

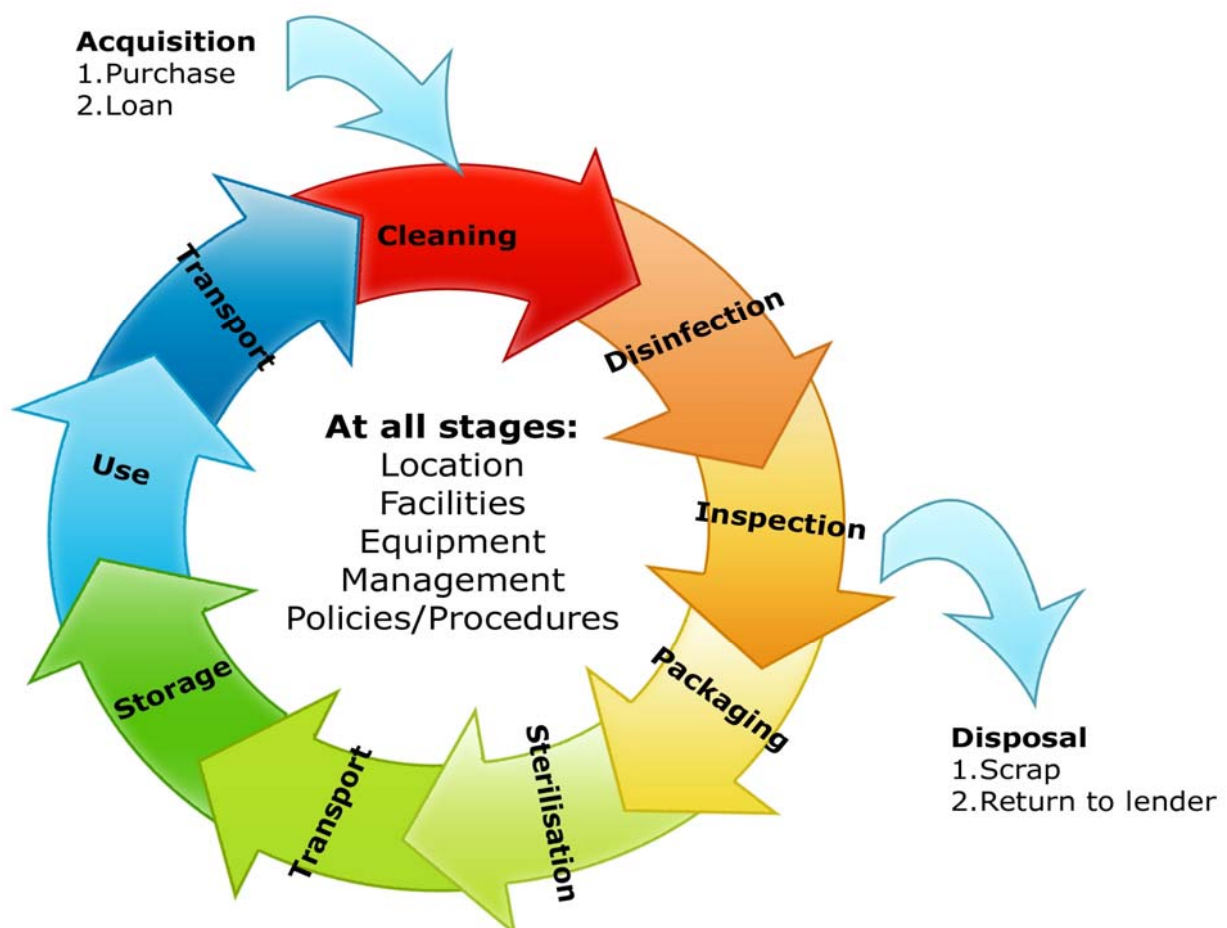
Health Service Executive

Standards and

Recommended Practices

for Endoscope

Reprocessing Units



Reader Information

Directorate:	Quality & Patient Safety
Title:	HSE Standards and Recommended Practices for Central Decontamination Units (CDUs)
Document Reference Number:	QPSD-D-005-2
Version Number:	2.0
Document Purpose:	Standards & Recommended Practices
Author:	HSE National Decontamination of Reusable Invasive Medical Devices Advisory Group
Approval Date:	July 2011
Target Audience:	All relevant staff in the public health service who work in Central Decontamination units, and other relevant staff with responsibility for decontamination of reusable invasive medical devices
Description:	The Standards and Recommended Practices are a guide to the Standards of practice required in the decontamination of reusable invasive medical devices in Central decontamination Units, based on current legal requirements and professional best practice
Superseded Docs:	HSE Code of Practice for Decontamination of RIMD V 1.0, 2007
Revision Date:	July 2014
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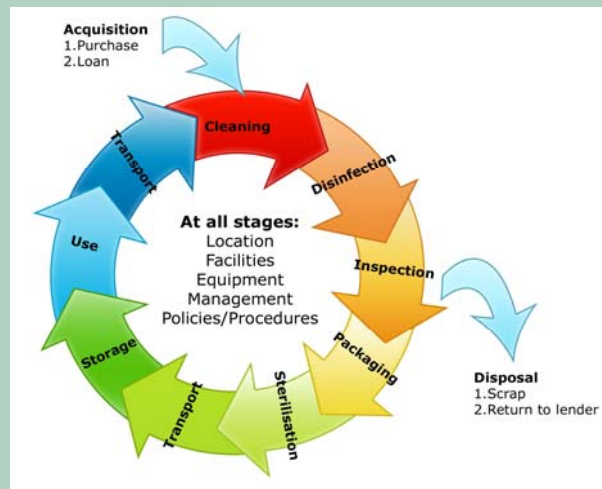
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Standards and Recommended Practices for Endoscope Reprocessing Units

Part 1

Introduction

Introduction

1. Introduction

1.1 Prevention and control of healthcare associated infection

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

1.2 Decontamination process

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

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

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

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

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

1.3 Effectiveness of decontamination

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

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

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

Introduction

2. Development of standards and recommended practices for decontamination of Reusable Invasive Medical Devices

2.1 Introduction

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

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

2.2 Definition

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

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

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

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

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

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

Introduction

3. Devices Directive (93/42/EEC)

3.1 Medical Devices Directives

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

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

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

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

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

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

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

There are four classes of general medical devices as follows:

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

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

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

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

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

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

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

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

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

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

3.3 Placing on the market

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

3.4 In-house manufacture

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

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

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

Introduction

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

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

3.6 CE marking

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

CE symbol

The CE marking symbolises the following:

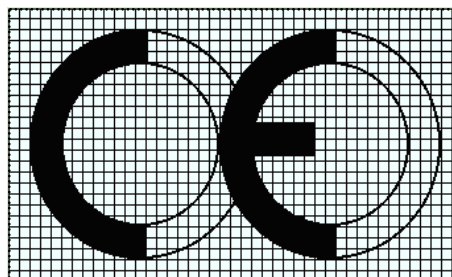
- That the product can be freely marketed throughout all the member states of the EC without further control.
- The manufacturer is declaring that the product meets all the relevant provisions of the Directives that apply to it and that it has been assessed in accordance with them.
- The manufacturer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

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

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

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

Figure 3.1: CE symbol



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3.7 Notified Body

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

4. Spaulding classification

4.1 Classification of infection risk

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

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

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

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

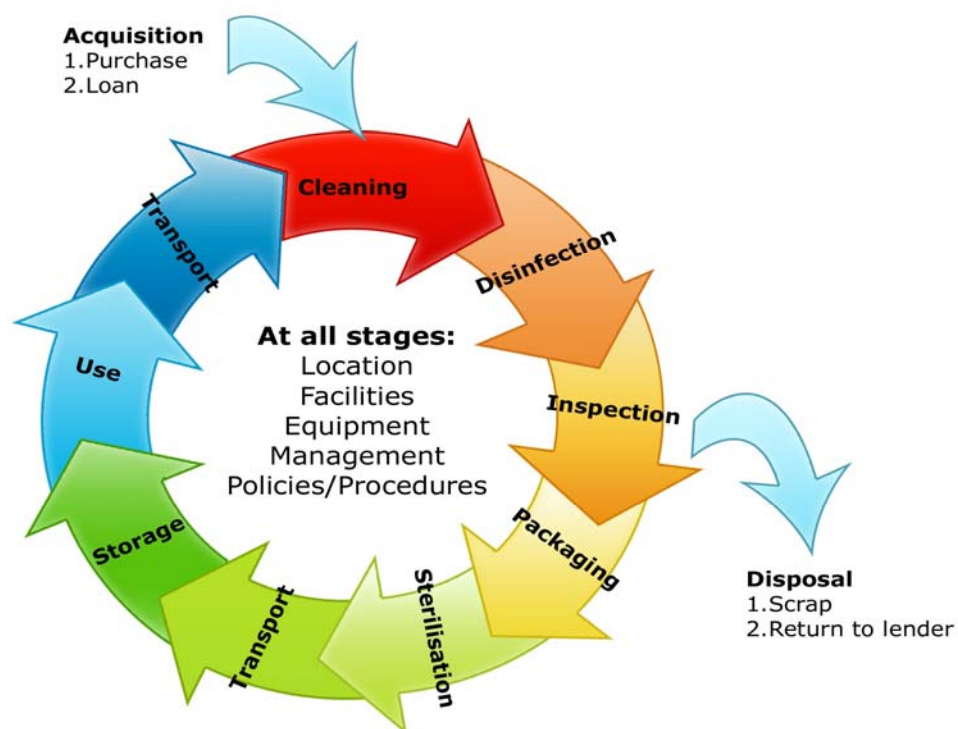
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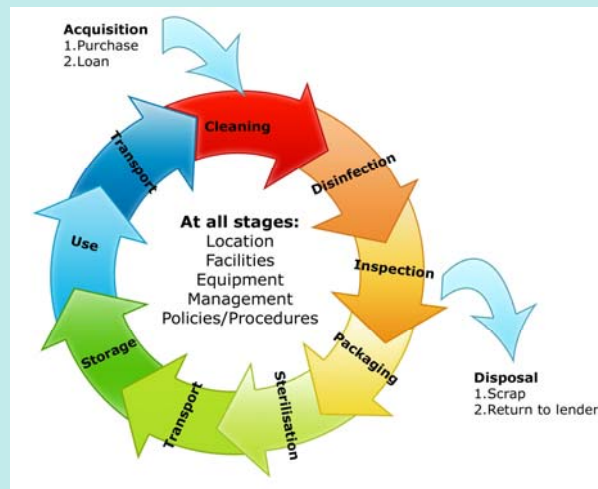
5. Life cycle for reusable invasive medical devices

5.1 Introduction

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

Figure 5.1: Decontamination life cycle





Standards and Recommended Practices for Endoscope Reprocessing Units

Part 2 Standards

Suitability of decontamination facilities

1. Suitability of decontamination facilities

1.1 Statement

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

1.2 Rationale

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

1.3 Criteria

Unit design

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

Suitability of decontamination facilities

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

Lighting and electricity

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

Ventilation and temperature

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

Walls, floors and ceilings

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

Suitability of decontamination facilities

- 1.3.16 The junction between the walls and floors is coved and flush.
- 1.3.17 The fitments (where possible) are flush with wall surfaces.
- 1.3.18 Floors are covered in a washable non-slip material which is securely sealed.

Workstations, furniture, shelving and equipment

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

Restricted entry and movement between areas

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

Storage facilities

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

Suitability of decontamination facilities

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

Environmental control

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

Cleaning

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

Other

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

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

Decontamination equipment**2. Decontamination equipment****2.1 Statement**

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

2.2 Rationale

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

2.3 Criteria*Specialist group*

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

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

Decontamination equipment

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

Key representatives on the specialist group include:

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

The group may also include as required:

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

Decontamination equipment

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

Manual washing

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

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

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

Ultrasonic cleaning

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

Decontamination equipment

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

Washer-disinfectors

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

Decontamination equipment

Steam steriliser

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

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

- 2.3.50 Each steam steriliser is fitted with a process monitoring system independent of the automatic controller.
- 2.3.51 The sterilisation hold period is at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
- 2.3.52 Steam sterilisers are double ended with the loading side in the clean room and the inspection and packaging room

Low temperature sterilisers

- 2.3.53 Low temperature sterilisation methods are used when recommended by and in accordance with the RIMD (including flexible/rigid scopes) manufacturers' instructions.
- 2.3.54 Low temperature sterilisation is carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Gas Plasma processes.
- 2.3.55 Low temperature sterilisation methods are validated and are subject to periodic testing in accordance with ISO 14937. Where ISO 14937 does not detail specific periodic tests these should be undertaken in accordance with manufacturers' recommendations.
- 2.3.56 Low temperature sterilisers are subject to planned preventative maintenance in accordance with manufacturers' instructions and at the manufacturers' recommended frequencies.

Decontamination equipment

Drying cabinet

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

Heat sealer

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

Decontamination process**3. Decontamination process****3.1 Statement**

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

3.2 Rationale

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

3.3 Criteria

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

Decontamination process

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

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

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

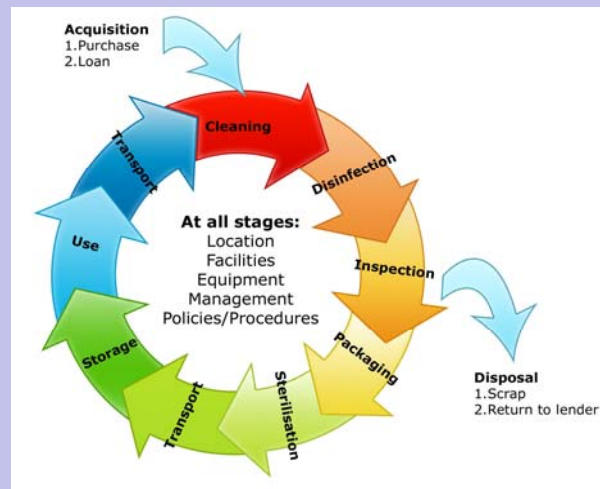
The organisation has processes in place to minimize the exposure of service users and employees to TSE agents.

4.2 Rationale

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

4.3 Criteria

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



Standards and Recommended Practices for Endoscope Reprocessing Units

Part 3 Recommended Practices

Design of endoscope reprocessing (decontamination) Unit

1. Design of endoscope reprocessing (decontamination) Unit

1.1 Introduction

Endoscopy Units should have designated non-clinical space provided within the unit for the decontamination of flexible endoscopes. This improves the efficiency of the decontamination process, minimises contamination and provides a safe working environment minimising opportunities for cross-infection of service users, clinical staff and cross-contamination of the working environment.

1.2 Scope

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

1.3 Contents

Section One: Unit design

Section Two: Lighting and electricity

Section Three: Ventilation and temperature

Section Four: Walls, floors and ceilings

Section Five: Sinks

Section Six: Workstations, furniture, shelving and equipment

Section Seven: Restricted entry and movement between areas

Section Eight: Storage facilities

Section Nine: Environmental control

Section Ten: Cleaning

Design of endoscope reprocessing (decontamination) Unit

1.4 Procedure

Section One: Unit design

- 1.4.1 Endoscope decontamination should be performed in a designated endoscope reprocessing unit.
- 1.4.2 The unit should be physically separated from all other work areas.
- 1.4.3 Changing shower facilities and toilet facilities should be provided in proximity to the decontamination area.
- 1.4.4 The unit should be designed to allow segregation of 'dirty' and 'clean' activities.
- 1.4.5 The design should facilitate a uni-directional work flow from the 'dirty' area (receipt of contaminated endoscopes) to the 'clean' area (inspection, drying and storage of decontaminated endoscopes).
- 1.4.6 The preferred configuration is for separate rooms for 'dirty' and 'clean' activities with a pass-through Automatic endoscope reprocessor (AER) installed within the wall between the 'dirty' and 'clean' rooms.
- 1.4.7 The endoscope reprocessing unit should not be used for any other purpose.
- 1.4.8 The endoscope reprocessing unit should not be used as a thoroughfare.
- 1.4.9 The endoscope reprocessing unit should not be part of any service user area.
- 1.4.10 There should be a designated changing area for donning work wear.
- 1.4.11 The receipt of contaminated endoscopes area and the inspection, drying and storage area should be free from 'opening' windows, ledges, and uncleanable areas.
- 1.4.12 The receipt of contaminated endoscopes area and the inspection, drying and storage area should be designed to minimise the ambient sound levels. (This will require attention to the installation of equipment, building finish, etc.).

Section Two: Lighting and electricity

- 1.4.13 There should be adequate lighting available to permit good working practices and visual examination of endoscope and accessories.

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

Design of endoscope reprocessing (decontamination) Unit

- 1.4.14 There should be adequate task lighting to allow the visual inspection of endoscopes and accessories.
- 1.4.15 There should be sufficient electricity supply points, computer terminal points and work stations in the department to support efficient functioning of the unit.

(Note: The department should have a UPS system in the event of a power cut)

Section Three: Ventilation and Temperature

- 1.4.16 All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures should be controlled between 18-22°Celsius and relative humidity should be controlled within the range 35-60%).
- 1.4.17 There should be adequate ventilation and extraction in place to protect staff and third parties from exposure to hazardous substances.
- 1.4.18 The configuration of the room and the ventilation system will depend on the choice of Automated endoscope reprocessor (AER). Where possible, airflows should be from clean areas to dirty areas (for example the contaminated endoscope area should be at a lower pressure than the clean area).

Section Four: Walls, floors and ceiling

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

Design of endoscope reprocessing (decontamination) Unit

Section Five: Sinks

- 1.4.23 There should be two separate sinks within the unit; one for washing and one for rinsing the washed endoscopes and accessories.
- 1.4.24 The sinks should be of sufficient size to permit immersion of the endoscopes.
- 1.4.25 There should be adequate put down spaces alongside and between the sinks.
- 1.4.26 There should be a dedicated wash hand basin for hand hygiene within the unit in addition to the two required in 1.4.23.

(Note: In some circumstances a third sink may be required in the unit for electrical leak testing in accordance with scope manufactures' instructions).

Section Six: Workstations, furniture, shelving and equipment

- 1.4.27 All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- 1.4.28 Designated customised trolleys should be available for the safe and efficient management of endoscopes.
- 1.4.29 There should be adequate space between workstations for equipment and staff movement.
- 1.4.30 The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- 1.4.31 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 Seven: Restricted entry

- 1.4.32 The area should be managed by dedicated, trained staff.
- 1.4.33 Entry to the endoscope reprocessing (decontamination) unit should be restricted to authorised personnel only.

Design of endoscope reprocessing (decontamination) Unit

Section Eight: Storage facilities

- 1.4.34 Safe storage facilities should be provided for process chemicals used in decontamination.
- 1.4.35 Storage facilities for bulk items should be provided external to the designated decontamination area.
- 1.4.36 Adequate storage should be provided for required personal protective equipment and should be easily accessible in each of the work areas.
- 1.4.37 Appropriate storage facilities should be provided for sterile products.

(Note: Adequate space should be provided for drying and storing of decontaminated endoscopes. This space should be independent of the area used to hold 'dirty' scopes awaiting decontamination. The decontaminated endoscopes should be stored as per manufacturers instructions not touching the floor of the storage unit in a designated drying storage cabinet or storage press).

Section Nine: Environmental control

- 1.4.38 The 'clean' area (inspection, drying and storage of decontaminated endoscopes). is monitored microbiologically. (Reference EN ISO 14698: Part 1:2003 and EN ISO 14698 Part 2:2003).

Section Ten: Cleaning

- 1.4.39 The environment in which decontamination of endoscopes takes place should be cleaned in accordance with methods, procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse and the Endoscopy Manager).
- 1.4.40 Dedicated cleaning provision (both equipment and storage) should be provided.

Environmental cleaning**2. Environmental cleaning****2.1 Introduction**

Adequate regular cleaning of all work areas is essential for the decontamination cycle to be effective. Environmental cleaning schedules based on policies, procedures, protocols and guidelines adopted 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 which should include methods and frequency of cleaning and should be approved by the appropriate local committee.

2.2 Scope

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

2.3 Contents

Section One: Cleaning equipment

Section Two: Cleaning frequency and cleaning efficacy

Section Three: Floor cleaning equipment and method

Section Four: Floor cleaning agents

Section Five: Spillage kits

Section Six: Records

Section Seven: Environmental monitoring

Environmental cleaning**2.4 Procedure****Section One: Cleaning equipment**

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

Section Two: Cleaning frequency and cleaning efficacy

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

Section Three: Floor cleaning equipment and method

The following floor cleaning equipment and method should be used:

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

Environmental cleaning

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

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

Section Four: Floor cleaning agents

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

2.4.16 Cleaning efficacy should be monitored routinely.

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

2.4.18 Disinfectants should be made up according to the manufacturers' instructions/healthcare organisations policy, procedure, protocol and guidelines.

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

Section Five: Spillage kits

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

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

Environmental cleaning

Section Six: Records

Records should be kept of the following:

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

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

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

Section Seven: Environmental monitoring

(Note: environmental monitoring applies to all units reprocessing RIMD including flexible scopes, irrespective of whether a formal classification can be achieved. It is useful to know /monitor the level of cleanliness /environmental hygiene being achieved, as the RIMD/flexible scope is manually cleaned, thermally/high level disinfected it is imperative that on release from the unit the decontamination status of the RIMD/flexible scope has not been compromised.)

(Note: Endoscope reprocessing units may not only process diagnostic flexible endoscopes, many of the scopes processed are now invasively intent (therapeutic) resulting in a need for awareness of the environmental (decontamination status) of processed endoscopes.)

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

Environmental cleaning

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

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

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

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

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

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

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

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

Environmental cleaning

Sampling device

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

Flat surfaces

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

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

Irregular surfaces

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

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

Alternative sampling procedure

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

Environmental cleaning

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

Air flows

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

Sampling sites.

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

Environmental cleaning

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

Environmental cleaning**Table 2.3: Typical microbial ‘Action’ limit values used in Class 7 or Class 8 cleanrooms and could be used as a typical benchmark for units with a unidirectional flow system**

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

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

2.4.39 Investigation should include checks such as:

- a. that all control samples gave appropriate results. This could include checking that plate media were within expiry date, were not excessively wet or dry or contaminated prior to use.
- b. do counts when area is unmanned show similar patterns?
- c. any unusual activity or circumstances prior to and including sampling time.
- d. any possibility of abuse of samples in transit (not inverted, open lids, damaged etc).
- e. any maintenance work undertaken e.g. changing or adjusting air filters.
- f. any malfunction of the air handling system.
- g. any problems with water quality.
- h. any problems with cleaning equipment.
- i. are disinfectants or detergents free from contamination?
- j. have shoes and PPE been checked for contamination?

Decontamination equipment

3. Decontamination equipment

3.1 Introduction

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

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

3.2 Scope

The objective of this recommended practice is to outline recommended practices in relation to the equipment required in the endoscope reprocessing (decontamination) unit and the validation and maintenance of this equipment.

3.3 Contents

Section One: Specialist group

Section Two: Manual washing

Section Three: Ultrasonic cleaning

Section Four: Automated endoscope reprocessors (AER's)

Section Five: Low temperature sterilisers

Section Six: Drying cabinets

Section Seven: Consumables

Decontamination equipment

3.4 Procedure

Section One: Specialist group

- 3.4.1 Each organisation should have a specialist group in place to consider the decontamination equipment in the healthcare organisation with regard to the following:
- a. ability to meet current standards.
 - b. age and condition of equipment and availability of replacement parts.
 - c. cost of maintaining, repairing and replacing the equipment.
 - d. ability to interface with other equipment in the decontamination facility.
 - e. ability to interface with user requirements.
 - f. ability to meet the requirements of current test methods.
 - g. ability to be validated and perform to intended purpose.
 - h. energy and water conservation.
 - i. ability for self-disinfection for washer-disinfectors.
- 3.4.2 Key representatives on the specialist group should include:
- a. Decontamination Coordinator.
 - b. Endoscopy Manager/Decontamination Unit Manager.
 - c. Clinical Unit Manager, e.g. Theatre Manager.
 - d. Infection prevention and control.
 - 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.

Decontamination equipment

- d. Other relevant experts (Qualified Person (Decontamination)/Sterivigilance Personnel/Microbiologist).
- 3.4.4 The specialist group should identify all decontamination equipment which needs to be replaced.
- 3.4.5 The specialist group should formulate a plan to replace or upgrade this equipment.
- 3.4.6 The plan should be submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer).
- 3.4.7 There should be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
- 3.4.8 There should be clearly defined policies, procedures, protocols and guidelines for maintaining, testing, validating and day to day operation of decontamination equipment.
- 3.4.9 The operational management of each item of decontamination equipment should be the defined responsibility of a named person (usually the Endoscopy Manager/ 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 Whichever type of automated endoscope reprocessor (AER) is used, manual cleaning should be done first in accordance with the endoscope manufacturers' instructions. The lumens of the endoscope channels may be too narrow to permit a sufficient flow of water or detergent solution to ensure the removal of all soiling if the channels are not cleaned of debris by brushing.

(Note: Immediate pre cleaning following procedure should be carried out if required as per manufacturers' instruction.)

Decontamination equipment

- 3.4.14 Dedicated manual cleaning equipment and accessories should be available for specified endoscopes, RIMD and endoscope accessories that cannot be cleaned in an automated cleaning process.
- 3.4.15 Separate sinks for washing and rinsing should be provided.
- 3.4.16 The detergent used should be one specified by the manufacturer as being suitable for manual cleaning of RIMD and compatible with the manufacturers' instructions for the RIMD being cleaned.
- 3.4.17 Means should be provided to control the concentration of detergent.

(Note: An automated dispenser is preferable.)

Section Three: Ultrasonic cleaning

- 3.4.18 Introduction in the instance where ultrasonic cleaning devices (as per manufacturers recommendations) are used within an endoscope reprocessing unit the following guidelines apply.
- 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 an automated endoscope reprocessor, washer-disinfector or steam steriliser.
- 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, part 1,2 & 5 2009.
- 3.4.26 The ultrasonic cleaner shall be subject to periodic testing in accordance with EN ISO 15833, parts 1,2, & 5.

Decontamination equipment

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

(Note: Reverse Osmosis water should be used for the final rinse stage.)

Section Four: Automated endoscope reprocessors (AER's)

- 3.4.28 There should be sufficient automated endoscope reprocessors to meet the needs of the endoscope reprocessing (decontamination) unit.

- 3.4.29 AER's are of two principle types; endoscope washer-disinfectors (EWD) and liquid chemical disinfectors (LCD).

- 3.4.30 The use of an endoscope washer-disinfector is strongly recommended as the best practice method.

(Note: Double ended endoscope washer-disinfectors are preferred with the clean side discharging into a designated 'clean' area.)

- 3.4.31 EWD provide process stages designed to clean and disinfect flexible endoscopes. Requirements for EWD are specified in EN ISO 15833-4.

- 3.4.32 LCD provide process stages to disinfect flexible endoscopes that have previously been cleaned manually. Prior to the disinfection stage the LCD may provide a rinse stage to ensure that residues from manual cleaning have been removed and to wet the surfaces to be disinfected.

- 3.4.33 Both EWD and LCD may provide:

- a. a leak test facility to verify the integrity of the endoscope before the admission of water, cleaning solutions or disinfectant solutions.
- b. a purging stage after the post-disinfection rinse to ensure that the channels are cleared of water.
- c. a drying stage to dry the channels and the outer surfaces of the endoscopes.

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

Decontamination equipment

Section Five: Low temperature sterilisers

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

3.4.36 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.)

3.4.37 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.

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

Section Six: Drying cabinets

3.4.39 If required a pass-through drying cabinet between the 'dirty' area (receipt of contaminated endoscopes/wash area) to the 'clean' area (inspection, drying and storage of decontaminated endoscopes) should be provided for endoscope accessories that cannot be processed through an automated endoscope reprocessor.

(Note: A leak proof covered container should be available in the 'dirty' area for accessories that are for transportation to the central decontamination unit for processing.)

3.4.40 The doors of the drying cabinet should be interlocked to prevent direct connection between the 'dirty' area (receipt of contaminated endoscopes) to the 'clean' area (inspection, drying and storage of decontaminated endoscopes).

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

3.4.42 The drying temperature throughout the cabinet should be within $\pm 5^{\circ}$ Celsius of the set temperature, or in accordance with drying cabinet /flexible scope manufacturers' recommendation.

Decontamination equipment

- 3.4.43 The drying cabinet should be fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than 10° Celsius the heating source is isolated.
- 3.4.44 The air in the cabinet should be mechanically circulated and items placed throughout the cabinet should be dried uniformly.
- 3.4.45 The drying cabinet should be subject to a planned preventative maintenance programme in accordance with the manufacturers' recommendations.
- 3.4.46 The drying cabinet should be subject to annual validation in accordance with manufacturers' recommendations.

Section Seven: Consumables

- 3.4.47 Single use cleaning brushes (double ended where required).
- 3.4.48 Disposable syringe (or adaptor mounted on water tap) for flushing inaccessible channels e.g. air/water.
- 3.4.49 Valve cleaning brushes as per manufacturers' recommendations.
- 3.4.50 Channel cleaning brushes – single-use as per manufacturers' recommendations.
- 3.4.51 Non linting single use cloth.
- 3.4.52 Automatic endoscope reprocessor.
- 3.4.53 Endoscope connectors for use in AER.
- 3.4.54 Ultrasonic cleaner.
- 3.4.55 Purified rinse water.
- 3.4.56 Process chemicals (detergents and disinfectants).
- 3.4.57 Leak tester device.

Procurement of reusable invasive medical devices (RIMD)

4. Procurement of reusable invasive medical devices (RIMD)

4.1 Introduction

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

4.2 Scope

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

4.3 Contents

Section One: Specialist group

Section Two: Procurement policy

Section Three: Specification

Section Four: General principles

4.4 Procedure

Section One: Specialist group

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

Procurement of reusable invasive medical devices (RIMD)

Section Two: Procurement policy

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

Section Three: Specification

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

Section Four: General principles

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

(Note: The procurement group should carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the reprocessing procedure. Hence it is essential to consult the endoscope reprocessing unit management before making a decision. This will require that the manufacturers' validated recommendations 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 RIMD.

5.2 Scope

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

5.3 Contents

Manufacturer

Section One: Requirements to be met by the RIMD manufacturer

Section Two: Label

Section Three: The instructions for use

Section Four: Precautions and contraindications

Section Five: Information supplied on request

Procedure for packs or sets in the central decontamination unit

Section Six: Label

Section Seven: Instructions for use

Manufacturers' instructions

5.4 Procedure

Manufacturer

Section One: Requirements to be met by the RIMD manufacturer

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

Manufacturers' instructions

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

Section Two: Label

The label should contain the following details:

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

Manufacturers' instructions

Section Three: The instructions for use

The instructions for use should contain the following particulars:

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

Manufacturers' instructions**Section Four: Precautions and contraindications**

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

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

Section Five: Information supplied on request

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

Procedures for packs or sets in the central decontamination unit**Section Six: Label**

The label should contain the following details:

- 5.4.40 The name or trade name and address of the decontamination unit.
- 5.4.41 The details strictly necessary for the user to identify the contents of the packaging.
- 5.4.42 Where appropriate, the word 'STERILE'.
- 5.4.43 An indication of the date by which the RIMD should be used, in safety, stating the month and the year.
- 5.4.44 Any special storage and/or handling conditions.

Manufacturers' instructions

- 5.4.45 Reference to any special operating instructions, warnings and/or precautions to be taken.
- 5.4.46 Year of manufacture.
- 5.4.47 Batch or serial number.
- 5.4.48 Where applicable, method of sterilisation

Section Seven: Instructions for use

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

Personal protective equipment

6. Personal protective equipment

6.1 Introduction

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

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

6.2 Scope

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

6.3 Contents

Endoscope reprocessing (*decontamination*) unit

Section One: Attire

Gowning for entry to the 'dirty' area (receipt of contaminated endoscopes)

Section Two: Head/hair cover

Section Three: Protection for eyes/nose and mouth

Section Four: Protection for skin and clothing

Personal protective equipment

Section Five: Gloves

Section Six: Footwear

Section Seven: 'clean' area (inspection drying and storage of decontaminated scopes) attire

6.4 Procedure

Endoscope reprocessing (decontamination) unit

Section One: Attire

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

Personal protective equipment

Gowning for entry to the 'dirty' area (receipt of contaminated endoscopes)

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. a face shield that covers the eyes, nose, mouth and chin.
 - b. fluid repellent mask and separate goggles.
 - c. fluid repellent mask with integrated eye shield.
- 6.4.14 Goggles, masks and face shields should be:
 - a. single-use.
 - b. fitted and worn according to the manufacturers' instructions.
 - c. removed immediately if moist or visibly soiled and discarded in the appropriate healthcare waste stream.
- 6.4.15 Goggles, masks and face shields with integrated eye protection should be:
 - a. optically clear, antifog, distortion free, close fitting and shielded at the side.

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

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

Personal protective equipment

Section Four: Protection for skin and clothing

- 6.4.16 Healthcare workers should wear plastic aprons or impermeable gowns with long cuffed sleeves and tuck-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 contaminants to splash into eyes or mouth or onto skin or other personnel in the area.

Personal protective equipment

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

Section Six: Footwear

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

Section Seven: 'Clean' area (inspection drying and storage of decontaminated scopes) attire

Attire

- 6.4.28 HCWs working in the 'clean' area (inspection drying and storage of decontaminated scopes) should wear a freshly laundered scrub suit.
- 6.4.29 Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- 6.4.30 Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet.
- 6.4.31 Appropriate clothing should be used by staff who are involved in the maintenance of reprocessing equipment.
- 6.4.32 When working within the endoscope reprocessing unit suitable cover attire should be worn.

Head/hair cover

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

Personal protective equipment

- 6.4.35 All hair should be confined as well as covered.
- 6.4.36 After use, headgear should be discarded in the appropriate healthcare waste stream.
- 6.4.37 Stud earrings may be worn and should be totally confined within the head cover.

**Figure 6-1: Personal protective equipment “decontamination” area
(receipt of contaminated scopes)**



Personal protective equipment

Figure 6-2: Personal protective equipment ‘clean’ area (inspection, drying and storage of decontaminated scopes)



Process chemicals

7. Process chemicals

7.1 Introduction

Chemicals such as detergents and disinfectants may have hazardous properties associated with them (may be irritant, corrosive, flammable), e.g. bleach and ammonia if mixed will release lethal chlorine gas. Process chemicals are potentially hazardous as they may cause irritation to the skin, eye, respiratory tract and mucous membranes. (Reference: The Safety, Health and Welfare at Work Act, 2005 (no. 10 of 2005). The Safety, Health and Welfare at Work (General Application) Regulations 1993, (S.I. no. 44 of 1993) as amended. The Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (S.I. no. 619 of 2001).

7.2 Scope

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

7.3 Contents

Section One: Choice of process chemicals

Section Two: Control of process chemicals

Section Three: Material Safety Data Sheets and labels

Section Four: Training

Section Five: Spillage kit

Process chemicals**7.4 Procedure****Section One: Choice of process chemicals**

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

Section Two: Control of process chemicals

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

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

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

Process chemicals

Section Four: Training

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

Section Five: Spillage kit

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

8 Traceability

8.1 Introduction

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

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

The tracing system should permit retrospective tracing of the endoscopes and accessories history including the service user on which it was used.

As a minimum, records should be kept that permit the tracking of endoscopes and accessories to the cleaning process used and the reprocessing cycle in which they were decontaminated.

8.2 Scope

The objective of this recommended practice is to provide guidelines for the effective tracking and traceability of endoscopes and accessories through the decontamination cycle ensuring that an effective audit trail can be created to service user use.

8.3 Contents

Section One: Processing

Section Two: Tracing

8.4 Procedure

Section One: Processing

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

Traceability

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

Section Two: Tracing

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

Choice of decontamination process

9. Choice of decontamination process

9.1 Introduction

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

9.2 Scope

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

9.3 Contents

Section One: General principles

9.4 Procedure

Section One: General principles

- 9.4.1 RIMD should be reprocessed and managed 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 as categorised under the Spaulding Classification.
- 9.4.2 The minimum levels of processing and storage requirements for RIMD, based on three risk categories of use, are shown in the Spaulding Classification. 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.

Choice of decontamination process

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

Transport of contaminated endoscopes and accessories

10. Transport of contaminated endoscopes and accessories

10.1 Introduction

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

10.2 Scope

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

10.3 Contents

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

Section Two: Containers and trolleys

Section Three: Staff

10.4 Procedure

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

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

Transport of contaminated endoscopes and accessories

Scenario 1:

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

ADR 2.2.62.1.5.1

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

Scenario 2:

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

ADR 2.2.62.1.5.3

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

Scenario 3:

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

Transport of contaminated endoscopes and accessories

Section Two: Containers and trolleys

- 10.4.4 Contaminated endoscopes and accessories should be placed in re-usable, solid walled, leak proof container with a hard lid that completely enclosed the endoscope/ trolleys and transported to the 'dirty' area (receipt of contaminated endoscopes) as soon as possible after use.
- 10.4.5 Transport containers should protect both the product during transit and the handler from inadvertent contamination.

(Note: The container should be labelled as "contaminated".)

Section Three: Staff

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

Figure 10-1: Transport of contaminated endoscopes and accessories



Cleaning and disinfection

11. Cleaning and disinfection

11.1 Introduction

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

11.2 Scope

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

11.3 Contents

Section One: Pre-cleaning

Section Two: Manual cleaning

Section Three: Rinsing

Section Four: Disinfection

Section Five Ultrasonic cleaning

11.4 Procedure

Section One: Pre-cleaning

Wipe the insertion tube

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

Cleaning and disinfection

- 11.4.2 Discard the lint free cloth appropriately after use.

Figure 11-1: Wiping the insertion tube



Aspirate enzymatic detergent in accordance with manufacturers' recommendations through the suction/biopsy channels

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

Figure 11-2: Aspirating the enzymatic detergent through the suction/biopsy channel



Cleaning and disinfection

Purge air/water channels

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

Figure 11-3: Purging air/water channels



Detach removable components

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

Figure 11-4: Removing the endoscope from the light source



Cleaning and disinfection

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

(Note: It is preferable to have extra valves/buttons/caps to allow for additional time to ensure that adequate cleaning is performed prior to disinfection/sterilisation.)

(Note: Accessories should not be interchangeable extra sets should remain with scopes as a unique set for traceability purposes.)

Figure 11-5: Removing valves/buttons and caps



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

Figure 11-6: Transporting to the cleaning area



Cleaning and disinfection

Leakage testing

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

(Note: There are two types of leakage tests manual (hand operated bulb) and electrical.)

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

Figure 11-7: Leak testing



- 11.4.16 **Attach the leak tester and pressurise the endoscope.** Some manufacturers specify removing detachable parts prior to leakage testing others do not.
- 11.4.17 **Immerse the endoscope in the designated sink in water and observe for a continuous stream of bubbles** If the leakage tester has a pressure gauge, observe for pressure loss prior to immersion (this indicates a significant leak).
- 11.4.18 Completely immerse the entire endoscope.

Cleaning and disinfection

- 11.4.19 Flex the distal portion of the endoscope in all directions using the controls.
- 11.4.20 Observe for a continuous stream of bubbles which indicates a leak.
- 11.4.21 Observe the head of the endoscope, the insertion tube, distal bending section and the umbilical cable for bubbles coming from the interior of the endoscope.
- 11.4.22 Repeat the leak test before and after automated reprocessing in an Automated endoscope reprocessor .
- 11.4.23 The instructions provided by the endoscope manufacturer and manufacturer should be followed.

Processing endoscopes that fail the leakage test

- 11.4.24 If a leak is detected, or the endoscope appears damaged, the endoscope manufacturer or supplier should be contacted to ascertain whether reprocessing can be undertaken without additional damage to the endoscope.
- 11.4.25 If the endoscope fails the leak test, follow manufacturers' recommendations for failed tests

Section Two: Manual Cleaning

Cleaning is either:

- 11.4.26 Carried out manually before disinfection in a liquid chemical disinfectant (LCD).
- 11.4.27 Carried out manually and then further cleaned and disinfected in an endoscope washer-disinfector.

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

Make up detergent solution

- 11.4.28 Make up detergent solution to the manufacturers' instructions for reprocessing each endoscope

(Note: An automated detergent dispenser with temperature monitor is preferred)

Immerse endoscope

- 11.4.29 Completely immerse the endoscope.

Cleaning and disinfection

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

Figure 11-8: Immersing the endoscope



Disassemble removable parts and clean

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

Cleaning and disinfection

Brush and wipe exterior

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

Cleaning tools

- 11.4.41 Use of non-abrasive and lint-free cleaning tools will prevent damage to the endoscope.
- 11.4.42 Soft brushes are useful to clean grooved control handles and to brush the distal tip.
- 11.4.43 Valve sets and biopsy ports should be brushed using brushes which are designed for this purpose.

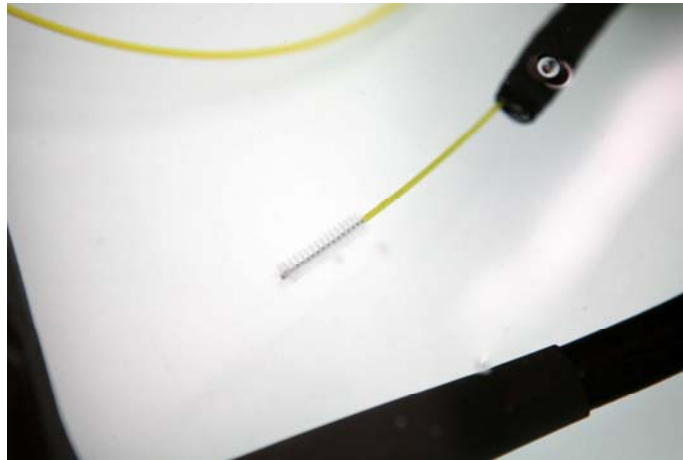
(Note: Single use brushes are preferred)

Brush all channels

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

Cleaning and disinfection

Figure 11-9: Brushing channels



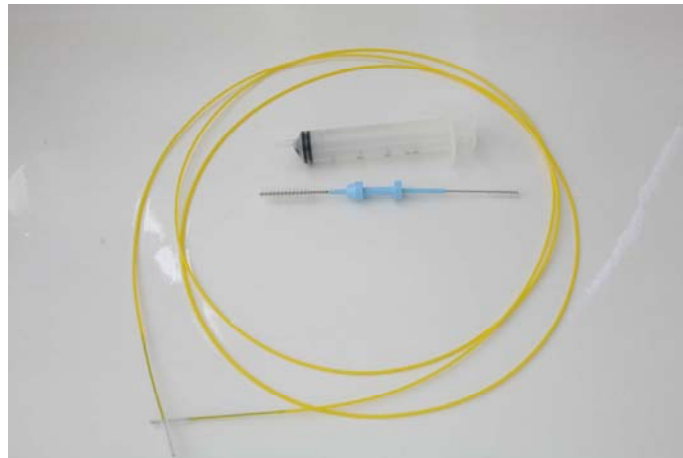
Brushes

(Note: Single-use brushes are preferred.)

- 11.4.52 When re-usable brushes are used, after each use they should be cleaned, inspected and sterilised before re-use.
- 11.4.53 Cleaning brushes for all brushable channels should be purchased and used in accordance with scope manufacturers' recommendations.
- 11.4.54 A brush size compatible with each channel should be used.
- 11.4.55 Rinsing the brush tip when it has emerged from the endoscope maximises cleaning of the channels by ensuring that as much debris as possible is removed before retraction or reinsertion of the brush.

Cleaning and disinfection

Figure 11-10: Brushes



Section Three: Rinsing

Water rinse

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

Purge internal channels with air

(Note: Relevant for AER's that do not have a pre-disinfected wash cycle.)

- 11.4.63 Purge water from all the channels with air to remove rinsing water.
- 11.4.64 Removing water from all channels and the exterior of the endoscope prevents dilution of the biocide used for disinfection.
- 11.4.65 This process can be completed using a syringe or compressed air.

Cleaning and disinfection

- 11.4.66 The endoscope should be transferred to the automated endoscope reprocessor in an appropriately sized receptacle so as to avoid contamination of the environment.

Section Four: Disinfection

(Note: The Health Service Executive regards the use of an automated endoscope reprocessor to process flexible endoscopes as mandatory. Unless specifically required by the endoscope manufacturer it is not acceptable to carry out chemical disinfection manually.)

- 11.4.67 The chemicals used throughout the decontamination process should be used at the correct concentration, volume, temperature and contact time as recommended by the manufacturer.
- 11.4.68 The chemical used in the disinfection stage should be Medical Devices Directive CE marked.
- 11.4.69 The chemical used in the disinfection stage should be accepted as compatible with the endoscope by the endoscope manufacturer.
- 11.4.70 The chemical used in the disinfection stage should be accepted as compatible with the automated endoscope reprocessor by the manufacturer.
- 11.4.71 The disinfectant should be in contact with all surfaces requiring disinfection at the required concentration for the required time.
- 11.4.72 The temperature throughout the disinfection stage should be monitored, or controlled and monitored, to ensure that it remains within specified limits.
- 11.4.73 Single-use disinfectants are preferred.
- 11.4.74 There should be a log of disinfectant batch numbers and expiry dates.
- 11.4.75 The water supplied to the automated endoscope reprocessor for the rinsing after the chemical disinfection stage should be purified water and should be free from microbial contamination.

Cleaning and disinfection

Section Five: Ultrasonic cleaning

- 11.4.76 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

- 11.4.77 See decontamination equipment, page 50

Procedure

- 11.4.78 Staff should wear personal protective equipment at all times while handling contaminated RIMD and working with the ultrasonic cleaner.
- 11.4.79 Fill the tank to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- 11.4.80 Bring the solution up to the operating temperature.
- 11.4.81 De-gas the water as recommended by the manufacturer.
- 11.4.82 Place the opened/dismantled RIMD into the basket.
- 11.4.83 Ensure all RIMD are fully immersed.
- 11.4.84 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.
- 11.4.85 Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.

Cleaning and disinfection

- 11.4.86 Close the lid and initiate the cleaning cycle.
- 11.4.87 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.
- 11.4.88 The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.
- 11.4.89 Combine only RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.
- 11.4.90 Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.
- 11.4.91 It is recommended that the tank be emptied between uses. This should be at intervals not exceeding four hours.

Validation

- 11.4.92 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.
- 11.4.93 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

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

Cleaning and disinfection

It consists of:

Installation qualification tests

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

Operational qualification tests

- 11.4.96 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.
- 11.4.97 These tests should be carried out when a new ultrasonic cleaner is purchased or when a used ultrasonic cleaner is has been relocated to another premises.
- 11.4.98 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.
- 11.4.99 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

- 11.4.100 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

- 11.4.101 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.

Cleaning and disinfection

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

11.4.103 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.

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

Table 11.1: The following table identifies the minimum level of periodic testing that should be undertaken:

Test	EN ISO 15883 Reference
Daily tests	
1. If fitted check spray arm rotation for free movement	N/A
2. If fitted check spray nozzles for blockage (paying particular attention to carriages for instruments)	N/A
3. Remove clean strainers and filters etc	N/A
Weekly tests	
1. Weekly safety checks	N/A
2. Carry out daily tests	N/A

Cleaning and disinfection

3. Automatic control test (if using automated ultrasonic cleaner)	
4. Cleaning efficacy test by residual soil detection	6.10.3
Quarterly tests	
1. Weekly safety checks	N/A
2. Automatic control tests (if using an automated ultrasonic cleaner)	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Test for ultrasonic activity*	6
5. Cleaning efficacy test	6.10.2, 6.10.3
Yearly and revalidation tests (Re-qualification in EN terminology)	
1. Yearly safety checks	N/A
2. Automatic control test (if using an automated ultrasonic cleaner)	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Water system	6.4
-chemical purity	6.2.2.2
-bacterial endotoxins	6.4.2.3
5. Drainage	
-free draining	6.5.2, 6.5.4
-efficacy of discharge	6.5.4
6. Doors and door interlocks	
-cycle start	6.3.1
-in-cycle	6.3.2, 6.3.3
-failed cycle	6.3.7

Cleaning and disinfection

7. Fault interlock	6.3.5, 6.3.6
8. Water vapour discharge test (fluid emission)	6.5.3
9. Chemical additive dosing tests (if using an automated ultrasonic cleaner)	
-reproducibility	6.9.1
-low level detection	6.9.2
10. Load carriers - alignment (if load carriers 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	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

11.4.105 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

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

Cleaning and disinfection

- 11.4.107 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 11.4.108 The ultrasonic cleaner should not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- 11.4.109 A qualified person (decontamination) should review the maintenance plan, main procedures and maintenance records periodically.

Test for Ultrasonic Activity (reference HTM 2030)

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

Equipment

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

Method

- 11.4.115 Measure the depth of the bath from the level of the lid to the bottom of the bath.
- 11.4.116 Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.
- 11.4.117 Carry out the manufacturer's recommended start-up procedure.
- 11.4.118 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.
- 11.4.119 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.
- 11.4.120 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.

Cleaning and disinfection

- 11.4.121 Operate the bath for the predetermined exposure time.
- 11.4.122 Remove the strips from the bath, blot dry and examine.
- 11.4.123 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).
- 11.4.124 On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

Automated endoscope reprocessing**12. Automated endoscope reprocessing****12.1 Introduction**

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

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

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

An (EWD) conforming to EN ISO 15883-4:2009 is preferred.

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

12.2 Scope

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

12.3 Contents

Section One: General principles

Section Two: Testing

Section Three: Validation

Section Four: Monitoring and control

Section Five: Maintenance

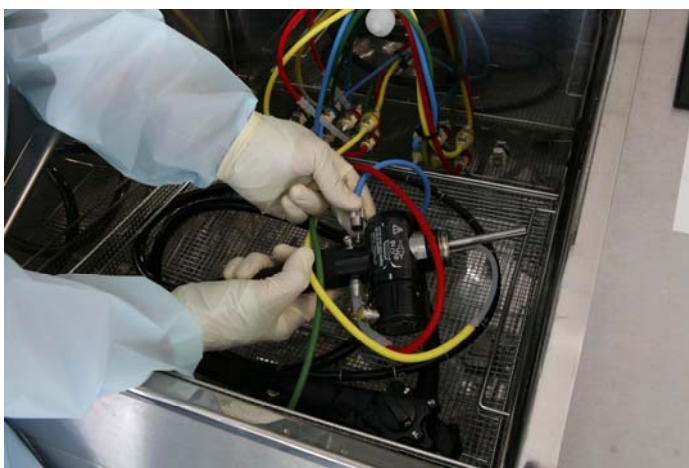
Automated endoscope reprocessing

12.4 Procedure

Section One: General principles

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

Figure 12 -1: Attaching the endoscope channels



- 12.4.7 Check that the endoscope blanks/caps are intact and secure.
- 12.4.8 Select appropriate cycle.

Automated endoscope reprocessing

- 12.4.9 Enter endoscope code and user code.
- 12.4.10 Initiate (AER) automatic cycle.
- 12.4.11 On completion of the cycle ensure that all stages and parameters have been achieved.
- 12.4.12 When the automated cleaning process is complete all the endoscopes processed should be inspected.

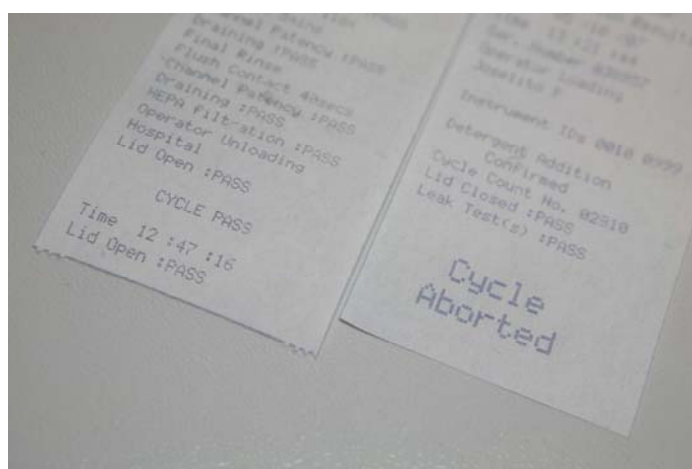
Figure 12-2: Selecting the cycle



- 12.4.13 Information should be recorded for every automated endoscope reprocessor cycle, and should contain the following:
 - a. automated endoscope reprocessor identification number.
 - b. cycle number.
 - c. type of (AER).
 - d. type of cycle used.
 - e. date and time of start of cycle.
 - f. load content.
 - g. critical parameters for the specific (AER) cycle.
 - h. operator's name.
 - i. results of (AER) process.

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- 12.4.14 Signature of a suitably qualified person confirming whether or not the process cycle was within recommended parameters.
- 12.4.15 Any notes or observation for the process cycle.
- 12.4.16 All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- 12.4.17 Cycles which were aborted should be documented with the action taken in a log book.
- 12.4.18 All automated endoscope reprocessors should undergo a self-disinfect cycle preferably at the beginning of each day, or in accordance with the AER manufacturers' recommendations. This should preferably be by thermal disinfection or with a chemical disinfectant different from that used for endoscope disinfection.
- 12.4.19 There should be a means to indicate that the self disinfection cycle has taken place and been completed satisfactorily and evidence that records are retained.

Figure 12-3: AER record**Section Two. Testing**

- 12.4.20 The automated endoscope reprocessor should be subjected to a planned programme of testing both before delivery and on-site.
- 12.4.21 Data from the tests and checks carried out during manufacture of the AER should be supplied with the AER.

Automated endoscope reprocessing

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

Automated endoscope reprocessing

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

Section Three: Validation

- 12.4.39 Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the endoscope washer-disinfector is functioning correctly and that it will produce cleaned and disinfected loads consistently.
- 12.4.40 The effectiveness of the disinfection process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if correct conditions are created throughout the EWD chamber and the load during every cycle.
- 12.4.41 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. in accordance with EN ISO 15883 –Part 1, 2, 4, &5.

Automated endoscope reprocessing

Commissioning

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

It consists of:

Installation qualification tests

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

Operational qualification tests

- 12.4.44 Weekly safety checks, automatic control test, verification of calibration of washer-disinfector instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical vapour discharge test, chemical additive dosing tests, load carriers, washer-disinfector self-disinfection test, final rinse decontamination test, channel patency test, disinfectant concentration test cleaning efficacy test, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric tests for thermal disinfection, microbiological test of disinfection efficacy, load dryness test, test for air quality and sound pressure.
- 12.4.45 These tests should be carried out when a new endoscope washer-disinfector is purchased or when a used EWD has been relocated to another premises. Installation and commissioning checks and tests should be performed by a Test Person or other suitably qualified person (decontamination) with specialist technical training in commissioning of EWDs. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the EWD is functioning correctly.
- 12.4.46 Even though the manufacturer should have tested a EWD before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is working correctly.

Automated endoscope reprocessing

Performance qualification

- 12.4.47 Performance qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean/disinfect. Performance qualification is indicated for initial use of a new/relocated endoscope washer-disinfector or when the load profile changes. It should be carried out by a Test Person (or other suitably qualified person).

These tests consist of

- a. thermometric tests for a full load of items not previously represented by the reference load.
- b. load dryness test.
- c. cleaning efficacy test.
- d. microbiological tests for efficacy of chemical disinfection for a full load of items not represented adequately by the reference load.
- e. process residues.

Periodic testing

- 12.4.48 After validation and when the EWD has been passed for use, it is subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals.
- 12.4.49 The daily, weekly and quarterly tests supply evidence that the EWD is still operating within the limits established during commissioning.
- 12.4.50 Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.

Periodic tests consist of the following:

- a. **Daily:** Remove and clean strainers and filters as per manufacturers' guidelines.
- b. **Weekly:** Automatic control test, weekly safety checks, daily tests, water hardness, water conductivity, cleaning efficacy test (residual soil detection) and final rinse water supply.
- c. **Quarterly tests:** Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection, cleaning efficacy test and channel patency test.

Automated endoscope reprocessing

- d. **Annual tests:** Weekly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, venting system, doors and door interlocks, fault interlock, chemical vapour discharge, chemical additive dosing, load carriers, washer-disinfector self-disinfection test, final rinse decontamination test, channel patency test, disinfectant concentration test, chamber wall temperature test, load carrier temperature test, cleaning efficacy, over-temperature cut-out, thermometric tests for disinfection stage, microbiological test of disinfection efficacy, load dryness test and tests for air quality.

Section Four: Monitoring and control

- 12.4.51 Cycle variables should be monitored to ensure that the specified parameters are obtained for each cycle by the user (e.g. AER cycle print out).
- 12.4.52 The critical cycle variables are temperature, time, detergent concentration and water pressure or flow rate.
- 12.4.53 Validation, routine monitoring and control should be carried out in accordance with European Standards, manufacturers' instructions and local policy, procedure, protocol and guideline including efficacy tests during operational conditions.

Section Five: Maintenance

- 12.4.54 There should be documented evidence of planned and unplanned maintenance for automated endoscope reprocessors, disinfectant generators, water treatment systems and storage cabinets according to manufacturers' instructions.
- 12.4.55 Preventative maintenance should be planned and performed in accordance with International Standards EN ISO 15883-1 and EN ISO 15883-4 the manufacturers' recommendations.
- 12.4.56 Planned preventative maintenance should include the following:
 - a. inspecting and cleaning all filters.
 - b. dismantling and cleaning spray arms and nozzles.

Automated endoscope reprocessing

- 12.4.57 The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- 12.4.58 The automated endoscope reprocessor should not be used to process endoscopes and accessories until all scheduled maintenance tasks have been completed satisfactorily and recorded.
- 12.4.59 A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- 12.4.60 An automated endoscope reprocessor maintenance and repair log book should be maintained for each AER.
- 12.4.61 All automated endoscope reprocessor should be under a service contract.
- 12.4.62 A schedule of maintenance and disinfection of any water purification system should be specified. Records of periodic sanitisation should be kept.

Automated endoscope reprocessing**Table: 12.1. Automatic endoscope reprocessor Periodic Test. This table identifies the minimum level of periodic testing that should be undertaken:**

Test	EN ISO 15883 Reference (Part 1 unless otherwise stated)
Daily tests	
1. If fitted check spray arm rotation for free movement	N/A
2. If fitted check spray nozzles for blockage (paying particular attention to those fitted to carriages for instruments)	N/A
3. 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. Water hardness (all process stages)	6.4.2.2
4. Water conductivity (final rinse stage)	6.4.2.2
5. Automatic control test	6.13
6. Cleaning efficacy test by residual soil detection	6.10.3
7. Water used for final rinsing	Part 4 6.3
Quarterly tests	
1. Weekly safety checks	N/A
2. Automatic control tests	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Thermometric test for thermal disinfection (if thermal disinfection is fitted)	6.8 and Part 4 6.9

Automated endoscope reprocessing

5. Cleaning efficacy test	6.10.2, 6.10.3, and Part 4 6.11
6. Channel patency test	Part 4 6.6 and Part 4 6.7
Yearly and revalidation tests (Re-qualification in EN 15883 terminology)	
1. Yearly safety checks	N/A
2. Automatic control test	6.13
3. Verification of calibration of WD instruments	6.6.1
4. Water system	6.4
-chemical purity	6.4.2.2 and Part 4 6.3
-bacterial endotoxins	6.4.2.3 and Part 4 6.3
-legionellae, Pseudomonas aeruginosa and mycobacteria	Part 4 6.3
5. Drainage	
-free drainage	6.5.2, 6.5.4
-efficacy of discharge	6.5.4
6. Venting system	Part 4.5.3 and IEC 62010-2-040
7. Doors and interlocks	
-cycle start	6.3.1
-in-cycle	6.3.2, 6.3.3
-failed cycle	6.3.7
8. Fault interlocks and alarms (including leak alarms where fitted)	6.3.5, 6.3.6, Part 4 6.5.3
9. Chemical vapour discharge test	N/A*

Post cleaning inspection and function testing**13. Post cleaning inspection and function testing****13.1 Introduction**

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

13.2 Scope

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

13.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Documentation post automated cleaning

Section Four: Monitoring and control

13.4 Procedure**Section One: Equipment**

13.4.1 Work bench.

13.4.2 Magnifying glass and oblique of stereo-microscope.

13.4.3 Light source.

Post cleaning inspection and function testing**Section Two: Procedure**

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

- 13.4.4 Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted.
- 13.4.5 If there is no record of cleaning, the endoscope is rejected and returned for re-cleaning
- 13.4.6 Make a visual inspection of the endoscope in order to ensure that there is no obvious damage, staining or residue.
- 13.4.7 Where an endoscope may not be properly cleaned the load is rejected and returned for re-cleaning.
- 13.4.8 Any damaged, incomplete or malfunctioning endoscopes should be reported immediately to the supervisor.
- 13.4.9 Each endoscope should be checked that there is free movement of all parts.

Section Three: Documentation post automated cleaning

- 13.4.10 All documentation for automated cleaning should contain the following information:
 - a. automated endoscope reprocessor (AER) identification number or serial number.
 - b. cycle number.
 - c. type of (AER).
 - d. type of cycle used.
 - e. date and time of start of cycle.
 - f. load content.
 - g. critical parameters for the specific washer-disinfector cycle.
 - h. operators name.

Post cleaning inspection and function testing

- i. results of washer-disinfector process.
 - j. signature of an authorised qualified person confirming whether or not the process cycle was within recommended parameters.
 - k. any notes or observation for the process cycle.
- 13.4.11 All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.

Section Four: Monitoring and control

- 13.4.12 The user should be aware of the factors that may alter the efficacy of the method:
- a. staff training/competence.
 - b. age, type and numbers of the channels of the endoscope.

Drying

14. Drying

14.1 Introduction

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

14.2 Scope

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

14.3 Contents

Section One: General principles

14.4 Procedure

Section One: General Principles

(Note: In many automated endoscope reprocessors (AERs) the operating cycle provides an option after the final rinse stage for a purge stage to remove excess rinse water from the endoscope when the endoscope is intended for immediate use or a more prolonged drying stage when it is intended to store the endoscope before use.)

- 14.4.1 When the purge cycle has been used, on removal from the (AER), the outside of the endoscope should be wiped with a disposable dry lint free cloth.

Low temperature sterilisation**15. Low temperature sterilisation****15.1 Introduction**

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

15.2 Scope

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

15.3 Contents

Section One: General principles

Section Two: Validation

Section Three: Periodic testing

Section Four: Chemical and Biological Indicators

Section Five: Sterilisation of RIMD

Section Six: Sterile product release

Section Seven: Storage and use

15.4 Procedure**Section One: General principles**

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

Low temperature sterilisation

15.4.2 The hydrogen peroxide based methods are preferred. (The residuals from EO and LTSF are toxic and must be degassed from RIMD after sterilisation whereas the residuals from hydrogen peroxide are innocuous (water and oxygen); also, EO and LTSF are alkylating processes which are believed to stabilise prion proteins).

15.4.3 Low temperature sterilisation methods should only be used for:

- a. RIMD (including flexible/rigid scopes) specifically identified by the RIMD (scope) manufacturer or steriliser manufacturer as suitable for processing in the steriliser.
- b. RIMD (including flexible/rigid scopes) made of materials of a size and configuration e.g. length and diameter of lumen within the criteria specified by the steriliser manufacturer.

(Note: Documentation of items that can and cannot be processed should be obtained from the RIMD (scope) and steriliser manufacturers)

15.4.4 RIMD (flexible/rigid scope) to be processed in a low temperature steriliser must be scrupulously clean and thoroughly dried prior to sterilisation. (The presence of residual soiling or droplets of water may seriously impair the sterilisation process.)

15.4.5 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

15.4.6 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.

15.4.7 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.

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

Low temperature sterilisation

It is comprised of:

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

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

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

Section Three: Periodic testing

- 15.4.12 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.
- 15.4.13 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).
- 15.4.14 A qualified person (decontamination) should review and approve the schedule for periodic testing.
- 15.4.15 It is the responsibility of the operational manager to ensure that these tests are performed and that the results were satisfactory before allowing the continued use of the steriliser.

Low temperature sterilisation

Section Four: Chemical and biological indicators

Chemical indicators

- 15.4.16 Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- 15.4.17 Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).
- 15.4.18 The type used should be in accordance with the steriliser manufacturers' recommendations.
- 15.4.19 The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- 15.4.20 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.
- 15.4.21 Indicators should not be used beyond their expiry date.
- 15.4.22 Two types of chemical indicator are commonly used:
 - a. **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
 - b. **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

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

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

- 15.4.27 Wear personal protective equipment.
- 15.4.28 Ensure that any checks and test that are to be carried out prior to sterilisation have been complete and were satisfactory.
- 15.4.29 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).
- 15.4.30 The steriliser door/s should be kept closed when the steriliser is not in use.
- 15.4.31 Select the validated cycle programme suitable for the load being processed.
- 15.4.32 Ensure the load is suitable for the process to which it will be exposed.
- 15.4.33 Manufacturers written instructions for operating the steriliser should be followed.

Section Six: Sterile product release

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

Parametric release

- 15.4.35 When cycle is complete post sterilisation inspection is carried out to verify that the sterilisation cycle has completed with defined, validated critical parameters (VCP).
- 15.4.36 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

- 15.4.37 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.

Low temperature sterilisation

- 15.4.38 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.
- a. 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.
 - b. the cause of failure should be investigated and documented.
 - c. 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.
- 15.4.39 The chemical process indicator should have undergone the expected colour change.
- 15.4.40 The integrity of the outer wrap and its seals should not have been compromised, e.g. torn wrap, sealing tape undone).
- 15.4.41 The packed RIMD (including flexible/rigid scopes) should be dry.
- 15.4.42 The labelling should remain in place and legible.
- 15.4.43 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.
- 15.4.44 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

- 15.4.45 Sterile RIMD (including flexible/rigid scopes) should be stored in a clean, dry area, which is secure, dust free and above floor level.
- 15.4.46 Packs should be labelled with the contents, the word 'Sterile', the date of sterilisation and a unique identifier from which all stages of the decontamination process to which it was subjected may be traced.
- 15.4.47 Packs should be stored so that they are used in sequential order, i.e. the oldest first.
- 15.4.48 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.

Transport of decontaminated endoscopes and accessories**16. Transport of decontaminated endoscopes and accessories****16.1 Introduction**

Decontaminated endoscopes and accessories should be transported in a manner that will not compromise their status. Decontamination is event related and depends on the extent and nature of handling and environmental conditions during transportation and storage.

16.2 Scope

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

16.3 Contents

Section One: General principles

16.4 Procedure**Section One: General principles**

- 16.4.1 Reprocessed endoscopes and accessories should be transported in clean dry containers and trolleys in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage.
- 16.4.2 The re-usable transport container should be clean and disinfected, dry, solid walled with a hard cover and should visibly state decontaminated endoscope.
- 16.4.3 There should be an adequate number of transport containers and trolleys in the endoscope reprocessing unit.
- 16.4.4 There should be documented cleaning and disinfection regime for all transport containers and trolleys.

Storage

17. Storage

17.1 Introduction

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

17.2 Scope

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

17.3 Contents

Section One: Storage cabinets and cupboards

Section Two: Detachable components and parts

Section Three: Cleanliness and functionality

17.4 Procedure

Section One: Storage cabinets and cupboards

Storage cabinets

- 17.4.1 The air filtered endoscope storage cabinet should maintain the microbiological quality of the reprocessed flexible endoscope and accessories for a predetermined period validated by and in accordance with the manufacturers' recommendations.
- 17.4.2 The drying process should remove moisture from and out of the endoscope.
- 17.4.3 After the drying process a conditioning process guarantees the endoscope maintains its condition for up to 72 hours or as specified by the manufacturer.

*(Note: If the maximum storage time has elapsed a process alarm should advise that maximum time has exceeded, **the scope should not be used until reprocessed again**)*

Storage

- 17.4.4 For routine release of endoscopes the following should be carried out:
- visually check that the endoscope is dry.
 - confirm and verify by signature that the endoscope was dry and the conditions for drying were achieved.
- 17.4.5 Remove the dry endoscope and accessories from the cabinet and place in the designated trolley or container.
- (Note: The use of single use tray liner and cover that denote cleanliness status of the endoscope are preferred)*
- 17.4.6 The cabinet should be electronically controlled and should be subject to validation and microbiological testing in accordance with manufacturers' recommendations.
- 17.4.7 The cabinet should be routinely serviced in accordance with manufacturers' recommendations.
- 17.4.8 The connection method for use should be determined by the scope manufacturer.
- (Note: For each endoscope series, there should be a set of connectors available for connecting the endoscope to the air connector as specified by the manufacturer)*
- 17.4.9 The cabinet should have the capability to store process information and data.

Storage cupboards

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

Storage

Section Two: Detachable components and parts

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

Section Three: Cleanliness and functionality

- 17.4.18 Endoscopes should be reprocessed before use if more than three hours has elapsed from the last decontamination process unless stored in a dedicated storage cabinet that has been validated for more prolonged storage.
- 17.4.19 Prior to reuse, all decontaminated endoscopes should be inspected for cleanliness.

Water supply for Automated endoscope reprocessors (AER)

18. Water supply for Automated endoscope reprocessors (AER)

18.1 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 scope prior to service user procedure.

18.2 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.

18.3 Contents

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

18.4 Procedure

Section One: General requirements

- 18.4.1 At each stage in the cleaning process the water quality should be compatible with:
- a. the materials of construction of the automated endoscope reprocessor .
 - b. the RIMD to be processed.
 - c. the process chemical to be used.
 - d. the process requirements of that particular stage.

Water supply for Automated Endoscope Reprocessors (AER)

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

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

- 18.4.4 Water hardness is caused by the presence of dissolved salts of the alkaline earths (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (lime-scale) when water is heated or evaporated.
- 18.4.5 The deposition of lime-scale on electrical heating elements or heat exchange components, within pipes and around the edges of spray nozzles will seriously impair the performance of an endoscope reprocessor.
- 18.4.6 Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- 18.4.7 Using hard water in the thermal disinfection and final rinse stages of the AER 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.
- 18.4.8 Hard water will cause reverse osmosis (RO) systems to malfunction more frequently. Generally, water softeners are used as a pre-treatment to remove hardness from water prior to passing through reverse osmosis systems. The limit for hardness in water prior to a RO System should be not more than 210ppm; however 0-10ppm is preferable.

Water supply for Automated Endoscope Reprocessors (AER)

Temperature

- 18.4.9 The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.
- 18.4.10 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.
- 18.4.11 When enzymatic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.
- 18.4.12 The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

Ionic contaminants

- 18.4.13 Ionic contaminants in the water may react with materials such as stainless steel.
- 18.4.14 Water used for stainless steel instruments should have a chloride concentration less than 120 mg/l Cl⁻ to minimise the risk of corrosion.
- 18.4.15 Tarnishing of stainless steel RIMD, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discoloration.
- 18.4.16 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 Endoscope reprocessing, the guideline limit for conductivity is no greater than 30 microSiemens.

Microbial population

- 18.4.17 The microbial population in the water used in the endoscope washer-disinfector, particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.

Water supply for Automated Endoscope Reprocessors (AER)

- 18.4.18 For items which are intended to be used without further processing (e.g. flexible endoscopes processed in an endoscope washer-disinfector) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the service user, either through infection or by leading to a erroneous diagnosis. It is recommended that a guideline limits for microbial contamination set at no greater than 10 CFU/100ml sample.

(Note: Sample tests for these parameters should be taken from the aseptic sample point on the RO loop water prior to the AER)

Bacterial endotoxins

- 18.4.19 Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse effects. They are not readily inactivated at the temperatures used for disinfection or sterilisation.
- 18.4.20 Water used for the final stages of processing in an AER, 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 AER is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.

(Note: Sample tests for these parameters should be taken from the aseptic sample port of the RO loop water prior to the AER)pH.)

- 18.4.21 The relative acidic or alkaline level of a solution is measured by pH. The pH is a measure of hydrogen ion concentration in the water. A pH of less than 7.0 is acidic and a pH of more than 7.0 is alkaline. The pH for a washer-disinfector should be between 5.5 & 8.0, any outlining values may indicate crossover of detergent or disinfectant.
- 18.4.22 All of the above parameters should be tested for on a regular minimum 3 month basis, however weekly testing is preferable. This is to ensure the water quality does not breach the minimum recommended guidelines at any stage.

Section Three: Water treatment

- 18.4.23 There are two main methods of water treatment generally used for water supplies to AER's
- reverse osmosis utilising manual chemical disinfection.
 - reverse osmosis utilising daily automatic heat disinfection.

Water supply for Automated Endoscope Reprocessors (AER)

Reverse osmosis – utilising manual chemical disinfection

- 18.4.24 Reverse osmosis treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.
- 18.4.25 When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population. However, the microbiological quality of the water can deteriorate following storage due to the proliferation of bacterial species appropriate measures include:
- a. a continuous recirculation system water.
 - b. filtration, e.g. through a 0.03 micron UF filter to remove microbial contaminants and endotoxins.
 - c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (regular chemical disinfection of treated water tank loop pipework and by the use of UV irradiation (wavelength 254nm).
- 18.4.26 The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Orbitally welded stainless steel or cleanPEX pipes are preferred for all qualities of purified water.

Reverse osmosis – utilising daily automatic heat disinfection

- 18.4.27 Reverse osmosis treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.
- 18.4.28 When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population. However, the microbiological quality of the water can deteriorate following storage due to the proliferation of bacterial species.
- 18.4.29 Appropriate measures include:
- a. a continuous recirculation system water.
 - b. filtration, e.g. through a 0.03 micron UF filter to remove microbial contaminants and endotoxins.

Water supply for Automated Endoscope Reprocessors (AER)

- c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (daily Heat disinfection of treated water tank, loop, pipework and UF filter to above 85°C and by the use of UV irradiation (wavelength 254nm).

18.4.30 The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Orbitally welded stainless steel or clean PEX pipes are preferred for all qualities of purified water.





Water supply and distribution

- 18.4.31 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.
- 18.4.32 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.
- 18.4.33 Regular disinfection of the storage and distribution system should be undertaken and the efficacy of such control procedures should be subject to microbiological testing.
- 18.4.34 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.
- 18.4.35 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).
- 18.4.36 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.
- 18.4.37 This information may aid identification of the contamination source and assist with any subsequent advice.

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

Water supply for Automated Endoscope Reprocessors (AER)

Table 18-1: Typical bacterial counts as indicators of process water quality

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

Water supply for Automated Endoscope Reprocessors (AER)

Table 18-2: Water quality for endoscope washer-disinfector

Endoscopy/ Washer- disinfector Process Stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Cold Water Rinse	Reverse Osmosis 0.05micron filter	Reverse Osmosis 0.05micron filter
Wash	Reverse Osmosis 0.05micron filter	Reverse Osmosis 0.05micron filter
Rinse	Reverse Osmosis 0.05micron filter	Reverse Osmosis 0.05micron filter
Disinfection	Reverse Osmosis 0.05micron filter	Reverse Osmosis 0.05micron filter
Rinse x 2	Reverse Osmosis 0.05micron filter	Reverse Osmosis 0.05micron filter

Table 18-3: Water quality for cleaning RIMD

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

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

Valves, detachable parts and accessories**19. Valves, detachable parts and accessories****19.1 Introduction**

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

19.2 Scope

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

19.3 Contents

Section One: Valves and detachable parts

Section Two: Accessories

19.4 Procedure**Section One: Valves and detachable parts**

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

Valves, detachable parts and accessories

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

Section Two: Accessories

Introduction

- 19.4.6 Endoscopic accessories are devices used in conjunction with an endoscope to perform diagnostic and therapeutic procedures. These may be passed via the biopsy channel/working channel of an endoscope during a procedure. Examples include biopsy forceps, snares, etc.

Single use accessories

- 19.4.7 Single use accessories should always be used in preference to re-usable accessories (unless no suitable alternative is available).

Re usable accessories

- 19.4.8 Where re-usable accessories have to be used they should be sterilised.

(Note: This should be carried out in a central decontamination unit and should be done in accordance with the manufacturer's instructions.)

- 19.4.9 Checks should be in place to ensure that the reusable item is fit for use on return to the endoscopy unit.
- 19.4.10 There should be evidence that a risk assessment involving the infection prevention and control team has taken place for re-usable items that cannot be sterilised.
- 19.4.11 Single use devices should be used for manual cleaning.
- 19.4.12 Single use biopsy forceps should be used for all procedures.
- 19.4.13 Reusable water bottles should be sent to the central decontamination unit at the end of the session to be cleaned and sterilised in accordance with the manufacturers' instructions.
- 19.4.14 Sterile water should be used in the water bottle.

Valves, detachable parts and accessories

- 19.4.15 Accessories and removable parts (other than single use items) should be kept together with a single endoscope forming a unique set.
- 19.4.16 Discard and replace reusable valves and distal tips regularly or if they become damaged during use.

Figure 19-1: Detachable parts



Single use invasive medical devices

20. Single use invasive medical devices

20.1 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.

20.2 Scope

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

20.3 Contents

Section One: General principles

20.4 Procedure

Section One: General principles

- 20.4.1 To avoid cross-contamination between service users, SIMD should be used wherever this is practical.
- 20.4.2 Single-use items should be used for a single service user and not reused on subsequent service users. Service user care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- 20.4.3 Devices intended for single-use and labelled 'single-use' by the manufacturer should be immediately disposed of after use.
- 20.4.4 Endoscope reprocessing (decontamination) unit managers who disregard this information and prepare single use products for further use, are transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them and have become the manufacturer of the device.

Single use invasive medical devices

- 20.4.5 The symbol for single use instruments is as given in EN 980:2003.
- 20.4.6 Synonyms for “do not reuse” are “single use”, “use only once”.
- 20.4.7 See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).
- 20.4.8 Healthcare organisations should have well established criteria for their choice of SIMD or RIMD where both are available.

Figure 20-1: Do not reprocess symbol

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

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

21.1 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.

21.2 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.

21.3 Contents

Section One: General principles

21.4 Procedure

Section One: General principles

- 21.4.1 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.
- 21.4.2 All RIMD must be decontaminated in accordance with the manufacturers' instructions.
- 21.4.3 If items are dispatched to suppliers, or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, the recipient may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.

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

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

Loan reusable invasive medical devices**22. Loan reusable invasive medical devices****22.1 Introduction**

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

22.2 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.

22.3 Contents

Section One: General principles

Section Two: Procedure for loaning and borrowing RIMD

22.4 Procedure**Section One: General principles**

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

Loan reusable invasive medical devices

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

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

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

Documentation

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

Loan reusable invasive medical devices*Log book*

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

Arrangements for return of RIMD

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

Action on non-conforming product**23. Action on non-conforming product****23.1 Introduction**

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

23.2 Scope

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

23.3 Contents

Section One: Policies, procedures, protocols and guidelines

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

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

- 23.4.1 Written policies, procedures, protocols and guidelines for the recall of non-conforming product should be developed, available and implemented in the healthcare organisation.

Action on non-conforming product

- 23.4.2 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.
- 23.4.3 The nature and seriousness of the fault and the risk category of the product will determine whether it will be necessary to issue an advisory notice or to institute a recall. These factors will also determine the speed and extent of the action. Ref: EN 724:1994.

Section Two: Recall procedure

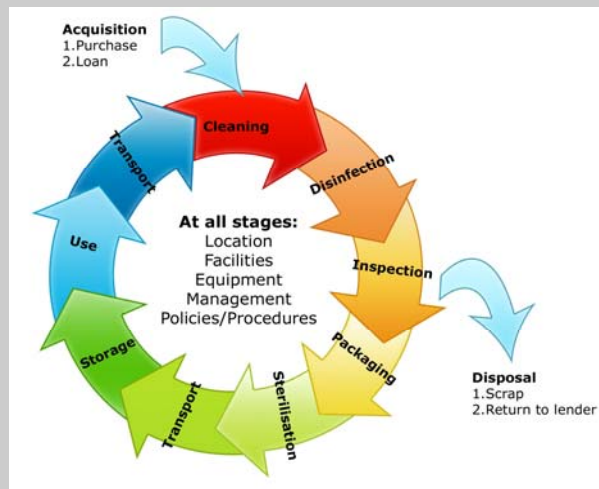
- 23.4.4 A recall policy, procedure, protocol and guideline should:
- be written.
 - outline the circumstances for issuing a recall order.
 - designate the person(s) authorised to issue a recall order.
 - designate the person(s) responsible for reporting on the execution of a recall order.

Section Three: Recall order

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

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

- 23.4.6 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 Endoscope Reprocessing Units

Part 4

Additional Resources and Appendices

1. Resources

AORN. Standards, Recommended Practices and Guidelines. AORN, 2006.

British Standards Institute. *A Standard for Standards—Part 2: Structure and drafting—requirements and guidance*. December 2005.

Chiba K (1994). Aspects of disinfectants for control of nosocomial infections,. *Hokkaido Igaku Zasshi* 69:182–187.

Code of Practice in relation to Infection Control in Dentistry (2004). The Dental Council, Dublin 2 (available at http://www.dentalcouncil.ie/g_crossinfection.php).

Department of Health and Ageing. *Infection Control Guidelines for the prevention of transmission of infectious diseases in the healthcare setting*. Department of Health and Ageing, Australia, 2004.

Glennie Group (NHS Scotland Sterile Services Provision Review Group) Report [HDL(2001) 66].

Health Building Note 13 Sterile Service Departments. HMSO

Health Technical Memorandum 01-01Part A: Decontamination of Reusable Medical Devices

Health Technical Memorandum 2010 Sterilisers, London: HMSO.

Health Technical Memorandum 2030 Washer Disinfectors, London: HMSO.

Health Technical Memorandum 2031 Steam for Sterilisation, London: HMSO.

Institute of Decontamination Sciences. *IDSc Standards & Practice*. Institute of Decontamination Sciences, 2006.

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

Irish Medicines Board. *The Procurement and Commissioning of Medical Equipment for Hospitals*. IMB Safety Notice. SN2006(03).

Kohn WG, Collins AS, Cleveland JL, Harte JA, Eklund KJ, Malvitz DM; Centers for Disease Control and Prevention (CDC), 2003. Guidelines for infection control in dental health-care settings–2003. *Morbidity and Mortality Weekly Report. Recommendations and Reports*, 52(RR-17), 1–61.

Resources

Medicines and Healthcare products Regulatory Agency, Sterilisation, disinfection and cleaning of medical equipment: Guidance on decontamination from Microbiology Advisory Committee to the Department of Health Medical Devices Agency (The MAC Manual) Part 1 Principles (1993 updated 2010) Part 2 Protocols (1996 updated 2005), Part 3 Procedures (1999 updated 2000, 2002 and 2006).

Muscarella LF (1998). Are all sterilisation processes alike? *AORN Journal* 67:966–970, 973–976.

NHS Health Protection Scotland. *Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management*. NHS Health Protection Scotland, 2004.

NHS Health Protection Scotland. *Local Decontamination Units: Guidance on the Requirements for Equipment, Facilities and Management*. NHS Health Protection Scotland, 2004.

NHS Wales. *Standard 36—Decontamination of Reusable Invasive Medical Devices and Equipment*. NHS Wales, 2006.

Safety, Health and Welfare at Work Act 2005 (10 of 2005), Republic of Ireland (available at <http://www.oireachtas.ie/documents/bills28/acts/2005/a1005.pdf>).

Spaulding E H, Chemical Disinfection of Medical and Surgical Materials in Lawrence CH, Black SS, Disinfection, Sterilisation and Preservation, (1968) 32: 517-531, Henry Kimpton, London.

Standards Australia, Standards New Zealand, Risk Management *Australian Standard® AS/NZS 31000: 2009*, Standards Australia, Standards New Zealand, 2009.

2. Abbreviations

AORN	Association of Perioperative Registered Nurses
AER	Automated Endoscope Reprocessor
ATP	Adenosine Triphosphate
CE	Conformité Européenne
CDU	Central Decontamination Unit
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
EEC	European Economic Community
EN	European Norm
EU	European Union
ERU	Endoscopy Reprocessing Unit
EWD	Endoscope Washer-Disinfector
HAS (H&S)	Health and Safety
HBN	Health Building Note
HCAI	Healthcare Associated Infection
HCW	Health Care Worker
HIQA	Health Information Quality Authority
HSE	Health Service Executive
IMB	Irish Medicines Board
ISO	International Standards Organisation
LCD	Liquid Chemical Disinfector

Abbreviations

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

3. Glossary

Adverse event	An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.
Cleaning	The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning removes microorganisms and the organic material on which they thrive. It is a necessary pre-requisite of effective disinfection or sterilisation.
Clinical Governance	Corporate accountability for clinical performance.
Decontamination	The removal of microorganisms or foreign matter (or both) from contaminated materials or living tissue. Three processes for decontamination are commonly used; cleaning, disinfection and sterilisation.
Disinfectant	A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms; and that is not represented by the manufacturer to be suitable for internal use.
Disinfection	The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation.
Hazard	A source of potential harm or a situation with a potential to cause loss.
Healthcare associated infection	Infection contracted as a result of health care. includes iatrogenic infections resulting from medical procedures and nosocomial infections resulting from the patient's presence in a health care establishment

Glossary

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	<p>Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of:</p> <ul style="list-style-type: none"> • 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.

Glossary

Primary Care	HSE healthcare provision outwith hospitals, for example, general medical practitioner and general dental practitioner services.
Risk	The chance of something happening that will have an impact upon objectives. It is measured in terms of the severity of the consequence and frequency.
Risk Assessment	The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria.
Risk Management	The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects.
Risk Management Process	The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk.
Risk Reduction	A selective application of appropriate techniques and management principles to reduce either likelihood or an occurrence or its consequences, or both.
Reprocessing	All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation.
Reusable item	An item designated or intended by the manufacturer to be suitable for reprocessing and reuse.
Sharps	Any object capable of inflicting penetrating injury, including needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.

Glossary

Stakeholders	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.
Standard	Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
Statutory	Required by law.
Sterilisation	A process used to render an object free from viable microorganisms including viruses and bacterial spores.
TSEs	TSEs are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans.
Validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications. Validation broadly encompasses three activities – commissioning, verification of a process specification and performance qualification.
Verification	Checking or confirmation of the truth or accuracy of something (e.g., self-assessment).
Suitably qualified person (decontamination)	<p>A suitably qualified person (decontamination) is defined as a (person designated by Management to provide testing, advice and review/witness documentation. Be qualified to graduate level in an appropriate discipline.</p> <p>The suitably qualified person (decontamination) should demonstrate extensive relevant experience on decontamination equipment testing and the subject of decontamination and a lower level qualification should also be considered. Each case should be considered on its merits.</p>

Appendices

Appendix 1: Membership of National Decontamination Advisory Group

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

Appendices

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

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

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

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

Appendix 3: Standards and Guidance on which the HSE standards and recommended standards are based

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

Legislation

Directive 93/42/EEC.

European and International Standards

i. Cleanroom Standards

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

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

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

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

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

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

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ii. Disinfectant Standards

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

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

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

iii. Equipment Standards

Sterilisers

EN 285:2006 + A2:2009 Sterilisation. Steam sterilisers. Large sterilisers.

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

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

EN 14180:2003 + A2:2009 Sterilisers for medical purposes. Low temperature steam and formaldehyde sterilisers. Requirements and testing.

Washer-disinfectors

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

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

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

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

iv. Management

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

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

v. Materials

Biological indicators

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

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

Chemical indicators

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

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

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

Packaging

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

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

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

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

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

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

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

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

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

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

vi. Medical devices

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

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

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

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

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

vii. ProcessesSterilisation

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

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

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

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

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

viii. Safety

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

UK Guidance Documents

HBN13 Sterile Service Departments.

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

HTM 2010 Sterilisers.

HTM 2030 Washer Disinfectors.

HTM 2031 Steam for sterilisation.

MAC Manual 2010.

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

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

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

MDB 2006 (05) Managing Medical Devices

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

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

MDB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse.

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

Appendix 4: Regulations and Guidance

Medical Device

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

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

Medical Devices Directive

Medical Devices are regulated by three main Directives

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

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These three Directives:

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

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

Irish Medicines Board

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

Legislation

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

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

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

Vigilance

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

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

Manufacturer of Medical Devices

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

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Legal Entity

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

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

Safety, Health and Welfare at Work Act, 2005

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

The 2004 Act sets out:

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

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

