO 13485.

**Endoscope and local decontamination units operate a quality system in accordance with the following key operational elements of EN ISO 13485.**

2. The organisation shall have documented policies, procedures and records for all the key elements of the decontamination process. For each decontamination unit, key policies, procedures and guidelines shall be in place, and where assessed as relevant, include:
  - i. Standard Precautions for Infection Prevention and Control.
  - ii. Transportation of contaminated equipment/RIMD.
  - iii. Sorting and Disassembly of contaminated RIMD.
  - iv. Cleaning.
  - v. Disinfection.
  - vi. Drying.
  - vii. Post Cleaning Inspection and Function Testing.

## Quality management system

- viii. Assembly.
  - ix. Packaging.
  - x. Sterilisation.
  - xi. Storage.
  - xii. Transportation of sterile equipment and RIMD.
  - xiii. Manufacturers' instructions for decontamination of RIMD.
  - xiv. Identification of RIMD anomalies.
  - xv. Procurement.
  - xvi. Testing, maintenance and validation of decontamination equipment.
  - xvii. Personal Protective Equipment specific to decontamination of RIMD.
  - xviii. Repair/loan equipment.
  - xix. Labelling and single use items and their disposal.
  - xx. Procedures for dealing with contaminated equipment (Transmissible Spongiform Encephalopathies—TSEs).
  - xxi. Maintaining environmental cleanliness.
  - xxii. Staff training.
- 3. All policies and procedures associated with decontamination of RIMD shall comply with current Standards, legislation and Health Service Executive guidance.
  - 4. The quality and risk management committee (or appropriate committee) shall approve policies, procedures and guidelines for decontamination of RIMD in the organisation.
  - 5. There shall be a system to ensure each department or service has a current copy of the approved decontamination of RIMD policies, procedures and guidelines pertinent to its activities.
  - 6. All relevant staff shall be required to read the decontamination of RIMD policies and procedures relevant to their area of work and to sign a statement to indicate that they have read, understood and will comply with same.
  - 7. All policy and procedure documents associated with decontamination of RIMD shall be controlled showing the date of issue and revision number.
  - 8. Master copies shall be kept in a secure location.

## Quality management system

9. Obsolete documents shall be removed from all points of use.
10. A biennial review of all policies, procedures and documents associated with decontamination of RIMD shall be undertaken to check their relevance and issue status.
11. A computerised documentary system shall be available within each decontamination unit to allow the provision of appropriate information to senior management as required. Decontamination unit personnel shall be proficient in the application and operation of such systems.
12. All data (electronic and manual) shall be stored securely. Electronic data shall be backed up and audited in accordance with the organisations policy.
13. Access to data/records shall be restricted to authorised named persons and specified information shall be maintained in line with the Data Protection Acts.
14. All records associated with the decontamination life cycle shall be retained for the life-time of the equipment/RIMD plus eleven years.
15. These records shall be readily accessible to permit traceability when required.

## **Risk management system**

# **10 Risk management system**

## **10.1 Standard Statement**

The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.

## **10.2 Rationale**

Effective risk management is essential for healthcare safety and overall quality improvement. It allows managers to be aware of potential risks and offers the opportunity to deal with them before any loss occurs.

## **10.3 Criteria**

1. The organisation shall compile a list of foreseeable hazards associated with each stage in the decontamination process.
2. The list of hazards shall be maintained in a risk management file.
3. All identified hazards shall be documented as part of a risk register and systematically assessed and prioritised.
4. The organisation shall identify and assess all risks associated with all stages in the decontamination process.
5. The organisation shall institute control measures for identified risks.
6. The organisation shall have a monitoring programme in place to verify compliance with policies and procedures.
7. The organisation shall have documented arrangements for responding to emergencies.
8. The organisation shall identify, record and analyse 'adverse events' and 'near misses'.

## **Risk management system**

9. The organisation shall have a reporting procedure for reporting accidents and incidents to the relevant authorities.
  - i. Reports to the Senior Management Team.
  - ii. Reporting clinical adverse incidents to the Clinical Indemnity Scheme (CIS).
  - iii. Reporting dangerous occurrences to the Health & Safety Authority (HSA) in accordance with organisation policy.
  - iv. Reporting adverse incidents involving medical device defects to the Irish Medicines Board (IMB).
  - v. Reporting incidents to the Health & Safety Authority (HSA) in respect of employees.
10. The organisation shall have a documented decontamination policy with clear reference to risk management that includes:
  - Health and Safety.
  - Management arrangements for emergencies and untoward incidents.
  - Provision to learn from incidents.
  - Compliance with all relevant legislation, including the Safety, Health and Welfare at Work Act, 2005 and Medical Devices Regulations.
11. The organisation shall have taken measures to ensure that all relevant employees receive adequate information concerning matters relating to the Safety, Health and Welfare at Work Act, 2005.
12. Material Safety Data Sheets shall be made available to all staff who are using potentially hazardous chemicals.
13. Chemical risk assessments shall be completed and brought to the attention of all relevant staff.
14. Each department where decontamination of RIMD takes place shall have a Departmental Safety statement which documents physical, chemical, biological and psychological hazards and associated protective and preventative measures.
15. The organisation shall have a documented staff decontamination training programme to include induction of all new staff through to continual professional development for all other grades.



## Health and safety

# 11 Health and safety

## 11.1 Standard Statement

Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used devices and process chemicals.

## 11.2 Rationale

Patient and staff safety, health and welfare is a vitally important issue and there should be an ongoing programme dealing with key issues identified from risk assessment and other processes.

## 11.3 Criteria

1. Each decontamination unit manager and their staff shall be aware of and shall have access to current health and safety regulations and guidelines as they apply to the decontamination unit.
2. Each decontamination unit shall have a health and safety policy which shall be available and disseminated to staff. This policy shall be up to date and shall be regularly reviewed.
3. Each decontamination unit shall have access to competent health and safety advice.
4. Each decontamination unit shall identify the decontamination processes that may generate substances hazardous to health.
5. These processes shall be contained by appropriate precautions.
6. There shall be regular audits of compliance with the control measures.
7. Each decontamination unit shall have procedures in place to deal with accidents, incidents and emergencies.
8. Flammable liquids and chemicals shall be stored in flame-proof cupboards which are kept locked and closed.
9. Emergency treatment kits for contact with personnel/spillages shall be provided and shall be easily accessible in the work area.

## Health and safety

10. There shall be procedures in place to ensure that all decontamination equipment and accessories are specified, installed, commissioned, tested and operated in accordance with current Standards.
11. Personal protective equipment shall be provided and shall be easily accessible in the work area.
12. There shall be a formal, documented release for sterile RIMD to ensure that the RIMD is only returned for use on a patient after it has been decontaminated using validated reprocessing equipment and in line with the manufacturers' instructions.
13. Current copies of approved infection prevention and control policies and procedures in relation to decontamination of RIMD shall be readily accessible to staff in each decontamination unit.
14. Occupational health services shall be provided for all staff.

## Complaints management

# 12 Complaints management

## 12.1 Standard Statement

All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information.

## 12.2 Rationale

Complaints, comments and incidents may be linked and are complementary sources of information for improving the safety and quality of the decontamination service.

## 12.3 Criteria

### *Complaints System*

1. The documented complaint system shall cover the following:
  - The person(s) responsible for operating the system.
  - Evaluation of the complaint.
  - Records and statistical summaries enabling the major causes of complaints to be determined.
  - Preventative and corrective action.
  - Segregation and disposition, or reprocessing of customer returns and faulty stock (special attention may need to be given to decontamination).
  - Filing of customer correspondence and other relevant records.

## Complaints management

### *Complaints Process*

2. Corrective action shall be implemented without undue delay when a finished product is found to be defective or is subject to adverse reports, such action shall include one or more of the following:
  - Withholding products available for sale.
  - Withdrawing products from circulation.
  - Giving advice to customers; this may take the form of checks to be carried out before use, providing additional guidance on the use of the product or for the replacement of certain products.
  - In extreme cases, the recall of products.
3. Preventative action shall be implemented to ensure as far as practicable that there will be no recurrence of the non-conformance. The efficacy of the preventative action shall be verified.

## **Audit and monitoring**

### **13 Audit and monitoring**

#### **13.1 Standard Statement**

Audits shall be carried out to ensure that the procedures for decontamination of RIMD conform to the required Standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

#### **13.2 Rationale**

Audit is necessary to ensure that the decontamination process is in compliance with current requirements; that documented procedures are implemented effectively and that processes are objectively reviewed to identify areas for improvement. Remedial action is necessary to correct any non-compliance identified by the audit.

#### **13.3 Criteria**

1. Audit of decontamination of RIMD shall include:
  - i. Accountability arrangements.
  - ii. Staff knowledge, expertise and resources.
  - iii. Processes, including risk management arrangements.
  - iv. Policies, procedures and guidelines.
2. Each decontamination unit manager shall be responsible for preparing a written agreed programme which shall ensure that all aspects of the decontamination processes and their management within the unit shall be audited at least once a year.
3. Each decontamination unit manager shall be responsible for ensuring that the audit is conducted in accordance with this programme.
4. Each decontamination unit manager shall be responsible for ensuring that remedial actions are carried out for any deficiencies found and for verifying the efficacy of remedial actions undertaken.
5. The quality and risk Committee (or appropriate committee) shall be responsible for ensuring that the audit activity, under the responsibility of the decontamination unit manager has been completed.

## **Audit and monitoring**

6. Audit results shall be fed back to the decontamination coordinator, the quality and risk Committee (or appropriate committee), relevant staff and the senior management team.
7. Audit results shall be included in the quality and risk management annual report (or appropriate annual report).
8. Audit results shall be used to help to inform and improve decontamination of RIMD practices.
9. The audits shall be carried out by appropriately trained auditors.
10. The senior management team shall submit an annual assurance statement on audit findings for consideration and approval by the Network Manager/Assistant National Director Primary Community and Continuing Care (PCCC).
11. The Network Manager/Assistant National Director PCCC shall submit annual assurance statements to the Director of the National Hospitals Office/Director of Primary, Community and Continuing Care.
12. External national audits of decontamination shall be carried out as appropriate under the direction of the Assistant National Directors of Quality, Risk and Customer Care.

## Key performance indicators

### 14 Key performance indicators

#### 14.1 Standard Statement

Key performance indicators that are capable of showing improvements in the efficacy of the decontamination process shall be used. The usefulness of the indicators shall be reviewed regularly.

#### 14.2 Rationale

Key performance indicators are designed to demonstrate improvement in the performance of decontamination services over time.

#### 14.3 Criteria

##### *Environment*

1. All rooms in the department shall be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures shall be controlled between 18-22 degrees Celsius and relative humidity shall be controlled within the range 35-60%).
2. The department shall be designed to allow segregation of 'dirty' and 'clean' activities.
3. The environment in which clean non-sterile RIMD are inspected, assembled and packed shall be controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8.
4. The clean area shall be micro-biologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003).
5. The environment in which decontamination of RIMD takes place shall be cleaned in accordance with procedures and schedules agreed by the decontamination coordinator, with advice when required from the Consultant Microbiologist and Infection Prevention and Control Nurse.
6. Dedicated cleaning provision (both equipment and storage) shall be provided for the clean room and the wash room.

## **Key performance indicators**

7. Access to the wash room and to the clean room shall be through separate dedicated gowning rooms provided with hand hygiene facilities.
8. Safe storage facilities shall be provided for process chemicals used in decontamination.
9. Storage facilities shall be provided for sterile product prior to despatch.
10. All work surfaces, fittings, fixtures and furniture shall be made of easily cleanable and robust material and shall be maintained in good condition.

## ***Equipment***

### **Manual washing**

11. Manual washing shall be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector.
12. Separate sinks for washing and rinsing shall be provided.
13. Means shall be provided to control the concentration of detergent.
14. A pass-through drying cabinet with inter-locking doors shall be provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector.
15. The detergent used shall be one specified by the manufacturer for the manual cleaning of RIMD.

### **Ultrasonic Cleaning**

16. A stand-alone ultrasonic cleaner shall 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.
17. Automatic filling of the ultrasonic cleaner and emptying directly to the drain shall in situ.
18. The detergent used shall be one specified by the manufacturer for the ultrasonic cleaning of RIMD.
19. Means shall be provided to control the concentration of detergent.
20. The ultrasonic cleaner shall be validated and shall be subject to periodic testing and planned preventative maintenance.



## Key performance indicators

### Washer-Disinfectors

21. The specification of the washer-disinfector shall comply with requirements of EN ISO 15883, parts 1 & 2.
22. The washer-disinfector shall be a pass-through design located between the wash room and the clean room.
23. Each washer-disinfector shall be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
24. When lumened devices are being reprocessed, the washer-disinfector shall be provided with load carriers that permit the irrigation of the lumened device.
25. The washer-disinfector shall be validated and shall be subject to periodic testing in accordance with EN ISO 15883, parts 1, 2 & 5. The Washer-Disinfector shall be subject to a planned preventative maintenance.

### Steam Steriliser

26. The specification of each steam steriliser shall comply with requirements of EN 285 and the steriliser shall be fitted with an air-detector.
27. Each steam steriliser shall be fitted with a process monitoring system independent of the automatic controller.
28. The sterilisation hold period shall be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
29. Sterilisers and accessories shall be specified, installed, commissioned, tested and operated in accordance with the current Standard EN 285 and EN ISO 17665, part

### Low temperature sterilisers

30. Low temperature sterilisation methods shall only be used where the manufacturers' instructions do not permit steam sterilisation.
31. Low temperature sterilisation shall be carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes
32. Low temperature sterilisation methods shall be validated and shall be subject to periodic testing in accordance with ISO 14937 and planned preventative maintenance.

## Key performance indicators

### Drying cabinet

33. A pass-through drying cabinet between the wash-room and the clean room shall be provided. The doors of the drying cabinet shall be interlocked to prevent direct connection between the wash room and the clean room.
34. The drying temperature throughout the cabinet shall be within  $\pm 5^{\circ}$  Celsius of the set temperature.
35. The drying cabinet shall be fitted with a temperature indicator and/or recorder independent of the controller.

### Heat sealer

36. Where heat seal packaging is to be used, a rotary heat sealer shall be provided.
37. The heat sealer shall be validated and tested daily to verify the efficacy of the seal.

### *Utilities*

38. Steam sterilisers shall be provided with clean steam, complying with IS EN 285.
39. Washer-disinfectors shall be provided with purified water, for all process stages and purified water for the final rinse stage.
40. The steam supply for sterilisation shall be tested at least annually for dryness value, super-heat and non-condensable gas concentration.
41. Compressed air used for testing power tools shall be medical grade and oil free.

### *Management and Personnel*

42. The CEO/Manager shall put in place arrangements to ensure effective decontamination of RIMD.
43. A decontamination coordinator shall be appointed, shall have formally defined responsibilities in accordance with these Standards and shall be provided with the necessary resource to discharge these responsibilities.
44. Each decontamination unit shall have a person appointed with responsibility for operational management of the unit, which may be in addition to other duties.
45. Maintenance and test personnel shall be available and suitably qualified for the decontamination equipment in use.

### **Key performance indicators**

46. A microbiologist shall be available to advise on the microbiological aspects of decontamination.
47. The decontamination unit manager shall have designated operatives to be responsible for each aspect of the decontamination process and shall ensure that these personnel have been trained to the necessary standard of competence.
48. Test Personnel (in-house or sub-contracted) shall be available and shall have documentary evidence to demonstrate competence in periodic testing of the decontamination equipment which they will be dealing with.
49. An Infection Prevention and Control Nurse shall be available to advise on all aspects of infection surveillance, prevention and control.

### ***Processes***

50. The organisation shall have a specialist group in place to consider the procurement of RIMD.
51. All stages of the decontamination process shall be clearly defined, documented, controlled and recorded.
52. All processes shall be carried out in accordance with documented procedures.
53. All RIMD sets shall be traced through the decontamination process to the patient.
54. All RIMD shall be visually inspected for cleanliness prior to packaging.
55. All RIMD shall be inspected and/or tested for functionality prior to packaging.
56. There shall be 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.
57. All product released from the decontamination unit shall be labelled with a clear indication of the pack contents, the expiry date and a unique number which shall be used to trace the decontamination processes to which the device was subjected.

## **Key performance indicators**

### *Service Quality*

- 58. The decontamination unit and clinical units which it supplies shall have a service level agreement.
- 59. The decontamination unit shall have in place a formal system for recording and analysing customer complaints.
- 60. The decontamination unit shall have in place a programme to reduce customer complaints.

## **Procedures relating to transmissible spongiform encephalopathies**

### **15 Procedures relating to transmissible spongiform encephalopathies (TSEs)**

#### **15.1 Standard Statement**

The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.

#### **15.2 Rationale**

Invasive interventions performed on patients who have been diagnosed as having, or who are at risk of developing, a TSE result in the need for additional control measures to prevent iatrogenic transmission of TSE's.

#### **15.3 Criteria**

1. RIMD and equipment used on patients at increased risk of developing a TSE shall be single-use where possible.
2. The organisation shall have written policies and procedures for the identification of patients at increased risk of developing a TSE.
3. These policies and procedures shall be based on Irish TSE Infection Control Guidelines Final Version, Sept 2004.

## **PART 3: RECOMMENDED PRACTICES FOR CENTRAL DECONTAMINATION UNITS**

# **Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices**



## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 3
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All relevant staff in the public health service who work in Central Decontamination Units (CDU), Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2008
<b>Pictures:</b>	All pictures in this document were taken with the kind assistance of the CDU staff in St. Vincent's Hospital, Dublin.
<b>Contact Details:</b>	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p><b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a></p> <p><b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a></p>

**Part 3**

*Part 3*  
*Recommended Practices*  
*For Central Decontamination Units*



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## **Design of central decontamination unit facilities**

# **1 Design of central decontamination unit facilities**

## **1.1 Introduction**

The decontamination of RIMD should take place in a designated and controlled area. This optimises the effect of the decontamination process, minimises contamination, provides a safe working environment and safeguards the products.

## **1.2 Scope**

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

## **1.3 Contents**

Section One: Unit design

Section Two: Lighting and electricity

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

Section Ten: Other

## **Design of central decontamination unit facilities**

### **1.4 Procedure**

#### **Section One: Unit design**

- The department should be designed so that it is physically separated from all other work areas.
- The department should be designed to allow segregation of 'dirty' and 'clean' activities.
- The department should be designed to facilitate a unidirectional flow from the 'dirty' area to the 'clean' area.
- The department should not be used for any other purpose.
- The department should not be used as a thoroughfare.
- The department should not be part of any patient treatment area.
- There should be a changing area for donning work wear which includes shower, toilet facilities and lockers in proximity to the decontamination area.
- Access to the wash room and to the clean room should be through dedicated gowning rooms provided with hand hygiene facilities.
- The wash room, clean room and steriliser unloading area should be free from 'opening' windows, ledges, and uncleanable areas.
- The wash area and clean room should be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).

#### **Section Two: Lighting and electricity**

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

## **Design of central decontamination unit facilities**

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

- 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**

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

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

- All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- The workstations should be equipped for the preparation of single or composite packs. They should be of adequate size to accommodate the wrapping material to be used and should be height adjustable.
- There should be adequate space between workstations for equipment and staff movement.
- The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- 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 central decontamination unit facilities**

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

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

### **Section Seven: Storage facilities**

- Safe storage facilities should be provided for process chemicals used in decontamination.
- Storage facilities for bulk items should be provided external to the clean room and the wash room.
- Required personal protective equipment should be easily accessible in each of the work areas.

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

- The clean area should be controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8.
- The environment in which clean non-sterile RIMD are inspected, assembled and packed should be micro-biologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003).

### **Section Nine: Cleaning**

- The environment in which decontamination of 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 Nurse).
- Dedicated cleaning provision (both equipment and storage) should be provided for the clean room and the wash room.

## **Design of central decontamination unit facilities**

### **Section Ten: Other**

- Further detailed guidance is given in Health Building Note 13 (Sterile Service Departments).

## **Environmental cleaning**

## **2 Environmental cleaning**

### **2.1 Introduction**

Adequate regular cleaning of all work areas is essential for the decontamination lifecycle to be effective. Environmental cleaning procedures and schedules adopted must ensure that contamination from dirty areas does not contaminate the clean areas. The cleaning should be monitored by regular documented inspection of the cleanliness of the environment and the cleaning equipment. Written cleaning protocols should be prepared and passed by the appropriate committee, including methods and frequency of cleaning.

### **2.2 Scope**

The objective of this procedure 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

### **2.4 Procedure**

#### **Section One: Cleaning Equipment**

- There should be a separate cleaner's utility room for the clean and dirty areas.
- Separate cleaning equipment should be used for the clean room and wash areas.
- Cleaning equipment should be regularly cleaned and maintained.

## Environmental cleaning

### Section Two: Cleaning frequency and cleaning efficacy

- Work surfaces should be cleaned at the start of the working day, periodically during the working day and whenever necessary.
- Entire rooms should be deep cleansed annually. Air vents and filters should be serviced regularly.
- There should be documented cleaning procedures for fixtures and fittings.
- There should be documented cleaning procedures for process equipment.
- There should be microbial count by passive sampling.
- Efficacy of cleaning should be monitored microbiologically.
- Warning/action limits should be set for microbial contamination in each area.

### Section Three: Floor cleaning equipment and method

The following floor cleaning equipment and method should be used:

- Mop and bucket using 'two bucket' system and a free rinsing detergent.
- Vacuum fitted with HEPA filtered exhaust.
- 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).
- Floors should be cleaned daily and also cleaned when visibly soiled.

### Section Four: Floor cleaning agents

- Disinfectants should be used to ensure infection control and to ensure that cleaning equipment does not spread microbial load.
- If visible blood/body fluids are present, disinfectants should be used following thorough cleaning.
- Disinfectants should be made up according to the manufacturers' instructions/organisations policy.

## Environmental cleaning

### Section Five: Spillage kits

- The areas where used RIMD are received and handled should have a chlorine based disinfectant to decontaminate blood spills.
- 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).

### Section Six: Records

Records should be kept of the following:

- Training of the personnel carrying out the cleaning.
- All cleaning carried out and by whom.
- Cleaning of the cleaning equipment.
- Periodic inspection of cleanliness.
- Any non-conformances found and the remedial action taken.



## **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 procedure 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

- Each organisation should have a specialist group in place to consider the decontamination equipment in the organisation with regard to the following:
  - i. Ability to meet current standards.
  - ii. Age and condition of equipment and availability of replacement parts.
  - iii. Cost of maintaining and repairing the equipment.
  - iv. Ability to interface with other equipment in the decontamination facility.
  - v. Ability to interface with user requirements.
  - vi. Ability to meet the requirements of current test methods.
  - vii. Ability to be validated and perform to intended purpose.
  - viii. Energy and water conservation.
  - ix. Ability for self-disinfection for washer-disinfectors and endoscope washer-disinfectors.
- Key representatives on the specialist group should include:
  - i. Decontamination Coordinator.
  - ii. Decontamination Unit Manager, e.g. Central Decontamination Unit Manager.
  - iii. Clinical Unit Manager, e.g. Theatre Manager.
  - iv. Infection Prevention and Control.
  - v. Bio-medical Engineering/Clinical Engineering/Medical Physics.
  - vi. Procurement.

The group may also include as required:

- i. Technical Services.
- ii. Materials Management.
- iii. Finance Manager/Budget Holder/Business Manager.
- iv. Other relevant experts (Authorised Person/Sterivigilance Nurse/Microbiologist).

## Decontamination equipment

- The specialist group should identify all decontamination equipment which needs to be replaced.
- The specialist group should formulate a plan to replace or upgrade this equipment.
- The plan should be submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer).
- The specialist group should ensure that the decontamination equipment procured is compatible with the current stock of RIMD, trays, trolleys, etc.
- There should be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
- There should be clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment.
- The operational management of each item of decontamination equipment should be the defined responsibility of a named person (usually the decontamination unit manager).
- Validation and periodic testing should be carried out by qualified personnel.
- The validation and periodic testing data should be adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive.
- The department should have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

### Section Two: Manual washing

- Manual washing should be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a washer-disinfector.
- Dedicated manual cleaning equipment and accessories should be available for specified RIMD that cannot be cleaned in an automated cleaning process.
- Separate sinks for washing and rinsing should be provided.
- The detergent used should be one specified by the manufacturer for the manual cleaning of RIMD.
- Means should be provided to control the concentration of detergent.
- 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.

## Decontamination equipment

### Section Three: Ultrasonic cleaning

- 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.
- The ultrasonic cleaner should be equipped with the facility for automatic filling and emptying directly to the drain.
- The ultrasonic cleaner should be fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- The detergent used should be one specified by the manufacturer for the ultrasonic cleaning of RIMD.
- Means should be provided to control the concentration of detergent.
- The ultrasonic cleaner should be used in accordance with the manufacturers' instructions.
- The ultrasonic cleaner should be validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006.

### Section Four: Washer-disinfectors

- The specification of the washer-disinfector should comply with requirements of EN ISO 15883, parts 1 & 2.
- Washer-disinfectors should be double ended with the clean side discharging into the inspection area of the clean room.
- Each washer-disinfector should be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
- When lumened devices are being reprocessed, the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- Washer-disinfectors and accessories should be specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1, 2 & 5.
- The washer-disinfector should be subject to planned preventative maintenance.

### Section Five: Steam sterilisers

- The specification of the steam steriliser should comply with requirements of EN 285 and the steriliser should be fitted with an air-detector.
- Each steam steriliser should be fitted with a process monitoring system independent of the automatic controller.

## Decontamination equipment

- 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.
- Steam sterilisers should be double ended with the loading side in the clean room.
- Sterilisers and accessories should be specified, installed, commissioned, tested and operated in accordance with the current standard EN 285 and EN ISO 17665, part 1.
- The steam sterilisers should be subject to planned preventative maintenance.

### Section Six: Low temperature sterilisers

- Low temperature sterilisation methods should only be used where the manufacturers' instructions do not permit steam sterilisation.
- Low temperature sterilisation should be carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes.
- Low temperature sterilisation methods should be validated and subject to periodic testing in accordance with ISO 14937.
- Low temperature sterilisers should be subject to planned preventative maintenance.

### Section Seven: Drying cabinets

- A pass-through drying cabinet between the wash-room and the clean 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.
- The drying cabinet should be fitted with a temperature indicator and/or recorder independent of the controller.
- The drying temperature throughout the cabinet should be within  $\pm 5^{\circ}$  Celsius of the set temperature.
- 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.
- The air in the cabinet should be mechanically circulated and items placed throughout the cabinet should be dried uniformly.
- The drying cabinet should be subject to planned preventative maintenance.

## Decontamination equipment

### Section Eight: Heat sealers

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

## **Procurement of reusable invasive medical devices**

# **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 procedure 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**

- Each organisation should have a specialist group in place to consider the procurement of RIMD.
- Key representatives on the specialist group should include:
  - i. Decontamination Coordinator.
  - ii. Decontamination Unit Manager, e.g. Central Department Unit Manager.
  - iii. Clinical Unit Manager, e.g. Theatre Manager.
  - iv. Infection Prevention and Control.

## **Procurement of reusable invasive medical devices**

The group should also include as required:

- i. Surgeon.
- ii. Technical Services.
- iii. Procurement.
- iv. Bio-medical Engineering/Clinical Engineering/Medical Physics.
- v. Materials Management.
- vi. Finance Manager/Budget Holder/Business Manager.
- vii. Other relevant experts (Authorised person/Sterivigilance Nurse/Microbiologist).
- viii. Health and Social Care Professional representative.

### **Section Two: Procurement policy**

- Each organisation should have a documented procurement policy.
- The procurement policy should comply with the Irish Medicines Board (IMB) recommendations on the procurement of RIMD. SN2006(03)

### **Section Three: Specification**

- The procurement of RIMD should be based on agreed specifications and should comply with the documented procurement policy.
- There should be a detailed specification for each RIMD which complies with current standards.

### **Section Four: General principles**

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



## **Procurement of reusable invasive medical devices**

**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 and procedures.

- Value for money issues should be considered when purchasing RIMD.
- Goods and services should be purchased from the suppliers in line with the HSE procurement policy.
- 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.
- 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.
- 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 RIMD must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the 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 must be set out in the leaflet supplied with one or more devices.

## **5.2 Scope**

The objective of this procedure is to outline the information that must accompany each 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

## **Manufacturers' instructions**

### **5.4 Procedure**

#### *Manufacturer*

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

- If the RIMD is intended by the manufacturer to be reused, the following information should be provided:
  - i. Appropriate processes to allow reuse, including cleaning, disinfection, packaging and (if appropriate), the methods of sterilisation of the RIMD to be resterilised.
  - ii. The number of reuses.
  - iii. Any restriction to the reuse.
- If the RIMD is supplied with the intention that it can be sterilised before use, instructions for sterilisation methods should be provided.
- If the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas should be provided.
- 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.
- The degree of accuracy claimed for RIMD with a measuring function should be provided.
- 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.
- Detachable components of the RIMD should be identified.
- Action to detect any potential risk posed by the RIMD and detachable components should be provided.
- Where parts are single use or have restricted use, this information should be provided.

## **Manufacturers' instructions**

### **Section Two: Label**

*The label should contain the following details:*

- The name or trade name and address of the manufacturer.
- The details strictly necessary for the user to identify the RIMD and the contents of the packaging.
- Where appropriate, the word 'STERILE'.
- Where appropriate, the batch code, preceded by the word 'LOT', or the serial number.
- Where appropriate, an indication of the date by which the RIMD should be used, in safety, stating the month and the year.
- Where appropriate, an indication that the RIMD is for single use.
- If the RIMD is custom-made, the words 'custom-made RIMD'.
- If the RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- Any special storage and/or handling conditions.
- Any special operating instructions.
- Any warnings and/or precautions to be taken.
- Year of manufacture.
- Batch or serial number.
- Where applicable, method of sterilisation.
- 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.

### **Section Three: The instructions for use:**

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

- 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.

## **Manufacturers' instructions**

- 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.
- Where appropriate, information to avoid certain risks in connection with the implantation of the RIMD should be provided.
- Information regarding the risks of reciprocal interference posed by the presence of the RIMD during specific investigations or treatment.
- The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of resterilisation.
- If the RIMD 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.
- Details of any further treatment or handling needed before the RIMD can be used (for example, sterilisation, final assembly, etc).
- 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:*

- Precautions to be taken in the event of changes in the performance of the RIMD.
- Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions; to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.
- 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.
- Precautions to be taken against any special, unusual risks related to the disposal of the RIMD.

## **Manufacturers' instructions**

### **Section Five: Information supplied on request**

- The identity or information on the test methods used.
- 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:

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

#### **Section Seven: Instructions for use**

In general, Class I and Class IIa devices (see part 1, page 17) which comprise most of the RIMD processed by a central 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

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

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

## 6.2 Scope

The objective of this procedure is the outline the PPE that must 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: Protective eyewear and face-shields

Section Four: Masks

Section Five: Plastic aprons and gowns

## Personal protective equipment

Section Six: Gloves

Section Seven: Footwear

### 6.4 Procedure

#### *Decontamination unit*

##### Section One: Attire

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

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

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

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.
- After use, headgear should be discarded in the appropriate healthcare waste stream.



## Personal protective equipment

- Stud earrings may be worn and should be totally confined within the head cover.
- **Note:** Make-up or jewellery (except wedding band) should not be worn in the decontamination unit.

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

- Healthcare workers (HCWs) should wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear or face shields should be single-use.
- Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- Face shields should cover the eyes, nose, mouth and chin.

### Section Four: Masks

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

## Personal protective equipment

### Section Five: Plastic aprons and attire

- Healthcare Workers (HCWs) should wear impermeable attire with long cuffed sleeves and tuck-inside-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.
- Fluid repellent attire and aprons should be changed whenever they become visibly soiled or wet.
- After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

### Section Six: Gloves

- Gloves should be used for handling contaminated RIMD and waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- 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.
- **It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.**
- HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves should be discarded in the appropriate healthcare waste stream.

## Personal protective equipment

### Section Seven: Footwear

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

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



## **Clean room attire and behaviour**

# **7 Clean room attire and behaviour**

## **7.1 Introduction**

Protective clothing must be worn by personnel entering the clean room, to reduce the risk of adventitious contamination of the clean product. Managers must ensure that protective clothing is made available and all personnel are responsible for ensuring the correct use and disposal of same.

## **7.2 Scope**

The objective of this procedure is the outline the personal protective equipment to be worn and the behaviour to be adopted by staff in the clean room to reduce the risk of contaminating clean devices.

## **7.3 Contents**

Section One: Attire

Section Two: Head/hair cover

## **7.4 Procedure**

### **Section One: Attire**

- All personnel working in the clean room should wear a freshly laundered scrub suit.
- Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet.
- Appropriate clothing should be used by staff who are involved in the maintenance of reprocessing equipment.
- When working outside the decontamination area suitable cover attire should be worn.

## Clean room attire and behaviour

### Section Two: Head/hair cover

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

Figure 7-1: Personal Protective Equipment (Clean Room)



## **Process chemicals**

# **8 Process chemicals**

## **8.1 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.

## **8.2 Scope**

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

## **8.3 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

## **8.4 Procedure**

### **Section One: Choice of process chemicals**

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

## Process chemicals

### Section Two: Control of process chemicals

- The methods to be used for handling and storage of process chemicals should be defined in written procedures.
- Chemicals that should not be stored together should be clearly identified.
- Chemicals should not be stored above shoulder height.

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

- Suppliers of chemical agents should provide MSDS for all chemical agents (including cleaning agents).
- 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.
- If information is incorporated into policies and procedures, the original wording should be used and the MSDS referred to.
- Personnel should read and follow the precautions and instructions given on the MSDS and on the label prior to handling and use.

### Section Four: Training

All personnel who handle chemicals e.g. detergents, 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

Each area where chemicals are used, a spillage kit should be available.

## **Traceability**

# **9 Traceability**

## **9.1 Introduction**

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

The tracking system should record the progress of sets of RIMD, or individual supplementary RIMD, through each stage of the decontamination process and allow retrospective demonstration that a particular set or supplementary RIMD has been correctly decontaminated.

The tracing system should permit retrospective tracing of the RIMD history including the patients on which it was used.

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

## **9.2 Scope**

The objective of this procedure is to provide guidelines for the effective tracking and traceability of RIMD through the decontamination life-cycle.

## **9.3 Contents**

Section One: Processing

Section Two: Tracing

## **9.4 Procedure**

### **Section One: Processing**

- Systems should be in place to allow the methods, operational cycles and personnel involved in the processing of a particular RIMD/RIMD set to be tracked through the decontamination processes in order to permit retrospective verification that the processes were carried out effectively.



## Traceability

- Records should be maintained of:
  - i. The cleaning, disinfection and sterilisation process cycle used.
  - ii. The name of the person undertaking each stage of the decontamination process.
  - iii. The date, time and test result.
  - iv. Details of the RIMD being processed.
- As a minimum, sets of RIMD should be individually identified.
- Identification of individual 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).
- 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.
- Records relating to decontamination processes should be maintained for the lifetime of the RIMD/decontamination equipment plus eleven years.

### Section Two: Tracing

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

## Choice of decontamination process

# 10 Choice of decontamination process

## 10.1 Introduction

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

## 10.2 Scope

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

## 10.3 Contents

Section One: General principles

## 10.4 Procedure

### Section One: General principles

- 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.
- The minimum levels of processing and storage requirements for RIMD, based on three risk categories of use, are shown in the Spaulding Classification (See Table 7-1, Part 1). In brief, the minimum levels of reprocessing are as follows for different types of site:
  - i. **Critical site** – instruments should be sterile at the time of use. This means instruments should be single use, should be steam sterilised (for instruments that are capable of withstanding heat), or should have undergone low temperature sterilisation (for heat-sensitive equipment).
  - ii. **Semicritical site** – instruments 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.

## Choice of decontamination process

- iii. **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.
- Decontamination processes should be chosen to be compatible with the RIMD to be processed.
- 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.
- Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- Decontamination processes should be chosen to be amenable to independent verification of the decontamination standards achieved.
- The decontamination methods selected should be economical and effective.
- The decontamination methods used should be compatible with recommended methods of validation.

## **Transportation—return of used items for reprocessing**

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

## **11.1 Introduction**

All RIMD are considered to be soiled and contaminated after each use and can be a potential source of infection. Contaminated RIMD should be handled, collected and transported in a manner that avoids dissemination of contamination. Transport of soiled RIMD to the decontamination area should be accomplished as soon **as possible after use**. If delay is unavoidable, the user must make sure that the item is safely contained and secured to await collection.

## **11.2 Scope**

The objective of this procedure is to provide guidelines in relation to the transportation of contaminated RIMD.

## **11.3 Contents**

Section One: Containers and trolleys

Section Two: Staff

## **11.4 Procedure**

### **Section One: Containers and trolleys**

- Contaminated RIMD should be placed in closed, sealed, secure containers and transported to the decontamination area as soon as possible after use. Transport containers should protect both the product during transit and the handler from inadvertent contamination.
- Bins with lids and closed sterilisation container systems are among the types of containers that may be used to transport contaminated items.
- Impermeable bags should be used also to contain RIMD within the container.

## **Transportation—return of used items for reprocessing**

- Containers should be selected based on the characteristics of the items being transported; in particular they should be:
  - i. Leak-proof.
  - ii. Rigid, to contain RIMD, preventing them becoming a hazard to anyone handling the goods and to protect them against accidental damage.
  - iii. Capable of being closed securely.
  - iv. Lockable, where appropriate, to prevent tampering.
  - v. Clearly labelled to identify the user and the contents where applicable.
  - vi. Robust enough to prevent RIMD being damaged in transit.
  - vii. Have the ability to be easily cleaned, disinfected and dried, or discarded (as appropriate) using agreed methods.
  - viii. Designated containers should be used for the collection of RIMD, unless the central decontamination unit is equipped with a washer-disinfector for cleaning and thermal disinfection of containers after each use.
- RIMD/RIMD sets should be separated from healthcare risk waste at the point of use.
- Sharps should be removed and placed into approved containers conforming to BS 7320 (1990).
- Reusable textiles should be held in appropriate linen bags and returned to the laundry service.
- All fluids, e.g. blood, bodily fluids, cleaning and antiseptic solutions should be disposed of before placing RIMD in transport containers.
- All transportation equipment has to be cleaned in accordance with local policy.

## Transportation—return of used items for reprocessing

### Section Two: Staff

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

Figure 11-1: Transportation—return of used items for reprocessing



## **Sorting and disassembly of contaminated reusable invasive medical devices**

### **12 Sorting and disassembly of contaminated reusable invasive medical devices**

#### **12.1 Introduction**

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

#### **12.2 Scope**

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

#### **12.3 Contents**

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

Section Two: Disassembly of RIMD

#### **12.4 Procedure**

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

- On receipt at the decontamination area, RIMD should be sorted according to the selected method of cleaning, e.g. manual cleaning process or automated cleaning process. The manufacturers' instructions for cleaning should be followed in order to ensure the RIMD is not damaged and is cleaned adequately.
- Policies and/or procedures should be developed for the handling, sorting and disassembly of RIMD.
- There should be written policies and/or procedures for handling specialised items.
- Care and handling of RIMD should be in accordance with manufacturers' instructions and organisation policies and procedures.

## Sorting and disassembly of contaminated reusable invasive medical devices

### Section Two: Disassembly of RIMD

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

- Open RIMD box locks.
- Place RIMD in mesh basket in a manner which ensures effective cleaning of RIMD. Do not place RIMD one on top of the other. **Overloaded baskets will result in ineffective cleaning.**
- Arrange RIMD in an orderly fashion in mesh trays so that all surfaces are exposed to the action of an automated cleaner, if used.
- Place each jointed RIMD in the open position in the mesh basket.
- If extra mesh baskets are required for cleaning purposes of an RIMD set, a marker should be placed in the extra baskets to identify the set name and number.
- Place heavy retractors and/or other heavy RIMD on the bottom or in a separate tray.
- 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 RIMD, and microsurgical RIMD next.
- Receivers and gallipots should not be placed over RIMD, as they may interfere with the cleaning process.
- Separate all sharp RIMD from general RIMD. This is to ensure ease of identification for personnel assembling the RIMD after cleaning, in order to prevent sharps injury.
- For RIMD with one or more lumens, each lumen should be connected to the appropriate flushing system provided for that purpose.

Figure 12-1: Sorting and Disassembly of contaminated RIMD





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

### **13 Cleaning (including pre-cleaning)**

#### **13.1 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. The process must not be used for items intended for single-use only.**

#### **13.2 Scope**

The objective of this procedure is to provide guidelines in relation to cleaning of contaminated RIMD. Cleaning is the initial and most crucial step in breaking the chain of disease transmission.

#### **13.3 Contents**

Section One: Manufacturers' instructions

Section Two: Automated versus manual cleaning

Section Three: Initial cleaning

Section Four: Automated cleaning

Section Five: Manual cleaning

#### **13.4 Procedure**

##### **Section One: Manufacturers' instructions**

- The manufacturers' instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the RIMD will tolerate immersion.
- RIMD should be cleaned, handled and inspected according to manufacturers' instructions. Manufacturers' instructions provide direction for care, cleaning and handling of RIMD and powered equipment. The instructions for cleaning and sterilisation should be such that if correctly followed the device can be reused, without causing injury to the patient or personnel using the RIMD. (ISO, 17664).

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

### **Section Two: Automated versus manual cleaning**

- The use of mechanical cleaners such as washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.
- 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.
- Automated processes are generally more convenient and also provide protection for the user in reducing exposure to contaminated RIMD and chemicals.

### **Section Three: Initial cleaning**

- Manual Cleaning (see section five) should be used where it is apparent that there is gross soiling on RIMD that it would be preferable to remove before automated cleaning takes place.

### **Section Four: Automated cleaning**

#### **1. *Washer-disinfectors***

##### **a. Introduction**

All washer-disinfectors used for decontamination of RIMD should conform to ISO/FDIS 15883 parts 1, 2 and 5, 2006. 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.

##### **b. Factors to be considered when determining if the RIMD is compatible with the washer-disinfector**

- Manufacturers' instructions.
- If the RIMD can be immersed in water.
- Maximum operating temperature.
- Mechanical damage which may occur from the impact of the water jets or other items in the load.
- The compatibility of the process chemicals.

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

### **c. Equipment**

- See decontamination equipment section, page 20.

### **d. Procedure**

- Ensure the washer-disinfector and all services are operational. The washer-disinfector should not start if any anomalies are present.
- 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.
- Only use load carrier and racks with the items for which they were intended.
- Keep a record of each RIMD/RIMD set processed in each washer-disinfector and each cycle in order to trace the RIMD/RIMD set through the decontamination process.
- Load the load carrier into the washer-disinfector.
- Secure the door (if fitted), select and start the cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the RIMD processed should be inspected.
- A typical cycle comprises the following phases:
  - i. Cold rinse.
  - ii. Warm wash.
  - iii. Rinse.
  - iv. Disinfection rinse.
  - v. Drying.
- Information should be recorded for each washer-disinfector cycle. Documentation is required for every washer-disinfector cycle and should contain the following:
  - i. Washer-disinfector identification number.
  - ii. Cycle number.
  - iii. Type of washer-disinfector.
  - iv. Type of cycle used.
  - v. Date and time of start of cycle.

### Cleaning (including pre-cleaning)

- vi. Load content e.g. general instrument set, stitch set, mayo scissors.
  - vii. Critical parameters for the specific washer-disinfector cycle.
  - viii. Operator's name.
  - ix. Results of washer-disinfector process
  - x. Signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters
  - xi. Any notes or observation for the process cycle
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
  - Cycles which were aborted should be documented with the action taken in a log book.
  - Where single-ended washer-disinfectors are used adequate segregation of unprocessed goods from processed goods should take place.
- e. **Thermal disinfection**
- 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 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 13-1 below.

Table 13-1: Automated washer-disinfector temperature bands (ref. EN ISO 15883-1)

$A_0$ value	Temperature	Holding Time (Seconds)	Holding Time (Minutes)
60	80	-	1
60	90	6	-
600	80	-	10
600	70	-	100
600	90	-	1
1200	93	-	1

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

### **f. Validation**

- 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.
- 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.
- 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:
  1. Commissioning (installation qualification and operational qualification).
  2. Performance qualification.
  3. Periodic testing.
  4. Annual and revalidation tests.

#### **1. Commissioning**

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**

- Verification of calibration of washer-disinfector instruments, automatic control test, water quality tests, water supply temperature and water supply pressure.

#### **Operational qualification tests**

- Weekly safety checks, automatic control test, verification of calibration of washer-disinfector instruments, 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.

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

- 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.
- 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 an Authorised Person 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.
- 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**.

### **2. Performance qualification**

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 RIMD). It should be carried out by a Test Person (or other suitably qualified person). These tests consist of:

- Thermometric tests for a full load of items not previously represented by the reference load, load dryness test (of RIMD requiring reprocessing), cleaning efficacy test and process residues.

### **3. Periodic testing**

- 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.
- The daily, weekly and quarterly tests supply evidence that the washer-disinfector is still operating within the limits established during commissioning.
- 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.
  - **Daily:** Spray arm rotation, spray nozzles, remove and clean strainers and filters.

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

- **Weekly:** Automatic control test, safety checks, daily tests, water hardness, water conductivity and cleaning efficacy test (residual soil detection).
- **Quarterly tests:** Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection and cleaning efficacy test.
- **Annual tests:** Yearly safety checks, automatic control test, verification of calibration of instruments, 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.

### **g. 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.
- Validation, routine monitoring and control should be carried out in accordance with documented procedures in accordance with European standard EN ISO 15883, part 2, 2006.

### **h. Maintenance**

- Preventative maintenance should be planned and performed in accordance with International Standards ISO 15883-1 and ISO 15883-2 and manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The washer-disinfector will not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.
- Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers' instructions and/or local policy, including:
  - i. Inspecting and cleaning all filters.
  - ii. Dismantling and cleaning spray arms and nozzles.
  - iii. Efficacy tests during operational conditions.

## Cleaning (including pre-cleaning)

Figure 13-1: Washer-Disinfector



Figure 13-2: Loading the Washer-Disinfector





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

### **2. Ultrasonic Cleaners**

#### **a. Introduction**

Ultrasonic cleaners work by the use of high intensity, high frequency sound waves which cause soil to be dislodged from the 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 RIMD for ultrasonic cleaning.

#### **b. Equipment Required**

- See decontamination equipment, page 20.

#### **c. Procedure**

- Staff should wear personal protective equipment at all times while handling contaminated RIMD and working with the ultrasonic cleaner.
- Fill the tank with potable water (drinking quality) to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- Bring the solution up to the operating temperature.
- De-gas the water as recommended by the manufacturer.
- Place the opened/dismantled RIMD into the basket.
- Ensure all RIMD are fully immersed.
- If the RIMD is not for further cleaning, e.g. automated cleaning, record the following:
  - i. Method used.
  - ii. Solution dilution and temperature.
  - iii. Healthcare worker carrying out procedure.
  - iv. Date.
- Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.
- Close the lid and initiate the cleaning cycle.

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

- 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.
- The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.
- Combine only RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.
- Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.
- 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.

### **d. Validation**

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.
- 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:
  - i. Commissioning (installation qualification and operational qualification).
  - ii. Performance qualification.
  - iii. Periodic testing.
  - iv. Annual and revalidation tests.

#### ***1. Commissioning***

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 tests

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

### Operational qualification tests

- 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.
- 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.
- Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of ultrasonic cleaner.
- 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.

## 2. *Performance qualification*

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:

- Cleaning efficacy test, load dryness test and process residues test.

## 3. *Periodic testing*

- 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.
- The daily, weekly and quarterly tests supply evidence that the ultrasonic cleaner is still operating within the limits established during commissioning.

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

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

### **e. Monitoring and control**

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.

### **f. Maintenance**

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

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

### **g. Test for Ultrasonic Activity (reference HTM 2030)**

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*

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

#### *Method*

- Measure the depth of the bath from the level of the lid to the bottom of the bath.
- Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.
- Carry out the manufacturer's recommended start-up procedure.
- 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.
- 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.
- 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.
- Operate the bath for the predetermined exposure time.
- Remove the strips from the bath, blot dry and examine.
- 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).
- On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

## Cleaning (including pre-cleaning)

### Section Five: Manual cleaning

#### 1. Immersion

##### a. Introduction

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

##### b. Equipment required

- 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.
- Dirty put-down area adjacent to the wash sink adjacent to a washed RIMD put-down area, adjacent to the rinse sink adjacent to the rinsed RIMD out-down area (See figure 13-3 below).

Figure 13-3: Sink required for manual cleaning



- A validated method of dispensing a measured quantity of detergent.
- A method of controlling temperature of the water in the wash and rinse sinks: thermostatic mixer taps are preferred.
- A warm detergent solution. (Follow manufacturers' instructions for dilution and temperature).

## Cleaning (including pre-cleaning)

- A selection of brushes in a range of diameters and lengths for cleaning both the external surfaces and the internal surfaces of RIMD.
- After cleaning, manually washed RIMD that are not to be further processed through the washer-disinfector should be dried.
- 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.

### c. Procedure

- Healthcare workers should wear personal protective equipment at all times while handling contaminated RIMD.
- 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 instruments and not for any other purpose.
- 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).
- Detergent dilution and water temperature should be in accordance with the manufacturers' instructions and local policies and procedures.
- Consideration should be given to the use of an enzymatic detergent to facilitate the cleaning of RIMD with channels or complex parts.
- 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.
- 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.
- Flush all lumened RIMD with a jet-gun (discharge under water).
- Rinse the item finally in warm-to-hot water (unless contra-indicated).
- 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.
- Inspect RIMD and equipment to establish that they are clean before further processing or storage.
- Thoroughly wash and dry receptacles before storing and re-use.

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

- Cleaning brushes should be identified for cleaning only and should be washed, thermally disinfected, and stored dry.
- A record should be kept of each RIMD/RIMD set that has been manually cleaned.
- The records should contain:
  - i. Name of RIMD/RIMD set.
  - ii. Name of processor.
  - iii. Date.
  - iv. Type of cleaning.
  - v. Type of detergent and detergent dilution used.

### **d. Monitoring and control**

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:

- i. Staff training/competence.
- ii. Water temperature.
- iii. Detergent concentration.
- iv. Nature of soil.
- v. Method of soil removal.
- vi. Accessibility of fluid to item.

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

### **e. Maintenance**

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.



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

### **2. *Non-Immersion***

#### **a. Introduction**

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.

#### **b. Equipment required**

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

#### **c. Procedure**

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- Wearing protective clothing immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Commencing with the upper surface of the RIMD, wipe thoroughly ensuring that the detergent solution does not enter electrical components.
- Periodically rinse the cloth in clean water and repeat the previous two steps.
- Remove detergent solution using clean, damp, non-linting cloth.
- 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)**

### **d. Monitoring and control**

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:

- Staff training/competence.
- Water temperature.
- Detergent concentration.
- Nature of soil.
- Method of soil removal.
- Accessibility of fluid to item.

## Disinfection

# 14 Disinfection

## 14.1 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.

## 14.2 Scope

The objective of this procedure is to provide guidelines in relation to disinfection of RIMD.

## 14.3 Contents

Section One: Level of disinfection

Section Two: Disinfection process

## 14.4 Procedure

### Section One: Level of disinfection

- **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.
- **Low-level disinfection** – this is the minimum treatment recommended for reprocessing RIMD for use in noncritical sites.

### Section Two: Disinfection process

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

## Disinfection

- 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.

### 1. *Thermal Disinfection*

#### a. Introduction

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.

#### b. Equipment required

- Automated equipment, such as washer-disinfectors are recommended for use in thermal disinfection processes.
- 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).
- The manufacturers' instructions should be followed to achieve the required level of disinfection.

#### c. Monitoring and control

- Whenever practicable disinfection should be carried out using a validated disinfection process using automated equipment (e.g. washer-disinfector).
- 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.
- The thermal disinfection process should provide adequate assurance of the required microbial lethality.

## **Disinfection**

### **2. Chemical Disinfection**

#### **a. Introduction**

- 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. Hospital 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).

#### **b. Equipment required**

- RIMD disinfectant or sterilant.
- Automated equipment.

#### **c. Monitoring and control**

- Chemical disinfection processes should provide adequate assurance of the required microbial lethality.
- Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.
- Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- 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.
- Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.
- 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.
- When rinsing, channels should be flushed thoroughly if rinsing is performed manually.

## **Drying**

# **15 Drying**

## **15.1 Introduction**

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

## **15.2 Scope**

The objective of this procedure is to provide guidelines in relation to the drying of RIMD.

## **15.3 Contents**

Section One: Equipment

Section Two: Procedure

Section Three: Monitoring and control

Section Four: Maintenance

## **15.4 Procedure**

### **Section One: Equipment**

- See decontamination equipment, page 20.

### **Section Two: Procedure**

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

## Drying

### Section Three: Monitoring and control

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

### Section Four: Maintenance

- Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- Drying cabinet maintenance and repair log book should be maintained for each dryer.
- The dryer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485: 2003(E).

## **Post cleaning inspection and function testing**

# **16 Post cleaning inspection and function testing**

## **16.1 Introduction**

Inspection, maintenance and testing of RIMD should be carried out by trained persons in accordance with the manufacturers' instructions. All 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 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 RIMD/RIMD sets.

## **16.2 Scope**

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

## **16.3 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

### 16.4 Procedure

#### Section One: Equipment

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

#### Section Two: Procedure

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

- 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.
- Check that the operating cycle is in accordance with the specification for the load used, (e.g. laryngeal masks do not require rinse aid).
- 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.
- Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- 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.
- 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.
- Make a visual inspection of the load for dryness.
- Where a load may not be properly cleaned the load is rejected and returned for re-cleaning.
- 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.
- Where a small percentage of the load is suspect the items are rejected and returned for re-cleaning.

## Post cleaning inspection and function testing

- 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

- All documentation for automated cleaning should contain the following information:
  - i. Washer-disinfector identification number.
  - ii. Cycle number.
  - iii. Type of washer-disinfector.
  - iv. Type of cycle used.
  - v. Date and time of start of cycle.
  - vi. Load content, e.g. general RIMD, stitch set, mayo scissors.
  - vii. Critical parameters for the specific washer disinfector cycle.
  - viii. Operators name.
  - ix. Results of washer-disinfector process.
  - x. Signature of an authorised qualified person confirming whether or not the process cycle was within recommended parameters.
  - xi. Any notes or observation for the process cycle.
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- Before commencing inspection the person carrying out inspection should ensure that:
  - i. RIMD/RIMD set has been recorded as being through the specific cleaning process.
  - ii. 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.
  - iii. The signature of identified responsible person confirming that the cycle has passed.

## Post cleaning inspection and function testing

### Section Four: Inspection and function testing

- Each RIMD set should be inspected separately.
- Box joints, serrations and crevices, should be critically inspected for cleanliness.
- Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.
- Jaws and teeth should be checked for alignment.
- Ratchets should be checked for security.
- Ratchets should close easily and hold firmly.
- Any damaged, incomplete or malfunctioning RIMD should be reported immediately to the supervisor.
- Cannulated RIMD should be checked to ensure channel is patent.
- Telescopes and light cables should be function checked as per manufacturers' instructions.
- Each RIMD set should be checked for completeness and defects.
- Cutting edges (on RIMD such as scissors, rongeurs, chisels, curettes) should be checked for sharpness.
- Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.
- 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 patients.
- 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.
- Each RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.
- Each RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.
- The diathermy pin hole detector should be used in accordance with the manufacturers' instructions to ensure safe use of equipment.

## Post cleaning inspection and function testing

### Section Five: Monitoring and control

The user should be aware of the factors that may alter the efficacy of the method:

- Staff training/competence.
- Age of the RIMD.

### Section Six: Maintenance

- 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' instructions.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485:2003(E).

Figure 16-1: Post cleaning inspection



## **Assembly**

### **17 Assembly**

#### **17.1 Introduction**

The purpose of assembly and checking is to ensure that:

- All RIMD are present in accordance with RIMD list.
- All RIMD are assembled correctly in accordance with manufacturers' instructions.
- All RIMD are placed in the correct tray in a manner that ensures ease of use by the user.

The area where assembly and checking takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the RIMD/RIMD sets.

#### **17.2 Scope**

The objective of this procedure is to provide guidelines in relation to the assembly of RIMD.

#### **17.3 Contents**

Section One: Equipment

Section Two: Procedure

Section Three: RIMD set weight

#### **17.4 Procedure**

##### **Section One: Equipment**

- RIMD list.
- Accessories, e.g. tray liner.
- RIMD protectors.

## Assembly

### Section Two: Procedure

- RIMD should be assembled in accordance with the manufacturers' instructions, prior to packaging and/or further reprocessing.
- In preparing RIMD for wrapping and sterilisation, it is essential that all surfaces are presented to the sterilisation media (i.e. steam). Where the manufacturers' instructions indicate that RIMD to be sterilised are disassembled, it is essential that they are presented in this state.
- For RIMD with ratchets, they should be closed on the first ratchet only, to ensure steam can penetrate to all surfaces.
- Similar RIMD should be kept together when placing in tray, e.g. artery forceps can be placed on an RIMD pin together.
- The RIMD tray should be selected so that the RIMD can preferably be placed in one single layer.
- Tray liners should be placed in the base of the RIMD tray.
- RIMD should be spread evenly by weight over the tray surface, this helps prevent condensate flowing together.
- Each RIMD should be checked against the RIMD list specific to the tray being assembled.
- Plastic items should be evenly placed in the tray; avoid collecting them in one area.
- Ensure sharp RIMD are assembled correctly to avoid penetration of the outer packaging.
- Protectors to be placed on sharp RIMD should be validated for steam penetration.
- Ensure delicate RIMD are placed in tray in a manner which will not cause damage to the RIMD.
- Any RIMD which is missing from a tray should be reported to supervisor for further action and non conformance documented.
- Any extra RIMD found while assembling tray should be reported to supervisor for further action and non conformance documented.

## Assembly

### Section Three: RIMD set weight

- The ability of a given sterilisation cycle to produce a dry load is largely dependant on the configuration and thermal mass of the load.
- The condensate is produced as the steam heats the load, the heat from the load is used to boil-off the condensate during the vacuum drying stage. The mass specific heat and thermal conductivity determine the efficacy of this process for any particular set of RIMD
- The configuration of sets of RIMD required to permit dry loads should be established during performance qualification testing of the steam steriliser.
- The validated configurations should be documented as specifications for use during packaging.

Figure 17-1: Assembly



## **Packaging**

# **18 Packaging**

## **18.1 Introduction**

RIMD require packaging prior to sterilisation. The packaging material and packaging techniques are designed to hold and protect the RIMD in order to facilitate sterilisation and to maintain sterility. The material selected depends on which particular method of sterilisation is recommended and must comply with EN 868, parts 1-10.

## **18.2 Scope**

The objective of this procedure is to provide guidelines in relation to the packaging of RIMD.

## **18.3 Contents**

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



## Packaging

### 18.4 Procedure

#### Section One: General principles

- The choice and type of wrapping material will depend on the type of sterilisation process used.
- 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.
- When selecting packaging system each specific products capability to meet predetermined requirements and criteria should be evaluated.
- The appropriate size wrapping material should be chosen to attain adequate coverage of the item being packaged.
- 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.
- Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.
- RIMD packs should be packed in a manner that prevents damage to delicate items.
- Trays used for packaging RIMD should be perforated to allow for penetration of the sterilant.
- Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.
- Hollowware should be packaged so that all openings face the same direction.
- Only the minimum of raw materials commensurate with daily production should be held within the clean room.
- Compatibility of the packaging material with the sterilisation process should be established.
- 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.
- Sequential wrapping using two barrier-type wrappers is recommended as it provides a torturous pathway to impede microbial migration.

## Packaging

### Section Two: Packaging systems

Packaging systems should:

1. *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.
2. *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.
3. *Be used according to the manufacturers' instructions*
4. *Be of the following*
  - Resistant to punctures, tears and other damage which may break the barrier and cause contamination.
  - Resistant to penetration by micro-organisms from the surrounding environment.
  - Free of holes.
  - Be free of toxic ingredients.
  - Low-linting.

## Packaging

- Tamper proof and able to seal only once.
- Provide an adequate barrier to particulate matter and fluids.

### Section Three: Packaging materials

Packaging materials should:

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

### Section Four: Single use packaging

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

#### 1. *Papers and non-wovens*

- 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.
- 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.
- 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.

## Packaging

### 2. Containers

#### *Rigid reusable containers:*

- Should be easily disassembled for cleaning, drying and storage.
- Should be suitable for the method of sterilisation being used.
- Should be compatible to the cleaning method and cleaning agent being used
- Should be suitable to the storage configuration.
- Should have locking devices which are tamperproof and non resealable.
- Should be packed in a manner which allows for penetration of the sterilising agent.
- Lid and contents should be removable without the risk of contamination of the contents.
- Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.
- The filter plate should be examined for integrity both before installation and after the sterilisation process.
- If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system should be used in the practice setting.
- 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.
- 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.
- 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.
- Containers should be cleaned between each use; automated cleaning is the preferred method of cleaning.

## Packaging

### Section Six: Packaging techniques

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

#### 1. *Flat wrapping material*

##### a. **Equipment required**

- Packaging material.
- Sterilisation chemical indicator tape.
- Marking pen.
- Label (where applicable).
- Tray liners.

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

- Select appropriate packaging material and place on work top.
- The RIMD set is placed on the wrap, approximately in the centre of the packaging material.
- Verify the accuracy of the RIMD identification label with the RIMD/RIMD set, (i.e. corresponds to RIMD list, internal tray label, etc).
- The long edge of the tray should be aligned parallel to the long edge of the wrap.
- One of the long edges of the wrap is folded over the pack contents to the base of the tray, and the edge of the wrap is turned back on itself.
- The 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.
- The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- The same procedure may then be repeated for an outer wrap(s).

## Packaging

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

Figure 18-1: Parcel-fold wrapping method



Step 1



Step 2



Step 3



Step 4



Step 5



Step 6



Step 7

## Packaging

### c. Procedure (envelope wrapping method)

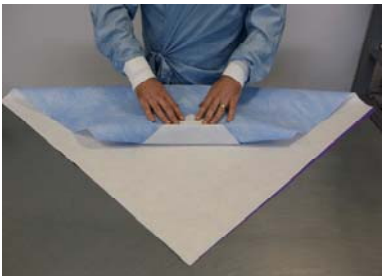
- Select appropriate packaging material and place on work top.
- The RIMD set is placed on the wrap diagonally and slightly off the centre line.
- Verify the accuracy of the RIMD identification label with the RIMD/RIMD set (i.e. corresponds to the RIMD list, tray internal label, etc).
- The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.
- This is repeated with the corners to the right and left of the first folded corner.
- In each case the corner is turned back to provide a flap for opening.
- Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.
- The same procedure may then be repeated for an outer wrap(s).
- The wrap is secured in position using 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.
- RIMD identification label is placed on the outside wrap.

Packaging

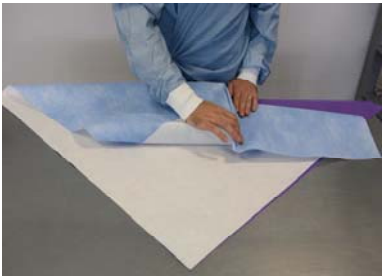
Figure 18-2: Envelope wrapping method



Step 1



Step 2



Step 3



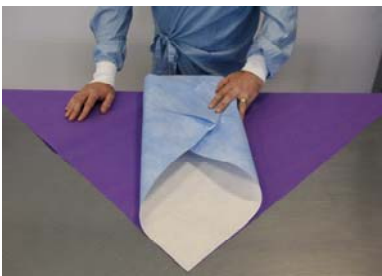
Step 4



Step 5



Step 6



Step 7



Step 8



Step 9



Step 10



## Packaging

### 2. *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.

#### a. Equipment required

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

#### b. Procedure

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

## Packaging

### 3. *Self-seal Pouches*

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

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

#### a. General Principles

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

#### b. Equipment required

- Heat-seal Pouches.
- Heat sealer.
- Marking pen.
- Label (where applicable).

#### c. Procedure

- Select appropriate size heat seal pouch.
- Place RIMD into pouch.
- Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.

## Packaging

- 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.
- Place open end of pouch in heat sealer.
- Apply heat and pressure to the surface of the open end of the heat seal pouch.
- Checks should be made that the seal is complete, especially over the gusset folds of the pouches.
- 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.
- The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- 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.
- Edges of inner heat seal pouches should not be folded as air maybe entrapped in the folds and inhibit sterilisation.
- 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.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the sterilant into and out of the package.
- If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.
- It is important to wrap the RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- Use adhesive RIMD identification label, do not write on the paper side of the pouch.
- RIMD identification label is placed on the outside packaging.

## Packaging

Figure 18-3: Using the heat seal



Figure 18-4: Heat seal pouch



## Packaging

### Section Seven: Sealing of packs and bags

#### a. Introduction

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 867-1.

#### b. Accessories used to close or secure packages should be able to perform the following:

- Allow sterilisation.
- Avoid constriction of the package.
- Maintain package integrity.

The accessories should also be recommended by the manufacturer.

#### c. The following accessories should not be used:

- Tape (other than sterilisation chemical indicator tape).
- Safety pins.
- Paper clips.
- Staples.

#### d. Sterilising indicator tape

Sterilising indicator should be:

- Specific to the method of sterilisation being used and which will change colour when exposed to the relevant sterilisation agent.
- Pressure sensitive.
- Non toxic, adhere to clean surfaces and leave no adhesive residue on removal.
- Compatible with the wrapping material used.
- Heat stable.
- Moisture-stable and permeable to the sterilising agent.

## Packaging

### Section Eight: Labelling

- Packages to be sterilised should be labelled before sterilisation.
- The information of the label should include the following:
  - i. Name of product.
  - ii. Name of wrapper.
  - iii. Lot control number.
  - iv. Use by date or/and sterilisation date.
  - v. Where appropriate the word sterile.
- 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.
- 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.
- Label fixed to the surface of the packaging should be able to withstand exposure to the sterilisation process.
- Policies and/or procedures for wrapping and labelling and sealing of RIMD to be sterilised should be developed, reviewed periodically, and readily available within the practice setting.

### Section Nine: Monitoring and control

The following should be monitored during labelling:

- General appearance of the packaging material.
- Whether packages are complete.
- Whether the correct products and packaging material are used.
- Whether the labelling is correct on the product.
- Whether the sealing is correct.
- Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.
- Material should be checked for tears, flaws and holes.
- Containers seals and filters should be checked.
- Containers should be checked for dints which may interfere with maintaining sterility.

## Packaging

### Section Ten: Maintenance

- Reusable containers should be subject to thermometric performance tests.
- Containers should be validated periodically for reuse according to manufacturers' instructions.
- Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policy.
- Heat seal efficiency, integrity and strength test should be performed on each heat sealer daily.
- Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.
- Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.
- Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The heat sealer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 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.
- A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

## **Sterilisation**

# **19 Sterilisation**

## **19.1 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.

## **19.2 Scope**

The objective of this procedure is to provide guidelines in relation to the sterilisation of RIMD.

## **19.3 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 RIMD

Section Seven: Criteria for release of processed RIMD

Section Eight: Sterilisation records

Section Nine: Validation

Section Ten: Monitoring and control

Section Eleven: Maintenance



## Sterilisation

### 19.4 Procedure

#### Section One: Types of sterilisers

- 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).
- 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.
- Low temperature processes include ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), and Hydrogen Peroxide Plasma.
- The preferred method of low temperature sterilisation is Hydrogen Peroxide Plasma.

#### Section Two: Choice of sterilisation process

- Whenever possible the preferred method of sterilisation for RIMD is high temperature steam at 134-137°C for three minutes in a porous load steriliser. A lower temperature steam sterilisation process may sometimes be required. (See table 19-1).

Figure 19-1: Steriliser



## Sterilisation

Table 19-1: Sterilisation temperatures, steam pressures and hold times

Minimum Sterilisation	Corresponding Steam Pressure	Maximum Permissible	Minimum Sterilisation
121°C	1.03 bar gauge	124°C	15 minutes
134°C	2.30 bar gauge	137°C	3 minutes

- For RIMD that cannot tolerate the temperature for steam sterilisation a low temperature process may be used.
- Whenever possible, RIMD that will withstand steam sterilisation should be chosen.
- **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. 132°C for ten minutes. In most cases these RIMD can be processed through the standard cycle but confirmation should be obtained from the RIMD manufacturer.
- Hydrogen Peroxide Plasma is the preferred low temperature sterilisation method because, compared with EO and LTSF, the installation and health and safety requirements are greatly reduced.

### Section Three: Steam sterilisation

- 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.
- For simple solid unwrapped devices, this may be achieved by the natural displacement of air by steam. For hollow devices, tubing, fabrics and wrapped goods, natural displacement cannot be relied upon to remove the air effectively and a forced air removal system is required.
- Flash sterilisers rely on natural air displacement and should not be used for wrapped goods, hollow devices or tubing.
- Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.

## **Sterilisation**

- The operating cycle of a porous load steriliser generally has five stages:
  - i. Air removal.
  - ii. Steam admission.
  - iii. Sterilisation holding time.
  - iv. Vacuum drying.
  - v. Filtered air admission.

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

#### **a. Equipment**

- See decontamination equipment, page 20.
- Loading trolley.
- IT based/Manual tracking system and accessories, i.e. paper, pen, scanner.
- Batch control labeller.
- Personal protective equipment—(heat resistant gloves).

#### **b. Procedure**

- Healthcare workers (HCWs) should wear personal protective equipment.
- HCWs should ensure that all items within the load are compatible with the process to which they are to be exposed.
- Loading should allow for free circulation of steam around each pack and each item.
- RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
- Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.
- Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.
- Hollowware should be placed upside-down or tilted, to prevent collection of condensate.

## Sterilisation

- 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.
- Containers should be loaded onto the trolley such that an air space is formed between each container layer.
- When using the basket system Healthcare Workers (HCWs) 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.
- When loading HCWs should ensure that each RIMD is labelled.
- 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

- HCWs should load the steriliser using the loading trolley.
- HCWs should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.
- 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.
- Manufacturers' instructions and protocols agreed during validation should be followed for loading.
- Overloading of sterilisers may compromise the process.

Figure 19-2: Loading the Steriliser



## Sterilisation

### Section Six: Steam sterilisation of RIMD

- HCWs should wear personal protective equipment.
- HCWs should ensure that all necessary tests and maintenance have been carried out satisfactorily before using the steriliser. HCWs should ensure that the cycle recorder(s) has sufficient paper and ink to record the cycle.
- HCWs should ensure that the correct operating cycle has been selected (**Note:** test cycles such as a Bowie and Dick test and leak rate test cannot be used for sterilising product).
- Healthcare workers (HCWs) should initiate the cycle in accordance with the steriliser manufacturers' instructions.
- Where single door steriliser is in use a system should be in place to ensure segregation of and sterile RIMD.
- When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.
- The fail cycle will require a special key to open the steriliser door.
- 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.

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

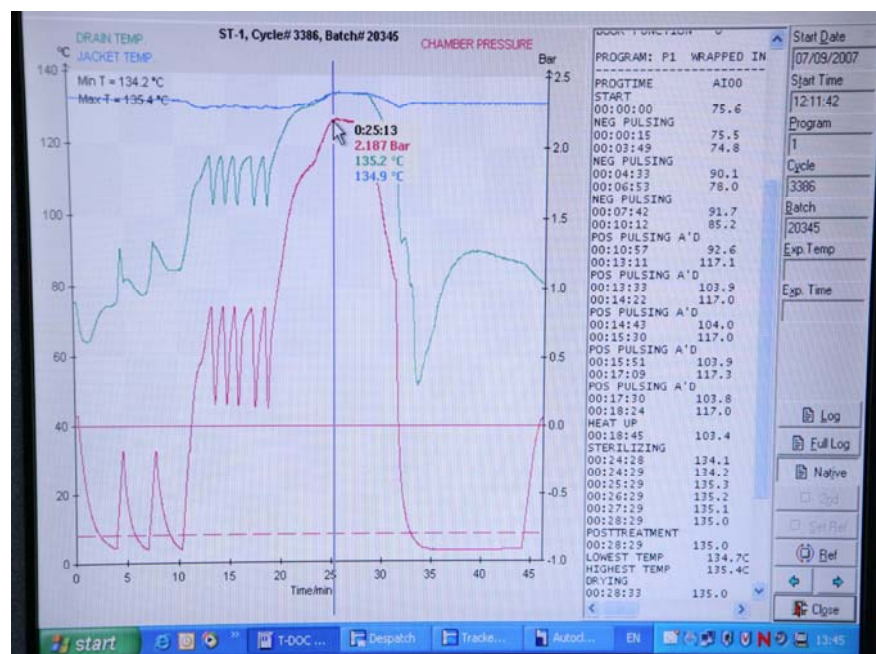
In order to release processed RIMD evidence is required that the sterilisation cycle was satisfactory, i.e. within the limits established during validation, and that the load items are undamaged and fit for use. There is a documented procedure specifying the actions to be taken and the criteria to be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

## Sterilisation

a. Sterilisation cycle verification

- The cycle records should be examined to confirm that the cycle variables were within the limits established as satisfactory during validation. This should include:
  - i. The number and extent of air removal pulses.
  - ii. The temperature and duration of the sterilisation plateau period.
  - iii. The depth and duration of the drying vacuum.
  - iv. The data should be read from the independent recorder not from the automatic controller record.
- 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.
- A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

### Figure 19-3: Cycle Records



## Sterilisation

### b. Inspection of sterilised load

- Each item sterilised should be inspected to ensure that:
  - i. 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).
  - ii. The packaging is in place and undamaged (i.e. seals, taped joints have not come undone, packs are not torn).
  - iii. The packaging is dry and free from visible dampness.
  - iv. All labels are intact and legible.
- 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

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

- i. Steriliser identification.
- ii. The cycle number and batch number if applicable.
- iii. Name of the loading operator and unloading operator.
- iv. Type of cycle used.
- v. Date and time of start of cycle.
- vi. Contents of the load.
- vii. Chart record and/or print-out from steriliser cycle.
- viii. Signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.
- ix. Any notes or observation for the process cycle.
- x. Read out results of physical, chemical or biological indicators that are used.
- xi. All records should be retained for the lifetime of the steriliser plus eleven years.

## Sterilisation

### Section Nine: Validation of steam sterilisers

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.

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.

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:

- Commissioning (installation qualification and operational qualification).
- Performance qualification.
- Periodic testing.
- Revalidation.

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

#### *i. Commissioning*

**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**

- Preliminary checks.
- Electrical checks.
- Functional checks.
- Response to faults.



## Sterilisation

**Operational qualification** is 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:

- i. Air leakage test.
  - ii. Thermometric test.
  - iii. Calibration.
  - iv. Steam Penetration test.
- These tests should be carried out when a new steriliser is purchased or when a used steriliser has been relocated to another premises.
  - The tests should be carried out before the steriliser is used for the first time
  - Installation and operational checks and tests should be performed by a person with specialist technical training in testing of sterilisers.
  - Data from the installation and operational tests provide evidence that the steriliser is functioning correctly.

### *ii. Performance Qualification*

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 instruments). It should be carried out by a Test Person (or other suitably qualified person).

These tests consist of:

- Air leakage tests (automatic).
- Thermometric tests of all RIMD to be processed.
- Steam penetration and complete sterilant contact of all test loads.
- Load dryness test (of RIMD requiring reprocessing).
- Microbiological tests.

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).

## **Sterilisation**

### *iii. Periodic testing*

Periodic testing consists of a programme of tests that are intended to demonstrate that the sterilisers' performance is satisfactory.

The appropriate tests should be carried out at daily, weekly, quarterly and annual intervals. A Test Person (or other suitably qualified person) should draw up a schedule for periodic testing. It is the responsibility of the Test Person (or other suitably qualified person) and the decontamination unit manager to ensure that these tests are performed.

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

#### **a. Introduction**

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.

#### **b. Test procedure**

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

Sterilisation

Figure 19-4: Bowie-Dick Test



II. Weekly tests

The user should perform safety checks before starting the sequence of weekly tests.  
The schedule of weekly tests is summarised in Table 19-2 below.

Table 19-2: 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

## Sterilisation

### 1. Safety checks

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.

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.

### 2. Vacuum leak test

- 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.
- 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.
- 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.
- 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.
- Ideally the steriliser/autoclave 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 other suitably qualified person) should do the test using special, calibrated instruments.

The pass/fail criteria are:

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

## **Sterilisation**

### **3. Air detector function test**

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.

### **4. Automatic control test**

- 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.
- 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 other suitably qualified person) had tested it using calibrated instruments.
- 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:
  - i. Chamber temperatures and pressures, their maximum values and duration in minutes and seconds.
  - ii. The values on the cycle record should be compared with those on the master process record.
  - iii. The test can be considered satisfactory if at the end of the cycle if:
    - 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 19-2.
    - b. A visual display of 'cycle complete' is indicated.
    - c. No mechanical or other anomaly is observed.

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

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

## Sterilisation

### *III. Quarterly tests*

These require specialised test equipment and only a person (e.g. a Test Person or other suitably qualified person) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate.

Quarterly tests for steam sterilisers are summarised in table 19-3.

**Table 19-3: 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
Thermometric Test for a Small Load
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration

## Sterilisation

### III. Annual Tests

These require specialised test equipment and only a person (e.g. a Test Person or other suitably qualified person) who has the necessary training, experience, skills and equipment should perform them. 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 19-4.

Table 19-4: 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
Tests for Performance Requalification (as required)
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration

## Sterilisation

### Section Ten: Monitoring and control

- 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.
- There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
- Routine monitoring and testing should be carried out in accordance with documented procedures in line with I.S. EN ISO 17665 part 1.

### Section Eleven: Maintenance

- Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' instructions and European Standards.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The steriliser should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665, 2006.
- A nominated **qualified** person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- 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.

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:

- Adjustment to steam controls.
- Adjustment to microprocessor controls.
- Adjustment to control parts.



## Low temperature sterilisation

## 20 Low temperature sterilisation

### 20.1 Introduction

Low temperature sterilisation methods may be required for heat-sensitive RIMD.

### 20.2 Scope

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

### 20.3 Contents

Section One: General principles

Section Two: Validation

Section Three: Periodic testing

Section Four: Chemical and Biological Indicators

Section Five: Sterilisation of RIMD

Section Six: Sterile product release

Section Seven: Storage and use

### 20.4 Procedure

#### Section One: General principles

- The microbial lethality provided by low temperature methods is less than that provided by high temperature steam (134 – 137°C for 3 minutes). Steam sterilisation should be used for all RIMD that will withstand the process.
- Four different methods of low temperature sterilisation are available for use in healthcare premises; ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), vapour phase hydrogen peroxide (VHP) and hydrogen peroxide plasma.
- 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).

## Low temperature sterilisation

- Low temperature sterilisation methods should only be used for:
  - i. RIMD specifically identified by the RIMD manufacturer or steriliser manufacturer as suitable for processing in the steriliser, or
  - ii. RIMD made of materials of a size and configuration (e.g. length and diameter of lumen) within the criteria specified by the steriliser manufacturer.
  - iii. **Note:** Documentation of items that can and cannot be processed should be obtained from the RIMD and steriliser manufacturers.
- 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.)
- 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

- 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.
- 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.
- 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:
  - i. Commissioning (installation qualification and operational qualification).
  - ii. Performance qualification.
  - iii. Periodic testing.
  - iv. Revalidation.

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

- Revalidation is required annually and whenever any major change is made to the steriliser, sterilisation cycle or nature of the loads to be sterilised.

## Low temperature sterilisation

- Validation and re-validation should be carried out in accordance with the requirements of EN ISO 14937.
- 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

- 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.
- 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 , 4 or 6 months).
- A qualified person (decontamination) should review and approve the schedule for periodic testing.
- 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.

### Section Four: Chemical and Biological Indicators

#### *Chemical indicators*

- Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).
- The type used should be in accordance with the steriliser manufacturers' recommendations.
- The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- 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.
- Indicators should not be used beyond their expiry date.

## Low temperature sterilisation

- Two types of chemical indicator are commonly used:
  - i. **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
  - ii. **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*

- Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained.
- Biological indicators must meet the requirements of BS EN ISO 11138-1:2006.
- 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.
- 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).

## Section Five: Sterilisation of RIMD

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

## Low temperature sterilisation

### Section Six: Sterile product release

In order to release processed RIMD as sterile evidence is required to ensure that the sterilisation cycle was completed satisfactorily.

#### *a. Parametric release*

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

#### *b. Non-parametric release*

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.

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.
  - i. 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.
  - ii. The cause of failure should be investigated and documented.
  - iii. 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.

### Low temperature sterilisation

- The chemical process indicator has undergone the expected colour change.
- The integrity of the outer wrap and its seals has not been compromised, e.g. torn wrap, sealing tape undone).
- The packed RIMD are sensibly dry.
- The labelling remains in place and legible.
- If the integrity of the packaging or labelling is compromised the sterilised load is regarded as non-sterile. The RIMD must be reprocessed and the cause of the failure investigated and documented.
- 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.

### Section Seven: Storage and use

- Sterile RIMD should be stored in a clean, dry area, which is secure, dust free and above floor level.
- Packs should be labelled 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.
- Packs should be stored so that they are used in sequential order, i.e. the oldest first.
- 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.

## **Storage**

# **21 Storage**

## **21.1 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.

## **21.2 Scope**

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

## **21.3 Contents**

Section One: Storage areas

Section Two: Storage equipment

Section Three: Shelf life/rotation of stock

Section Four: Non-conforming stock

## **21.4 Procedure**

### **Section One: Storage areas**

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:

1. The processed goods store.
2. The raw materials store.

## Storage

### *1. Processed goods store*

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.

- 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.
- Raw materials should not be stored in the processed goods store.
- Loose, processed RIMD should be stored separately from those packed in cases.
- Storage areas should be kept secure and access should be restricted to authorised personnel.
- 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.
- The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.
- Medical and surgical process goods should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.
- Processed goods should be stored on appropriate designated shelving.

### *2. Raw materials store*

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. The raw materials store should be located between the goods reception and the clean room area.

- Materials should be segregated and stored separately according to their specific requirements.
- Sterile RIMD should not be stored in this area (unless supplies are bulk cased).
- Single items should be stored separately from those in cases.
- Storage areas should be kept secure and access restricted.



## **Storage**

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

### **Section Two: Storage equipment**

#### **a. General principles**

- 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.
- 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.
- 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.
- 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).

#### **b. Shelving and racking**

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

#### **c. Closed or covered cabinets**

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

## Storage

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

- General factors which influence shelf life are event related and include the following:
  - i. Packaging materials.
  - ii. Storage and handling conditions.
  - iii. Likelihood of product material deterioration.
  - iv. Package design.
- 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.
- 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.
- 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

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

## Storage

Figure 21-1: Storage



## **Transportation—of sterile items**

## **22 Transportation – of sterile items**

### **22.1 Introduction**

Sterile 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.

### **22.2 Scope**

The objective of this procedure is to provide guidelines in relation to the transportation of sterile RIMD.

### **22.3 Contents**

Section One: General principles

Section Two: External transportation

### **22.4 Procedure**

#### **Section One: General principles**

- Sterile 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.
- Sterile RIMD should be cooled before they can be transported.
- Sterile 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

- Where sterile RIMD are transported in vehicles the vehicles should be dedicated to the purpose, should provide appropriate segregation for the transport of sterile and used RIMD and the loading area should be constructed so that it is easily cleanable.
- Where small quantities of sterile RIMD are to be transferred 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.

Figure 22-1: Transportation of sterile items



## **Water supply for washer-disinfectors**

### **23 Water supply for washer-disinfectors**

#### **23.1 Introduction**

The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process.

#### **23.2 Scope**

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

#### **23.3 Contents**

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

#### **23.4 Procedure**

##### **Section One: General requirements**

- At each stage in the cleaning process the water quality should be compatible with:
  - i. The materials of construction of the washer-disinfector.
  - ii. The RIMD to be processed.
  - iii. The process chemical to be used.
  - iv. The process requirements of that particular stage.

## Water supply for washer-disinfectors

- The key quality elements to be considered are:
  - i. Hardness.
  - ii. Temperature.
  - iii. Ionic contaminants (e.g. heavy metals, halides, phosphates and silicates).
  - iv. Microbial population.
  - v. Bacterial endotoxins.
- The water supply should be controlled to ensure that it is of the required quality.

### Section Two: Water Quality

#### *i. Hardness*

- 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.
- 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 (WD).
- Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- 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.

#### *ii. Temperature*

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

## Water supply for washer-disinfectors

- 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.
- 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.

### *iii. Ionic contaminants*

- Ionic contaminants in the water may react with materials such as stainless steel.
- Water used for stainless steel instruments should have a chloride concentration less than 120 mg/l Cl<sup>-</sup> to minimise the risk of corrosion.
- Tarnishing of stainless steel instruments, 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.

### *iv. Microbial population*

- The microbial population in the water used in the washer-disinfector (WD), particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.
- 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 patient, either through infection or by leading to a erroneous diagnosis.

### *v. Bacterial endotoxins*

- 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. They are not readily inactivated at the temperatures used for disinfection or sterilisation.
- 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 0.25EU/ml when the WD is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.



## Water supply for washer-disinfectors

### Section Two: Water treatment

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

- i. “Base-exchange” softeners.
- ii. De-ionisers.
- iii. Reverse osmosis.

#### *i. “Base-exchange” softeners*

- 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).
- 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.
- 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.

#### *ii. Deionisers*

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

## Water supply for washer-disinfectors

### *iii. Reverse osmosis*

- Reverse osmosis (RO) treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.
- When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.
- Appropriate measures include:
  1. A continuous recirculation system water.
  2. Filtration, e.g. through a 0.22 µm filter to remove microbial contaminants.
  3. Treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J. m<sup>-2</sup>)).
- The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Stainless steel pipes are preferred for all qualities of purified water.
- 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.

## Water supply for washer-disinfectors

Table 23-1: 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	Reverse osmosis 0.22 mm filtered	De-ionised 0.22 mm

\*Endoscope washer-disinfector only

Table 23-2: 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

## **Textiles and non-wovens**

# **24 Textiles and non-wovens**

## **24.1 Introduction**

Textiles (re-usable) and non-wovens (single-use) may be used as drapes, gowns and wrapping materials. Drapes should provide a safe effective means of protecting patients and healthcare workers. (Reference EN 13795).

## **24.2 Scope**

The objective of this procedure is to provide guidelines in relation to the use and processing of textiles and non-wovens in a central decontamination unit.

## **24.3 Contents**

Section One: General principles

## **24.4 Procedure**

### **Section One: General principles**

- Re-usable textile drapes and gowns should not be inspected, folded and packed in the same area as clean RIMD.
- If it is intended to process re-usable textiles through a central decontamination unit a separate clean room must be provided to deal with the re-usable textiles because of their high particulate generation rate.
- Single-use (disposable) drapes and gowns are preferred.
- Single-use (disposable) drapes and gowns may be provided within an RIMD set if this is convenient to the end-user.
- If it is intended to sterilise water repellent single-use (disposable) drapes in a steam steriliser it will be necessary to specify the folding method and to carry out performance qualification tests during validation in order to establish that there is steam penetration to all surfaces of the drape.
- Re-usable textiles should not be used as wrapping materials for RIMD sets.
- Single-use (disposable) drapes and gowns should be disposed of within the healthcare risk waste in the clinical unit.

## **Textiles and non-wovens**

- Single-use (non-woven) wrapping materials may be retained on used RIMD being returned to the central decontamination unit to provide added protection. Any single-use (non-woven) wrapping materials returned with used RIMD should be discarded as healthcare risk waste.

## Single use invasive medical devices

# 25 Single use invasive medical devices

## 25.1 Introduction

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

## 25.2 Scope

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

## 25.3 Contents

Section One: General principles

## 25.4 Procedure

### Section One: General principles

- To avoid cross-contamination between patients, SIMD should be used wherever this is practical.
- Single-use items should be used for a single patient and not reused on subsequent patients. Patient care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- Devices intended for single-use and labelled 'single-use' by the manufacturer should be immediately disposed of after use.
- 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.
- The symbol for single use instruments is as given in ISO EN 980:2003.
- Synonyms for "do not reuse" are "single use", use only once".
- See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).
- Organisations should have well established criteria for their choice of SIMD or RIMD where both are available.

## **Transfer of used reusable invasive medical devices to third parties**

# **26 Transfer of used reusable invasive medical devices to third parties**

## **26.1 Introduction**

Anyone who inspects, services, repairs or transports RIMD, either on hospital 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.

## **26.2 Scope**

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

## **26.3 Contents**

Section One: General principles

## **26.4 Procedure**

### **Section One: General principles**

- 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.
- All RIMD must be decontaminated in accordance with the manufacturers' instructions.
- 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.
- RIMD that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.
- When RIMD are returned after being repaired, the RIMD must be decontaminated and, where relevant, replaced in the original RIMD set.
- Each RIMD set should be checked for completeness as per hospital policy.

## **Loan reusable invasive medical devices**

# **27 Loan reusable invasive medical devices**

## **27.1 Introduction**

RIMD may be loaned to an organisation so that a particular procedure can be performed. The RIMD may be borrowed either from manufacturers or other hospitals 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.

## **27.2 Scope**

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

## **27.3 Contents**

Section One: General principles

Section Two: Procedure for loaning and borrowing RIMD

## **27.4 Procedure**

### **Section One: General principles**

- Borrowed RIMD must be accompanied by relevant reprocessing instructions (including disassemble and reassemble instructions where relevant) and a list of contents.
- All borrowed RIMD must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly.
- RIMD on loan must be registered, including ownership, service history, current location, service responsibility and instructions for use.



## **Loan reusable invasive medical devices**

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

#### ***a. Requests***

- All requests for the loan of RIMD must be made directly by clinical manager of the unit intending to use the RIMD.
- 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.

#### ***b. Documentation***

- The owner of the RIMD being loaned is responsible for ensuring that the loaned RIMD are accompanied by the following documentation:
  - i. Contents list.
  - ii. Decontamination certificate.
  - iii. Reprocessing instructions, including disassembly and reassembly, where relevant.

#### ***c. Log book***

- Details of all RIMD which are loaned to/borrowed from other institutions should be entered into a log book detailing:
  - i. Name and description of the RIMD.
  - ii. RIMD identification number(s).
  - iii. Name of the person to whom the RIMD is being loaned to/borrowed from.
  - iv. Identity of the institution providing/receiving the RIMD.
  - v. Identity of the person who is making the loan.
  - vi. Date of loan.
  - vii. Expected date of return.
  - viii. The unique identifier permitting traceability of the decontamination cycle(s) for the RIMD prior to use.
  - ix. The unique identifier for the patients on which the RIMD was used.
  - x. The unique identifier permitting traceability of the decontamination cycle(s) for the RIMD after use.

## **Loan reusable invasive medical devices**

### *d. Arrangements for return of RIMD*

- Arrangements for the return of RIMD must be made directly by the person who borrowed the RIMD within the defined time period agreed.
- Responsibility for logging the safe and complete return of the RIMD rest with the designated person to whom the RIMD are returned.
- The return date, the name of the institution and the person returning the RIMD should be recorded.

## Action on non-conforming product

## 28 Action on non-conforming product

### 28.1 Introduction

To ensure patient 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 patients as well as remedial action to prevent any recurrence.

### 28.2 Scope

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

### 28.3 Contents

Section One: Policies and procedures

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

### 28.4 Procedure

#### Section One: Policies and procedures

- Written policies and procedures for the recall of non-conforming product should be developed, available and implemented in the organisation.
- 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 patients can be conducted.
- 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.

## **Action on non-conforming product**

### **Section Two: Recall procedure**

A recall procedure should:

- Be written.
- Outline the circumstances for issuing a recall order.
- Designate the person(s) authorised to issue a recall order.
- Designate the person(s) responsible for reporting on the execution of a recall order.

### **Section Three: Recall order**

A recall order should:

- Be written.
- Identify by sterilisation lot number the products to be recalled.
- Identify the persons or departments to whom the order is addressed.
- Require the recording in terms of kind and quantity of the products obtained in the recall.
- Specify the action to be taken by the person or persons receiving the order (e.g. destruction or return of product).

### **Section Four: Recall report**

A report of a recall order should:

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

## PART 4: RECOMMENDED PRACTICES FOR ENDOSCOPY UNITS

# Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices



## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 4
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2008
<b>Pictures:</b>	All pictures in this document were taken with the kind assistance of the Endoscopy staff in St. Vincent's Hospital, Dublin.
<b>Contact Details:</b>	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p><b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a></p> <p><b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a></p>

**Part 4**

*Part 4*  
*Recommended Practices*  
*for Endoscopy Units*

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## **Facility design**

# **1 Facility design**

## **1.1 Introduction**

The reprocessing of endoscopes should take place in a designated and controlled area. This improves the efficiency of the decontamination process, minimises contamination and provides a safe working environment.

## **1.2 Scope**

The objective of this procedure is to outline the principles of a safe working environment for decontamination of endoscopes.

## **1.3 Contents**

Section One: Unit design

Section Two: Lighting and electricity

Section Three: Ventilation

Section Four: Temperature

Section Five: Walls, floors and ceilings

Section Six: Sinks

Section Seven: Workstations, furniture, shelving and equipment

Section Eight: Storage facilities

Section Nine: Restricted entry

## Facility design

### 1.4 Procedure

#### Section One: Unit design

- Endoscope decontamination should be performed in a designated endoscope reprocessing unit.
- The unit should be physically separated from all other work areas including patient treatment areas.
- The unit should be designed to allow segregation of 'dirty' and 'clean' activities.
- The design should facilitate a uni-directional work flow from the 'dirty' area (receipt of contaminated endoscopes) to the 'clean' area (inspection, drying and storage of decontaminated endoscopes).
- Changing, shower and toilet facilities and lockers should be provided in proximity to the decontamination area.

#### Section Two: Lighting and electricity

- There should be sufficient electricity supply points, computer terminal points and work stations in the endoscope decontamination unit.
- There should be adequate task lighting to allow the visual inspection of endoscopes, accessories etc.

#### Section Three: Ventilation

- There should be adequate ventilation and extraction in place to protect staff and third parties from exposure to hazardous substances.
- The configuration of the room and the ventilation system will depend on the choice of automated endoscope reprocessor (AER).
- The preferred configuration is for separate rooms for 'dirty' and 'clean' activities with a pass-through AER installed within the wall between the 'dirty' and 'clean' rooms.

#### Section Four: Temperature

- Temperature should be controlled within a range of 18°C - 22°C.

## **Facility design**

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

- The finishes on walls and other surfaces should be smooth, water resistant and able to withstand frequent cleaning.
- The junctions between walls, floors and ceilings should be coved and flush.
- The floors should be covered in a washable non-slip sheet material which should be adequately sealed.

### **Section Six: Sinks**

- There should be two separate sinks within the unit; one for washing and one for rinsing the washed endoscopes and accessories.
- The sinks should be of sufficient size to permit immersion of the endoscopes.
- There should be adequate put down spaces alongside and between the sinks.
- There should be a dedicated wash hand basin for hand hygiene within the unit.

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

- The area should be free from opening windows.
- The work surfaces should be smooth and have impact resistant surfaces which are impermeable, water resistant and able to withstand frequent cleaning.
- The furniture and fittings should be made from non-shedding materials.
- The shelving and equipment used for holding raw materials and finished products should be designed to allow adequate protection and accommodation for the goods to prevent contamination or deterioration.

## Facility design

### Section Eight: Storage facilities

- Adequate space should be provided for drying and storing of decontaminated endoscopes. This space should be independent of the area used to hold 'dirty' scopes awaiting decontamination. The decontaminated endoscopes should be stored hanging vertically in a designated dry and well ventilated cupboard.
- There should be a locked, flameproof cupboard for storage of hazardous chemicals.
- Storage facilities for bulk items should be provided external to the decontamination area.
- Required personal protective equipment should be easily accessible in the work area.

### Section Nine: Restricted entry

- The area should be managed by dedicated, trained staff.
- Entry to the decontamination area should be restricted to authorised personnel only.

## **Procurement**

## **2 Procurement**

### **2.1 Introduction**

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

### **2.2 Scope**

The objective of this procedure is to provide guidelines on the procurement of decontamination equipment, endoscopes and ancillary materials.

### **2.3 Contents**

Section One: Specialist group

Section Two: Procurement policy

Section Three: Decontamination assessment

Section Four: CE marking

Section Five: Value for money

Section Six: Prior to use

Section Seven: Asset register/inventory

Section Eight: Maintenance



## Procurement

### 2.4 Procedure

#### Section One: Specialist group

- The organisation should have a specialist group in place to consider the procurement of endoscopes and their accessories.
- Key representatives on the specialist group should include:
  - i. Decontamination Coordinator
  - ii. Endoscopy Clinical Staff
  - iii. Endoscope Decontamination Unit Staff
- And where appropriate should also include:
  - i. Infection Prevention and Control Personnel
  - ii. Quality and Risk Management
  - iii. Bio-medical Engineering/Clinical Engineering/Medical Physics
  - iv. Materials Management
  - v. Finance Holder/Budget Holder/Business Manager
  - vi. Other relevant experts (Qualified Person (Decontamination), Microbiologist)
  - vii. Health and Social Care Professional Representative

#### Section Two: Procurement policy

- The organisation should have a documented procurement policy.
- Goods and services should be purchased from suppliers in line with HSE procurement policy.
- There should be a detailed specification for each endoscope which should include the type, model number and design features relevant to the decontamination of each endoscope.
- The endoscope specifications should be available in the endoscope decontamination unit.
- The procurement of endoscopes and accessories should be based on agreed specifications and should comply with documented procurement policy.
- Whenever possible, only single-use biopsy forceps should be purchased.

## **Procurement**

### **Section Three: Decontamination assessment**

- A decontamination assessment should be undertaken prior to purchase of reusable endoscopes to:
  - i. Ensure that the organisation has the facilities to decontaminate the endoscopes in accordance with the manufacturers' instructions.
  - ii. Verify that the endoscopes and their accessories are compatible with the process chemicals used for decontamination.
- Where the decontamination instructions for new equipment are not consistent with existing departmental decontamination procedures, a new procedure should be produced and endoscopy staff trained as necessary.
- Where practicable, single-use components and accessories should be used. Where re-usable accessories are used they should be capable of being sterilised by steam.
- Where parts are single-use or have restricted use, this information should be provided prior to purchasing.

### **Section Four: CE Marking**

- The endoscope and accessories should be CE marked as this will constitute the manufacturer's assurance that the device will be safe and will perform as intended.

### **Section Five: Value for Money**

- Value for money issues should be considered when purchasing endoscopes and accessories.

### **Section Six: Prior to use**

- The endoscope should undergo a full decontamination process prior to use.

## Procurement

### Section Seven: Asset Register/Inventory

- Sufficient endoscopes should be available to allow adequate time for reprocessing in the endoscope decontamination unit without requiring 'shortcuts' to be taken in the decontamination process or adversely affecting clinical throughput.
- The organisation should maintain an asset register or inventory of all endoscopes. This should include details of the type, model number and design features relevant to the decontamination (e.g. number and type of channels) of each endoscope.
- Records should be kept of endoscopes sent for service and repair and of endoscopes received on loan (whether from the manufacturer or another organisation) and on service exchange.

### Section Eight: Maintenance

- There should be documented evidence of planned and unplanned maintenance for endoscopes.
- Preventive maintenance should be planned and performed in accordance with the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

## **Decontamination equipment**

### **3 Decontamination equipment**

#### **3.1 Introduction**

The decontamination unit should be equipped in accordance with the guidance on decontamination equipment in the HSE Code of Practice for Decontamination of RIMD, 2007. All decontamination equipment should be procured, validated, periodically tested, monitored and maintained to current standards.

#### **3.2 Scope**

The objective of this procedure is to outline recommended practices in relation to the equipment required in the endoscopy unit and the validation and maintenance of this equipment.

#### **3.3 Contents**

Section One: Equipment and consumables

Section Two: Specialist group

Section Three: Procurement policy

Section Four: General principles

Section Five: Testing

Section Six: Validation

Section Seven: Monitoring and control

Section Eight: Maintenance

## Decontamination equipment

### 3.4 Procedure

#### Section One: Equipment and consumables

- Disposable cleaning brush (similar to tooth brush).
- Disposable syringe (or adaptor mounted on water tap) for flushing inaccessible channels e.g. air/water.
- Cotton buds.
- Valve cleaning brushes.
- Channel cleaning brushes – single-use.
- Automatic Endoscope Reprocessor (AER).
- Endoscope connectors for use in AER.
- Ultrasonic cleaner.
- Purified rinse water.
- Process chemicals (Detergents and Disinfectants).

#### Section Two: Specialist group

- The organisation has a specialist group in place to consider the procurement of AERs.
- Key representatives on the specialist group should include:
  - i. Decontamination Coordinator
  - ii. Bio-medical Engineering/Clinical Engineering/Medical Physics
  - iii. Endoscope Decontamination Unit Staff
- And where appropriate should also include:
  - i. Infection Prevention and Control Personnel
  - ii. Quality and Risk Management
  - iii. Materials Management
  - iv. Endoscopy Clinical Staff
  - v. Finance Holder/Budget Holder/Business Manager
  - vi. Other relevant experts (Qualified Person (Decontamination), Microbiologist)
  - vii. Health and Social Care Professional Representative.

## Decontamination equipment

### Section Three: Procurement policy

- The organisation should have a documented procurement policy.
- There should be a detailed specification for each automated endoscope reprocessor (AER) which includes the type, model number and design features relevant to the decontamination of the types of endoscope used.
- The AER specifications should be available in the endoscope decontamination unit.
- The procurement of AERs and accessories should be based on agreed specifications and should comply with documented procurement policy.
- Goods and services should be purchased from suppliers in line with HSE procurement policy.
- All ancillary materials and components should be fit for their intended use.
- All process chemicals should be fit for their intended use.

### Section Four: General principles

- There should be sufficient AERs to meet the needs of the endoscope decontamination unit.
- AERs are of two principle types; endoscope washer-disinfectors (EWD) and liquid chemical disinfectors (LCD).
- The use of an endoscope washer-disinfector (EWD) is strongly recommended as the best practice method.
- EWDs provide process stages designed to clean and disinfect flexible endoscopes. Requirements for EWDs are specified in ISO/FDIS 15833-4.
- LCDs provide process stages to disinfect flexible endoscopes that have previously been cleaned manually. Prior to the disinfection stage the LCD may provide a rinse stage to ensure that residues from manual cleaning have been removed and to wet the surfaces to be disinfected.
- Both EWDs and LCDs may provide:
  - i. A leak test facility to verify the integrity of the endoscope before the admission of water, cleaning solutions or disinfectant solutions.
  - ii. A purging stage after the post-disinfection rinse to ensure that the channels are cleared of water.
  - iii. A drying stage to dry the channels and the outer surfaces of the endoscopes.

## Decontamination equipment

- Whichever type of automated endoscope reprocessor (AER) is used, manual cleaning should be done first in accordance with the endoscope manufacturers' instructions. The lumens of the endoscope channels may be too narrow to permit a sufficient flow of water or detergent solution to ensure the removal of all soiling if the channels are not cleaned of debris by brushing.

Figure 3-1 Automated Endoscope Reprocessor (AER)



## Decontamination equipment

### Section Five: Testing

- The automated endoscope reprocessor (AER) should be subjected to a planned programme of testing both before delivery and on-site.
- Data from the tests and checks carried out during manufacture of the AER should be supplied with the AER.
- The data supplied with the AER should include microbiological validation of the process and should define the disinfectant concentration, contact time and the minimum and maximum temperatures. These data may be provided either by the AER manufacturer or the disinfectant manufacturer.
- The on-site test procedures should include installation qualification, operational qualification and performance qualification.
- The AER process should provide adequate assurance of the required microbial lethality (see ISO/DIS 15883-4).
- The AER should include a self-disinfection (machine disinfection) cycle. This disinfection process should provide thermal disinfection of the machine, or chemical disinfection, with a disinfectant different from that used to disinfect the endoscopes.
- AER processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- AER processes should be controlled and monitored to demonstrate attainment of the required disinfectant concentration at the required temperature for the required time.
- The AER should be revalidated following the introduction of a new disinfectant.
- Periodic testing should be undertaken in accordance with European Standards, manufacturers' instructions and local policy including efficacy tests during operational conditions.
- The operational manager for the endoscope decontamination unit should be responsible for ensuring that the automated endoscope reprocessor (AER) is tested in accordance with ISO/FDIS 15883-4.
- A trained person should have designated responsibility for undertaking testing of the AER in accordance with ISO/FDIS 15883-4.
- A qualified person (decontamination) should have designated responsibility for auditing the test data obtained and advising on remedial action required. An action plan for any necessary remedial action should be available.
- A record of all test results should be retained within the endoscope decontamination unit.



## Decontamination equipment

- For endoscope washer-disinfectors (EWDs) the validation should include confirmation of the cleaning efficacy of the process. The test method should include the use of one or more test soils specified in EN ISO 15883-5.
- EWDs should be tested quarterly for cleaning efficacy.
- Protein residue tests should be carried out weekly on cleaned endoscopes.
- There should be evidence of weekly testing of the final rinse water for bacterial counts and of annual testing for atypical mycobacteria. Where water test results are outside accepted standards there should be evidence that a remedial action plan has been implemented.
- An action plan, compiled in conjunction with the infection control team, should be available which describes the action to be taken in the event of failed water tests.

### Section Six: Validation

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the endoscope washer-disinfector (EWD) is functioning correctly and that it will produce cleaned and disinfected loads consistently.
- 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 EWD chamber and the load during every cycle.
- 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:
  1. Commissioning (installation qualification and operational qualification).
  2. Performance qualification.
  3. Periodic testing.
  4. Annual and revalidation tests.

## Decontamination equipment

### 1. *Commissioning*

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

- Verification of calibration of washer-disinfector instruments, automatic control test, water quality tests, water supply temperature and water supply pressure.

#### Operational qualification tests

- Weekly safety checks, automatic control test, verification of calibration of washer-disinfector instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical vapour discharge test, chemical additive dosing tests, load carriers, washer-disinfector self-disinfection test, final rinse decontamination test, channel patency test, disinfectant concentration test cleaning efficacy test, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric tests for thermal disinfection, microbiological test of disinfection efficacy, load dryness test, test for air quality and sound pressure.
- These tests should be carried out when a new endoscope washer-disinfector (EWD) is purchased or when a used EWD has been relocated to another premises. Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of EWDs. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the EWD is functioning correctly.
- Even though the manufacturer should have tested a EWD 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**.

## Decontamination equipment

### 2. *Performance qualification*

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 endoscope washer-disinfector (EWD) or when the load profile changes. It should be carried out by a Test Person (or other suitably qualified person). These tests consist of:

- Thermometric tests for a full load of items not previously represented by the reference load, load dryness test, cleaning efficacy test, microbiological tests for efficacy of chemical disinfection for a full load of items not represented adequately by the reference load, and process residues.

### 3. *Periodic testing*

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

- i. **Daily:** Remove and clean strainers and filters.
- ii. **Weekly:** Automatic control test, weekly safety checks, daily tests, water hardness, water conductivity, cleaning efficacy test (residual soil detection) and final rinse water supply.
- iii. **Quarterly tests:** Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection, cleaning efficacy test and channel patency test.
- iv. **Annual tests:** Weekly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical vapour discharge, chemical additive dosing, load carriers, washer-disinfector self-disinfection test, final rinse decontamination test, channel patency test, disinfectant concentration test, chamber wall temperature test, load carrier temperature test, cleaning efficacy, over-temperature cut-out, thermometric tests for disinfection stage, microbiological test of disinfection efficacy, load dryness test, test for air quality and sound pressure.

## Decontamination equipment

### Section Seven: 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.
- Validation, routine monitoring and control should be carried out in accordance with European Standards, manufacturers' instructions and local policy including efficacy tests during operational conditions.

### Section Eight: Maintenance

- There should be documented evidence of planned and unplanned maintenance for automated endoscope reprocessors (AERs), disinfectant generators, water treatment systems and storage cabinets according to manufacturers' instructions.
- Preventative maintenance should be planned in accordance with the manufacturers' instructions.
- Planned preventative maintenance should be undertaken in accordance with manufacturers' instructions and local policy including:
  - i. Inspecting and cleaning all filters.
  - ii. Dismantling and cleaning spray arms and nozzles.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The automated endoscope reprocessor (AER) should not be used to process endoscopes and accessories until all scheduled maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- An automated endoscope reprocessor (AER) maintenance and repair log book should be maintained for each AER.
- All AERs should be under a service contract.
- A schedule of maintenance and disinfection of any water purification system should be specified. Records of periodic sanitization should be kept.

## **Personal Protective Equipment**

### **4 Personal protective equipment**

#### **4.1 Introduction**

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

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

#### **4.2 Scope**

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

#### **4.3 Contents**

Section One: Attire

Section Two: Head/hair cover

Section Three: Protective eyewear and face-shields

Section Four: Masks

Section Five: Plastic aprons and gowns

Section Six: Gloves

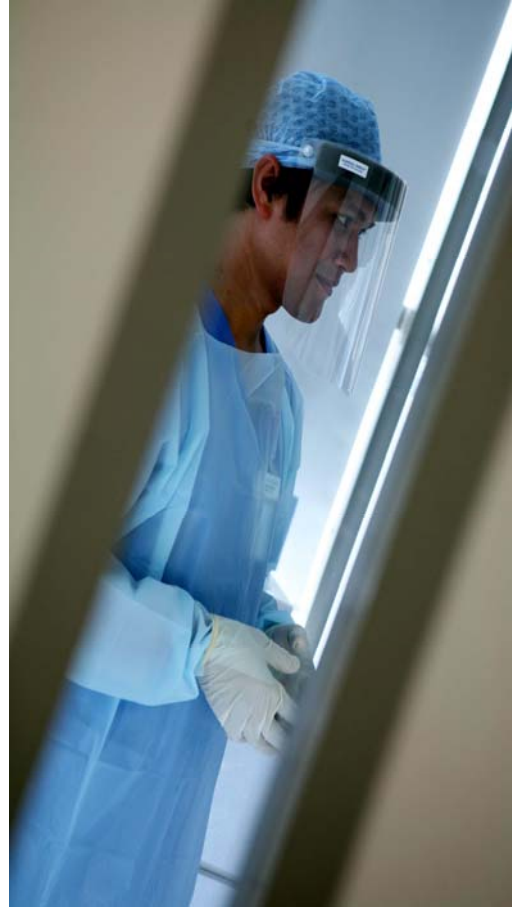
Section Seven: Footwear

## Personal Protective Equipment

### 4.4 Procedure

#### Section One: Attire

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



**Figure 4-1: Personal Protective Equipment (Decontamination Area)**

#### Section Two: Head/hair cover

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.
- After use, headgear should be discarded in the appropriate healthcare waste stream.
- 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.

## Personal Protective Equipment

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

- Healthcare workers (HCWs) should wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear or face shields should be single-use.
- Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- Face shields should cover the eyes, nose, mouth and chin.

### Section Four: Masks

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

Figure 4-2: Face shield



## Personal Protective Equipment

### Section Five: Plastic aprons and attire

- Healthcare Workers (HCWs) should wear impermeable attire with long cuffed sleeves and tuck-inside-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.
- Fluid repellent attire and aprons should be changed whenever they become visibly soiled or wet.
- After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

### Section Six: Gloves

- Gloves should be used for handling contaminated RIMD and waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- 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.
- **It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.**
- HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves should be discarded in the appropriate healthcare waste stream.



## Personal Protective Equipment

### Section Seven: Footwear

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

## **Transport of contaminated endoscopes and accessories**

# **5 Transport of contaminated endoscopes and accessories**

## **5.1 Introduction**

All endoscopes and their accessories are considered to be soiled and contaminated after each use and can be a potential source of infection. Contaminated endoscopes and accessories should be handled, collected and transported in a manner that avoids dissemination of contamination. Transport of soiled endoscopes and accessories to the decontamination area should be accomplished **as soon as possible after use**. If delay is unavoidable, the user must make sure that the items safely contained and secured to await collection.

## **5.2 Scope**

The objective of this procedure is to provide guidelines in relation to the transportation of contaminated endoscopes and accessories.

## **5.3 Contents**

Section One: Containers and trolleys

Section Two: Staff

## **5.4 Procedure**

### **Section One: Containers and trolleys**

- Contaminated endoscopes and accessories should be placed in re-usable, solid walled, leak proof containers/trolleys and transported to the decontamination area as soon as possible after use.
- Transport containers should protect both the product during transit and the handler from inadvertent contamination.

## Transport of contaminated endoscopes and accessories

### Section Two: Staff

- Personnel should be trained to handle, collect and transport contaminated endoscopes and accessories and should wear PPE in accordance with local safety policies and procedures.
- Policies and procedures for transportation of contaminated endoscopes (return of used items for reprocessing) and accessories should be developed, reviewed periodically, and readily available within the practice setting.

Figure 5-1      Transport of contaminated endoscopes and accessories



## **Cleaning and disinfection**

# **6 Cleaning and disinfection**

## **6.1 Introduction**

Endoscopes and their accessories are classified as medical devices under the Medical Devices Directive (MDD). Flexible endoscopes and their accessories present particular problems in terms of cleaning, disinfection and sterilisation. Failure to adequately decontaminate flexible endoscopes between use may increase the risk of transmission of infection between patients and/or compromise the quality of clinical samples.

## **6.2 Scope**

The objective of this procedure is to provide guidelines in relation to cleaning and disinfection of contaminated endoscopes and accessories. Cleaning is the initial and most crucial step in breaking the chain of disease transmission.

## **6.3 Contents**

Section One: Pre-cleaning

Section Two: Manual cleaning

Section Three: Rinsing

Section Four: Disinfection

## Cleaning and disinfection

### 6.4 Procedure

#### Section One: Pre-cleaning

##### 1. *Wipe the insertion tube*

- Immediately on removal of the endoscope from the patient, with the endoscope still attached to the light source, grasp the control head and using a disposable cloth dampened in freshly prepared enzymatic detergent solution, wipe the insertion tube from the control head to the distal tip.
- Discard the cloth appropriately after use.

Figure 6-1: Wiping the insertion tube



## Cleaning and disinfection

### 2. *Aspirate enzymatic detergent through the suction/biopsy channels*

- Place the distal tip in the enzymatic detergent solution.
- Aspirate the enzymatic detergent through the entire suction/biopsy channel system until the expelled solution is visibly clean.
- Alternate the suctioning of enzymatic detergent solution and air several times - finish by suctioning air.



Figure 6-2: Aspirating the enzymatic detergent through the suction/biopsy channel

### 3. *Purge air/water channels*

- Depress and release air/water button several times to flush water channel.
- Occlude air button to force air through air channel.



Figure 6-3: Purging air/water channels

## Cleaning and disinfection

### 4. *Detach removable components*

- Remove the endoscope from the light source.
- Attach protective video cap (if using video endoscope).



Figure 6-4: Removing the endoscope from the light source

- Remove all valves/buttons/caps and soak in enzymatic detergent solution.

Note: Where valves/buttons/caps are interchangeable it is preferable to have extra valves/buttons/caps to allow more time to ensure that adequate cleaning is performed prior to disinfection/sterilisation.



Figure 6-5: Removing valves/buttons and caps

## Cleaning and disinfection

- Transport to the cleaning area in a re-usable, solid walled, leak proof container/trolley that prevents dispersal of contamination to the environment.



Figure 6-6: Transporting to the cleaning area

### 5. *Leak testing*

Note: Endoscope washer-disinfectors (EWDs) complying with ISO FDIS 15883-4 should include leak testing as part of the automatic cycle.

- The endoscope should be leak tested according to the manufacturers' instructions.
- All endoscopes should be leak tested prior to immersion and between each patient use.
- The leak test will detect damage to the interior or exterior of the endoscope.
- Perforated channels of endoscopes are an infection control risk and damage may also occur to parts of the endoscope not designed for fluid exposure.



## Cleaning and disinfection

Figure 6-7: Leak testing

- a. **Attach the leak tester and pressurise the endoscope**
  - Some manufacturers specify removing detachable parts prior to leak testing - others do not.
- b. **Immerse the endoscope in water and observe for a continuous stream of bubbles**
  - If the leak tester has a pressure gauge, observe for pressure loss prior to immersion (this indicates a significant leak).
  - Completely immerse the entire endoscope.
  - Flex the distal portion of the endoscope in all directions.
  - Observe for a continuous stream of bubbles which indicates a leak.
  - Observe the head of the endoscope, the insertion tube, distal bending section and the umbilical cable for bubbles coming from the interior of the endoscope.
  - Repeat the leak test before and after automated reprocessing in an automated endoscope reprocessor (AER).
  - The instructions provided by the endoscope manufacturer and AER manufacturer should be followed.
- c. **Processing endoscopes that fail the leak test**
  - If a leak is detected, or the endoscope appears damaged, the endoscope manufacturer or supplier should be contacted to ascertain whether reprocessing can be undertaken without additional damage to the endoscope.
  - If the endoscope fails the leak test, staff should not attempt to clear a blocked endoscope by blowing air under pressure through the lumen.



## Cleaning and disinfection

### Section Two: Manual Cleaning

Cleaning is either:

- i. Carried out manually before disinfection in a liquid chemical disinfectant (LCD).
- or:
- ii. Carried out manually and then further cleaned and disinfected in an endoscope washer-disinfector (EWD).

The manual cleaning process is common to both processes. Appropriate PPE must be worn by staff

#### *1. Make up detergent solution*

- Make up fresh enzymatic detergent solution to the manufacturers' instructions for reprocessing each endoscope (fresh solution prevents cross contamination).

#### *2. Immerse endoscope*

- Completely immerse the endoscope.
- Whenever practical, leave the endoscope immersed in the detergent solution while performing all subsequent cleaning steps to prevent the production of aerosols of contaminated fluid.



Figure 6-8: Immersing the endoscope

## **Cleaning and disinfection**

### ***3. Disassemble removable parts and clean***

- Remove all buttons/valves/caps and other removable parts (if you have not already done so).
- Correctly dispose of parts designated as single use.
- Brush and clean non-disposable parts with a small soft brush paying particular attention to internal surfaces and lumens.
- The preferred method of reprocessing re-usable accessories (buttons and valves) is in a central decontamination unit, in accordance with manufacturers instructions .
- The endoscope should be completely disassembled so that all surfaces may be reached for a thorough cleaning.

### ***4. Brush and wipe exterior***

- Wash all debris from outer surfaces by brushing and wiping the endoscope.
- Use a soft brush to gently clean the distal tip.
- Brush control handles and the biopsy port.
- Brush around valves seats and clean thoroughly.
- Check that all visible debris has been removed.

### **Cleaning tools**

- Use of non-abrasive and lint-free cleaning tools will prevent damage to the endoscope.
- Soft brushes are useful to clean grooved control handles and to brush the distal tip.
- Valve seats and biopsy ports should be brushed using brushes supplied by the manufacturer which are designed for this purpose.
- Cotton buds should be used to clean the suction valve port but should not be used in the air/water port as threads can become caught and cause blocked channels.
- Cleaning brushes for valve ports should be available from manufacturer.

## Cleaning and disinfection

### 5. *Brush all channels*

- Brush all accessible endoscope channels including the body, insertion tube and the umbilical cable or universal cord of the endoscope.
- After each brush passage, rinse the brush tip in the detergent solution, removing any visible debris before retracting the brush and reinserting it.
- Continue brushing each channel a minimum of three times or until there is no debris visible on the brush.
- Finish brushing process with use of valve port brush to remove any debris which has been translocated to this area from brushing the channels.
- Drain water from the sink.
- Curl endoscope for transfer to a separate sink.
- Discard the brush appropriately after use.

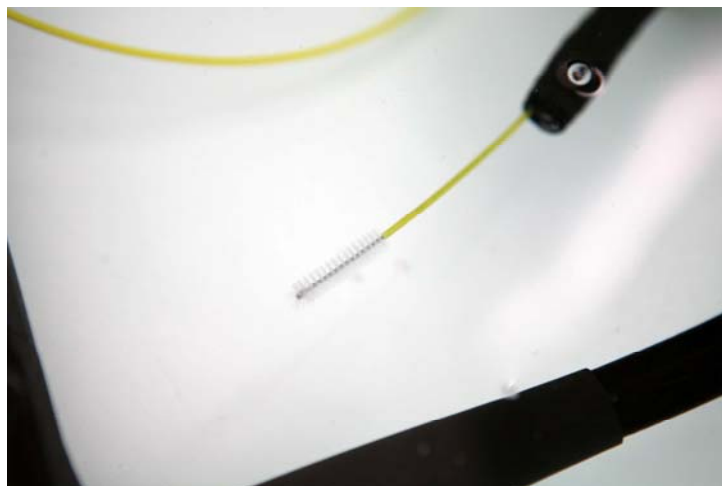


Figure 6-9: Brushing channels

## Cleaning and disinfection

### Brushes

- Single-use brushes are preferred.
- When re-usable brushes are used, after each use they should be cleaned, inspected and steam sterilised before re-use.
- If on inspection, the re-usable brush is worn, frayed or bent or the shaft is kinked or the brush is otherwise damaged it should be discarded.
- Cleaning brushes for all brushable channels should be supplied by the manufacturer.
- A brush size compatible with each channel should be used.
- Rinsing the brush tip when it has emerged from the endoscope maximises cleaning of the channels by ensuring that as much debris as possible is removed before retraction or reinsertion of the brush.



Figure 6-10: Brushes

## **Cleaning and disinfection**

### **Section Three: Rinsing**

#### **1. *Water rinse***

- Transfer the endoscope to a sink, (separate to that used for manual cleaning), for rinsing to remove residual detergent.
- Flush all channels thoroughly with water.
- Rinse outer surfaces of the endoscope with water.
- Rinse all removable parts with clean water.
- Clean running water should be used to remove all traces of detergent prior to disinfection.
- The use of clean water for each endoscope will limit the potential for cross infection.
- The amount of water required to thoroughly rinse the endoscope after cleaning will vary according to the design and length of the endoscope.

#### **2. *Purge internal channels with air***

- Purge water from all the channels with air to remove rinsing water.
- Removing water from all channels and the exterior of the endoscope prevents dilution of the biocide used for disinfection.
- This process can be completed using a syringe or compressed air.
- The endoscope should be transferred to the automated endoscope reprocessor (AER) in an appropriately sized receptacle so as to avoid contamination of the environment.

## Cleaning and disinfection

### Section Four: Disinfection

- The Health Service Executive regards the use of an automated endoscope reprocessor (AER) to process flexible endoscopes as mandatory. Unless specifically required by the endoscope manufacturer it is not acceptable to carry out chemical disinfection manually.
- The chemicals used throughout the decontamination process should be used at the correct concentration, volume, temperature and contact time as recommended by the manufacturer.
- The chemical used in the disinfection stage should be CE marked.
- The chemical used in the disinfection stage should be accepted as compatible with the endoscope by the endoscope manufacturer.
- The chemical used in the disinfection stage should be accepted as compatible with the AER by the AER manufacturer.
- The disinfectant should be in contact with all surfaces requiring disinfection at the required concentration for the required time.
- The temperature throughout the disinfection stage should be monitored, or controlled and monitored, to ensure that it remains within specified limits.
- Single-use disinfectants are preferred.
- There should be a log of disinfectant batch numbers and expiry dates.
- The water supplied to the AER for the rinsing after the chemical disinfection stage should be purified water and should be free from microbial contamination.

## **Automated endoscope reprocessing**

# **7 Automated endoscope reprocessing**

## **7.1 Introduction**

Automated reprocessing of endoscopes should take place in an Automated Endoscope Reprocessor (AER). These may be of two types; an endoscope washer-disinfector (EWD) or a liquid chemical disinfectant (LCD)

An EWD provides an automated process with leak test, cleaning, rinsing disinfection and final rinsing stages.

An LCD process provides a high level chemical disinfection stage and a post-disinfection rinse stage to remove chemical disinfectant residuals. It does not provide an automated cleaning process although there may be an initial rinse to remove residues from the manual washing process and to ensure that all contact surfaces of the endoscope are wetted.

An EWD conforming to EN ISO FDIS 15883-4:2007 is preferred.

Manual washing is normally required whether or not the AER includes a cleaning stage. The narrow internal diameters of the channels of an endoscope require the mechanical action of brushing to ensure that they are cleaned. Manual cleaning in accordance with the endoscope manufacturers instructions followed by a validated automated cleaning process is the preferred method.

## **7.2 Scope**

The objective of this procedure is to provide guidance in relation to automated cleaning and disinfection of contaminated endoscopes.

## **7.3 Contents**

Section One: General principles



## Automated endoscope reprocessing

### 7.4 Procedure

#### Section One: General principles

- Determine the exact number of channels on the endoscope to be used.
- Determine the number of irrigation ports available for use in the automated endoscope reprocessor (AER).
- Ensure that the automated process on the AER will irrigate, clean where relevant, and disinfect all channels (including auxiliary and elevator wire channels) on the endoscope.
- Ensure that the AER and all services are operational. **Note:** The AER should not start if any anomalies are present.
- Transfer the endoscope(s) (that have been manually cleaned) to the AER.
- The channels of the endoscope should be attached to the appropriate connection in the AER to ensure the free passage of fluids through the channels during processing.
- Check that the attachment tubing is not kinked.



Figure 7-1: Attaching the endoscope channels

- Check that the endoscope blanks/caps are intact and secure.
- Select appropriate cycle.
- Enter endoscope code and user code.
- Initiate AER automatic cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the endoscopes processed should be inspected.



Figure 7-2: Selecting the cycle

## Automated endoscope reprocessing

- Information should be recorded for each automated endoscope reprocessor (AER) cycle. Documentation is required for every AER cycle and should contain the following:
  - i. AER identification number.
  - ii. Cycle number.
  - iii. Type of AER.
  - iv. Type of cycle used.
  - v. Date and time of start of cycle.
  - vi. Load content.
  - vii. Critical parameters for the specific AER cycle.
  - viii. Operator's name.
  - ix. Results of AER process.
  - x. Signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters
  - xi. Any notes or observation for the process cycle
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- Cycles which were aborted should be documented with the action taken in a log book.
- All automated endoscope reprocessors (AERs) should undergo a self-disinfect cycle at the beginning of each day. This should preferably be by thermal disinfection or with a chemical disinfectant different from that used for endoscope disinfection.
- There should be a means to indicate that the self disinfection cycle has taken place and been completed satisfactorily and evidence that records are retained.



Figure 7-3: AER record

## **Post cleaning inspection and function testing**

# **8 Post cleaning inspection and function testing**

## **8.1 Introduction**

All cleaned and disinfected endoscopes should be inspected for cleanliness. All cleaned and disinfected endoscopes should be tested or inspected for functionality. Inspection, maintenance and testing of endoscopes should be carried out by trained persons in accordance with the manufacturers' instructions.

## **8.2 Scope**

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

## **8.3 Contents**

Section One: Equipment

Section Two: Procedure

Section Three: Documentation post automated cleaning

Section Four: Monitoring and control

## **8.4 Procedure**

### **Section One: Equipment**

- Work bench.
- Magnifying glass and oblique of stereo-microscope.
- Light source.

## **Post cleaning inspection and function testing**

### **Section Two: Procedure**

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

- 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.
- If there is no record of cleaning the endoscope is rejected and returned for re-cleaning.
- Make a visual inspection of the endoscope in order to ensure that there is no obvious damage, staining or residue.
- Make a visual inspection of the endoscope for dryness.
- Where an endoscope may not be properly cleaned the load is rejected and returned for re-cleaning.
- Any damaged, incomplete or malfunctioning endoscopes should be reported immediately to the supervisor.
- Each endoscope should be checked that there is free movement of all parts.

### **Section Three: Documentation post automated cleaning**

- All documentation for automated cleaning should contain the following information:
  - i. Automated endoscope reprocessor (AER) identification number.
  - ii. Cycle number.
  - iii. Type of AER.
  - iv. Type of cycle used.
  - v. Date and time of start of cycle.
  - vi. Load content.
  - vii. Critical parameters for the specific washer disinfectant cycle.
  - viii. Operators name.
  - ix. Results of washer-disinfectant process.
  - x. Signature of an authorised qualified person confirming whether or not the process cycle was within recommended parameters.
  - xi. Any notes or observation for the process cycle.

### **Post cleaning inspection and function testing**

- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.

#### **Section Four: Monitoring and control**

The user should be aware of the factors that may alter the efficacy of the method:

- Staff training/competence.
- Age of the endoscope.

## **Drying**

# **9 Drying**

## **9.1 Introduction**

Drying minimises rusting, staining and reduces the risk of recontamination during inspection and assembly of endoscopes. Residual moisture can damage endoscopes.

## **9.2 Scope**

The objective of this procedure is to provide guidelines in relation to the drying of endoscopes.

## **9.3 Contents**

Section One: General principles

## **9.4 Procedure**

### **Section Two: General Principles**

- In many automated endoscope reprocessors (AERs) the operating cycle provides an option after the final rinse stage for either a purge stage to remove excess rinse water from the endoscope when the endoscope is intended for immediate use or a more prolonged drying stage when it is intended to store the endoscope before use.
- When the purge cycle has been used, on removal from the AER, the outside of the endoscope should be wiped with a disposable dry lint free cloth.

## **Transport of decontaminated endoscopes and accessories**

# **10 Transport of decontaminated endoscopes and accessories**

## **10.1 Introduction**

Decontaminated endoscopes and accessories 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 and environmental conditions during transportation and storage.

## **10.2 Scope**

The objective of this procedure is to provide guidelines in relation to the transportation of reprocessed endoscopes and accessories.

## **10.3 Contents**

Section One: General principles

## **10.4 Procedure**

### **Section One: General principles**

- Reprocessed endoscopes and accessories should be transported in clean dry containers and trolleys in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage.
- The re-usable transport container should be clean and disinfected, dry, solid walled and leak proof.
- There should be an adequate number of transport containers and trolleys in the endoscope reprocessing unit.

## **Storage**

# **11 Storage**

## **11.1 Introduction**

All items should be stored in such a way that their level of processing is maintained (e.g. sterile, high-level disinfected). Endoscopes and accessories should be stored in a clean, dry environment and protected from sharp objects that may damage them.

## **11.2 Scope**

The objective of this procedure is to provide guidelines in relation to the storage of endoscopes and accessories.

## **11.3 Contents**

Section One: Storage facilities

Section Two: Detachable components and parts

Section Three Cleanliness and functionality

## **11.4 Procedure**

### **Section One: Storage facilities**

- Separate storage facilities should be provided for sterile and non sterile goods.
- Endoscopes should be stored hanging vertically in a designated dry and well-ventilated storage cupboard.
- Storage cupboards should be cleaned weekly with warm water and detergent and dried well and cleaning should be recorded.
- Storage cupboards should be well ventilated.
- Endoscopes should be stored so that residual fluid does not remain in the channels.
- Endoscopes should be protected from the risk of environmental contamination.
- Storage facilities for decontaminated endoscopes should be secure and only accessible to personnel who have a legitimate need.



## Storage

### Section Two: Detachable components and parts

- All detachable components should remain detached during storage and should not be replaced until the endoscope is next used.
- All detachable parts should be stored in a manner that ensures security of the items and keeps components together as a unique set.

### Section Three: Cleanliness and functionality

- Endoscopes should be reprocessed if more than three hours has elapsed from the last decontamination process unless stored in a dedicated storage cabinet that has been validated for more prolonged storage.
- Prior to reuse, all decontaminated endoscopes should be inspected for cleanliness.
- Prior to reuse, all decontaminated endoscopes should be tested or inspected for functionality.
- All endoscopes that fail inspection for cleanliness or functionality should be segregated.

**Note:** Prior to storage at the end of the day the rubber seals of the suction and air/water valve should be lubricated sparingly with silicone oil in accordance with manufacturers' instructions.



Figure 11-1: Storage

## Valves, detachable parts and accessories

# 12 Valves, detachable parts and accessories

## 12.1 Introduction

Endoscope accessories should be cleaned, disinfected, or sterilised, and maintained in accordance with the manufacturers' instructions.

## 12.2 Scope

The objective of this procedure is to provide guidelines in relation to valves, detachable parts and accessories

## 12.3 Contents

Section One: Valves and detachable parts

Section Two: Accessories

## 12.4 Procedure

### Section One: Valves and detachable parts

- Biopsy caps should be discarded after all procedures involving the passage of accessories through the endoscope.
- Unless otherwise specified by the manufacturer, the surfaces and lumens of re-usable valves and detachable parts should be cleaned using a purpose-built single-use cleaning device and rinse with clean water prior to reprocessing.
- Visual checks should be made to ensure valves are visually clean and not damaged.
- Reusable valves should be decontaminated in accordance with manufacturers' instructions and processed with their corresponding endoscope.
- Valves including flushing valves and removable parts should be kept with the endoscope to form a unique set of equipment.

**Note:** Prior to storage at the end of the day the rubber seals of the suction and air/water valve should be lubricated sparingly with silicone oil in accordance with manufacturers' instructions.

## Valves, detachable parts and accessories

### Section Two: Accessories

- Endoscopic accessories are devices used in conjunction with an endoscope to perform diagnostic and therapeutic procedures. These may be passed via the biopsy channel/working channel of an endoscope during a procedure. Examples include biopsy forceps, water bottles, snares, buttons etc.
- Single use accessories should always be used in preference to re-usable accessories (unless no suitable alternative is available).
- Where re-usable accessories have to be used they should be sterilised. This should be carried out in a central decontamination unit and should be done in accordance with the manufacturer's instructions.
- Checks should be in place to ensure that the item is fit for use on return to the endoscopy unit.
- There should be evidence that a risk assessment involving the infection prevention and control team has taken place for re-usable items that cannot be sterilised.
- Single use devices should be used for manual cleaning.
- Single use biopsy forceps should be used for all procedures.
- Water bottles should be sent to the central decontamination unit to be cleaned and sterilised in accordance with the manufacturers' instructions.
- Sterile water should be used in the water bottle.
- Accessories and removable parts (other than single use items) should be kept together with a single endoscope forming a unique set.



Figure 12-1: Accessories

## **Traceability**

### **13 Traceability**

#### **13.1 Introduction**

In order to provide full traceability it is essential to be able to identify which endoscopes and accessories were used on which patients and to trace the process records through the decontamination life cycle. Systems should be in place to allow the methods, operational cycles and personnel involved in the processing a particular endoscope/endoscope set to be tracked through the decontamination process and to the patient on whom devices have been used.

#### **13.2 Scope**

The objective of this procedure is to provide guidelines for the effective tracking of endoscopes and accessories through the decontamination life-cycle.

#### **13.3 Contents**

Section One: Unique identifier

Section Two: Records

Section Three Recording system

#### **13.4 Procedure**

##### **Section One: Unique identifier**

- All endoscopes should have a unique identifier/serial number before use and there should be a system in place to track loan scopes.

## Traceability

### Section Two: Records

- Records should be maintained for all the endoscopes/endoscopes set, identifying:
  - i. The cleaning, disinfection and sterilisation method used.
  - ii. The name of the person undertaking each step of the decontamination cycle.
  - iii. Details of the actual endoscope/endoscope set being processed.
  - iv. These details should be directly associated to individual patient use.
- Records relating to decontamination processes should be maintained for the life-time of the equipment plus eleven years.

### Section Three: Recording system

- Tracking should be undertaken using and IT based or manual (paper based) recording system.
- An IT based system is preferred.



Figure 13-1: Manual traceability system

**PART 5a: RECOMMENDED PRACTICES FOR  
DENTAL SERVICES IN A CENTRAL  
DECONTAMINATION UNIT**

**Health Service Executive  
Code of Practice for  
Decontamination of  
Reusable Invasive Medical Devices**



**Reader Information**

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 5a
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	October 2007
<b>Target Audience:</b>	All relevant staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	October 2008
<b>Pictures:</b>	All pictures in this document were taken with the kind assistance of the staff in the Dublin Dental School & Hospital, Trinity College, Dublin.
<b>Contact Details:</b>	Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.  <b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a>  <b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a>

**Part 5a**

*Part 5a*

*Recommended Practices for Dental  
Services (Central Decontamination  
Units)*



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## **Design of designated area for decontamination of dental RIMD in a CDU**

# **1 Design of designated area for decontamination of dental 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 patients, clinical staff and cross-contamination of the working environment.

## **1.2 Scope**

The objective of this procedure 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 RIMD in a CDU**

### **1.4 Procedure**

#### **Section One: Unit design**

- The Central Decontamination Unit (CDU) should be designed so that it is physically separated from all other work areas.
- The CDU should be designed to allow segregation of 'dirty' and 'clean' activities.
- The CDU should be designed to facilitate a unidirectional flow from the 'dirty' area to the 'clean' area.
- The CDU should not be used for any other purpose.
- The CDU should not be used as a thoroughfare.
- There should be a designated changing area for donning work wear.
- The CDU area should be free from 'opening' windows, ledges, and uncleanable areas.
- The decontamination area 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**

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

## **Design of designated area for decontamination of dental RIMD in a CDU**

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

- 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**

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

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

- All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- 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.
- There should be adequate space between workstations for equipment and staff movement.
- The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- 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 RIMD in a CDU**

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

- The area should be managed by trained staff.
- Entry to the decontamination unit should be restricted to authorised personnel only.

### **Section Seven: Storage facilities**

- Safe storage facilities should be provided for process chemicals used in decontamination.
- Storage facilities for bulk items should be provided external to the designated decontamination area.
- Required personal protective equipment should be easily accessible in each of the work areas.

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

- The environment in which clean non-sterile dental RIMD are inspected, assembled and packed should be microbiologically monitored periodically to demonstrate low levels of microbial contamination.

### **Section Nine: Cleaning**

- The environment in which decontamination of dental RIMD takes place should be cleaned in accordance with methods, procedures and schedules as outlined by HSE Protocols).

## **Environmental cleaning**

## **2 Environmental cleaning**

### **2.1 Introduction**

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

### **2.2 Scope**

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

### **2.3 Contents**

Section One: Cleaning equipment

Section Two: Cleaning frequency and cleaning efficacy

Section Three: Floor cleaning equipment and method

Section Four: Floor cleaning agents

Section Five: Records

### **2.4 Procedure**

#### **Section One: Cleaning equipment**

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

#### **Section Two: Cleaning frequency and cleaning efficacy**

- Work surfaces should be cleaned daily and whenever necessary.
- Entire rooms should be deep cleansed annually. Air vents and filters should be serviced regularly.

## Environmental cleaning

- There should be documented cleaning procedures for fixtures and fittings.
- There should be documented cleaning procedures for process equipment.

### Section Three: Floor cleaning equipment and method

- Floors should be cleaned daily and also cleaned when visibly soiled.
- Adhere to colour coding policy for cleaning equipment.

### Section Four: Floor cleaning agents

- Floors should be cleaned using a neutral detergent.
- If visible blood/body fluids are present it should be neutralised using chlorine based disinfectant, and then thorough cleaning should be completed.
- Disinfectants should be made up according to the manufacturers' instructions/organisations policy.

### Section Five: Records

- Records should be kept of the following:
  - Training of the personnel carrying out the cleaning.
  - Periodic inspection of cleanliness.
  - Vaccination Status of the cleaning staff.
- **Note:** The scope of responsibility shall include the competence of contractors where the organisation buys in services.

## **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**

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.

#### **3.3 Contents**

Section One: Advisory user group (or relevant committee)

Section Two: Ultrasonic cleaning

Section Three: Washer-disinfectors

Section Four: Steam sterilisers

Section Five: Heat sealers

## Decontamination equipment

### 3.4 Procedure

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

- Each organisation should have a advisory user group (or relevant committee) in place to consider the decontamination equipment in the organisation with regard to the following:
  - i. Ability to meet current standards.
  - ii. Age and condition of equipment and availability of replacement parts.
  - iii. Cost of maintaining and repairing the equipment.
  - iv. Ability to interface with other equipment in the dental facility.
  - v. Ability to interface with user requirements.
  - vi. Ability to meet the requirements of current test methods.
  - vii. Ability to be validated and perform to intended purpose.
  - viii. Energy and water conservation.
  - ix. Ability for self-disinfection for washer-disinfectors.
  
- Key representatives on the specialist group should include (where available):
  - i. Decontamination Coordinator.
  - ii. Dental Staff.
  - iii. Microbiologist.
  - iv. Infection Prevention and Control.
  - v. Procurement.

The group may also include as required:

- i. Finance Manager/Budget Holder
- ii. Other relevant experts (Authorised Person/Sterivigilance Nurse).

## Decontamination equipment

- The group should identify all decontamination equipment which needs to be replaced.
- The group should formulate a plan to replace or upgrade this equipment.
- The plan should be submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer).
- The group should ensure that the decontamination equipment procured is compatible with the current stock of dental RIMD.
- There should be sufficient decontamination equipment available to meet the needs of the dental unit(s) and patient throughput.
- There should be clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment.
- Validation and periodic testing should be carried out by qualified personnel.
- The validation and periodic testing data should be adequately audited annually by a qualified person (decontamination) registered with the Health Service Executive.
- The department should have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

### Section Two: Ultrasonic cleaning

- A stand-alone ultrasonic cleaner should be provided for pre-treatment of those dental RIMD which are required to be cleaned by this method according to the manufacturers' instructions. Ultrasonic cleaning should preferably only be used as a pre-treatment for dental RIMD prior to further processing through a washer-disinfector.
- The ultrasonic cleaner should be fitted with a lid which is (preferably) interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- The dental RIMD manufacturer should be consulted to ensure that the enzymatic/detergent preparation is suitable for cleaning the dental RIMD they manufacture.
- Means should be provided to control the concentration of detergent. **Note:** An automated dispenser is preferable.



## Decontamination equipment

- The ultrasonic cleaner should be used in accordance with the manufacturers' instructions.
- The ultrasonic cleaner should be validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006.
- **Note:** The only effective way of cleaning the lumen of a dental hand-piece is to process it through a washer-disinfector with each lumen connected to a flushing system.

### Section Three: Washer-disinfectors

- The specification of the washer-disinfector should comply with requirements of EN ISO 15883 parts 1, 2 and 5, 2006.
- Each washer-disinfector should be fitted with a process monitoring system.
- When lumened devices are being reprocessed (e.g. dental handpieces), the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- Washer-disinfectors and accessories should be specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1, 2 & 5.
- The washer-disinfector should be subject to planned preventative maintenance.

### Section Four: Steam sterilisers

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

## Decontamination equipment

- All dental RIMD, items and equipment for use on patients should be packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- 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 Five: Heat sealers

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

## **Procurement of dental RIMD**

### **4 Procurement of dental RIMD**

#### **4.1 Introduction**

Procurement includes all activities from requisition, through payment to disposal and is the responsibility of all staff involved in the process. All staff engaged in procurement related activities are required to familiarize 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 procedure is to provide guidelines on the procurement of dental RIMD and ancillary materials.

#### **4.3 Contents**

Section One: Advisory user group

Section Two: Procurement policy

Section Three: Specification

Section Four: General principles

## **Procurement of dental RIMD**

### **4.4 Procedure**

#### **Section One: Advisory user group**

- Each organisation should have an advisory user group (or relevant committee) in place to consider the procurement of dental RIMD.
- Key representatives on the specialist group should include (where available):
  - i. Dental Staff.
  - ii. Competent Infection Prevention and Control Advisor (e.g. microbiologist).
- The group should also include as required:
  - i. Procurement.
  - ii. Technical Services.
  - iii. Other relevant experts as required (Authorised person/Sterivigilance Nurse).

#### **Section Two: Procurement policy**

- Each organisation should have a documented procurement policy.

#### **Section Three: Specification**

- The procurement of dental RIMD should be based on agreed specifications and should comply with the documented procurement policy.
- There should be a detailed specification for each dental RIMD which complies with current standards.

#### **Section Four: General principles**

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

## Procurement of dental RIMD

**Note:** The group should carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the processing procedure. Thus the manufacturers' validated instructions for the reprocessing of dental RIMD should be available prior to purchase and comply with local policies and procedures.

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

## **Manufacturers' instructions**

# **5 Manufacturers' instructions**

## **5.1 Introduction**

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

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

## **5.2 Scope**

The objective of this procedure is to outline the information that must accompany each dental RIMD to ensure the safe use of the device.

## **5.3 Contents**

### ***Manufacturer***

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

Section Two: Label

Section Three: The instructions for use

Section Four: Precautions and contraindications

Section Five: Information supplied on request

### ***Procedure for packs or sets in the central decontamination unit***

Section Six: Label

Section Seven: Instructions for use

## **Manufacturers' instructions**

### **5.4 Procedure**

#### *Manufacturer*

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

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

## **Manufacturers' instructions**

### **Section Two: Label that is placed on the pack**

*The label should contain the following details:*

- The name or trade name and address of the manufacturer.
- The details strictly necessary for the user to identify the dental RIMD and the contents of the packaging.
- Where appropriate (in the case of a single-use medical device), the method of sterilisation and the word 'STERILE'.
- Where appropriate, the batch code preceded by the word 'LOT', or the serial number.
- Where appropriate, an indication of the date by which the dental RIMD should be used, in safety, stating the month and the year.
- Where appropriate, an indication that the dental RIMD is for single use.
- If the dental RIMD is custom-made, the words 'custom-made dental RIMD'.
- If the dental RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- Any special storage and/or handling conditions.
- Any special operating instructions.
- Any warnings and/or precautions to be taken.
- Year of manufacture.
- Batch or serial number.
- 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.

### **Section Three: The instructions for use:**

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

- If the dental RIMD must be installed with, or connected to, other dental RIMD or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct dental RIMD or equipment to use in order to obtain a safe combination should be provided.



## **Manufacturers' instructions**

- All the information needed to verify whether the dental RIMD is properly installed and can be operated correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the dental RIMD operates properly and safely at all times should be provided.
- Where appropriate, information to avoid certain risks in connection with the implantation of the dental RIMD should be provided.
- The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of resterilisation.
- If the dental RIMD is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the dental RIMD to be resterilised, and any restriction on the number of reuses.
- Details of any further treatment or handling needed before the dental RIMD can be used (for example, sterilization, final assembly, etc).

### **Section Four: Precautions and contraindications**

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

- Precautions to be taken in the event of changes in the performance of the dental RIMD.
- Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions; to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.
- Adequate information regarding the medicinal product or products which the dental RIMD in question is designed to administer, including any limitations in the choice of substances to be delivered.
- Precautions to be taken against any special, unusual risks related to the disposal of the dental RIMD.

### **Section Five: Information supplied on request**

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

## **Manufacturers' instructions**

### *Procedures for packs or sets processed in the central decontamination unit*

#### **Section Six: Label**

The label should contain the following details:

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

#### **Section Seven: Instructions for use**

In general, Class I and Class IIa devices (see part 1, page 17) which comprise most of the dental RIMD processed by the local decontamination unit, do not require specific instructions for use. Exceptionally where these are required, copies should be retained by the clinical user and should be referenced on the label on the dental RIMD.

## Personal protective equipment

# 6 Personal protective equipment

## 6.1 Introduction

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

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

## 6.2 Scope

The objective of this procedure is the outline the PPE that must 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: Protective eyewear and face-shields

Section Four: Masks

## Personal protective equipment

Section Five: Plastic aprons and gowns

Section Six: Gloves

Section Seven: Footwear

### 6.4 Procedure

#### *Decontamination area*

##### **Section One: Attire**

- All personnel working in the decontamination area should don freshly laundered low linting attire at the beginning of the working day.
- Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered attire should be changed daily or whenever it becomes visibly soiled or wet.
- Staff who are involved in the maintenance of decontamination equipment should be required to wear the same type of clothing.
- On leaving the decontamination area, staff should change into their normal day wear.
- After use, the attire should be discarded appropriately in a designated post use container/bag.
- Work attire should never be worn outside the decontamination area.

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

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

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.

## Personal protective equipment

- After use, headgear should be discarded in the appropriate healthcare waste stream.
- 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 area.

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

- All personnel working in the decontamination area should wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear or face shield should be single-use.
- Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- Face shields should cover the eyes, nose, mouth and chin.

### Section Four: Masks

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

## Personal protective equipment

### Section Five: Plastic aprons and attire

- Healthcare Workers (HCWs) should wear impermeable attire with long cuffed sleeves and tuck-inside-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.
- Fluid repellent attire and aprons should be changed daily or whenever they become visibly soiled or wet.
- After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

### Section Six: Gloves

- Gloves should be used for handling contaminated dental RIMD and waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- 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.
- **It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.**
- HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves should be discarded in the appropriate healthcare waste stream.

## Personal protective equipment

### Section Seven: Footwear

- All personnel working in the decontamination area should wear non-slip enclosed footwear that are sufficiently robust to protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally). **Note:** Shoes that are made from canvas or cloth material are unsuitable and should not be worn.
- Footwear should be regularly cleaned.
- Footwear should be appropriate to the area in which HCWs are designated.

## **Process chemicals**

# **7 Process chemicals**

## **7.1 Introduction**

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

- Process chemicals should be chosen to be compatible with:
  - i. The dental RIMD to be processed.
  - ii. 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

- The methods to be used for handling and storage of process chemicals should be defined in written procedures.
- Chemicals that should not be stored together should be clearly identified.
- Chemicals should not be stored above shoulder height.
- Chemicals should be stored in locked cabinet.

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

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

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

- In each area where chemicals are used, a spillage kit should be available to allow safe and easy removal of spills.
- A first aid eye wash station should be available nearby or on hand.
- Where chemicals may contact HCWs 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/packs (tracking) and link them with patients on which they have been used (tracing).

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

## **8.2 Scope**

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

## **8.3 Contents**

Section One: Processing

Section Two: Tracing

## **8.4 Procedure**

### **Section One: Processing**

Systems should be in place to allow the methods, operational cycles and personnel involved in the processing of a particular dental RIMD/dental RIMD set to be tracked through the decontamination (sterilization) processes in order to permit retrospective verification that the processes were carried out effectively.

Records should be maintained of:

- i. The cleaning, disinfection and sterilisation process cycle used.
- ii. The name of the person undertaking each stage of the decontamination process.
- iii. The date, time and test result.
- iv. Details of the RIMD being processed.

## Traceability

- As a minimum, sets of dental RIMD should be individually identified. **Note:** RIMD should not be labelled with tape.
- Identification of individual dental RIMD may not be required. (The technology required for efficient and economical identification of individual dental RIMD is not sufficiently developed to recommend this as a requirement, although it is desirable).
- 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.
- Records relating to decontamination processes should be maintained for the lifetime of the dental RIMD/decontamination equipment plus eleven years.

### Section Two: Tracing

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

## **Choice of decontamination process**

# **9 Choice of decontamination process**

## **9.1 Introduction**

To prevent infection, all dental RIMD that come into contact with the patient 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 procedure is to provide guidelines on the choice of decontamination processes.

## **9.3 Contents**

Section One: General principles

Section Two: Choice of process

## **9.4 Procedure**

### **Section One: General principles**

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

## Choice of decontamination process

### Section Two: Choice of process

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

## **10.3 Contents**

Section One: General principles

## **10.4 Procedure**

### **Section One: General principles**

- RIMD should be removed from the surgery or clinical environment using a defined process.
- 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.
- Contaminated dental RIMD should preferably be transported to the decontamination area in a covered container, as there is potential for dropping the RIMD en-route or indeed colliding with patients or staff resulting in injury. This will also prevent contact between contaminated and sterilised/disinfected RIMD which should always be transported separately.
- Depending on how long the RIMD are stored before cleaning, it may be necessary to store them in a disinfectant solution.

### **Transportation—return of used items for reprocessing**

- Some commercial disinfectant products recommended for this purpose result in corrosion if in contact with RIMD for extended periods.
- Preferably, RIMD should be cleaned and disinfected immediately or shortly after use.
- In the case of heavily contaminated RIMD (e.g. RIMD used for oral surgery) it is best to remove as much of the contamination as possible prior to collection for transport to the decontamination area; e.g. RIMD heavily contaminated with blood should be wiped carefully with damp gauze using a single-handed technique.
- The spent gauze should then be disposed of appropriately as healthcare risk waste.
- All disposable items should be removed from the kit prior to transportation, e.g. disposable needles, cartridges etc.
- Broken RIMD or RIMD that require repair should be decontaminated and sterilised prior to disposal or repair.
- Policies and procedures for transportation (return of used items for reprocessing) of contaminated dental RIMD should be developed, reviewed periodically, and readily available within the practice setting.



## **Sorting and disassembly of contaminated dental RIMD**

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

## **11.1 Introduction**

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

## **11.2 Scope**

The objective of this procedure 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**

- 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.
- Policies and/or procedures should be developed for the handling, sorting and disassembly of dental RIMD.
- There should be written policies and/or procedures for handling specialised items.
- Care and handling of dental RIMD should be in accordance with manufacturers' instructions and organisation policies and procedures.

## Sorting and disassembly of contaminated dental RIMD

### Section Two: Disassembly of dental RIMD

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

- 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.**
- 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.
- Place each jointed dental RIMD in the open position in the mesh basket.
- If extra mesh baskets are required for cleaning purposes of an dental RIMD set, a marker should be placed in the extra baskets to identify the set name and number.
- Place heavy dental RIMD on the bottom or in a separate tray.
- 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.
- 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 procedure 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

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

### **12.4 Procedure**

#### **Section One: Manufacturers' instructions**

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

#### **Section Two: Automated versus manual cleaning**

- The use of mechanical cleaners such as washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.
- 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.
- 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**

- Automated washer disinfectors can significantly reduce the risks of transmission of infectious agents from contaminated dental RIMD.
- A washer disinfectant is an automated piece of equipment similar to a domestic dishwasher that is specially designed to clean, decontaminate and thermally disinfect RIMD and equipment.
- The washer disinfectant runs a washing cycle with detergent followed by a disinfection cycle and a drying cycle.
- Disinfection is performed by flushing with hot water of approximately 90°C for 1-10 minutes.

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

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

### **1. Washer-disinfectors**

#### **a. Introduction**

- All washer-disinfectors used for decontamination of dental RIMD should conform to ISO/FDIS 15883 parts 1, 2 and 5, 2006. The water for the final rinse stage should be compliant with the manufacturers' recommendations.

#### **b. Factors to be considered when determining if the RIMD is compatible with the washer-disinfecter**

- Manufacturers' instructions.
- If the dental RIMD can be immersed in water.
- Maximum operating temperature. (In general if a RIMD is suitable for autoclaving it is suitable for decontamination in a washer/disinfecter).
- Mechanical damage which may occur from the impact of the water jets or other items in the load.
- The compatibility of the process chemicals.

#### **c. Equipment**

- See decontamination equipment section, page 18.

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

### **d. Procedure**

- Ensure the washer-disinfector and all services are operational. The washer-disinfector should not start if any anomalies are present.
- 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.
- Only use load carrier and racks with the items for which they were intended.
- Keep a record of each RIMD/RIMD set processed in each washer-disinfector and each cycle in order to trace the RIMD/RIMD set through the decontamination process.
- Load the load carrier into the washer-disinfector.
- Secure the door (if fitted), select and start the cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the RIMD processed should be inspected.
- A typical cycle comprises the following phases:
  - i. Cold rinse.
  - ii. Warm wash.
  - iii. Rinse.
  - iv. Disinfection rinse.
  - v. Drying.
- Information should be recorded for each washer-disinfector cycle. Documentation is required for every washer-disinfector cycle and should contain the following. This information may be recorded in a log book.
  - i. Washer-disinfector identification number.
  - ii. Cycle number.
  - iii. Type of washer-disinfector.
  - iv. Type of cycle used.

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

- v. Date and time of start of cycle.
  - vi. Critical parameters for the specific washer-disinfector cycle.
  - vii. Results of washer-disinfector process
  - viii. Signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters
  - ix. Any notes or observation for the process cycle
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
  - Cycles which were aborted should be documented with the action taken in a log book.
  - Where single-ended washer-disinfectors are used adequate segregation of unprocessed goods from processed goods should take place.
- e. **Validation**
- 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.
  - 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.
  - 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:
    - i. Commissioning (installation qualification and operational qualification).
    - ii. Performance qualification.
    - iii. Periodic testing.
    - iv. Annual and revalidation tests.

## Cleaning (including pre-cleaning)

### 1. *Commissioning*

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

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

#### Operational Qualification

- Weekly 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.
- 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.
- 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 an Authorised Person 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.
- 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**.



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

### **2. *Performance qualification***

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). These tests consist of:

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

### **3. *Periodic testing***

- 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.
- The daily, weekly and quarterly tests supply evidence that the washer-disinfector is still operating within the limits established during commissioning.
- 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.
- **Daily:** Spray arm rotation, spray nozzles, remove and clean strainers and filters.
- **Weekly:** Automatic control test, safety checks, daily tests, water hardness, water conductivity and cleaning efficacy test (residual soil detection).
- **Quarterly:** Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection and cleaning efficacy test.
- **Annual:** Yearly safety checks, automatic control test, verification of calibration of instruments, 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)**

### **f. 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 and enzymatic detergent concentration.
- Validation, routine monitoring and control should be carried out in accordance with documented procedures in accordance with European standard EN ISO 15883, part 2, 2006.

### **g. Maintenance**

- Preventative maintenance should be planned and performed in accordance with International Standards ISO 15883-1 and ISO 15883-2 and manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The washer-disinfector should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.
- Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers' instructions and/or local policy, including:
  - i. Inspecting and cleaning all filters.
  - ii. Dismantling and cleaning spray arms and nozzles.
  - iii. Efficacy tests during operational conditions.

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

### *2. Ultrasonic Cleaners*

#### **a. Introduction**

- 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.

#### **b. Equipment Required**

- See decontamination equipment, page 18.

**Figure 12-1: Loading the ultrasonic cleaner**



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

### **c. Procedure**

- Staff should wear personal protective equipment at all times while handling contaminated dental RIMD and working with the ultrasonic cleaner.
- Fill the tank with potable water (drinking quality) to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- Bring the solution up to the operating temperature.
- De-gas the water as recommended by the manufacturer.
- Place the opened/dismantled dental RIMD into the basket.
- Ensure all dental RIMD are fully immersed.
- If the dental RIMD is not for further cleaning, e.g. automated cleaning, record the following:
  - i. Method used.
  - ii. Solution dilution and temperature.
  - iii. Healthcare worker carrying out procedure.
  - iv. Date.
- Place the basket of dental RIMD into the tank. Never put dental RIMD directly onto the base of an ultrasonic washer.
- Close the lid and initiate the cleaning cycle.
- 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.
- The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.
- 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.
- Combine only dental RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.
- Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.

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

### **d. Validation**

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.
- 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:
  - i. Commissioning (installation qualification and operational qualification).
  - ii. Performance qualification.
  - iii. Periodic testing.
  - iv. Annual and revalidation tests.

### **2. Commissioning**

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**

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

#### **Operational qualification**

- Weekly safety checks, verification of calibration, safety interlocks, 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 test, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasound activity and sound pressure.
- 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 or following critical repairs.

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

- Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of ultrasonic cleaner.
- 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.

### **2. *Performance qualification***

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 suitably qualified person). These tests consist of:

- Cleaning efficacy test and process residue test.

### **3. *Periodic testing***

- After validation and when the ultrasonic cleaner has been passed for use, it is subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals.
- The daily, weekly and quarterly tests supply evidence that the ultrasonic cleaner is still operating within the limits established during commissioning.
- 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.
- **Daily:** Remove and clean strainers and filters.
- **Weekly:** Daily tests, automatic control test (if using an automated ultrasonic cleaner) safety checks, and cleaning efficacy test (residual soil detection).
- **Quarterly:** Weekly safety checks, automatic control test, verification of calibration of instruments, test for ultrasonic activity and cleaning efficacy test.

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

- **Annual:** Weekly safety checks, automatic control test, verification of calibration of instruments, 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.

### **e. Monitoring and control**

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.

### **f. Test for Ultrasonic Activity (reference HTM 2030)**

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***

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

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

### *Method*

- Measure the depth of the bath from the level of the lid to the bottom of the bath.
- Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.
- Carry out the manufacturers recommended start-up procedure.
- 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.
- 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.
- 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.
- Operate the bath for the predetermined exposure time.
- Remove the strips from the bath, blot dry and examine.
- 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). Photostat pattern and save as documented record.
- On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

### **g. Maintenance**

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



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

### **Section Four: Manual Cleaning**

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

#### **a. Monitoring and control**

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:

- i. Staff training/competence.
- ii. Water temperature.
- iii. Detergent concentration.
- iv. Nature of soil.
- v. Method of soil removal.
- vi. Accessibility of fluid to item.

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

#### **b. Maintenance**

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.

## Cleaning (including pre-cleaning)

### Section Five: Dental hand-pieces

- After each patient 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 patient-derived material that may have been retracted into the air and/or water lines due to failure of antiretraction valves.
- These valves are designed to prevent material or fluids from being retracted or siphoned back into air and/or waterlines but studies have shown that failure of antiretraction valves is not uncommon.
- 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.
- Automated pre-sterilisation cleaning of handpieces is the preferred method of handpiece decontamination.
- 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).
- 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).
- Cover the working end of the handpiece with disposable paper towel to absorb the residual oil and clean away any excess oil.
- Following cleaning, package appropriately and sterilise in a steriliser with a pre-sterilisation vacuum phase.
- Dental handpieces should preferably be processed through a washer-disinfector equipped with lumen attachments.

Figure 12-2: Dental handpieces



## Disinfection

### 13 Disinfection

#### 13.1 Introduction

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

#### 13.2 Scope

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

#### 13.3 Contents

Section One: Disinfection process

#### 13.4 Procedure

Section One: Disinfection process

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

## **Disinfection**

### ***1. Thermal Disinfection***

#### **a. Introduction**

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

### ***2. Chemical Disinfection***

#### **a. Introduction**

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

#### **b. Equipment required**

- Dental RIMD disinfectant or sterilant.
- Automated equipment.

## Disinfection

### c. Monitoring and control

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

## **Drying**

# **14 Drying**

## **14.1 Introduction**

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

## **14.2 Scope**

The objective of this procedure 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**

- See decontamination equipment, page 18.

### **Section Two: Procedure**

- The preferred method of drying is to use a washer-disinfector with a validated drying cycle. Alternatively a drying cabinet can be used. If neither are available a clean disposable lint-free, absorbent wipe should be used, taking care to prevent percutaneous injury.
- Care should be taken not to exceed the temperature tolerances advised by the manufacturer.
- Dry the dental RIMD in a sloping position to facilitate drainage.

## **Drying**

### **Section Three: Monitoring and control**

- Manual drying should be avoided unless a single-use lint free cloth.
- Items should not be left to dry in ambient air.
- Alcohol or other flammable liquids should not be used as drying agents, other than in automated equipment designed for this purpose, e.g. some endoscopes washer–disinfectors.

### **Section Four: Maintenance**

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

## **Post cleaning inspection and function testing**

# **15 Post cleaning inspection and function testing**

## **15.1 Introduction**

Inspection, maintenance and testing of dental RIMD should be carried out by trained persons in accordance with the manufacturers' instructions. All dental RIMD should be inspected to ensure that they are intact and that there are no chips, worn spots, flaking or other damage. The functionality of all dental RIMD should be tested or checked before being packaged for further processing or storage. The 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 procedure 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

- Work bench.
- Magnifying glass and/or stereo microscope.
- Light source.
- Diathermy pin hole detector

#### Section Two: Procedure

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

- 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.
- Check that the operating cycle is in accordance with the specification for the load used.
- 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.
- Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the dental RIMD or dental RIMD may not be compatible with automated washing.
- 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.
- Make a visual inspection of the load for dryness.
- Where a load may not be properly cleaned, the entire load is rejected and returned for re-cleaning.
- 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.

### **Post cleaning inspection and function testing**

- The diathermy pin hole detector should be used in accordance with the manufacturers' instructions to ensure safe use of equipment.

#### **Section Three: Documentation post automated cleaning**

- All documentation for automated cleaning should contain the following information:
  - i. Washer-disinfector identification number.
  - ii. Cycle number.
  - iii. Type of washer-disinfector.
  - iv. Type of cycle used.
  - v. Date and time of start of cycle.
  - vi. Critical parameters for the specific washer disinfector cycle.
  - vii. Results of washer-disinfector process.
  - viii. Any notes or observation for the process cycle.
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- Before commencing inspection the person carrying out inspection should ensure that:
  - i. The dental RIMD/dental RIMD set has been recorded as being through the specific cleaning process.
  - ii. If there is no record of cleaning, the dental RIMD/dental RIMD set is rejected and returned for re-cleaning. Items which have been manually cleaned should also be recorded as being cleaned through the manual cleaning process.
  - iii. The signature of identified responsible person confirming that the cycle has passed.

## Post cleaning inspection and function testing

### Section Four: Inspection and function testing

- Each dental RIMD/dental RIMD set should be inspected separately.
- Box joints, serrations and crevices, should be critically inspected for cleanliness.
- Hinges should be checked for ease of movement.
- Jaws and teeth should be checked for alignment.
- Ratchets should be checked for security.
- Ratchets should close easily and hold firmly.
- Any damaged, incomplete or malfunctioning dental RIMD should be reported immediately.
- Cannulated dental RIMD should be checked to ensure channel is patent.
- Telescopes and light cables should be function checked as per manufacturers' instructions.
- Each dental RIMD set should be checked for completeness and defects.
- The sharpness of cutting edges should be assessed.
- Dental RIMD that have an outer insulation coating, for example diathermy forceps etc., require close inspection to ensure that the insulation remains intact. Insulated dental 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 patients.
- Each dental 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. The lubricant should be used as directed by the RIMD manufacturer.
- Each dental RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.
- Each dental RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.

## **Post cleaning inspection and function testing**

### **Section Five: Monitoring and control**

The user should be aware of the factors that may alter the efficacy of the method:

- Staff training/competence.
- Age of the dental RIMD.

### **Section Six: Maintenance**

- 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' instructions.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485:2003(E).

## **Packaging**

# **16 Packaging**

## **16.1 Introduction**

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

## **16.2 Scope**

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

## **16.3 Contents**

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

## Packaging

### 16.4 Procedure

#### Section One: General principles

- The choice and type of wrapping material will depend on the type of sterilisation process used.
- Materials used should comply with EN ISO 11607-1 and EN ISO 11607-2, 2006 and EN 868 parts 2-10, inclusive. Dental RIMD may be packaged in any of the following products: papers/non-wovens, polypropylene, containers, and plastic/paper pouches.
- When selecting packaging system each specific products capability to meet predetermined requirements and criteria should be evaluated.
- The appropriate size wrapping material should be chosen to attain adequate coverage of the item being packaged.
- 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.
- Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.
- Dental RIMD packs should be packed in a manner that prevents damage to delicate items.
- Trays used for packaging RIMD should be perforated to allow for penetration of the sterilant.
- Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.
- Hollowware should be packaged so that all openings face the same direction.
- Only the minimum of raw materials commensurate with daily production should be held within the clean room.
- Compatibility of the packaging material with the sterilisation process should be established.

## Packaging

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

### Section Two: Packaging systems

Packaging systems should:

#### *1. 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.

## Packaging

### 2. *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.

### 3. *Be used according to the manufacturers' instructions*

### 4. *Be of the following*

- Resistant to punctures, tears and other damage which may break the barrier and cause contamination.
- Resistant to penetration by micro-organisms from the surrounding environment.
- Free of holes.
- Be free of toxic ingredients.
- Low-linting.
- Tamper proof and able to seal only once.
- Provide an adequate barrier to particulate matter and fluids.

## Section Three: Packaging materials

Packaging materials should:

- 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.
- 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.



## Packaging

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

### Section Four: Single use packaging

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

### Section Five: Types of packaging

#### 1. *Papers and non-wovens*

- 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 sterilization and most gas processes because they are permeable to air, steam and other gases.
- Appropriate lain 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.
- 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.

#### 2. *Containers*

##### *Rigid reusable non-perforated containers:*

- Should be easily disassembled for cleaning, drying and storage.
- Should be suitable for the method of sterilisation being used.
- Should be compatible to the cleaning method and cleaning agent being used
- Should be suitable to the storage configuration.
- Should have locking devices which are tamperproof and non resealable.

## Packaging

- Should be packed in a manner which allows for penetration of the sterilising agent.
- Lid and contents should be removable without the risk of contamination of the contents.
- Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.
- The filter plate should be examined for integrity both before installation and after the sterilisation process.
- If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system should be used in the practice setting.
- 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.
- 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.
- 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.
- Containers should be cleaned between each use; automated cleaning is the preferred method of cleaning.

### Section Six: Packaging techniques

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

## Packaging

### 1. *Flat wrapping material*

#### a. **Equipment required**

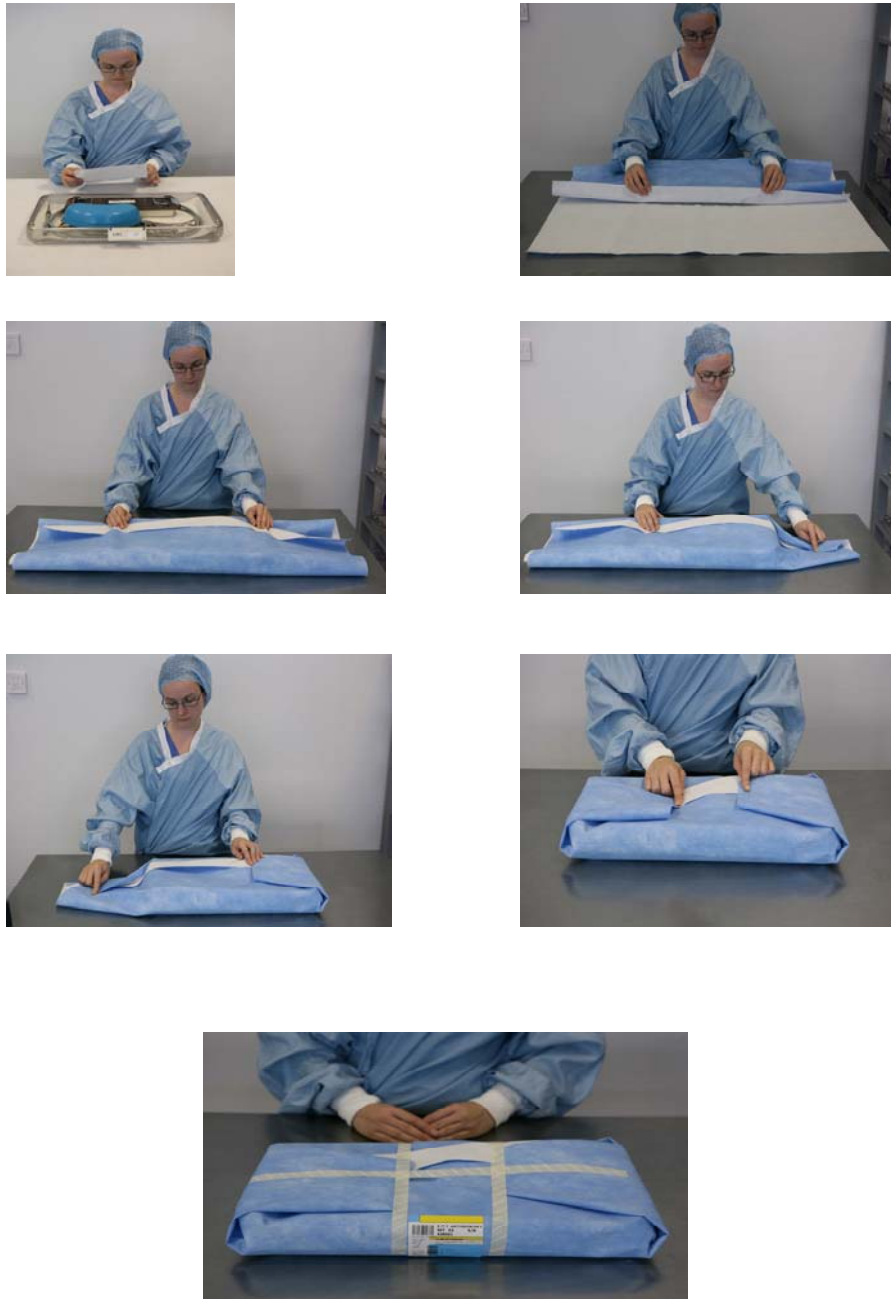
- Packaging material.
- Sterilisation chemical indicator tape.
- Indelible marking pen.
- Label (where applicable).
- Tray liners.

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

- Select appropriate packaging material and place on work top.
- The dental RIMD set is placed on the wrap, approximately in the centre of the packaging material.
- Verify the accuracy of the dental RIMD identification label with the dental RIMD/dental RIMD set, (i.e. corresponds to dental RIMD list, internal tray label, etc).
- The long edge of the tray should be aligned parallel to the long edge of the wrap.
- One of the long edges of the wrap is folded over the pack contents to the base of the tray, and the edge of the wrap is turned back on itself. The fold made by the turning back of the wrap should overlap the centre line of the contents.
- 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.
- The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- The same procedure may then be repeated for an outer wrap(s).
- The wrap is secured in position using sterilisation indicator tape.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- The dental RIMD identification label is placed on outside wrap.

## Packaging

Figure 16-1: Parcel-fold wrapping method



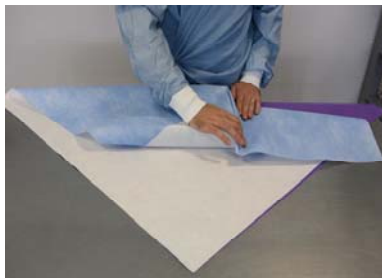
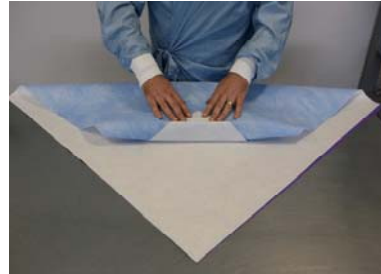
## Packaging

### c. Procedure (envelope wrapping method)

- Select appropriate packaging material and place on work top.
- The dental RIMD set is placed on the wrap diagonally and slightly off the centre line.
- Verify the accuracy of the dental RIMD identification label with the dental RIMD/dental RIMD set (i.e. corresponds to the dental RIMD list, tray internal label, etc).
- The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.
- This is repeated with the corners to the right and left of the first folded corner.
- In each case the corner is turned back to provide a flap for opening.
- Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.
- The same procedure may then be repeated for an outer wrap(s).
- The wrap is secured in position using 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.
- The dental RIMD identification label is placed on the outside wrap.

## Packaging

Figure 16-2: Envelope wrapping method



## Packaging

### *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.

#### **a. Equipment required**

- Pouches and/or bags.
- Sterilisation chemical indicator tape.
- Indelible marking pen.
- Label (where applicable).

#### **b. Procedure**

- The corners at the open end of the pouch are folded diagonally to give mitred corners.
- The top of the pouch is then folded over three times in succession.
- The same procedure may then be repeated for an outer wrap(s).
- 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.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the dental RIMD to be viewed.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- The dental RIMD identification label is placed on the outside wrap.

### **3. Self-seal Pouches**

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

## Packaging

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

#### **a. General Principles**

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

#### **b. Equipment required**

- Heat-seal Pouches.
- Heat sealer.
- Indelible marking pen.
- Label (where applicable).

#### **c. Procedure**

- Select appropriate size heat seal pouch.
- Place dental RIMD into pouch.
- Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.



## Packaging

- 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.
- Place open end of pouch in heat sealer.
- Apply heat and pressure to the surface of the open end of the heat seal pouch.
- Check should be made that the seal is complete, especially over the gusset folds of the pouches.
- 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.
- The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- 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.
- Edges of inner heat seal pouches should not be folded as air may be entrapped in the folds and inhibit sterilisation.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the dental RIMD to be viewed.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the sterilant into and out of the package.
- If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.
- It is important to wrap the dental RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- Use adhesive dental RIMD identification label, do not write on the paper side of the pouch.
- The dental RIMD identification label is placed on the outside packaging.

## Packaging

Figure 16-3: Using the heat sealer



Figure 16-4: Heat seal pouch



## Packaging

### Section Seven: Sealing of packs and bags

#### a. Introduction

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 867-1.

#### b. Accessories used to close or secure packages should be able to perform the following:

- Allow sterilisation.
- Avoid constriction of the package.
- Maintain package integrity.
- The accessories should also be recommended by the manufacturer.

#### c. The following accessories should not be used:

- Tape (other than sterilisation chemical indicator tape).
- Safety pins.
- Paper clips.
- Staples.

#### d. Sterilising indicator tape

Sterilising indicator should be:

- Specific to the method of sterilisation being used and which will change colour when exposed to the relevant sterilisation agent.
- Pressure sensitive.
- Non toxic, adhere to clean surfaces and leave no adhesive residue on removal.
- Compatible with the wrapping material used.
- Heat stable.
- Moisture-stable and permeable to the sterilising agent.

## Packaging

### Section Eight: Labelling

- Packages to be sterilised should be labelled after sterilisation.
- The information of the label should include the following:
  - i. Name of product.
  - ii. Sterilisation date.
- Label information should be documented on sterilisation chemical indicator tape or label and not on the packing material. Plastic/paper pouches can be labelled on the plastic portion.
- 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.
- Label fixed to the surface of the packaging should be able to withstand exposure to the sterilisation process.
- Policies and/or procedures 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 16-5: Labelling



## Packaging

### Section Nine: Monitoring and control

The following should be monitored during labelling:

- General appearance of the packaging material.
- Whether packages are complete.
- Whether the correct products and packaging material are used.
- Whether the labelling is correct on the product.
- Whether the sealing is correct.
- Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.
- Material should be checked for tears, flaws and holes.
- Containers seals and filters should be checked.
- Containers should be checked for dints which may interfere with maintaining sterility.

### Section Ten: Maintenance

- Reusable containers should be subject to thermometric performance tests.
- Containers should be validated periodically for reuse according to manufacturers' instructions.
- Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policy.
- Heat seal efficiency, integrity and strength test should be preformed on each heat sealer daily.
- Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.
- Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.

## Packaging

- Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The heat sealer should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 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.
- A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

## **Sterilisation**

# **17 Sterilisation**

## **17.1 Introduction**

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

## **17.2 Scope**

The objective of this procedure 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

## Sterilisation

### 17.4 Procedure

#### Section One: Types of sterilisers

- 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).
- Thermal processes include dry heat (not covered in this document) and high temperature steam sterilisation. The steam sterilisers intended to be used for sterilisation of wrapped dental RIMD are referred to as porous load sterilisers.
- The preferred method of low temperature sterilisation is Hydrogen Peroxide Plasma.
- Sterilisers that have a pre-vacuum stage are the most appropriate for sterilisation for heat-tolerant dental RIMD and other items and should conform to current European Union Standards (e.g. EN285, EN17665 EN556 (for large sterilisers) and EN13060 (for benchtop sterilisers).
- The manufacturer's instructions for correct use of equipment should always be followed and the equipment should be used by trained and competent personnel.
- Many dental practices use sterilisers without a pre-sterilisation vacuum phase in which air is removed from the steriliser chamber by steam displacement (i.e. downward displacement sterilisers).
- Downward displacement sterilisers are not appropriate for sterilising wrapped loads of RIMD or for items that contain a lumen (e.g. dental handpieces), and **should not be used for these purposes under any circumstances.**
- All dental RIMD, items and equipment for use on patients should be packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- Flash sterilisers rely on natural air displacement and should not be used for wrapped goods, hollow devices or tubing.
- Boiling water sterilisers, hot air ovens, ultra violet light treatment, hot bead sterilisers and chemoclaves are not appropriate for sterilising dental RIMD and should not be used.



## Sterilisation

### Section Two: Choice of sterilisation process

- Steam sterilisation is the most practical method for sterilising reusable invasive medical devices (RIMD) in dental clinics. It is rapid; non-toxic can effectively destroy micro-organisms and thus is the method of choice for sterilising dental RIMD.
- Steam sterilisation requires direct contact between saturated steam and all surfaces of the load at one of the pressure, time, and temperature relationships shown in table 17-1 below. The highest temperature compatible with the RIMD/equipment to be sterilised should be used.
- **Note:** The manufacturers instructions for dental RIMD purchased from the United States will often specify steam sterilisation cycles that are different from the standard cycle given above, e.g. 132°C for ten minutes. In most cases these dental RIMD can be processed through the standard cycle but confirmation should be obtained from the dental RIMD manufacturer.

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

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilisation Hold Time	Dental RIMD Category
121°C	1.03 bar gauge	124°C	15 minutes	Dental handpieces
134°C	2.30 bar gauge	137°C	3 minutes	Dental RIMD

## **Sterilisation**

### **Section Three: Steam sterilisation**

- 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.
- 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.
- Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.
- These sterilisers have a pump to remove air from the steriliser chamber and load. When loading the steriliser, RIMD and other items to be sterilised should be arranged to facilitate free circulation of steam and care should be taken not to over-fill the steriliser chamber.
- Sterilised RIMD packs should be allowed to dry inside the steriliser before removing and handling.
- Many modern vacuum sterilisers have a post-sterilisation drying cycle that facilitates drying of RIMD packs.
- The operating cycle of a porous load steriliser generally has five stages:
  - i. Air removal.
  - ii. Steam admission.
  - iii. Sterilisation holding time.
  - iv. Vacuum drying.
  - v. Filtered air admission.

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

#### **a. Equipment**

- See decontamination equipment, page 20.
- Loading trolley.

## **Sterilisation**

- IT based/Manual tracking system and accessories, i.e. paper, pen, scanner.
- Batch control labeller.
- Personal protective equipment—(heat resistant gloves).

### **b. Procedure**

- Healthcare workers (HCWs) should wear personal protective equipment.
- HCWs should ensure that all items within the load are compatible with the process to which they are to be exposed.
- Loading should allow for free circulation of steam around each pack and each item.
- RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
- Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.
- Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.
- Hollowware should be placed upside-down or tilted, to prevent collection of condensate.
- 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.
- Containers should be loaded onto the trolley such that an air space is formed between each container layer.
- When using the basket system Healthcare Workers (HCWs) 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.
- When loading HCWs should ensure that each RIMD is labelled.
- When loading is complete each item on the loading trolley should be recorded using the IT (or manual) tracking system.

## **Sterilisation**

### **Section Five: Loading the Steriliser**

- Healthcare Workers (HCWs) should load the steriliser using the loading trolley.
- HCWs should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.
- 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.
- Manufacturers' instructions and protocols agreed during validation should be followed for loading.
- Overloading of sterilisers may compromise the process.

## Sterilisation

### Section Six: Steam sterilisation of dental RIMD

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

Figure 17-1: Un-loading the Steriliser



## **Sterilisation**

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

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

#### **a. Sterilisation cycle verification**

- The cycle records should be examined to confirm that the cycle variables were within the limits established as satisfactory during validation. This should include:
  - i. The number and extent of air removal pulses.
  - ii. The temperature and duration of the sterilisation plateau period.
  - iii. The depth and duration of the drying vacuum.
  - iv. The data should be read from the independent recorder not from the automatic controller record.
- 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.
- A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

#### **b. Inspection of sterilised load**

- Each item sterilised should be inspected to ensure that:
  - i. Chemical process indicators have changed colour as described in the indicator manufacturers' instructions. (Chemical process indicators, e.g. autoclave tape, do not indicate sterilisation; they are evidence only that the load has been exposed to the sterilising process).
  - ii. The packaging is in place and undamaged (i.e. seals, taped joints have not come undone, packs are not torn).
  - iii. The packaging is dry and free from visible dampness.
  - iv. All labels are intact and legible.

## Sterilisation

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

### Section Eight: Sterilisation records

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

- i. Steriliser identification.
  - ii. The cycle number and batch number if applicable.
  - iii. Name of the loading operator and unloading operator.
  - iv. Type of cycle used.
  - v. Date and time of start of cycle.
  - vi. Contents of the load.
  - vii. Chart record and/or print-out from steriliser cycle.
  - viii. Signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.
  - ix. Any notes or observation for the process cycle.
  - x. Read out results of physical, chemical or biological indicators that are used.
  - xi. All records should be retained for the lifetime of the steriliser plus eleven years.
- Many modern sterilisers are supplied with integral recording equipment that print out sterilisation cycle details, such as cycle time, temperature and pressure. Larger autoclaves, such as those used in hospitals, may also have a remote data archiving facility that allows data for each autoclave cycle to be recorded automatically in a database on a laptop computer.

## Sterilisation

### Section Nine: Validation:

Sterilisation cannot be confirmed by inspection and testing of the product. In order to ensure that a steriliser is functioning properly and will consistently produce sterile loads, validation, maintenance, periodic testing and record keeping are necessary.

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:

- Commissioning (installation qualification and operational qualification).
- Performance qualification.
- Periodic testing.
- Revalidation.

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

#### *1. Commissioning*

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

**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**

- Preliminary checks.
- Electrical checks.
- Functional checks.
- Response to faults.



## Sterilisation

**Operational qualification** is 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:

- i. Air leakage test.
  - ii. Thermometric test.
  - iii. Calibration.
  - iv. Steam Penetration test.
- These tests should be carried out when a new steriliser is purchased, when a used steriliser has been relocated to another premises or following critical repairs.
  - The tests should be carried out before the steriliser is used for the first time.
  - Installation and operational checks and tests should be performed by a person with specialist technical training in testing of sterilisers.
  - Data from the installation and operational tests provide evidence that the steriliser is functioning correctly.

### *2. Performance qualification*

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

These tests consist of:

- Air leakage tests (automatic).
- Thermometric tests of all dental RIMD to be processed.
- Steam penetration test (e.g. Bowie and Dick).
- Load dryness test (only required for sterilisers with drying cycles).
- Microbiological tests (e.g. Spore tests).

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

## Sterilisation

### 3. *Periodic testing*

Periodic testing consists of a programme of tests that are intended to show that the steriliser's performance is continually satisfactory. The appropriate tests should be carried out at daily, weekly and annual intervals. A suitably trained person(s), (usually the individual(s) that operates the steriliser on a daily basis), should draw up a schedule for periodic testing. It is the responsibility of the practice manager to ensure that these tests are performed.

After appropriate training the user should perform the daily tests. Many modern sterilisers have an integrated automated test facility that enables the steriliser to perform some of the specialised weekly tests itself. These can be undertaken by the user after appropriate training. Older sterilisers may require the services of a test person (or other suitably qualified person) to undertake weekly tests. Annual tests should be performed by a test person (or other suitably qualified person). Each cycle available to the user should be tested. If the steriliser is not tested periodically it will not be possible to know if it is working correctly. Failure of a test implies that the steriliser is not working to specification.

The user should have a written procedure for handling test failures but, in all cases, the steriliser must be withdrawn from service, the failure investigated, the cause rectified, and the steriliser re-tested successfully before being used. The user has the ultimate responsibility for certifying that the steriliser is fit for use.

## Sterilisation

### *I. Daily Test—Steam Penetration Test /Bowie and Dick*

#### **a. Introduction**

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 (usually it changes colour – and should do so completely) only when steam penetration is adequate. If a cycle is provided specifically to test the effectiveness of steam penetration, it should have the same air removal stage as used during routine sterilisation cycles.

#### **b. Test procedure**

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

**Figure 17-2: Bowie-Dick Test**



## Sterilisation

### II. Weekly tests

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

#### 1. Safety checks

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.
- 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.

#### 2. Vacuum leak test

- 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.
- 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.
- 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

- 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.
- 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 should do the test using special, calibrated RIMD.

The pass/fail criteria are:

- 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.
- 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.

### 3. Air detector function test

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.

### 4. Automatic control test

- 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.
- The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the steriliser was validated to be working correctly, e.g. immediately after the Test Person had tested it using calibrated RIMD.
- 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:
  - i. Chamber temperatures and pressures, their maximum values and duration in minutes and seconds.
  - ii. The values on the cycle record should be compared with those on the master process record.

## Sterilisation

- i. The test can be considered satisfactory if at the end of the cycle if:
  - 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.

For vacuum sterilisers the test can be done at the same time as the steam penetration test but the steam penetration test must be performed with the chamber empty except for the test device. The test is not required if the steriliser is equipped with a recorder that provides a permanent record of the temperature, pressure and elapsed time during all sterilising cycles. Verification should be sought from the manufacturer as to whether it is necessary to pre-heat the steriliser chamber before performing these tests, as this can extend the test time.

### 5. Test Procedure for automatic control test of a steriliser without a cycle recorder:

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

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

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

## Sterilisation

### *III. Quarterly tests*

These require specialised test equipment and only a person (e.g. a Test Person or other suitably qualified person) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate.

Quarterly tests for steam sterilisers are summarised in table 17-3.

**Table 17-3: Summary of Quarterly Tests for Steam Sterilisers (EN285)**

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

## Sterilisation

### IV. Annual Tests

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

**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
Tests for Performance Requalification (as required)
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration



## Sterilisation

### Section Ten: Monitoring and control

- 134°C is the preferred sterilisation temperature. For dental RIMD, which may be damaged at 134°C, any of the other lower temperature bands may be used.
- There should be evidence through measurements, biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
- Routine monitoring and testing should be carried out in accordance with documented procedures in line with I.S. EN ISO 17665 part 1.

### Section Eleven: Maintenance

- Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' instructions and European Standards.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The steriliser should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665, 2006.
- A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- 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.

Revalidation may be required after steriliser relocation, engineering work, repair work, software control function modifications and when required by the user. Some examples of requirement for revalidation are:

- Adjustment to steam controls.
- Adjustment to microprocessor controls.
- Adjustment to control parts.

## Sterilisation

### Section Twelve: Chemical and Biological Indicators

#### *Chemical indicators*

- Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).
- The type used should be in accordance with the steriliser manufacturers' recommendations.
- The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- 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.
- Indicators should not be used beyond their expiry date.
- Spore tests provide the only absolute evidence of the sterilisation capability of a steriliser cycle.
- One disadvantage of spore tests is that test results usually take 24-48 hours. If spore testing is used as the principal parameter for assessing the sterility of a sterilised load of dental RIMD, the sterilised RIMD packs should be withheld from use until the results of the spore test are available.
- Two types of chemical indicator are commonly used:
  1. **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
  2. **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.

## **Sterilisation**

### *Biological indicators*

- Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained.
- Biological indicators must meet the requirements of BS EN ISO 11138-1:2006.
- 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.
- 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).

## **Storage**

# **18 Storage**

## **18.1 Introduction**

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

## **18.2 Scope**

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

## **18.3 Contents**

Section One: Storage areas

Section Two: Storage equipment

Section Three: Shelf life/rotation of stock

Section Four: Non-conforming stock

## **18.4 Procedure**

### **Section One: Storage areas**

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:

- i. The processed goods store.
- ii. The raw materials store.

### **i. Processed goods store**

## Storage

- The processed goods store is for dental RIMD produced by the department and dental RIMD which have been commercially manufactured and sterilised.
- The outer packaging (shipper carton) should be removed from dental RIMD which have been commercially manufactured and sterilised – if stored in the same store as those dental RIMD which have been produced by the department.
- Raw materials should not be stored in the processed goods store.
- Packed, processed, single dental RIMD should be stored separately from those packed in cassettes or sealed containers.
- Storage areas should be kept secure and access should be restricted to authorised personnel.
- 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.
- The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility and integrity is not otherwise compromised.
- Medical and surgical process goods should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.
- Processed goods should be stored on appropriate designated shelving.

### ii. Raw materials store

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. The raw materials store should be located between the goods reception and the clean room area.

- Materials should be segregated and stored separately according to their specific requirements.
- Sterile RIMD should not be stored in this area (unless supplies are bulk cased).
- Single items should be stored separately from those in cases.
- Storage areas should be kept secure and access restricted.

## Storage

### Section Two: Storage equipment

#### a. General principles

- 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.
- 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.
- 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.
- 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).

Figure 18-1: Storage of sterile items



## **Storage**

### **b. Shelving and racking**

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

### **c. Closed or covered cabinets**

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

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

- General factors which influence shelf life are event related and include the following:
  - i. Packaging materials.
  - ii. Storage and handling conditions.
  - iii. Likelihood of product material deterioration.
  - iv. Package design.
- Each designated dental decontamination area should develop a system of stock rotation based on the date of sterilisation. Good management practices demand that stock be maintained at adequate levels.
- 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.
- 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.

## Storage

### Section Four: Nonconforming Stock

- A package should be considered nonconforming, i.e. non sterile and not suitable for use when:
  - i. It is incorrectly wrapped.
  - ii. It is damaged, opened or has been dropped.
  - iii. The product has been unused for six months.
  - iv. The sterilisation process indicator does not confirm that the pack has been subject to an appropriate sterilisation process.



## **Transportation—of sterile items**

### **19 Transportation – of sterile items**

#### **19.1 Introduction**

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

#### **19.2 Scope**

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

#### **19.3 Contents**

Section One: General principles

Section Two: External transportation

#### **19.4 Procedure**

##### **Section One: General principles**

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

- 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.
- 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**

# **20 Water supply for washer-disinfectors**

## **20.1 Introduction**

The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process.

## **20.2 Scope**

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

## **20.3 Contents**

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

## **20.4 Procedure**

### **Section One: General requirements**

- At each stage in the cleaning process the water quality should be compatible with:
  - i. The components of the washer-disinfector.
  - ii. The dental RIMD to be processed.
  - iii. The process chemical to be used.
  - iv. The process requirements of that particular stage.

## Water supply for washer-disinfectors

- The key quality elements to be considered are:
  - i. Hardness.
  - ii. Temperature.
  - iii. Ionic contaminants (e.g. heavy metals, halides, phosphates and silicates).
  - iv. Microbial population.
  - v. Bacterial endotoxins.
- The water supply should be controlled to ensure that it is of the required quality.

### Section Two: Water Quality

#### *i. Hardness*

- 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.
- 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 (WD).
- Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- 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.

#### *ii. Temperature*

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

## Water supply for washer-disinfectors

- When enzymic 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.
- 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.

### *iii. Ionic contaminants*

- Ionic contaminants in the water may react with materials such as stainless steel.
- 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.
- 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.
- Total Dissolved Solids should be checked with conductivity meter at an agreed period with User Group or Authorised Person

### *iv. Microbial population*

- The microbial population in the water used in the washer-disinfector (WD), particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.
- 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 patient, either through infection or by leading to a erroneous diagnosis.
- Suitable Potable water with < 100 cfu/ml is suitable for final rinse

### *iv. Bacterial endotoxins*

- 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. They are not readily inactivated at the temperatures used for disinfection or sterilization.

## Water supply for washer-disinfectors

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

### Section Three: Water treatment

There are three methods of water treatment generally used on water supplies for washer-disinfectors (WDs): *Note: Distilled water is not suitable.*

- i. “Base-exchange” softeners.
- ii. De-ionisers.
- iii. Reverse osmosis.

#### *i. “Base-exchange” softeners*

- 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).
- 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.
- 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.

#### *ii. Deionisers*

- De-ionisation (demineralization) 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.
- 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.

## Water supply for washer-disinfectors

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

### *iii. Reverse osmosis*

- Reverse osmosis (RO) treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.
- When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.
- Appropriate measures include:
  1. A continuous recirculation system water.
  2. Filtration, e.g. through a 0.22 µm filter to remove microbial contaminants.
  3. Treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J. m<sup>-2</sup>)).
- The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Stainless steel pipes are preferred for all qualities of purified water.
- 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.

## Water supply for washer-disinfectors

Table 20-1: 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	Reverse osmosis 0.22 mm filtered	De-ionised 0.22 mm

\*Endoscope washer-disinfector only

Table 20-2: Water quality for cleaning dental 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

# 21 Single use invasive medical devices

## 21.1 Introduction

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

## 21.2 Scope

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

## 21.3 Contents

Section One: General principles

## 21.4 Procedure

### Section One: General principles

- If an item is marked single-use, it should only be used on a single occasion and then it should be discarded into healthcare risk waste or a sharps box, as appropriate.
- A single-use item or device should not be used on multiple occasions either on an individual patient or on a different patient. Examples of single-use items include plastic syringes used for irrigation, suction tips, endodontic files, matrix bands and polishing cups.
- If a medical device is marked for single-patient-use, the item may be used on several occasions with the same patient and then must be discarded.
- The medical device should have cleaning and storage instructions attached.
- Before using a pre-packed sterile single-use or single-patient-use item, check that the packaging is intact and the product is within its use-by date.
- These devices should be stored in clean, designated areas where there is no risk of moisture, droplet and aerosol contamination.
- To avoid cross-contamination between patients, SIMD should be used wherever this is practical.

## Single use invasive medical devices

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

Figure 21-1 Do not reprocess symbol



## Action on non-conforming product

## 22 Action on non-conforming product

### 22.1 Introduction

To ensure patient 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 dental RIMD, notification of clinicians and surveillance of patients as well as remedial action to prevent any recurrence.

### 22.2 Scope

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

### 22.3 Contents

Section One: Policies and procedures

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

### 22.4 Procedure

#### Section One: Policies and procedures

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

## **Action on non-conforming product**

### **Section Two: Recall procedure**

A recall procedure should:

- Be written.
- Outline the circumstances for issuing a recall order.
- Designate the person(s) authorised to issue a recall order.
- Designate the person(s) responsible for reporting on the execution of a recall order.

### **Section Three: Recall order**

A recall order should:

- Be written.
- Identify by sterilisation lot number the products to be recalled.
- Identify the persons or departments to whom the order is addressed.
- Require the recording in terms of kind and quantity of the products obtained in the recall.
- Specify the action to be taken by the person or persons receiving the order (e.g. destruction or return of product).

### **Section Four: Recall report**

A report of a recall order should:

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

## **Records management**

### **23 Records management**

#### **23.1 Introduction**

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

#### **23.2 Scope**

The objective of this procedure is to provide guidelines in relation to records management in dental facilities.

#### **23.3 Contents**

Section One: Steriliser logbook

Section Two: Master process record

Section Three: Traceability

Section Four: Recorders

#### **23.4 Procedure**

##### **Section One: Steriliser logbook**

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

## Records management

- iii. Actions taken to correct any cycle failure and details of what happened to the unsatisfactory load
- iv. Results of all periodic testing: daily, weekly, quarterly and annual tests. Steam penetration indicator test sheets, (marked with the result of the test, dated and signed by the operator), should be retained for at least six months and stored under the conditions recommended by the manufacturer of the test sheet.
- v. Maintenance, repair, or any modifications
- vi. Operator training should include name of trainee, name of trainer, date of competency achieved in parameters as detailed in the staff training section.

### Section Two: Master process record

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

### Section Three: Traceability

- A record of every load should be kept in the steriliser log book which should include the load number (unique identifier cycle number), date, time, and type of load, test result and identity of the operator.
- An adhesive load label bearing the load number and date should be created and manually placed on each RIMD pouch before sterilisation, and a duplicate should be placed in the patient's clinical chart when the RIMD is used.

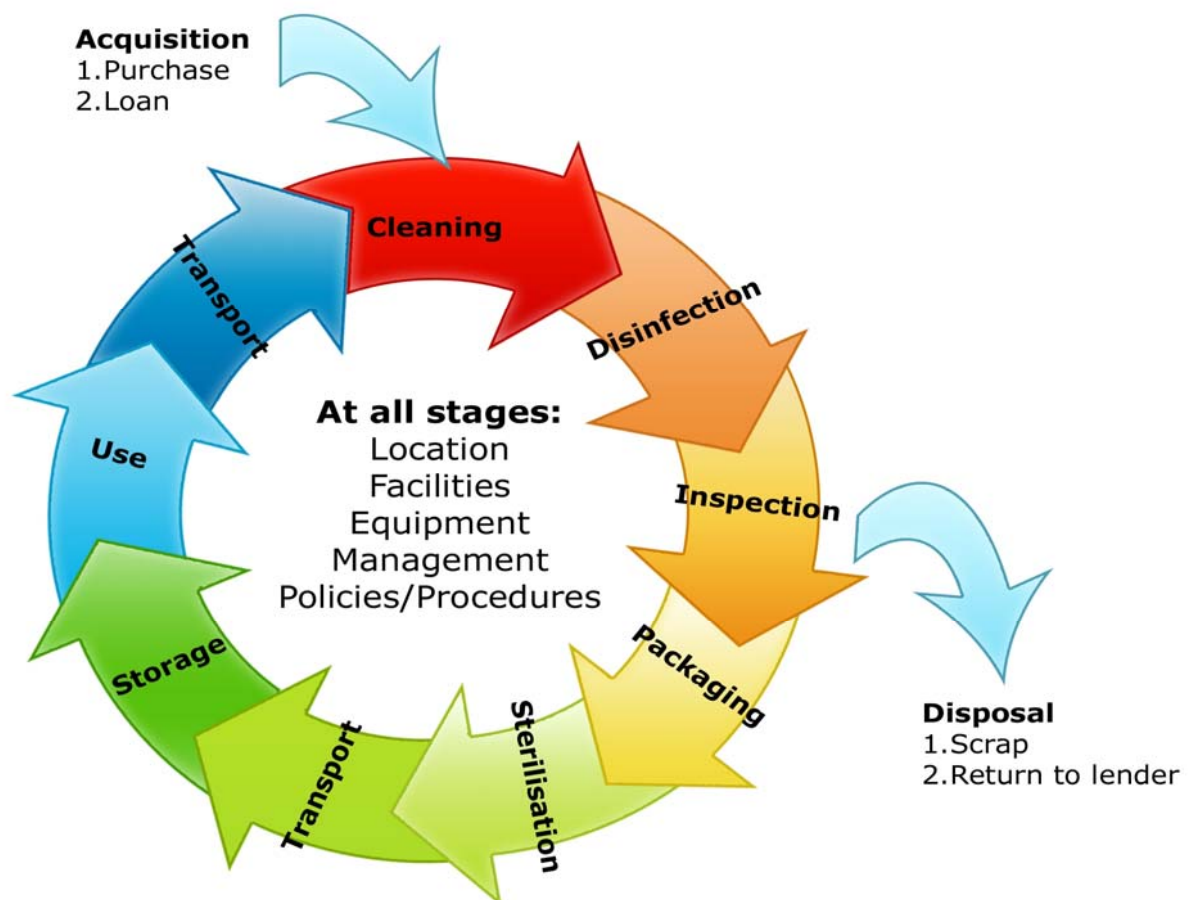
## Records management

### Section Four: Recorders

- All sterilisers should be fitted with a recorder or a process evaluation system (EN 13060; EN 285 (2006)). These systems:
  - i. Provide a permanent record of daily tests and all production cycles
  - ii. Reduce time spent in performing daily tests
  - iii. Generate a unique cycle number that can be entered in the patients' notes to assist traceability
  - iv. Eliminate the possibility of transcription errors.
- The recorder printout should be kept securely in the steriliser logbook. Some types of cycle printouts fade quickly (e.g. from thermal recorders) and therefore special action may be required to preserve these records (e.g. photocopying). Electronic data storage can replace printed records and is strongly recommended.

## PART 6: AUDIT TOOL

# Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices





## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 6
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2008
<b>Contact Details:</b>	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p><b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a> <b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a></p>

**Part 6**

*Part 6*  
*Audit Tool*

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## Introduction

# 1 Introduction

## 1.1 Standards for decontamination of reusable invasive medical devices

During 2007, standards for decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD) were developed using a consistent methodology. A literature review was undertaken which included a search for all relevant guidance and evidence. Expert opinion was also sought for the standards. A national consultation process was undertaken and feedback, where appropriate, was incorporated into the final version of the standards. An e-audit tool (based on the 'Safety and Health Audit Tool for the Healthcare Sector') was then developed to assist in the monitoring of the standards for decontamination of RIMD in the Health Service Executive.

## 1.2 Audit

Audit is a function of all developing and progressive organisations. The outcome from an audit can facilitate an organisation to be knowledgeable about its areas of non-conformance and to identify and implement corrective action where necessary.

## 1.3 Audit Tool

This audit tool in this document relates to the principles of the decontamination process and includes: organisational structure and accountability, suitability of decontamination facilities and management and key personnel. The audit tool can be used to provide objective data on conformance with the standards within the Health Service Executive (HSE). Year-on-year data can assist in monitoring the effectiveness of decontamination of RIMD programmes and assist in strategic planning to meet long term objectives in relation to decontamination of RIMD.

## 1.4 Levels of Audit

There are two levels of audit against the HSE Decontamination of RIMD Standards: self-assessment and external review.

Self assessment is a process whereby the healthcare facility measures its conformance against National Standards. Each healthcare facility will be asked to undertake a self-assessment exercise for its service against the standards. This will be completed annually and signed by the CEO/Manager.

External review uses the same National Standards to independently measure the healthcare facility through an on-site audit.

## **Guidelines for using the audit tool**

## **2 Guidelines for using the audit tool**

### **2.1 Decontamination of RIMD audit tool**

The audit tool is intended for use by the decontamination coordinator, decontamination unit managers, staff with a demonstrated interest in decontamination of RIMD and trained audit personnel.

### **2.2 Planning the audit programme**

It is envisaged that the quality and risk committee (or appropriate committee) will plan and prioritise the use of the audit tool based on a review of specific policies, on the results of a previous audit or in response to specific clinical incidents.

### **2.3 Time required**

The time required to complete a specific audit will vary according to the tool, the size of the healthcare facility, the type of procedures audited and the experience of the auditor.

### **2.4 Conformance**

A conformance categorisation has been incorporated into the scoring system to provide a clear indication of conformance. The allocation of conformance levels is based on the scores obtained, which will be automatically allocated within the database. For the purpose of these audits the categories will be allocated as follows: minimal conformance 75% or less, partial conformance 76-84% and conforming 85% or above.

### **2.5 Feedback of information and report findings**

It is advised that the auditor should verbally report any areas of concern and of good practice to the decontamination unit manager in charge of the area being audited prior to leaving. A written report should also be developed by the auditor and should be given to the relevant decontamination unit manager for action. The report should clearly identify areas requiring action. The decontamination unit manager is responsible for developing an action plan to address the issues identified within a given timescale.

The audit team may decide to reaudit the department if there are concerns or a minimal conformance rating is observed. A system of feedback to the quality and risk committee (or appropriate committee) on the action taken by wards/departments should be in place. This may involve feedback meetings or the return of completed action plans to the quality and risk committee (or appropriate committee).

Guidelines for using the audit tool

2.6 Scoring

Fifteen standards for audit of decontamination of RIMD are described in the following sections. Each standard is stated and followed by questions based on the standard criteria. Below is an explanation of the abbreviation used under each criterion.

- I = Interview
- O = Observation
- D = Documentation
  
- Y = Yes
- P = Partial
- N = No

Instructions on the completion of a standard worksheet

In order to effectively audit decontamination of RIMD it is necessary that all standards are audited as part of the audit process. The auditor can repeat a full audit of all standards at regular intervals in order to measure the level of improvement in the effectiveness of decontamination of RIMD.

There are fifteen standards in this audit tool and for each standard there is a worksheet, which details a list of questions to be answered. There is specific information to be completed in the worksheet and this is explained below:

Step 1:

For each question the auditor can use an “X” to indicate the appropriate answer, which is “Yes”, “Partial” or “No”. In this example we will assume the answer is “No”

	I								Y	P	N	
I	<input type="checkbox"/>	Is the department designed to allow segregation of ‘dirty’ and ‘clean’ activities?	Yes	No	Partial	A	B	C	Total score			X
O	<input type="checkbox"/>		Score 10	Score 0		Score 8	Score 5	Score 2				
D	<input type="checkbox"/>		Supporting Evidence/Comments									
		Risk Category_____										

## Guidelines for using the audit tool

### Step 2

For each question the auditor can use an “X” to indicate the method of verification used in trying to get an answer to the question. The auditor may have interviewed ( **I** ) an employee, observed ( **O** ) a particular work practice or reviewed a particular document ( **D** ). The auditor may have used all three methods. For this example the auditor observed the layout of the department and used an “X” to indicate this on the worksheet.

	<b>I</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<b>Is the department designed to allow segregation of ‘dirty’ and ‘clean’ activities?</b>			<b>X</b>														
<b>O</b>	<input checked="" type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
		Supporting Evidence/Comments																	
		Risk Category_____																	

### Step 3

The auditor can then detail some supporting evidence or comments to explain the reason for the relevant answer. In this example the answer to the question was “No” because clean and dirty activities take place in the same areas in the department.

### Step 7

	<b>I</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<b>Is the department designed to allow segregation of ‘dirty’ and ‘clean’ activities?</b>			<b>X</b>														
<b>O</b>	<input checked="" type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
		Supporting Evidence/Comments																	
		<b>There is no segregation of activities in the department. Clean and dirty activities take place in the same areas.</b>																	
		Risk Category_____																	

**Guidelines for using the audit tool**

**Step 4**

The auditor can use an “X” to indicate the appropriate answer for each question, which will be “Yes”, “Partial” or “No”.

**The different scoring options are as set out below:**

If the auditor selects “Yes” as his/her answer to the question, then the auditor uses an “X” to select “Yes” in the score table and enters a total score of “10” in the score table. An answer of “Yes” means there is full evidence of conformance and this is allocated a score of 10.

YES X
Score 10

If the auditor selects “No” as his/her answer to the question, then the auditor uses an “X” to select “No” in the score table and enters a total score of “0” in the score table. An answer of “No” means there is no evidence of conformance and this will be allocated a score of “0”.

NO X
Score 0

If the auditor selects “Partial” as his/her answer to the question, then the auditor must choose from one of three options. A, B and C. The categories have the following meaning:

- A: Evidence of significant level of conformance
- B: Evidence of a reasonable level of conformance
- C: Very little evidence of conformance

The auditor uses an “X” to select the appropriate option A, B or C.

A	B	C
Score 8	Score 5	Score 2



## Guidelines for using the audit tool

### Step 5

The auditor should check that he/she has entered the appropriate total score in the score table for each question.

Yes	No	Partial	A	B	C	Total score
Score 10	Score 0		Score 8	Score 5	Score 2	X

### Step 6

The auditor should calculate the criterion score as a percentage. This is explained by a worked example below:

Number of Questions in Standard:	13
Maximum Standard Score ( MS )	
(Total Number of Questions x Maximum Score (10)):	130 (13 x 10)
Actual Standard Score ( AS ) (Sum of the total scores for each question)	100

**Note:** In this example the actual score used was 100, however the actual score will vary depending on the scores allocated to each question.

Standard Score as a percentage =  $AS/MS \times 100/1$

In this example Standard Score as a percentage =  $100/130 \times 100/1 = 76.92\%$

Note: Where a question in a standard is not applicable, it will not be given a score.

*Example:*

*In the above case; if there were only 12 questions applicable then the maximum criterion score (MS) would be 120 (12 x 10).*

## Guidelines for using the audit tool

The auditor repeats Step 1-6 for each question in the standard worksheet.

### Step 8

When a standard has been fully audited, the auditor can detail a summary of the results in the standard report form. This information can be taken from the worksheet or the auditor may use his/her own notes taken during the audit. This report form should be completed for each standard. An example of what information can be included in this report form is detailed below.

### Step 9

<b>Standard 2: Organisational structure and accountability</b>
Individual responsibility for decontamination of RIMD is clearly defined throughout the organization and there are clear lines of accountability leading up to the most Senior Manager or Director.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area</b> <i>Managers are aware of responsibilities</i>
<b>Non-conformance in the area</b>
<b>Standard Score:</b> 100/130 76.92%

## Guidelines for using the audit tool

The areas of non-conformance in each standard report form should be transferred to a Quality Improvement Action Plan. An example of a blank Quality Improvement Action Plan is detailed in section 5 of this document. Below is an example of the type of information that would be documented in this quality improvement action plan by the auditor.

<i>Standard</i>	<i>Area of Non Conformance</i>	<i>Corrective Action</i>	<i>Responsible Person</i>	<i>Time-frame</i>	<i>Review</i>
1	<i>No segregation of clean and dirty activities in the department</i>	<i>Discuss with decontamination unit manager. Identify any resources required.</i>	<i>CEO/Manager</i>	<i>Oct 2007</i>	<i>Feb 2008</i>

The auditor may have a number of areas of non-conformance for each standard. The Quality Improvement Action Plan should be agreed in consultation with the senior management committee (or appropriate committee). The action plan is used to summarise the main findings of the audit and it is used as a tool for continuous improvement.

**Note:** The auditor may use the Auditors Notes section in section 7 of this document to compile further relevant information.

## Guidelines for using the audit tool

### STANDARD SCORING SUMMARY SHEET

Step 10:

The auditor should detail the scoring for each standard in a Standard Scoring Summary Sheet. A completed Standard Scoring Summary sheet is detailed below and a blank Standard Scoring Summary sheet is detailed in section 6 of this document.

Standard	Actual Standard Score (AS)	Maximum Standard Score (MS) Total Number of Question x Maximum Score (10)	Standard Score as a percentage (AS/MS x 100/1)
1	70	80	87.5
2	90	130	69.2
3	240	340	70.6
4	400	510	78.4
5	110	130	84.6
6	90	110	81.8
7	50	100	50
8	60	80	75
9	100	170	58.8
10	120	150	80
11	90	140	64.3
12	15	30	50
13	90	110	81.8
14	100	120	83.3
15	15	30	50
Overall Audit Score	1,640	2,230	73.5

## **Guidelines for using the audit tool**

### **Step 11:**

Using the example above the auditor needs to calculate the Overall Audit Score.

### **Overall**

**Audit Score** = Sum of all actual standard scores (AS)/Sum of all maximum standard  
Scores (MS) x 100/1

**Overall Audit Score** = 1640/2230 x 100/1 = 73.54%

This Overall Audit Score can be used to benchmark performance from year to year and the individual standard score allows the auditor to identify areas where most attention is needed.

A summary sheet with Standard and Overall Audit Score could be attached to the Quality Improvement Action Plan as a full Audit Report.

## Risk level categories

### 3 Risk level categories

A response is categorised as non-conforming if it does not meet the criteria identified in the HSE Standards for decontamination of RIMD. An indication of the seriousness of the non-conformance is given by a risk category that is attached to each non-conformance statement. The categorisation of risk should provide some assistance in prioritising remedial actions.

On the right hand side of each statement is a risk level categorisation. These are organised as shown in Table 1.

Table 1: Definition of risk levels used in non-conformance statements

Level	Category	Description
1	Observation	This category includes reported facts which, although not necessarily non-conformances, should be considered when any remedial action is planned.
2	Low Risk	The reported fact(s) indicate a minor hazard with a low likelihood of the hazard occurring.
3	Medium Risk	The reported fact(s) indicate either a minor hazard with a significant likelihood of the hazard occurring or a significant hazard with a low likelihood of the hazard occurring.
4	High Risk	The reported fact(s) indicate a significant hazard with a significant likelihood of the hazard occurring.

## **Standards for decontamination of reusable invasive medical devices**

### **4 Standards for Decontamination of RIMD**

#### **Standard 1: Communication and consultation**

Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD), with key stakeholders within and outside the organisation.

#### **Standard 2: Organisational structure and accountability**

Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.

#### **Standard 3: Suitability of decontamination facilities**

Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD. 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) and Health Building Note 52 (Endoscopy Units).

#### **Standard 4: Decontamination equipment**

All decontamination equipment that does not meet the requirements of current standards shall be identified and upgraded or replaced in accordance with a planned replacement programme.

All new decontamination equipment shall be procured in conformance with extant harmonized standards.

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

#### **Standard 5: Procurement of reusable invasive medical devices**

Decontamination issues shall be considered prior to the acquisition of RIMD.

## **Standards for decontamination of reusable invasive medical devices**

### **Standard 6: Decontamination process**

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

### **Standard 7: Management and key personnel**

Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.

### **Standard 8: Education and training**

Education and Training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.

### **Standard 9: Quality management system**

Central decontamination units shall operate a quality management system in accordance with EN ISO 13485.

Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.

### **Standard 10: Risk management system**

The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.

### **Standard 11: Health and safety**

Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used devices and process chemicals.

### **Standard 12: Complaints management**

All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information.



## **Standards for decontamination of reusable invasive medical devices**

### **Standard 13: Audit and monitoring**

Audits shall be carried out to ensure that the procedures for decontamination of RIMD conform to the required standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

### **Standard 14: Key performance indicators**

Key performance indicators that are capable of showing improvements in the efficacy of the decontamination process shall be used. The usefulness of the indicators shall be reviewed regularly.

### **Standard 15: Procedures relating to transmissible spongiform encephalopathies (TSEs)**

The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.

## Communication and consultation

### Standard 1: Communication and Consultation

Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD), with key stakeholders within and outside the organisation.

1.3.1		Y	P	N														
I  O  D	<input type="checkbox"/>	<b>Has the organisation developed a set of shared values, behavioural guidelines and quality principles in support of the Health Service Executive Code of Practice for Decontamination of RIMD that are reflected in job descriptions and vision statements?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

1.3.2		Y	P	N														
I  O  D	<input type="checkbox"/>	<b>Have Healthcare Workers been given an opportunity to provide feedback on these values, guidelines and quality principles?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

1.3.3		Y	P	N														
I  O  D	<input type="checkbox"/>	<b>Are these values, guidelines and quality principles reflected in each departments business plans?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

## Communication and consultation

		1.3.4		Y	P	N													
I O D	<input type="checkbox"/>	<p>Are regular reviews undertaken to ensure that business plans are translated into action?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
	<input type="checkbox"/>																		

		1.3.5		Y	P	N													
I O D	<input type="checkbox"/>	<p>Has the organisation developed and implemented a practical methodology for sharing best practice both internally and with key stakeholders in relation to decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
	<input type="checkbox"/>																		

		1.3.6		Y	P	N													
I O D	<input type="checkbox"/>	<p>Has the organisation informed their staff and patients about the Health Service Executive Code of Practice for Decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
	<input type="checkbox"/>																		

**Communication and consultation**

	1.3.7		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are educational materials provided (in relation to decontamination of RIMD) using a variety of different media as required?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
	<input type="checkbox"/>																		

	1.3.8		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are staff and key stakeholders encouraged to use feedback procedures to the organisation for any concerns they have in relation to decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
	<input type="checkbox"/>																		

	1.3.9		Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the decontamination unit and the clinical units which it supplies have a service level agreement?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
	<input type="checkbox"/>																		

**Communication and consultation**

		1.3.10		Y	P	N														
I O D	<input type="checkbox"/>	Does the decontamination unit have in place a formal system for recording and analysing customer complaints?																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2					
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Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

		1.3.11		Y	P	N														
I O D	<input type="checkbox"/>	Does the decontamination unit have in place a programme to reduce customer complaints?																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2					
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Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

## Communication and consultation—Standard Report Form

## Standard 1 Report Form

<b>Standard 1: Communication and consultation</b>
Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices, with key stakeholders within and outside the organisation.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
Conformance in the area:
Non-conformance in the area:
<b>Standard Score:</b>

## Communication and consultation

		1.3.10		Y	P	N														
I O D	<input type="checkbox"/>	Does the decontamination unit have in place a formal system for recording and analysing customer complaints?																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2					
	Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

		1.3.11		Y	P	N														
I O D	<input type="checkbox"/>	Does the decontamination unit have in place a programme to reduce customer complaints?																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2					
	Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

## Organisational structure and accountability

### Standard 2: Organisational structure and accountability

Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.

2.3.1		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Is individual responsibility for decontamination of RIMD clearly defined throughout the organization and are there clear lines of accountability leading up to the most senior manager or director?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.2		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Does the scope of responsibility also include the competence of contractors where the organisation buys in services and professional liability where the organisation sells services to other organisations?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.3		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Is decontamination of RIMD a standard item on the agenda of the quality and risk management committee (or appropriate committee) in the organisation? Does the Decontamination Coordinator submit regular reports on management of decontamination to the committee?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		



**Organisational structure and accountability**

2.3.4			Y	P	N													
I O D	<input type="checkbox"/>	<p>Is a twice yearly report on the conformity of the decontamination process within the organisation submitted to the Quality and Risk committee (or appropriate committee) for review. Does this committee, (which includes in its membership the CEO/Manager or CEO/Manager nominee), present the report to the Senior Management Team?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.5			Y	P	N													
I O D	<input type="checkbox"/>	<p>Has the organisation identified a Decontamination Co-ordinator? Do the duties of the co-ordinator encompass all aspects of the decontamination process which are not confined to any one aspect or decontamination function but encompass all decontamination processes wherever they occur within the organisation?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.6			Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the Decontamination Coordinator have responsibility and authority for developing and monitoring policies, continuous quality improvement and/or strategies for decontamination of RIMD for approval by the Quality and Risk committee (or appropriate committee)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Organisational structure and accountability**

2.3.7		Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the Decontamination Coordinator attend appropriate meetings/conferences local and national, relevant to decontamination of RIMD, which will increase their knowledge and improve their ability to undertake the role?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.8		Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the Decontamination Coordinator undertake the dissemination of all information, received from the National Hospitals Office and/or PCCC Directorates/relevant agencies relating to decontamination of RIMD within the organisation?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.9		Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the Decontamination Coordinator work with clinicians and decontamination unit managers to develop and improve the systematic approach to decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Organisational structure and accountability**

2.3.10		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is the Decontamination Coordinator responsible for ensuring that the audit activity for decontamination of RIMD, under the responsibility of each decontamination unit manager has been completed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.11		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is the quality and risk committee (or appropriate committee) responsible for the implementation and monitoring of a decontamination of RIMD audit and monitoring programme in the organisation?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

2.3.12		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is each relevant member of staff made aware of their responsibility in relation to the decontamination process?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

Organisational structure and accountability

	2.3.13		Y	P	N														
I	<input type="checkbox"/>	Does the organisation have a specific resource provision for decontamination of RIMD related at least in part to throughput?																	
O	<input type="checkbox"/>	<table><tr><td>Yes</td><td>No</td><td>Partial</td><td>A</td><td>B</td><td>C</td><td>Total score</td></tr><tr><td>Score 10</td><td>Score 0</td><td></td><td>Score 8</td><td>Score 5</td><td>Score 2</td><td></td></tr></table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

## Organisational structure and accountability—Standard Report Form

## Standard 2 Report Form

Standard 2: Organisational structure and accountability
Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Suitability of decontamination facilities

### Standard 3: Suitability of decontamination facilities

Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD. 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) and Health Building Note 52 (Endoscopy Units).

3.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is the department designed so that it is physically separated from all other work areas?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> Supporting Evidence/Comments  Risk Category_____			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

3.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is the department designed to allow segregation of 'dirty' and 'clean' activities?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> Supporting Evidence/Comments  Risk Category_____			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

3.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is the department designed to facilitate a unidirectional work flow from the 'dirty' area to the 'clean' area?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> Supporting Evidence/Comments  Risk Category_____			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.4		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	Is the department <i>not used</i> for any other purpose?						
		Yes	No	Partial	A	B	C	Total score
		Score 10	Score 0		Score 8	Score 5	Score 2	
		Supporting Evidence/Comments						
<b>O</b>	<input type="checkbox"/>							
<b>D</b>	<input type="checkbox"/>	Risk Category_____						

	3.3.5		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	Is the department <i>not used</i> as a thoroughfare?						
		Yes	No	Partial	A	B	C	Total score
		Score 10	Score 0		Score 8	Score 5	Score 2	
		Supporting Evidence/Comments						
<b>O</b>	<input type="checkbox"/>							
<b>D</b>	<input type="checkbox"/>	Risk Category_____						

	3.3.6		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	Is the department <i>not part</i> of any patient treatment area?						
		Yes	No	Partial	A	B	C	Total score
		Score 10	Score 0		Score 8	Score 5	Score 2	
		Supporting Evidence/Comments						
<b>O</b>	<input type="checkbox"/>							
<b>D</b>	<input type="checkbox"/>	Risk Category_____						

**Suitability of decontamination facilities**

3.3.7		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are all rooms in the department mechanically ventilated and controlled to provide a comfortable working environment? (typically temperatures shall be controlled between 18-22 degrees Celsius and relative humidity shall be controlled within the range 35-60%)</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

3.3.8		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is the environment in which clean non-sterile RIMD are inspected, assembled and packed controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

3.3.9		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is the clean area microbiologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003)?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		



**Suitability of decontamination facilities**

	3.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<b>Are safe storage facilities provided for process chemicals used in decontamination?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

	3.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<b>Are storage facilities for bulk items provided external to the clean room and the wash room?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

	3.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<b>Are storage facilities provided for sterile product prior to despatch?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

**Suitability of decontamination facilities**

	3.3.13		Y	P	N														
I	<input type="checkbox"/>	Is the shelving in storage facilities manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

	3.3.14		Y	P	N														
I	<input type="checkbox"/>	Is required personal protective equipment easily accessible in each of the work areas?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

	3.3.15		Y	P	N														
I	<input type="checkbox"/>	Is entry to the decontamination unit restricted to authorised personnel only?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

**Suitability of decontamination facilities**

3.3.16		Y	P	N														
I O D	<input type="checkbox"/>	Is there a changing area for donning work wear which includes shower facilities, toilet facilities and lockers in proximity to the decontamination area?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B	C	Total score											
Score 10	Score 0		Score 8	Score 5	Score 2													
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

3.3.17		Y	P	N														
I O D	<input type="checkbox"/>	Is access to the wash room and to the clean room through separate dedicated gowning rooms provided with hand hygiene facilities?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B	C	Total score											
Score 10	Score 0		Score 8	Score 5	Score 2													
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

3.3.18		Y	P	N														
I O D	<input type="checkbox"/>	Is the area managed by trained staff whose sole or primary responsibility is management of the decontamination unit?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2													
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Suitability of decontamination facilities**

	3.3.19		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the environment in which decontamination of RIMD takes place cleaned in accordance with procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.20		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is dedicated cleaning provision (both equipment and storage) provided for the clean room and the wash room?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.21		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are there are sufficient electricity supply, computer terminal points and work stations in the department?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.22		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<b>Are the finishes on the walls and other surfaces flush, smooth, non-linting, water resistant and able to withstand frequent cleaning?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

	3.3.23		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<b>Are the junctions between the walls and floors coved and flush?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

	3.3.24		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<b>Are the fitments (where possible) flush with wall surfaces?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

**Suitability of decontamination facilities**

	3.3.25		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p><b>Are floors covered in a washable non-slip material which is securely sealed?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.26		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p><b>Is there adequate lighting available to permit good working practices and visual examination of RIMD?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.27		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p><b>Are task lighting and magnification in situ?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.28		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are all work surfaces, fittings, fixtures and furniture made of easily cleanable and robust material and maintained in good condition?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.29		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are the workstations equipped for the preparation of single or composite packs? Are they of adequate size to accommodate the wrapping material to be used and height adjustable?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.30		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is there adequate space between workstations for equipment and staff movement?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.31		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I O D</b>		Is the shelving of sufficient depth for all the materials to be held and not more than two metres high, unless special provision is made for loading and un-loading higher shelves?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
	Supporting Evidence/Comments																		
		Risk Category_____																	

	3.3.32		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I O D</b>		Are the wash room, clean room and steriliser unloading area free from 'opening' windows, ledges, and uncleanable areas?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
	Supporting Evidence/Comments																		
		Risk Category_____																	

	3.3.33		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I O D</b>		Are the wash area and clean room designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.)?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
	Supporting Evidence/Comments																		
		Risk Category_____																	



## Suitability of decontamination facilities—Standard Report Form

## Standard 3 Report Form

<p align="center"><b>Standard 3: Suitability of decontamination facilities</b></p>
<p>Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination on clean and disinfected RIMD. 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) and Health Building Note 52 (Endoscopy Units).</p>
<p align="center"><b>Standard Summary</b></p>
<p> </p>
<p align="center"><b>Summary of Main Findings of the Audit</b></p>
<p>Conformance in the area:</p> <p> </p> <p>Non-conformance in the area:</p> <p> </p>
<p>Standard Score:</p>

## Decontamination equipment

### Standard 4: Decontamination equipment

All decontamination equipment that does not meet the requirements of current standards shall be identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment shall be procured in conformance with extant harmonized standards. All decontamination equipment shall be validated, maintained, periodically tested and monitored to current standards.

4.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the organisation have a specialist group in place to consider the decontamination equipment in the organisation? (See Standard 4, page 14, Part 2).</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		
4.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are key representatives represented on the specialist group? (See Standard 4, page 15, Part 2).</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		
4.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<p>Has the specialist group identified all decontamination equipment that needs to be replaced?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination equipment**

4.3.4		Y	P	N														
I O D	<input type="checkbox"/>	<p>Has the specialist group formulated a plan to replace or upgrade this equipment?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

4.3.5		Y	P	N														
I O D	<input type="checkbox"/>	<p>Has the plan been submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

4.3.6		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is there sufficient decontamination equipment available to meet the needs of the decontamination unit(s)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination equipment**

		4.3.7		Y	P	N												
I O D	<input type="checkbox"/>	<p>Are there clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

		4.3.8		Y	P	N												
I O D	<input type="checkbox"/>	<p>Is the operational management of each item of decontamination equipment the defined responsibility of a named person (usually the decontamination unit manager)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

		4.3.9		Y	P	N												
I O D	<input type="checkbox"/>	<p>Is the validation and periodic testing carried out by qualified personnel?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination equipment**

4.3.10		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are the validation and periodic testing data adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

4.3.11		Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the department have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

4.3.12		Y	P	N														
<b>Manual Washing</b>																		
I O D	<input type="checkbox"/>	<p>Is manual washing used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector (WD)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination equipment**

		4.3.13	Manual Washing					Y	P	N		
I O D	<input type="checkbox"/>		Are dedicated manual cleaning equipment and accessories available for specified RIMD that cannot be cleaned in an automated cleaning process?									
	<input type="checkbox"/>		Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>		Score 10	Score 0		Score 8	Score 5	Score 2				
			Supporting Evidence/Comments									
			Risk Category_____									

		4.3.14	Manual Washing					Y	P	N		
I O D	<input type="checkbox"/>		Are separate sinks provided for washing and rinsing?									
	<input type="checkbox"/>		Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>		Score 10	Score 0		Score 8	Score 5	Score 2				
			Supporting Evidence/Comments									
			Risk Category_____									

		4.3.15	Manual Washing					Y	P	N		
I O D	<input type="checkbox"/>		Is the detergent used one that is specified by the manufacturer for the manual cleaning of RIMD?									
	<input type="checkbox"/>		Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>		Score 10	Score 0		Score 8	Score 5	Score 2				
			Supporting Evidence/Comments									
			Risk Category_____									

**Decontamination equipment**

4.3.16		Manual Washing					Y	P	N		
I O D	<input type="checkbox"/>	Are means provided to control the concentration of detergent?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments									
	<input type="checkbox"/>	Risk Category_____									

4.3.17		Manual Washing					Y	P	N		
I O D	<input type="checkbox"/>	Is a pass-through drying cabinet with inter-locking doors provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments									
	<input type="checkbox"/>	Risk Category_____									

4.3.18		Ultrasonic Cleaning					Y	P	N		
I O D	<input type="checkbox"/>	Is a stand-alone ultrasonic cleaner 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?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments									
	<input type="checkbox"/>	Risk Category_____									

**Decontamination equipment**

		4.3.19	Ultrasonic Cleaning				Y	P	N		
I O D	<input type="checkbox"/>	Is the ultrasonic cleaner equipped with the facility for automatic filling and emptying directly to the drain?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		4.3.20	Ultrasonic Cleaning				Y	P	N		
I O D	<input type="checkbox"/>	Is the ultrasonic cleaner fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		4.3.21	Ultrasonic Cleaning				Y	P	N		
I O D	<input type="checkbox"/>	Is the detergent used one specified by the manufacturer for the ultrasonic cleaning of RIMD?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									



**Decontamination equipment**

		4.3.22	Ultrasonic Cleaning				Y	P	N		
I O D	<input type="checkbox"/>	Are means provided to control the concentration of detergent?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
	<input type="checkbox"/>	Risk Category_____									

		4.3.23	Ultrasonic Cleaning				Y	P	N		
I O D	<input type="checkbox"/>	Is the ultrasonic cleaner used in accordance with the manufacturers instructions?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
	<input type="checkbox"/>	Risk Category_____									

		4.3.24	Ultrasonic Cleaning				Y	P	N		
I O D	<input type="checkbox"/>	Is the ultrasonic cleaner is validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
	<input type="checkbox"/>	Risk Category_____									

**Decontamination equipment**

4.3.25		Ultrasonic Cleaning					Y	P	N										
I O D	<input type="checkbox"/>	Is the temperature of the cleaning solution in the ultrasonic cleaner thermostatically controlled?																	
	<input type="checkbox"/>																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>								Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
Risk Category_____																			

4.3.26		Washer-Disinfectors					Y	P	N										
I O D	<input type="checkbox"/>	Does the specification of the washer-disinfector comply with requirements of EN ISO 15883, parts 1 & 2?																	
	<input type="checkbox"/>																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>								Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
Risk Category_____																			

4.3.27		Washer-Disinfectors					Y	P	N										
I O D	<input type="checkbox"/>	Are washer-disinfectors double ended with the clean side discharging into the inspection area of the clean room?																	
	<input type="checkbox"/>																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>								Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
Risk Category_____																			

**Decontamination equipment**

	<b>4.3.28</b>	<b>Washer-Disinfectors</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Is each washer-disinfector fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	<b>4.3.29</b>	<b>Washer-Disinfectors</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>When lumened devices are being reprocessed, is the washer-disinfector provided with load carriers that permit the irrigation of the lumened device?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	<b>4.3.30</b>	<b>Washer-Disinfectors</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Are washer-disinfectors and accessories specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1,2 &amp; 5?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

**Decontamination equipment**

		4.3.31	Washer-Disinfectors				Y	P	N		
I  O  D	<input type="checkbox"/>	Is the Washer-Disinfector subject to planned preventative maintenance?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		4.3.32	Steam Steriliser				Y	P	N		
I  O  D	<input type="checkbox"/>	Does the specification of the steam steriliser comply with requirements of EN 285 and is the steriliser fitted with an air-detector?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		4.3.33	Steam Steriliser				Y	P	N		
I  O  D	<input type="checkbox"/>	Is the steam steriliser fitted with a process monitoring system independent of the automatic controller?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

**Decontamination equipment**

		4.3.34	Steam Steriliser	Y	P	N												
I O D	<input type="checkbox"/>	Is the sterilisation hold period at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No				Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No	Partial	A					B	C	Total score							
Score 10	Score 0	Score 8		Score 5	Score 2													
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

		4.3.35	Steam Steriliser	Y	P	N												
I O D	<input type="checkbox"/>	Are steam sterilisers double ended with the loading side in the clean room?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No				Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No	Partial	A					B	C	Total score							
Score 10	Score 0	Score 8		Score 5	Score 2													
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

		4.3.36	Steam Steriliser	Y	P	N												
I O D	<input type="checkbox"/>	Are sterilizers and accessories specified, installed, commissioned, tested and operated in accordance with the current standard EN 285 and EN ISO 17665, part 1?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No				Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No	Partial	A					B	C	Total score							
Score 10	Score 0	Score 8		Score 5	Score 2													
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

**Decontamination equipment**

	4.3.37	Steam Steriliser	Y	P	N														
I O D	<input type="checkbox"/>	Are the steam sterilisers subject to planned preventative maintenance?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.38	Low Temperature Sterilisers	Y	P	N														
I O D	<input type="checkbox"/>	Are low temperature sterilisation methods only used where the manufacturers' instructions do not permit steam sterilisation?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.39	Low Temperature Sterilisers	Y	P	N														
I O D	<input type="checkbox"/>	Is low temperature sterilisation carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Decontamination equipment**

4.3.40		Low Temperature Sterilisers	Y	P	N														
I O D	<input type="checkbox"/>	Have low temperature sterilisation methods been validated and are they subject to periodic testing in accordance with ISO 14937?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

4.3.41		Low Temperature Sterilisers	Y	P	N														
I O D	<input type="checkbox"/>	Are low temperature sterilisers subject to planned preventative maintenance?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

4.3.42		Drying Cabinet	Y	P	N														
I O D	<input type="checkbox"/>	Is a pass-through drying cabinet provided between the wash-room and the clean room? Are the doors of the drying cabinet interlocked to prevent direct connection between the wash room and the clean room?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Decontamination equipment**

4.3.43		Drying Cabinet	Y	P	N													
I O D	<input type="checkbox"/>	<p>Is the drying cabinet fitted with a temperature indicator and/or re-corder independent of the controller?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

4.3.44		Drying Cabinet	Y	P	N													
I O D	<input type="checkbox"/>	<p>Is the drying temperature throughout the cabinet within <math>\pm 5^{\circ}</math> Celsius of the set temperature?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

4.3.45		Drying Cabinet	Y	P	N													
I O D	<input type="checkbox"/>	<p>Is the drying cabinet fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than <math>10^{\circ}</math> Celsius the heating source is isolated?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		



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		4.3.46	Drying Cabinet	Y	P	N					
I O D	<input type="checkbox"/>	Is the air in the cabinet mechanically circulated and are items placed throughout the cabinet dried uniformly?									
	<input type="checkbox"/>	Yes	No	Partial	A				B	C	Total score
	Score 10	Score 0		Score 8	Score 5				Score 2		
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		4.3.47	Drying Cabinet	Y	P	N					
I O D	<input type="checkbox"/>	Is the drying cabinet subject to planned preventative maintenance?									
	<input type="checkbox"/>	Yes	No	Partial	A				B	C	Total score
	Score 10	Score 0		Score 8	Score 5				Score 2		
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		4.3.48	Heat Sealer	Y	P	N					
I O D	<input type="checkbox"/>	Where heat seal packaging is to be used, is a rotary heat sealer provided?									
	<input type="checkbox"/>	Yes	No	Partial	A				B	C	Total score
	Score 10	Score 0		Score 8	Score 5				Score 2		
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

**Decontamination equipment**

	4.3.49	Heat Sealer	Y	P	N														
I O D	<input type="checkbox"/>	Is heat-sealing equipment used as part of the terminal packaging process maintained and tested to manufacturer's performance criteria?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.50	Heat Sealer	Y	P	N														
I O D	<input type="checkbox"/>	Is the heat sealer validated and tested daily to verify the efficacy of the seal?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.51	Heat Sealer	Y	P	N														
I O D	<input type="checkbox"/>	Is the heat sealer subject to planned preventative maintenance?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

## Decontamination Equipment—Standard Report Form

## Standard 4 Report Form

<p><b>Standard 4: Decontamination equipment</b></p>
<p>All decontamination equipment that does not meet the requirements of current standards shall be identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment shall be procured in conformance with extant harmonized standards. All decontamination equipment shall be validated, maintained, periodically tested and monitored to current standards.</p>
<p><b>Standard Summary</b></p>
<p><b>Summary of Main Findings of the Audit</b></p>
<p><b>Conformance in the area:</b></p>
<p><b>Non-conformance in the area:</b></p>
<p><b>Standard Score:</b></p>

## Procurement of reusable invasive medical devices

### Standard 5: Procurement of reusable invasive medical devices (RIMD)

Decontamination issues are considered prior to the acquisition of RIMD.

5.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the organisation have a specialist group in place to consider the procurement of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

5.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<p>Are key representatives represented on the specialist group? (see Standard 5, Page 19, Part 2).</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

5.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the organisation have a documented procurement policy?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

**Procurement of reusable invasive medical devices**

	5.3.4		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	Does the procurement policy comply with the Irish Medicines Board (IMB) recommendations on the procurement of RIMD?						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments						
		Risk Category_____						

	5.3.5		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	Is the procurement of RIMD based on agreed specifications and does the procurement of RIMD comply with the documented procurement policy?						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments						
		Risk Category_____						

	5.3.6		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	Is there a detailed specification for each RIMD which complies with current standards?						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments						
		Risk Category_____						

**Procurement of reusable invasive medical devices**

	5.3.7		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p>Are sufficient RIMD and accessories purchased to allow adequate time for reprocessing in the decontamination unit(s) without adversely affecting throughput?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	5.3.8		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p>Is a decontamination assessment undertaken prior to the purchase of RIMD to ensure that the organisation has the facilities to reprocess the RIMD in accordance with the manufacturers instructions?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	5.3.9		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p>Are value for money issues considered when purchasing RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

**Procurement of reusable invasive medical devices**

5.3.10			Y	P	N														
I  O  D	<input type="checkbox"/>	Are goods and services purchased from suppliers in line with HSE procurement policy?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

5.3.11			Y	P	N														
I  O  D	<input type="checkbox"/>	Are all RIMD and accessories CE marked?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

5.3.12			Y	P	N														
I  O  D	<input type="checkbox"/>	Are suppliers selected based on their ability to supply RIMD in accordance with the specified requirements and provide service support over the lifetime of the RIMD, where applicable?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Procurement of reusable invasive medical devices**

	5.3.13		Y	P	N														
I	<input type="checkbox"/>	Are there means to ensure that where parts are single-use or have restricted use that this information is provided prior to purchasing?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	



## Procurement of reusable invasive medical devices—Standard Report Form

### Standard 5 Report Form

Standard 5: Procurement of reusable invasive medical devices (RIMD)
Decontamination issues shall be considered prior to the acquisition of RIMD.
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Decontamination process

### Standard 6: Decontamination process

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

6.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Are all stages of the decontamination process clearly defined, documented, controlled and recorded?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

6.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<b>Are all processes carried out in accordance with documented procedures?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

6.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<b>Are all RIMD sets traced through the decontamination process to the patient?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

**Decontamination process**

6.3.4		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are processing data retained for the lifetime of the equipment plus eleven years?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

6.3.5		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is there a regular review of all procedures and are any necessary changes implemented by a documented change in procedures?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

6.3.6		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are RIMD checked and reprocessed in accordance with the manufacturers' instructions?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination process**

6.3.7		Y	P	N														
I O D	<input type="checkbox"/>	<b>Are all RIMD visually inspected for cleanliness prior to packing?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

6.3.8		Y	P	N														
I O D	<input type="checkbox"/>	<b>Are all RIMD inspected and/or tested for functionality prior to packing?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

6.3.9		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is there 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?</b>  <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Decontamination process**

		6.3.10						Y	P	N									
I  O  D	<input type="checkbox"/>	<p>Is all product released from the decontamination unit labelled with a clear indication of the pack contents, the expiry date and a unique number which can be used to trace the decontamination processes to which the device was subjected?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

		6.3.11						Y	P	N									
I  O  D	<input type="checkbox"/>	<p>Are single use devices <i>not</i> reprocessed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

## Decontamination process—Standard Report Form

## Standard 6 Report Form

<b>Standard 6: Decontamination process</b>
RIMD e.g. surgical instruments, powered devices, rigid and flexible endoscopes, etc. shall be decontaminated in accordance with the recommendations of the manufacturers validated instructions for decontamination (Ref. EN ISO 17664:2004) current legislation and quality system standards.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
Conformance in the area:
Non-conformance in the area:
<b>Standard Score:</b>

## Management and key personnel

### Standard 7: Management and key personnel

Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.

7.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Has the <i>CEO/Manager</i> put in place arrangements to ensure effective decontamination of RIMD?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

7.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<b>Has a <i>Decontamination Coordinator</i> been appointed? Does s/he have formally defined responsibilities in accordance with these standards? Has s/he been provided with the necessary resource to discharge these responsibilities?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

7.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<b>Does each <i>Decontamination Unit</i> have a person appointed with responsibility for operational management of the unit, which may be in addition to other duties?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

## Management and key personnel

7.3.4		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are <i>Maintenance Personnel</i> (in-house or sub-contracted) available and is there documentary evidence to demonstrate competence in the maintenance of the decontamination equipment they will be dealing with?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

7.3.5		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are <i>Test Personnel</i> (in-house or sub-contracted) available and is there documentary evidence to demonstrate competence in periodic testing of the decontamination equipment which they will be dealing with?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

7.3.6		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is a <i>Microbiologist</i> available to advise on microbiological aspects of decontamination?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		



## Management and Key Personnel

7.3.7		Y	P	N													
I O D	<input type="checkbox"/>	<p>Is an <i>Infection Prevention and Control Nurse</i> available to advise on all aspects of infection surveillance, prevention and control?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

7.3.8		Y	P	N													
I O D	<input type="checkbox"/>	<p>Has the Decontamination Unit Manager designated <i>Operatives</i> to be responsible for each aspect of the decontamination process and has s/he ensured that these personnel have been trained to the necessary standard of competence?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

7.3.9		Y	P	N													
I O D	<input type="checkbox"/>	<p>Is a <i>Biomedical Engineer/Clinical Engineer</i> available and designated by management for the testing and validation of decontamination equipment?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

## Management and key personnel

	7.3.10		Y	P	N													
I	<input type="checkbox"/>	<p>Is the <i>Qualified Person (decontamination)</i> used by the organisation a person registered as an Authorised Person (Sterilisers) with the Institute of Healthcare Engineering and Estates Management and registered with the Health Service Executive as competent to discharge the duties of a Qualified Person (decontamination) in Ireland?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No		Partial	A		B	C	Total score										
Score 10	Score 0			Score 8	Score 5	Score 2												
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	

## Management and key personnel—Standard Report Form

## Standard 7 Report Form

Standard 7: Management and key personnel
Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Education and training

### Standard 8: Education and training

Education and Training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.

8.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<b>Does the organisation have a general induction training programme that includes the areas as outlined in Standard 8, Page 25, Part 2?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category_____																	

8.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<b>Are the issues as outlined in Standard 8, Page 26, Part 2 addressed in the training of clinical staff?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category_____																	

8.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<b>Are the issues as outlined in Standard 8, Page 27, Part 2 addressed in the training of staff who work in decontamination units?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category_____																	

**Education and training**

8.3.4		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is induction training recorded in the relevant individuals training record?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

8.3.5		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is there a continuing programme of training and education for staff?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

8.3.6		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is training supported with adequate resources and facilities?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Education and training**

		8.3.7					Y	P	N		
I O D	<input type="checkbox"/>	<b>Are individual competencies assessed and are records kept in the unit?</b>									
	<input type="checkbox"/>	Yes Score 10	No Score 0	Partial	A Score 8	B Score 5				C Score 2	Total score
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

		8.3.8					Y	P	N		
I O D	<input type="checkbox"/>	<b>Is there a formal appraisal system in place to monitor staff performance and to identify individual training needs?</b>									
	<input type="checkbox"/>	Yes Score 10	No Score 0	Partial	A Score 8	B Score 5				C Score 2	Total score
	<input type="checkbox"/>	Supporting Evidence/Comments									
		Risk Category_____									

## Standard 8 Report Form

<b>Standard 8: Education and training</b>
Education and training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Quality management system

### Standard 9: Quality management system

Central decontamination units shall operate a quality management system in accordance with EN ISO 13485. Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.

9.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Do the Central Decontamination Units in the organisation operate a quality management system in accordance with EN ISO 13485?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

9.3.2		Y	P	N														
Endoscope and Local Decontamination Units																		
I O D	<input type="checkbox"/>	<b>Does the organisation have documented policies, procedures and records for all the key elements of the decontamination process? For each decontamination unit, are key policies, procedures and guidelines (where relevant) in place as outlined in Standard 9, Page 29, Part 2?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

9.3.3		Y	P	N														
Endoscope and Local Decontamination Units																		
I O D	<input type="checkbox"/>	<b>Do all policies and procedures associated with decontamination of RIMD comply with current standards, legislation and Health Service Executive guidance?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		



**Quality management system**

9.3.4		Endoscope and Local Decontamination Units					Y	P	N		
I  O  D	<input type="checkbox"/>	Does the quality and risk committee (or appropriate committee) approve policies, procedures and guidelines for decontamination of RIMD in the organisation?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
		Supporting Evidence/Comments									
		Risk Category_____									

9.3.5		Endoscope and Local Decontamination Units					Y	P	N		
I  O  D	<input type="checkbox"/>	Is there a system to ensure each department or service has a current copy of the approved decontamination of RIMD policies, procedures and guidelines pertinent to its activities?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
		Supporting Evidence/Comments									
		Risk Category_____									

9.3.6		Endoscope and Local Decontamination Units					Y	P	N		
I  O  D	<input type="checkbox"/>	Are all relevant staff required to read the decontamination of RIMD policies and procedures relevant to their area of work and to sign a statement to indicate that they have read, understood and will comply with same?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
		Supporting Evidence/Comments									
		Risk Category_____									

**Quality management system**

9.3.7		Endoscope and Local Decontamination Units	Y	P	N														
I O D	<input type="checkbox"/>	Are all policy and procedure documents associated with decontamination of RIMD controlled showing the date of issue and revision number?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

9.3.8		Endoscope and Local Decontamination Units	Y	P	N														
I O D	<input type="checkbox"/>	Are master copies kept in a secure location?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

9.3.9		Endoscope and Local Decontamination Units	Y	P	N														
I O D	<input type="checkbox"/>	Are obsolete documents removed from all points of use?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Quality management system**

		9.3.10	Endoscope and Local Decontamination Units					Y	P	N	
I  O  D	<input type="checkbox"/>	Is there a biennial review of all policies, procedures and documents associated with decontamination of RIMD undertaken to check their relevance and issue status?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score			
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
		Supporting Evidence/Comments									
		Risk Category_____									

		9.3.11	Endoscope and Local Decontamination Units					Y	P	N	
I  O  D	<input type="checkbox"/>	Is there a computerised documentary system available within each decontamination unit to allow the provision of appropriate information to senior management as required? Are decontamination unit personnel proficient in the application and operation of such systems?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score			
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
		Supporting Evidence/Comments									
		Risk Category_____									

		9.3.12	Endoscope and Local Decontamination Units					Y	P	N	
I  O  D	<input type="checkbox"/>	Is all data (electronic and manual) stored securely? Is electronic data backed up and audited in accordance with the organisations policy?									
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score			
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
		Supporting Evidence/Comments									
		Risk Category_____									

**Quality management system**

	<b>9.3.13</b>	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	Is access to data/records restricted to authorised named persons and is specified information maintained in line with the Data Protection Acts?																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

	<b>9.3.14</b>	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	Are all records associated with the decontamination life cycle retained for the life-time of the equipment/RIMD plus eleven years?																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

## Quality management system

	9.3.15	Endoscope and Local Decontamination Units					Y	P	N										
I  O  D	<input type="checkbox"/>	Are these records securely stored and readily accessible to permit traceability when required?																	
	<input type="checkbox"/>																		
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A				B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B	C				Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
	Supporting Evidence/Comments																		
		Risk Category_____																	

**Quality management system—Standard Report Form**

**Standard 9 Report Form**

<b>Standard 9: Quality management system</b>
Central decontamination units shall operate a quality management system in accordance with EN ISO 13485. Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>          
<b>Standard Score:</b>

## Risk management system

### Standard 10: Risk management system

The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.

10.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Has the organisation compiled a list of foreseeable hazards associated with each stage in the decontamination process?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

10.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is the list of hazards maintained in a risk management file?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

10.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<b>Are all identified hazards documented as part of a risk register and systematically assessed and prioritised?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
Supporting Evidence/Comments  Risk Category_____																		

**Risk management system**

	10.3.4		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	Has the organisation identified and assessed all risks associated with all stages in the decontamination process?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No		Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes	No	Partial	A			B	C	Total score										
Score 10	Score 0	Score 8		Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	10.3.5		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	Has the organisation instituted control measures for identified risks?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No		Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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Score 10	Score 0	Score 8		Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	10.3.6		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	Does the organisation have a monitoring programme in place to verify conformance with policies and procedures?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No		Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes	No	Partial	A			B	C	Total score										
Score 10	Score 0	Score 8		Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	



**Risk management system**

		10.3.7		Y	P	N													
I O D	<input type="checkbox"/>	<b>Has the organisation documented arrangements for responding to emergencies?</b>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10			Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																			
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																		

		10.3.8		Y	P	N													
I O D	<input type="checkbox"/>	<b>Has the organisation identified, recorded and analysed 'adverse events' and 'near misses'?</b>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10			Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																			
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																		

		10.3.9		Y	P	N													
I O D	<input type="checkbox"/>	<b>Does the organisation have a reporting procedure for reporting accidents and incidents to the relevant authorities? (See Standard 10, Page 33, Part 2)</b>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes			No	Partial		A	B	C	Total score									
	Score 10			Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																			
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																		

**Risk management system**

		10.3.10						Y	P	N								
I  O  D	<input type="checkbox"/>	<p>Does the organisation have a documented decontamination policy with clear reference to risk management? (See Standard 10, Page 33, Part 2).</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

		10.3.11						Y	P	N								
I  O  D	<input type="checkbox"/>	<p>Has the organisation taken measures to ensure that all relevant employees receive adequate information concerning matters relating to the Safety, Health and Welfare at Work Act, 2005?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

		10.3.12						Y	P	N								
I  O  D	<input type="checkbox"/>	<p>Are Material Safety Data Sheets made available to all staff who are using potentially hazardous chemicals?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Risk management system**

	10.3.13		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Have chemical risk assessments been completed and brought to the attention of all relevant staff?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>																	

	10.3.14		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Does each department where decontamination of RIMD takes place have a Departmental Safety statement which documents physical, chemical, biological and psychological hazards and associated protective and preventative measures?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>																	

	10.3.15		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Does the organisation have a documented staff decontamination training programme to include induction of all new staff through to continual professional development for all other grades?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>																	

## **Risk Management System—Standard Report Form**

### **Standard 10 Report Form**

<b>Standard 10: Risk management system</b>
The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>          
<b>Standard Score:</b>

## Health and safety

### Standard 11: Health and safety

Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used RIMD and process chemicals.

11.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<p>Is each decontamination unit manager and their staff aware of and do they have access to current health and safety regulations and guidelines as they apply to the decontamination unit?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

11.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does each decontamination unit have a health and safety policy which is available and disseminated to staff. Is this policy up to date and regularly reviewed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

11.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does each decontamination unit has access to competent health and safety advice?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

**Health and safety**

		11.3.4		Y	P	N												
I O D	<input type="checkbox"/>	<b>Has each decontamination unit identified the decontamination processes that may generate substances hazardous to health?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

		11.3.5		Y	P	N												
I O D	<input type="checkbox"/>	<b>Are these processes contained by appropriate precautions?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

		11.3.6		Y	P	N												
I O D	<input type="checkbox"/>	<b>Are there regular audits of conformance with the control measures?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Health and safety**

		11.3.7		Y	P	N												
I O D	<input type="checkbox"/>	<p>Does each decontamination unit have procedures in place to deal with accidents, incidents and emergencies?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

		11.3.8		Y	P	N												
I O D	<input type="checkbox"/>	<p>Are flammable liquids and chemicals stored in flame-proof cupboards which are kept locked and closed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

		11.3.9		Y	P	N												
I O D	<input type="checkbox"/>	<p>Are emergency treatment kits for contact with personnel/spillages provided and easily accessible in the work area?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Health and safety**

	11.3.10		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p>Are there procedures in place to ensure that all decontamination equipment and accessories are specified, installed, commissioned, tested and operated in accordance with current standards?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<b>O</b>	<input type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		

	11.3.11		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p>Is personal protective equipment provided and easily accessible in the work area?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<b>O</b>	<input type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		

	11.3.12		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p>Is there a formal, documented release for sterile RIMD to ensure that the RIMD is only returned for use on a patient after it has been decontaminated using validated reprocessing equipment and in line with the manufacturers' instructions?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<b>O</b>	<input type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		



**Health and safety**

		11.3.13						Y	P	N														
I  O  D	<input type="checkbox"/>	Are current copies of approved infection prevention and control policies and procedures in relation to decontamination of RIMD readily accessible to staff in each decontamination unit?																						
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>										Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B	C	Total score																	
Score 10	Score 0	Score 8		Score 5	Score 2																			
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																							

		11.3.14						Y	P	N														
I  O  D	<input type="checkbox"/>	Are occupational health services provided for all staff?																						
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>										Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B	C	Total score																	
Score 10	Score 0	Score 8		Score 5	Score 2																			
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																							

## Health and safety—Standard Report Form

## Standard 11 Report Form

Standard 11: Health and safety
Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used RIMD and process chemicals.
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Complaints management

### Standard 12: Complaints management

All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information.

12.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Does the documented complaint system covers the areas as outlined in Standard 12, Page 36, Part 2?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2			
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
		Supporting Evidence/Comments  Risk Category_____																

12.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is corrective action implemented without undue delay when a finished product is found to be defective or is subject to adverse reports? (See Standard 12, Page 37, Part 2)</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2			
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
		Supporting Evidence/Comments  Risk Category_____																

12.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is preventative action implemented to ensure as far as practicable that there will be no recurrence of the non-conformance? Is the efficacy of the preventative action verified?</b>																
	<input type="checkbox"/>																	
	<input type="checkbox"/>																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2			
Yes	No	Partial	A	B	C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2													
		Supporting Evidence/Comments  Risk Category_____																

## Complaints management—Standard Report Form

### Standard 12 Report Form

Standard 12: Complaints management
All complaints and comments shall be properly managed and shall be systematically re- corded and analysed to identify trends and other performance information
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:          Non-conformance in the area:
Standard Score:

## Audit and monitoring

### Standard 13: Audit and monitoring

Audits shall be carried out to ensure that the procedures for decontamination of RIMD conforms to the required standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

13.3.1		Y	P	N														
I O D	<input type="checkbox"/>	<b>Does audit of decontamination of RIMD include:</b> <ul style="list-style-type: none"> <li>Accountability arrangements?</li> <li>Staff knowledge, expertise and resources?</li> <li>Processes, including risk management arrangements?</li> <li>Policies, procedures and guidelines?</li> </ul> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
	<input type="checkbox"/>																	
<input type="checkbox"/>																		
13.3.2		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is each decontamination unit manager responsible for preparing a written agreed programme which ensures that all aspects of the decontamination process and its management within the unit are audited at least once a year?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
	<input type="checkbox"/>																	
<input type="checkbox"/>																		
13.3.3		Y	P	N														
I O D	<input type="checkbox"/>	<b>Is each decontamination unit manager responsible for ensuring that the audit is conducted in accordance with this programme?</b> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
	<input type="checkbox"/>																	
<input type="checkbox"/>																		

**Audit and monitoring**

13.3.4		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is each decontamination unit manager responsible for ensuring that remedial actions are carried out for any deficiencies found and for verifying the efficacy of remedial actions undertaken?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

13.3.5		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is the quality and risk committee (or appropriate committee) responsible for ensuring that the audit activity, under the responsibility of each decontamination unit manager has been completed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

13.3.6		Y	P	N														
I O D	<input type="checkbox"/>	<p>Are audit results fed back to the decontamination coordinator, the quality and risk committee (or appropriate committee), relevant staff and the Senior Management Team?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Audit and monitoring**

13.3.7		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Are audit results included in the quality and risk management annual report (or appropriate annual report)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

13.3.8		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Are audit results used to help to inform and improve practices in relation to decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

13.3.9		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Are the audits carried out by appropriately trained auditors?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes				No	Partial	A	B	C	Total score								
	Score 10				Score 0		Score 8	Score 5	Score 2									
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Audit and monitoring**

	13.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Does the Senior Management Team submit an annual assurance statement on audit findings for consideration and approval by the Network Manager/Assistant National Director Primary Community and Continuing Care (PCCC)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	13.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Does the Network Manager/Assistant National Director PCCC submit annual assurance statements to the Director of the National Hospitals Office/Director of Primary, Community and Continuing Care?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	13.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are external national audits of decontamination carried out as appropriate under the direction of the Assistant National Directors of Quality, Risk and Customer Care?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		



## Audit and monitoring—Standard Report Form

## Standard 13 Report Form

Standard 13: Audit and monitoring
Audits shall be carried out to ensure that the procedures for decontamination of RIMD conforms to the required standard
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Key performance indicators

### Standard 14: Key performance indicators

Key performance indicators that are capable of showing improvements in the efficacy of the decontamination process shall be used. The usefulness of the indicators shall be reviewed regularly

14.3.1 -10			Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to the Environment?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

14.3.11 -15			Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment—Manual Washing?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

14.3.16 -20			Y	P	N														
I O D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment—Ultrasonic Cleaning?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

**Key performance indicators**

	14.3.21-25		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment—Washer-Disinfectors</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	14.3.26-29		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment—Steam Sterilisers?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	14.3.30-32		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment—Low Temperature Sterilisers?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

## Key Performance Indicators

	14.3.33-35		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment—Drying Cabinet?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	14.3.38-41		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Utilities?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	14.3.42-49		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Management and Key Personnel?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Key performance indicators**

	14.3.50-57		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Processes?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	14.3.58-60		Y	P	N														
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Service Quality?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

## Key performance indicators—Standard Report Form

## Standard 14 Report Form

Standard 14: Key performance indicators
Key performance indicators that are capable of showing improvements in the efficacy of the decontamination process shall be used. The usefulness of the indicators shall be reviewed regularly
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:
Non-conformance in the area:
Standard Score:

## Procedures relating to TSEs

### Standard 15: Procedures relating to Transmissible Spongiform Encephalopathies (TSEs)

The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.

15.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<b>Is RIMD and equipment used on patients at increased risk of developing a TSE, single-use where possible?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category_____																	

15.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<b>Does the organisation have written policies and procedures for the identification of patients at increased risk of developing a TSE?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category_____																	

15.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<b>Are these policies and procedures based on Irish TSE Infection Control Guidelines Final Version, Sept 2004?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category_____																	

## Procedures relating to TSEs—Standard Report Form

### Standard 15 Report Form

<b>Standard 15: Procedures relating to Transmissible Spongiform Encephalopathies</b>
The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>          
<b>Standard Score:</b>



Quality Improvement Action Plan

5. QUALITY IMPROVEMENT ACTION PLAN

Com- ment <i>Office Use Only</i>																	
Review of Implementa- tion of Ac- tion																	
Cost Implications																	
Time Frame																	
Responsible Person																	
Corrective Action to be taken																	
Level of Risk																	
Area of Non- Conformance																	
Stan- dard Refer- ence																	

**Standard Scoring Summary Sheet****6. STANDARD SCORING SUMMARY SHEET**

Standard	Actual Standard Score (AS)	Maximum Standard Score (MS) Total Number of Question x Maximum Score (10)	Standard Score as a percentage (AS/MS x 100/1)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
Overall Audit Score			

**Auditors Notes**

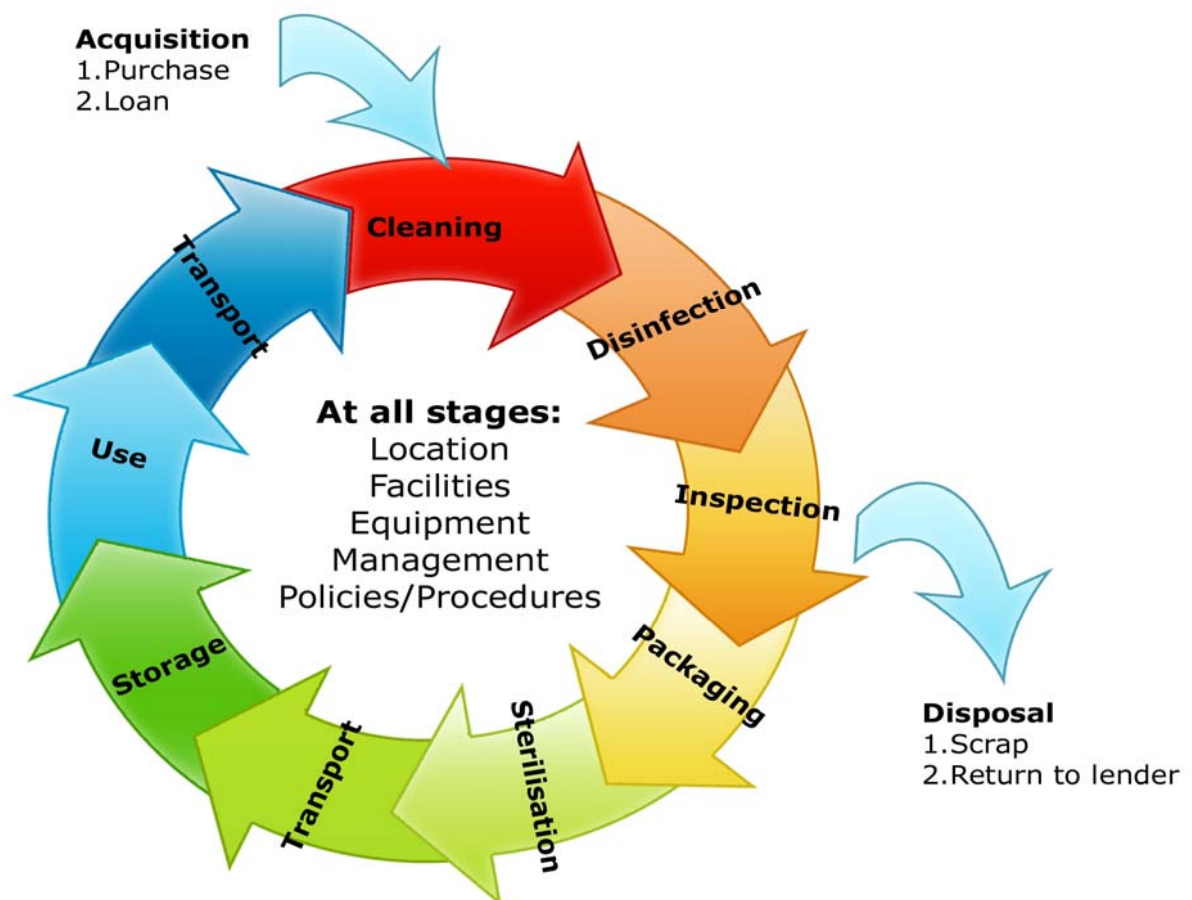
7. AUDITORS NOTES


**Auditors Notes**

7. AUDITORS NOTES


## PART 7: ADDITIONAL RESOURCES AND APPENDICES

# Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices



## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 7
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All relevant staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2008
<b>Contact Details:</b>	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p><b>Email:</b> <a href="mailto:winifred.ryan1@hse.ie">winifred.ryan1@hse.ie</a></p> <p><b>Web:</b> <a href="http://www.hse.ie">www.hse.ie</a></p>

**Part 7**

*Part 7*  
*Additional Resources*  
*and Appendices*

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- AORN. Standards, Recommended Practices and Guidelines. AORN, 2006.
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## 2. Abbreviations

AORN	Association of periOperative Registered Nurses
AER	Automated Endoscope Reprocessor
CE	La Conformité Européenne
CDU	Central Decontamination Unit
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
EEC	European Economic Community
EN	European Norm
EU	European Union
EDU	Endoscopy Decontamination Unit
EWD	Endoscope Washer-Disinfector
HAS (H&S)	Health and Safety
HBN	Health Building Note
HAI	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
MSDS	Material Safety Data Sheets
NHO	National Hospitals Office
NSAI	National Standards Authority of Ireland
PCCC	Primary, Community and Continuing Care
PPE	Personal Protective Equipment
RIMD	Reusable Invasive Medical Devices
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 of foreign matter (or both) from contaminated materials or living tissue. Three processes of 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.
<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.

### 3. Glossary

<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>	<p>To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change.</p>
<b>Prion</b>	<p>The small proteinaceous infectious unit that appears to cause TSEs.</p>
<b>Primary Care</b>	<p>HSE healthcare provision outwith hospitals, for example, general medical practitioner and general dental practitioner services.</p>
<b>Risk</b>	<p>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.</p>
<b>Risk Assessment</b>	<p>The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria.</p>
<b>Risk Management</b>	<p>The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects.</p>
<b>Risk Management Process</b>	<p>The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk.</p>

### 3. Glossary

<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.
<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).

## Appendix 1: Membership of Decontamination of RIMD Steering Committee

Name	Title	Address
Dr. Ronnie Russell	Applied Microbiologist and Immunologist	Moyne Institute of Preventative Medicine Trinity College Dublin (Joint Chair)
Winifred Ryan	Quality Risk & Customer Care	National Hospitals Office, Health Service Executive (Joint Chair)
Ann O'Connor	Medical Devices Director	IMB, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2
Sheila Sheahan	Chairperson of the Irish Association of Sterile Services Managers	Health Service Executive, Mid Western Regional Hospital, Limerick
Mary Owens	Vice-President of the Irish Association of Directors of Nursing and Midwifery	Mallow General Hospital Cork
Caroline Dolan	Chairperson of Irish Association of Thea- tre Managers	Portiuncula Hospital, Ballinasloe, Co. Galway
Tracy Doherty—Replaced in February 2007 by Michelle Bergin	Infection Control Nurse representing the ICNA	Beaumont Hospital, Dublin/ Midland Regional Hospital, Tullamore
Donna Roche—Rotated with Mary Fogarty	Chairperson of the Irish Society of Endo- scopy Nurses	Bons Secours Hospital, Co. Cork/ Mater Hospital, Dublin
Dr Robert Cunney	Consultant Microbiologist	Health Protection Surveillance Centre, Dublin
Dr Anne Gilleece	Consultant Microbiologist	Connolly Hospital Blanchardstown Dub- lin
Gerry Clerkin	Risk Advisor	Health Service Executive, North East Management Dept, Kells, Co. Meath
Hugh O'Connor, MBB	Authorised Person (Sterilisers)	St. James' Hospital, Dublin
Wilf Higgins	Principal Engineering Advisor	Hospital Planning Office, Department of Health and Children
Oonagh Ryan (In attendance)	Sterile Services Manager	St Vincents Private Hospital Dublin
Niall Creggy (In attendance)	Sterile Services Manager	Mater Private Hospital Dublin
Sandra Kehoe (Secretariat)	Quality Risk & Customer Care NHO	Health Service Executive

## Appendix 2: Membership of Standards Sub-Group

Name	Title	Address
Winifred Ryan	Quality Risk & Customer Care	National Hospitals Office Health Service Executive (Chair)
Sheila Sheahan	Sterile Services Manager	Health Service Executive Mid Western Regional Hospital Limerick
Caroline Dolan	Theatre Manager	Portiuncla Hospital, Ballinasloe, Co. Galway
Tracy Doherty—Replaced in February 2007 by Michelle Bergin	Infection Control Nurse representing the ICNA	Beaumont Hospital, Dublin/ Midland Regional Hospital, Tullamore
Brid Lennon	Irish Society of Endoscopy Nurses	South Tipperary General Hospital
Alan Cherryman	Technical Services Department	Health Service Executive Mid Western Regional Hospital Limerick
Hugh O'Connor, MBB	Authorised Person (Sterilisers)	St. James' Hospital, Dublin
Wilf Higgins	Principal Engineering Advisor	Department of Health and Children
Dr Anne Gillecce	Consultant Microbiologist	Connolly Hospital, Blanchardstown
Professor David C. Coleman	Professor of Oral & Applied Microbiology	Dublin Dental School & Hospital, University of Dublin, Trinity College, Lincoln Place, Dublin 2.
Nick Armstrong	Senior Administrative Dental Surgeon	HSE Eastern Area.
Dr Jane Renehan	Principal Dental Surgeon	HSE Dublin North West
Mary O'Donnell	Dublin Dental School & Hospital	University of Dublin, Trinity College, Lincoln Place, Dublin 2.
Joy Markey	Sterile Services Manager	Dublin Dental School & Hospital, University of Dublin, Trinity College, Lincoln Place, Dublin 2.
Sandra Kehoe (Secretariat)	Quality Risk & Customer Care, NHO	Health Service Executive



**Appendix 3: List of hospitals who participated in the consultation process**

Waterford Regional Hospital, Co. Waterford
St Luke's General Hospital, Kilkenny
Lourdes Orthopaedic Hospital, Kilcreene, Kilkenny
Wexford General Hospital, Wexford
South Tipperary General Hospitals, Clonmel, Co. Tipperary
Cork University Hospital, Wilton Road, Cork
Cork University Maternity Hospital, Cork
St. Finbarr's Hospital, Douglas Road, Cork
St Mary's Orthopaedic Hospital, Gurranbraher, Cork
Mallow General Hospital, Mallow, Co. Cork
Kerry General Hospital, Tralee
Bantry General Hospital, Bantry, Co. Cork
Mercy University Hospital, Grenville Place, Cork
South Infirmary-Victoria University Hosp., Old Blackrock Rd, Cork
Our Lady of Lourdes Hospital, Drogheda, Co. Louth
Louth County Hospital, Dundalk, Co. Louth
Cavan General Hospital, Cavan
Monaghan General Hospital, Co. Monaghan
Our Lady's Hospital, Navan, Co. Meath
Sligo General Hospital, Sligo
University College Hospital, Galway
Merlin Park Reg. Hospital, Galway

### Appendix 3: List of hospitals who participated in the consultation process

Mayo General Hospital, Castlebar, Co. Mayo
Roscommon County Hospital, Roscommon
Portiuncula Hospital, Portiuncula, Ballinasloe, Co. Galway
Letterkenny General Hospital, Letterkenny, Co. Donegal
Midland Regional Hospital, Mullingar, Co. Westmeath
Midland Regional Hospital, Tullamore, Co. Offaly
Adelaide & Meath Incorp National Children's Hospital, Tallaght, D24
Naas General Hospital, Naas, Co. Kildare
Coombe Women's Hospital, Dolphins Barn, Dublin 8
Our Lady's' Hospital for Sick Children, Crumlin, Dublin 12
Midland Regional Hospital Portlaoise
Mid Western Regional Hospital Limerick, Dooradoyle, Limerick City
Mid Western Regional Orthopaedic, Croom, Co. Limerick
Mid Western Regional Maternity Hospital, Limerick City
Mid Western Regional Hospital, Ennis, Co. Clare
Mid Western Regional Hospital, Nenagh, Co. Tipperary
St John's Hospital, Limerick City
St Vincent's University Hospital, Elm Park, Dublin 4
St Michaels Hospital, Lower George's St., Dun Laoghaire, Co. Dublin
St Columcille's Hospital, Loughlinstown, Co. Dublin
National Maternity Hospital, Holles St., Dublin 2

### Appendix 3: List of hospitals who participated in the consultation process

St Luke's Hospital, Highfield Rd., Rathgar, Dublin 6
Royal Victoria Eye & Ear, Adelaide Road, Dublin 2.
St James's Hospital, James's St., Dublin 8
Mater Misericordiae University Hospital, Eccles St., Dublin 7
Beaumont Hospital, Beaumont Road, Dublin 9
Connolly Hospital, Blanchardstown, Dublin 15
Cappagh National Orthopaedic Hospital, Cappagh, Finglas, Dublin 1
Children's University Hospital, Temple Street, Dublin 1
Rotunda Hospital, Parnell St., Dublin 1
Dublin Dental School and Hospital, University of Dublin, Trinity College

#### Appendix 4: List of External Consultees

Consultees (External)	Consultees (External)
Department of Health and Children	SARI National Committee
RCPI Faculty of Occupational Health	Maintenance Management Association
Royal College of Surgeons of Ireland	Health Care Risk Managers Forum
Royal College of Physicians of Ireland	DATHs Risk Management Forum
RCPI Faculty of Public Health	Clinical Indemnity Scheme
Irish Society of Clinical Microbiologists	Association of Occupational Therapists in Ireland
Irish Directors of Nursing and Midwifery Association	Irish Society of Chartered Physiotherapists
Irish Association of Sterile Services Managers	Irish Association of Speech & Language Therapy
Irish Society of Endoscopy Nurses	Association of Physical Scientists in Medicine
Irish Association of Theatre Managers	Irish Medicines Board
Infection Control Nurses Association	

## **Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is 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 (42/93/EEC) they have been published in the Official Journal of the European Union as harmonized 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 42/93/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.

## **Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based**

### **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 13627:2003 Chemical disinfectant 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 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 Sterilization. Steam sterilizers. Large sterilizers.

EN ISO 13060: 2004 Small steam sterilizers.

EN 1422:1998 Sterilization of medical device. Ethylene oxide sterilizers. Requirements and test methods.

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

#### Washer-disinfectors

EN ISO 15883-1: 2006 Washer-disinfectors – Part 1: General requirements, definitions and tests.

EN ISO 15883-2: 2006 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.

PD CEN ISO TR 15883-5: 2005 Washer-disinfectors – Part 5 Test soils.

## **Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based**

### **iv. Management**

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

PD CEN ISO/TR 14969:2004 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 sterilization processes.

EN ISO 14161:2001 Sterilization 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 15882:2003 Sterilization of health care products. Chemical indicators. Guidance for selection, use and interpretation of results – Not in stock.

#### Packaging

EN ISO 11607-1: 2006 Packaging for terminally sterilized Medical Devices – Part 1 Requirements for materials, sterile barrier systems and packaging systems.

BS EN 868-2:1999 Packaging materials and systems for medical devices which are to be sterilized. Sterilization wrap. Requirements and test methods.

BS EN 868-3:1999 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 868-4:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper bags. Requirements and test methods.

EN 868-5:1999 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.

## **Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based**

EN 868-6:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation. Requirements and test methods.

EN 868-7:1999 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 sterilization by ethylene oxide or irradiation. Requirements and test methods.

EN 868-8:1999 Packaging materials and systems for medical devices which are to be sterilized. Re-usable sterilization containers for steam sterilizers conforming to EN 285. Requirements and test methods.

EN 868-9:2000 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 868-10:2000 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 Sterilization of medical devices. Requirements for medical devices to be designated 'STERILE'. Requirements for terminally sterilized medical devices.

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

EN 1041:1998 Information supplied by the manufacturer with medical devices.

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

### **vii. Processes**

#### **Sterilization**

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

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

EN ISO 14937:2001 Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.



## **Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based**

### **viii. Safety**

EN 61010-2-041:1997 (Dual no: IEC 61010-2-041:1995) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using steam for the treatment of medicinal materials, and for laboratory processes.

EN 61010-2-042:1997 (Dual no: IEC 61010-2-042:1997) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using toxic gas for the treatment of medicinal materials, and for laboratory processes.

EN 61010-2-043:1998 (Dual no: IEC 61010-2-043:1997) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using either hot air or hot inert air for the treatment of medicinal materials, and for laboratory processes.

EN 61010-2-045:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields.

EN ISO 13848-2:2003 Safety machinery. Safety-related parts of control systems. Validation.

## **UK Guidance Documents**

HBN13 Sterile Service Departments.

HTM 2010 Sterilizers.

HTM 2030 Washer Disinfectors.

HTM 2031 Steam for sterilization.

MAC Manual 2006.

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

MDA SN 2000 (18) Handling of surgical instruments on loan from another organization.

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

MDA SN 9701 Reporting adverse incidents relating to medical devices.

MDB 9801 Medical Device and Equipment Management for Hospitals and Community based Organizations.

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

## **Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based**

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

MDB 2000(04) Re-use of single-use devices.

MDB 2003(05) Management of medical devices prior to repair, service or investigation.

*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.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm>.

## Appendix 6: Regulations and Guidance

### Medical Device

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 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).

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.

## Appendix 6: Regulations and Guidance

### 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.

- 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.

## **Appendix 6: Regulations and Guidance**

### **Manufacturer of Medical Devices**

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

### **Legal Entity**

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

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

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

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

The 2004 Act sets out:

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

The enforcement procedures needed to ensure that the goals are met.

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

**Appendix 7: Suggested Membership of Decontamination Advisory Group**

Group Membership	Group Membership
Chair	Health & Safety Personnel
Senior Medical Staff/Consultant Surgeon	Quality Manager
Consultant Microbiologist	Procurement Personnel
Senior Administrative Staff/ Business Manager	Bio-Medical Engineering Personnel/ Clinical Engineering Personnel/Medical Physics
Senior Nursing Staff	Dangerous Goods Safety Advisor
Decontamination Unit Manager – CDU Operatives	Porter
Decontamination Unit Manager - Endoscopy	Technical Services Personnel
Decontamination Unit Manager - Theatre	Risk Manager
Dentist/Orthodontist	Union Representative
Infection Prevention and Control Nurse	Links to local partnership committee
Health & Social Care Professional	