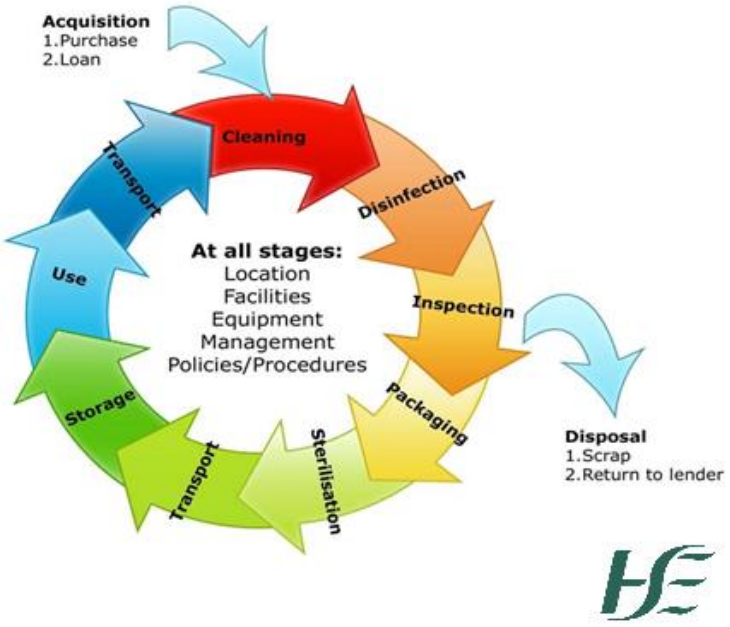
Health Service Executive Standards and Recommended Practices for Central Decontamination Units



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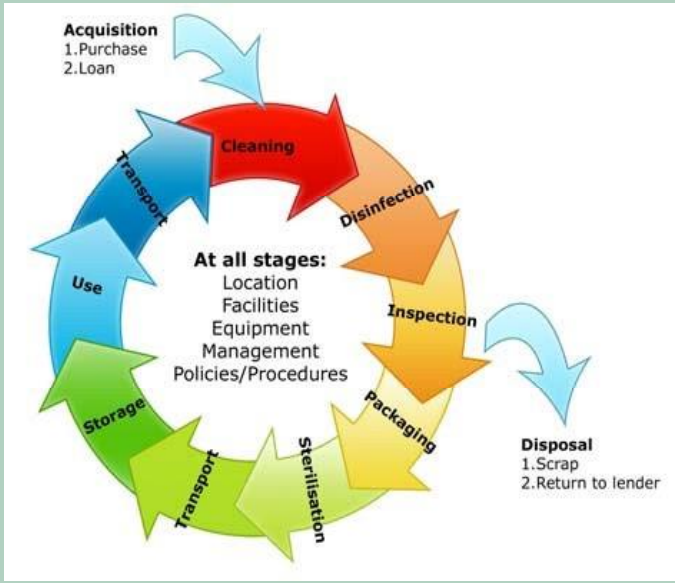


Standards and Recommended Practices for CDUs

Part 1
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 destroys, inactivates, or significantly reduces the concentration of pathogens (such as bacteria, viruses, and fungi).

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

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.
- 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.
- 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. Medical Devices Regulation (EU) 2017/745

3.1 Medical Devices Regulations

The Medical Devices Regulation (EU) 2017/745 is known as the MDR. This replaces the Medical Device Directives (90/385/EEC) for Active Implantable Medical Devices and General Medical Devices Directive 93/42/EEC. The in vitro Diagnostics Medical Devices Regulation (EU) 2017/746 is known as IVDR and replaces the previous Directive 98/79/EEC.

The Medical Devices Regulation (EU) 2017/745 applies to Manufacturers placing medical devices on the market, in doing so, it specifies the General Requirements (Annex 1) to be met by Manufacturer for any medical device.

These general 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 as defined in the Medical Device Regulation (EU) 2017/745 (Article 2) (1) (2) means:

Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specified medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of, or compensation for injury or disability.
- Investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state.
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations.

The following products shall also be deemed to be Medical Devices:

- Devices for the control or support of conception.
- Products specifically intended for the cleaning, disinfection, or sterilisation of devices as referred to in Article 1(4) (and of those referred to in the paragraph of this point).

Accessory for a medical device means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical devices(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

Article 2 of the Medical Devices Regulation (EU) 2017/745 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. (Annex VIII).

The Regulation distinguishes a **surgically invasive** device as an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation and a device which produces penetration other than through a body orifice.

Implantable device means any device, including those that are partially or wholly absorbed, which is intended:

- To be totally introduced into the human body, or
- To be replace an epithelial surface or the surface of the eye.
- Any device intended to be partially introduced into the human body by clinical intervention and which is intended to remain in place after the procedure for at least 30 days shall also be deemed to an implantable device.

Annex VIII of the Medical Devices Regulation (EU) 2017/745 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.

The Medical Devices Regulation also applies 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.

3.2 General requirements of the Medical Devices Regulation (EU) 2017/745

The Medical Devices Regulation specifies the minimum standards in relation to decontamination of medical devices in (Annex 1Chapter II) general requirements of the Regulation which are of particular relevance to sterile products include:

- Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patient, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.
- Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and where applicable, other persons.
- Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.
- Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods. (The label shall give indication of sterile state and the sterilisation method- Annex 1, Chapter 3, 23.2(L))
- Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.
- Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.
- The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that the device is sterile.

All devices placed on the market must meet the requirements of the medical devices regulation and in doing so must not compromise the clinical condition or safety of

service users, or the safety and health or 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 Regulation (EU) 2017/745 Article V. Thus if a central decontamination unit supplies a separate legal entity, this would constitute placing goods on the market and so the Medical Device Regulation 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 (Article 5, Annex I). However, there should not be one Standard for industry (ISO 13485) 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 general requirements of the Regulation.

3.5 System and Procedure Packs Article 12

Procedure pack means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purposes (Article 2 (10). The decontamination of RIMD in central decontamination units almost invariably requires the assembly of devices into sets or packs intended for a specific purpose.

The provisions of Article 12 of the Medical Device Regulation 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. It imposes obligations on the manufacturer to declare the following:

- They have 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 they have 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.

3.6 CE marking

CE stands for: 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.

Within the EU, medical devices are regulated under the Medical Device Regulation (EU) 2017/745. Compliance to Medical Device Regulation is upheld by the Health Products Regulatory Authority (HPRA). A medical device intended to be used in HSE/HSE funded services must be CE marked to indicate that it meets regulatory safety and performance requirements. CE certificates are issued by independent certification organisations called Notified Bodies.

CE symbol

The CE marking symbolises the following:

- That the product can be freely marketed throughout all the member states of the EU without further control.
- The manufacturer is declaring that the product meets all the relevant provisions of the Directives and Regulations 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 Regulation. For low risk RIMD the manufacturer declares they are in conformance and for medium to high-risk RIMD the manufacturer declares conformance which is then verified by a Notified Body with the issue of a certificate of conformance.

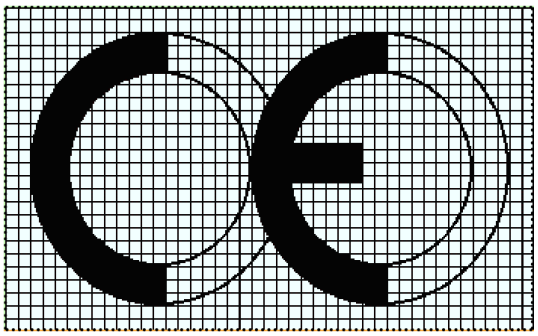
The Medical Devices Regulation (EU) 2017/745 clarifies the rules and procedures for affixing the CE mark.

Summary of rules and procedures for affixing the CE mark

- 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.
- The CE marking must also appear in any instructions for use and 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.
- 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.
- The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.
- A medical device CE mark will come with a four-digit number **** below it to indicate the specified notified body that assessed and certified it.
- The CE marking shall consist of the initials 'CE' taking the following form (Figure 3.1):

Figure 3.1: CE Symbol



If a HPRA authorised, but non-CE marked medical device is being considered for (for clinical research or compassionate use) it is essential that informed consent is obtained from the patient/service user involved (HSE, National Patient Safety Alert, 2023). Available at:

https://assets.hse.ie/media/documents/NPSA_-_Medical_Device_Regulation_and_CE_Marking_aAYPMyG.pdf

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 Healthcare Products Regulatory Authority (HPRA has

designated the National Standards Authority of Ireland (NSAI) to act as Notified Body for the medical devices legislation. There are more than 60 such bodies designated by Member States in the European Union (EU) and a manufacturer can choose to work with any one of these.

4. Spaulding classification

4.1 Classification of infection risk

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

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

Table 4.1: Classification of infection risk associated with the decontamination of RIMD

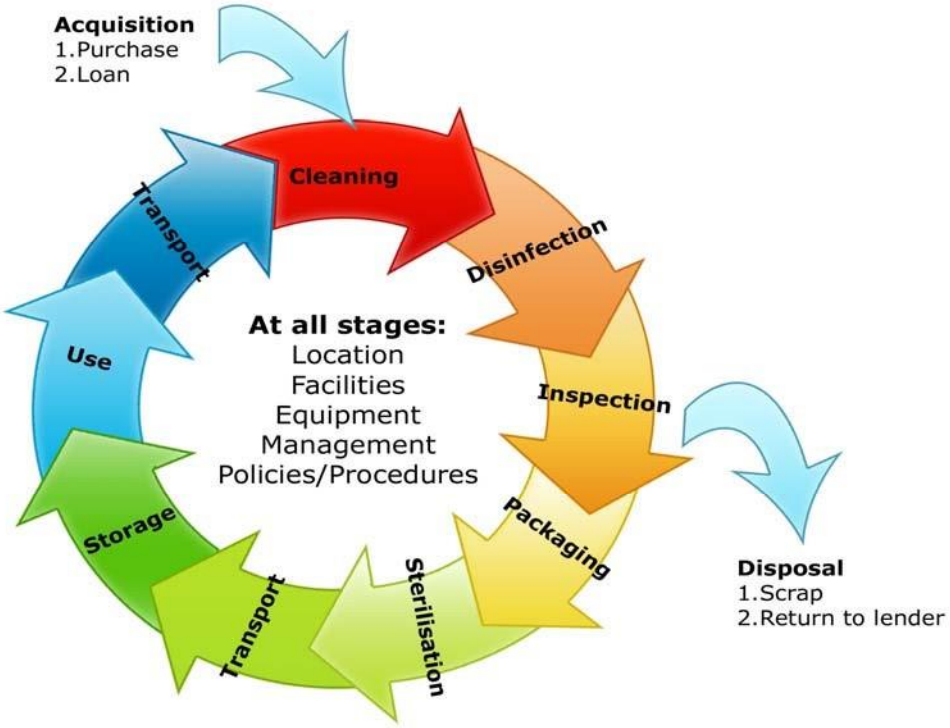
Risk	Application	Recommendation
Critical Invasive High Risk	Items that enter sterile tissue or the vascular system e.g. theatre surgical instrument set	Requires Sterilisation
Semi-critical Semi-invasive Medium Risk	Items in contact with intact mucous membranes or non-intact skin or body fluids e.g. some flexible endoscopes	Requires high level disinfection at a minimum level of reprocessing. Consider sterilisation if possible.
Non-critical Non-invasive Low risk	Items in contact with healthy skin but not mucous membranes, e.g. a blood pressure cuff	Can be processed by cleaning and additional low level disinfection maybe appropriate in specific circumstances

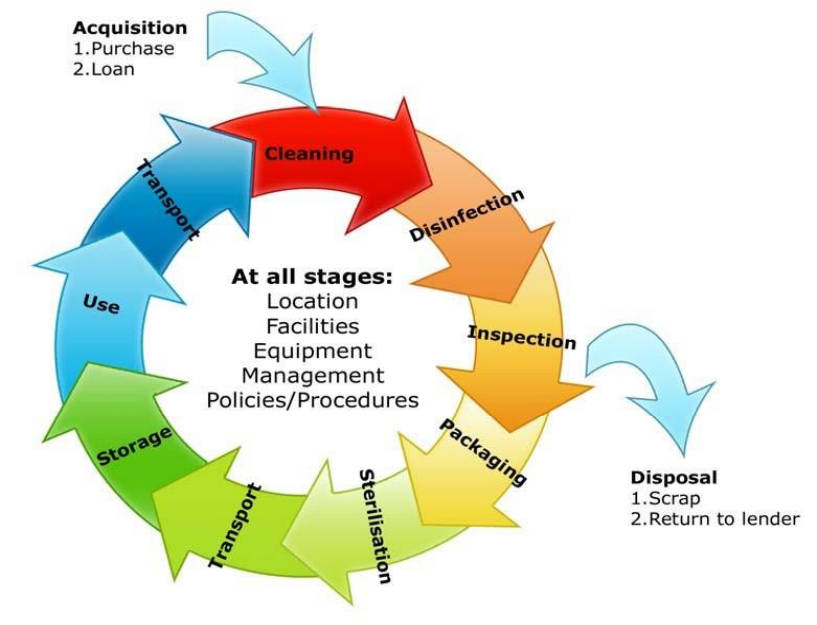
5. Life cycle for reusable invasive medical devices

5.1 Introduction

The decontamination life cycle highlights the extent to which decontamination effects the whole organisation and not just areas processing RIMD. Figure 5.1 highlights each stage of the decontamination process through which RIMD must pass prior to every use. Effective decontamination requires the attainment of acceptable Standards at all stages of the adequate decontamination.

Figure 5.1: Decontamination Life Cycle





Standards and Recommended Practices for CDUs

Part 2
Standards

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. Additional detailed guidance is available in Health Building Note 13 (Sterile Service Departments).

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).

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.

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 is through separate dedicated gowning rooms provided with hand hygiene facilities.

1.3.9. The wash room, clean room and steriliser unloading area are free from 'opening' windows, ledges, and uncleanable areas.

1.3.10. The wash area, clean room are designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.). Careful consideration should be given to the choice of building finishes especially in the wash room and clean room to achieve sound absorption while meeting cleaning and microbiological requirements.

Lighting and electricity

1.3.11 The quality of lighting is crucial in all aspects of decontamination practice and should be appropriate for the activity carried out in each operational area and be of good quality (750-lux).

1.3.12 Lighting, including magnification inspection lights, is required where Instruments and other items are inspected and should preferably be adjustable Lighting must permit good working practices and visual examination of RIMD.

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 must be mechanically ventilated and 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%). Review Appendix I Health Technical Memorandum 03-01: Specialised Ventilation for Healthcare Premises (2021).

Walls, floors and ceilings

1.3.15 Walls should be protected against accidental damage from wheeled traffic by buffer rails and corner guards. 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.

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

1.3.18 Throughout the processing areas, stores and circulation spaces, a uniform floor level should be maintained. The finish should be suitable for heavy trolley traffic. The flooring should be turned up at walls using an integral coved skirting. Floors are covered in a washable non-slip material which is securely sealed. The IAP room ceiling should be to clean-room standard should be solid, to prevent ingress of airborne particles or other contaminants from the ceiling void.

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. Provision should also be made for CDU products with special handling/storage requirements e.g., chemical detergents.

1.3.28 Storage facilities for bulk items are provided external to the wash room, cleanroom 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- Part 1 -Class 8 (manned/unmanned).

1.3.32 The clean room is monitored microbiologically. (Reference EN ISO 14698: Part 1 and EN ISO 14698 -Part 2).

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 lead (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. Cleaning equipment used should be segregated to the specific areas of use, thus, minimising the risk of contamination from dirty area to clean.

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.
2.3.8 Energy and water conservation.

Key representatives on the specialist group include:

2.3.9 Decontamination Lead.
2.3.10 Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/ Endoscopy Manager.
2.3.11 Clinical Unit Manager, e.g. Theatre Manager.
2.3.12 Infection Prevention and Control.

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

2.3.14 Procurement.

The group may also include as required:

2.3.15 Technical Services.

2.3.16 Materials Management.

2.3.17 Finance Manager/Budget Holder/Business Manager.

2.3.18 Other relevant experts (Qualified Person (decontamination)/Infection Prevention and Control Nurse/Microbiologist).

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

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

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

2.3.22 There is sufficient decontamination equipment available to meet the needs of the decontamination unit(s).

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

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

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

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

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

Manual washing

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

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

2.3.30 Separate sinks for washing and rinsing are provided.

2.3.31 The detergent used is one specified by the manufacturer for the manual cleaning of RIMD.

2.3.32 Means are provided to control the concentration of detergent and the temperature of the water in accordance with the detergent manufacturer's instructions for use.

2.3.33 A drying cabinet may be provided for hot-air drying of manually washed RIMD that cannot be processed through a washer-disinfector.

Ultrasonic cleaning

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

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

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

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

2.3.38 Means are provided to control the concentration of detergent.

2.3.39 The ultrasonic cleaner is used in accordance with the manufacturers' instructions.

2.3.40 The ultrasonic cleaner is validated, periodically tested, maintained and monitored in accordance with EN ISO 15883- Part 1 and Part 2.

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

Washer-disinfectors

2.3.42 The specification of the washer-disinfector complies with the requirements of EN ISO 15883, parts 1 &2 (washer-disinfectors).

2.3.43 Washer-disinfectors are double ended with the clean side discharging into the inspection area of the clean room.

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

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

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

2.3.47 The washer-disinfector is subject to planned preventative maintenance.

Steam steriliser

2.3.48 The specification of each steam steriliser complies with requirements of EN 285- Sterilisation- Steam sterilisers- Large sterilisers.

EN ISO 17665:2024 –Sterilisation of Healthcare Products. Requirements for the development, validation and routine control of a sterilization process for medical devices.

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

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

2.3.51 Steam sterilisers are double ended with the loading side in the clean room.

Low temperature sterilisers (LTS)

2.3.52 Low temperature sterilisation methods are used when recommended by and in accordance with, the RIMD (including flexible/rigid scopes, channelled and non-channelled endoscopes and robotic devices) manufacturers' instructions. Loads intended for sterilisation by LTS should not be reprocessed using a steam sterilizer as they might not be compatible and not in keeping with manufactures instructions.

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

2.3.54 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 (satisfactory completion of a full cycle and the achievement of the defined process parameters including IMS data and a satisfactory Biological Indicator).

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

Drying cabinet

2.3.56 A pass-through drying cabinet with inter-locking door may be provided between the Washroom and Clean room.

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

2.3.58 The drying temperature throughout the cabinet is within ±5º Celsius of the set temperature.

2.3.59 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.

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

2.3.61 The drying cabinet is subject to planned preventative maintenance and microbiological sampling in line with local Infection Prevention and Control guidance.

Heat sealer

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

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

2.3.64 The heat sealer is tested daily to verify the efficacy of the seal.

2.3.65 The heat sealer is subject to planned preventative maintenance and validation.

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 and EN ISO 20417), 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 The term 'singe use' device means a device that is intended to be used on one individual during a single procedure (MDR 2017/745). A single use medical device

or accessory is not intended by its manufacturer to be further processed and used again (ISO 20417).

The HSE current policy is that CDUs do not reprocess single use devices.

Table 3.1: Symbols and Meanings

Symbol	Meaning
	**Do Not Re-use** Indicates a medical device that is intended for one single use only. Synonyms for "Do not re-use" are "single use" and "use only once".
	**Do Not Re-Sterilise** Indicates a medical device that is not to be re-sterilised.
	**Single Patient Multiple Use** Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.

4. General Principles relating to transmissible spongiform encephalopathies (TSEs)

4.1 Statement

The organisation has documented 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 TSEs.

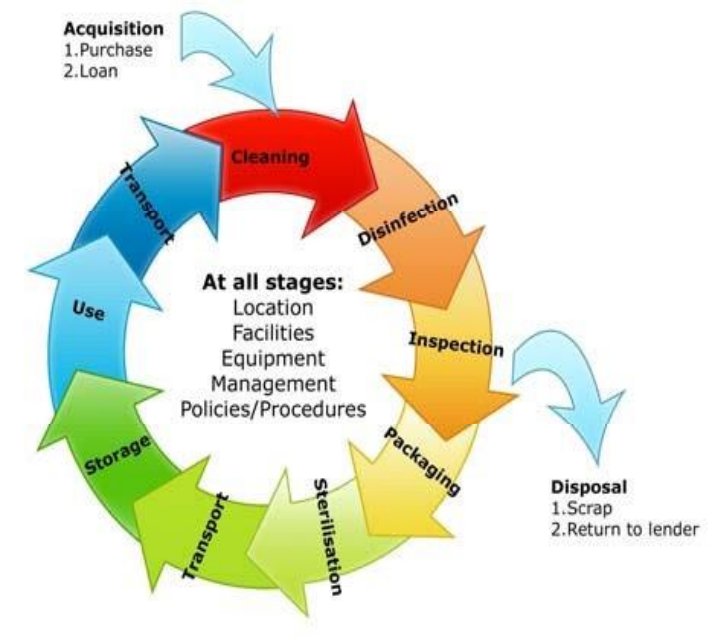
4.3 Criteria

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.

4.3.2 The organisation has written policies, procedures, protocols and guidelines to manage RIMD (or where possible, use single use equipment) that are currently based on the Guidelines devised by:

- The Health Protection Surveillance Centre (2019) Protocol for reporting and Management of cases of Creutzfeldt Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSEs).
- The Advisory Committee and Dangerous Pathogens (2021) Minimising transmission risk of CJD and vCJD in healthcare settings (Annex E, Quarantining of surgical instruments).
- National Institute of Clinical Excellence (2020) Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues.
  Available at: Overview | Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues | Guidance | NICE

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

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

1.4 General Principles

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 decontamination unit.

1.4.8. Access to the wash room and to the clean room should be through dedicated gowning rooms provided with hand hygiene facilities.

1.4.9. The wash room, clean room and steriliser unloading area should be free from 'opening' windows, ledges, and uncleanable areas.

1.4.10. The wash room and clean room should be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.). Careful consideration should be given to the choice of building finishes especially in the washroom and clean room to achieve sound absorption while meeting cleaning and microbiological requirements.

Section Two: Lighting and electricity

1.4.11 The quality of lighting is crucial in all aspects of decontamination practice and should be appropriate for the activity carried out in each operational area and be of good quality (750-lux).
(Note: Full spectrum lighting is desirable to reduce fatigue and facilitate inspections relying on colour balance e.g. corrosion).

1.4.12 Task lighting, including magnification inspection lights, is required where instruments and other items are inspected and should preferably be adjustable. Lighting must permit good working practices and visual examination of RIMD. 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 18-22ºCelsius and relative humidity should be controlled within the range 35-60%). Review Appendix I, for more information on ventilation systems for CDUs.

Section Four: Walls, floors and ceilings

1.4.15 Walls should be protected against accidental damage from wheeled traffic by buffer rails and corner guards. 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 Throughout the processing areas, stores and circulation spaces, a uniform floor level should be maintained. The finish should be suitable for heavy trolley traffic. The flooring should be turned up at walls using an integral coved skirting. Floors should be covered in a washable non-slip material which is securely sealed. The clean room ceiling should be to clean-room standard should be solid, to prevent ingress of airborne particles or other contaminants from the ceiling void.

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.

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. Provision should also be made for CDU products with special handling/storage requirements e.g., chemical detergents.

1.4.28 Storage facilities for bulk items should be provided external to the clean 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.

Section Eight: CFU control

1.4.31 The clean room should be controlled as a clean room to ISO 14644 Part 1, Class 8 (manned/unmanned).

1.4.32 The clean room in which clean non-sterile RIMD are inspected, assembled and packed is monitored microbiologically. (Reference EN ISO 14698 Part 1 and EN ISO 14698 Part 2).

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 Lead and Decontamination Manager (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 and the wash room. Cleaning equipment used can be segregated to the specific areas of use, thus, minimising the risk of contamination from dirty area to clean.

Section Ten: Other

1.4.35 Further detailed guidance is given in Health Building Note 13.

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

2.4 General Principles

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 and wash room with consideration for local hospital cleaning policies.

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 inspected and serviced.

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 in line with EN 14644 Cleanrooms and associated controlled environments.

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

2.4.10 Alert and 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 Damp mopping is preferable to dry mopping. Flat mops are recommended for effective cleaning and these should be decontaminated in washing machines dedicated for this purpose.

2.4.12 Vacuum cleaners are fitted with HEPA filtered exhaust.

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 in line with EN 14644.

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 Safety Data Sheet (SDS) supplied by the process chemical manufacturer).

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

Section Seven: Environmental monitoring

2.4.28 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.

2.4.29 Microbiological sampling methods suited to locations and purpose should be chosen.
(Note: Alert and action limits should be set for microbial contamination in each area, after a period of baseline monitoring.)

Microbiological analysis should be undertaken by a laboratory that is accredited by the Irish National Accreditation Board (INAB).

2.4.30 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) and Sabaroud Dextrose Agar (SDA).

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

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

b. by active sampling using a calibrated microbiological air sampler

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

	Tryptone soya agar (TSA)	Scabrous Dextrose agar (SDA)
Target microbes	Broad range of bacteria, some yeasts and moulds	Mainly yeasts and moulds
Exposure volume	200 - 1000 litres	200 - 1000 litres
Incubation temperature	30 -35°C	20 -25°C
Incubation time	5 days to show moulds	5 days
Results reported as:	Colony-forming units/m^3	Colony-forming units/m^3

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

Flat surfaces

a. Where surfaces to be sampled are flat, contact plates can be used to directly sample.

(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. Carefully remove the swab from its tube, allowing any excess moisture to remain in the tube. Then rub the swab against a predefined area (cm2) the sample surface using a twisting motion, and replace it in the tube and send to the designated laboratory for analysis. *(Note: Swabs for environmental sampling are commercially available and these types should be used rather than swabs designed for clinical sampling. Seek advice from the analysing laboratory regarding the supply of the appropriate swabs and neutralising buffer)*

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 colour change rather than light output.)

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 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. At the commission of an air handling unit, a scale drawing of the decontamination unit should be obtained. On this should be marked all

points of air intake and extract. The path that airflow takes during normal working conditions should be mapped using a small smoke generator. This can show anomalies e.g. during filter malfunction or can aid in choosing sampling sites for air quality.

Sampling sites

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

2.4.35 The absolute CFU value has limited scientific meaning but is used to identify adverse trends and deviations (these should cover a twelve-month period).

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 baseline conditions and may not require action, but may need to be monitored more closely.
d. **Action level** – CFU levels that, that when exceeded, indicate a deviation from normal operating baseline conditions and require immediate action.

Table 2.3: Suggested microbial alert and action limit values which may be used as a benchmark for CDUs

	Contact plate CFU/plate	Settle plate CFU/ plate
Class 8 Alert	5	5
Class 8 Action	30	20

2.4.36 Each healthcare organisation should have its own unique baseline patterns.

2.4.37 Monitoring results should be used to plot simple graphs to determine baselines and trends. The absolute CFU value has limited scientific meaning but results can be used to identify adverse trends and deviations from the baseline trends.

2.4.38 Investigation procedures and corrective actions should be prepared for response to a breach of the action limits. Guidance may be sought from a microbiologist.

2.4.39 Risk assessment, if action limits are exceeded may include identification of organisms. It is also important to know if disinfectants in use are effective against these and at what concentration.

2.4.40 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 cleaning equipment.
h. are disinfectants or detergents free from contamination?
i. 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-disinfectors

Section Five: Steam sterilisers

Section Six: Low temperature sterilisers

Section Seven: Drying cabinets

Section Eight: Heat sealers

3.4 General Principles

Section One: Specialist group

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

a. ability to meet current standards.
b. age and condition of equipment and availability of replacement parts.
c. cost of maintaining, repairing and replacing the equipment.
d. ability to interface with other equipment in the decontamination facility.
e. ability to interface with user requirements.
f. ability to meet the requirements of current test methods.
g. ability to be validated and perform to intended purpose.
h. energy and water conservation.

3.4.2 Key representatives on the specialist group should include:

a. Decontamination Lead.
b. Decontamination Unit Manager, e.g. Endoscope Reprocessing. (Decontamination) Unit Manager.
c. Clinical Unit Manager, e.g. Theatre Manager.
d. Infection Prevention and Control Manager.
e. Bio-medical Engineering/Clinical Engineering/Medical Physics.
f. Procurement.

3.4.3 The group may also include as required:

a. Technical Services.
b. Materials Management.
c. Finance Manager/Budget Holder/Business Manager.
d. Other relevant experts (Qualified Person (decontamination)/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 lead (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.

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 and the water. (Note: an automated dispenser is preferable.)

3.4.18 A pass-through drying cabinet with inter-locking doors may 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.

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 &5.

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& 5.

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

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.

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 134-137ºC for not less than 3 minutes or 121-124ºC for not less than 15 minutes.

3.4.38 Steam sterilisers should be double ended with the loading side in the clean room.

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 17665:2024

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 (LTS)

3.4.41 Low temperature sterilisation methods are used when recommended by and in accordance with the RIMD (including flexible/rigid scopes, channelled and non-channelled endoscopes and robotic devices) manufacturers' instructions. Loads intended for sterilisation by LTS should not be reprocessed using a steam sterilizer as they might not be compatible and not in keeping with manufactures instructions.

3.4.42 Low temperature sterilisation should be carried out using vapour phase Hydrogen Peroxide, Hydrogen Peroxide Gas Plasma processes.
(Note: The low temperature sterilisation process must be compatible with the device for processing.)

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

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

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 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.

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 validation and 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 tested daily to verify the efficacy of the seal.

3.4.54 The heat sealer should be validated to EN ISO 11607- Part 1 and Part 2-and subject to planned preventative maintenance programme in line with manufacturers' recommendations.

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 General Principles

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 Health Products Regulatory Authority (HPRA) - Medical Devices Regulations 2021.

Section Two: Procurement policy

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

Section Three: Specification

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

Section Four: General principles

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

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

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

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

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

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

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: 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 General Principles

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 re-sterilised.
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.

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 batch code preceded by the word 'LOT', or the serial number.

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

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

5.4.16 If the RIMD is custom-made, the words 'custom-made RIMD'.

5.4.17 If the RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.

5.4.18 Any special storage and/or handling conditions.

5.4.19 Any special operating instructions.

5.4.20 Any warnings and/or precautions to be taken.

5.4.21 Year of manufacture.

5.4.22 Batch or serial number.

5.4.23 Where applicable, method of sterilisation.

5.4.24 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:

5.4.25 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.

5.4.26 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.

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

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

5.4.29 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.

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

5.4.31 In the case of RIMDs emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

Section Four: Precautions and contraindications

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

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

5.4.33 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.

5.4.34 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.

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

Section Five: Information supplied on request

5.4.36 The identity or information on the test methods used.

5.4.37 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:

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

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

5.4.40 An indication of the date by which the RIMD should be used, in safety, stating the month and the year.

5.4.41 Any special storage and/or handling conditions.

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

5.4.43 Year of manufacture.

5.4.44 Batch or serial number.

5.4.45 Where applicable, method of sterilisation.

Section Seven: Instructions for use

5.4.46 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 the Health and Welfare at Work Act -Personal Protective Equipment at Work (Amendment) Regulations 2022.

Available at: https://enterprise.gov.ie/en/legislation/si-no-325-of-2022.html

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

Section Five: Gloves

Section Six: Footwear

6.4 General Principles

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) and dedicated footwear.

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.

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.

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)

7. Clean room attire and behaviour

7.1 Introduction

Protective clothing should be worn by personnel entering the clean 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 to reduce the risk of contaminating clean devices.

7.3 Contents

Section One: Attire

Section Two: Head/hair cover

7.4 General Principles

Section One: Attire

7.4.1 Healthcare Workers (HCWs) working in the clean room should wear a freshly laundered scrub suit and dedicated footwear.

7.4.2 Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.

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. Facial hair should be neatly shaven and covered with a beard cover.

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, false eye lashes, nail polish (including false nails) and jewellery should not be worn in the clean room/inspection, assembly and packaging room.

Figure 7.1: Personal protective equipment

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). The Safety, Health and Welfare at Work (General Application) Regulations2007. The Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2021.

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 General Principles

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: Safety Data Sheets (SDS) and labels

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

8.4.7 Copies of all SDS 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 SDS referred to.

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

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.

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

Section Three: Unique Device Identification (UDI)

9.4 General Principles

Section One: Processing

9.4.1 Electronic 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.
e. Details of the RIMD non-conformances and equipment failures.

9.4.3 All RIMD should be individually identified with a Global Standard 1 (GS1) Global Individual Asset Identifier (GIAI) code.

9.4.4 Manually based systems should only be used for back-up in the event of IT failure.

9.4.5 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 Electronic 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.

Section Three: UDI (Unique Device Identification)

A new feature of the Regulations is the unique device identification (UDI) system (MDR Article 27), which will apply to all devices placed on the EU market. The UDI will be a barcode, a QR code or any other machine-readable code. This will enhance the identification and traceability of devices and the effectiveness of post-market safety-related activities through targeted field safety corrective actions and better monitoring by competent authorities. Economic operators shall be able to identify any health

institution or healthcare professional to which they have directly supplied a device (MDR Article 25).

9.4.8 A UDI is a unique identifier for the trade item that is created through a globally accepted device identification and coding standard, in the form of a series of numeric or alphanumeric characters.

9.4.9 The UDI system will facilitate easier traceability of medical devices, significantly enhance the effectiveness of the post-market safety-related activities for devices and allow for better monitoring by competent authorities. It will also help to reduce medical errors and to fight against falsified devices

9.4.10 Under Article 27(9) of the MDR, healthcare institutions are required to store and keep the UDIs of the Class III implantable devices they have supplied, or with which they have been supplied. The Regulations oblige Member States to encourage (and may require) healthcare institutions to store and keep the UDIs of the devices with which they have been supplied, irrespective of their class.

9.4.11 The HSE in collaboration with the Department of Health and HSE stakeholders is in the process of developing and testing electronic tracking systems for Class III implantable medical devices.

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 General Principles

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 Page 19). In brief, the minimum levels of reprocessing are as follows for different types of site:

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. **Semi-critical 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.

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: European Agreement Concerning the International Carriage of Dangerous Goods by Road 2023

Section Two: Containers and trolleys

Section Three: Staff

11.4 General Principles

Section One: European Agreement Carriage of Dangerous Goods by Road 2023.

11.4.1 The ADR 2023 (European Agreement Concerning the International Carriage of Dangerous Goods by Road) states that:

For the purposes of ADR, infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals (2.2.62.1.1).

Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to the ADR unless they meet the criteria for inclusion in another class (2.2.62.1.5.3 & 2.2.62.1.5.9).

Therefore, the following advice should be adhered to when transporting contaminated RIMD for reprocessing.

Scenario 1:

If the contaminated RIMD have been cleaned and thermally disinfected so that 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 2:

The RIMD have not been cleaned and thermally 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 accordance with 2.2.62.1.5.9 of the Regulation. Packaging systems must meet the requirements of 4.1.1.1 and 4.1.1.2 of the regulation (see link to the Regulation below).

https://unece.org/sites/default/files/2023-01/ADR2023_Vol1e.pdf

The Health and Safety Authority (HSA) provided an Exemption on 03/2016 that allowed the carriage of uncleaned Reusable Invasive Medical Devices (RIMD) by road, in packaging that was not tested to meet the criteria of withstanding the required 1.2 m drop test. The exemption applied to both transport boxes and transport trollies. In 2018 the HSA exemption expired and will not be renewed. For guidance on transport packaging see the link below.

https://assets.hse.ie/media/documents/Transport_of_uncleaned_reusable_invasive_medical_devices_by_road_safety_alert.pdf

Section Two: Containers and trolleys

11.4.2 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.

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

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

11.4.5 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.

11.4.6 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.

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

11.4.8 Sharps should be removed and placed into approved containers conforming to European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations 2014.

11.4.9 Reusable textiles should be held in appropriate linen bags and returned to the laundry service.

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

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

Section Three: Staff

11.4.12 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.

11.4.13 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 General Principles

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.

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. lace each jointed RIMD in the open position in the mesh basket.

12.4.8 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.

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

12.4.10 Secure small and light items with a hold down screen or by other means, to ensure they are not free to move around during the cleaning process. Place scissors, lightweight RIMD, and microsurgical RIMD next.

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

12.4.12 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.

12.4.13 For RIMD with one or more lumens, each lumen should be connected to the appropriate flushing system provided for that purpose.

Figure 12.1: Sorting and disassembly of contaminated RIMD

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

13.4 General Principles

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) may be used where it is apparent that there is gross soiling on RIMD that it would be preferable to remove before automated cleaning takes place.

Section Four: Automated cleaning

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-disinfector 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 page 45.

General Principles

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.

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 decontamination technician/operative 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.

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 A0 values (see EN ISO 15883-Part 1)

a. Each operating cycle shall include a thermal disinfection stage for which the time at the load, internal surfaces of the chamber and the load carrier are maintained at the disinfection temperature that gives an A0 of at least 600 on all surfaces of the load to be disinfected when tested in accordance with clause 6.3 EN ISO 15883-Part 2. For thermal disinfection of RIMD an A0 of not less than 600 is required.
b. All washer-disinfectors complying with EN ISO 15883- Part 2 must have the capability to facilitate disinfection times and temperatures to give an A0 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 13.1: Automated washer-disinfector temperature bands (ref. EN ISO 15883- Part 1)

A_0 value	Temperature	Minimum Holding Time (Minutes)
600	90 -95	1

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.

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.

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 in compliance with 15883- Part 2 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 (Authorised Engineer in Decontamination (AED).

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. For internal surfaces of processed cannulated devices ISO15883-2 clause 4.4 & 6.2.
d. process residue test.
e. Temperature of internal surfaces of processed devices e.g. for anaesthetic and respiratory tubing, lumen devices and powered devices, the temperature requirements for the inner surfaces shall be deemed to have been achieved ISO15883-2 clause 4.4 & 6.3.3 Temperature probes inserted inside. E.g. Phaco Handpieces & DaVinci robotic instruments. Verification of flow & pressure through lumen & powered devices ISO15883-2 clause 4.4, 5.1.1, 5.1.2 & 6.3.3.

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.

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 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.

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

Test
Daily Tests
1. Check spray arms rotation for free movement
2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages
3. Remove and clean strainers and filters etc.
Weekly Tests
1. Weekly Safety Check
2. Carry out daily tests
3. Water conductivity (final rinse stage)
4. Automatic control test recommended
5. Cleaning Efficacy test by residual soil detection
Quarterly tests
1. Weekly safety checks
2. Automatic control tests
3. Verification of calibration of WD instruments
4. Thermometric test for thermal disinfection
5. Cleaning efficacy test
Yearly and revalidation tests (Requalification in EN 15883 terminology)
1. Yearly safety checks
2. Automatic control tests
3. Verification of calibration of WD instruments
4. Water system
-chemical purity
-bacterial endotoxins and TVC
5. Drainage
-free draining
-efficacy of discharge
6. Doors and door interlocks
-cycle start
-in-cycle

-failed cycle
7. Fault interlock
8. Water vapour discharge test (fluid emission)
9. Chemical additive dosing tests
-reproducibility
-low level detection
10 Load carriers—alignment
11. Test for air quality
12. Cleaning Efficacy test
13. Over temperature cut-out test
14. Thermometric test for Thermal disinfection
15. Load dryness test
16. Process residues—chemical additives (for performance re-qualification only if required)

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.

13.4.38 Preventative maintenance should be planned and performed in accordance with International Standards EN ISO 15883-Part 1 and EN ISO 15883- Part 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.

Figure 13.1: Washer-Disinfector

Figure 13.2: Loading the washer-disinfector

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 45.

General Principles

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 De-gas 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.

13.4.53 Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.

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).

Commissioning 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.

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, overtemperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasonic activity and sound pressure test.

Table 13.3: Periodic tests for Ultrasonic cleaners

Test	**EN ISO 15883**
Daily tests	
1. Remove and clean strainers and filters etc.	N/A
Weekly tests	
1. Weekly safety checks	N/A
2. Carry out daily tests	N/A
3. Automatic control test recommended	6.13
4. Cleaning efficacy test by residual soil detection	6.10.3
Quarterly tests	
1. Weekly safety checks	N/A
2. Automatic control test (if using an automated ultrasonic cleaner)	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Test for ultrasonic activity*	6
5. Cleaning efficacy test	6.10.2 6.10.3
6. Water Quality	

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

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

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 SHTM 01-01 Part D)

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. Tests carried out during commissioning (IQ/OQ) are intended to establish the variation in activity at different positions and levels within the bath and the time required to obtain a characteristic erosion pattern. 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 nominal thickness 0.015–0.025 mm.

13.4.79 Steriliser indicator tape.

13.4.80 Stopwatch.

13.4.81 Ruler/tape measure graduated in mm.

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). File the strips.

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.

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.

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

General Principles

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.

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.

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.)

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

General Principles

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.

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.

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 General Principles

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.

Section Two: Disinfection process

14.4.3 Thermal disinfection using a minimum A0 value of 600 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, most frequently used to clean and disinfect flexible endoscopes.

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 e.g. flexible endoscopes.

Thermal Disinfection

14.4.6 If items can withstand heat and moisture and do not require sterilisation, then thermal disinfection using moist heat with using temperatures and contact time with a minimum A0 value of 600 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.

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

15.4 General Principles

Section One: Equipment

15.4.1 See decontamination equipment page 45.

Section Two: General Principles

15.4.2 RIMD should be placed in a drying cabinet. Where a drying cabinet is not available a clean disposable lint-free cloth should be used.

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 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.

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

16.4 General Principles

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: General Principles

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

16.4.5 Check that the Independent monitoring system 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.

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.

16.4.13 Unless there is clear indication why a small percentage of RIMD in a load were not cleaned, 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 Where one instrument in a set is rejected the whole set must be sent back for re-cleaning.

16.4.16 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

16.4.17 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 required parameters established during validation parameters.
k. any notes or observation for the process cycle.

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

16.4.19 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

16.4.20 Each RIMD set should be inspected separately.

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

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

16.4.23 Jaws and teeth should be checked for alignment.

16.4.24 Ratchets should be checked for security.

16.4.25 Ratchets should close easily and hold firmly.

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

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

16.4.28 Telescopes and light cables should be function checked as per manufacturers' instructions.

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

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

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.

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 General Principles

Section One: Equipment

17.4.1 RIMD list.

17.4.2 Accessories, e.g. tray liner.

17.4.3 RIMD protectors, type 6 chemical indicators.

Section Two: General Principles

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 or follow manufactures instructions.

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

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 and ISO 11607 Parts 1 and 2.

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

18.4 General Principles

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 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.

18.4.13 If chemical indicators are used inside the pack, they should conform to 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.

18.4.36 **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.

18.4.37 **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:

18.4.38 Be stored at room temperature 18ºC to 22ºC 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.

18.4.39 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.

18.4.40 Be stored on shelves and clear of the floor.

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

Section Four: Single use packaging

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

Section Five: Types of packaging

Papers and non-wovens

18.4.43 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.

18.4.44 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.

18.4.45 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:

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

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

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

18.4.49 Should be suitable to the storage configuration.

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

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

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

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

18.4.54 Filter plate should be examined for integrity both before installation and after the sterilisation process.

18.4.55 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.

18.4.56 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.

18.4.57 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.

18.4.58 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.

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

Section Six: Packaging techniques

18.4.60 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.

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

Flat wrapping material

Equipment required

18.4.62 Packaging material.

18.4.63 Sterilisation chemical indicator tape.

18.4.64 Marking pen.

18.4.65 Label (where applicable).

18.4.66 Tray liners.

Procedure (parcel-fold wrapping method)

18.4.67 Select appropriate packaging material and place on work top.

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

18.4.69 Verify the accuracy of the RIMD identification label with the RIMD/RIMD set, (i.e. corresponds to RIMD checklist, internal tray label, etc.). The checklist is to be folded with the ink facing inwards and the checklist is to be placed between the two layers of tray wrap to avoid ink transfer onto the RIMD.

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

18.4.71 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.

18.4.72 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.

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

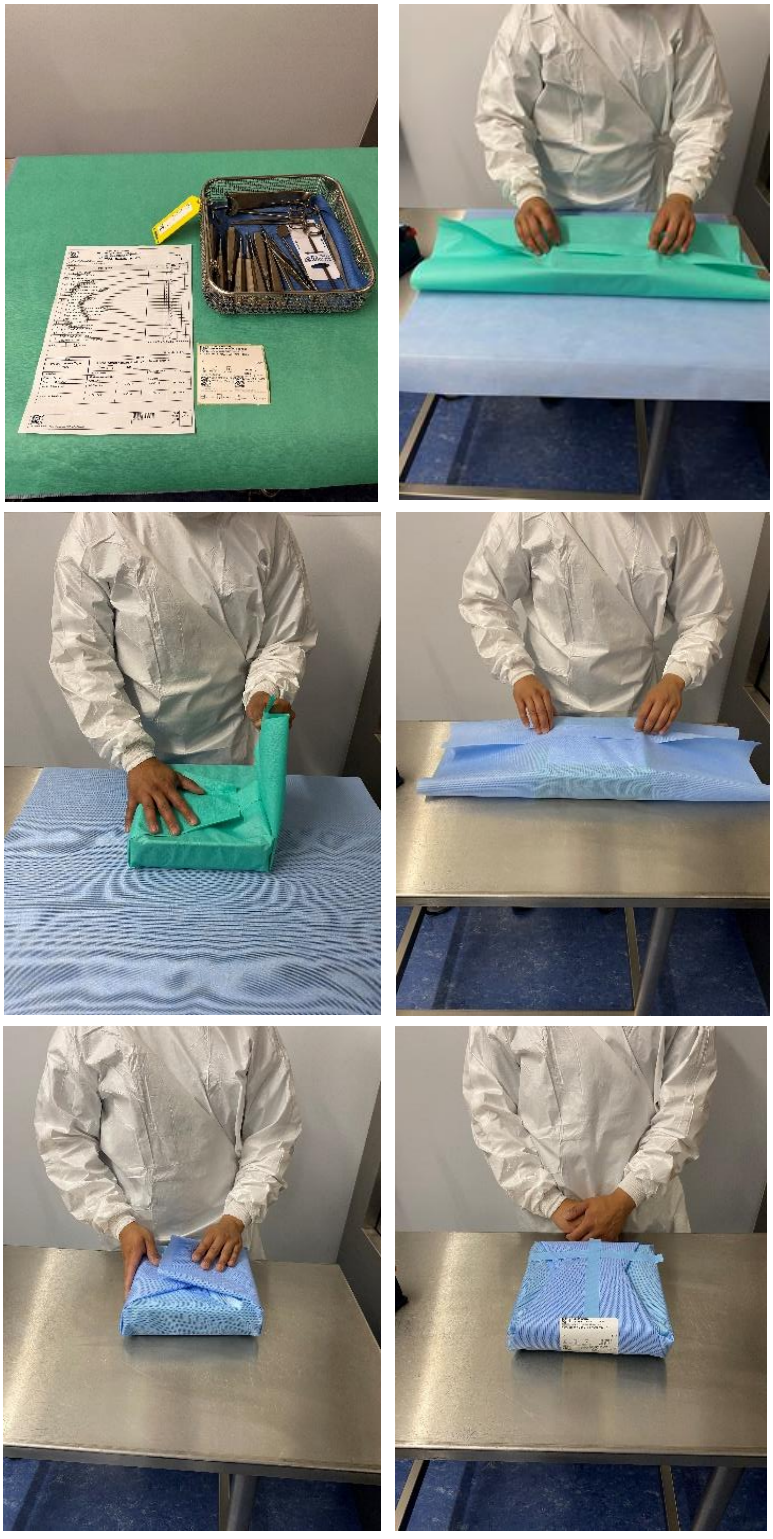
18.4.74 The same procedure may then be repeated for an outer wrap(s).

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

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

18.4.77 RIMD identification label is placed on outside wrap.

Figure 18.1: Parcel-fold wrapping method



Procedure (envelope wrapping method)

18.4.78 Select appropriate packaging material and place on work top.

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

18.4.80 Verify the accuracy of the RIMD identification label with the RIMD/RIMD set (i.e. corresponds to the RIMD checklist, tray internal label, etc.). The checklist is to be folded with the ink facing inwards and the checklist is to be placed between the two layers of tray wrap to avoid ink transfer onto the RIMD.

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

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

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

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

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

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

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

18.4.88 RIMD identification label is placed on the outside wrap.

Figure 18.2: Envelope wrapping method

Pouches and bags (requiring folding)

18.4.89 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

18.4.90 Pouches and/or bags.
18.4.91 Sterilisation chemical indicator tape.
18.4.92 Marking pen.
18.4.93 Label (where applicable).

Procedure

18.4.94 The corners at the open end of the pouch are folded diagonally to give mitred corners.
18.4.95 The top of the pouch is then folded over three times in succession.
18.4.96 The same procedure may then be repeated for an outer wrap(s).
18.4.97 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.
18.4.98 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.
18.4.99 It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
18.4.100 RIMD identification label is placed on the outside wrap.

Self-seal pouches

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

Paper and paper/plastic pouches using heat seal

General principles

18.4.102 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.

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

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

18.4.105 Heat seal pouches should be hermetically sealed.

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

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

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

Equipment required

18.4.109 Heat-seal pouches.

18.4.110 Heat sealer.

18.4.111 Marking pen.

18.4.112 Label.

18.4.113 Chemical indicator (where applicable).

18.4.114 Instrument tip protector (where applicable).

Procedure

18.4.115 Select appropriate size heat seal pouch.

18.4.116 Place RIMD into pouch.

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

18.4.118 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.

18.4.119 Place open end of pouch in heat sealer.

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

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

18.4.122 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.

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

18.4.124 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.

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

18.4.126 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.

18.4.127 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.

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

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

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

18.4.131 RIMD identification label is placed on the outside packaging.

Figure 18.3: Using the heat seal

Figure 18.4: Heat seal pouch

Section Seven: Sealing of packs and bags

18.4.132 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 EN ISO 11140 Part 1.

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

18.4.133 Allow sterilisation.
18.4.134 Avoid constriction of the package.
18.4.135 Maintain package integrity.
(Note: The accessories should also be recommended by the manufacturer.)

The following accessories should not be used:

18.4.136 Tape (other than sterilisation chemical indicator tape).
18.4.137 Safety pins.
18.4.138 Paper clips.
18.4.139 Staples.

Sterilising indicator tape

Sterilising indicator should be:

18.4.140 Specific to the method of sterilisation being used and which will change colour when exposed to the relevant sterilisation agent.
18.4.141 Pressure sensitive.
18.4.142 Nontoxic, adhere to clean surfaces and leave no adhesive residue on removal.
18.4.143 Compatible with the wrapping material used.

18.4.144 Heat stable.

18.4.145 Moisture-stable and permeable to the sterilising agent.

Section Eight: Labelling

18.4.146 Packages to be sterilised should be labelled before sterilisation.

18.4.147 The information of the label should include the following:

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

18.4.148 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.

18.4.149 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.

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

18.4.151 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:

18.4.152 General appearance of the packaging material.

18.4.153 Whether packages are complete.

18.4.154 Whether the correct products and packaging material are used.

18.4.155 Whether the labelling is correct on the product.

18.4.156 Whether the sealing is correct.

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

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

18.4.159 Containers seals and filters should be checked.

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

Section Ten: Maintenance

18.4.161 Reusable containers should be subject to thermometric performance tests.

18.4.162 Containers should be validated periodically for reuse according to manufacturers' instructions.

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

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

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

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

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

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

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

18.4.170 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.

18.4.171 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

19.4 General Principles

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 Hydrogen Peroxide and Hydrogen Peroxide Gas 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 134-137oC for a minimum of 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.

Figure 19.1: Steriliser

Table 12.1: Sterilisation temperatures, steam pressures and hold times

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilisation Hold time
121^0C	1.03 bar gauge	124^0C	15 minutes
134^0C	2.30 bar gauge	137^0C	3 minutes

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

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 hollow devices, tubing 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 Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.

19.4.12 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

19.4.13 See decontamination equipment, page 45.
19.4.14 Loading trolley.
19.4.15 IT based/Manual tracking system and accessories, i.e. paper, pen, scanner.
19.4.16 Batch control labeller.
19.4.17 Personal protective equipment - (heat resistant gloves).

General Principles

19.4.18 Healthcare workers should wear personal protective equipment.
19.4.19 Healthcare workers should ensure that that all items within the load are compatible with the process to which they are to be exposed.
19.4.20 Loading should allow for free circulation of steam around each pack and each item.
19.4.21 RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
19.4.22 Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.
19.4.23 Hollowware should be placed upside-down or tilted, to prevent collection of condensate.
19.4.24 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.
19.4.25 Containers should be loaded onto the trolley such that an air space is formed between each container layer.
19.4.26 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.
19.4.27 When loading, healthcare workers should ensure that each RIMD is labelled.

19.4.28 When loading is complete, each item on the loading trolley should be recorded using the IT (or manual) tracking system.

Section Five: Loading the steriliser

19.4.29 Healthcare workers should load the steriliser using the loading trolley.

19.4.30 Healthcare workers should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.

19.4.31 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.

19.4.32 Manufacturers' instructions and protocols agreed during validation should be followed for loading.

19.4.33 Overloading of sterilisers may compromise the process.

Figure 2: Loading the steriliser

Section Six: Steam sterilisation of RIMD

19.4.34 Healthcare workers should wear personal protective equipment.

19.4.35 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.

19.4.36 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.)

19.4.37 Healthcare workers should initiate the cycle in accordance with the steriliser manufacturers' instructions.

19.4.38 Where single door steriliser is in use a system should be in place to ensure segregation of non-sterile and sterile RIMD.

19.4.39 When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.

19.4.40 The fail cycle may require a special key to open the steriliser door.

19.4.41 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

19.4.42 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

19.4.43 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.

19.4.44 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.

19.4.45 A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

Figure 3: Cycle records

Inspection of sterilised load

19.4.46 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.

19.4.47 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

19.4.48 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.

19.4.49 Any notes or observation for the process cycle.

19.4.50 Read out results of physical, chemical or biological indicators that are used.

19.4.51 All records should be retained for the lifetime of the steriliser plus eleven years.

Section Nine: Validation

19.4.52 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.

19.4.53 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.

19.4.54 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

19.4.55 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

19.4.56 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.

19.4.57 These tests should be carried out when a new steriliser is purchased or when a used steriliser has been relocated to another premises.

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

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

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

Performance Qualification

19.4.61 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.

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

Periodic testing

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

19.4.64 The appropriate tests should be carried out at daily, weekly, quarterly and annual intervals.

19.4.65 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)

19.4.66 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

19.4.67 A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.

19.4.68 At the end of the process the test device is removed from the chamber.

19.4.69 The test device is checked for a pass or fail in accordance with the manufacturer's instructions. The test results should be recorded.

19.4.70 If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results. 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.

19.4.71 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.

19.4.72 A batch (cycle) process record should be made in the steriliser log book.

Figure 4.4: Bowie-Dick test

Weekly tests

19.4.73 The user should perform safety checks before starting the sequence of weekly tests. The schedule of weekly tests is summarised in Table 19.2 below.

Table 19.2: Summary of weekly tests for steam sterilisers
(Note: All tests can be combined into one test)

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

Safety checks

19.4.74 These tests are intended to ensure the steriliser is both safe to use and to test.
They consist of:

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

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

19.4.75 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.

19.4.76 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.

19.4.77 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.

19.4.78 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.

19.4.79 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:

19.4.80 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.

19.4.81 If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results. 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

19.4.82 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 EN ISO 17665:2024.

Automatic control test

19.4.83 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.

19.4.84 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.

19.4.85 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.

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

19.4.86 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.

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

Quarterly tests

19.4.88 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.

19.4.89 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 19.3: Summary of quarterly tests for steam sterilisers

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

Annual 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 annual tests are intended to confirm that the data generated during validation remain consistent and accurate. Annual tests for steam sterilisers are summarised in table 19.4.

Table 19.4: Summary of annual tests for steam sterilisers (EN285)

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

Section Ten: Monitoring and control

19.4.92 134ºC is the preferred sterilisation temperature. For RIMD, which may be damaged at 134ºC, any of the other lower temperature bands may be used.

19.4.93 There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.

19.4.94 Routine monitoring and testing should be carried out in accordance with documented procedures in line with EN ISO 17665:2024.

19.4.95 Section Eleven: Maintenance

19.4.96 Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' recommendations and standards.

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

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

19.4.99 Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665:2024.

19.4.100 A nominated qualified person (AED Authorised Engineer in Decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

19.4.101 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

19.4.102 Revalidation may be required after steriliser relocation, engineering work, repair 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 present best practice guidance on sterilisation by vaporised hydrogen peroxide of medical devices within the (CDU).

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 General Principles

Section One: General principles

20.4.1 Two different methods of low temperature sterilisation are available for use in healthcare organisation; vapour phase hydrogen peroxide (VHP) and hydrogen peroxide gas plasma.

20.4.2 Hydrogen peroxide based methods are preferred

20.4.3 Low temperature sterilisation methods should only be used for:

a. RIMD (including flexible/rigid scopes/ channelled and non-channelled endoscope and robotic devices) specifically identified by the RIMD manufacturer or steriliser manufacturer as suitable for processing in the steriliser, or

b. RIMD (including flexible/rigid scopes channelled and non-channelled endoscope and robotic devices) made of materials of a size and configuration (e.g. length and diameter of lumen) within the criteria specified by the steriliser manufacturer.

Loads intended for sterilisation by LTS should not be reprocessed using a steam sterilizer as they might not be compatible and not in keeping with manufactures instructions.

(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 channelled and non-channelled endoscope and robotic devices) 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.

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. The release of the sterile product should be on the basis of defined release criteria, which should include all or some of the following:

1. Satisfactory completion of a full cycle and the achievement of the defined process parameters including IMS data;
2. Satisfactory Biological Indicator (BI) or Process Challenge Device (PCD) test results;
3. Satisfactory product or package integrity including label information;
4. Any other tests as defined by internal quality procedures such as satisfactory H2O2 residual results.

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 (AED Authorised Engineer in 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 (AED Authorised Engineer in 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:

Process indicators:

20.4.23 These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.

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

20.4.24 Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained. The spores of the type Geobacillus stearothermophilus are the most resistant test germ to the sterilisation methods used in the CDU. The use of B1's for low

temperature sterilisation processes, complies with the normative requirements of EN ISO 14937 and ISO 11138 Part 1.

20.4.25 Biological indicators must meet the requirements of EN ISO 11138 Part 1.

20.4.26 New technologies regarding BI ensure that test results can be available prior to releasing an item from a low temperature steriliser. Satisfactory completion of a cycle and the achievement of the defined process parameters including IMS data and a satisfactory Biological Indicator will support product release from a low temperature steriliser.

20.4.27 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)

20.4.28 Wear personal protective equipment.

20.4.29 Ensure that any checks and test that are to be carried out prior to sterilisation have been complete and were satisfactory.

20.4.30 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).

20.4.31 The steriliser door/s should be kept closed when the steriliser is not in use.

20.4.32 Select the validated cycle programme suitable for the load being processed.

20.4.33 Ensure the load is suitable for the process to which it will be exposed.

20.4.34 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

20.4.35 When the cycle is complete post sterilisation inspection is carried out to verify that the sterilisation cycle has completed with defined, validated critical parameters (VCP) including IMS data and a satisfactory Biological Indicator test.

20.4.36 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

20.4.37 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.

20.4.38 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.

20.4.39 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.

20.4.40 The cause of failure should be investigated and documented.

20.4.41 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.

20.4.42 The chemical process indicator has undergone the expected colour change.

20.4.43 The integrity of the outer wrap and its seals has not been compromised, e.g. torn wrap, sealing tape undone).

20.4.44 The packed RIMD (including flexible/rigid scopes) are dry.

20.4.45 The labelling remains in place and legible.

20.4.46 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.

20.4.47 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

20.4.48 Sterile RIMD (including flexible/rigid scopes) should be stored in a clean, dry area, which is secure, dust free and above floor level with controlled temperature and relative humidity settings.

20.4.49 Packs should be labelled with the contents, the date of sterilisation and a unique identifier from which all stages of the decontamination process to which it was subjected may be traced.

20.4.50 Packs should be stored so that they are used in sequential order, i.e. the oldest first.

20.4.51 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. Temperature and relative humidity in the storage area is controlled.

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 General Principles

Section One: Storage areas

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

There are two types of storage area:

a. the processed goods store.
b. the raw materials store.

Processed goods store

21.4.3 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.)

21.4.4 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.

21.4.5 Raw materials should not be stored in the processed goods store.

21.4.6 Loose, processed RIMD should be stored separately from those packed in cases.

21.4.7 Storage areas should be kept secure and access should be restricted to authorised personnel.

21.4.8 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.

21.4.9 The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.

21.4.10 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.

21.4.11 Processed goods should be stored on appropriate designated shelving.

Raw materials store

21.4.12 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.

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

21.4.14 Materials should be segregated and stored separately according to their specific requirements.

21.4.15 Sterile RIMD should not be stored in this area (unless supplies are bulk cased).

21.4.16 Single items should be stored separately from those in cases.

21.4.17 Storage areas should be kept secure and access restricted.

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 micro-organisms from the air and surfaces.

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 5: 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 General Principles

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

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.

Hospital water systems have frequently been identified as a source of nosocomial infection and steps should be taken to minimise the risk. The requirements and governance structures as detailed Guidelines for the Prevention and Control of Infection from Water Systems in Healthcare Facilities should be taken into consideration and reviewed with the members of the Environmental Monitoring Committee (EMC).

23.3 Contents

Section One: General Requirements

Section Two: Water Treatment

Section Three: General Requirements

Section Four: Water Quality

23.4 General Principles

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.

Section Two: Water treatment

23.4.2 The methods of water treatment generally used on water supplies for washer-disinfectors is reverse osmosis.

Water Softeners

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

Reverse osmosis

23.4.4 Reverse osmosis treatment systems remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will also remove organic material, bacterial endotoxins and microorganisms.

23.4.5 When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water should be endotoxin-free and has a negligible microbial population. However, the microbiological quality of the water can deteriorate following storage due to microbial proliferation.

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. >80o C)

Water supply and distribution after purification

23.4.6 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.

23.4.7 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.

23.4.8 Regular disinfection of the storage and distribution system should be undertaken and the efficacy of such control procedures should be subject to microbiological testing.

23.4.9 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.

23.4.10 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.

23.4.11 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.

23.4.12 This information may aid identification of the contamination source and assist with any subsequent advice.

Section Three: General Requirements

23.4.13 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) Colony Forming Units (cfu)/100ml.
e. bacterial endotoxins.
f. pH

23.4.14 The water supply should be controlled to ensure that it consistently of the required quality.

Section Four: Water quality

Hardness

23.4.15 Water hardness is caused by the presence of dissolved salts of the alkaline earths (calcium, magnesium and strontium) which come out of solution and

deposit as hard mineral layers (lime-scale) when water is heated or evaporated.

23.4.16 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.

23.4.17 Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.

23.4.18 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.

23.4.19 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).

23.4.20 The hardness is normally removed by a water softener; this can then be used to pre-treat the water prior to washer-disinfector system.

23.4.21 The hardness for RO water should be less than 50 CaCO3(mg/L) and the maximum permitted values for other stages is 200 CaCO3(mg/L).

Temperature

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

23.4.23 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.

23.4.24 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.

23.4.25 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

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

23.4.27 Water used for stainless steel RIMD should have a chloride concentration less than 120 mg/l Cl– to minimise the risk of corrosion.

23.4.28 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.

23.4.29 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

23.4.30 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.

23.4.31 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.

Bacterial endotoxins

23.4.32 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.

23.4.33 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

23.4.34 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,

tested at source, 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 3 Water Quality

Table 3.1: Suggested bacterial counts as indicators of RO water quality (EN 15883)

Microbiology		
Aerobic colony count in 100 mL at 35°C for 72 hr	**Interpretation/action**	**Colour grade**
Less than 9	Satisfactory	Green
Over 10	Unsatisfactory - undertake risk assessment and carry out corrective action	Orange
Over 100	Unacceptable - undertake risk assessment and carry out corrective action	Red

Table 23.24: Water Quality for washer-disinfector

Washer-disinfector Process stage	**Water Quality**	
	Preferred	**Acceptable**
Flush	Cold soft/mains	Cold mains
Wash	Reverse osmosis	Hot soft/mains
Rinse	Reverse osmosis	Reverse osmosis
Thermal disinfection	Reverse osmosis	Reverse osmosis

**Endoscope washer disinfector only*

Table 23.3: Water quality for cleaning RIMD

Washer-disinfector Process stage	Water Quality	
	Preferred	Acceptable
Manual wash	Reverse osmosis @ 35-45^{0}C	Soft/mains @ 35-45^{0}C
Manual rinse	Reverse osmosis	Soft/mains[1]
Ultrasonic wash	Reverse osmosis @ 35-55^{0}C	Soft/mains @ 35-55^{0}C

24. Textiles and non-wovens

24.1 Introduction

Textiles (re-usable) and non-wovens (single-use) may be used as drapes, gowns and wrapping materials. Drapes should provide a safe effective means of protecting 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 General Principles

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 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.

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.

The term 'singe use' device means a device that is intended to be used on one individual during a single procedure (MDR 2017/745).

The term 'reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.

Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with Article 17 of the MDR 2017/745.

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 General Principles

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 device

25.4.5 The symbol for single use instruments is as given in EN ISO 15223-1:2021.

25.4.6 Synonyms for "do not reuse" are "single use", use only once".

Figure 25.1: Do not reprocess symbol

Symbol	Meaning
	**Do Not Re-use** Indicates a medical device that is intended for one single use only. Synonyms for "Do not re-use" are "single use" and "use only once".
	**Do Not Re-Sterilise** Indicates a medical device that is not to be re-sterilised.
	**Non-sterile** Indicates a medical device that has not been subjected to a sterilisation process.

25.5 Implantable single use devises

The MDR 2017/745 states that an 'Implantable device' is any device, including those that are partially or wholly absorbed which is intended:

- To be totally introduced into the human body, or to replace an epithelial surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.
- Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to implantable device.

25.5.1 Implants may be supplied sterile or non-sterile and are all labelled as single use. Non-sterile implants must be decontaminated (cleaned, disinfected and sterilised) prior to use in accordance with the manufacturer's decontamination instructions. Instructions for Use (IFU) document must be provided by the non-sterile implant manufacturer/supplier.

25.5.2 Article 18.

25.5.3 Implant card and information to be supplied to the patient with implantable device.

25.5.4 The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.

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 General Principles

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.

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 and the Voluntary Agencies Risk Management Forum Recommended Best Practice for Use of Reusable Invasive Medical Devices on Trial or on Loan to/from Other Hospitals and /or Companies/ Suppliers.

https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/017-vharmf-framework-loaning-and-borrowing-rimd-october-2021

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

27.4 General Principles

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 loan RIMD must be packed in mesh trays (no plastic trays), there should be no sharp edges or projections. The mesh tray must have a format conform DIN or ISO or derive from that format (maximum H x L x W: 48*25*10 cm respectively 46*32*10 cm). For exceptionally long instruments it is allowed to use a tray with a maximum length of 52 cm.

27.4.3 Only one layer of instruments is allowed per tray. The tray must be filled in such a way that all instruments can be reached easily by water and detergents, and spray shadow must be avoided.

27.4.4 The weight of the tray must not exceed 8kgs.

27.4.5 All borrowed RIMD must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly.

27.4.6 RIMD on loan/trial must be registered, including ownership, service history, current location, service responsibility and instructions for use.

27.4.7 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

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

27.4.9 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.

27.4.10 All loan items must be received at least 2 working days before required procedure takes place. This is to ensure enough time is given to process the set & to ensure all items are present & correct and in good working order.

27.4.11 If the parameters are not suitable for our parameters it is the responsibility of the loan company to ensure appropriate information is given in order for the CDU to reprocess the RIMD.

27.4.12 If an RIMD is challenging the reprocessing, the loan company must provide additional information on how to reprocess it through CDU or the RIMD should not/must not be decontaminated.

Documentation

27.4.13 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 and including the autoclave number and cycle number.
d. reprocessing instructions, including disassembly and reassembly, where relevant.
e. instruction for use.
f. the above data is presented in an accessible and appropriate manor so that it can be used throughout the reprocessing cycle.

Log book

27.4.14 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.

Arrangements for return of RIMD

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

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

27.4.17 The return date, the name of the institution and the person returning the RIMD should be recorded. This should be at least 2 working days after the procedure to ensure all items are present & correct.

Internal Tracking of Loan RIMD sets and singles

27.4.18 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.

27.4.19 The contents within the tray of RIMD or details relating to a supplementary item should be entered in full into the tracking system.

27.4.20 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. If the loan item/sets are being used sterile from another entity, it is the responsibility of the theatre department to ensure there is an indemnity form signed by the surgeon to say they are aware the set was not processed in the organisation & they are happy to use the loan item/set. This should only happen in an emergency situation.

27.4.21 Any deviation from local policy should be based on risk assessment and managed via internal governance structures. Corrective action plans should be put in place with ongoing review to ensure compliance, safe practices and that learning is shared.

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 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 General Principles

Section One: Policies, procedures, protocols and guidelines

28.4.1 Written policies, procedures, protocols and guidelines for the recall of nonconforming 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.

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:

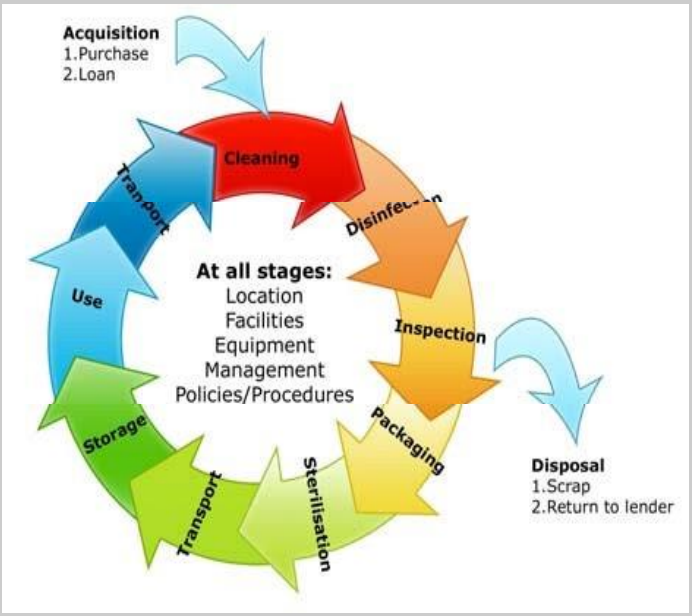
a. be written.
b. identify by sterilisation lot number the products to be recalled.
c. identify the persons or departments to whom the order is addressed.
d. require the recording in terms of kind and quantity of the products obtained in the recall.
e. specify the action to be taken by the person or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

Appendix 1: Ventilation Systems in the CDU

All rooms in the department must be mechanically ventilated and 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%). Air will need to be introduced and removed so as to efficiently ventilate the entire workspace with air flowing from the cleaner areas to the less clean areas of the facility.

The ventilation system should be designed and operated to ensure that contaminants arising from the decontamination process are removed within the facility, and that airborne contaminants are excluded from the point that the decontaminated RIMDS are stored. These objectives will be achieved both by supplying filtered air to the 'clean' areas, and maintaining them at a positive pressure with respect to surrounding areas, and by extracting air from the less clean areas, and maintaining them at a negative pressure with respect to surrounding areas. Contaminants arising from the decontamination machines themselves must be as far as is practical, captured at source, and removed before they enter the workplace. Ventilation should be provided by an Air-Handling Unit (AHU) that conforms to the standards set out in the UK Health Technical Memorandum 03-01.

An AHU is required for CDU. The Air-Handling Unit should have the facility to heat, cool, and filter the air delivered to the working space. If the AHU does not supply air of the correct quality, then an additional filter may be required in the branch duct to achieve the quality required. Air should be filtered by an 'F7 type' filter. An extract system should be provided with energy recovery between the extract and the supply via the insertion of a plate heat exchanger or run-around coil, a thermal wheel should not be used. The decontamination facility will need 10 air changes per hour to dilute possible airborne contamination. An AHU that support CDUs must be capable of supporting a clean room that meets the requirements of ISO 14644 Class 8 when at rest. In many cases this could be achieved using F7 filtration but may need HEPA filtration in some locations. They should have minimum of 20 air changes per hour and a pressure differential with adjoining rooms of +10 Pascals.

Processing and storage areas will require mechanical ventilation. A well-designed ventilation system can mitigate the airborne risks to Staff. It should: supply sufficient unvitiated air to:

- dilute the possible air contaminants;
- have air terminals located to efficiently scour the ventilated space;
- move the air from the clean to the less clean space and/or out of the building;
- supply the air at high level and remove it at low level so that the breathing zone of staff is in a clean airflow path.

Appendix 2: Abbreviations

AORN	Association of Perioperative Registered Nurses
AER	Automated Endoscope Reprocessor
ATP	Adenosine Triphosphate
CE	Conformité Européenne
CDU	Central Decontamination Unit
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
EEC	European Economic Community
EN	European Norm
EU	European Union
ERU	Endoscopy Reprocessing Unit
EWD	Endoscope Washer-Disinfector
HSA	Health and Safety Authority
HBN	Health Building Note
HCAI	Healthcare Associated Infection
HCW	Health Care Worker
HIQA	Health Information Quality Authority
HSE	Health Service Executive
IMB	Irish Medicines Board
ISO	International Standards Organisation
LCD	Liquid Chemical Disinfector
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
SDS	Safety Data Sheets
TSA	Tryptose Soya Agar
TSE	Transmissible Spongiform Encephalopathies
WD	Washer-disinfector

Appendix 3: Glossary of Terms

Adverse event	An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.
Cleaning	The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning removes microorganisms and the organic material on which they thrive. It is a necessary pre-requisite of effective disinfection or sterilisation.
Clinical Governance	Corporate accountability for clinical performance.
Decontamination	The removal of microorganisms or foreign matter (or both) from contaminated materials or living tissue. Three processes for decontamination are commonly used; cleaning, disinfection and sterilisation.
Disinfectant	A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms; and that is not represented by the manufacturer to be suitable for internal use.
Disinfection	The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation.
Hazard	A source of potential harm or a situation with a potential to cause loss.
Healthcare associated infection	Infection contracted as a result of health care. Includes iatrogenic infections resulting from medical procedures and nosocomial infections resulting from the patient's presence in a health care establishment.
Health Care Workers	Refers to all health care professionals, including students and trainees, and employees of health care establishments, who have contact with patients or with blood or body substances from patients.
Incidence (of infection)	Rate at which new cases occur.
Invasive procedure	Any procedure that pierces skin or mucous membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities or organs, or repair of traumatic injuries.

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 outreach hospitals, for example, general medical practitioner and general dental practitioner services
Risk	The chance of something happening that will have an impact upon objectives. It is measured in terms of the severity of the consequence and frequency
Risk Assessment	The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria
Risk Management	The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects
Risk Management Process	The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk
Risk Reduction	A selective application of appropriate techniques and management principles to reduce either likelihood or an occurrence or its consequences, or both

Reprocessing	All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation.
Reusable item	An item designated or intended by the manufacturer to be suitable for reprocessing and reuse.
Sharps	Any object capable of inflicting penetrating injury, including needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.
Stakeholders	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.
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.
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.
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).

Appendix 4: Membership of National Decontamination Stakeholder Group

Subject matter experts representing each hospital group and specialty hospitals including Dental, Eye and Ear, Paediatrics and private hospital representation, developed V.3 of the HSE Standards and Recommended Practices for Central Decontamination Units.

Ms. Caroline Conneely	Chairperson National Decontamination Stakeholder Group
Ms. Tracey Scott	Dental & Chairperson, Irish Decontamination Institute
Ms. Carol Gaskin	Eye & Ear IEHG
Ms. Niamh O'Callaghan	South/South West Hospital Group
Ms. Inga Sirvinskaite	Outsourced Services
Ms. Aileen Byrne	Private Hospitals
Mr. Damien Doherty	Children's Health Ireland
Mr Trevor Duffy	Ireland East Hospital Group
Mr. Martin Coogan	RSCI
Ms. Ursula Morby	University of Limerick Hospital Group
Mr Andrew Smyth	Dublin Midlands Hospital Group
Ms. Pauline Roach	Saolta Hospital Group
Mr. John Oyedeji	Maternity Services
Mr. Mark Hichens	Environmental Microbiologist

Appendix 5: 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 Regulation (EU) 2017/715 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

Medical Device Regulation (EU) 2017/745. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#d1e6855-1-1

European Union (Prevention of sharp injuries in the healthcare sector) Regulations 2014. Available at: https://www.hsa.ie/eng/Legislation/New_Legislation/S_I_135_of_2014.pdf

Safety Health and Welfare at Work Act 2005. Available at: https://www.hsa.ie/eng/topics/managing_health_and_safety/safety,_health_and_welfare_at_work_act_2005/

European and International Standards

Cleanroom Standards

EN ISO 14644- series- Cleanrooms and associated controlled environments.

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

EN ISO 14698- Cleanrooms and associated controlled environments.

Biocontamination control- Part 2- Evaluation and interpretation of biocontamination data

Disinfectant Standards

EN 14885- Chemical disinfectant and antiseptics- Application of European Standards for chemical disinfectants and antiseptics

EN 14348- 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).

Equipment Standards

Sterilisers

EN 285- Sterilisation. Steam sterilisers. Large sterilisers.

EN ISO 17665:2024- Sterilization of health care products - moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices.

EN 14180- Sterilisers for medical purposes. Low temperature steam and formaldehyde sterilisers. Requirements and testing.

Washer-disinfectors

EN ISO 15883- Washer-disinfectors- Part - General requirements, definitions and tests.

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

EN ISO 15883- Washer-disinfectors – Part 5 -Test soils.

Management Standard

EN ISO 13485- Quality managements systems – Requirement for regulatory purposes – Medical Devices.

Materials Standards

Biological indicators

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

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

Chemical indicators

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

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

Packaging

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

EN ISO 11607- Packaging for terminally sterilised Medical Devices- Part 2 -Validation requirements for forming, sealing and assembly processes.

EN 868- series- Packaging materials and systems for medical devices which are to be sterilised

Medical devices Standards

EN 556- Sterilisation of medical devices- Part 1- Requirements for medical devices to be designated 'STERILE'. Requirements for terminally sterilised medical devices.

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

EN 20417- Information to be supplied by the manufacturer with medical devices.

EN 15223- Symbols to be used with information to be supplied by the manufacturer - Part 1- General requirements.

EN ISO 17664- Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1- Critical and semi-critical medical devices.

Processes Standards

Sterilisation

EN ISO 17665:2024- Sterilisation of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilisation process for medical devices.

EN ISO 11737- part 2 - Sterilisation of medical devices - Microbiological methods. Determination of a population of microorganisms on products.

Tests of sterility performed in the definition, validation and maintenance of a sterilisation process

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

Safety Standards

EN IEC 61010-2-040:2021- 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

Scottish Health Planning Note 13- Part 1-Sterile Service Departments.

Scottish Health Technical Memorandum 01-01 Parts A, B, C, D, E, F, Guide 5017 and 5019: decontamination of medical devices processed through a CDU. Available at: https://www.nss.nhs.scot/publications/decontamination-of-medical-devices-in-a-central-decontamination-unit-shtm-01-01/

National Institute of HealthCare Excellence: Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues. Available at: https://www.nice.org.uk/guidance/ipg666/resources/reducing-the-risk-of-transmission-of-creutzfeldtjakob-disease-cjd-from-surgical-instruments-used-for-interventional-procedures-on-highrisk-tissues-pdf-1899874227866821

Advisory Committee on Dangerous Pathogens: Minimise Transmission Risk of CJD and vCJD in healthcare settings. Available at: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

Appendix 6: Regulations and Guidance

Medical Device

The Medical Devices Regulation (EU) 2017/745 is known as the MDR. This replaces the Medical Device Directives (90/385/EEC) for Active Implantable Medical Devices and General Medical Devices Directive 93/42/EEC. The in vitro Diagnostics Medical Devices Regulation (EU) 2017/746 is known as IVDR and replaces the previous Directive 98/79/EEC.

These Regulations:

- 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 Regulations 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.

Healthcare Products Regulatory Authority

The Healthcare Products Regulatory Authority (HPRA) is the Competent Authority for general medical devices, active implantable medical devices and in-vitro diagnostic medical devices in Ireland. The HPRA 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.

Vigilance

The vigilance system is the name given to the process of notification and evaluation of adverse incidents. The Medical Regulation includes requirements for medical devices manufacturers to report certain types of incidents to the Competent Authority (CA). The Regulations 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 Regulation the Healthcare Products Regulatory Authority, (HPRA) 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 MDR Regulation, 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, regional health area, 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 2005 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, employee's medical fitness for work, penalties upon conviction and the introduction of 'on the spot fines'.