Health Service Executive

Standards and

Recommended Practices for

Central Decontamination Units

At all stages:
Location
Facilities
Equipment
Management
Policies/Procedures

Acquisition
1. Purchase
2. Loan

Transport
Use
Storage
Transport
Sterilisation

Cleaning

Disinfection

Inspection

Packaging

Disposal
1. Scrap
2. Return to lender

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# Reader Information

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# Table of contents

<table>
<thead>
<tr>
<th>No.</th>
<th>Part</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Part 1 Introduction</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Introduction</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>Development of Decontamination Code of Practice</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Medical Devices Directive</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>Guide to classification of infection risk</td>
<td>19</td>
</tr>
<tr>
<td>5</td>
<td>Life-cycle for reusable invasive medical devices</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Part 2 Standards</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Suitability of decontamination facilities</td>
<td>24</td>
</tr>
<tr>
<td>2</td>
<td>Decontamination equipment</td>
<td>28</td>
</tr>
<tr>
<td>3</td>
<td>Decontamination process</td>
<td>34</td>
</tr>
<tr>
<td>4</td>
<td>Procedures relating to transmissible spongiform encephalopathies (TSEs)</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>Part 3 Recommended practices</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Design of central decontamination unit facilities</td>
<td>38</td>
</tr>
<tr>
<td>2</td>
<td>Environmental cleaning</td>
<td>43</td>
</tr>
<tr>
<td>3</td>
<td>Decontamination equipment</td>
<td>53</td>
</tr>
<tr>
<td>4</td>
<td>Procurement</td>
<td>60</td>
</tr>
<tr>
<td>5</td>
<td>Manufacturers’ instructions</td>
<td>62</td>
</tr>
<tr>
<td>6</td>
<td>Personal protective equipment</td>
<td>68</td>
</tr>
<tr>
<td>7</td>
<td>Clean room attire and behaviour</td>
<td>73</td>
</tr>
<tr>
<td>8</td>
<td>Process chemicals</td>
<td>76</td>
</tr>
<tr>
<td>9</td>
<td>Traceability</td>
<td>79</td>
</tr>
<tr>
<td>10</td>
<td>Choice of decontamination process</td>
<td>82</td>
</tr>
<tr>
<td>11</td>
<td>Transportation – return of used items for reprocessing</td>
<td>84</td>
</tr>
</tbody>
</table>

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Table of contents

No.          Page
12 Sorting and disassembly of contaminated RIMD 88
13 Cleaning (including pre-cleaning) 91
14 Disinfection 116
15 Drying 119
16 Post Cleaning inspection and function testing 121
17 Assembly 127
18 Packaging 130
19 Sterilisation 147
20 Low temperature sterilisation 166
21 Storage 173
22 Transportation – of sterile items 178
23 Water supply for washer-disinfectors 180
24 Textiles and non-wovens 189
25 Single use invasive medical devices 191
26 Transfer of used RIMD to third parties 193
27 Loan RIMD 195
28 Action on non-conforming product 199

Part 4 Additional resources and appendices

Resources 203
Abbreviations 205
Glossary of Terms 207
Appendices 212
Tables

Introduction:

4.1 Classification of infection risk associated with decontamination of RIMD

Recommended practices:

2-1 Parameters for assessment of microbiological air quality by ‘settle plate’ method
2-2 Parameters for assessment of microbiological air quality using an’ active sampling device’
2-3 Typical microbial ‘action’ limit values used in Class 7 or 8 cleanrooms
13-1 Automated washer-disinfector temperature bands
13-2 Minimum level of periodic testing to be undertaken for washer-disinfectors
13.3 Minimum level of periodic testing to be undertaken for ultrasonic cleaner
19-1 Sterilisation temperatures, steam pressures and hold times
19-2 Summary of Weekly Tests for Steam Sterilisers
19-3 Summary of Quarterly Tests for Steam Sterilisers
19-4 Summary of Annual Tests for Steam Sterilisers
23-1 Typical bacterial counts as indicators of process water quality
23-2 Water quality for washer-disinfectors
23-3 Water quality for cleaning RIMD

Appendices:

Appendix 1 Membership of National Decontamination Advisory Group
Appendix 2 List of hospitals/consultees who participated in the consultation process

Figures

Introduction:

3.1 CE symbol
5.1 Decontamination life-cycle
Tables/Figures

Recommended practices:

6-1 Personal Protective Equipment (Decontamination Unit)
7-1 Personal Protective Equipment
   (Clean Room, inspection, assembly and packaging room)
11-1 Transportation—return of used items for reprocessing
12-1 Sorting and Disassembly of contaminated RIMD
13-1 washer-disinfector
13-2 Loading the washer-disinfector
13-3 Sink required for manual cleaning
16-1 Post cleaning inspection
17-1 Assembly
18-1 Parcel-fold wrapping method
18-2 Envelope wrapping method
18-3 Using the heat sealer
18-4 Heat seal pouch
19-1 Steriliser
19-2 Loading the steriliser
19-3 Cycle records
19-4 Bowie-Dick test
21-1 Storage
22-1 Transportation of sterile items
25-1 Do not reprocess symbol
Standards and Recommended Practices for CDUs

Part 1
Introduction
Introduction

1. Introduction

1.1 Prevention and control of healthcare associated infection

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

1.2 Decontamination process

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

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

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

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

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

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

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

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

2. Development of standards and recommended practices for decontamination of RIMD

2.1 Introduction

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

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

2.2 Definition

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

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

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

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

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

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

3.1 Medical Devices Directives

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

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

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

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

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
Introduction

- Control of conception, and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.

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

There are four classes of general medical devices as follows:

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

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

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

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

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

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

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

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

- That devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Annex 1, paragraph 8.1).

- That devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile under the storage and transport conditions laid down.

- Devices should remain sterile unless the protective packaging is damaged or opened. (Annex 1 paragraph 8.3.).

- That devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. (Annex 1 paragraph 8.4.).

- That devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions. (Annex 1 paragraph 8.5.).

- That packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. (Annex 1 paragraph 8.6.).

- That the packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. (Annex 1 paragraph 8.7.).

- That devices be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (Annex 1, paragraph 7.2).
Introduction

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

3.3 Placing on the market

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

3.4 In-house manufacture

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

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

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

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

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

3.6 CE marking

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

CE symbol

The CE marking symbolises the following:

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

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

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

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

![Figure 3.1: CE symbol](image-url)
Introduction

3.7 Notified Body

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

4.1 Classification of infection risk

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

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

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

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

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

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

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

Important Note: ‘Specific procedures apply to RIMD used in high or medium risk procedures on patients with, or “at increased risk” of, Creutzfeldt-Jakob disease or other transmissible spongiform encephalopathies. Ref to www.hse.ie
5. **Life cycle for reusable invasive medical devices**

5.1 **Introduction**

The decontamination life cycle highlights the extent to which decontamination affects 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 adequate decontamination.

![Figure 5.1: Decontamination life cycle](image)

Note: Variants of this life-cycle apply for example to the endoscope reprocessing unit.
Standards and Recommended Practices for CDUs

Part 2
Standards
Suitability of decontamination facilities

1. Suitability of decontamination facilities

1.1 Statement

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

1.2 Rationale

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

1.3 Criteria

Unit design

1.3.1 The department is designed so that it is physically separated from all other work areas.

1.3.2 The department is designed to allow segregation of ‘dirty’ and ‘clean’ activities.

1.3.3 The department is designed to facilitate a unidirectional work flow from the ‘dirty’ area to the ‘clean’ area (clean room and inspection, assembly and packaging (IAP) room).

1.3.4 The department is not used for any other purpose.

1.3.5 The department is not used as a thoroughfare.

1.3.6 The department is not part of any service user treatment area.
Suitability of decontamination facilities

1.3.7 There is a changing area for donning work wear which includes shower facilities, toilet facilities and lockers in proximity to the decontamination area.

1.3.8 Access to the wash room, clean room and to the inspection, assembly and packaging (IAP) room is through separate dedicated gowned rooms provided with hand hygiene facilities.

1.3.9 The wash room, clean room, inspection, assembly and packaging (IAP) room and steriliser unloading area are free from ‘opening’ windows, ledges, and uncleanable areas.

1.3.10 The wash area, clean room and inspection, assembly and packaging (IAP) room are designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).

Lighting and electricity

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

1.3.12 Task lighting and magnification are in situ.

1.3.13 There is sufficient electricity supply, computer terminal points and work stations in the department.

Ventilation and temperature

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

Walls, floors and ceilings

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

1.3.16 The junctions between the walls and floors is coved and flush.
Suitability of decontamination facilities

1.3.17 The fitments (where possible) are flush with wall surfaces.

1.3.18 Floors are covered in a washable non-slip material which is securely sealed.

Workstations, furniture, shelving and equipment

1.3.19 All work surfaces, fittings, fixtures and furniture are made of easily cleanable and robust material and are maintained in good condition.

1.3.20 The workstations are equipped for the preparation of single or composite packs. They are of adequate size to accommodate the wrapping material to be used and are height adjustable.

1.3.21 There is adequate space between workstations for equipment and staff movement.

1.3.22 The shelving in storage facilities is manufactured from non-shedding material, easily cleanable and with a smooth surface that will not damage packaging.

1.3.23 The shelving is of sufficient depth for all the materials to be held and is not more than two meters high, unless special provision is made for loading and un-loading higher shelves.

Restricted entry and movement between areas

1.3.24 The area is managed by trained staff whose sole or primary responsibility is management of the decontamination unit.

1.3.25 Entry to the decontamination unit is restricted to authorised personnel only.

1.3.26 Staff movement, between dirty and clean areas is not possible without passing through a clothing change and hand-wash area.

Storage facilities

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

1.3.28 Storage facilities for bulk items are provided external to the wash room, clean room and inspection, assembly and packaging (IAP) room.

1.3.29 Storage facilities are provided for sterile product prior to dispatch.

1.3.30 Adequate storage is provided for required personal protective equipment (PPE) is easily accessible in each of the work areas.

Environmental control

1.3.31 The environment in which clean non-sterile RIMD are inspected, assembled and packed are controlled as a clean room to ISO 14644-1: 1999 Class 8 (manned/unmanned).


Cleaning

1.3.33 The environment in which decontamination of (RIMD) takes place is cleaned in accordance with policies, procedures, protocols, guidelines and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse).

1.3.34 Dedicated cleaning provision (both equipment and storage) is provided for the wash room, clean room and the inspection, assembly and packaging (IAP) room.

Other

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

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

2. Decontamination equipment

2.1 Statement

All decontamination equipment that does not meet current Standards is identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment is procured in conformance with extant harmonised Standards. All decontamination equipment is validated, maintained, periodically tested and monitored to current Standards.

2.2 Rationale

Decontamination equipment that does not meet current Standards cannot be relied upon to meet current requirements for decontamination or to provide the required level of assurance. Organisations must have a specialist group in place to consider the full implications of procurement of decontamination equipment. Validation, maintenance, periodic testing and monitoring are required to demonstrate compliance of installed equipment with current Standards.

2.3 Criteria

Specialist group

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

2.3.1 Ability to meet current Standards.
2.3.2 Age and condition of equipment and availability of replacement parts.
2.3.3 Cost of maintaining and repairing the equipment.
2.3.4 Ability to interface with other equipment in the decontamination facility.
2.3.5 Ability to interface with user requirements.
2.3.6 Ability to meet the requirements of current test methods.
2.3.7 Ability to be validated and perform to intended purpose.
Decontamination equipment

2.3.8 Energy and water conservation.

2.3.9 Ability for self-disinfection for washer-disinfectors and endoscope washer-disinfectors.

Key representatives on the specialist group include:

2.3.10 Decontamination Co-ordinator.

2.3.11 Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/Endoscopy Manager.

2.3.12 Clinical Unit Manager, e.g. Theatre Manager.

2.3.13 Infection Prevention and Control.

2.3.14 Bio-medical Engineering/Clinical Engineering/Medical Physics.

2.3.15 Procurement.

The group may also include as required:

2.3.16 Technical Services.

2.3.17 Materials Management.

2.3.18 Finance Manager/Budget Holder/Business Manager.

2.3.19 Other relevant experts (Qualified Person (decontamination)/Sterivigilance Nurse/Microbiologist).

2.3.20 The specialist group identifies all decontamination equipment that needs to be replaced.

2.3.21 The specialist group formulates a plan to replace or upgrade this equipment.

2.3.22 The plan is submitted to the senior management team and is revised annually by the decontamination coordinator (or designated officer).

2.3.23 There are sufficient decontamination equipment available to meet the needs of the decontamination unit(s).

2.3.24 There are clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and the day to day operation of decontamination equipment.
Decontamination equipment

2.3.25 The operational management of each item of decontamination equipment is the defined responsibility of a named person (usually the decontamination unit manager).

2.3.26 The validation and periodic testing is carried out by qualified personnel.

2.3.27 The validation and periodic testing data is adequately audited quarterly by a qualified person (decontamination).

2.3.28 The department has a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

Manual washing

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

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

2.3.30 Dedicated manual cleaning equipment and accessories are available for specified (RIMD) that cannot be cleaned in an automated cleaning process.

2.3.31 Separate sinks for washing and rinsing are provided.

2.3.32 The detergent used is one specified by the manufacturer for the manual cleaning of (RIMD).

2.3.33 Means are provided to control the concentration of detergent.

2.3.34 A pass-through drying cabinet with inter-locking doors is provided for hot-air drying of manually washed RIMD that cannot be processed through a washer-disinfector.

Ultrasonic cleaning

2.3.35 A stand-alone ultrasonic cleaner is provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers’ instructions or as a pre-treatment for RIMD prior to processing through a washer-disinfector.
Decontamination equipment

2.3.36 The ultrasonic cleaner is equipped with the facility for automatic filling and emptying directly to the drain.

2.3.37 The ultrasonic cleaner is fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.

2.3.38 The detergent used is one specified by the manufacturer for the ultrasonic cleaning of (RIMD).

2.3.39 Means are provided to control the concentration of detergent.

2.3.40 The ultrasonic cleaner is used in accordance with the manufacturers’ instructions.

2.3.41 The ultrasonic cleaner is validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1.

2.3.42 The temperature of the cleaning solution in the ultrasonic cleaner is thermostatically controlled.

Washer-disinfectors

2.3.43 The specification of the washer-disinfector complies with the requirements of EN ISO 15883, parts 1 & 2 (washer-disinfectors), part 3 (thermal washer-disinfector), part 4 (endoscope washer-disinfector).

2.3.44 Washer-disinfectors are double ended with the clean side discharging into the inspection area of the clean room and the inspection, assembly and packaging (IAP) room.

2.3.45 Each washer-disinfector is fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.

2.3.46 When lumened devices are being reprocessed, the washer-disinfector is provided with load carriers that permit the irrigation of the lumened device.

2.3.47 Washer-disinfectors and accessories are specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1, 2 & 5.

2.3.48 The washer-disinfector is subject to planned preventative maintenance.
Decontamination equipment

Steam steriliser

2.3.49 The specification of each steam steriliser complies with requirements of EN 85 and the steriliser is fitted with an air-detector.

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

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

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

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

Low temperature sterilisers

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

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

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

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

**Drying cabinet**

2.3.57 Where a pass through washer-disinfector is not available, a pass-through drying cabinet between the wash-room, clean room and the inspection, assembly and packaging (IAP) room is provided. The doors of the drying cabinet are interlocked to prevent direct connection between the wash room, clean room and the inspection and packaging (IAP) room.

2.3.58 The drying cabinet is fitted with a temperature indicator and/or recorder independent of the controller.

2.3.59 The drying temperature throughout the cabinet is within ±5º Celsius of the set temperature. Or in accordance with drying cabinet /flexible scope manufacturer’s recommendation.

2.3.60 The drying cabinet is fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than 10º Celsius - the heating source is isolated.

2.3.61 The air in the cabinet is mechanically circulated and items placed throughout the cabinet is dried uniformly.

2.3.62 The drying cabinet is subject to planned preventative maintenance.

**Heat sealer**

2.3.63 Where heat seal packaging is to be used, a rotary heat sealer is provided.

2.3.64 Heat-sealing equipment used as part of the terminal packaging process is maintained and tested to manufacturer’s performance criteria.

2.3.65 The heat sealer is validated and tested daily to verify the efficacy of the seal.

2.3.66 The heat sealer is subject to planned preventative maintenance.
Decontamination process

3. Decontamination process

3.1 Statement

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

3.2 Rationale

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

3.3 Criteria

3.3.1 All stages of the decontamination process are clearly defined, documented, controlled and recorded.

3.3.2 All processes are carried out in accordance with documented policies, procedures, protocols and guidelines.

3.3.3 All RIMD sets (including flexible scopes) are traced through the decontamination process to the service user.

3.3.4 Processing data are retained for the lifetime of the equipment plus eleven years.

3.3.5 There is a regular review of all procedures and any necessary changes are implemented by a documented change in procedures.

3.3.6 RIMD are checked and reprocessed in accordance with the manufacturers’ instructions.

3.3.7 All RIMD are visually inspected for cleanliness prior to release and transportation.
3.3.8 All RIMD are inspected and/or tested for functionality prior to release and transportation.

3.3.9 There is a formal release procedure for sterile product to ensure that only RIMD that have been subjected to a satisfactory sterilisation cycle are released for use.

3.3.10 All product released from the decontamination unit is labelled with a clear indication of the pack contents, the review date and a unique number which is used to trace the decontamination processes to which the RIMD/flexible scope was subjected.

3.3.11 Single use devices are not reprocessed. Any device with the following symbol is deemed single use only.

Note: Single patient interrupted use in accordance with the manufacturers' instructions for use is not considered to breach this criterion.
Procedures relating to transmissible spongiform encephalopathies (TSEs)

4. Procedures relating to transmissible spongiform encephalopathies (TSEs)

4.1 Statement

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

4.2 Rationale

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

4.3 Criteria

4.3.1 The organisation has written policies, procedures, protocols and guidelines for the identification of service users at increased risk of developing a TSE’s

4.3.2 The organisation has written policies, procedures, protocols and guidelines to manage RIMD (or where possible, use single use equipment) currently based on the Guidelines on Minimising the Risk of Transmission TSEs in Healthcare Settings in Ireland; 2004 (DoHC) and reviewed when the guidance is updated.

4.3.3 The organisation will regularly evaluate the implementation of the policies, procedures, protocols and guidelines to minimise the risk of iatrogenic transmission of TSEs and develop quality improvement plans to address any deficiencies.
Standards and Recommended Practices for CDUs

Part 3

Recommended Practices
Design of central decontamination facilities

1. Design of central decontamination unit facilities

1.1 Introduction

The decontamination of reusable invasive medical devices (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 recommended practice 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
1.4 Procedure

Section One: Unit design

1.4.1 The department should be designed so that it is physically separated from all other work areas.

1.4.2 The department should be designed to allow segregation of ‘dirty’ and ‘clean’ activities.

1.4.3 The department should be designed to facilitate a unidirectional flow from the ‘dirty’ area to the ‘clean’ area.

1.4.4 The department should not be used for any other purpose.

1.4.5 The department should not be used as a thoroughfare.

1.4.6 The department should not be part of any service user treatment area.

1.4.7 There should be a changing area for donning work wear which includes shower, toilet facilities and lockers in proximity to the department.

1.4.8 Access to the wash room and to the clean room, inspection, assembly and packaging room (IAP) should be through dedicated gowning rooms provided with hand hygiene facilities.

1.4.9 The wash room, clean room, inspection, assembly and packaging room (IAP) and steriliser unloading area should be free from ‘opening’ windows, ledges, and uncleanable areas.

1.4.10 The wash room and clean room, inspection, assembly and packaging room (IAP) should be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).
Design of central decontamination facilities

Section Two: Lighting and electricity

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

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

1.4.12 Task lighting and magnification should also be in situ.

1.4.13 There should be sufficient electricity supply points, computer terminal points and work stations in the department.

Section Three: Ventilation and temperature

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

Section Four: Walls, floors and ceilings

1.4.15 The finishes on the walls and other surfaces should be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning.

1.4.16 The junctions between the walls and floors should be coved and flush.

1.4.17 The fitments (where possible) should be flush with wall surfaces.

1.4.18 Floors should be covered in a washable non-slip material which is securely sealed.

Section Five: Workstations, furniture, shelving and equipment

1.4.19 All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.

1.4.20 The workstations should be equipped for the preparation of single or composite packs. They should be of adequate size to accommodate the wrapping material to be used and should be height adjustable.
Design of central decontamination facilities

1.4.21 There should be adequate space between workstations for equipment and staff movement.

1.4.22 The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.

1.4.23 The shelving should be of sufficient depth for all the materials to be held and should not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.

Section Six: Restricted entry and movement between areas

1.4.24 The area should be managed by trained staff whose sole or primary responsibility is management of the decontamination unit.

1.4.25 Entry to the decontamination unit should be restricted to authorised personnel only.

1.4.26 Staff movement between dirty and clean areas should not be possible without passing through a clothing change and hand wash area.

Section Seven: Storage facilities

1.4.27 Safe storage facilities should be provided for process chemicals used in decontamination.

1.4.28 Storage facilities for bulk items should be provided external to the clean room, Inspection, assembly and packaging room and the wash room.

1.4.29 Adequate storage should be provided for required personal protective equipment and should be easily accessible in each of the work areas.

1.4.30 Appropriate storage facilities should be provided for sterile products prior to dispatch.
Design of central decontamination facilities

Section Eight: Environmental control

1.4.31 The clean room, inspection, assembly and packaging room (IAP) should be controlled as a clean room to ISO 14644-1: 1999 Class 8 (manned/unmanned).

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

Section Nine: Cleaning

1.4.33 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).

1.4.34 Dedicated cleaning provision (both equipment and storage) should be provided for the clean room, Inspection, assembly and packaging area and the wash room.

Section Ten: Other

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

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

2.1 Introduction

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

2.2 Scope

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

2.3 Contents

Section One: Cleaning equipment
Section Two: Cleaning frequency and cleaning efficacy
Section Three: Floor cleaning equipment and method
Section Four: Floor cleaning agents
Section Five: Spillage kits
Section Six: Records
Section Seven: Environmental monitoring
Environmental cleaning

2.4 Procedure

Section One: Cleaning Equipment

2.4.1 There should be a separate cleaner’s utility room for the clean and dirty areas.

2.4.2 Separate colour coded cleaning equipment should be used for the clean room inspection, assembly and packaging area and wash areas.

2.4.3 Cleaning equipment should be regularly cleaned and maintained.

Section Two: Cleaning frequency and cleaning efficacy

2.4.4 Work surfaces should be cleaned at the start of the working day, periodically during the working day and whenever necessary.

2.4.5 Entire rooms should be deep cleansed annually. Air vents and filters should be serviced regularly.

2.4.6 There should be documented cleaning procedures for fixtures and fittings.

2.4.7 There should be documented cleaning procedures for process equipment.

2.4.8 There should be microbial settlement monitoring by passive sampling.

2.4.9 Efficacy of cleaning should be monitored microbiologically using contact media containing neutralisers.

2.4.10 Warning/action limits should be set for microbial contamination in each area after a period baseline monitoring.

Section Three: Floor cleaning equipment and method

The following floor cleaning equipment and method should be used:

2.4.11 Mop and bucket using ‘two bucket’ system and a free rinsing detergent.

2.4.12 Vacuum fitted with HEPA filtered exhaust.
Environmental cleaning

2.4.13 Rotary scrubbers and polishers should not be used (unless all devices are first removed from the area, or covered, and all horizontal work surfaces are cleaned after floor cleaning).

2.4.14 Floors should be cleaned daily and also cleaned when visibly soiled.

Section Four: Floor cleaning agents

2.4.15 Suitably approved detergent/chemical should be used routinely to ensure infection prevention and control and to ensure that cleaning equipment does not spread microbial load. Therefore monitoring efficacy is essential.

2.4.16 Cleaning efficacy should be monitored routinely.

2.4.17 If visible blood/body fluids are present, disinfectants should be used following thorough cleaning.

2.4.18 Disinfectants should be made up according to the manufacturers’ instructions/healthcare organisations policies, procedures, protocols and guidelines.

2.4.19 Where disinfectant containers are reused they should not be ‘topped up’ but should be cleaned and thoroughly rinsed with clean water prior to refilling with disinfectant solution at its working concentration.

Section Five: Spillage kits

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

2.4.21 The wash area should be equipped with spillage kits to contain, neutralise if necessary and remove spillages of process chemicals (guidance on the specific requirements should be found in the Material Safety Data Sheet (MSDS) supplied by the process chemical manufacturer).
Environmental cleaning

Section Six: Records

Records should be kept of the following:

2.4.22 Training of the personnel carrying out the cleaning.

2.4.23 All cleaning carried out and by whom.

2.4.24 Cleaning of the cleaning equipment.

2.4.25 Periodic inspection and testing of cleanliness.

2.4.26 Any non-conformances found and the remedial action taken.

2.4.27 Vaccination status of the cleaning staff.

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

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

Section Seven: Environmental monitoring

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

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

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

2.4.31 Air may be sampled in two ways:

a. by passive settling of microbes using 90mm diameter ‘settle’ plates which contain either Tryptone Soya Agar (TSA) or Sabaroud Dextrose Agar (SDA).
Environmental cleaning

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

<table>
<thead>
<tr>
<th>Settle Plates</th>
<th>Tryptose soya agar (TSA)</th>
<th>Sabaroud Dextrose agar (SDA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target microbes</td>
<td>Broad range of bacteria, some yeasts and moulds</td>
<td>Mainly yeasts and moulds</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 - 4 hours</td>
<td>1 - 4 hours</td>
</tr>
<tr>
<td>Incubation temperature</td>
<td>30 -35°C</td>
<td>20 -25°C</td>
</tr>
<tr>
<td>Incubation time</td>
<td>3 days (5 days to show moulds)</td>
<td>5 days</td>
</tr>
<tr>
<td>Results reported as:</td>
<td>Colony-forming units/plate</td>
<td>Colony-forming units/plate</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th></th>
<th>Tryptose soya agar (TSA)</th>
<th>Scabrous Dextrose agar (SDA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target microbes</td>
<td>Broad range of bacteria, some yeasts and moulds</td>
<td>Mainly yeasts and moulds</td>
</tr>
<tr>
<td>Exposure volume</td>
<td>200 - 1000 litres</td>
<td>200 - 1000 litres</td>
</tr>
<tr>
<td>Incubation temperature</td>
<td>30 -35°C</td>
<td>20 -25°C</td>
</tr>
<tr>
<td>Incubation time</td>
<td>3 days (5 days to show moulds)</td>
<td>5 days</td>
</tr>
<tr>
<td>Results reported as:</td>
<td>Colony-forming units/m³ or 1000 per litres</td>
<td>Colony-forming units/m³ or per 1000 litres</td>
</tr>
</tbody>
</table>

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

Flat surfaces

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

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

Irregular surfaces

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

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

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

2.4.33 A monitoring plan (locations) of the sampling sites should be prepared.

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

Air flows

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

Sampling sites.

c. drawings of rooms should be prepared and sampling sites marked clearly on them using a simple numbering system such as S Series (S1, S2, S3 etc.) for settle plate locations, C Series for contact sample locations, A Series for active air sampling, W Series for water samples etc. The number of sites will vary with the size of the facility. Settle plates sampling locations should be close to areas where medical devices are handled and stored or at points of air inflow but should not interfere with normal work flow. Active air sampling locations should be in front of air inflows or areas of high activity. Contact sampling locations should be critical areas such as work surfaces, control panels and personal protective equipment.

d. a number of sampling locations may be chosen and identified on the plan but not all of these will be sampled regularly. Just a limited core number will sampled regularly to obtain baseline values whilst some may be sampled on a rotating programme.

2.4.34 A monitoring programme (frequency and timing sampling) should be prepared. This will define when the samples are to be taken. A typical programme for a Class 8 facility are as follows:

a. settle plates carried out every month.

b. contact plates carried out weekly.

c. active air sampling ideally should be carried out monthly (where a sampler is available).

d. additional sampling rounds may occur in response to unusual circumstances e.g. breakdown in air supply, maintenance of ventilation system.

e. part of the sampling programme should be carried out when the facility is unoccupied to achieve a baseline contamination level prior to active sampling.

2.4.35 Monitoring results should be used to plot simple graphs to determine baselines and trends (these should cover a 12 month period).
2.4.36 ‘Alert’ limits and ‘action’ limits should be adopted for the respective sampling sites.

a. Environmental monitoring should be used as an early warning system to alert staff when environmental quality is drifting out of control. Any formal environmental-monitoring system requires the establishment of alert and action levels (threshold numbers of viable microbial colony forming units (CFUs) that indicate a facility's loss of control). The absolute CFU value has limited scientific meaning but is used to identify adverse trends and deviations from a known baseline of microorganisms within controlled an environment. Each healthcare organisation should have its own unique baseline patterns.

b. The limit values chosen should be based on averaged values achieved over at least a six month or twelve month period.

c. **Alert level** – CFU levels that, when exceeded, signal a possible deviation from normal operating conditions and may not require action, but may need to be monitored more closely.

d. **Action level** – CFU levels that, when exceeded, indicate a deviation from normal operating conditions and require immediate action.

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

<table>
<thead>
<tr>
<th></th>
<th>Contact plate CFU/plate</th>
<th>Settle plate CFU/plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 8 Alert</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Class 8 Action</td>
<td>30 (floor counts)</td>
<td>20</td>
</tr>
<tr>
<td>Class 7 Alert</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Class 7 Action</td>
<td>5 (10 floor) (20 floor, dirty side)</td>
<td>5</td>
</tr>
</tbody>
</table>

2.4.37 Investigation procedures and corrective actions should be prepared for response to breaches of action limits. Guidance may be sought from a microbiologist concerning the type of microorganisms present on the plates which may help assess risk or may point to a contamination source. It is also important to know if disinfectants in use are effective against these and at what concentration.
Environmental cleaning

2.4.38 Investigation should include the following checks:

a. that all control samples gave appropriate results. This could include checking that plate media were within expiry date, were not excessively wet or dry or contaminated prior to use.

b. do counts when area is unmanned show similar patterns?

c. any unusual activity or circumstances prior to and including sampling time.

d. any possibility of abuse of samples in transit (not inverted, open lids, damaged etc).

e. any maintenance work undertaken e.g. changing or adjusting air filters.

f. any malfunction of the air handling system.

g. any problems with water quality.

h. any problems with cleaning equipment.

i. are disinfectants or detergents free from contamination?

j. have shoes and PPE been checked for contamination?
3. Decontamination equipment

3.1 Introduction

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

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

3.2 Scope

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

3.3 Contents

Section One: Specialist group
Section Two: Manual washing
Section Three: Ultrasonic cleaning
Section Four: Washer-disinfacters
Section Five: Steam sterilisers
Section Six: Low temperature sterilisers
Section Seven: Drying cabinets
Section Eight: Heat sealers
3.4 Procedure

Section One: Specialist group

3.4.1 Each organisation should have a specialist group in place to consider the decontamination equipment in the healthcare organisation with regard to the following:

a. ability to meet current standards.

b. age and condition of equipment and availability of replacement parts.

c. cost of maintaining, repairing and replacing the equipment.

3.4.2 Key representatives on the specialist group should include:

a. Decontamination Coordinator.

b. Decontamination Unit Manager, e.g. Endoscope Reprocessing (Decontamination) Unit Manager.

c. Clinical Unit Manager, e.g. Theatre Manager.

d. Infection Prevention and Control Co-ordinator


f. Procurement.
3.4.3 The group may also include as required:


b. Materials Management.

c. Finance Manager/Budget Holder/Business Manager.

d. Other relevant experts (Qualified Person (decontamination)/Sterivigilance personnel/Microbiologist).

3.4.4 The specialist group should identify all decontamination equipment which needs to be replaced.

3.4.5 The specialist group should formulate a plan to replace or upgrade this equipment.

3.4.6 The plan should be submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer).

3.4.7 There should be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).

3.4.8 There should be clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and day to day operation of decontamination equipment.

3.4.9 The operational management of each item of decontamination equipment should be the defined responsibility of a named person (usually the decontamination unit manager).

3.4.10 Validation and periodic testing should be carried out by qualified personnel (decontamination).

3.4.11 The validation and periodic testing data should be adequately audited quarterly by a qualified person (decontamination).

3.4.12 The department should have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.
Decontamination equipment

Section Two: Manual washing

3.4.13 Manual washing should be used only when required by manufacturers’ instructions or as a pre-treatment prior to reprocessing through a washer-disinfector.

3.4.14 Dedicated manual cleaning equipment and accessories should be available for specified RIMD that cannot be cleaned in an automated cleaning process.

3.4.15 Separate sinks for washing and rinsing should be provided.

3.4.16 The detergent used should be one specified by the manufacturer as being suitable for manual cleaning of RIMD and compatible with the manufacturers’ instructions for the RIMD being cleaned.

3.4.17 Means should be provided to control the concentration of detergent.

(Note: An automated dispenser is preferable.)

3.4.18 A pass-through drying cabinet with inter-locking doors should be provided for hot-air drying of manually washed RIMD that cannot be processed through a washer-disinfector.

Section Three: Ultrasonic cleaning

3.4.19 A stand-alone ultrasonic cleaner should be provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers’ instructions or as a pre-treatment for RIMD prior to processing through a washer-disinfector.

3.4.20 The ultrasonic cleaner should be equipped with the facility for automatic filling and emptying directly to the drain.

3.4.21 The ultrasonic cleaner should be fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.

3.4.22 The detergent used should be one specified by the manufacturer as being suitable for the ultrasonic cleaning of RIMD.

3.4.23 Means should be provided to control the concentration of detergent.

3.4.24 The ultrasonic cleaner should be used in accordance with the manufacturers’ instructions.
Decontamination equipment

3.4.25 The ultrasonic cleaner and accessories should be specified, installed, validated, commissioned and operated in accordance with EN ISO 15883, parts 1,2 & 5.

3.4.26 The ultrasonic cleaner shall be subject to periodic testing in accordance with EN ISO 15833, parts 1,2, & 5.

3.4.27 The ultrasonic cleaner should be subject to a planned preventative maintenance programme in accordance with the manufacturers’ recommendations.

Section Four: Washer-disinfectors

3.4.28 The specification of the washer-disinfector should comply with requirements of EN ISO 15883, parts 1 & 2.

3.4.29 Washer-disinfectors should be double ended with the clean side discharging into a designated area of the clean room, inspection, assembly and packaging room (IAP).

3.4.30 Each washer-disinfector should be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.

3.4.31 When lumened devices are being reprocessed, the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.

3.4.32 Washer-disinfectors and accessories should be specified, installed, validated, commissioned, and operated in accordance with EN ISO 15883, parts 1, 2 & 5.

3.4.33 The washer-disinfector should be subject to periodic testing in accordance with EN ISO 15883, parts 1, 2 & 5.

3.4.34 The washer-disinfector should be subject to a planned preventative maintenance programme in accordance with the manufacturers’ recommendations.
Decontamination equipment

Section Five: Steam sterilisers

3.4.35 The specification of the steam steriliser should comply with requirements of EN 285 and the steriliser should be fitted with an air-detector.

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

3.4.36 Each steam steriliser should be fitted with a process monitoring system independent of the automatic controller.

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

3.4.38 Steam sterilisers should be double ended with the loading side in the clean room, inspection, assembly and packaging room (IAP).

3.4.39 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.

3.4.40 The steam sterilisers should be subject to a planned preventative maintenance programme in accordance with the manufacturers’ recommendations.

Section Six: Low temperature sterilisers

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

3.4.42 Low temperature sterilisation should be carried out using vapour phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma processes.

(Note: The low temperature sterilisation process must be compatible with the device for processing.)

3.4.43 Low temperature sterilisation methods should be validated and subject to periodic testing in accordance with EN ISO 14937. Where EN ISO 14937 does not detail specific periodic tests these should be undertaken in accordance with manufacturers’ recommendations.
Decontamination equipment

3.4.44 Low temperature sterilisers should be subject to planned preventative maintenance in accordance with manufacturers’ instructions and at the manufacturers’ recommended frequencies.

Section Seven: Drying cabinets

3.4.45 Where a pass through washer-disinfector is not available, a pass-through drying cabinet between the wash-room and the clean room, inspection, assembly and packaging (IAP) room should be provided. The doors of the drying cabinet should be interlocked to prevent direct connection between the wash room and the clean room, Inspection, assembly and packaging room.

3.4.46 The drying cabinet should be fitted with a temperature indicator and/or recorder independent of the controller.

3.4.47 The drying temperature throughout the cabinet should be within ±5º Celsius of the set temperature. Or in accordance with drying cabinet /flexible scope manufacturers recommendation.

3.4.48 The drying cabinet should be fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than 10º Celsius the heating source is isolated.

3.4.49 The air in the cabinet should be mechanically circulated and items placed throughout the cabinet should be dried uniformly.

3.4.50 The drying cabinet should be subject to a planned preventative maintenance programme in accordance with the manufacturers’ recommendations.

Section Eight: Heat sealers

3.4.51 Where heat seal packaging is to be used, a rotary heat sealer should be provided.

3.4.52 Heat-sealing equipment used as part of the terminal packaging process should be maintained and tested to manufacturer’s performance criteria.

3.4.53 The heat sealer should be validated and tested daily to verify the efficacy of the seal.

3.4.54 The heat sealer should be subject to a planned preventative maintenance programme in accordance with manufacturers’ recommendations.
Procurement of reusable invasive medical devices (RIMD)

4. Procurement of reusable invasive medical devices (RIMD)

4.1 Introduction

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

4.2 Scope

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

4.3 Contents

Section One: Specialist group
Section Two: Procurement policy
Section Three: Specification
Section Four: General principles

4.4 Procedure

Section One: Specialist group

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

**Section Two: Procurement policy**

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

**Section Three: Specification**

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

**Section Four: General principles**

4.4.4 Sufficient RIMD and accessories should be purchased to allow adequate time for reprocessing in the decontamination unit(s) without adversely affecting throughput.

4.4.5 A decontamination assessment should be undertaken prior to the purchase of RIMD to ensure that the healthcare organisation has the facilities to reprocess the RIMD in accordance with the manufacturers’ instructions.

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

4.4.6 Value for money issues should be considered when purchasing RIMD.

4.4.7 All RIMD and accessories should be Medical Device Directive CE marked as this will constitute the manufacturer’s assurance that a device will be safe and will perform as intended.

4.4.8 Suppliers should be selected based on their ability to supply RIMD in accordance with the specified requirements and ability to provide service support over the lifetime of the RIMD, where applicable.

4.4.9 Where parts are single-use or have restricted use, this information should be provided prior to purchasing.

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**Note:** The lifecycle diagram used in this document is © Crown Copyright. Source—Department of Health, United Kingdom.
Manufacturers’ instructions

5. Manufacturers’ instructions

5.1 Introduction

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

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

5.2 Scope

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

5.3 Contents

Manufacturer

Section One: Requirements to be met by the RIMD manufacturer

Section Two: Label

Section Three: The instructions for use

Section Four: Precautions and contraindications

Section Five: Information supplied on request

Procedure for packs or sets in the central decontamination unit

Section Six: Label

Section Seven: Instructions for use
5.4 Procedure

Manufacturer

Section One: Requirements to be met by the RIMD manufacturer

5.4.1 If the RIMD is intended by the manufacturer to be reused, the following information should be provided in English:

a. appropriate processes to allow reuse, including cleaning, disinfection, packaging and (if appropriate), the methods of sterilisation of the RIMD to be resterilised.

b. the number of reuses.

c. any restriction to the reuse.

5.4.2 If the RIMD is supplied with the intention that it can be sterilised before use, instructions for sterilisation methods should be provided.

5.4.3 If the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas should be provided.

5.4.4 Instructions for use should be included in the packaging of every RIMD. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to the harmonised European Standards. In areas for which no Standards exist, the symbols and colours should be described in the documentation supplied with the RIMD.

5.4.5 The degree of accuracy claimed for RIMD with a measuring function should be provided.

5.4.6 If the intended purpose of the RIMD is not obvious to the user, the manufacturer should clearly state the intended purpose on the label and in the instructions for use.

5.4.7 Detachable components of the RIMD should be identified.

5.4.8 Action to detect any potential risk posed by the RIMD and detachable components should be provided.
Manufacturers’ instructions

5.4.9 Where parts are single use or have restricted use, this information should be provided.

5.4.10 Technical/user training should be provided by the manufacturer and training records maintained.

Section Two: Label

The label should contain the following details:

5.4.11 The name or trade name and address of the manufacturer.

5.4.12 The details strictly necessary for the user to identify the RIMD and the contents of the packaging.

5.4.13 Where appropriate, the word ‘STERILE’.

5.4.14 Where appropriate, the batch code preceded by the word ‘LOT’, or the serial number.

5.4.15 Where appropriate, an indication of the date by which the RIMD should be used, in safety, stating the month and the year.

5.4.16 Where appropriate, an indication that the medical device is for single use.

5.4.17 If the RIMD is custom-made, the words ‘custom-made RIMD’.

5.4.18 If the RIMD is intended for clinical investigations, the words ‘exclusively for clinical investigations’.

5.4.19 Any special storage and/or handling conditions.

5.4.20 Any special operating instructions.

5.4.21 Any warnings and/or precautions to be taken.

5.4.22 Year of manufacture.

5.4.23 Batch or serial number.

5.4.24 Where applicable, method of sterilisation.
Manufacturers’ instructions

5.4.25 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

Section Three: The instructions for use

The instructions for use should contain the following particulars:

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

5.4.27 All the information needed to verify whether the RIMD is properly installed and can be operated correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the RIMD operate properly and safely at all times should be provided.

5.4.28 Where appropriate, information to avoid certain risks in connection with the implantation of the RIMD should be provided.

5.4.29 Information regarding the risks of reciprocal interference posed by the presence of the RIMD during specific investigations or treatment.

5.4.30 The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of resterilisation.

5.4.31 If the medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the RIMD to be resterilised, and any restriction on the number of reuses.

5.4.32 Details of any further treatment or handling needed before the RIMD can be used (for example, sterilisation, final assembly, etc).

5.4.33 In the case of RIMDs emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.
Manufacturers’ instructions

Section Four: Precautions and contraindications

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

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

5.4.35 Precautions should be taken as regards exposure, in reasonably foreseeable environmental conditions; to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.

5.4.36 Adequate information regarding the medicinal product or products which the RIMD in question is designed to administer, including any limitations in the choice of substances to be delivered.

5.4.37 Precautions should be taken against any special, unusual risks related to the disposal of the RIMD.

Section Five: Information supplied on request

5.4.38 The identity or information on the test methods used.

5.4.39 If the manufacturer differentiates between critical and less critical areas of the product, the rationale for this distinction.

Procedures for packs or sets in the central decontamination unit

Section Six: Label

The label should contain the following details:

5.4.40 The name or trade name and address of the central decontamination unit.

5.4.41 The details strictly necessary for the user to identify the contents of the packaging.

5.4.42 Where appropriate, the word ‘STERILE’.

5.4.43 An indication of the date by which the RIMD should be used, in safety, stating the month and the year.
Manufacturers’ instructions

5.4.44 Any special storage and/or handling conditions.

5.4.45 Reference to any special operating instructions, warnings and/or precautions to be taken.

5.4.46 Year of manufacture.

5.4.47 Batch or serial number.

5.4.48 Where applicable, method of sterilisation.

Section Seven: Instructions for use

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

6.1 Introduction

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

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

6.2 Scope

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

6.3 Contents

Decontamination unit

Section One: Attire

Gowning for entry to the wash area

Section Two: Head/hair cover

Section Three: Protection for eyes/nose and mouth

Section Four: Protection for skin and clothing
Personal protective equipment

Section Five: Gloves

Section Six: Footwear

6.4 Procedure

Decontamination unit

Section One: Attire

6.4.1 All personnel working in the decontamination unit should wear freshly laundered low linting attire. (Low linting attire minimises bacterial shedding and provides comfort and professional appearance should be selected).

6.4.2 Freshly laundered attire should be changed daily or whenever it becomes visibly soiled or wet.

6.4.3 Staff who are involved in the maintenance of decontamination equipment should be required to wear the same type of clothing as other personnel working in the department.

6.4.4 On leaving the decontamination unit, staff should change into their normal day wear.

6.4.5 After use, the attire should be discarded appropriately in a designated post use container/bag.

6.4.6 Hands should be decontaminated before leaving the changing area.

6.4.7 Work attire should never be worn outside the decontamination unit.

Gowning for entry to the wash room

Section Two: Head/hair cover

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

6.4.9 The hat or hood should be designed so that microbial dispersal is minimised.
Personal protective equipment

6.4.10 All hair should be confined as well as covered.

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

6.4.12 Stud earrings may be worn and should be totally confined within the head cover.

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

Section Three: Protection for eyes /nose and mouth

6.4.13 Healthcare workers should wear single use PPE to reduce the risk of body fluid exposure from splashing and spraying of blood or body fluids, protection for eyes/ nose and mouth should include the following:

a. face shield that covers the eyes, nose, mouth and chin.

b. fluid repellent mask and separate goggles.

c. fluid repellent mask with integrated eye shield.

6.4.14 Goggles, masks and face shields should be:

a. single-use.

b. fitted and worn according to the manufacturers’ instructions.

c. removed immediately if moist or visibly soiled and discarded in the appropriate healthcare waste stream.

6.4.15 Goggles, masks and face shields with integrated eye protection should be:

a. optically clear, antifog, distortion free, close fitting and shielded at the side.

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

(Note: All PPE should be discarded in the appropriate healthcare waste stream.)
Section Four: Protection for skin and clothing

6.4.16 Healthcare workers should wear plastic aprons or impermeable gowns with long cuffed sleeves and tuck-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.

6.4.17 Fluid repellent attire and aprons should be changed whenever they become visibly soiled or wet.

6.4.18 After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

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

Section Five: Gloves

6.4.19 Healthcare workers should decontaminate their hands before and after removing gloves by:

a. handwashing.

b. using alcohol gel.

(Note: Alcohol gel should not be used on visibly soiled hands.)

6.4.20 Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.

6.4.21 Gloves should be:

a. used for handling contaminated RIMD, waste and when performing environmental cleaning activities.

b. selected and worn according to the task and if torn or perforated.

6.4.22 When removing gloves:

a. the outer surface of the gloves should not come into contact with skin.

b. avoid letting the gloves snap, as this may cause contaminates to splash into eyes or mouth or onto skin or other personnel in the area.
Personal protective equipment

6.4.23 After use, gloves should be discarded in the appropriate healthcare waste stream.

6.4.24 It is important to remove used gloves and decontaminate hands before touching a clean surface such as worktops, or pens.

Section Six: Footwear

6.4.25 Healthcare workers should wear non-slip enclosed footwear that can protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally).

6.4.26 Footwear should be regularly cleaned and disinfected.

6.4.27 Footwear should be appropriate to the area in which healthcare worker is designated.

Figure 6-1: Personal protective equipment (decontamination unit)
Clean room, inspection, assembly and packaging room (IAP) attire and behaviour

7. Clean room, inspection, assembly and packaging room (IAP) attire and behaviour

7.1 Introduction

Protective clothing should be worn by personnel entering the clean room, inspection, assembly and packaging room to reduce the risk of adventitious contamination of the clean product. Managers should 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 recommended practice is to outline the attire to be worn and the behaviour to be adopted by staff in the clean room, inspection, assembly and packaging 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

7.4.1 Healthcare Workers (HCWs) working in the clean room, inspection, assembly and packaging room (IAP) should wear a freshly laundered scrub suit.

7.4.2 Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
Clean room, inspection, assembly and packaging room (IAP) attire and behaviour

7.4.3   Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet.

7.4.4   Appropriate clothing should be used by staff who are involved in the maintenance of reprocessing equipment.

7.4.5   When working outside the decontamination area suitable cover attire should be worn.

Section Two: Head/hair cover

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

7.4.7   The hat or hood should be designed so that microbial dispersal is minimised.

7.4.8   All hair should be confined as well as covered.

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

7.4.10  Stud earrings may be worn and should be totally confined within the head cover.

7.4.11  Make-up and jewellery should not be worn in the clean room/inspection, assembly and packaging room.
Clean room, inspection, assembly and packaging room (IAP) attire and behaviour

Figure 7-1: Personal protective equipment (clean room, inspection, assembly and packaging room)
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. (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).

8.2 Scope

The objective of this recommended practice 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

8.4.1 Process chemicals should be chosen to be compatible with:

a. the RIMD to be processed.

b. the decontamination equipment to be used and the intended use of the RIMD.

c. the least hazardous chemical that will fulfil a process requirement should be chosen.

Section Two: Control of process chemicals

8.4.2 The methods to be used for handling and storage of process chemicals should be defined in written policies, procedures, protocols and guidelines.

8.4.3 Chemicals that should not be stored together should be clearly identified.

8.4.4 Chemicals should not be stored above shoulder height.

8.4.5 Chemicals should be stored in locked cabinet.

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

8.4.6 Suppliers of chemical agents should provide MSDS for all chemical agents (including cleaning agents).

8.4.7 Copies of all MSDS should be available to all employees in a designated area at all times, so that appropriate action can be taken in case of exposure to a hazardous substance.

8.4.8 If information is incorporated into policies, procedures, protocols and guidelines the original wording should be used and the MSDS referred to.

8.4.9 Personnel should read and follow the precautions and instructions given on the MSDS and on the label prior to handling and use.
Process chemicals

Section Four: Training

8.4.10 All personnel who handle chemicals e.g. detergents, rinse aid, disinfectants, etc should be trained in following:

a. safe handling of chemicals.
b. method of cleaning process chemical spillages.
c. first aid required in the event of personal exposure.
d. correct disposal of material used.

Section Five: Spillage kit

8.4.11 In each area where chemicals are used, a spillage kit should be available to allow safe and easy removal of spills.

8.4.12 A first aid eye wash station should be available nearby or on hand.

8.4.13 Where chemicals may contact eyes/skin, consideration should be given to the availability of chemical neutralisation within the department. (e.g. the hypertonic, polyvalent, amphoteric compound DipHoterine can be used to neutralise and inactivate up to 600 chemicals, including spills on environmental surfaces and inadvertent chemical contact with skin, eyes or mucous membranes).
9. Traceability

9.1 Introduction

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

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

The tracing system should permit retrospective tracing of the RIMD history including the service user on which the RIMD 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 recommended practice is to provide guidelines for the effective tracking and traceability of RIMD through the decontamination life-cycle ensuring that an effective audit trail can be created to service user use.

9.3 Contents

Section One: Processing

Section Two: Tracing
Traceability

9.4 Procedure

Section One: Processing

9.4.1 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.

9.4.2 Records should be maintained of:
   a. the cleaning, disinfection and sterilisation process cycle used.
   b. the name of the person undertaking each stage of the decontamination process.
   c. the date, time and test result.
   d. details of the RIMD being processed.

9.4.3 As a minimum, sets of RIMD should be individually identified with a Global Standard 1 (GS1) Global Individual Asset Identifier (GIAI) code.

9.4.4 Identification of all 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).

(Note: For sites reprocessing RIMD used in identified high risk procedures, single use instrument tracking at set and supplementary level is required.)

9.4.5 IT based systems are preferred. Manually based systems should only be used for small units with a very low turn-over or for back-up in the event of IT failure. The IT systems selected to track RIMD should be capable of maintaining traceability for items that have been loaned from commercial organisations of other healthcare organisations utilising the unique coding of that set or item.

9.4.6 Records relating to decontamination processes should be maintained for the lifetime of the RIMD/decontamination equipment plus eleven years.
Section Two: Tracing

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

10.1 Introduction

To prevent cross infection, all RIMD that come into contact with the service user 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 recommended practice is to provide guidelines on the choice of decontamination processes.

10.3 Contents

Section One: General principles

10.4 Procedure

Section One: General principles

10.4.1 RIMD should be reprocessed to a level appropriate for their intended use. The appropriate level depends on the body sites where the RIMD will be used and the risk associated with a particular procedure.

10.4.2 The minimum levels of processing and storage requirements for RIMD, based on three risk categories of use, are shown in the Spaulding Classification (see overleaf). In brief, the minimum levels of reprocessing are as follows for different types of site:
Choice of decontamination process

a. **Critical site** — RIMD should be sterile at the time of use. This means RIMD should be single use, should be steam sterilised (for RIMD that are capable of withstanding heat), or should have undergone low temperature sterilisation.

b. **Semicritical site** — RIMD should be single use or sterilised after each use. If this is not possible, high-level disinfection is the minimum level of reprocessing that is acceptable.

c. **Noncritical site** — cleaning alone is generally sufficient for all noncritical items after every individual use, although either intermediate or low-level disinfection may be appropriate in specific circumstances.

10.4.3 Decontamination processes should be chosen to be compatible with the RIMD to be processed.

10.4.4 Decontamination processes should be chosen to be capable of providing not less than the standard of decontamination required for the clinical procedures to be undertaken.

10.4.5 Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.

10.4.6 Decontamination processes should be chosen to be amenable to independent verification of the decontamination standards achieved.

10.4.7 The decontamination methods selected should be economical and effective.

10.4.8 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 recommended practice is to provide guidelines in relation to the transportation of contaminated RIMD.

11.3 Contents

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

Section Two: Containers and trolleys

Section Three: Staff

11.4 Procedure

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

11.4.1 Recommendations regarding the transport of contaminated surgical RIMD with reference to the ‘Agreement on Dangerous Goods by Road European Agreement Concerning the International Carriage of Dangerous Goods by road regulations 2009’. Therefore the following advice should be adhered to when transporting contaminated RIMD for reprocessing.
**Transportation—return of used items for reprocessing**

**Scenario 1:**

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

ADR 2.2.62.1.5.1

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

**Scenario 2:**

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

ADR 2.2.62.1.5.3

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

**Scenario 3:**

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

Note: The lifecycle diagram used in this document is © Crown Copyright. Source—Department of Health, United Kingdom.
Transportation—return of used items for reprocessing

Section Two: Containers and trolleys

11.4.5 Contaminated RIMD should be placed in closed, sealed, secure containers/trolleys (transport containers) and transported to the wash room as soon as possible after use. Transport containers should protect both the product during transit and the handler from inadvertent contamination.

11.4.6 Bins with lids and closed sterilisation container systems are among the types of containers that may be used to transport contaminated items.

11.4.7 Impermeable bags should be used also to contain RIMD within the container.

11.4.8 Containers should be selected based on the characteristics of the items being transported; in particular they should be:
   a. leak-proof.
   b. rigid, to contain RIMD, preventing them becoming a hazard to anyone handling the goods and to protect them against accidental damage.
   c. capable of being closed securely.
   d. lockable, where appropriate, to prevent tampering.
   e. clearly labelled to identify the user and the contents where applicable.
   f. robust enough to prevent RIMD being damaged in transit.
   g. have the ability to be easily cleaned, disinfected and dried, or discarded (as appropriate) using agreed methods.

11.4.9 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.

11.4.10 RIMD/RIMD sets should be separated from healthcare risk waste at the point of use.

11.4.11 Sharps should be removed and placed into approved containers conforming to BS 7320 (1990).

11.4.12 Reusable textiles should be held in appropriate linen bags and returned to the laundry service.
Transportation—return of used items for reprocessing

11.4.13 All fluids, e.g. blood, bodily fluids, cleaning and antiseptic solutions should be disposed of before placing RIMD in transport containers.

11.4.14 All transportation equipment has to be cleaned in accordance with local policy.

Section Three: Staff

11.4.15 Personnel should be trained to handle, collect and transport contaminated RIMD/RIMD sets and should wear personal protective equipment (PPE) in accordance with local safety policies, procedures, protocols and guidelines.

11.4.16 Policies, procedures, protocols and guidelines for transportation (return of used items for reprocessing) of contaminated RIMD/RIMD sets should be developed, reviewed periodically, and readily available within the department.

Figure 11-1: Transportation—return of used items for reprocessing
12. Sorting and disassembly of contaminated reusable invasive medical devices (RIMD)

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 recommended practice 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

12.4.1 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.

12.4.2 Policies, procedures, protocols and guidelines should be developed for the handling, sorting and disassembly of RIMD.
Sorting and disassembly of contaminated reusable invasive medical devices (RIMD)

12.4.3 There should be written policies, procedures, protocols and guidelines for handling specialised items.

12.4.4 Care and handling of RIMD should be in accordance with manufacturers’ instructions and healthcare organisation policies, procedures, protocols and guidelines.

Section Two: Disassembly of RIMD

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

12.4.5 Open RIMD box locks.

12.4.6 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.

12.4.7 Arrange RIMD in an orderly fashion in mesh trays so that all surfaces are exposed to the action of an automated cleaner, if used.

12.4.8 Place each jointed RIMD in the open position in the mesh basket.

12.4.9 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.

12.4.10 Place heavy retractors and/or other heavy RIMD on the bottom or in a separate tray.

12.4.11 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, lightweight RIMD, and microsurgical RIMD next.

12.4.12 Receivers and gallipots should not be placed over RIMD, as they may interfere with the cleaning process.

12.4.13 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.

12.4.14 For RIMD with one or more lumens, each lumen should be connected to the appropriate flushing system provided for that purpose.
Sorting and disassembly of contaminated reusable invasive medical devices (RIMD)

Figure 12-1: Sorting and disassembly of contaminated RIMD
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 recommended practice 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
Cleaning (including pre-cleaning)

13.4 Procedure

Section One: Manufacturers’ instructions

13.4.1 The manufacturers’ instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the RIMD will tolerate immersion.

13.4.2 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 service user or personnel using the RIMD. (ISO, 17664).

Section Two: Automated versus manual cleaning

13.4.3 The use of mechanical cleaners such as washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.

13.4.4 The advantage of using automated cleaning equipment is that it provides an efficient, validated, reproducible process which can be more easily controlled than manual methods.

13.4.5 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

13.4.6 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.
Cleaning (including pre-cleaning)

Section Four: Automated cleaning

Washer-disinfectors

13.4.7 All washer-disinfectors used for decontamination of RIMD should conform to EN ISO 15883 parts 1, 2 and 5. The water for the final rinse stage should be purified water (prepared by reverse osmosis or deionisation) as this gives the lowest levels of process residuals.

13.4.8 Factors to be considered when determining if the RIMD is compatible with the washer-disinfector:

a. manufacturers’ instructions.

b. if the RIMD can be immersed in water. Or subject to a high pressure water spray as appropriate for the type of washer disinfecter being used.

c. maximum operating temperature.

d. mechanical damage which may occur from the impact of the water jets or other items in the load.

e. the compatibility of the process chemicals.

Equipment

13.4.9 See decontamination equipment section, page 51.

Procedure

13.4.10 Ensure the washer-disinfector and all services are operational. The washer-disinfector should not start if any anomalies are present.

13.4.11 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.

13.4.12 Only use load carrier and racks with the items for which they were intended.

13.4.13 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.

13.4.14 Load the load carrier into the washer-disinfector.
### Cleaning (including pre-cleaning)

13.4.15 Secure the door (if fitted), select and start the cycle.

13.4.16 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.

13.4.17 A typical cycle comprises the following phases:

a. cold rinse.

b. warm wash.

c. rinse.

d. disinfection rinse.

e. drying.

13.4.18 Information should be recorded for each washer-disinfector cycle. Documentation is required for every washer-disinfector cycle and should contain the following:

a. washer-disinfector identification or serial number.

b. cycle number.

c. type of washer-disinfector.

d. type of cycle used.

e. date and time of start of cycle.

f. load content e.g. general RIMD set, stitch set, mayo scissors.

g. critical parameters for the specific washer-disinfector cycle.

h. operator’s name.

i. results of washer-disinfector process.

j. signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters.

k. any notes or observation for the process cycle.

13.4.19 All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
Cleaning (including pre-cleaning)

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

13.4.21 Where single-ended washer-disinfectors are used adequate segregation of unprocessed goods from processed goods should take place.

13.4.22 Thermal disinfection conditions are defined as $A_0$ values (see EN ISO 15883-1, Annex B).
   a. For thermal disinfection of RIMD an $A_0$ of not less than 60 is required.
   b. All washer-disinfectors complying with EN ISO 15883-2 are required to be capable of providing for disinfection times and temperatures to give an $A_0$ value up to a maximum value of not less than 3000.
   c. Typical time-temperature relationships providing these values are shown in table 13-1 below.

<table>
<thead>
<tr>
<th>$A_0$ value</th>
<th>Temperature</th>
<th>Holding Time (Seconds)</th>
<th>Holding Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>80</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>60</td>
<td>90</td>
<td>6</td>
<td>-</td>
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<td>600</td>
<td>70</td>
<td>-</td>
<td>100</td>
</tr>
<tr>
<td>600</td>
<td>90</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>1200</td>
<td>93</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

Validation

13.4.23 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.
Cleaning (including pre-cleaning)

13.4.24 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.

13.4.25 Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications.

It is considered as a process which comprises of:

a. commissioning (installation qualification and operational qualification).

b. performance qualification.

c. periodic testing.

d. annual and revalidation tests.

Commissioning

13.4.26 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

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

Operational qualification tests

13.4.28 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.
Cleaning (including pre-cleaning)

13.4.29 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.

13.4.30 The tests should be carried out before the washer-disinfector is used for the first time. Installation and commissioning checks and tests should be performed by a qualified person (decontamination) or other person with specialist technical training in commissioning of washer-disinfector. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the washer-disinfector is functioning correctly.

13.4.31 Even though the manufacturer should have tested a washer-disinfector before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is working correctly and is performing correctly to specification.

Performance qualification

13.4.32 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 decontamination).

These tests consist of:

a. thermometric tests for a full load of items not previously represented by the reference load.

b. load dryness test (of RIMD requiring reprocessing).

c. cleaning efficacy test.

d. process residue test.

Periodic testing

13.4.33 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.

13.4.34 The daily, weekly and quarterly tests supply evidence that the washer-disinfector is still operating within the limits established during commissioning.
Cleaning (including pre-cleaning)

13.4.35 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.

13.4.36 Periodic tests consist of the following:

a. **Daily**: Spray arm rotation, spray nozzles, removes and clean strainers and filters.

b. **Weekly**: Automatic control test, safety checks, daily tests, water hardness, water conductivity and cleaning efficacy test (residual soil detection).

c. **Quarterly tests**: Weekly safety checks, automatic control test, verification of calibration of RIMD, thermometric test for thermal disinfection and cleaning efficacy test.

d. **Annual tests**: Yearly safety checks, automatic control test, verification of calibration of RIMD, water system, drainage, doors, door interlocks, fault interlocks, water vapour discharge, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, over-temperature cut-out, thermometric tests for thermal disinfection, load dryness test and process residues.
## Cleaning (including pre-cleaning)

Table 13.2 The following table identifies the minimum level of periodic testing that should be undertaken for washer-disinfectors:

<table>
<thead>
<tr>
<th>Test</th>
<th>EN ISO 15883 Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Daily Tests</strong></td>
<td></td>
</tr>
<tr>
<td>1. Check spray rotation for free movement</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages for instruments)</td>
<td>N/A</td>
</tr>
<tr>
<td>3. Remove and clean strainers and filters etc.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Weekly Tests</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly Safety Check</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Carry out daily tests</td>
<td>N/A</td>
</tr>
<tr>
<td>3. Water hardness (all process stages)</td>
<td>6.4.2.2</td>
</tr>
<tr>
<td>4. Water conductivity (final rinse stage)</td>
<td>6.4.2.2</td>
</tr>
<tr>
<td>5. Automatic control test</td>
<td>6.13</td>
</tr>
<tr>
<td>6. Cleaning Efficacy test by residual soil detection</td>
<td>6.10.3</td>
</tr>
<tr>
<td><strong>Quarterly tests</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly safety checks</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Automatic control tests</td>
<td>6.13</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>6.6.1</td>
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<tr>
<td>4. Thermometric test for thermal disinfection</td>
<td>6.8</td>
</tr>
<tr>
<td>5. Cleaning efficacy test</td>
<td>6.10.2 6.10.3</td>
</tr>
<tr>
<td><strong>Yearly and revalidation tests (Requalification in EN 15883 terminology)</strong></td>
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<td>1. Yearly safety checks</td>
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### Cleaning (including pre-cleaning)

<table>
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<tr>
<td>2. Automatic control tests</td>
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<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>6.6.1</td>
</tr>
<tr>
<td>4. Water system</td>
<td>6.4</td>
</tr>
<tr>
<td>-chemical purity</td>
<td>6.4.2.2</td>
</tr>
<tr>
<td>-bacterial endotoxins</td>
<td>6.4.2.3</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>-free draining</td>
<td>6.5.2</td>
</tr>
<tr>
<td>-efficacy of discharge</td>
<td>6.5.4</td>
</tr>
<tr>
<td>6. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>-cycle start</td>
<td>6.3.1</td>
</tr>
<tr>
<td>-in-cycle</td>
<td>6.3.2</td>
</tr>
<tr>
<td>-failed cycle</td>
<td>6.3.3</td>
</tr>
<tr>
<td>7. Fault interlock</td>
<td>6.3.5</td>
</tr>
<tr>
<td>8. Water vapour discharge test (fluid emission)</td>
<td>6.5.3</td>
</tr>
<tr>
<td>9. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>-reproducibility</td>
<td>6.9.1</td>
</tr>
<tr>
<td>-low level detection</td>
<td>6.9.2</td>
</tr>
<tr>
<td>10 Load carriers—alignment</td>
<td>6.7.1</td>
</tr>
<tr>
<td>11. Test for air quality</td>
<td>6.11</td>
</tr>
<tr>
<td>12. Cleaning Efficacy test</td>
<td>6.10.2</td>
</tr>
<tr>
<td>13. Over temperature cut-out test</td>
<td>6.10.3</td>
</tr>
<tr>
<td>14. Thermometric test for Thermal disinfection</td>
<td>6.8</td>
</tr>
<tr>
<td>15. Load dryness test</td>
<td>6.12</td>
</tr>
<tr>
<td>16. Process residues—chemical additives (for performance re-qualification only if required)</td>
<td>6.10.4</td>
</tr>
</tbody>
</table>
Cleaning (including pre-cleaning)

13.4.37 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, 2009.

13.4.38 Preventative maintenance should be planned and performed in accordance with International Standards EN ISO 15883-1 and EN ISO 15883-2 and the manufacturers’ recommendations.

13.4.39 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

13.4.40 The washer-disinfector should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.

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

13.4.42 Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.

13.4.43 Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers’ instructions and/or local policy, procedure, protocol and guidelines, including:

a. inspecting and cleaning all filters.

b. dismantling and cleaning spray arms and nozzles.

c. efficacy tests during operational conditions.
Cleaning (including pre-cleaning)

Figure 13-1: Washer-Disinfector

Figure 13-2: Loading the washer-disinfector
Cleaning (including pre-cleaning)

_Ultrasonic Cleaners_

13.4.44 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.

_Equipment Required_

13.4.45 See decontamination equipment, page 51.

_Procedure_

13.4.46 Staff should wear personal protective equipment at all times while handling contaminated RIMD and working with the ultrasonic cleaner.

13.4.47 Fill the tank to the manufacturers’ designated level; add the detergent solution as recommended by the manufacturer.

13.4.48 Bring the solution up to the operating temperature.

13.4.49 Degas the water as recommended by the manufacturer.

13.4.50 Place the opened/dismantled RIMD into the basket.

13.4.51 Ensure all RIMD are fully immersed.

13.4.52 If the RIMD is not for further cleaning, e.g. automated cleaning, record the following:
   a. method used.
   b. solution dilution and temperature.
   c. healthcare worker carrying out procedure.
   d. date.
   e. ultrasonic cleaner identification or serial number.

15.4.53 Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.
Cleaning (including pre-cleaning)

13.4.54 Close the lid and initiate the cleaning cycle.

13.4.55 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.

13.4.56 The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers’ instructions.

13.4.57 Combine only RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.

13.4.58 Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.

13.4.59 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.

Validation

13.4.60 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.

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

a. commissioning (installation qualification and operational qualification).

b. performance qualification.

c. periodic testing.

d. annual and revalidation tests.

Commissioning

13.4.62 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

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

Operational qualification tests

13.4.64 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.

13.4.65 These tests should be carried out when a new ultrasonic cleaner is purchased or when a used ultrasonic cleaner has been relocated to another premise.

13.4.66 Installation and commissioning checks and tests should be performed by a qualified person (decontamination) or other person with specialist technical training in commissioning of ultrasonic cleaner.

13.4.67 Even though the manufacturer should have tested the ultrasonic cleaner before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is working correctly.

Performance qualification

13.4.68 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 (decontamination).

These tests consist of:

a. cleaning efficacy test, load dryness test and process residues test.

b. load dryness test.

c. process residue test.
Cleaning (including pre-cleaning)

Periodic testing

13.4.69 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.

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

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

These tests consist of:

a. **Daily**: Remove and clean strainers and filters.

b. **Weekly**: Daily tests, automatic control test (if using an automated ultrasonic cleaner) safety checks, and cleaning efficacy test (residual soil detection).

c. **Quarterly tests**: Weekly safety checks, automatic control test, verification of calibration of RIMD, test for ultrasonic activity and cleaning efficacy test.

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

Table 13.3: The following table identifies the minimum level of periodic testing that should be undertaken for automated ultrasonic cleaner:

<table>
<thead>
<tr>
<th>Test</th>
<th>EN ISO 15883 Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Daily tests</strong></td>
<td></td>
</tr>
<tr>
<td>1. If fitted check spray arm rotation for free movement</td>
<td>N/A</td>
</tr>
<tr>
<td>2. If fitted check spray nozzles for blockage (paying particular attention to those fitted to carriages for instruments)</td>
<td>N/A</td>
</tr>
<tr>
<td>3. Remove and clean strainers and filters etc</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Weekly tests</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly safety checks</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Carry out daily tests</td>
<td>N/A</td>
</tr>
<tr>
<td>3. Automatic control test (if using an automated ultrasonic cleaner)</td>
<td>6.13</td>
</tr>
<tr>
<td>4. Cleaning efficacy test by residual soil detection</td>
<td>6.10.3</td>
</tr>
<tr>
<td><strong>Quarterly tests</strong></td>
<td></td>
</tr>
<tr>
<td>1. Weekly safety checks</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Automatic control test (if using an automated ultrasonic cleaner)</td>
<td>6.13</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>6.6.1</td>
</tr>
<tr>
<td>4. Test for ultrasonic activity*</td>
<td>6</td>
</tr>
<tr>
<td>5. Cleaning efficacy test</td>
<td>6.10.2 6.10.3</td>
</tr>
<tr>
<td><strong>Yearly and revalidation tests (Requalification in EN 15883 terminology)</strong></td>
<td></td>
</tr>
<tr>
<td>1. Yearly safety checks</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Automatic control tests</td>
<td>6.13</td>
</tr>
<tr>
<td>3. Verification of calibration of WD instruments</td>
<td>6.6.1</td>
</tr>
<tr>
<td>4. Water system</td>
<td>6.4</td>
</tr>
</tbody>
</table>
**Cleaning (including pre-cleaning)**

<table>
<thead>
<tr>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>chemical purity</td>
<td>6.4.2.2</td>
</tr>
<tr>
<td>bacterial endotoxins</td>
<td>6.4.2.3</td>
</tr>
<tr>
<td>5. Drainage</td>
<td></td>
</tr>
<tr>
<td>- free draining</td>
<td>6.5.2</td>
</tr>
<tr>
<td>- efficacy of discharge</td>
<td>6.5.4</td>
</tr>
<tr>
<td>6. Doors and door interlocks</td>
<td></td>
</tr>
<tr>
<td>- cycle start</td>
<td>6.3.1</td>
</tr>
<tr>
<td>- in-cycle</td>
<td>6.3.2</td>
</tr>
<tr>
<td>- failed cycle</td>
<td>6.3.3</td>
</tr>
<tr>
<td>7. Fault interlock</td>
<td>6.3.5</td>
</tr>
<tr>
<td>8. Water vapour discharge test (fluid emission)</td>
<td>6.5.3</td>
</tr>
<tr>
<td>9. Chemical additive dosing tests</td>
<td></td>
</tr>
<tr>
<td>- reproducibility</td>
<td>6.9.1</td>
</tr>
<tr>
<td>- low level detection</td>
<td>6.9.2</td>
</tr>
<tr>
<td>10. Load carriers- alignment (if load carriers are used)</td>
<td>6.7.1</td>
</tr>
<tr>
<td>11. Test for air quality (if a ventilation system is fitted)</td>
<td>6.11</td>
</tr>
<tr>
<td>12. Cleaning efficacy test</td>
<td>6.10.2, 6.10.3</td>
</tr>
<tr>
<td>13. Over temperature cut-out test (if using an automated ultrasonic cleaner)</td>
<td>6.8.5</td>
</tr>
<tr>
<td>14. Thermometric test for thermal disinfection (if a disinfection stage is fitted)</td>
<td>6.8</td>
</tr>
<tr>
<td>15. Load dryness test (if a drying stage is fitted)</td>
<td>6.12</td>
</tr>
<tr>
<td>16. Test for ultrasonic activity*</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

Monitoring and control

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

Maintenance

13.4.73 Preventative maintenance should be planned and performed in accordance with documented procedures as recommended by the manufacturers’ recommendations.

13.4.74 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

13.4.75 The ultrasonic cleaner should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.

13.4.76 A qualified person (decontamination) should review the maintenance plan, main procedures and maintenance records periodically.

Test for Ultrasonic Activity (reference HTM 2030)

13.4.77 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

13.4.78 Aluminium foil (sold as aluminium foil wrap for cooking).

13.4.79 Steriliser indicator tape.

13.4.80 Stopwatch.

13.4.81 Ruler/tape measure graduated in mm.
**Cleaning (including pre-cleaning)**

**Method**

13.4.82 Measure the depth of the bath from the level of the lid to the bottom of the bath.

13.4.83 Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.

13.4.84 Carry out the manufacturer’s recommended start-up procedure.

13.4.85 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.

13.4.86 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.

13.4.87 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.

13.4.88 Operate the bath for the predetermined exposure time.

13.4.89 Remove the strips from the bath, blot dry and examine.

13.4.90 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).

13.4.91 On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

**Section Five: Manual cleaning**

**Immersion**

**Introduction**

13.4.92 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.
Cleaning (including pre-cleaning)

Equipment required

13.4.93 A separate 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.

13.4.94 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

13.4.95 A validated method of dispensing a measured quantity of detergent.

13.4.96 A method of controlling temperature of the water in the wash and rinse sinks: thermostatic mixer taps are preferred.

13.4.97 A warm detergent solution. (Follow manufacturers’ instructions for dilution and temperature).

13.4.98 A selection of brushes in a range of diameters and lengths for cleaning both the external surfaces and the internal surfaces of RIMD.

13.4.99 After cleaning, manually washed RIMD that are not to be further processed through the washer-disinfector should be dried.
Cleaning (including pre-cleaning)

13.4.100 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.

Procedure

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

13.4.102 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 RIMD and not for any other purpose.

13.4.103 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).

13.4.104 Detergent dilution and water temperature should be in accordance with the manufacturers’ instructions and local policies, procedures, protocols and guidelines.

13.4.105 Consideration should be given to the use of an enzymatic detergent to facilitate the cleaning of RIMD with channels or complex parts.

13.4.106 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.

13.4.107 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.

13.4.108 Flush all lumened RIMD with a jet-gun (discharge under water).

13.4.109 Rinse the item finally in warm-to-hot water (unless contra-indicated).

13.4.110 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.)

13.4.111 Inspect RIMD and equipment to establish that they are clean before further processing or storage.

13.4.112 Thoroughly wash and dry receptacles before storing and re-use.
Cleaning (including pre-cleaning)

13.4.113 Cleaning brushes should be identified for cleaning only and should be washed, thermally disinfected, and stored dry.

13.4.114 A record should be kept of each RIMD/RIMD set that has been manually cleaned.

13.4.115 The records should contain:
   a. name of RIMD/RIMD set.
   b. name of processor.
   c. date.
   d. type of cleaning.
   e. type of detergent and detergent dilution used.

Monitoring and control

13.4.116 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.

13.4.117 For manual washing, these include:
   a. staff training/competence.
   b. water temperature.
   c. detergent concentration.
   d. nature of soil.
   e. method of soil removal.
   f. accessibility of fluid to item.

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

Maintenance

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

Non-immersion

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

Equipment required

13.4.120 A warm detergent solution. Follow manufacturers’ instructions for dilution and temperature.

13.4.121 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.

Procedure

13.4.122 If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.

13.4.123 Wearing protective clothing immerse the cleaning cloth in the detergent solution and wring thoroughly.

13.4.124 Commencing with the upper surface of the RIMD, wipe thoroughly ensuring that the detergent solution does not enter electrical components.

13.4.125 Periodically rinse the cloth in clean water and repeat the previous two steps.

13.4.126 Remove detergent solution using clean, damp, non-linting cloth.

13.4.127 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)

**Monitoring and control**

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

*For manual washing, these include:*

a.  staff training/competence.

b.  water temperature.

c.  detergent concentration.

d.  nature of soil.

e.  method of soil removal.

f.  accessibility of fluid to item.
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 recommended practice 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

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

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

Section Two: Disinfection process

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

14.4.4 **Chemical disinfection** can be achieved with a compatible RIMD-grade disinfectant of the required level, used alone or in conjunction with a chemical washer–disinfector.

14.4.5 Disinfection should be carried out using a thermal disinfection process whenever practicable. Chemical disinfection should be employed only when required by the RIMD manufacturers’ instructions.

**Thermal Disinfection**

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

**Equipment required**

14.4.7 Automated equipment, such as washer–disinfectors are recommended for use in thermal disinfection processes.

14.4.8 The level of disinfection depends on the water temperature and the exposure time. Thermal washer–disinfectors can be programmed to deliver a range of disinfection levels, depending on the cycle selected (i.e. set temperature and exposure times).

14.4.9 The manufacturers’ instructions should be followed to achieve the required level of disinfection.

**Monitoring and control**

14.4.10 Whenever practicable, disinfection should be carried out using a validated disinfection process using automated equipment (e.g. washer-disinfector).

14.4.11 Thermal disinfection equipment should be provided with means to independently monitor and/or record the time for which the load was exposed to the required temperature.

14.4.12 The thermal disinfection process should provide adequate assurance of the required microbial lethality.
**Disinfection**

*Chemical Disinfection*

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

**Equipment required**

14.4.14 RIMD disinfectant or sterilant.

14.4.15 Automated equipment.

**Monitoring and control**

14.4.16 Chemical disinfection processes should provide adequate assurance of the required microbial lethality.

14.4.17 Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.

14.4.18 Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.

14.4.19 All surfaces should be immersed and channels flushed whether manually or automatically to ensure the solution is present within the channels during ensuring the decontamination process.

14.4.20 Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.

14.4.21 After chemical disinfection RIMD should be free from toxic residues and should be rinsed free from disinfectant with purified water free from microbial contamination. The quality of water used should be appropriate to the clinical procedures being undertaken.

14.4.22 When rinsing, channels should be flushed thoroughly if rinsing is performed manually.
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 recommended practice 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

15.4.1 See decontamination equipment, page 51.

Section Two: Procedure

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

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

15.4.4 Dry the RIMD in a sloping position to facilitate drainage.

**Section Three: Monitoring and control**

15.4.5 Manual drying should be avoided unless a single-use lint free cloth is used.

15.4.6 Items should not be left to dry in ambient air.

15.4.7 Alcohol or other flammable liquids should not be used as drying agents, other than in automated equipment designed for this purpose, e.g. some endoscope washer-disinfectors.

**Section Four: Maintenance**

15.4.8 Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers’ instructions.

15.4.9 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

15.4.10 A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.

15.4.11 Drying cabinet maintenance and repair log book should be maintained for each dryer.

15.4.12 The dryer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.

15.4.13 Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485: 2003E.
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 recommended practice 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

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

Section Two: Procedure

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

16.4.5 Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted.
16.4.6 Check that the operating cycle is in accordance with the specification for the load used, (e.g. laryngeal masks do not require rinse aid).
16.4.7 Check that arms rotate. If arms do not rotate, loads should be rejected as the load has not been exposed to the water spray effectively.
16.4.8 Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
16.4.9 If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the RIMD or RIMD may not be compatible with automated washing.
16.4.10 If staining and/or residue are present, this may be due to the configuration of the load, overloaded cart or malfunction in the washing cycle.
16.4.11 Make a visual inspection of the load for dryness.
16.4.12 Where a load may not be properly cleaned the load is rejected and returned for re-cleaning.
Post cleaning inspection and function testing

16.4.13 Unless there is clear indication why a small percentage of RIMD in a load were not cleaned and/or dried effectively, the entire load should be returned for re-processing.

16.4.14 Where a small percentage of the load is suspect the items are rejected and returned for re-cleaning.

16.4.15 Any load or items rejected should be documented as a non conformance; this non conformance should also be documented into the washer-disinfector log book for further investigation.

Section Three: Documentation post automated cleaning

16.4.16 All documentation for automated cleaning should contain the following information:

a. washer-disinfector serial or identification number.
b. cycle number.
c. type of washer-disinfector.
d. type of cycle used.
e. date and time of start of cycle.
f. load content, e.g. general RIMD, stitch set, mayo scissors.
g. critical parameters for the specific washer-disinfector cycle.
h. operators name.
i. results of washer-disinfector process.
j. signature of an authorised qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters.
k. any notes or observation for the process cycle.

16.4.17 All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
Post cleaning inspection and function testing

16.4.18 Before commencing inspection the person carrying out inspection should ensure that:

a. RIMD/RIMD set has been recorded as being through the specific cleaning process.

b. 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.

c. the signature of identified responsible person confirming that the cycle has passed.

Section Four: Inspection and function testing

16.4.19 Each RIMD set should be inspected separately.

16.4.20 Box joints, serrations and crevices, should be critically inspected for cleanliness.

16.4.21 Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.

16.4.22 Jaws and teeth should be checked for alignment.

16.4.23 Ratchets should be checked for security.

16.4.24 Ratchets should close easily and hold firmly.

16.4.25 Any damaged, incomplete or malfunctioning RIMD should be reported immediately to the supervisor.

16.4.26 Cannulated RIMD should be checked to ensure channel is patent.

16.4.27 Telescopes and light cables should be function checked as per manufacturers’ instructions.

16.4.28 Each RIMD set should be checked for completeness and defects.

16.4.29 Cutting edges (on RIMD such as scissors, rongeurs, chisels, curettes) should be checked for sharpness.

16.4.30 Hinges (on RIMD such as artery forceps and clamps) should be checked for ease of movement.
Post cleaning inspection and function testing

16.4.31 RIMD that have an outer insulation coating, for example diathermy forceps etc., require close inspection to ensure that the insulation remains intact. Insulated RIMD should be checked using a diathermy pin point tester. Damaged surfaces not only will allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and service users.

16.4.32 Each RIMD should be checked that there is free movement of all parts and that joints do not stick. A water based lubricant may be used if required.

16.4.33 Each RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.

16.4.34 Each RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.

16.4.35 The diathermy pin hole detector should be used in accordance with the manufacturers’ instructions to ensure safe use of equipment.

Section Five: Monitoring and control

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

a. staff training/competence.

b. age of the RIMD.

Section Six: Maintenance

16.4.37 Preventative maintenance is to be planned and performed for all equipment, (e.g. light source and pin hole detector) in accordance with documented procedures as recommended by the manufacturers’ recommendations.

16.4.38 Records of all maintenance, validation and servicing should be maintained in accordance with EN ISO 13485:2003E.
Post cleaning inspection and function testing

Figure 16-1: Post cleaning inspection
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 recommended practice 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

17.4.1 RIMD list.
Assembly

17.4.2 Accessories, e.g. tray liner.

17.4.3 RIMD protectors.

Section Two: Procedure

17.4.4 RIMD should be assembled in accordance with the manufacturers’ instructions, prior to packaging and/or further reprocessing.

17.4.5 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.

17.4.6 For RIMD with ratchets, they should be closed on the first ratchet only, to ensure steam can penetrate to all surfaces.

17.4.7 Similar RIMD should be kept together when placing in tray, e.g. artery forceps can be placed on an RIMD pin together.

17.4.8 The RIMD tray should be selected so that the RIMD can preferably be placed in one single layer.

17.4.9 Tray liners should be placed in the base of the RIMD tray.

17.4.10 RIMD should be spread evenly by weight over the tray surface, this helps prevent condensate flowing together.

17.4.11 Each RIMD should be checked against the RIMD list specific to the tray being assembled.

17.4.12 Plastic items should be evenly placed in the tray; avoid collecting them in one area.

17.4.13 Ensure sharp RIMD are assembled correctly to avoid penetration of the outer packaging.

17.4.14 Protectors to be placed on sharp RIMD should be validated for steam penetration.

17.4.15 Ensure delicate RIMD are placed in tray in a manner which will not cause damage to the RIMD.
17.4.16 Any RIMD which is missing from a tray should be reported to supervisor for further action and non conformance documented.

17.4.17 Any extra RIMD found while assembling tray should be reported to supervisor for further action and non conformance documented.

Section Three: RIMD set weight

17.4.18 The ability of a given sterilisation cycle to produce a dry load is largely dependent on the configuration and thermal mass of the load.

17.4.19 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.

17.4.20 The configuration of sets of RIMD required to permit dry loads should be established during performance qualification testing of the steam steriliser.

17.4.21 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 recommended practice 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

18.4.1 The choice and type of wrapping material will depend on the type of sterilisation process used.

18.4.2 Materials used should comply with EN ISO 11607-1 and EN ISO 11607-2, 2006 and EN 868 parts 2-10, inclusive. RIMD may be packaged in any of the following products: papers/non-wovens, polypropylene, containers, and plastic/paper pouches.

18.4.3 When selecting a packaging system each specific products capability to meet predetermined requirements and criteria should be evaluated.

18.4.4 The appropriate size of wrapping material should be chosen to attain adequate coverage of the item being packaged.

18.4.5 Hollowware, RIMD or dressings should not be placed in textile (linen) packs as difficulty may be experienced in drying the combined pack materials and sterilisation may be compromised as the temperature increases in these materials at different rates.

18.4.6 Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.

18.4.7 RIMD packs should be packed in a manner that prevents damage to delicate items.

18.4.8 Trays used for packaging RIMD should be perforated to allow for penetration of the sterilant.

18.4.9 Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.

18.4.10 Hollowware should be packaged so that all openings face the same direction.

18.4.11 Only the minimum of raw materials commensurate with daily production should be held within the clean room.

18.4.12 Compatibility of the packaging material with the sterilisation process should be established.
Packaging

18.4.13 If chemical indicators are used inside the pack, they should conform to European Standard EN ISO 11140-1 and should be compatible with the pack.

18.4.14 Sequential wrapping using two barrier-type wrappers is recommended as it provides a torturous pathway to impede microbial migration.

Section Two: Packaging systems

Packaging systems should:

18.4.15 **Be appropriate to the items being sterilised, i.e.**

a. permit identification of contents.

b. permit complete and secured enclosure of items.

c. protect package contents from physical damage.

d. permit delivery of contents without contamination.

e. maintain sterility of package contents until opened.

f. should facilitate aseptic technique at all times including opening of package.

18.4.16 **Be appropriate to the method of sterilisation, i.e.**

Be of the following

a. provide adequate seal integrity.

b. provide an adequate barrier to particulate matter and fluids.

c. be compatible with and able to withstand physical conditions of the sterilisation process.

d. allow penetration and removal of sterilant.

e. maintain integrity of the pack.

f. permit use of material compatible (i.e. non-degradable) with the sterilisation process.
Packaging

18.4.17 *Be used according to the manufacturers’ instructions*

a. resistant to punctures, tears and other damage which may break the barrier and cause contamination.

b. resistant to penetration by microorganisms from the surrounding environment.

c. free of holes.

d. be free of toxic ingredients.

e. low-linting.

f. tamper proof and able to seal only once.

g. provide an adequate barrier to particulate matter and fluids.

Section Three: Packaging materials

*Packaging materials should:*

18.4.18 Be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity equilibrium of packaging material is important to maintain the integrity of the product.

18.4.19 Not be stored adjacent to external walls or other surfaces which may be at a lower temperature or a higher temperature than the ambient temperature of the store room.

18.4.20 Be stored on shelves and clear of the floor.

18.4.21 Be rotated to ensure it does not exceed its shelf life.

Section Four: Single use packaging

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

Section Five: Types of packaging

Papers and non-wovens

18.4.23 Both papers, which are made from cellulose fibres, and non-wovens made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilisation and most gas processes because they are permeable to air, steam and other gases.

18.4.24 Plain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gusseted to accommodate bulky items.

18.4.25 Non-wovens are generally less effective as a microbial barrier and may need to be used in, or as one of, two layers; they are however generally softer with better handling and drape characteristics.

Containers

Rigid reusable containers:

18.4.26 Should be easily disassembled for cleaning, drying and storage.

18.4.27 Should be suitable for the method of sterilisation being used.

18.4.28 Should be compatible to the cleaning method and cleaning agent being used.

18.4.29 Should be suitable to the storage configuration.

18.4.30 Should have locking devices which are tamperproof and non resealable.

18.4.31 Should be packed in a manner which allows for penetration of the sterilising agent.

18.4.32 Lid and contents should be removable without the risk of contamination of the contents.

18.4.33 Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.

18.4.34 The filter plate should be examined for integrity both before installation and after the sterilisation process.
18.4.35 If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system should be used.

18.4.36 The integrity of the rigid container system is essential to permit sterilisation of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination.

18.4.37 Loosened rivets, improperly maintained valves, worn gaskets or dents compromises to the integrity of the container system, will compromise the sterilisation process and may not permit the contents to remain sterile or be delivered aseptically.

18.4.38 When re-usable containers are being evaluated it is important that the sterilisation, cleaning, inspection, maintenance and storage procedures and methods are also evaluated for their ability to be consistently re-used and for their compatibility with the process being used.

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

Section Six: Packaging techniques

18.4.40 RIMD may be packaged in any combination of flat wrapping material (sheets, bags, pouches, or reels) or containers to maintain the integrity of the product. Devices wrapped with sheet material using either the envelope or parcel fold technique.

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

Flat wrapping material

Equipment required

18.4.42 Packaging material.

18.4.43 Sterilisation chemical indicator tape.

18.4.44 Marking pen.

18.4.45 Label (where applicable).

18.4.46 Tray liners.
Packaging

Procedure (parcel-fold wrapping method)

18.4.47 Select appropriate packaging material and place on work top.

18.4.48 The RIMD set is placed on the wrap, approximately in the centre of the packaging material.

18.4.49 Verify the accuracy of the RIMD identification label with the RIMD/RIMD set, (i.e. corresponds to RIMD list, internal tray label, etc).

18.4.50 The long edge of the tray should be aligned parallel to the long edge of the wrap.

18.4.51 One of the long edges of the wrap is folded over the pack contents to the base of the tray, and the edge of the wrap is turned back on itself.

18.4.52 The opposite side of the wrap is then folded over the pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself.

18.4.53 The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.

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

18.4.55 The wrap is secured in position using sterilisation indicator tape.

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

18.4.57 RIMD identification label is placed on outside wrap.
Figure 18.1: Parcel-fold wrapping method
Packaging

Procedure (envelope wrapping method)

18.4.58 Select appropriate packaging material and place on work top.

18.4.59 The RIMD set is placed on the wrap diagonally and slightly off the centre line.

18.4.60 Verify the accuracy of the RIMD identification label with the RIMD/RIMD set (i.e. corresponds to the RIMD list, tray internal label, etc).

18.4.61 The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.

18.4.62 This is repeated with the corners to the right and left of the first folded corner.

18.4.63 In each case the corner is turned back to provide a flap for opening.

18.4.64 Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.

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

18.4.66 The wrap is secured in position using sterilisation chemical indicator tape.

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

18.4.68 RIMD identification label is placed on the outside wrap.
Figure 18-2: Envelope wrapping method
Packaging

Pouches and bags (requiring folding)

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

Equipment required

18.4.70 Pouches and/or bags.
18.4.71 Sterilisation chemical indicator tape.
18.4.72 Marking pen.
18.4.73 Label (where applicable).

Procedure

18.4.74 The corners at the open end of the pouch are folded diagonally to give mitred corners.
18.4.75 The top of the pouch is then folded over three times in succession.
18.4.76 The same procedure may then be repeated for an outer wrap(s).
18.4.77 The pouch is secured in place with sterilisation chemical indicator tape. It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
18.4.78 When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the RIMD to be viewed.
18.4.79 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
18.4.80 RIMD identification label is placed on the outside wrap.

Self-seal pouches

18.4.81 When closing self seal bags follow manufacturers’ instructions for sealing.
Packaging

*Paper and paper/plastic pouches using heat seal*

**General principles**

18.4.82 The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above or below those specified by the packaging manufacturer.

18.4.83 Packaging intended for heat sealing may be film coated; grids lacquered, or have an adhesive band.

18.4.84 Heat seal pouches should be sealed using suitable heat sealing equipment.

18.4.85 Heat seal pouches should be hermetically sealed.

18.4.86 Heat seal pouches should provide a seal of proven integrity and not allow resealing.

18.4.87 Before commencing wrapping procedure ensure that work area and packaging equipment are clean.

18.4.88 Check size of edges for easy aseptic opening by user.

**Equipment required**

18.4.89 Heat-seal pouches.

18.4.90 Heat sealer.

18.4.91 Marking pen.

18.4.92 Label (where applicable).

**Procedure**

18.4.93 Select appropriate size heat seal pouch.

18.4.94 Place RIMD into pouch.

18.4.95 Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.

18.4.96 As much air as possible should be removed from the pouches before sealing. Air acts as a barrier to heat and moisture. Expansion of air during the sterilisation process may cause the bag to rupture during the sterilisation process.
Packaging

18.4.97 Place open end of pouch in heat sealer.

18.4.98 Apply heat and pressure to the surface of the open end of the heat seal pouch.

18.4.99 Checks should be made that the seal is complete, especially over the gusset folds of the pouches.

18.4.100 A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.

18.4.101 The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.

18.4.102 When double wrapping using heat seal pouches the packages should be used in such a way as to avoid folding the inner package to fit into the outer package.

18.4.103 Edges of inner heat seal pouches should not be folded as air maybe entrapped in the folds and inhibit sterilisation.

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

18.4.105 When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the sterilant into and out of the package.

18.4.106 If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.

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

18.4.108 Use adhesive RIMD identification label, do not write on the paper side of the pouch.

18.4.109 RIMD identification label is placed on the outside packaging.
Section Seven: Sealing of packs and bags

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

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

18.4.111 Allow sterilisation.
18.4.112 Avoid constriction of the package.
18.4.113 Maintain package integrity.

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

The following accessories should not be used:

18.4.114 Tape (other than sterilisation chemical indicator tape).
18.4.115 Safety pins.
18.4.116 Paper clips.
18.4.117 Staples.

Sterilising indicator tape

Sterilising indicator should be:

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

Section Eight: Labelling

18.4.124 Packages to be sterilised should be labelled before sterilisation.
18.4.125 The information of the label should include the following:

   a. name of product.
   b. name of wrapper.
Packaging

c. use by date or/and sterilisation date.
d. where appropriate the word sterile.

18.4.126 Label information should be documented on sterilisation chemical indicator tape or label and not on the packaging material. Plastic/paper pouches can be labelled on the plastic portion.

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

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

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

Section Nine: Monitoring and control

The following should be monitored during labelling:

18.4.130 General appearance of the packaging material.

18.4.131 Whether packages are complete.

18.4.132 Whether the correct products and packaging material are used.

18.4.133 Whether the labelling is correct on the product.

18.4.134 Whether the sealing is correct.

18.4.135 Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.

18.4.136 Material should be checked for tears, flaws and holes.

18.4.137 Containers seals and filters should be checked.

18.4.138 Containers should be checked for dints which may interfere with maintaining sterility.
Packaging

Section Ten: Maintenance

18.4.139 Reusable containers should be subject to thermometric performance tests.

18.4.140 Containers should be validated periodically for reuse according to manufacturers’ instructions.

18.4.141 Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers’ instructions and/or local policies, procedures, protocols and guidelines.

18.4.142 Heat seal efficiency, integrity and strength test should be performed on each heat sealer daily.

18.4.143 Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.

18.4.144 Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.

18.4.145 Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers’ instructions.

18.4.146 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

18.4.147 The heat sealer should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.

18.4.148 Records of all maintenance, validation and servicing should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.

18.4.149 A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
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 recommended practice 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

19.4.1 Sterilisers can be divided into those based on exposure to elevated temperature (thermal processes) and those based on exposure to microbicidal chemical agents. (low temperature processes).

19.4.2 Thermal processes include dry heat (not covered in this document) and high temperature steam sterilisation. The steam sterilisers intended to be used for sterilisation of wrapped RIMD are referred to as porous load sterilisers.

19.4.3 Low temperature processes include ethylene oxide (EO), low temperature steam and formaldehyde (LTSF), and Hydrogen Peroxide Plasma.

19.4.4 The preferred method of low temperature sterilisation is vapour phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma.

Section Two: Choice of sterilisation process

19.4.5 High temperature steam sterilisation at 134-137°C for three minutes in a porous load steriliser is generally the method of sterilisation used for RIMD.

19.4.6 A lower temperature steam sterilisation process may be required for sterilisation of RIMD.

19.4.7 Low temperature vapour phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma sterilisation may be required for sterilisation of RIMD (including flexible/rigid scopes in accordance with manufacturers’ instruction).

19.4.8 Hydrogen Peroxide Plasma, Hydrogen Peroxide Gas Plasma is the preferred low temperature sterilisation method because, compared with EO and LTSF, the installation and health and safety requirements are greatly reduced.
Table 19-1: Sterilisation temperatures, steam pressures and hold times

<table>
<thead>
<tr>
<th>Minimum Sterilisation Temperature</th>
<th>Corresponding Steam Pressure</th>
<th>Maximum Permissible Temperature</th>
<th>Minimum Sterilisation Hold Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>121°C</td>
<td>1.03 bar gauge</td>
<td>124°C</td>
<td>15 minutes</td>
</tr>
<tr>
<td>134°C</td>
<td>2.30 bar gauge</td>
<td>137°C</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

(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.)
Sterilisation

Section Three: Steam sterilisation

19.4.9 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.

19.4.10 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.

19.4.11 Flash sterilisers rely on natural air displacement and should not be used for wrapped goods, hollow devices or tubing.

19.4.12 Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.

19.4.13 The operating cycle of a porous load steriliser generally has five stages:

a. air removal.

b. steam admission.

c. sterilisation holding time.

d. vacuum drying.

e. filtered air admission.

Section Four: Loading the loading trolley prior to sterilisation

Equipment

19.4.14 See decontamination equipment, page 51.

19.4.15 Loading trolley.

19.4.16 IT based/Manual tracking system and accessories, i.e. paper, pen, scanner.

19.4.17 Batch control labeller.

19.4.18 Personal protective equipment—(heat resistant gloves).
Sterilisation

Procedure

19.4.19 Healthcare workers should wear personal protective equipment.

19.4.20 Healthcare workers should ensure that that all items within the load are compatible with the process to which they are to be exposed.

19.4.21 Loading should allow for free circulation of steam around each pack and each item.

19.4.22 RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.

19.4.23 Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.

19.4.24 Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.

19.4.25 Hollowware should be placed upside-down or tilted, to prevent collection of condensate.

19.4.26 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.

19.4.27 Containers should be loaded onto the trolley such that an air space is formed between each container layer.

19.4.28 When using the basket system healthcare workers should ensure that the appropriate size basket is used. Select the height of the basket so that there will always be a few centimetre air gap between the pack and the basket above.

19.4.29 When loading, healthcare workers should ensure that each RIMD is labelled.

19.4.30 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

19.4.31 Healthcare workers should load the steriliser using the loading trolley.

19.4.32 Healthcare workers should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.

19.4.33 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.

19.4.34 Manufacturers’ instructions and protocols agreed during validation should be followed for loading.

19.4.35 Overloading of sterilisers may compromise the process.

Figure 19-2: Loading the steriliser

Section Six: Steam sterilisation of RIMD

19.4.36 Healthcare workers should wear personal protective equipment.

19.4.37 Healthcare workers should ensure that all necessary tests and maintenance have been carried out satisfactorily before using the steriliser. Healthcare workers should ensure that the cycle recorder(s) has sufficient paper and ink to record the cycle.
19.4.38 Healthcare workers should ensure that the correct operating cycle has been selected.

(Note: Test cycles such as a Bowie and Dick test and leak rate test cannot be used for sterilising products.)

19.4.39 Healthcare workers should initiate the cycle in accordance with the steriliser manufacturers’ instructions.

19.4.40 Where single door steriliser is in use a system should be in place to ensure segregation of non-sterile and sterile RIMD.

19.4.41 When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.

19.4.42 The fail cycle may require a special key to open the steriliser door.

19.4.43 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

19.4.44 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 should be a documented policy, procedure, protocol and guideline specifying the actions to be taken and the criteria to be met in accepting the sterilisation cycle and releasing product as sterile. The sterilisation release procedure should only carried out by healthcare workers who have been trained to undertake this task and have been authorised to do so by the decontamination unit manager.

Sterilisation cycle verification

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

This should include:

a. the number and extent of air removal pulses.

b. the temperature and duration of the sterilisation plateau period.

c. the depth and duration of the drying vacuum.

d. the data should be read from the independent recorder not from the automatic controller record.
**Sterilisation**

19.4.46 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.

19.4.47 A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

**Figure 19-3: Cycle records**

![Cycle records graph](image)

**Inspection of sterilised load**

19.4.48 Each item sterilised should be inspected to ensure that:

a. 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).

b. the packaging is in place and undamaged (i.e. seals, taped joints have not come undone, packs are not torn).

c. the packaging is dry and free from dampness.

d. all labels are intact and legible.
19.4.49 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

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

a. steriliser identification or serial number.
b. the cycle number and batch number if applicable.
c. name of the loading operator and unloading operator.
d. type of cycle used.
e. date and time of start of cycle.
f. contents of the load.
g. chart record and/or print-out from steriliser cycle.
h. signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.

19.4.51 Any notes or observation for the process cycle.

19.4.52 Read out results of physical, chemical or biological indicators that are used.

19.4.53 All records should be retained for the lifetime of the steriliser plus eleven years.
Sterilisation

Section Nine: Validation

19.4.54 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.

19.4.55 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.

19.4.56 Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications.

It is comprised of:

a. commissioning (installation qualification and operational qualification).

b. performance qualification.

c. periodic testing.

d. revalidation.

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

Commissioning

19.4.57 Installation qualification is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications by the supplier and that it is safe to operate.

Installation checks and tests:

a. preliminary checks.

b. electrical checks.

c. functional checks.

d. response to faults.
Operational qualification

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

It consists of:

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

19.4.59 These tests should be carried out when a new steriliser is purchased or when a used steriliser has been relocated to another premises.

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

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

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

Performance Qualification

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

These tests consist of:

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

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

**Periodic testing**

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

19.4.66 The appropriate tests should be carried out at daily, weekly, quarterly and annual intervals.

19.4.67 A Test Person or qualified person (decontamination) should draw up a schedule for periodic testing. It is the responsibility of the Test Person or qualified person (decontamination) and the decontamination unit manager to ensure that these tests are performed.

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

19.4.68 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.

**Test procedure**

19.4.69 A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.

19.4.70 At the end of the process the test device is removed from the chamber.

19.4.71 The test device is checked for a pass or fail in accordance with the manufacturers instructions. The test results should be recorded.

19.4.72 If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results.

19.4.73 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.
19.4.74 A batch (cycle) process record should be made in the steriliser log book.

Figure 19.4: Bowie-Dick test

Weekly tests

19.4.75 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)

<table>
<thead>
<tr>
<th>Weekly Checks/Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Checks</td>
</tr>
<tr>
<td>Vacuum Leak Test (automatic)</td>
</tr>
<tr>
<td>Air Detector Function test</td>
</tr>
<tr>
<td>Automatic Control test</td>
</tr>
<tr>
<td>Bowie-Dick test for Steam penetration</td>
</tr>
</tbody>
</table>
Sterilisation

Safety checks

19.4.76 These tests are intended to ensure the steriliser is both safe to use and to test. They consist of:

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

(Note: No attempt should be made to open the door while the chamber is pressurised. Any defects should be corrected before attempting to perform the weekly tests or before using the steriliser.)

Vacuum leak test

19.4.77 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.

19.4.78 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.

19.4.79 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.

19.4.80 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.

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

The pass/fail criteria are:

19.4.82 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.
Sterilisation

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

**Air detector function test**

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

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

**Automatic control test**

19.4.85 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.

19.4.86 The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the steriliser was validated to be working correctly, e.g. immediately after the Test Person or qualified person (decontamination) had tested it using calibrated RIMD.

19.4.87 The test should be performed using the sterilising cycle with the highest temperature compatible with the load. The following parameters should be noted during the sterilising (holding) stage of the cycle:

a. chamber temperatures and pressures, their maximum values and duration in minutes and seconds.

b. the values on the cycle record should be compared with those on the master process record.

c. the test can be considered satisfactory if at the end of the cycle the following has been achieved:

- 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.

- a visual display of ‘cycle complete’ is indicated.

- no mechanical or other anomaly is observed.
**Sterilisation**

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

19.4.88  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.

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

*Quarterly tests*

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

19.4.91  The tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate. Quarterly tests for steam sterilisers are summarised in table 19-3.

<table>
<thead>
<tr>
<th>Test Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Checks</td>
</tr>
<tr>
<td>Vacuum Leak Test</td>
</tr>
<tr>
<td>Vacuum leak Test (temperature and pressure sensors connected)</td>
</tr>
<tr>
<td>Automatic Control test</td>
</tr>
<tr>
<td>Verification of Calibration of Steriliser Instruments</td>
</tr>
<tr>
<td>Thermostatic Test for a Small Load</td>
</tr>
<tr>
<td>Vacuum Leak Test (automatic) (sensors removed)</td>
</tr>
<tr>
<td>Air Detector Function (automatic)</td>
</tr>
<tr>
<td>Bowie-Dick Test for Steam Penetration</td>
</tr>
</tbody>
</table>
**Annual Tests**

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

19.4.93 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>
<thead>
<tr>
<th>Test description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Checks</td>
</tr>
<tr>
<td>Vacuum Leak Test (automatic)</td>
</tr>
<tr>
<td>Vacuum leak test (temperature and pressure sensors connected)</td>
</tr>
<tr>
<td>Automatic Control Test</td>
</tr>
<tr>
<td>Verification of Calibration of Steriliser Instruments</td>
</tr>
<tr>
<td>Steam Non-condensable Gas Test</td>
</tr>
<tr>
<td>Steam Super-heat Test</td>
</tr>
<tr>
<td>Air Detector Performance Test for a Small Load</td>
</tr>
<tr>
<td>Air Detector Performance Test for a Full Load</td>
</tr>
<tr>
<td>Steam Dryness Test</td>
</tr>
<tr>
<td>Thermometric Test for a Small Load</td>
</tr>
<tr>
<td>Thermometric Test for a Full Load</td>
</tr>
<tr>
<td>Test Performance Requalification (as required)</td>
</tr>
<tr>
<td>Vacuum leak Test (automatic) (sensors removed)</td>
</tr>
<tr>
<td>Air Detector Function Test (automatic)</td>
</tr>
<tr>
<td>Bowie-Dick test for Steam Penetration</td>
</tr>
</tbody>
</table>
Sterilisation

Section Ten: Monitoring and control

19.4.94 134°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.

19.4.95 There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.

19.4.96 Routine monitoring and testing should be carried out in accordance with documented procedures in line with EN ISO 17665 part 1 and with consideration given to the further detail in EN ISO/TS 17665 part 2.

Section Eleven: Maintenance

19.4.97 Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers’ recommendations and standards.

19.4.98 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.

19.4.99 The steriliser should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.

19.4.100 Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665, 2006.

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

19.4.102 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.
19.4.103 Revalidation may be required after steriliser relocation, engineering work, repair work, software control function modifications and when required by the decontamination unit manager.

Some examples of requirement for revalidation are:

a. adjustment to steam controls.

b. adjustment to microprocessor controls.

c. adjustment to control parts.
20. Low temperature sterilisation

20.1 Introduction

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

20.2 Scope

The objective of this recommended practice 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 (including flexible/rigid scopes)
Section Six: Sterile product release
Section Seven: Storage and use
20.4 Procedure

Section One: General principles

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

20.4.2 The hydrogen peroxide based methods are preferred. (The residuals from EO and LTSF are toxic and must be degassed from RIMD after sterilisation whereas the residuals from hydrogen peroxide are innocuous (water and oxygen); also, EO and LTSF are alkylating processes which are believed to stabilise prion proteins).

20.4.3 Low temperature sterilisation methods should only be used for:

a. RIMD (including flexible/rigid scopes) specifically identified by the RIMD (scope) manufacturer or steriliser manufacturer as suitable for processing in the steriliser, or

b. RIMD (including flexible/rigid scopes) made of materials of a size and configuration (e.g. length and diameter of lumen) within the criteria specified by the steriliser manufacturer.

(Note: Documentation of items that can and cannot be processed should be obtained from the RIMD (scope) and steriliser manufacturers.)

20.4.4 RIMD (flexible/rigid scope) 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).

20.4.5 The packaging used to contain RIMD (flexible/rigid scope) to be sterilised must be compatible with the process. Only products designed for use with the particular process should be used.
Low temperature sterilisation

Section Two: Validation

20.4.6 The effectiveness of the sterilisation process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if sterilising conditions are created throughout the steriliser chamber and the load during every cycle.

20.4.7 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the steriliser is functioning correctly and that it will produce sterilised loads consistently.

20.4.8 Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications.

It consists of:

a. commissioning (installation qualification and operational qualification).

b. performance qualification.

c. periodic testing.

d. revalidation.

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

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

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

20.4.11 A qualified person (decontamination) with specific training on the process to be validated should advise on the validation programme and audit the data obtained.

Section Three: Periodic testing

20.4.12 Periodic testing consists of a programme of tests that are intended to demonstrate that the performance of the steriliser remains within the limits established during validation.
20.4.13 The tests and checks specified by the steriliser manufacturer should be carried out at the intervals specified by the steriliser manufacturer. (This will normally require detailed functional and calibration tests and checks at intervals of 3, 6, or 12 months).

20.4.14 A qualified person (decontamination) should review and approve the schedule for periodic testing.

20.4.15 It is the responsibility of the operational manager to ensure that these tests are performed and that the results were satisfactory before allowing the continued use of the steriliser.

Section Four: Chemical and biological indicators

Chemical indicators

20.4.16 Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.

20.4.17 Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).

20.4.18 The type used should be in accordance with the steriliser manufacturers’ recommendations.

20.4.19 The indicator manufacturer’s instructions should be followed precisely in relation to use and storage.

20.4.20 The use of an inappropriate indicator may give dangerously misleading results; indicator performance can be adversely affected by the storage conditions and methods of use.

20.4.21 Indicators should not be used beyond their expiry date.

20.4.22 Two types of chemical indicator are commonly used:

20.4.23 Process indicators: These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
Low temperature sterilisation

20.4.24 Integrating indicators and/or emulating indicators: These indicators are intended to monitor the attainment of two or more critical variables in the sterilisation process, either by a graduated response or a defined end point reaction. These types of indicators are not currently available for hydrogen peroxide processes.

Biological indicators

20.4.25 Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained.

20.4.26 Biological indicators must meet the requirements of EN ISO 11138-1:2006.

20.4.27 They are of limited value in routine process control (because of the delay before the results are available) and are restricted to a few special applications e.g. in process validation.

20.4.28 When used for validation studies they should always be regarded as additional to the physical measurement of the critical control variables (e.g. temperature, pressure, sterilant concentration and time).

Section Five: Sterilisation of RIMD (including flexible/rigid scopes)

20.4.29 Wear personal protective equipment.

20.4.30 Ensure that any checks and test that are to be carried out prior to sterilisation have been complete and were satisfactory.

20.4.31 Where single door steriliser is in use a system must be in place to ensure segregation of non-sterile and sterile RIMD (including flexible/rigid scopes).

20.4.32 The steriliser door/s should be kept closed when the steriliser is not in use.

20.4.33 Select the validated cycle programme suitable for the load being processed.

20.4.34 Ensure the load is suitable for the process to which it will be exposed.

20.4.35 Manufacturers written instructions for operating the steriliser should be followed.
Section Six: Sterile product release

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

Parametric release

20.4.36 When cycle is complete post sterilisation inspection is carried out to verify that the sterilisation cycle has completed with defined, validated critical parameters (VCP).

20.4.37 Parameter release should show evidence that the RIMD (including flexible/rigid scopes) were subjected to a process and have met all-processing variables achieved during performance qualification.

Non-parametric release

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

20.4.39 In both parametric and non-parametric release post-sterilisation inspection is carried out to ensure that the values of the recorded cycle variables (e.g. temperature, pressure, time) are checked to ensure that they are within the limits determined as satisfactory during validation.

20.4.40 Failure of one or more of the cycle variables to meet the specified value(s) must lead to the steriliser load being transferred to the clean room to be repacked and sterilised.

20.4.41 The cause of failure should be investigated and documented.

20.4.42 A steriliser cycle in which there is no record from the automatic controller or from the independent recorder should be regarded as a sterilisation failure.

20.4.43 The chemical process indicator has undergone the expected colour change.

20.4.44 The integrity of the outer wrap and its seals has not been compromised, e.g. torn wrap, sealing tape undone).
Low temperature sterilisation

20.4.45 The packed RIMD (including flexible/rigid scopes) are dry.

20.4.46 The labelling remains in place and legible.

20.4.47 If the integrity of the packaging or labelling is compromised the sterilised load is regarded as non-sterile. The RIMD (including flexible/rigid scopes) must be reprocessed and the cause of the failure investigated and documented.

20.4.48 A record of mechanical testing, repairs and preventative maintenance should be recorded in a logbook for each steriliser. Records should be maintained in a designated storage area for the lifetime of the steriliser plus eleven years.

Section Seven: Storage and use

20.4.49 Sterile RIMD (including flexible/rigid scopes) should be stored in a clean, dry area, which is secure, dust free and above floor level.

20.4.50 Packs should be labeled with the contents, the word ‘Sterile’, the date of sterilisation and a unique identifier from which all stages of the decontamination process to which it was subjected may be traced.

20.4.51 Packs should be stored so that they are used in sequential order, i.e. the oldest first.

20.4.52 Packs should be inspected for damage before they are opened. If there is any sign of damage to the packaging, the contents should be returned to the decontamination unit to be re-sterilised before they are used.
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 recommended practice 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

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

There are two types of storage area:

a. the processed goods store.

b. the raw materials store.

Processed goods store

21.4.2 The processed goods store should be located adjacent to the cooling bay in the sterilisation area and with access to the despatch area. This store is for RIMD produced by the department and RIMD which have been commercially manufactured and sterilised.

(Note: Storage areas should be kept secure and access should be restricted to authorised personnel.)

21.4.3 The outer packaging (shipper carton) should be removed from RIMD which have been commercially manufactured and sterilised – if stored in the same store as those RIMD which have been produced by the department.

21.4.4 Raw materials should not be stored in the processed goods store.

21.4.5 Loose, processed RIMD should be stored separately from those packed in cases.

21.4.6 Storage areas should be kept secure and access should be restricted to authorised personnel.

21.4.7 Sterile materials should be stored at least 20 to 80 centimetres from the floor, at least 18 inches from the ceiling, and at least 5 centimetres from outside walls.

21.4.8 The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.

21.4.9 Medical and surgical process goods should not to be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.

21.4.10 Processed goods should be stored on appropriate designated shelving.
Raw materials store

21.4.11 The storage area is for the reception, storage and supply of all non-sterile materials including textiles and where appropriate, bulk cased supplies of commercially sterilised RIMD.

21.4.12 The raw materials store should be located between the goods reception and the clean room inspection, assembly and packaging area.

21.4.13 Materials should be segregated and stored separately according to their specific requirements.

21.4.14 Sterile RIMD should not be stored in this area (unless supplies are bulk cased).

21.4.15 Single items should be stored separately from those in cases.

21.4.16 Storage areas should be kept secure and access restricted.

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

Section Two: Storage equipment

General principles

21.4.18 Sterile items should not be stored anywhere but on, or in, designated shelving, counters, or containers, because other areas may not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside.

21.4.19 Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that may form on the interior surfaces of outside walls.

21.4.20 Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces.
Storage

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

Shelving and racking

21.4.22 Shelves and racking should afford adequate space to store the required stock in line with local supply policy and production demands.

21.4.23 Shelving and racking should be purpose built, easily cleaned and maintained.

21.4.24 There should be enough space between shelves and racking to allow an adequate passageway between fixtures.

21.4.25 Shelving or racking should enable items to be clearly labelled.

Closed or covered cabinets

21.4.26 Closed or covered cabinets are recommended for the storage of seldom-used sterile supplies.

21.4.27 Closed cabinets limit dust accumulation, discourage handling, and minimise inadvertent contact with sterile items.

Section Three: Shelf life/rotation of stock

21.4.28 General factors which influence shelf life are event related and include the following:

a. packaging materials.

b. storage and handling conditions.

c. likelihood of product material deterioration.

d. package design.

21.4.29 Each central decontamination unit should develop a system of stock rotation based on the date of sterilisation. Good management practices demand that stock be maintained at adequate levels.

21.4.30 As a “rule of thumb”, product which has remained unused for more than six months should be deemed to be a product of over-stocking and an assessment undertaken as to its future need.
21.4.31 There are occasions where devices must form part of emergency stocks and as a result may not be used within this time frame. Procedures should be put in place to ensure that these products are subject to a reprocessing regime over time.

Section Four: Nonconforming Stock

21.4.32 A package should be considered nonconforming, i.e. non sterile and not suitable for use when:

a. it is incorrectly wrapped.

b. it is damaged or opened.

c. the product is outside the expiry date.

21.4.33 The sterilisation process indicator does not confirm that the pack has been subject to an appropriate sterilisation process.

Figure 21-1: Storage
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

22.4.1 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.

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

22.4.3 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.
Section Two: External transportation

22.4.4 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.

22.4.5 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, as the water is the last product to make contact with the RIMD prior to the user procedure.

23.2 Scope

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

23.3 Contents

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

23.4 Procedure

Section One: General requirements

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

a. the materials of construction of the washer-disinfector (WD).

b. the RIMD to be processed.

c. the process chemical to be used.

d. the process requirements of that particular stage.
23.4.2 The key quality elements to be considered are:

a. hardness.

b. temperature.

c. ionic contaminants (e.g. heavy metals, chlorides, phosphates, silicates, iron, total dissolved solids and collective conductivity).

d. microbial population. e.g. Total Viable Count (TVC) as cfu/100ml.

e. bacterial endotoxins.

f. pH

23.4.3 The water supply should be controlled to ensure that it consistently of the required quality.

Section Two: Water quality

Hardness

23.4.4 Water hardness is caused by the presence of dissolved salts of the alkaline earths (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (limescale) when water is heated or evaporated.

23.4.5 The deposition of lime-scale on electrical heating elements or heat exchange components, within pipes and around the edges of spray nozzles will seriously impair the performance of a washer-disinfector.

23.4.6 Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.

23.4.7 Using hard water in the thermal disinfection and final rinse stages of the WD cycle is one of the major causes of white powdery deposits on load items. These are unsightly and act as a focus for soiling and recontamination of the item in use. In some applications (e.g. with optical systems) such deposits may seriously impair the utility of the item.

23.4.8 When hard water is used in the process of reverse osmosis (RO), it can cause the RO to reduce the quality and quantity of water required for the washer-disinfector (WD).
Water supply for washer-disinfectors

23.4.9 The hardness is normally removed by a water softener; this can then be used to pretreat the water prior to washer-disinfector system.

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

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

**Temperature**

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

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

23.4.14 When enzymatic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes, too low and they may not activate.

23.4.15 The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

**Ionic contaminants**

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

23.4.17 Water used for stainless steel RIMD should have a chloride concentration less than 120 mg/l Cl– to minimise the risk of corrosion.

23.4.18 Tarnishing of stainless steel RIMD, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discoloration.
23.4.19 Ionic contaminants conduct electricity, because pure water has a high resistance to electrical current, the measurement of electrical conductivity can provide an accurate assessment of ionic concentration. Conductivity is described in micro Siemens and is measured by a conductivity meter and probes. In washer-disinfector, the guideline limit for conductivity is no greater than 30 microsiemens.

*Microbial population*

23.4.20 The microbial population in the water used in the washer-disinfector, particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.

23.4.21 For items which are intended to be used without further processing (e.g. flexible endoscopes processed in an endoscope washer-disinfector) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the service user, either through infection or by leading to an erroneous diagnosis. It is recommended that a guideline limit for microbial contamination is set at no greater than 10 CFU/100ml sample.

*Bacterial endotoxins*

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

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

*pH*

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

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

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


b. de-ionisers.

c. reverse osmosis.

“Base-exchange” softeners

23.4.26 Base-exchange softeners, consist of an ion exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride).

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

23.4.28 After regeneration high levels of chloride ions may be present in the initial output from the softener which should be configured to automatically run an initial volume to waste.

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

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

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

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

23.4.33 De-ionisation (demineralisation) systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in separate columns.

23.4.34 Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers. Deionising columns are also subject to microbial biofilm contamination and require periodic preventive maintenance and microbiological testing of output water.

23.4.35 De-ionised (DI) water may be heavily contaminated with microorganisms and DI water stored at ambient temperatures will deteriorate rapidly due to proliferation of microorganisms, particularly bacterial species. Contamination of DI with skin bacteria is common. Containers used for DI should be cleaned regularly and should not be constantly topped up. Ideally, DI containers should be sterilised following cleaning. (The chloride ions normally present in drinking water which can control microbial growth have been removed).

23.4.36 DI water should not be used for the final rinse of products intended for invasive use without further water treatment.

23.4.37 De-ionisers should be disinfected regularly.

**Reverse osmosis**

23.4.38 Reverse osmosis treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and microorganisms, as well as ionic species.

23.4.39 When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population. However, the microbiological quality of the water can deteriorate following storage due to proliferation of bacterial species.
**Water supply for washer-disinfectors**

**Appropriate measures include:**

a. a continuous recirculation system.

b. filtration, e.g. through a 0.22 mm filter to remove microbial contaminants.

c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J. m–2). and by periodic disinfection (elevated water temperature e.g. >80°C).

**Water supply and distribution**

23.4.40 The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Orbitally welded stainless steel pipes or clean pex are preferred for all qualities of purified water.

23.4.41 All pipe work should be installed with a continuous fall towards the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.

23.4.42 Regular disinfection of the storage and distribution system should be undertaken and the efficacy of such control procedures should be subject to microbiological testing.

23.4.43 It may be helpful if microbiological results from weekly tests are plotted on a graph to give a trend. This will allow the ‘normal’ and ‘unusual’ results to be distinguished for a particular situation.

23.4.44 Investigation of unusual, or unsatisfactory results are then undertaken if the results demand (e.g. if routine results are below 10cfu/100ml and some of the results are above 10cfu/100ml.

23.4.45 If a bacterial count is obtained from test water the identification of bacterial species is advised and the results presented to the Microbiologist or Infection Prevention and Control team for consideration.

23.4.46 This information may aid identification of the contamination source and assist with any subsequent advice.

(Note: For washer-disinfectors in which the RIMD is rinsed after the disinfection stage (e.g. those using a chemical process for disinfection) the quality of the final rinse water should be as follows (table: 23-1).)
### Table 23-1: Typical bacterial counts as indicators of process water quality

<table>
<thead>
<tr>
<th>Aerobic colony count in 100 mL at 35°C for 72 hr</th>
<th>Interpretation/action</th>
<th>Colour grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>Satisfactory</td>
<td>Green</td>
</tr>
<tr>
<td>1-9 on a regular basis</td>
<td>Acceptable</td>
<td>Yellow</td>
</tr>
<tr>
<td>- indicates that bacterial numbers are under a reasonable level of control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-100</td>
<td>Unsatisfactory</td>
<td>Orange</td>
</tr>
<tr>
<td>- investigate potential problems and self-disinfect or super-chlorinate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 100</td>
<td>Unacceptable</td>
<td>Red</td>
</tr>
<tr>
<td>- take AER out of service until water quality improved</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Note: *Mycobacterium sp.* not detected in 100 mL water satisfactory)
Water supply for washer-disinfectors

Table 23.2: Water quality for washer–disinfector

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

*Endoscope washer disinfector only

Table 23.3: Water quality for cleaning RIMD

<table>
<thead>
<tr>
<th>Washer-disinfector Process stage</th>
<th>Water Quality</th>
<th>Preferred</th>
<th>Acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual wash</td>
<td>Reverse osmosis @ 35-45°C</td>
<td>Soft/mains @ 35-45°C</td>
<td></td>
</tr>
<tr>
<td>Manual rinse</td>
<td>Reverse osmosis</td>
<td>Soft/mains ¹</td>
<td></td>
</tr>
<tr>
<td>Ultrasonic wash</td>
<td>Reverse osmosis @ 35-55°C</td>
<td>Soft/mains @ 35-55°C</td>
<td></td>
</tr>
<tr>
<td>Ultrasonic rinse</td>
<td>Reverse osmosis</td>
<td>Soft/mains ¹</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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 service users and healthcare workers. (Reference EN 13795).

24.2 Scope

The objective of this recommended practice 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

24.4.1 Re-usable textile drapes and gowns should not be inspected, folded and packed in the same area as clean RIMD.

24.4.2 If it is intended to process re-usable textiles through a central decontamination unit a separate clean room, inspection, assembly and packaging room must be provided to deal with the re-usable textiles because of their high particulate generation rate.

24.4.3 Single-use (disposable) drapes and gowns are preferred.

24.4.4 Single-use (disposable) drapes and gowns may be provided within an RIMD set if this is convenient to the end-user.
Textiles and non-woven’s

24.4.5 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.

24.4.6 Re-usable textiles should not be used as wrapping materials for RIMD sets.

24.4.7 Single-use (disposable) drapes and gowns should be disposed of within the healthcare risk waste in the clinical unit.

24.4.8 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.
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 service user during one procedure. The device is not intended for reprocessing and/or use on another service user or on the same service user at another time.

25.2 Scope

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

25.3 Contents

Section One: General principles

25.4 Procedure

Section One: General principles

25.4.1 To avoid cross-contamination between service users, SIMD should be used wherever this is practical.

25.4.2 Single-use items should be used for a single service user and not reused on subsequent service users.

25.4.3 Devices intended for single-use and labelled ‘single-use’ by the manufacturer should be immediately disposed of after use.

25.4.4 Decontamination unit managers who disregard this information and prepare single use products for further use, are transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them and have become the manufacturer of the device.
Single use invasive medical devices

25.4.5  The symbol for single use instruments is as given in EN 980:2003.

25.4.6  Synonyms for “do not reuse” are “single use”, use only once”.


25.4.8  Healthcare organisations should have well established criteria for their choice of SIMD or RIMD where both are available.

Figure 25-1: Do not reprocess symbol

![Do not reuse symbol]

Synonyms for this are:
- Single-use
- Use only once
26. Transfer of used reusable invasive medical devices (RIMD) to third parties

26.1 Introduction

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

26.2 Scope

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

26.3 Contents

Section One: General principles

26.4 Procedure

Section One: General principles

26.4.1 All RIMD intended for inspection, service, repair, or disposal must be decontaminated before despatch and must be accompanied by a certificate stating the method by which they were decontaminated.

26.4.2 All RIMD must be decontaminated in accordance with the manufacturers’ instructions.

26.4.3 If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, the recipient may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.
Transfer of used reusable invasive medical devices (RIMD) to third parties

26.4.4 RIMD that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.

26.4.5 When RIMD are returned after being repaired, the RIMD must be decontaminated and, where relevant, replaced in the original RIMD set.

26.4.6 Each RIMD set should be checked or completeness as per healthcare organisation policy, procedure, protocol and guideline.
27. Loan reusable invasive medical devices

27.1 Introduction

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

27.2 Scope

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

27.3 Contents

Section One: General principles

Section Two: Procedure for loaning and borrowing RIMD
Loan reusable invasive medical devices

27.4 Procedure

Section One: General principles

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

27.4.2 All borrowed RIMD must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly.

27.4.3 RIMD on loan must be registered, including ownership, service history, current location, service responsibility and instructions for use.

27.4.4 It is the responsibility of the user to ensure that a full record of use for the RIMD will be available from the loan organisation, and that the usage history is both available and complete.

Section Two: Procedure for loaning and borrowing RIMD

Requests

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

27.4.6 When agreement has been reached that the RIMD may be borrowed, the manager of the central decontamination unit that will be responsible for decontamination must be informed.
Loan reusable invasive medical devices

**Documentation**

27.4.7 The owner of the RIMD being loaned is responsible for ensuring that the loaned RIMD are accompanied by the following documentation:

a. the tray of RIMD or single RIMD is tracked using a globally accepted Global Standards 1 (GS1 code).

b. contents list.

c. decontamination certificate.

d. reprocessing instructions, including disassembly and reassembly, where relevant.

e. instruction for use.

f. the above data is presented in an accessible and appropriate manner so that it can be used throughout the reprocessing cycle.

**Log book**

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

a. name and description of the RIMD.

b. RIMD identification number(s).

c. name of the person to whom the RIMD is being loaned to/borrowed from.

d. identity of the institution providing/receiving the RIMD.

e. identity of the person who is making the loan.

f. date of loan.

g. expected date of return.

h. confirmation that the relevant supporting documentation required to track reprocess and use the RIMD have been received and are available to all person departments requirement that information.

i. the unique identifier permitting traceability of the decontamination cycle(s) for the RIMD prior to use. Global Standard 1 (GS1) GIAI code.
Loan reusable invasive medical devices

Arrangements for return of RIMD

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

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

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

Internal Tracking of Loan RIMD sets and singles

27.4.12 The unique reference supplied by the loan organisation should be used to track the set/items through the decontamination cycle and subsequent use on a service user to ensure traceability.

27.4.13 The contents within the tray of RIMD or details relating to a supplementary item should be entered in full into the tracking system.

27.4.14 The required supporting documentation should be made available at all points of the decontamination process to ensure that the RIMD is dismantled, processed and reassembled in accordance with manufacturers’ recommendations.
28. Action on non-conforming product

28.1 Introduction

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

28.2 Scope

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

28.3 Contents

Section One: Policies, procedures, protocol and guidelines

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

28.4 Procedure

Section One: Policies, procedures, protocols and guidelines

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

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

Section Two: Recall procedure

28.4.4 A recall policy, procedure, protocol and guideline should:
   a. be written.
   b. outline the circumstances for issuing a recall order.
   c. designate the person(s) authorised to issue a recall order.
   d. designate the person(s) responsible for reporting on the execution of a recall order.

Section Three: Recall order

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

28.4.6 A report of a recall order should:

   a. identify the circumstances that prompted the recall or order.

   b. specify the corrective action(s) taken to prevent a recurrence.

   c. state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall.
Standards and Recommended Practices for CDUs

Part 4
Additional Resources and Appendices
1. Resources


Health Building Note 13 Sterile Service Departments. HMSO

Health Technical Memorandum 01-01Part A: Decontamination of Reusable Medical Devices

Health Technical Memorandum 2010 Sterilisers, London: HMSO.

Health Technical Memorandum 2030 Washer Disinfectors, London: HMSO.

Health Technical Memorandum 2031 Steam for Sterilisation, London: HMSO.


Irish Medicines Board. The Procurement and Commissioning of Medical Equipment for Hospitals. IMB Safety Notice. SN2006(03).

Resources


## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AORN</td>
<td>Association of Perioperative Registered Nurses</td>
</tr>
<tr>
<td>AER</td>
<td>Automated Endoscope Reprocessor</td>
</tr>
<tr>
<td>ATP</td>
<td>Adenosine Triphosphate</td>
</tr>
<tr>
<td>CE</td>
<td>Conformité Européenne</td>
</tr>
<tr>
<td>CDU</td>
<td>Central Decontamination Unit</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>CIS</td>
<td>Clinical Indemnity Scheme</td>
</tr>
<tr>
<td>EEC</td>
<td>European Economic Community</td>
</tr>
<tr>
<td>EN</td>
<td>European Norm</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>ERU</td>
<td>Endoscopy Reprocessing Unit</td>
</tr>
<tr>
<td>EWD</td>
<td>Endoscope Washer-Disinfector</td>
</tr>
<tr>
<td>HAS (H&amp;S)</td>
<td>Health and Safety</td>
</tr>
<tr>
<td>HBN</td>
<td>Health Building Note</td>
</tr>
<tr>
<td>HCAI</td>
<td>Healthcare Associated Infection</td>
</tr>
<tr>
<td>HCW</td>
<td>Health Care Worker</td>
</tr>
<tr>
<td>HIQA</td>
<td>Health Information Quality Authority</td>
</tr>
<tr>
<td>HSE</td>
<td>Health Service Executive</td>
</tr>
<tr>
<td>IMB</td>
<td>Irish Medicines Board</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organisation</td>
</tr>
<tr>
<td>LCD</td>
<td>Liquid Chemical Disinfector</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheets</td>
</tr>
</tbody>
</table>
Abbreviations

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

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse event</strong></td>
<td>An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.</td>
</tr>
<tr>
<td><strong>Cleaning</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Clinical Governance</strong></td>
<td>Corporate accountability for clinical performance.</td>
</tr>
<tr>
<td><strong>Decontamination</strong></td>
<td>The removal of microorganisms or foreign matter (or both) from contaminated materials or living tissue.</td>
</tr>
<tr>
<td></td>
<td>Three processes for decontamination are commonly used; cleaning, disinfection and sterilisation.</td>
</tr>
<tr>
<td><strong>Disinfectant</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Disinfection</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Hazard</strong></td>
<td>A source of potential harm or a situation with a potential to cause loss.</td>
</tr>
<tr>
<td><strong>Healthcare associated infection</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
### Glossary

<table>
<thead>
<tr>
<th><strong>Health Care Workers</strong></th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incidence (of infection)</strong></td>
<td>Rate at which new cases occur.</td>
</tr>
<tr>
<td><strong>Invasive procedure</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
| **Medical device** | Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of:  
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;  
  - diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap;  
  - investigation, replacement or modification of the anatomy or of a physiological process; or  
  - control of conception and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. |
| **Monitor** | To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change. |
| **Prion** | The small proteinaceous infectious unit that appears to cause TSEs. |
Primary Care  HSE healthcare provision outwith hospitals, for example, general medical practitioner and general dental practitioner services.

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

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

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

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

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

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

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

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

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

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

**Statutory**  
Required by law.

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

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

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

**Verification**  
Checking or confirmation of the truth or accuracy of something (e.g., self-assessment).
Suitably qualified person (decontamination)

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

The suitably qualified person (decontamination) should demonstrate extensive relevant experience on decontamination equipment testing and the subject of decontamination and a lower level qualification should also be considered. Each case should be considered on its merits.
### Appendix 1: Membership of National Decontamination Advisory Group

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Ronnie Russell</td>
<td>Chairperson National Decontamination Advisory Group</td>
</tr>
<tr>
<td>Ms. Winifred Ryan</td>
<td>Quality &amp; Patient Safety Directorate, Health Service Executive</td>
</tr>
<tr>
<td>Ms. Joy Markey</td>
<td>Quality &amp; Patient Safety Directorate, Health Service Executive</td>
</tr>
<tr>
<td>Mr. Tom Finn</td>
<td>Assistant National Director commercial unit, Health Service Executive</td>
</tr>
<tr>
<td>Ms. Fiona Kennedy</td>
<td>Decontamination advisor</td>
</tr>
<tr>
<td>Mr. Wayne Spencer</td>
<td>Decontamination technical advisor</td>
</tr>
<tr>
<td>Professor David Coleman</td>
<td>Professor of Oral &amp; Applied Microbiology, Head of division of oral biosciences</td>
</tr>
<tr>
<td>Dr. Anne Gilleece</td>
<td>Consultant Microbiologist Connolly hospital</td>
</tr>
<tr>
<td>Ms. Sinead Horgan</td>
<td>Chairperson, Irish Endoscopy Nurses Association</td>
</tr>
<tr>
<td>Mr. Tony Mc Loughlin</td>
<td>Vice Chairperson, Irish Decontamination Institute</td>
</tr>
<tr>
<td>Ms. Paschal Kent</td>
<td>Decontamination coordinator, CUH Group</td>
</tr>
<tr>
<td>Ms. Monica Griffin</td>
<td>Irish Theatre Nurses Association</td>
</tr>
<tr>
<td>Ms. Sheila Donlan</td>
<td>Health Protection Surveillance Centre</td>
</tr>
<tr>
<td>Ms. Mary Owens</td>
<td>Chairperson, Irish Association Director of Nursing and Midwives</td>
</tr>
<tr>
<td>Mr. Jim Murphy</td>
<td>Health Service Executive, Estates</td>
</tr>
<tr>
<td>Mr. Wilf Higgins</td>
<td>Irish Medicines Board</td>
</tr>
</tbody>
</table>
Appendix 2: List of hospitals /consultees who participated in the consultation process

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

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

<table>
<thead>
<tr>
<th>Consultees (External)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health and Children</td>
</tr>
<tr>
<td>RCPI Faculty of Occupational Health</td>
</tr>
<tr>
<td>Royal College of Surgeons Ireland</td>
</tr>
<tr>
<td>Royal College of Physicians Ireland</td>
</tr>
<tr>
<td>Faculty of Public Health</td>
</tr>
<tr>
<td>Irish Society of Clinical Microbiologists</td>
</tr>
<tr>
<td>Irish Directors of Nursing and Midwifery Association</td>
</tr>
<tr>
<td>Irish Association of Sterile Services Managers</td>
</tr>
<tr>
<td>SARI National Committee</td>
</tr>
<tr>
<td>Maintenance Management Association</td>
</tr>
<tr>
<td>Health Care Risk Managers Forum</td>
</tr>
<tr>
<td>DATHs Risk Management Forum</td>
</tr>
<tr>
<td>Clinical Indemnity Scheme</td>
</tr>
<tr>
<td>Association of Occupational therapists Ireland</td>
</tr>
<tr>
<td>Irish Society of Chartered Physiotherapists</td>
</tr>
<tr>
<td>Irish Speech and Language Therapist Association</td>
</tr>
<tr>
<td>Irish Medicines Board</td>
</tr>
<tr>
<td>Association of Physical Scientists in Medicine</td>
</tr>
<tr>
<td>Infection Control Nurses Association</td>
</tr>
<tr>
<td>Irish Society of Endoscopy Nurses</td>
</tr>
<tr>
<td>Irish Association of Theatre Managers</td>
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<tr>
<td>Irish Patients Association</td>
</tr>
</tbody>
</table>
Appendices

Appendix 3: Standards and Guidance on which the HSE standards and recommended standards are based

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

Legislation

Directive 93/42/EEC.

European and International Standards

i. Cleanroom Standards


Appendices

ii. Disinfectant Standards

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

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

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

iii. Equipment Standards

Sterilisers


Washer-disinfectors


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


Appendices

iv. Management


v. Materials

Biological indicators

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


Chemical indicators

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

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


Packaging

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

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

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

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


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

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

Appendices

vii. Processes

Sterilisation


viii. Safety

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

UK Guidance Documents

HBN13 Sterile Service Departments.

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

HTM 2010 Sterilisers.

HTM 2030 Washer Disinfectors.

HTM 2031 Steam for sterilisation.

Appendices


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

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

MDB 2006 (05) Managing Medical Devices

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

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


Appendices

Appendix 4: Regulations and Guidance

Medical Device

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

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

Medical Devices Directive

Medical Devices are regulated by three main Directives

These three Directives:

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

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

Irish Medicines Board

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

Legislation

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

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

- S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994 which became mandatory on 14th June 1998.

Vigilance

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

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

Manufacturer of Medical Devices

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

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

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

Safety, Health and Welfare at Work Act, 2005

The Safety, Health and Welfare at Work Act, 2005 came into effect on 1st 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’.