Decontamination Services in Acute Hospitals

Draft Standards and Recommended Practices for Reusable Invasive Medical Devices in Acute Hospitals

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National Hospitals Office

Foreword

This document outlines draft standards and recommended practices for the decontamination of reusable invasive medical devices (hereafter referred to in this document as **RIMD**) in acute care hospitals.

The document has been drafted by members of the National Hospitals Office Decontamination Steering Committee and was prepared by utilising published guidance from expert bodies, and existing best practice guidance and standards. Information has been drawn from various expert groups and reference sources. These are referenced throughout the document.

The document has been prepared in five main parts

Part 1 Background	**This part provides the foundation for all standards and recommended practices detailed in the remainder of the document.**
Part 2 Standards	**This part describes the decontamination standards that reflect the values and priorities of the National Hospitals Office. The standards will be used to direct and evaluate decontamination services in acute hospitals.**
Part 3 **Recommended Practices**	**This part identifies the recommended practices that are intended to define correct decontamination practice and to promote patient safety.**
Part 4 **Additional Resources**	**This part includes a glossary, list of abbreviations, reference list and contact details.**
Part 5 Appendices	**This part includes appendices providing information on the membership of the Steering Committee, standards sub-group and consultees.**

There is an overall table of contents following the foreword. Each part of the document also has its own contents page, which provides a detailed breakdown of all the sections, subsections, tables and figures in that part of the document.

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Part 1

Background

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1 Decontamination Services in Acute Hospitals

1.1 Introduction

Improving the quality of care and providing a safe working environment are fundamental activities for the National Hospitals Office. Prevention and control of healthcare associated infection (HCAI) is central to these activities. Hospital and clinical managers must ensure that they have effective systems in place to minimize the risks of infection to patients and staff.

1.2 Steering Committee

Following concern about the risk of healthcare associated infection and review of a report on reprocessing of medical devices in hospital sterile services departments by the Irish Association of Sterile Services Managers in 2003, Dr Mary Hynes, Assistant Director of Quality, Risk and Customer Care in the National Hospitals Office (NHO) set up a Steering Committee to provide guidance on decontamination services in publicly funded acute care facilities. The development of standards and guidelines on the decontamination process was an important part of the Steering Committees remit.

1.3 Decontamination Process

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

1.4 Effectiveness of Decontamination

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

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

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

1.5 Decontamination Standards and Recommended Practices

This document sets out proposals for **decontamination standards** and **recommended practices** for RIMD in acute care hospitals in the NHO and will be distributed during a consultation process with key stakeholders. The views emerging from this consultation process will help to revise and develop an agreed set of decontamination standards and recommended practices. The standards and recommended practices will then be widely distributed and discussed with regard to their implementation during a number of workshops in the hospital networks.

1.6 Assessing Performance

The standards will be used by the National Hospitals Office to assess performance in decontamination services in publicly funded acute care facilities throughout the Health Service Executive (HSE).

2 Terms of Reference

2.1 Introduction

The terms of reference of the Standards sub-group were as follows:

- Compile a list of relevant European Standards for Decontamination (see Part 4).
- Formulate recommended practices for decontamination of RIMD based on these standards.
- Develop organisational management standards for decontamination of RIMD.
- Make recommendations on an audit and monitoring programme for decontamination of RIMD.
- Develop performance indicators capable of showing improvements in the organisation and management of decontamination services in the National Hospitals Office.

2.2 Addressing Remit

In addressing its remit, the Standards Sub-Group recognised that a considerable amount of work had already been undertaken to develop decontamination standards by the National Health Services in Scotland, Wales and England, the AORN and by the Institute of Decontamination Sciences in the United Kingdom. This work was used as a basis for the development of standards in the HSE.

The Standards Sub-Group decided to address its remit by:

- Developing detailed proposals for national decontamination standards and recommended practices by **Friday 19th January 2007**.
- Distributing the draft standards and recommended practices on Monday 22nd January 2007 and inviting comments from key stakeholders by **Friday 6th April 2007**.
- Engaging in a detailed consultation process and inviting comments from interested parties from the **Monday 22nd January 2007 to Friday 6th April 2007**.
- Taking account of the views emerging from the consultation process and the decontamination services review to develop agreed national standards by **Monday 7th May 2007**.

3 Development of Decontamination Standards and Recommended Practices

3.1 Introduction

The Standards Sub-Group decided to develop the standards and recommended practices as follows:

- An extensive literature search.
- Consideration of the opinion of experts knowledgeable in the subject.
- Consider the available scientific evidence and current best practice, both in Ireland and internationally, that may impact on decontamination of RIMD.
- Merge findings into a draft document for distribution for consultation to key stakeholders.

3.2 Definitions

The standards and recommended practices are defined as follows:

1. **Standards** = Organisational structures and processes needed to identify, assess and manage specified risks in relation to decontamination services.

2. **Recommended Practices** = recommendations concerning the technical aspects of the decontamination of reusable invasive medical devices.

The Standards reflect the values and priorities of the National Hospitals Office and will be used to direct and evaluate decontamination services in acute hospitals .The Standards Sub-Group agreed to produce standards that are realistically achievable.

The Recommended Practices are intended to define correct decontamination practice and to promote patient safety. They are also intended to serve as the basis for policy and procedure development in decontamination settings in acute hospitals.

4 Format of Standards/Recommended Practices and Definition of Terminology

4.1 Definition—Standards

- 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.

4.2 Definition—Recommended Practices

- 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 fleshed out in the section headed **procedure**, where it states how each recommended practice can be achieved.

4.3 Aims

The Working Group aim to set standards that are achievable and appropriate. This is reflected in the criteria.

Each hospital should use the recommended practices as a basis to establish and/or update their own policies and procedures.

4.4 Criteria

The criteria are numbered, for the sole reason of making the document easier to work with, particularly for the assessment process. The numbering of the criteria is not a reflection of priority.

5 Consultation

5.1 Feedback

The Standards Sub-Group presents the following draft standards for your comments by **Friday the 6th April 2007.**

Your comments and requests for additional copies should be sent to:

Winifred Ryan,

Quality, Risk and Customer Care,

National Hospitals Office,

Health Service Executive,

Mid-Western Regional Hospital Nenagh,

Nenagh,

Co. Tipperary.

Or emailed to Winifred_ryan@hse.ie

5.2 Workshops

The Health Service Executive intends to organise a series of half-day workshops between the **5th and the 15th of February 2007** within the hospital networks with groups of key stakeholders. The format of the workshops will be as follows:

- Setting the context.
- Discussion of reactions to the draft standards and recommended practices.
- Outline the practical steps that need to be taken to ensure that a ***comprehensive consultation process*** is undertaken in each hospital.

5.3 Consultees

A list of consultees is set out in **Appendix 3**.

6 Medical Devices Directive & CE Marking

6.1 Medical Device

The Medical Devices Directive applies to manufacturers placing medical devices on the market. In doing so, it specifics 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.

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices defines a 'medical device' as: 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 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 or metabolic means, but which may be assisted in its function by such means.

6.2 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).

6.3 Essential Requirements of the Medical Devices Directive (93/42/EEC)

The essential requirements of this directive include:

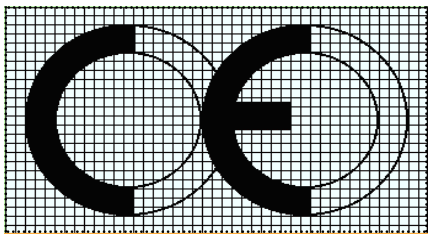
- that devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Annex 1, paragraph 8.1).

- All that devices be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (Annex 1, paragraph 7.2).
- All devices placed on the market must meet the essential requirements of the medical devices legislation and in doing so must not compromise the clinical condition or safety of patients, or the safety and health or users or where applicable other persons. The devices must also perform as intended by the manufacturer.

6.4 CE Marking

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

Figure 6-1 CE Symbol



6.5 CE Directive

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

The CE Directive (Council 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 device, to the packaging or to the instruction leaflet accompanying the device 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.

6.6 CE Symbol

The CE marking symbolises the following:

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

6.7 Article 12 of the CE Directive (Council Directive 93/42/EEC)

Article 12 makes special provision for procedure packs. Sets of theatre instruments would be included in this category and are not required to carry the CE mark.

6.8 Notified Body

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

7 Spaulding Classification

7.1 Introduction

Appropriate Level of Decontamination

Failure to adequately decontaminate RIMD, will increase the risk of transmission of cross-infection between patients. Effective decontamination of patients is also necessary to maintain the functionality of RIMD, maintain integrity of biopsy specimens and protect the patient from the adverse consequences of sterile contaminants. The choice of appropriate decontamination process for devices used in a range of clinical procedures is typically based on the classification system first proposed by Dr E H Spaulding. The appropriate level of decontamination will depend on the procedure for which the device is used (see Table 7-1).

The Spaulding Classification is a strategy developed by Dr. Earle Spaulding (1968) for reprocessing RIMD. The system classifies devices as:

1. Critical
2. Semicritical
3. Noncritical

This is based on the risk from contamination of a device to a patient. Three different levels of disinfection are applied based on this risk scheme. (See Table 7-1 below)

Table 7-1: Classification of infection risk associated with the decontamination of RIMD

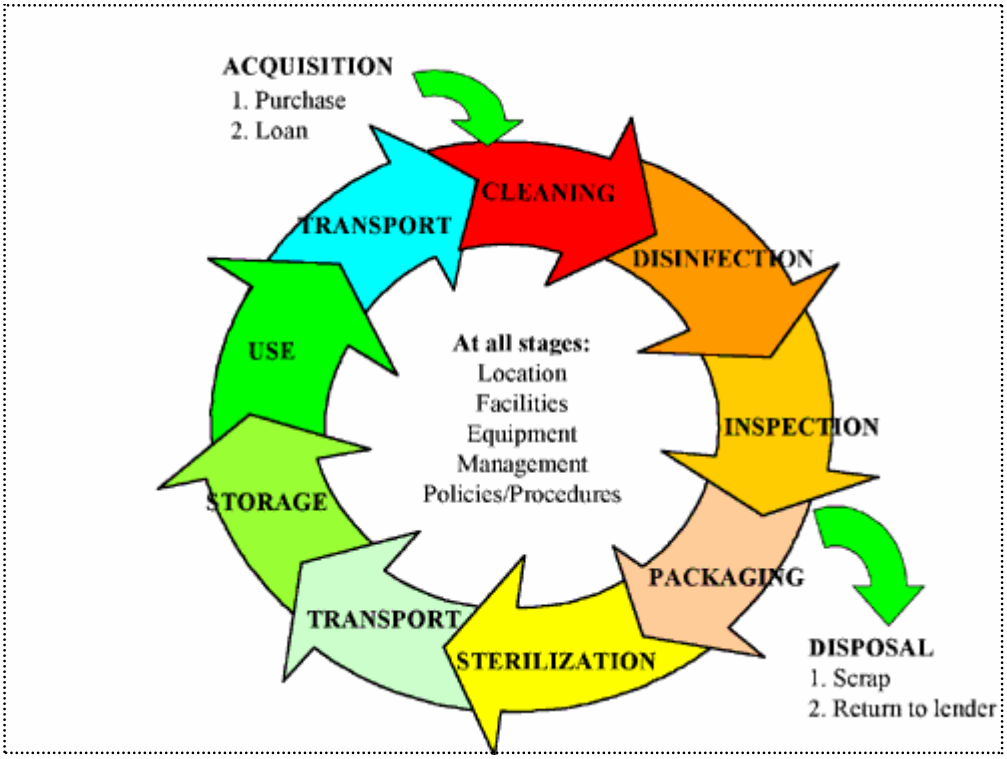
Risk	Application	Recommendation
Critical	Items in close contact with a break in the skin or mucous membrane are introduced into a sterile body area, e.g. theatre surgical instrument set	Requires Sterilisation
Semi-critical	Items in close contact with intact skin, mucous membranes or body fluids, particularly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

8 Life Cycle for Centralised Sterile Services Unit

8.1 Introduction

The decontamination life cycle highlights the extent to which decontamination effects the whole organisation and not just areas processing RIMD. Figure 8-1 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 will result in inadequate decontamination.

Figure 8.1 Decontamination Life Cycle



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

Part 2

Standards

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9 Suitability of Decontamination Facilities

9.1 Standard Statement

Decontamination facilities should be properly designed and maintained, controlled to provide effective segregation of clean and dirty activities. For guidance see PD CEN ISO/TR 14969:2005 and Health Building Note 13 (HBN 13, 2004).

9.2 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.

9.3 Criteria

1. Any area in which the decontamination process takes place meets the principles contained in the document CEN ISO/TR 14969:2005, i.e. it should:

- Not be used for any other purpose and not be used as a thoroughfare.
- Not be in direct connection with any patient treatment area.
- Be mechanically ventilated.
- Be a clean room to EN ISO 14644-1:1999 (Class 8 or greater).
- Have temperatures controlled between 18-22°C and relative humidity controlled between 35-60%.
- Have walls and other surfaces finished flush, which are smooth, non-linting, water resistant and able to withstand frequent cleaning.
- Have floors with a washable non-slip finish.
- Have adequate lighting available to permit good working practices and visual examination of RIMD.
- Have access to the inspection, assembly and packing room only through a gowning facility with interlocking doors/alarmed doors (where appropriate). Hand hygiene facilities must be available in this area.
- Have access to the wash room/clean room through a gowning facility with interlocking doors/(or where appropriate alarmed). Hand hygiene facilities must be available in this area.

4. To achieve the required standard there must be segregation of dirty, clean and sterile supplies. HBN 13 refers to the design of new Sterile Service Department facilities. This document can be referenced for the implementation of an appropriate Sterile Services Department.

10 Procurement of RIMD

10.1 Standard Statement

Decontamination issues are considered prior to the acquisition of RIMD.

10.2 Rationale

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

10.3 Criteria

1. Hospitals have a specialist group in place to consider the procurement of re-usable invasive medical devices.

2. The specialist group oversees the purchasing issues relevant to decontamination including:

    - Ensuring that the medical device manufacturers' validated decontamination instructions are compatible with the decontamination equipment available and policies in place.
    - Technical specifications and service requirements of RIMD.

    The specialist group may also oversee a wider range of purchasing issues including:

    - Comparing costs and features of alternative devices.
    - Standardising on a single model where possible.
    - Training and maintenance implications.
    - Organisational/departmental policy.
    - Safety and Hazard notices issued by the IMB and HSA (ref. IMB safety notice).

3. Key representatives on the specialist group must include:
    - Decontamination Coordinator.
    - Decontamination Unit Manager, e.g. SSD Manager/Endoscopy Manager.
    - Clinical Unit Manager, e.g. Theatre Manager.
    - Infection Prevention and Control personnel.

    The following may also be included where relevant:

    - Technical Services.
    - Procurement.
    - Bio-engineering.
    - Materials Management.
    - Finance Manager/Budget Holder/Business Manager.
    - Other relevant experts (Authorised person/Sterivigilance Nurse/Microbiologist).
4. There should be minimal reliance on a purchase questionnaire.
5. All medical devices should be purchased from CE registered suppliers on the HSE approved suppliers list.
6. Each hospital must comply with the IMB recommendations on the procurement of RIMD for hospitals.
7. Each hospital must have a formal procedure in place that ensures that decontamination issues are fully considered prior to a purchase of any device of a type not previously purchased.

11 Decontamination of Reusable Invasive Medical Devices

11.1 Standard Statement

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

11.2 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.

11.3 Criteria

1. Policies and procedures should be available as a point of reference, and should be available for all personnel involved in any aspect of decontamination.
2. RIMD should be decontaminated in a controlled environment.
3. All stages of the decontamination process should be clearly defined, documented controlled and recorded.
4. Processing data should be retained for a minimum of 8 years.
5. There should be a regular review of all procedures and any necessary changes implemented by a documented change in procedures.
6. RIMD must be cleaned and disinfected/sterilised in accordance with the manufacturers' instructions.
7. There should be a full review to identify any RIMD that cannot easily be cleaned and disinfected/sterilised. These should be replaced in accordance with a planned replacement programme.
8. Single use devices must not be reprocessed or reused. Any device with the following symbol is deemed single use only.

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

Figure 11-1 Do not reprocess symbol

12 Decontamination Equipment

12.1 Standard Statement

All decontamination equipment that does not meet the requirements of current standards (see sections 36 and 42 of this document) is upgraded or replaced in accordance with a planned replacement programme. Decontamination equipment must be validated and periodically tested to current standards.

12.2 Rationale

Decontamination equipment that does not meet current standards cannot be relied upon to meet current requirements for decontamination or provide the required level of assurance. Validation and periodic testing are required to demonstrate compliance of installed equipment with current standards.

12.3 Criteria

1. Hospitals should have a specialist group in place to consider the hospital decontamination equipment as follows:

    - Ability to meet current standards (see sections 36 and 42 of this document).
    - Age and condition of equipment.
    - Ability to interface with other equipment in the decontamination facility.
    - Ability to meet the requirements of current test methods.
    - Ability to be validated and perform to intended purpose.
    - Availability of replacement parts.
    - Energy conservation.

2. Key representatives on the specialist group must include:

   - Decontamination Coordinator.
   - Decontamination Unit Manager, e.g. SSD Manager/Endoscopy Manager.
   - Technical Services and Bio-engineering Manager.
   - Infection Prevention and Control personnel.

   The following may also be included where relevant:

   - Clinical Unit Manager, e.g. Theatre Manager.
   - Materials Management/Procurement.
   - Finance Manager/Budget Holder/Business Manager.
   - Other relevant experts (Authorised person/Sterivigilance Nurse/Microbiologist).

3. The group should identify all decontamination equipment which needs to be replaced and formulate a plan to replace or upgrade this equipment. This plan should be submitted to the hospital management team and revised annually by the decontamination lead.

4. There should be a specification prepared to tender for supply of the equipment. The specification should:

   - Identify the nature of the loads to be processed and the throughput required.
   - Identify any constraints on access, plant room space or services (e.g. steam, electricity, water)
   - Require compliance with EN standards
   - Identify specific technical requirements.
   - Identify responsibility for validation (including IQ, OQ and PQ).
   - Specify any accessories required, e.g. loading equipment.

The tender document should also require potential suppliers to identify their service response time, spares availability and periodic testing capability.

5. All decontamination equipment should be purchased from CE registered suppliers on the HSE approved suppliers list.

6. Each hospital must comply with the IMB recommendations on the procurement and commissioning of decontamination equipment for hospitals.

7. Each hospital must have a formal procedure in place that ensures that decontamination issues are fully considered prior to a purchase of any equipment of a type not previously purchased.

8. Each hospital must have a formal procedure to ensure that all decontamination equipment is validated and periodically tested by appropriately qualified personnel.

9. Each hospital must ensure that validation and periodic testing data are adequately audited at least annually by a qualified person registered with the HSE.

13 Organisational Structure and Accountability

13.1 Standard Statement

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

13.2 Rationale

The CEO/hospital manager through the hospital management team is responsible for ensuring that there are effective arrangements for the decontamination of RIMD. Arrangements should include a senior member of staff with defined responsibility (decontamination coordinator) that is provided with the necessary resources and authority for the task. It is expected that this person will report directly to the CEO/ hospital manager.

13.3 Criteria

1. The Assistant National Director of Quality, Risk and Customer Care in the NHO is responsible for:

   - Ensuring that there are effective arrangements for the decontamination of RIMD within the NHO.

   - Receiving and ensuring the circulation of relevant advice and working with the Health Information Quality Authority (HIQA) and other agencies on improving practice.

2. Clear lines of accountability, for all parts of the decontamination cycle should be established. This should define the relationships between Clinical Users, Decontamination Operational Management, Materials Management, Transport Services, Technical Services, Health & Safety, Risk Management and Infection Prevention and Control Committees.

3. The scope of responsibility should also consider the competence of contractors where the organisation buys in services and professional liability where the organisation sells services to other organisations.

4. Decontamination of RIMD is a standard agenda item on the Infection Prevention and Control Committee and Risk Management Committee meetings.

5. A bi-annual report on the efficacy and efficiency of the decontamination process is submitted to the Clinical Governance Committee (or equivalent) for review. This committee, which includes in its membership the CEO/Hospital Manager or CEO/ Manager nominee, should present the report to the hospital management team.

6. The hospital management team will submit an annual assurance statement on audit findings for consideration and approval by the Assistant Director of Quality and Risk in the NHO.

7. External reviews findings will be submitted to the Assistant Director of Quality and Risk in the NHO for consideration and approval.
8. Each hospital should identify to HSE a Decontamination Co-ordinator. The duties of the co-ordinator should encompass all aspects of the decontamination process and not be confined to any one aspect or decontamination function but should encompass all decontamination processes wherever they occur within the hospital.
9. The Decontamination Coordinator should have sound technical knowledge of a least one of the following areas:
   - Clinical use of RIMD.
   - Cleaning of RIMD.
   - Chemical Disinfection of RIMD.
   - Sterilisation of RIMD.
   - Decontamination equipment.
   - Infection Control.
10. The Decontamination Co-ordinator will need good organisational and personal communication skills and will need to have the ability to assimilate and evaluate new technical information. It is envisaged that the Decontamination Coordinator will be required to complete a course of training developed specifically for this role.
11. The Decontamination Co-ordinator must be given the resources and authority to:
    - Identify all the places at which cleaning, disinfection sterilisation of RIMD is carried out.
    - To identify any processes which may be considered unsatisfactory.
    - To ensure that measures to rapidly improve or curtail any processes they deem unsafe are instigated
12. In addition, the Decontamination Co-ordinator should:
    - Develop policies and/or strategies for the decontamination of RIMD for approval by the appropriate committee (e.g. infection control committee).
    - Be a member of the Infection Control Committee and the Risk Management Committee.
    - Attend appropriate meetings/conferences local and national relevant to the Decontamination of RIMD, which will increase knowledge and improve ability to undertake their role.
    - Ensure that all information, received from the NHO/relevant agencies relating to Decontamination of RIMD is disseminated within the hospital.

- Ensure that, through the line managers, a training needs analysis is undertaken and a prioritised programme developed identifying training needs for appropriate personnel.
- Work with Decontamination Unit Managers and Clinical Unit Managers to develop and improve the decontamination systems.
- Be responsible for an annual internal audit of all decontamination facilities within the hospital.
- Carry out an annual review of decontamination of RIMD within the hospital, based on—the audit results, complaints from clinical users, recorded product defects and decontamination process records.
- Be responsible for informing the hospital management team of the outcome of the annual review and the standards to which decontamination is being carried out.
- Ensure compliance via departmental heads with best practice standards.
- Ensure that all proposed hospital service developments consider the issue of decontamination of RIMD in accordance with relevant guidelines.
- Liaise with appropriate personnel when purchasing decontamination equipment to ensure compliance with Standard 12 of this document.

14 Management and Key personnel

14.1 Standard Statement

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

14.2 Rationale

To ensure that all personnel within the services are appropriately trained and competent to carry out decontamination services

14.3 Criteria

Key persons and responsibilities are as follows:

1. The CEO/Hospital Manager is ultimately accountable for the operation of the premises and the decontamination process.
2. The Decontamination Coordinator (see 13.3.9) is defined as the person designated by hospital management to be responsible for the coordination of decontamination services in the hospital.
3. The Decontamination Unit Manager is defined as the person designated by hospital management to be responsible for the operation of the decontamination unit.
4. The Maintenance Personnel (in-house or sub-contracted) should have documentary evidence to demonstrate competence in the maintenance the types of decontamination equipment with which they will be dealing.
5. The Test Personnel (in-house or sub-contracted) should have documentary evidence to demonstrate competence in the periodic testing of the types of decontamination equipment with which they will be dealing.
6. The Microbiologist is defined as the person designated by management to be responsible for advising on microbiological aspects of decontamination.
7. The Infection Control Nurse is the person designated by management to be responsible for advising on all aspects of infection prevention and control.
8. The Operative is defined as the person designated by management to be responsible for carrying out all aspects of the decontamination process.
9. The Biomedical Engineer is defined as the person designated by management to be responsible for the testing and maintenance of electrical medical equipment.
10. The Qualified Person is a person registered as an Authorised Person (Sterilisers) with the Institute of Healthcare Engineering and Estates management and registered with the HSE as competent to discharge the duties of a QP in Ireland.

15 Education and Training

15.1 Standard Statement

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

15.2 Rationale

All clinical and relevant support staff should have a clear understanding of the principles of the decontamination process and the part it plays in the control of infection.

15.3 Criteria

1. It is assumed that general induction training should include:

i. Departmental policies, procedures and standards, including:

- Infection Control.
- Health and Safety at Work Act.
- Risk Management.
- Occupational Health.

ii. Quality issues in the department.

iii. Safe operation of equipment.

iv. Communications within the HSE/NHO.

v. Fire hazards and regulations.

vi. Manual handling.

vii. First Aid.

2. In particular, the following issues should be addressed in the training of clinical staff

i. Give an appreciation of what goes on in the decontamination unit

ii. Explain why processes and procedures take time and give an understanding of the issues faced by decontamination staff

iii. Explain the governing polices that are in place to ensure a quality system

iv. Standard Precautions for infection control.

v. Transportation of contaminated equipment/RIMD.

vi. Principles of Cleaning, Disinfection, Inspection, Assembly, Packaging, Sterilisation and Despatch.

vii. Transportation of sterile RIMD.

viii. Storage of sterile RIMD.

ix. Manufacturers instructions for use of RIMD.

x. Identification of RIMD anomalies.

xi. Procurement (service records)

xii. Risk Management (how to deal with adverse events)

xiii. Repair/loan equipment – what to do before and after

xiv. Labelling and single use and disposal

xv. Roles and responsibilities

xvi. Contaminated equipment (CJD) what to do, quarantine etc.

xvii. Audit

xvii. Maintaining environmental cleanliness

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

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

i. Standard Precautions for infection control.

ii. Transportation of contaminated equipment/RIMD.

iii. Cleaning.

iv. Disinfection.

v. Inspection.

vi. Assembly.

vii. Packaging.

viii. Sterilisation.

ix. Storage.

x. Despatch.

xi. Transportation of sterile equipment/RIMD.

xii. Manufacturers instructions for decontamination of RIMD.

xiii. Identification of RIMD anomalies.

xiv. Clean room technology

xv. Procurement (service records)

xvi. Testing of equipment

xvii. Maintenance & Validation (processes)

xviii. PPE specific to decontamination of RIMD

xix. Risk Management (how to deal with adverse events)

xx. Standards and legislation

xxi. The build environment (HBN13)

xxii. Repair/loan equipment – what to do before and after

xxiii. Labelling and single use and disposal

xxiv. Roles and responsibilities

xxv. Contaminated equipment (CJD) what to do, quarantine etc.

xxvi. Audit

xxvii. Maintaining environmental cleanliness

4. ***Individual competencies must be assessed and records kept.***
5. ***Departmental records must be kept of attendance of all staff who have received the necessary competencies.***

6. Qualified Person (Decontamination).

A Qualified Person (Decontamination) shall:

- Have undertaken the advanced course in sterilization technology and passed the course examination.
- Be registered with the Institute of Engineering and Estates Management (IHEEM), as an Authorised Person (Sterilisers).
- Have met the criteria established by the HSE for undertaking work in Irish hospitals (including a knowledge of the administrative system, legislative and best practice guidance applicable in Ireland).
- Have been registered by the HSE

16 Risk Management

16.1 Standard Statement

A risk management process is in place to manage the risks associated with the decontamination of RIMD.

16.2 Rationale

Decontamination of RIMD involves processes employing chemicals and process conditions that are potentially hazardous to staff. Failure of decontamination processes puts patients at risk. It is essential that all decontamination processes are carried out in a manner that minimises the risk to staff and patients.

16.3 Criteria

1. The NHO has a risk management system in place identify risks associated with the decontamination of RIMD through the following:

   - Risk Assessment (Clinical & H&S).
   - There is prospective review of each process and the equipment and chemicals used to identify, analyse and prioritise the hazards for likelihood of occurrence and impact.
   - To identify the necessary actions to be undertaken to eliminate or minimise the potential to cause harm.
   - The risk assessment to be reviewed when:

   i. There is a change in the task or activity

   ii. The result of health surveillance

   iii. A confirmed case of occupational disease/illness

   iv. Results of a monitoring exercise

   v. Occurrence of an adverse event or near miss

   vi. New equipment or technology is introduced

- Incident Reporting:
    i. To the Hospital Management Team.
    ii. Reporting clinical adverse incidents to the Clinical Indemnity Scheme (CIS).
    iii. Reporting dangerous occurrences to the Health & Safety Authority (HSA).
    iv. Reporting adverse incidents involving medical device defects to the Irish Medicines Board (IMB).
    v. Reporting incidents to the Health & Safety Authority (HSA) in respect of employees.
- Incident Review.
- Medical Device Safety Notices from the Irish Medicines Board (IMB).
- Audit Reports.
- Internal & External Inspections.

2. The following risk management elements should be in place:
    - All identified risks should be documented as part of a risk register and systematically assessed and prioritised.
    - Risk treatment plans should be developed and implemented in order of priority and alongside other risk treatments which are necessary to deal with the wider risks faced by the organisation.
    - Risks and the effectiveness of implemented risk treatments should be monitored and reviewed frequently.
    - Senior hospital management should be informed of any significant risks and associated risk management plans.
    - All relevant staff, including those on a fixed contract and other relevant stakeholders should receive information on systems in place to minimise risk of the decontamination process.
    - MSDS should be made available to all staff who are using potentially hazardous chemicals.
    - Staff training must be undertaken.

17 Quality Management System

17.1 Standard Statement

The hospital should identify and manage all of the processes necessary for effective decontamination of RIMD in accordance with a formal quality system.

17.2 Rationale

Formal documented control of decontamination within a quality management system is necessary to provide consistent decontamination of RIMD and a system that can be audited to demonstrate compliance with current legislation and guidance.

17.3 Criteria

1. Current copies of relevant legislation, standards and best practice guidance must be accessible. Documents retained should include European and National legislation, recognised and approved standards for materials, practices and equipment, Technical Memoranda, Device Bulletins, Safety Notices, Hazards, Training Manuals, professional publications and instruction manuals for processing equipment.

2. The organisation should determine:

   - The sequence and interaction of decontamination processes.
   - The criteria and methods needed to ensure that the operation and control of these processes is effective.
   - The resources necessary to support these processes.

3. The organisation should implement the actions necessary to maintain the effectiveness of decontamination processes.

4. All policies, procedures and records associated with the decontamination process must be controlled documents to ensure that current versions are available to all who need to use them and to ensure that the process history of any RIMD can be established.

5. All electronic data should be stored securely and backed up and audited regularly.

4. Access to data/records should be restricted to authorised named persons and specified information should be maintained in line with the Data Protection Act.

8. All documents should be controlled showing the date of issue and revision number; master copies should be kept in a secure location.

9. Obsolete documents should be removed from all points of use.

10. An annual review of all policies, procedures and documents should be undertaken to check their relevance and issue status.

11. All records associated with the decontamination life cycle must be retained for eight years.

11. All surgical instrument sets are tracked through the decontamination process such that the immediate decontamination history of all RIMD used on any individual patients can be traced.

18 Audit and Monitoring

18.1 Standard Statement

Audits are carried out to ensure that the procedures for decontamination of RIMD conforms to the required standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

18.2 Rationale

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

18.3 Criteria

1. Internal Audit of decontamination of RIMD includes:
    i. Accountability arrangements.
    ii. Staff knowledge, expertise and resources.
    iii. Processes, including risk management arrangements.
    iv. Policies, procedures and guidelines.
2. Each decontamination unit manager is responsible for preparing a written agreed programme which ensures that all aspects of the decontamination processes and their management within the unit are audited at least once a year.
3. Each decontamination unit manager is responsible for ensuring that the audit is conducted in accordance with this programme.
4. Each decontamination unit manager is responsible for ensuring that remedial actions are carried out for any deficiencies found and for verifying the efficacy of remedial actions undertaken.
5. The decontamination coordinator is responsible for ensuring that the audit activity, under the responsibility of the decontamination unit manager has been completed.
6. Audit results are fed back to the decontamination coordinator, staff, relevant members of the hospital management team and are included in the risk management/clinical governance annual report.
7. Audit results are used to help to inform and improve decontamination practices.
8. The audits should be carried out by appropriately trained auditors.

19 Key Performance Indicators

19.1 Standard Statement

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

19.2 Rationale

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

19.3 Criteria

Environment

1. All decontamination of RIMD takes place in a controlled environment.
2. During the decontamination process, sterile devices, clean non-sterile devices and used devices being cleaned are physically segregated from one another.
3. The environment in which clean non-sterile RIMD are inspected, assembled and packed is controlled and monitored to ISO 14644 , Class 8.
4. The environment in which clean non-sterile RIMD are inspected, assembled and packed is micro-biologically monitored to demonstrate consistently low levels of microbial contamination.
5. The environment in which decontamination of RIMD takes place is cleaned in accordance with procedures and schedules agreed by the microbiologist.
6. Dedicated cleaning provision (both equipment and storage) for IAP and wash room.
7. Access to controlled areas is through dedicated gowning rooms provided with hand hygiene facilities.
8. Safe storage facilities are provided for process chemicals used in decontamination.
9. Dedicated storage facilities for raw materials, e.g. packaging and dedicated storage facilities for sterile products prior to despatch.
10. The IAP has workstations with smooth, cleanable surfaces and lighting, including task lighting suitable for detailed inspection of cleaned RIMD, e.g. 400 lux at the work surface.

Equipment

1. Manual washing

- Used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector.
- Separate sinks for washing and rinsing are provided.
- Means are provided to control the concentration of detergent.
- A pass-through drying cabinet is provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector.
- The detergent used is one specified by the manufacturer for manual cleaning of RIMD.

2. Ultrasonic Cleaning

- 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.
- The detergent used is one specified by the manufacturer for ultrasonic cleaning of RIMD.
- Means are provided to control the concentration of detergent.
- The ultrasonic cleaner has been validated and is subject to periodic testing and planned preventative maintenance.

3. Washer-Disinfectors

- The specification of the washer-disinfector complies with requirements of EN ISO 15883, parts 1 &2.
- The washer-disinfector is a pass-through design located between the wash room and the IAP room.
- Each washer-disinfector is fitted with a process monitoring system to type C of EN ISO 15883, part 1.
- When lumened devices are being reprocessed, the washer-disinfector is provided with load carriers that permit the irrigation of lumen of devices.
- The washer-disinfector has been validated and is subject to periodic testing in accordance with EN ISO 15883, parts 1, 2 & 5. The Washer –Disinfector is subject to a planned preventative maintenance.

4. Steam Sterilisation

- The specification of the steam steriliser complies with requirements of EN 285 and the steriliser is fitted with an air-detector.
- The steam steriliser is a pass-through design located between the IAP room and the sterile store/cooling area.
- Each steam steriliser is fitted with a process monitoring system independent of the automatic controller.
- The sterilisation hold period shall be at 134-137C for not less than 3 minutes.
- The steam steriliser has been validated and is subject to periodic testing in accordance with EN 285 and EN ISO 17665, part 1 and planned preventative maintenance.

5. Low temperature sterilisers

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

6. Drying cabinet

- A pass-through drying cabinet between the wash-room and the IAP is provided. The doors of the drying cabinet are interlocked to prevent direct connection between the wash room and the IAP.
- The drying cabinet is validated and periodically tested and is subject to planned preventative maintenance.
- The drying cabinet is fitted with a temperature indicator and/or recorder independent of the controller.

7. Heat sealer

- Where heat seal packaging is to be used, a rotary heat sealer is provided.
- The drying cabinet is validated and periodically tested and is subject to planned preventative maintenance.

Utilities

1. Steam sterilisers are provided with clean steam, complying with IS EN 285.
2. Washer-disinfectors are provided with soft water, for all process stages and purified water for the final rinse stage.
3. The steam supply for sterilisation is tested at least annually for dryness value, super-heat and non-condensable gas concentration.
4. Compressed air used for testing power tools is medical grade and oil free.

Management and Personnel

1. The hospital CEO/Manager has put in place arrangements to ensure effective decontamination of RIMD.
2. A decontamination coordinator has been appointed, has formally defined responsibilities in accordance with these standards and has been provided with the necessary resource to discharge these responsibilities.
3. An annual review of decontamination is carried out and reported to the hospital manager/CEO.
4. Each decontamination unit has a person appointed with responsibility for operational management of the unit, which may be in addition to other duties.
5. Maintenance and test personnel are available and suitably qualified for the decontamination equipment in use.
6. A microbiologist is available to advise on microbiological aspects of decontamination.
7. The decontamination unit manager has designated operatives to be responsible for each aspect of the decontamination process and has ensured that these personnel have been trained to the necessary standard of competence.
8. The management have identified the resource necessary (personnel, equipment, environment, materials) and these have been provided.
9. All personnel are trained in the basic principles of hygiene and decontamination of RIMD.

Processes

1. The hospital has in place a formal system to ensure that the requirements for decontamination are fully considered prior to the acquisition of RIMD.
2. The hospital has reviewed existing stocks of RIMD to ensure they are compatible with existing decontamination processes.
3. All decontamination processes are controlled, monitored and recorded.
4. All processes are carried out in accordance with documented procedures.

5. All RIMD are visually inspected for cleanliness prior to packing.

6. All RIMD are inspected and/or tested for functionality prior to packing.

7. There is a formal release procedure for sterile product to ensure that only product that has been subjected to a satisfactory sterilisation cycle is released for use.

8. All product released from the decontamination unit is labelled with a clear indication of the pack contents, the expiry date and a unique number which can be used to trace the decontamination processes to which the device was subjected.

Service Quality

1. The decontamination unit and clinical units which it supplies have a service level agreement.

2. The decontamination unit has in place a formal system for recording and analysing customer complaints.

3. The decontamination unit has in place a programme to reduce customer complaints.

4. The decontamination unit is managed in accordance with a formal quality management system.

20 Procedures relating to Transmissible Spongiform Encephalopathies (TSEs)

20.1 Standard Statement

The hospital has processes in place to minimize the exposure of patients and employees to TSE agents.

20.2 Rationale

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

20.3 Criteria

1. Instruments and equipment used on patients at increased risk of developing a TSE should be single-use where possible.

2. The HSE has written policies and procedures for the identification of patients at increased risk of developing a TSE.

Note: The HSE has written policies and procedures for the management of RMID used on patients at a risk of developing a TSE. The policies and procedures contain guidelines on the handling of RIMD that are not designated for single use.

Part 3

Recommended Practices

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49.2 Scope

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Tables

Figures

21 Design of decontamination facilities

21.1 Introduction

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

21.2 Scope

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

21.3 Contents

Section One: Unit Design

Section Two: Clean and Dirty Areas

Section Three: Lighting and Electricity

Section Four: Ventilation

Section Five: Temperature

Section Six: Walls, floors and ceilings

Section Seven: Workstations, Furniture, Shelving and Equipment

Section Eight: Restricted Entry

Section Nine: Storage Facilities

21.4 Procedure

Section One: Unit Design

- The reprocessing unit should conform to the principles of good manufacturing practice and the environmental conditions recommended in HBN 13. Particle count and positive air pressure requirements should conform to ISO Class 9 Clean Room standards described in BS 5295 – Environmental Cleanliness in Enclosed Spaces and BS EN ISO 14644:1999. (See idealised schematic in Figure 21-1).
- The unit should be designed so that it is physically separated with restricted access, independent and self-contained.

Section Two: Clean and Dirty Areas

- 'Dirty' and 'Clean' activities should be segregated.
- Workflow should be from 'dirty' to 'clean' areas, taking care to avoid contaminated equipment re-entering clean work areas.
- There should be separate cleaner sluice facilities in both the 'dirty' and 'clean' areas.
- Ensure that the area is maintained in a good condition and cleaned regularly.

Section Three: Lighting and Electricity

- Ensure that lighting is adequate to allow proper inspection of devices and equipment without glare (300-600 lux is recommended); light fittings should be designed to be flush, prevent dust entrapment and easy to clean.
- Ensure there is sufficient electricity supply, computer terminal points and work stations within the unit to allow optimum use of Information Technology (IT), Management Information Systems (MIS) and on-line training.

Section Four: Ventilation

- The unit should be mechanically ventilated to ensure a pressure differential between areas.
- The ventilation system should be appropriate to provide a comfortable working environment.

Section Five: Temperature

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

Section Six: Walls, floors and ceilings

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

Section Seven: Workstations, Furniture, Shelving and Equipment

- The area must be free from 'opening' windows.
- The workstations must be smooth, have impact resistant surfaces and facilitates environmental cleaning.
- The furniture must be manufactured from non-shedding materials.
- The workstations must be equipped for the preparation of single or composite packs ensuring adequate space for equipment and staff movement.
- The shelving and equipment used for holding raw materials and finished products must be designed to allow adequate protection and accommodation for the goods to prevent contamination or deterioration.

Section Eight: Restricted Entry

- Entry into the decontamination room should be restricted to authorised personnel only.

Section Nine: Storage Facilities

- Separate storage facilities should be provided for sterile and non sterile goods.
- Storage facilities should be provided for bulk items, external to the decontamination facility.

Figure 21-1 Reprocessing Unit Design—To be included

22 Procurement of RIMD and ancillary materials

22.1 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 action s are required to familiarise themselves with all relevant regulations. Any procurement undertaken must meet the terms of the HSE procurement policy.

22.2 Scope

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

22.3 Contents

Section One: General Principles

22.4 Procedure

Section One: General Principles

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

- Documented procedures must be established to ensure that purchased RIMD conform to specified purchase requirements.
- Suppliers should be selected based on their ability to supply RIMD in accordance with requirements.
- Ensure value for money when purchasing RIMD.
- Ensure that where parts are single-use or have restricted use that this information is provided prior to purchasing.
- Effective medical equipment management systems, which should include a comprehensive organisation-wide policy for the procurement and commissioning of medical equipment and RIMD.
- A medical device procurement committee should be in place to manage purchases of medical equipment and RIMD. The membership of the committee should be multidisciplinary.
- Ensure that all RIMD that are currently in stock can be decontaminated by the available decontamination processes.

- Ensure that all RIMD that are purchased can be decontaminated by the available decontamination processes or use single use devices.
- Use single-use devices where RIMD are impossible or difficult to clean/sterilize and where it is economically viable to do so.
- Ensure that there are sufficient RIMD to allow the necessary time for reprocessing without adversely affecting throughput.
- Ensure that purchased RIMD meets specified purchase requirements.
- Ensure that all ancillary materials are appropriate for their intended use.
- Ensure that manufacturer's instructions for the reprocessing of RIMD are available and comply with local policies and/or procedures. Note: The procurement group must carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the processing procedure. Hence it is essential to consult the SSD management before making a decision.
- Ensure that goods and services are purchased from the HSEs approved suppliers list.
- Ensure the RIMD is CE marked as this will constitute the manufacturers assurance that a device will be safe and will perform as intended.
- All new RIMD must be cleaned prior to sterilisation as they are manufactured in an uncontrolled environment and oil or grease may also be left on the item by the manufacturer.
- Ensure training is provided on the procurement of all new RIMD.

23 Manufacturers Instructions

23.1 Introduction

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

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

23.2 Scope

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

23.3 Contents

Section One:	Information to be supplied by the manufacturer or processor
Section Two:	The label must bear the following particulars
Section Three:	The instructions for use must contain the following particulars
Section Four:	The instructions for use must contain the following precautions and contraindications
Section Five:	The following information shall be supplied on request

23.4 Procedure

Section One: Information to be supplied by the manufacturer or processor

- If the device is intended by the manufacturer to be reused, information on the appropriate processes to allow reuse, including cleaning, disinfection, packing and, if appropriate, the methods of sterilisation of the device to be resterilized, the number of reuses and any restriction to the reuse.
- If the device is supplied with the intention that it can be sterilized before use, instructions for sterilization methods.
- If the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas.
- Instructions for use must be included in the packaging for every device. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.
- Degree of accuracy claimed for devices with a measuring function.
- 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.
- Where reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate.
- Action to detect any potential risk posed by the devices and detachable components.

Section Two: The label must bear the following particulars

- The name or trade name and address of the manufacturer.
- The details strictly necessary for the user to identify the device and the contents of the packaging.
- Where appropriate, the word 'STERILE'.
- Where appropriate, the batch code, preceded by the word 'LOT', or the serial number.
- Where appropriate, an indication of the date by which the device should be used, in safety, stating the month and the year.
- Where appropriate, an indication that the device is for single use.
- If the device is custom-made, the words 'custom-made device'.

- If the device is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- Any special storage and/or handling conditions.
- Any special operating instructions.
- Any warnings and/or precautions to take.
- Year of manufacture.
- Batch or serial number.
- Where applicable, method of sterilization.
- In the case of a device within the meaning of **Article (4a),** an indication that the device contains a human blood derivative.

Section Three: The instructions for use must contain the following particulars:

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

Section Four: The instructions for use must contain the following precautions and contraindications

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

Section Five: The following information shall be supplied on request

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

24 Management of the decontamination service

24.1 Introduction

The CEO/Hospital Manager is ultimately accountable for the operation of the premises and the decontamination process. Each hospital should identify to HSE a Decontamination Co-ordinator. The duties of the co-ordinator should encompass all aspects of the decontamination process and not be confined to any one aspect or decontamination function but should encompass all decontamination processes wherever they occur within the hospital.

24.2 Scope

The objective of this procedure is to outline the responsibilities of the decontamination coordinator in relation to decontamination of RIMD.

24.3 Contents

Section One: General Principles

24.4 Procedure

Section One: General Principles

- The Decontamination Coordinator should have sound technical knowledge of a least one of the following areas:
    i. Clinical use of RIMD.
    ii. Cleaning of RIMD.
    iii. Chemical Disinfection of RIMD.
    iv. Sterilisation of RIMD.
    v. Decontamination equipment.
    vi. Infection Control.
- The Decontamination Co-ordinator will need good organisational and personal communication skills and will need to have the ability to assimilate and evaluate new technical information. It is envisaged that the Decontamination Coordinator will be required to complete a course of training developed specifically for this role.

- The Decontamination Co-ordinator must be given the resources and authority to:

    i. Identify all the places at which cleaning, disinfection sterilisation of RIMD is carried out.

    ii. To identify any processes which may be considered unsatisfactory.

    iii. To ensure that measures to rapidly improve or curtail any processes they deem unsafe are instigated

- In addition, the Decontamination Co-ordinator should:

    i. Develop policies and/or strategies for the decontamination of RIMD for approval by the appropriate committee (e.g. infection control committee).

    ii. Be a member of the Infection Control Committee and the Risk Management Committee.

    iii. Attend appropriate meetings/conferences local and national relevant to the Decontamination of RIMD, which will increase knowledge and improve ability to undertake their role.

    iv. Ensure that all information, received from the NHO/relevant agencies relating to Decontamination of RIMD is disseminated within the hospital.

    v. Ensure that, through the line managers, a training needs analysis is undertaken and a prioritised programme developed identifying training needs for appropriate personnel.

    vi. Work with Decontamination Unit Managers and Clinical Unit Managers to develop and improve the decontamination systems.

    vii. Be responsible for an annual internal audit of all decontamination facilities within the hospital.

    viii. Carry out an annual review of decontamination of RIMD within the hospital, based on—the audit results, complaints from clinical users, recorded product defects and decontamination process records.

    ix. Be responsible for informing the hospital management team of the outcome of the annual review and the standards to which decontamination is being carried out.

    x. Ensure compliance via departmental heads with best practice standards.

    xi. Ensure that all proposed hospital service developments consider the issue of decontamination of RIMD in accordance with relevant guidelines.

    xii. Liaise with appropriate personnel when purchasing decontamination equipment to ensure compliance with Standard 12 of this document.

25 Key Personnel

25.1 Introduction

There should be sufficient personnel at all levels with the ability, training, experience and professional and technical qualifications appropriate for the decontamination of RIMD. Their duties and responsibilities should be clearly explained and recorded, e.g. as a job description.

25.2 Scope

The objective of this procedure is to outline the roles and responsibilities of key personnel in relation to decontamination of RIMD.

25.3 Contents

Section One: General Principles

25.4 Procedure

Section One: General Principles

- The decontamination coordinator (see 24.1) is defined as the person designated by hospital management to be responsible for the management of decontamination services in the hospital.
- The Decontamination Unit Manager is defined as the person designated by hospital management to be responsible for the operation of the decontamination unit.
- The Maintenance Personnel (in-house or sub-contracted) should have documentary evidence to demonstrate competence in the maintenance the types of decontamination equipment with which they will be dealing.
- The Test Personnel (in-house or sub-contracted) should have documentary evidence to demonstrate competence in the periodic testing of the types of decontamination equipment with which they will be dealing.
- The Microbiologist is defined as the person designated by management to be responsible for advising on microbiological aspects of decontamination.

- The Infection Control Nurse is the person designated by management to be responsible for advising on all aspects of infection prevention and control.
- The Operative is defined as the person designated by management to be responsible for carrying out all aspects of the decontamination process.
- The Biomedical Engineer is defined as the person designated by management to be responsible for the testing and maintenance of electrical medical equipment.
- The Qualified Person is a person registered as an Authorised Person (Sterilisers) with the Institute of Healthcare Engineering and Estates management and registered with the HSE as competent to discharge the duties of a QP in Ireland.

26 Training and Education

26.1 Introduction

The quality of a product depends to a large extent upon the personnel involved with its manufacture. Each individual has a responsibility for carrying out satisfactorily a particular stage, or stages, in decontamination, and adequate training is important to ensure that each one understands the nature of the work for which he/she is responsible and the possible consequences of failure to observe best practice.

26.2 Scope

The objective of this procedure is to ensure that all decontamination process are carried out by trained staff.

26.3 Contents

Section One: General Induction Training

Section Two: Specific Decontamination Issues

Section Three: General Principles

26.4 Procedure

Section One: General Induction Training

The following hospital and departmental policies, procedures and standards should be addressed in the general induction training of staff working in the decontamination service:

- Infection Control.
- Health and Safety at Work Act.
- Risk Management.
- Occupational Health.
- Quality issues in the department.
- Safe operation of equipment.

- Communications within the HSE/NHO.
- Fire hazards and regulations.
- Manual handling.
- First Aid.

Section Two: Specific Decontamination Issues

Staff undertaking decontamination should receive on-going education in the techniques and skills relevant to decontamination and the procedures they are undertaking. The following **specific decontamination issues** should be addressed in the training of staff undertaking decontamination:

- Standard Precautions for infection control.
- Transportation of contaminated equipment/RIMD.
- Cleaning.
- Disinfection.
- Inspection.
- Assembly.
- Packaging.
- Sterilisation.
- Storage.
- Despatch.
- Transportation of sterile equipment/RIMD.
- Manufacturers instructions for decontamination of RIMD.
- Identification of RIMD anomalies.
- Clean room technology
- Procurement (service records)
- Testing of equipment
- Maintenance & Validation (processes)
- PPE specific to decontamination of RIMD
- Risk Management (how to deal with adverse events)
- Standards and legislation

- The build environment (HBN13)
- Repair/loan equipment – what to do before and after
- Labelling and single use and disposal
- Roles and responsibilities
- Contaminated equipment (CJD) what to do, quarantine etc.
- Audit
- Maintaining environmental cleanliness

Section Three: General Principles

- Ensure that each individual is aware of the relevance and importance of their activities and how they contribute to the achievement of a sterile RIMD.
- Competence for staff performing work affecting the decontamination life cycle should be established.
- Effectiveness of training should be evaluated.
- Appropriate records of education, training, skills and experience should be maintained.
- For all staff undertaking decontamination there should be on-going education including up-date of policies, feedback of audit results and actions needed to correct deficiencies.
- There should be a documented record of all training.

27 Personal Protective Equipment

27.1 Introduction

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

PPE involves use of protective barriers such as gloves, gowns, aprons, masks or protective eyewear. PPE also provides protection against other hazards in the healthcare facility such as chemicals and physical injury. Standard precautions and safe work practices are required to minimise the risk of infection to both patients and HCW. 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.

27.2 Scope

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

27.3 Contents

Section One: Attire

Section Two: Head/Hair Cover

Section Three: Protective eyewear and face-shields

Section Four: Masks

Section Five: Plastic aprons and gowns

Section Six: Gloves

Section Seven: Footwear

27.4 Procedure

Section One: Attire

- All personnel working in the decontamination area should wear a freshly laundered scrub suit.
- Low linting surgical attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered surgical attire should be changed daily or whenever it becomes visibly soiled or wet.
- Appropriate clothing must be used by staff who are involved in the maintenance of reprocessing equipment.
- When working outside the decontamination area suitable cover attire should be worn.
- After use, surgical attire should be discarded appropriately in a designated post use container.
- Surgical attire must never be worn outside the hospital.

Section Two: Head/Hair Cover

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

Section Three: Protective eyewear and face-shields

- Health Care Workers (HCWs) must wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear must be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear should be single-use.
- Protective eyewear or face shield should be discarded in the appropriate healthcare waste stream.
- Make-up must not be worn.
- Facial jewellery must not be worn.

Section Four: Masks

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

Section Five: Plastic Aprons and Gowns

- HCWs should wear single use plastic aprons and impermeable gowns during procedures that are likely to generate splashes of blood or body fluids or during activities that may contaminate clothing, uniforms and personnel with microorganisms or infectious material.
- Fluid repellent gowns and aprons should be changed whenever they become visibly soiled or wet.
- After use, fluid repellent gowns and aprons should be discarded in the appropriate healthcare waste stream.

Section Six: Gloves

- Gloves must used for handling contaminated RIMD, waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves must be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- Avoid letting the gloves snap, as this may cause contaminates to splash into eyes or mouth or onto skin or other personnel in the area.
- It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.
- HCWs should wash their hands both before and after using gloves. Wearing gloves must not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves must be discarded in the appropriate healthcare waste stream.

Section Seven: Footwear

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

28 Hand Hygiene

28.1 Introduction

Hand hygiene is the most important measure in preventing the spread of infection in healthcare establishments. Health Care Workers must wash their hands before applying PPE and after handling equipment or instruments soiled with blood or other body substances.

28.2 Scope

The objective of this procedure is provide hand hygiene guidelines for staff who are working in the area of decontamination of RIMD.

28.3 Contents

Section One: Hand Hygiene technique

Section Two: Hand care

28.4 Procedure

Section One: Hand Hygiene technique

- Remove hand and wrist jewellery (wedding bands allowed). N.B. Keep nails short.
- Wet hands thoroughly under running water.
- Apply 5mls of soap/antiseptic soap to cupped hand by pressing dispenser with heel of hand (do not use finger tips on the dispenser).
- Wet hands and rub palm to palm 5 times.
- Rub right palm over the back of the left hand up to wrist level 5 times. Do the same with the other hand.
- With right hand over back of left hand rub fingers 5 times. Do same with the other hand.
- Rub palm to palm with the fingers interlaced.
- Wash thumbs of each hand separately using a rotating movement.

- Rub the tips of the fingers against the opposite palm using a circular motion. Also ensure nail beds are washed.
- Rinse hands thoroughly under running water to remove all traces of soap.
- Turn off taps using elbows.
- Dry hands completely using a disposable paper towel.
- Discard paper towel in waste bin. Open bin using foot pedal to avoid contaminating clean hands.

Section Two: Hand Care

- Hand care is important because intact skin (with no cuts or abrasions) is a natural defence against infection. Any breaks or lesions of the skin are possible sources of entry for pathogens.
- Hand and wrist jewellery should not be worn as these are likely to increase the presence of bacteria and interferes with hand hygiene.
- Finger nails must be short, clean and healthy and should be maintained in good condition.
- Nail polish and artificial nails must not be worn.
- Repeated hand washing and wearing of gloves can cause irritation or sensitivity leading to dermatitis or allergic reactions. This can be minimised by early intervention, including assessment of hand hygiene technique, the use of suitable hand creams and the appropriate wearing of PPE.

29 Chemicals

29.1 Introduction

Chemicals such as detergents and rinse aid may be caustic and can cause adverse effects when exposed to tissue. Chemical disinfectants are potentially hazardous as they may cause irritation to the skin, eye, respiratory tract and mucous membrane and may be volatile, flammable and corrosive.

29.2 Scope

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

29.3 Contents

Section One: Training

Section Two: Material Safety Data Sheets

29.4 Procedure

Section One: Training

All personnel who handle chemicals e.g. detergents, rinse aid, Ethylene Oxide, gas plasma and RIMD stain remover, should be trained in the action in the following:

- First aid.
- Safe handling of chemicals.
- Method of cleaning the affected area.
- Correct disposal of material used.

Section Two: Material Safety Data Sheets (MSDS)

- Suppliers of chemical agents must provide MSDS for all chemical agents (including cleaning agents).
- Copies of all MSDS must be available to all employers at all times in a designated area, so that appropriate action can be taken in case of exposure to a hazardous substance.
- If information is incorporated into policies and procedures, it is important to use the original wording and refer to the MSDS.
- Users are advised to check each MSDS for chemical incompatibilities before storing different chemicals together.
- Personnel should read and follow the precautions and instructions given on the MSDS and on the label prior to handling and use.

30 First Aid

30.1 Introduction

The Health & Safety at Work Act (2005) requires employers to protect the health and safety of their personnel. In fulfilling this obligation, the employer is responsible for ensuring that first aid services, supplies and equipment are available at the work site.

30.2 Scope

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

30.3 Contents

Section One: General Principles

30.4 Procedure

Section One: General Principles

- A First aid box should be available within the department.
- Local guidelines must be adhered for burns, eye splashes and sharps injuries.
- A first aid eye wash station should be available nearby or on hand.

31 Immunisation

31.1 Introduction

Health care establishments should provide infection protection measures for all healthcare workers (HCWs). These must include physical protection (immunisation), implementation of safe work practices and provision of health screening.

31.2 Scope

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

31.3 Contents

Section One: General Principles

31.4 Procedure

Section One: General Principles

Hepatitis B immunisation is available and recommended for all staff directly involved in patient care, embalming or the handling of human blood or tissue. Immunisation should be considered for staff who are at risk from injury by blood contaminated sharps.

32 Traceability

32.1 Introduction

In order to provide full traceability it is essential to be able to identify which RIMD were used on which patients and to trace the process records through the decontamination life cycle. Clear records are a key factor in enabling the hospital to trace RIMD/RIMD sets through their life cycle. This will enable corrective action to be taken when necessary.

32.2 Scope

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

32.3 Contents

Section One: Processing

Section Two: Labelling

Section Three: Flexible/Rigid Endoscopes

32.4 Procedure

Section One: Processing

- Systems should be in place to allow the methods, operational cycles and personnel involved in the processing a particular RIMD/RIMD set to be tracked through the decontamination processes in order to ensure that the processes have been carried out effectively.
- Records should be maintained for all the RIMD/RIMD set, identifying:
    i. The cleaning, disinfection and sterilisation method used.
    ii. The name of the person undertaking these processes.
    iii. Details of the actual RIMD/RIMD set being processed.
- Systems should be implemented to enable the identification of patients on whom the RIMD/RIMD set have been used. This is important so that the relevant patients can be identified in the event of exposure to potential risk, and is relevant to both the primary and secondary care sectors.
- IT based systems or manual (paper based) recording systems may be used.
- Records relating to decontamination processes should be maintained in accordance with the NHO medical records retention policy (draft).

Section Two: Labelling

- Each RIMD/RIMD set or pack intended for use as a sterile product must be labelled with a batch control identifier and the RIMD identification label, which enables tracking the RIMD to be tracked back to the steriliser.
- The batch control identifier should designate the steriliser identification number or code, the date of sterilisation, and the cycle number (cycle run of the steriliser).
- The RIMD identification label (manual or electronic) should designate the date of sterilisation, the RIMD number (e.g. cataract set number 1), the name and the use-by date of the RIMD.
- The batch control label and/or RIMD identification label are affixed to the outer packing of the RIMD/RIMD set.
- The batch control identifier and/or the RIMD identification label should be placed in the patient records.
- Packages must be labelled prior to sterilisation.
- The labelling must be done immediately before the load is processed.

Section Three: Flexible/Rigid Endoscopes

- Batch or serial numbers on products permit traceability in two directions; forward to purchasers and backward to raw materials, components and processes used in manufacture.
- The former is important if it is necessary to trace products to the user, e.g. patients or hospitals, and the latter enables investigation of quality problems and feedback for the prevention of the nonconforming product....ref EN 724:1994.

33 Choice of decontamination processes

33.1 Introduction

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

33.2 Scope

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

33.3 Contents

Section One: General Principles

33.4 Procedure

Section One: General Principles

- RIMD must be reprocessed to a level appropriate for their intended use. The appropriate level depends on the body sites where the instrument will be used and the risk associated with a particular procedure.
- The minimum levels of processing and storage requirements for RIMD, based on three risk categories of use, are shown in Table 7-1. In brief, the minimum levels of reprocessing are as follows for different types of site:

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

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

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

- Decontamination processes should be chosen to be compatible with the RIMD to be processed.
- Decontamination processes should be chosen to be capable of providing the standard of decontamination required for the clinical procedures to be undertaken.
- Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- Decontamination processes should be chosen to be amenable to independent verification of the decontamination standards achieved.
- The decontamination methods selected should be economical and of demonstrated effectiveness.

34 Transportation – return of used items for reprocessing

34.1 Introduction

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

34.2 Scope

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

34.3 Contents

Section One: Containers and Trolleys

Section Two: Staff

34.4 Procedure

Section One: Containers and Trolleys

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

- Containers should be selected based on the characteristics of the items being transported; in particular they must be:

    i. Leak-proof.

    ii. Rigid, to contain instruments, preventing them becoming a hazard to anyone handling the goods and to protect them against accidental damage.

    iii. Capable of being closed securely.

    iv. Lockable, where appropriate, to prevent tampering.

    v. Clearly labelled to identify the user and the contents where applicable.

    vi. Robust enough to prevent instruments being damaged in transit.

    vii. Have the ability to be easily cleaned, disinfected and dried, or discarded (as appropriate) using agreed methods.

- RIMD/RIMD set must be separated from healthcare risk waste at the point of use.
- Sharps must be removed and placed into approved containers conforming to BS 7320 (1990).
- Reusable textiles should be held in appropriate linen bags and returned to the laundry service.
- Dispose of all fluids, e.g. blood, bodily fluids, cleaning and antiseptic solutions before placing RIMD in transport containers.
- All transportation equipment has to be cleaned in accordance with local policy.

Section Two: Staff

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

Figure 34-2 Containers and Trolleys

35 Sorting and Disassembly of Contaminated RIMD

35.1 Introduction

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

35.2 Scope

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

35.3 Contents

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

Section Two: Disassembly of instruments

35.4 Procedure

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

- All RIMD should be sorted according to the selected method of cleaning e.g. manual cleaning process or automated cleaning process. This is to ensure that the manufacturer instructions for cleaning are followed in order to ensure the RIMD is not damaged and is cleaned adequately.
- Policies and/or procedures should be developed for the handling sorting and disassembly of RIMD.
- On receipt at the decontamination area, items should be sorted according to type and corresponding cleaning method.
- A check for completeness and defects should be made during sorting.
- There should be written policies and/or procedures for handling specialised items.

- Care and handling of powered tools should be in accordance with manufacturers' instructions and hospital policies and/or procedures.
- Care and handling of flexible and rigid endoscopes, and accessory equipment should be in accordance with manufacturer's instructions and hospital policies and/or procedures.

Section Two: Disassembly of instruments

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

- Open instrument box locks.
- All jointed instruments must be open to make sure that all surfaces are effectively cleaned.
- Place RIMD in mesh basket in a manner which ensures effective cleaning of RIMD. **Overloaded baskets will result in ineffective cleaning**.
- RIMD should be arranged in an orderly fashion in mesh bottom trays so that all surfaces are exposed to the action of an automated cleaner, if used.
- If extra mesh baskets are required for cleaning purposes of an RIMD set a marker should be placed in the extra baskets to identify the set name and number.
- Place heavy retractors and/or other heavy instruments on the bottom or in a separate tray.
- Small and light items should be secured with a hold down screen or by other means, to ensure they are not free to move around during the cleaning process. Place scissors, lighter-weight instruments, and microsurgical instruments next.
- Receivers and gallipots should not be placed over RIMD, as they may interfere with the cleaning process.
- Each jointed RIMD should be in the open position when placed in the mesh basket.
- Separate all reusable sharp instruments from general instruments. This is to ensure ease of identification for personnel assembling the RIMD after cleaning, in order to prevent sharps injury.

36 Cleaning (including pre-cleaning)

36.1 Introduction

Cleaning is an essential prerequisite for all effective disinfection and sterilisation processes, as organic residue may prevent the disinfectant or sterilant from contacting the item being processed and may also bind and inactivate chemical disinfectants (Muscarella, 1998). **If the item cannot be cleaned, it cannot be disinfected or sterilised. The process must not be used for items intended for single-use only.**

36.2 Scope

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

36.3 Contents

Section One: Manufacturers Instructions

Section Two: Automated versus Manual Cleaning

Section Three: Initial Cleaning

Section Four: Automated Cleaning

Section Five: Manual Cleaning

36.4 Procedure

Section One: Manufacturers Instructions

- The manufacturers instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the device will tolerate immersion (air-powered instruments, for example, should not be immersed).
- RIMD should be cleaned, handled, and used according to manufacturers' instructions. Manufacturers' instructions provide direction for care, cleaning, handling, and the correct use of surgical instruments and powered equipment. The instructions for cleaning and sterilisation must be such that if correctly followed the device can be reused, without causing injury to the patient or personnel using the RIMD.

Section Two: Automated versus Manual Cleaning

- The use of mechanical cleaners such as automated washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.
- The advantage of using automated cleaning equipment is that it provides an efficient, validated, reproducible process which can be more easily controlled than manual methods.
- Automated processes are generally more convenient and also provide protection for the user in reducing exposure to contaminated RIMD and chemicals.

Section Three: Initial Cleaning

- Gross soil must be removed from RIMD as soon as possible after use. Initial cleaning is required to soften and creaks down dried blood and other organic material, but it does not decontaminate items. This can be carried out using an initial cold water rinse or using an enzyme spray.
- After pre-treatment, RIMD may then be either processed mechanically or manually.

Section Four: Automated Cleaning

1. Washer-Disinfectors

a. Introduction

All automated washer-disinfectors used for decontamination should be purchased against the Model Engineering Specification C30 and be capable of being tested in accordance with ISO/ FDIS 15883 part 1 and ISO/FDIS 15883 part 2. The main purpose of the automated washer disinfector is to remove the hazards of contaminants.

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

- If the RIMD can be immersed in water.
- Maximum operating temperature.
- Mechanical damage which may occur for the impact of the water jets of other items in the load.
- The compatibility of the detergent and/or rinse aid.
- The compatibility of deionised and reversed osmosis water.

c. Equipment required

- An automated washer-disinfector, cabinet or continuous process type; Note: the cycle/process chosen must have a validated cycle.
- Load carrier, racks, accessorised and loading trolley (where applicable).
- A sufficient number of racks for placing the items to be processed.
- A compatible detergent and rinse-aid – calibrated automatic dosing system is essential.
- Purified water/RO is preferred for the final rinse stage since this gives the lowest levels of process residuals.

d. Procedure

- Ensure the automated washer-disinfector and all services are operational. The WD should not start if any anomalies are present.
- Wearing protective clothing, load the rack/machine ensuring that the loading configuration does not impede the cleansing process and the rotatory arms can rotate.
- Load carrier and racks should only be used with the items for which they were intended.
- A record should be kept of each RIMD/RIMD set processed in each automated washer disinfector and each cycle in order to trace the RIMD/RIMD set through the decontamination process.
- Load the load carrier into the AWD.
- Secure the door (if fitted), select and start the cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved; remove the load and visually check and inspect the cleanliness of the item, drain off excess water and dry if necessary.
- A typical cycle comprises the following phases:
    i. Cold rinse.
    ii. Warm wash.
    iii. Disinfection rinse.
    iv. Drying.

- Information should be recorded for each washer disinfector cycle. Documentation is required for every washer disinfector cycle and should contain, but not be limited to, the following:

    i. Washer disinfector identification number e.g. washer disinfector number.

    ii. Cycle number.

    iii. Type of washer disinfector.

    iv. Type of cycle used.

    v. Date and time of start of cycle.

    vi. Load content e.g. general instrument set, stitch set, mayo scissors.

    vii. Critical parameters for the specific washer disinfector cycle.

    viii. Operators name.

    ix. Results of washer disinfector process

    x. Signature of a qualified person confirming whether or not the process cycle was within recommended parameters

    xi. Any notes or observation for the process cycle

- All records should be maintained for a period of time recommended by the NHO.
- Cycles which were aborted should be documented with the action taken in a log book.
- Where double doors are used it should not be possible to open the door on the processed side until the load has completed the process cycle, except for maintenance purposes.
- Where single-ended washer-disinfectors are used it is important to ensure adequate segregation of unprocessed goods from processed goods.

e. Monitoring & Control

- Cycle parameters must be monitored to ensure that the temperature is within the parameters outlined in Table 36-5. Each processed load is monitored to ensure that load is clean.
- Validation, Routine monitoring and control should be carried out in accordance with documented procedures in line with European standard ISO/FDIS 15883.

Table 36-4a: Automated washer disinfector temperature bands (ref. EN ISO 15883)

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

a. The disinfection temperature is measured at the surface to be disinfected.

b. The exposure time of 1 second is too short for reliable measurement and a minimum time of 12 (0.2 min) should be used

c. Is time/temperature relationship is only used for items known to be contaminated with large amounts of pathogenic organism.

c. A^o reduction time should be the equivalent of 3000 (seconds) at 80 degrees.

f. Validation

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that a steam Washer Disinfector (WD) is functioning correctly and that it will produce sterilised loads consistently.
- The effectiveness of the Efficacy/Disinfection process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if washing conditions are created throughout the Washer chamber and the load during every cycle.

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

    i. Commissioning.

    ii. Performance qualification (revalidation).

    iii. Periodic testing (operational qualification).

    iv. Continuous Validation during Sterilizer Life cycle.

g. Commissioning

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications by the supplier, that it is safe to operate and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions. It consists of:

Installation checks and tests

i. Preliminary checks.

ii. Electrical checks.

iii. Functional checks.

iv. Response to faults.

Commissioning tests

i. Chemical residue tests.

ii. Efficacy tests (Test Soils).

iii. Thermometric test.

iv. Calibration.

v. Water penetration and lumen tests test.

vi. Microbiological tests (recommended).

- These tests should be carried out when a new WD is purchased or when a used (WD) has been relocated to another premises.

- The tests should be carried out before the WD is used for the first time. Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of WD data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the autoclave is functioning correctly.
- Even though the manufacturer should have tested a (WD) before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it must be tested before use to ensure that it is **working** correctly.

h. Performance Qualification

Performance Qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to sterilise. Performance qualification is indicated for initial use of a new/relocated (WD) or when the load profile changes (e.g. new instruments). It should be carried out by a Test Person (or suitably qualified person). These tests consist of:

i. Water leakage tests.

ii. Thermometric tests of all RIMD/Loading Equipment to be processed.

iii. Water /Detergent penetration/contact times of all test loads.

iv. Load dryness test (of RIMD'S requiring reprocessing).

v. Microbiological tests.

Table X: Validation of single chamber washer processes as per prEN15883-2/HTM 2030

Quarterly tests
User-Weekly Safety Checks (Automatic Control Test/check spray arm rotation for free movement/check
spray nozzles for blockages/remove and clean strainer and filters
cleaning efficacy test by residual soil reduction
water conductivity (final rinse stage)
Automatic Control Test
Verification of calibration of WD Instruments
Thermometric test for thermal disinfection (Ao lethality verification,conductivity/ph check of final rinse)
Cleaning efficiency test (Test soil or Ninhydrigin test)
Reference load General Instruments, devices, instruments hollowware (plastic and metal), containers and load carriers
Test Soil
Independent Meters and Probes check
Air Temperature
Water temperature
Conductivity meter
Panel check
Water pressure
Transfer of information to Data Archiving System 8535(if appropriate)
Annual Re-validation
Yearly Safety Checks
Automatic control Test
Verification of calibration of WD instruments
Water System test- deionizer 1. Chemical Purity and 2. Bacterial endotoxins (seemly not required)
Drainage Test 1. Free draining and 2.efficacy of discharge
Doors and Doors interlocks both sides
Fault interlock
Water vapour discharge test
Chemical additive dosing tests 1.reproducibility 2.low level detection
Load Carriers- Carriage
Test for Air quality
Cleaning efficacy test reference load General Instruments,devices- poly/plastic and metal
Over temperature cut out test
Thermometric test reference load General Instruments,devices - (poly/ plastic and metal), containers
Load dryness Test reference load General Instruments,devices, hollowware (poly/ plastic and metal), containers
Process residues-Chemical additives- dozer check
Stainless steel chambers integrity check

i. Maintenance

- Preventative maintenance is to be planned and performed in accordance with International Standards ISO/FDIS 15883-1 and ISO/FDIS 15883-2 and manufacturers instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out shall be specified and documented.
- The automated washer disinfector will not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- A nominated qualified person shall review the maintenance plan maintenance procedures and maintenance records periodically.
- Automated washer disinfector maintenance and repair log book should be maintained for each automated washer.
- Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers' instructions and/or local policy, including:

  i. Inspecting and cleaning all filters.

  ii. Dismantling and cleaning spray arms and nozzles.

  iii. Efficacy tests during operational conditions.

2. Ultrasonic Cleaners

a. Introduction

Ultrasonic cleaners do not disinfect instruments. They work by the use of high intensity of high frequency sound waves which cause soil to be dislodged from the instruments and drop to the bottom of the tank, 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. Note the manufacturers instructions should be considered in relation to the suitability of its equipment for ultrasonic cleaning.

b. Equipment Required

- An ultrasonic washer with a lid should hold a sufficient volume of solution so that the RIMD to be cleaned can be fully immersed.
- Supporting racks or trays to suit a range of RIMD processed.
- A timing device.
- A warm detergent solution. Follow manufacturers' instructions for dilution and temperature (<35°).
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (e.g. drying cabinet or industrial hot air dryer).
- A chemical neutraliser, first-aid kit and eye wash bottle, in case of leakage or splashing with detergent.

c. Procedure

- Staff must wear PPE at all times while handling contaminated RIMD and working with the ultrasonic cleaner.
- Fill the tank with potable water (drinking quality) to the manufacturers designated level; add the detergent solution as recommended by the manufacturer.
- Bring the solution up to the operating temperature.
- De-gas the water as recommended by the manufacturer.
- Place the opened/dismantled RIMD into the basket.

- If the RIMD is not for further cleaning, e.g. automated cleaning, record the following:

i. Method used.

ii. Solution dilution and temperature.

iii. HCW carrying our procedure.

iv. Date.

- Place the basket of RIMD into the tank. Never put RIMD directly onto the base of an ultrasonic washer.
- Re-place the lid and leave for the recommended time to prevent aerosolization of contaminants.
- 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.
- After use, the ultrasonic washer should be drained, cleaned, dried, and covered and left dry and empty until further use, as per the manufacturers instructions.
- Combine only RIMD made of similar metals in the ultrasonic cleaner to avid ion transfer, which may result in instrument etching and pitting.
- Avoid placing chrome-plated instruments in the unit because the mechanical vibrations can cause the plating to flake.
- It is recommended that the tank be emptied regularly – as a minimum, every four hours, or when the water is visibly soiled.

d. Monitoring and Control

Validation, Routine monitoring and control should be carried out in accordance with documented procedures as recommended by the manufacturers' instructions. It is recommended that a soil tests 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. It should not, however, replace the detailed tests specified in HTM 2030.

Test (may move this to appendix section) Tin Foil Test and PIEZO electric effect test

- Clamp the edge of a piece of aluminium foil (approximately 5cm^2) in a pair of metal forceps.
- Hold in the centre of the bath for approximately three minutes.
- Remove, dry and inspect the aluminium foil for changes.

- File the strips as a record of the test having been undertaken, together with all relevant test details, that is machine number, date, test result (pass/fail), name of operator etc.
- Effective ultrasonic action will serrate the edge and pit/perforate the centre of the foil.
- If the aluminium foil is withdrawn without any noticeable change to its condition, this may indicate that the machine is not functioning properly and the manufacturer/supplier should be consulted.
- When test is complete tank should be emptied and cleaned in order to remove any residue foil.
- Record results in log book.

e. Maintenance

- Preventative maintenance is to be planned and performed in accordance with documented procedures as recommended by the manufacturers instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out shall be specified and documented.
- The ultrasonic cleaner will not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.

Section Five: Manual Cleaning

1. Immersion

a. Introduction

The use of mechanical methods may be contra-indicated for washing certain delicate or complex instruments. These instruments should be carefully hand-washed and rinsed according to the manufacturers instructions. This procedure is not a disinfection process and therefore some items may require subsequent disinfection.

b. Equipment required

- A sink (not a hand hygiene sink), or a receptacle which will hold sufficient volume of water/detergent such that the item of equipment to be cleaned can be fully immersed.
- A warm detergent solution. Follow manufacturers' instructions for dilution and temperature.
- A receptacle to contain rinse water (<35°).
- A drainage surface.
- A brush(es) and jet washer.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (e.g. drying cabinet).

b. Procedure

- HCWs must wear PPE at all times while handling contaminated RIMD.
- Fill the sink (not a hand hygiene sink or other cleaning receptacle) with potable water to a predetermined level, at the specified temperature and with the appropriate amount of detergent (as per manufacturers' instructions). The sink must be solely dedicated for the cleaning of instruments and not for any other purpose.
- Detergents used must be specifically designed to clean surgical instruments: washing up liquid must not be used. A mild detergent is preferred for manual cleaning. Mild detergents (pH range 8.0–11.5) are more efficient cleaning agents for RIMD.
- Detergent dilution and water temperature must be in accordance with the manufacturers' instructions and local policy.
- Consideration should be given to the use of an enzymatic detergent to facilitate the cleaning of RIMD with channels or complex parts.

- Carefully immerse the item in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reaches all surfaces including those of lumened RIMD.
- Remove all visible soiling from the RIMD, including lumens and valves. Remove stubborn staining by using the non-abrasive scouring pad or soaking in an approved stain-removing solution.
- Rinse the item finally in warm-to-hot running water, unless contra-indicated.
- Dry mechanically in a drying cabinet or hand dry with a clean, lint-free cloth. Note: items must not be left to dry in ambient air.
- Inspect instruments and equipment to establish that they are clean before further processing or storage.
- Thoroughly wash and dry receptacles before storing and re-use.
- Cleaning brushes must be identified for cleaning only and must be washed, thermally disinfected, and stored dry.

d. Monitoring and control

Due to the lack of acknowledged methods of control available to the user to test the efficacy of immersion cleaning, the user should be aware of the factors that may alter the efficacy of the method:

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

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

e. Maintenance

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

2. Non-Immersion

a. Introduction

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

b. Equipment required

- A warm detergent solution. Follow manufacturers' instructions for dilution and temperature.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (e.g. drying cabinet).

c. Procedure

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- Wearing protective clothing immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Commencing with the upper surface of the item, wipe thoroughly ensuring that detergent solution does not enter electrical components.
- Periodically rinse the cloth in clean water and repeat the previous two steps.
- Remove detergent solution using clean, damp, non-linting cloth.
- Surfaces should be carefully hand-dried using a cloth or placed into a drying cabinet.

d. Monitoring and Control

Due to the lack of acknowledged methods of control available to the user to test the efficiency of non-immersion cleaning, the user should be aware of the factors that may alter the efficiency of the method:

- Staff training.
- Physical application.
- Nature of soil.
- Accessibility of cleaner to item/part of equipment.
- Detergent concentration.

37 Disinfection

37.1 Introduction

Disinfection is a process that inactivates infectious agents, using either thermal (moist or dry heat) or chemical means. The level of chemical disinfection achieved depends on the temperature, exposure time and/or type of chemical disinfectant used.

37.2 Scope

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

37.3 Contents

Section One: Level of Disinfection

Section Two: Disinfection Process

37.4 Procedure

Section One: Level of Disinfection

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

Section Two: Disinfection Process

- **Thermal disinfection** can be achieved in an automated thermal washer–disinfector by choosing the appropriate cycle.
- **Chemical disinfection** can be achieved with a compatible instrument-grade disinfectant of the required level, used alone or in conjunction with an automated chemical washer–disinfector.

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

1. Thermal Disinfection

a. Introduction

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

b. Equipment required

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

c. Monitoring and Control

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

2. Chemical Disinfection

a. Introduction

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

b. Equipment required

- RIMD disinfectant or sterilant.
- Automated equipment.

c. Monitoring and Control

- Chemical disinfection processes should provide adequate assurance of the required microbial lethality.
- Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.
- Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.
- After chemical disinfection devices should be free from toxic residues and should be rinsed free from disinfectant with purified water free from microbial contamination. The quality of water used should be appropriate to the clinical procedures to be undertaken.

38 Drying

38.1 Introduction

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

38.2 Scope

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

38.3 Contents

38.4 Procedure

Section One: Equipment

- Drying cabinets.
- A drying section or stage may be incorporated as part of the automated cleaning equipment cycle.
- If manual drying is used carried out, a lint free material should be used.
- Manual drying should be avoided if possible.

Section Two: Procedure

- All RIMD components should be thoroughly dried either by hand, in a drying cabinet or hot air dryer.
- Care should be taken not to exceed the temperature tolerances advised by the manufacturer.
- Dry the RIMD in a sloping position to facilitate drainage.

Section Three: Monitoring and Control

- Manual drying should be avoided unless lint free material is used.
- Items must not be dried in ambient air.
- Alcohol or other flammable liquids should not be used as drying agents, except in the case of endoscopes.
- A nominated, qualified person should review the maintenance plan, maintenance procedures and maintenance records periodically.
- Drying cabinet maintenance and repair log book should be maintained for each dryer.

Section Four: Maintenance

- Preventative maintenance is to be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out shall be specified and documented.
- The dryer will not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485: 2003(E).

39 Post Cleaning Inspection and Function Testing

39.1 Introduction

Inspection, maintenance and testing of RIMD should be carried out by trained persons in accordance with the manufacturers' instructions. All RIMD should be inspected to ensure that they are intact and that there are no chips, worn spots, flaking or sharp edges. All RIMD should be function tested before being packaged for further processing or storage. The area where inspection takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the RIMD/RIMD sets.

39.2 Scope

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

39.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Documentation post automated cleaning

Section Four: Inspection

Section Five: Function testing

Section Six: Monitoring and Control

Section Seven: Maintenance

39.4 Procedure

Section One: Equipment

- Work bench.
- Magnifying light.
- Light source.
- Diathermy pin point tester.

Section Two: Procedure

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

- Check that the instrument/indicator reading and/or chart record for cycle conforms to the information established during validation and are within the parameters permitted. Check the disinfection stage of the process has been achieved.
- Check that the operating cycle is in accordance with the specification for the load used, e.g. laryngeal masks do not require rinse aid.
- Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the RIMD or RIMD may not be compatible with automated washing.
- If staining and/or residue are present, this may be due to the configuration of the load, overloaded cart or malfunction in the washing cycle.
- Make a visual inspection of the load for dryness.
- Where a load may not be properly cleaned the load is rejected and returned for recleaning.
- If load is wet, this maybe due to the configuration of the load, over loaded cart, or malfunctioning in the automated washer.
- Where a small percentage of the load is suspect the items are rejected and returned for recleaning.
- Any load or items rejected should be documented as a non conformance; this non conformance should also be documented into the automated washer disinfector log book for further investigation.

Section Three: Documentation post automated cleaning

- All documentation for automated cleaning should contain, but not be limited to the following information:

  i. Washer disinfector identification number e.g. washer disinfector number.

  ii. Cycle number.

  iii. Type of washer disinfector.

  iv. Type of cycle used.

  v. Date and time of start of cycle.

  vi. Load content, e.g. general instrument set, stitch set, mayo scissors.

  vii. Critical parameters for the specific washer disinfector cycle.

  viii. Operators name.

  ix. Results of washer disinfector process.

  x. Signature of an authorised qualified person confirming whether or not the process cycle was within recommended parameters.

  xi. Any notes or observation for the process cycle.

- All records should be maintained for a period of time recommended by the NHO.

- Before commencing inspection the person carrying out inspection must ensure that:

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

  ii. If there is no record of cleaning the RIMD/RIMD set is rejected and returned for recleaning. Items which have been manually cleaned should also be recorded as being cleaned through the manual cleaning process.

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

Section Four: Inspection

- Each RIMD set should be inspected separately.
- Box joints, serrations and crevices, should be critically inspected for cleanliness.
- Cutting edges (on instruments such as scissors, rongeurs, chisels, curettes) should be checked for sharpness.
- Hinges (on instruments such as artery forceps and clamps) should be checked for ease of movement.
- Jaws and teeth should be checked for alignment.
- Ratchets should close easily and hold firmly.
- Any damaged, incomplete or malfunctioning RIMD should be reported immediately to the supervisor.
- Cannulated RIMD should be checked to ensure channel is patent.
- Function check telescopes and light cables as per manufacturers' instructions.

Section Five: Function testing

- Cutting edges (on instruments such as scissors, rongeurs, chisels, curettes) should be checked for sharpness.
- Hinges (on instruments such as artery forceps and clamps) should be checked for ease of movement.
- RIMD that have an outer insulation coating, for example diathermy forceps etc., require close inspection to ensure that the insulation remains intact. Insulated RIMD should be checked using a diathermy pin point tester. Damaged surfaces not only will allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and patients.
- Check that there is free movement of all parts and that joints do not stick.
- Check that the edges of clamping instruments meet with no overlap and that teeth mesh together.
- Check that all screws on jointed instruments are tight and have not become loose during the cleaning process.

Section Six: Monitoring and control

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

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

Section Seven: Maintenance

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

40 Assembly

40.1 Introduction

The purpose of assembly and checking is to ensure that:

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

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

40.2 Scope

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

40.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: RIMD set weight

40.4 Procedure

Section One: Equipment

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

Section Two: Procedure

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

Section Three: RIMD Set Weight

- There is no magic number for RIMD set weight. Preparation and assembly procedures should take into account the ratio between the number of RIMD and total set weight and density. This ratio is more important than an arbitrary weight limit.
- The basic principle determining the size, mass and contents of RIMD sets and hollowware packs is that the contents are sterile and dry immediately on completion of the sterilisation process.
- RIMD sets and container systems should be of a weight specified by the manufacturer of the RIMD, manufacturer of the steriliser and manufacturer of the container systems.

41 Packaging

41.1 Introduction

Packaging should be designed to hold and protect the RIMD, to facilitate sterilisation, to maintain sterility and to allow procedures to be carried out aseptically.

41.2 Scope

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

41.3 Contents

Section One: General Principles

Section Two: Packaging Systems

Section Three: Packaging Materials

Section Four: Single use packaging

Section Five: Types of packaging

Section Six: Packaging Techniques

Section Seven: Sealing of packs and bags

Section Eight: Labelling

Section Nine: Monitoring and Control

Section Ten: Maintenance

41.4 Procedure

Section One: General Principles

- The choice and type of wrapping material will depend on the type of sterilisation process used.
- Materials used should comply with EN 868- 1 to EN 868-10 (inclusive). RIMD may be packaged in any of the following products: papers/non-wovens, polypropylene, containers, and plastic/paper pouches.

- When selecting packaging system evaluate each specific products capability to meet predetermined requirements and criteria.
- The appropriate size wrapping material should be chosen to attain adequate coverage of the item being packaged.
- Hollowware, instruments or dressings should not be placed in textile (linen) packs as difficulty may be experienced in drying the combined pack materials and sterilisation may be compromised as the temperature increases in these materials at different rates.
- Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.
- RIMD packs should be packed in a manner that prevents damage to delicate items.
- Trays used for packaging instruments should be perforated to allow for penetration of the sterilant.
- Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.
- Hollowware should be packaged so that all openings face the same direction.
- Only the minimum of raw materials commensurate with daily production should be held within the Clean Room.
- Compatibility of the packaging material with the sterilisation process should be established.
- If chemical indicators are used inside the pack, they must conform to European Standard EN 867-1 and must be compatible with the pack.
- Sequential wrapping using two barrier-type wrappers provides a torturous pathway to impede microbial migration.

Section Two: Packaging Systems

Packaging systems should:

1. ***Be appropriate to the items being sterilised, i.e.***
   - Permit identification of contents.
   - Permit complete and secured enclosure of items.
   - Protect package contents from physical damage.
   - Permit delivery of contents without contamination.
   - Maintain sterility of package contents until opened.

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

   - Provide adequate seal integrity.
   - Provide an adequate barrier to particulate matter and fluids.
   - Be compatible with and able to withstand physical conditions of the sterilisation process.
   - Allow penetration and removal of sterilant.
   - Maintain integrity of the pack.
   - Permit use of material compatible (i.e. non-degradable) with the sterilisation process.

3. ***Be used according to the manufacturers' instructions***

4. ***Be of the following***

   - Resistant to punctures, tears and other damage which may break the barrier and cause contamination.
   - Be resistant to penetration by micro-organisms from the surrounding environment.
   - Be free of holes.
   - Be free of toxic ingredients.
   - Be low-linting.
   - Be tamper proof and able to seal only once.
   - Provide an adequate barrier to particulate matter and fluids.

Section Three: Packaging Materials

Packaging materials should:

- Be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity equilibrium of packaging material is important to maintain the integrity of the product.
- Not be stored adjacent to external walls or other surfaces which may be at a lower temperature or a higher temperature than the ambient temperature of the store room.
- Be stored on shelves and clear of the floor.
- Be rotated to ensure it does not exceed its shelf life.

Section Four: Single use packaging

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

Section Five: Types of Packaging

1. Papers and non-wovens

- Both papers, which are made from cellulose fibres, and non-wovens made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilization and most gas processes because they are permeable to air, steam and other gases.
- Plain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gusseted to accommodate bulky items.
- Non-wovens are generally less effective as a microbial barrier and may need to be used in, or as one of, two layers; they are however generally softer with better handling and drape characteristics.

2. Containers

Rigid reusable containers:

- Should be easily dissembled for cleaning, drying and storage.
- Should be suitable method of sterilisation being used.
- Should be compatible to the cleaning method and cleaning agent being used
- Should be suitable to the storage configuration.
- Should have locking devices which should be tampereproof and non resealable.
- Should be packed in a manner which allows for penetration of the sterilising agent.
- Lid and contents should be removable without the risk of contamination of the contents.
- Rigid containers have filter and/or valve systems that should be secure and in proper working order before sterilisation.
- The filter plate should be examined for integrity both before installation and after the sterilisation process.
- If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system be used in the practice setting.
- The integrity of the rigid container system is to permit sterilisation of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination.
- Loosened rivets, improperly maintained valves, worn gaskets, dents, or other compromises to the integrity of the container system will compromise the sterilisation process and may not permit the contents to remain sterile or be delivered aseptically.
- When re-usable containers are being evaluated it is important that the sterilisation, cleaning, inspection, maintenance and storage procedures and methods are also evaluated for their ability to be consistently re-used and their compatibility with the process being used.
- Containers should be cleaned between uses; automated cleaning is the preferred method of cleaning.

Section Six: Packaging Techniques

- RIMD may be packaged in any combination of **flat wrapping material** (sheets, bags, pouches, or reels) or **containers** to maintain the integrity of the product. Devices wrapped with sheet material using either the **envelope** or **parcel fold** technique.
- RIMD should be wrapped in a manner which minimises the risk of contamination during opening and removal of contents.

1. Flat Wrapping Material

a. Equipment required

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

b. Procedure (parcel-fold wrapping method)

- Select appropriate packaging material and place on work top.
- The RIMD set is placed on the wrap, approximately in the centre of the packaging material.
- Verify that the accuracy of the RIMD identification label with the RIMD/RIMD set, (i.e. corresponds to RIMD list, internal tray label).
- The long edge of the tray should be aligned parallel to the long edge of the wrap.
- One of the long edges of the wrap is folded over the pack contents to overlap the centre line, and the edge of the wrap is turned back on itself. The fold made by the turning back of the wrap should overlap the centre line of the contents.
- The opposite side of the wrap is then folded over pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself.
- The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- The same procedure may then be repeated for an outer wrap(s).
- The wrap is secured in position using sterilisation indicator tape.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- RIMD identification label is placed on outside wrap.

c. Procedure (envelope wrapping method)

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

2. Pouches and bags (requiring folding)

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

a. Equipment required

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

b. Procedure

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

3. Self-seal pouches

When closing self seal bags follow manufacturer's instructions for sealing.

4. Paper and paper/plastic pouches using heat seal

a. General Principles

- The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above or below those specified by the packaging manufacturer.
- Packaging intended for heat sealing may be film coated; grid lacquered, or have an adhesive band.
- Heat seal pouches should be sealed using suitable heat sealing equipment.
- Heat seal pouches should be hermetically sealed.
- Heat seal pouches should provide a seal of proven integrity and not allow resealing.
- Before commencing wrapping procedure ensure that work area and packaging equipment are clean.

b. Equipment required

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

c. Procedure

- Select appropriate size heat seal pouch.
- Place RIMD into pouch.
- Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.
- As much air as possible should be removed from the pouches before sealing. Air acts as a barrier to heat and moisture. Expansion of air during the sterilisation process may cause the bag to rupture during the sterilisation process.
- Place open end of pouch in heat sealer.

- Apply heat and pressure to the surface of the open end of the heat seal pouch.
- Check should be made that the seal is complete, especially over the gusset folds of the pouches.
- A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.
- The heat-sealing process must be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- When double wrapping using heat seal pouches the packages should be used in such a way as to avoid folding the inner package to fit into the outer package.
- Edges of inner heat seal pouches should not be folded as air maybe entrap in the folds and inhibit sterilisation.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. this also enables the RIMD to be viewed.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the steriliant into and out of the package.
- If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.
- Is important to wrap the RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- RIMD identification label is placed on the outside packaging.

Section Seven: Sealing of Packs and bags

a. Introduction

The purpose of sealing is to maintain pack integrity, this can be achieved by the use of heat sealers, sterilising chemical indicator tape and seal secures. The indicator tape must meet European standard EN 867-1.

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

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

The accessories should also be recommended by the manufacturer.

c. The following accessories should not be used:

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

d. Sterilising indicator tape

Sterilising indicator should be:

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

Section Eight: Labelling

- Packages to be sterilised should be labelled before sterilisation.
- The information of the label should include but not be limited to the following:
    i. Name of product.
    ii. Name of wrapper.
    iii. Lot control number.
    iv. Use by date or/and sterilisation date.
    v. Where appropriate the word sterile.
- Label information should be documented on sterilisation chemical indicator tape or label and not on the packing material. Plastic/paper pouches can be labelled on the plastic portion.
- Marking pen used to label the pack should be indelible, nonbleeding, and non-toxic. Sharp tipped water based or ball type pens must not be used as these may compromise the integrity of the pack.
- Label fixed to the surface of the packaging must be able to withstand exposure to the sterilisation process.
- Policies and/or procedures for wrapping and labelling and sealing of RIMD to be sterilised should be developed, reviewed periodically, and readily available within the practice setting.

Section Nine: Monitoring and control

The following should be monitored during labelling:

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

Section Ten: Maintenance

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

42 Sterilisation

42.1 Introduction

Sterilisation is a process that kills or removes all types of microorganisms, including resistant bacterial spores. The function of sterilisation is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones. To be effective, cleaning must precede sterilisation.

42.2 Scope

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

42.3 Contents

Section One: Two groups of sterilisers

Section Two: Types of sterilisation used in healthcare facilities

Section Three: Selecting a steriliser

Section Four: Porous load sterilisation

Section Five: Loading the loading trolley prior to sterilisation

Section Six: Sterilisation of RMD

Section Seven: Criteria for the release of processed RIMD

Section Eight: Post sterilisation release/inspection

Section Nine: Sterilisation Records

Section Ten: Monitoring and Control

Section Eleven: Maintenance

Section Twelve: Validation

Section Thirteen: Sterilisers and the Medical Devices Directive

Section Fourteen: Commissioning

Section Fifteen: Performance Qualification

Section Sixteen: Periodic Testing

Section Seventeen: Revalidation

Section Eighteen: Wrapped RIMD

Section Nineteen: Chemical and Biological Indicators

42.4 Procedure

Section One: Two groups of sterilisers

1. Clinical sterilisers which are designed to process medical devices or other products which are used in the clinical care of patients.
2. Laboratory sterilisers which are designed to process products not directly used on the patient*.

* Note: Laboratory sterilisers are not included in this document.

Section Two: Types of sterilisation used in health care facilitates

- Porous load steriliser (High temperature steam sterilisation).
- Hydrogen Peroxide and Plasma.

Section Three: Selecting a steriliser

When selecting a sterilisation process for a given RIMD the following should be taken into consideration:

- Is sterilisation required (see Table 7-1)
- Will the RIMD be damaged by exposure to the process?
- Will the RIMD fail to sterilise when exposed to the process?
- Have certain sterilisation processes been excluded by health and safety considerations i.e. ethylene oxide, formaldehyde?
- What are the manufacturers recommendations?
- Is the item single-use?

Section Four: Porous load sterilisation

- High temperature steam sterilisation is used to process porous loads and is usually known as porous load sterilisation. Its economy and lack of toxicity gives it an advantage over other sterilisation methods. Porous load sterilisation (class IIA medical device) is the most common and the preferred method of sterilisation used in the NHO.
- In porous load sterilisation the combination of heat and moisture maintained at a pre determined temperature-pressure-time relationship, coagulate cell protein, efficiently killing the microorganisms. Both porous and non porous materials are sterilised in a porous load sterilisers.
- The operating cycle of a porous load steriliser generally has five stages:
    i. Air removal.
    ii. Steam admission.
    iii. Holding time.
    iv. Drying.
    v. Air admission.

Section Five: Loading the loading trolley prior to sterilisation

a. Equipment

- Loading trolley.
- Manual and/or electronic tracking system and accessories i.e paper, pen, scanner.
- Batch control labeller.

b. Procedure

- Wear PPE.
- Ensure that that the load compatible with the process to which it is to be exposed.
- Loading must allow for free circulation of steam around each pack and each item.
- RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
- Always place heavy RIMD below the light RIMD to avoid the condensate wetting the light RIMD

- Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.
- Hollowware should be placed upside-down or tilted, to prevent collection of condensate.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the steriliant into and out of the package.
- Containers should be loaded onto the trolley such that an air space is formed between each container layer.
- When using the basket system ensure the appropriate size basket is used select the height of the basket so that there will always be a few centimetre air gap between the pack and the basket above.
- When loading ensure that each RIMD has a sterilisation label with correct details.
- When loading ensure that each RIMD has a RIMD identification label and a batch control number.
- When loading is complete each item on the loading trolley should be recorded either using a manual tracking system and/or electronic tracking system.
- Load the steriliser using the loading trolley.
- Never let the RIMD touch the chamber walls since it will cause the RIMD to become wet.
- Doors should be open only when loading and unloading. On open door will cause the chamber to cool down and may cause condensation during the subsequent process.
- It is important that manufacturers' instructions are followed for loading.
- Overloading of sterilisers may compromise the process

Section Six: Sterilisation of RIMD

a. Procedure

- Wear PPE.
- Ensure that any checks and test that are to be carried out prior to sterilisation have been complete and have passed (see Table X).
- Where single door steriliser is in use a system must be in place to ensure segregation of unsterile and sterile RIMD.

- Where double doors are used it should not be possible to open the door on the processed side until a load has completed the process cycle, except for maintenance purposes.
- The steriliser door/s should be kept closed when the steriliser is not in use.
- Before commencing a sterilising cycle, ensure steriliser door is closed.
- Select a validated cycle programme suitable for the load being processed.
- Ensure the load is suitable for the process to which it will be exposed.
- Manufacturers written instructions for operating the steriliser should be followed.

  When cycle is complete steriliser is emptied using the unloading trolley (where applicable).

Section Seven:Criteria for release of processed RIMD

In order to release processed RIMD evidence is required to ensure that the process cycle is complete.

a. Parameter release

- When cycle is complete post sterilisation inspection is carried out to verify that the sterilisation cycle has completed with defined, validated critical parameters (VCP).
- Parameter release should show evidence that the RIMD were subjected to a process and have met all-processing variables achieved during performance qualification.
- During holding time parameters must be:
  i. Within recommended temperature bands for porous load sterilisation outlined in Table 42-4a
  ii. Within the minimum holding time outlined in table 42-4a

b. Non-parameter release

- Non-parameter release involves the use of external chemical indicators, e.g. indicator tape.
- Steriliser indicator tape, indicating labels or an indicating printed message should be affixed to all items sterilised.

- The external chemical indicator will visually denote that the package has been exposed to the physical conditions present in the steriliser.
- Chemical indicators do not indicate sterilisation.
- Chemical indicators are evidence that the load has been exposed to the conditions of the sterilising process.
- Chemical indicator should change colour (follow manufacturers instructions).

Section Eight: Post sterilisation release/inspection

Post sterilisation inspection is carried out to ensure that:

- Parameters are checked by the identified responsible person, to ensure cycle variables are within predetermined specifications (see Table X).
- Correct colour change of the external chemical indicator.
- Integrity of the outer wrap (visual inspection for i.e. dryness, torn wrap).
- Integrity of seals.
- Non-recorded cycle is deemed as a failure of the process.
- Failure of the cycle to meet the physical specification or indicator to meet its specified requirements must lead to the sterilisation load being placed in quarantine and the cause of failure investigated and documented.
- If the integrity of the packaging is in doubt the sterilised load is regarded as non-sterile and item must be placed in quarantine and the cause of the failure investigates, documented and RIMD reprocessed.
- Process parameters outside their specified tolerance must lead to the item being placed in quarantine and the cause of the failure investigated and documented . All RIMD should be reprocessed.
- All records should be retained in accordance with the NHO medical records retention policy (draft)
- ***Note: Sterile products are the result of a well packaged load in a well operated steriliser, running the right process***

Section Nine: Sterilisation Records

Sterilisation cycle record should contain a the following information for each sterilisation cycle but is not limited to:

- Steriliser identification number code.
- The specific content cycle load number.
- Name of the loading operator.
- Type of cycle used.
- Date and time of start of cycle.
- The specific content of the load, e.g. general instrument set, stitch set, mayo scissors.
- Critical parameters for the specific steriliser cycle, exposure time, temperature and pressure.
- Signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.
- Any notes or observation for the process cycle.
- Read out results of physical, chemical or biological indicators that are used.
- All records should be maintained for a period of time recommended by the NHO.
- ***Note: Not recorded is considered not done.***

Section Ten: Monitoring and control

- 134°C is the preferred sterilisation temperature. For RIMD, which may be damaged at 134°C, any of the other lower temperature bands may be used.
- Sterilisation cannot be confirmed by inspection and testing of the product. Thus the sterilisation processes have to be validated before use, the performance of the process monitored routinely and the equipment maintained. The purpose of routine monitoring and control is to demonstrate that the validated and specified sterilisation process has been completed.
- There should be evidence through measurements, supplemented as necessary by biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
- Routine monitoring and testing should be carried out in accordance with documented procedures in line with I.S. EN ISO 17665 part 1 (check IS status)

Table 42-4a Recommended sterilisation temperature bands for porous load sterilisers

Sterilisation Temperature	**Maximum Allowable Temperature**	**Minimum Holding Time**
121°C-134°C	124°C-137°C	Up to 3 minutes

Section Eleven: Maintenance

- Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers instructions, European standards.
- The procedure for each planned maintenance task and the frequency at which it is carried out shall be specified and documented.
- The steriliser must not be used to process RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all tests, checks and maintenance are to be retained as specified in ISO 14937:2000(E), 4.3.4.
- A nominated **qualified** person should review the maintenance plan maintenance procedures and maintenance records periodically.
- A record of mechanical testing, repairs and preventative maintenance should be recorded in a logbook for each steriliser. Records should be maintained in a designated storage area for a period of time recommended by the NHO.

Section Twelve: Validation:

Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that a steam sterilizer is functioning correctly and that it will produce sterilised loads consistently. 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 autoclave chamber and the load during every cycle.

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

- Commissioning.
- Performance qualification (revalidation).
- Periodic testing (operational qualification).
- Continuous Validation during Sterilizer Life cycle.

Table 42-4b: Pressures, temperature bands, holding times for steam sterilisation

Approximate Pressure	Temperature Range	Minimum Holding Time
2.25	134-137	3
1.50	126-129	10
1.15	121-124	15

Section Thirteen: Sterilisers and the Medical Devices Directive

The medical device directive which came into force on June 14th 1998, provides rules for classifying medical devices into one of four classes, depending on the hazard which a defective device would cause to a patient. (Class I: least hazard, Class IIa , Class IIb; Class III: most serious hazard). Sterilizers for use in clinical environment for reprocessing RIMD are considered therefore as medical devices (Class 11a).

Section Fourteen: Commissioning

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications by the supplier, that it is safe to operate and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions. It consists of:

Installation checks and tests

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

Commissioning tests

- Air leakage test.
- Thermometric test.
- Calibration.
- Steam Penetration test.
- Microbiological tests (recommended).

- These tests should be carried out when a new sterilizer is purchased or when a used sterilizer has been relocated to another premises.
- The tests should be carried out before the sterilizer is used for the first time. Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of sterilizers.
- Data from the commissioning tests provide assurance that sterilising conditions are attained through most loads, i.e. the autoclave is functioning correctly.
- Even though the manufacturer should have tested a steam autoclave before it left the factory, there is no guarantee that it will function correctly following delivery.
- Therefore, it must be tested before use to ensure that it is working correctly.

Section Fifteen: Performance Qualification

Performance Qualification is required to show that sterilising conditions are attained even for loads and test loads that are assessed by the user to be difficult to sterilise. Performance Qualification is indicated for initial use of a new/relocated sterilizer or when the load profile changes (e.g. new instruments). It should be carried out by a Test Person (or suitably qualified person). These tests consist of:

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

Section Sixteen: Periodic Testing

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

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

a. Daily Test—Steam Penetration Test /Bowie Dick (EN 867-4)

i. Introduction

The steam penetration test is intended to show that steam will penetrate rapidly and evenly into a test device that is at least as difficult to sterilise as the intended load. The test device contains an indicator that responds (usually it changes colour – and should do so completely) only when steam penetration is adequate. It is essential to use both the steam penetration test device and the indicator specified by the autoclave manufacturer, otherwise the test results may be dangerously misleading. The test device and the indicator should be as specified in EN 867, or an alternative, provided that it is equivalent (see section on chemical and biological indicators). If a cycle is provided specifically to test the effectiveness of steam penetration, it must have the same air removal stage as used during routine sterilisation cycles.

ii. Test Procedure

- A standard test device should be placed in the chamber, in the position specified by the sterilizer manufacturer.
- The sterilisation temperature for the operating cycle to be tested should be selected – this should be the highest temperature compatible with the load. The cycle should be commenced.
- A batch (cycle) process record should be made in the sterilizer log book.

b. Weekly Tests

The user should perform safety checks before starting the sequence of weekly tests. The schedule of weekly tests is summarised in Table 42.4c.

Table 42.4c: Summary of Weekly Tests (Note: All tests can be combined into one test)

Weekly Checks/Tests	Steriliser (Vacuum)
Safety Checks	Yes
Air Leakage Test (automatic)	Yes
Automatic Air Detection Systems Function Test	Yes
Automatic Control Test	Yes
Steam Penetration Test	Yes

1. Safety Checks

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

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

No attempt should be made to open the door while the chamber is pressurised.

Any defects must be corrected before attempting to perform the weekly tests or before using the sterilizer.

2. Air Leakage Test

- The air leakage test is intended to check that air does not leak into the steriliser during periods of vacuum, at a rate that is greater than that specified by the autoclave manufacturer.
- Air leaking into the chamber can impair steam penetration into the load and prevent sterilisation and/or recontaminate the damp load during the drying phase.
- Air is first removed from the chamber until the pressure is the lowest achieved in all of the cycles available on the sterilizer and then the vacuum source is isolated and all valves connected to the chamber are closed.
- The absolute pressure is measured at the end of the vacuum stage. Any subsequent rise in the chamber pressure will be caused by air leaking into it - and the rate of pressure rise in the chamber is measured.
- Ideally the steriliser/autoclave should be equipped with an automated test cycle so that the user can do the test. If there is not an automatic test facility, a Test Person should do the test using special, calibrated instruments.

The pass/fail criteria are:

- The absolute pressure at the end of the air removal stage should be within the limits specified by the manufacturer and the rate of pressure rise should not be greater than 1.3 mbar per minute.
- A machine that fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.

3. Automatic Air Detection Systems Functions Test

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

4. Automatic Control Test

- The purpose of this test is to verify that all the operational components of the steam autoclave are satisfactory and that no anomalies are observed.
- The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the autoclave was known to be working correctly, e.g. immediately after the Test Person had tested it using calibrated instruments.

- The test should be performed using the sterilising cycle with the highest temperature compatible with the load. If the autoclave does not have a recorder, the following parameters should be noted during the sterilising (holding) stage of the cycle:

i. Chamber temperatures and pressures indicated on the gauges, their maximum values and its duration in minutes and seconds.

ii. The values noted, or the values on the print out should be compared with those on the master process record.

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

   a. The chamber temperature and pressure is within the limits of the appropriate band, for the duration of the holding time, as specified in Table 42-4b.

   b. A visual display of 'cycle complete' is indicated.

   c. No mechanical or other anomaly is observed.

- The test is not required if the sterilizer is equipped with a recorder that provides a permanent record of the temperature, pressure and elapsed time during all sterilising cycles.

- Verification should be sought from the manufacturer as to whether it is necessary to pre-heat the autoclave chamber before performing these tests, as this can extend the test time.

5. **Test Procedure for Automatic Control Test of a Sterilizer without a cycle recorder**

- The elapsed time, and indicated chamber temperatures and pressures at all significant points of the operating cycle, e.g. the beginning and end of each stage or sub-stage, and the maximum values during the holding time should be observed and recorded.

- The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be recorded.

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

6. **Test Procedure for Automatic Control Test of an Sterilizer with a cycle recorder**

- The recorder should make a batch process printout. The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be noted.
- All the parameters recorded should be compared with the parameter results obtained during the commissioning qualification.

c. Quarterly Tests

These require specialised test equipment and only a person (e.g. a Test Person or equivalent) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate. Quarterly tests for vacuum sterilizers are summarised in Table 42.4d.

Table 42.4d: Summary of Quarterly Tests for Vacuum Sterilizers

Test Description	Steriliser (Vacuum)
Safety Checks	Yes
Air Leakage Test (automatic)	Yes
Air Leakage Test (manual) (temperature and pressure sensors con-	Yes
Automatic Control Test	Yes
Verification of Calibration of Autoclave Instruments	Yes
Air Detection System Performance Test for a Small Load	Yes
Thermometric Test for a Small Load	Yes
Thermometric Test for a Solid Load	Yes
Tests for Performance Requalification (as required)	Yes
Air Leakage Test (automatic) (sensors removed)	Yes
Air Detector System Function Test (automatic)	Yes
Steam Penetration Test	Yes

d. Annual Tests

These require specialised test equipment and only a person (e.g. a Test Person or equivalent) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during validation remain consistent and accurate. Annual tests for vacuum autoclaves are summarised in Table 42-4e.

Table 42-4e: Summary of Annual Tests for Vacuum Sterilizers (EN285)

Test Description	Steriliser (Vacuum)
Safety Checks	Yes
Air Leakage Test (automatic)	Yes
Air Leakage Test (manual) (temperature and pressure sensors connected)	Yes
Automatic Control Test	Yes
Verification of Calibration of Autoclave Instruments	Yes
Chamber Wall Temperature Test	Yes
Steam Generator Overheat Cut-Out Test	Yes
Air Detection System Performance Test for a Small Load	Yes
Air Detection System Performance Test for a Full Load	Yes
Thermometric Test for a Full Load	Yes
Porous Load Dryness Test	Yes
Thermometric Test for a Small Load	Yes
Thermometric Test for a Solid Load	
Solid Load Dryness Test	
Tests for Performance Requalification (as required)	
Air Leakage Test (automatic) (sensors removed)	
Air Detector System Function Test (automatic)	
Steam Penetration Test	
Steam Quality if Requested	

Section Seventeen: Revalidation

Revalidation comprises re-commissioning and performance re-qualification. It is required after sterilizer relocation, engineering work, repair work, software control function modifications and when required by the user. Some examples of requirement for revalidation are:

- Adjustment to Steam controls.
- Adjustment to Micro processor controls.
- Adjustment to control parts.

Section Eighteen: Wrapped Devices

- Items within suitable packaging can only be regarded as sterile if they have been subjected to a validated sterilisation process and a post sterilisation drying cycle.
- Sterile pouches should be stored in a clean, dry area, which is secure, dust free and off floor level. Pouches should be labelled with the date of sterilisation and cycle number and should be stored and used in sequential order.
- Pouches should be inspected for damage before they are opened. If there is any sign of damage to the packaging, the contents should be re-sterilised before they are used.
- If instruments are not used within 3 months of processing, resterilisation is recommended.

Section Nineteen: Chemical and Biological Indicators

- Chemical indicators are designed to show by a change of colour whether a specified sterilisation conditions have been attained.
- Chemical indicators should meet the requirements of relevant standards (e.g. EN 867, ISO 11140) and they should be used for each load.
- The type used should be in accordance with the manufacturers' recommendations. Instructions should be followed precisely in relation to use and storage.
- The use of an inappropriate indicator may give dangerously misleading results; indicator performance can be adversely affected by the storage conditions and methods of use.

- Indicators should not be used beyond their expiry date. Three types of chemical indicator are commonly used in steam autoclaves:

i. **Process indicators—**e.g. autoclave tape and indicators printed onto bags and pouches. These indicators serve only to distinguish processed items from unprocessed items, and should not be used for any other purpose.

ii. **Integrating indicators—**(emulating integrators) are available for monitoring steam autoclaves. They are designed 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. Integrating indicators do not indicate sterility of the product.

iii. **Biological indicators—**are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained. Biological indicators must meet the requirements of the standard BS EN 866 (BSI 1997). They are of limited value in steam sterilisation and are restricted to a few special applications e.g. in process validation. In those applications they should always be regarded as additional to the measurement of temperature, pressure and time.

43 Storage

43.1 Introduction

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

43.2 Scope

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

43.3 Contents

Section One: Storage Areas

Section Two: Storage Equipment

Section Three: Shelf Life/Rotation of Stock

Section Four: Non-conforming stock

43.4 Procedure

Section One: Storage Areas

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

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

1. Processed goods store

The processed goods store should be located near the cooling bay in the sterilization area and with access to the despatch area. This store is for RIMD produced by the department and RIMD which have been commercially manufactured and sterilized.

- The outer casing must be removed from RIMD which have been commercially manufactured and sterilised – if stored in the same store as those RIMD which have been produced by the department.
- Processed RIMD must be stored separately from raw materials.
- Loose, processed RIMD should be stored separately from those packed in cases.
- Storage areas should be kept secure and access should be restricted to authorised personnel.
- Accommodation should be designed in accordance with HBN 13 requirements.
- Sterile materials should be stored at least 8 to 10 inches from the floor, at least 18 inches from the ceiling, and at least 2 inches from outside walls.
- The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.
- Medical and surgical supplies are not to be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.
- Storage of supplies on floors, window sills, and areas other than designated shelving, counters or carts must be avoided.

2. Raw Materials Store

The storage area is for the reception, storage and supply of all non-sterile materials including textiles and where appropriate, bulk cased supplies of commercially sterilized RIMD. The raw materials store should be located between the goods reception and the Clean Room area.

- Materials should be segregated and stored separately according to their specific requirements.
- Sterile RIMD must not be stored in this area (unless supplies are bulk cased).
- Single items should be stored separately from those in cases.
- Storage areas should be kept secure and access restricted.
- Accommodation should be designed in accordance with Health Building Note 13 requirements.

Section Two: Storage Equipment

a. General Principles

- Sterile items must not be stored anywhere but on or in designated shelving, counters, or containers, because other areas may not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside.
- Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that may form on the interior surfaces of outside walls.
- Compression of packages can force air and micro organisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it micro organisms from the air and surfaces.

b. Shelving and Racking

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

c. Closed or covered cabinets

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

Section Three: Shelf Life/Rotation of Stock

- General factors which influence shelf life are event related and include the following:

    i. Packaging materials.

    ii. Storage and handling conditions.

    iii. Likelihood of product material deterioration.

    iv. Package design.

- Each hospital should develop a system of stock rotation based on the date of sterilization. Good management practices demand that stock be maintained at adequate levels.

- As a "rule of thumb", product which has remained unused for more than six months should be deemed to be a product of over-stocking and an assessment undertaken as to its future need.

- There are occasions where devices must form part of emergency stocks and as a result may not be used within this time frame. Procedures should be put in place to ensure that these products are subject to a reprocessing regime over time.

Section Four: Nonconforming Stock

- A package shall be considered nonconforming, i.e. non sterile and not suitable for use when:

    i. It is incorrectly wrapped.

    ii. It is damaged or opened.

    iii. The product is outside the expiry date.

- The sterilisation chemical indicator tape does not confirm that the pack has been subject to an appropriate sterilisation process.

44 Transportation – of sterile items

44.1 Introduction

Sterile devices should be transported in a manner that will not compromise their status. Loss of sterility is event related and depends on the amount of handling, conditions during transportation and storage, and the quality of the packaging material.

44.2 Scope

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

44.3 Contents

Section One: General Principles

44.4 Procedure

Section One: General Principles

- Sterile RIMD must be transported in clean dry conditions in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage to devices and flexible packaging.
- Sterile RIMD should be transported in covered or enclosed carts with solid-bottom shelves.
- Sterile items placed in covered or enclosed carts will be protected from exposure to environmental contaminants along the transportation route.

45 Single-Use Instruments

45.1 Introduction

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

45.2 Scope

The objective of this procedure is to provide guidelines in relation to single-use instruments.

45.3 Contents

Section One: General Principles

45.4 Procedure

Section One: General Principles

- To avoid cross-contamination between patients, single-use instruments should be used wherever this is practical.
- Single-use items should be used for a single patient and not reused on subsequent patients. Patient care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- Instruments intended for single-use and labelled 'single-use' by the manufacturer should be disposed of after use.
- Users who disregard this information and prepare single use products for further use, are transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them and have become the manufacturer of the device.
- The symbol for single use instruments is as given in ISO EN 980:2003.
- Synonyms for "do not reuse" are "single use", use only once".
- See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).

46 Repair, loan and disposal of RIMD

46.1 Introduction

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

46.2 Scope

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

46.3 Contents

Section One: General Principles

Section Two: Procedure for loaning and borrowing RIMD

46.4 Procedure

Section One: General Principles

- All RIMD intended for inspection, service, repair, loan or transportation must be decontaminated before despatch and must be accompanied by a certificate stating the method by which they were decontaminated.
- All RIMD must be reprocessed using the manufacturers' instructions.
- Loaned RIMD must be accompanied by relevant reprocessing instructions (including dissemble and reassemble instructions where relevant) and a list of contents.
- All loaned RIMD must be checked for functionality, safety checks and repairs at the inspection/function/assembly point and signed off accordingly.
- Loaned RIMD must be registered, including ownership, service history, current location, service responsibility and instructions for use.
- If items are dispatched to suppliers, loaned or presented for service or inspection on hospital premises without a declaration of contamination status and without prior agreement, suppliers may refuse to handle such items until they have been decontaminated and a declaration provided. This may result in delays and/or additional costs.
- RIMD that are being scrapped should be transported and destroyed by known, reliable contractors who will certify their destruction.

Section Two: Procedure for loaning and borrowing RIMD

1. Loaning of Instruments

a. Requests

- All requests for the loan of RIMD must be made directly by xxx to xxx in the hospital, which owns the RIMD.

b. Documentation

- Loaned RIMD must be accompanied by the following documentation:
    i. Contents list.
    ii. Decontamination certificate.
    iii. Reprocessing instructions, including disassembly and reassembly, where relevant.

c. Log Book

- Details of all RIMD which are loaned to other institutions should be entered into a log book detailing:
    i. Name and description of the RIMD.
    ii. RIMD identification number.
    iii. Name of the person to whom the instrument is being loaned.
    iv. Identity of the institution where RIMD are being sent.
    v. Identity of the person who is making the loan.

d. Arrangements for return of RIMD

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

48 Risk Management

48.1 Introduction

All premises, equipment and processes used to decontaminate re-usable medical devices contain elements of risk and hazards which need to be identified, monitored, controlled and managed.

48.2 Scope

The objective of this procedure is to provide risk management guidelines in relation to the decontamination of RIMD.

48.3 Contents

Section One: Risk Management System

Section Two: Risk Management Elements

48.4 Procedure

Section One: Risk Management System

The NHO has a risk management system in place identify risks associated with the decontamination of RIMD through the following:

- Risk Assessment (Clinical & H&S).
- There is prospective review of each process and the equipment and chemicals used to identify, analyse and prioritise the hazards for likelihood of occurrence and impact.
- To identify the necessary actions to be undertaken to eliminate or minimise the potential to cause harm.
- The risk assessment to be reviewed when:

i. There is a change in the task or activity

ii. The result of health surveillance

iii. A confirmed case of occupational disease/illness

iv. Results of a monitoring exercise

v. Occurrence of an adverse event or near miss

vi. New equipment or technology is introduced

- Incident Reporting:
    i. To the Hospital Management Team.
    ii. Reporting clinical adverse incidents to the Clinical Indemnity Scheme (CIS).
    iii. Reporting dangerous occurrences to the Health & Safety Authority (HSA).
    iv. Reporting adverse incidents involving medical device defects to the Irish Medicines Board (IMB).
    v. Reporting incidents to the Health & Safety Authority (HSA) in respect of employees.
- Incident Review.
- Medical Device Safety Notices from the Irish Medicines Board (IMB).
- Audit Reports.
- Internal & External Inspections.

Section One: Risk Management Elements

The following risk management elements should be in place:

- All identified risks should be documented as part of a risk register and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented in order of priority and alongside other risk treatments which are necessary to deal with the wider risks faced by the organisation.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed frequently.
- Senior hospital management should be informed of any significant risks and associated risk management plans.
- All relevant staff, including those on a fixed contract and other relevant stakeholders should receive information on systems in place to minimise risk of the decontamination process.
- MSDS should be made available to all staff who are using potentially hazardous chemicals.
- Staff training must be undertaken.

49 Adverse Reporting

49.1 Introduction

To ensure patient safety and compliance with the Health & Safety Act 2005 and S.I. 252 of 1994, the hospital must establish recall procedures to expedite to retrieval of reprocessed items that are suspected to be non-sterile/contaminated and to ensure adequate follow-up actions, such as quarantine of the sterilisers/instruments, notification of physicians and surveillance of patients.

49.2 Scope

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

49.3 Contents

Section One: Policies and Procedures

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

49.4 Procedure

Section One: Policies and Procedures

- Written policies and procedures for the recall of supplies must be developed in cooperation with the infection control and risk management committees of the hospital.
- These policies and procedures must be documented and records must be maintained.
- Whenever there is evidence of sterilisation failure/instrument contamination the infection control nurse and risk manager should be notified so that follow-up surveillance of patients can be conducted.

Section Two: Recall procedure

A recall procedure must:

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

Section Three: Recall order

A recall order must:

- 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 b y the person or persons receiving the order (e.g. destruction or return of product).

Section Four: Recall report

A report of a recall order must:

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

50 Customer Complaints

50.1 Introduction

Xxx

50.2 Scope

The objective of this procedure is to provide guidelines in relation to dealing with customer complaints.

50.3 Contents

Section One: Complaints System

Section Two: Complaints Process

Section Three: Advisory Notices and Product Recall

50.4 Procedure

Section One: Complaints System

The documented complaint system should cover:

- The person(s) responsible for operating the system.
- Evaluation of the complaint.
- Records and statistical summaries enabling the major causes of complaints to be determined.
- Corrective action.
- Segregation and disposition, or reprocessing of customer returns and faulty stock (special attention may need to be given to decontamination).
- Filing of customer correspondence and other relevant records (ref. NHO records retention policy).

Section Two: Complaints Process

Corrective action should be implemented without undue delay when a finished product is found to be defective or is subject to adverse reports; such action may include one or more of the following:

- Withholding products available for sale.
- Withdrawing products from circulation.
- Giving advice to customers; this may take the form of checks to be carried out before use, providing additional guidance on the use of the product or for the replacement of certain products.
- In extreme cases, the recall of products.

Section Three: Advisory notices and product recall

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

51 Environmental Cleaning

51.1 Introduction

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

51.2 Scope

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

51.3 Contents

Section One: Cleaning Equipment

Section Two: Cleaning Frequency

Section Three: Floor cleaning equipment and method

Section Four: Floor Cleaning Agents

Section Five: Spillage Kits

Section One: Cleaning Equipment

- There should be a separate cleaner's utility room for the clean and dirty areas.
- All cleaning equipment should be segregated for the clean area/dirty area.
- Regular maintenance and cleaning of cleaning equipment is required.

Section Two: Cleaning Frequency

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

Section Three: Floor Cleaning Equipment and Method

The following floor cleaning equipment and method shall be used:

- Mop and bucket using 'two bucket' system and a free rinsing detergent (see NHO Cleaning Manual).
- Vacuum fitted with HEPA filtered exhaust.
- Rotary scrubbers and polishers should not be used (unless all devices are first removed from the area and all horizontal work surfaces are cleaned after the floors).
- Floors should be cleaned daily and also cleaned when visibly soiled.

Section Four: Floor Cleaning Agents

The following **floor cleaning agents** shall be used:

- Free rinsing neutral detergent.
- Disinfectants are not required.
- If visible blood/body fluids are present, disinfectants should be used following thorough cleaning.
- Disinfectants should be made up according to the manufacturers' instructions/ hospital policy.

Section Five: Spillage Kits

- The dirty areas should be equipped with spillage kits to contain and remove spillages of blood and body fluids.
- 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 supplied by the process chemical manufacturer).

52 Communication

52.1 Introduction

Each hospital should develop a communication plan and process in order to increase awareness of its infection control programme and to increase the level of compliance with the programme throughout the hospital. Increasing awareness will facilitate the staff and patient cooperation required to minimise cross-infection.

52.2 Scope

The objective of this procedure is to provides guidelines in relation communication of the hospital infection control programme.

52.3 Contents

Section One: Health Care Workers (HCWs)

Section Two: Patients

52.4 Procedure

Section One: Health Care Workers

- Each hospital should develop and communicate its infection control objectives to HCWs.
- HCWs should be allowed an opportunity to provide feedback on these objectives.
- These infection control objectives should be reflected in each departments business plans.
- Regular reviews should be undertaken to ensure that business plans are translated into action.

Section Two: Patients

- Each hospital must communicate the reasons for their infection control policies and procedures to their patients.
- Each hospital must inform their patients about the risks associated with medical and surgical treatment.
- Educational material should be provided using a variety of different media.
- Patients should be encouraged to use feedback procedures to the hospital for any concerns they have in relation to infection prevention and control.

Part Four

Additional Resources

Contents – Part 4

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55 Standards and Guidance on which the NHO draft standards and recommended practices 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 (42/93/EEC) they have been published in the Official Journal of the European Union as harmonized standards. In addition, the Health Departments of a number of countries and various professional bodies and trade associations have published guidance on best practice for decontamination of RIMD. The list below is not exhaustive but includes the key documents that may be used to inform the management of decontamination of RIMD within a health service environment.

55.1 Legislation

Directive 42/93/EEC

55.2 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

ii. Disinfectant standards

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

EN 13627:2003 Chemical disinfectant and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area. Test method and requirements (phase 2/step 1)

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

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

iii. Equipment standards

Sterilizers

EN 285:2006 Sterilization. Steam sterilizers. Large sterilizers

EN ISO 13060: 2004 Small steam sterilizers

EN 1422:1998 Sterilization of medical device. Ethylene oxide sterilizers. Requirements and test methods

EN 14180:2003 Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers**.** Requirements and testing

Washer-disinfectors

EN ISO 15883-1: 2006 Washer-disinfectors — Part 1: General requirements, definitions and

tests

EN ISO 15883-2: 2006 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc.

PD CEN ISO TR 15883-5 : 2005 Washer-disinfectors – Part 5 Test soils

iv. Management

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

PD CEN ISO/TR 14969:2004 Medical devices - - Quality management systems - Guidance on the application of EN ISO 13485:2003

v. Materials

Biological indicators

EN ISO 11138 series Biological systems for testing sterilizers and sterilization processes.

EN ISO 14161:2001 Sterilization of health care products. Biological indicators. Guidance for the selection, use and interpretation of results

Chemical indicators

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

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

EN ISO 15882:2003 Sterilization of health care products. Chemical indicators. Guidance for selection, use and interpretation of results – Not in stock

Packaging

EN ISO 11607-1: 2006 Packaging for terminally sterilized Medical Devices – Part 1 Requirements for materials, sterile barrier systems and packaging systems.

BS EN 868-2:1999 Packaging materials and systems for medical devices which are to be sterilized. Sterilization wrap. Requirements and test methods

BS EN 868-3:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5). Requirements and test methods

EN 868-4:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper bags. Requirements and test methods

EN 868-5:1999 Packaging materials and systems for medical devices which are to be sterilized. Heat and self-sealable pouches and reels of paper and plastic film construction. Requirements and test methods

EN 868-6:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation. Requirements and test methods

EN 868-7:1999 Packaging materials and systems for medical devices which are to be sterilized. Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation. Requirements and test methods

EN 868-8:1999 Packaging materials and systems for medical devices which are to be sterilized. Re-usable sterilization containers for steam sterilizers conforming to EN 285. Requirements and test methods

EN 868-9:2000 Packaging materials and systems for medical devices which are to be sterilized. Uncoated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids. Requirements and test methods

EN 868-10:2000 Packaging materials and systems for medical devices which are to be sterilized. Adhesive coated nonwoven materials of polyolefines for use in the manufacture of heat sealable pouches, reels and lids. Requirements and test methods

vi. Medical devices

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

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

EN 1041:1998 Information supplied by the manufacturer with medical devices

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

vii. Processes

Sterilization

EN ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

EN ISO 11737-1:2006 Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products

EN ISO 14937:2001 Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

viii. Safety

EN 61010-2-041:1997 (Dual no: IEC 61010-2-041:1995) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using steam for the treatment of medicinal materials, and for laboratory processes

EN 61010-2-042:1997 (Dual no: IEC 61010-2-042:1997) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using toxic gas for the treatment of medicinal materials, and for laboratory processes

EN 61010-2-043:1998 (Dual no: IEC 61010-2-043:1997) Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using either hot air or hot inert air for the treatment of medicinal materials, and for laboratory processes

EN 61010-2-045:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields

EN ISO 13848-2:2003 Safety machinery. Safety-related parts of control systems. Validation

55.3 UK Guidance Documents

HBN13 Sterile Service Departments

HTM 2010 Sterilizers

HTM 2030 Washer Disinfectors

HTM 2031 Steam for sterilization)

MAC Manual 2006;

MDA SN 1999 (32) Storage of sterile medical devices

MDA SN 2000 (18) Handling of surgical instruments on loan from another organization

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

MDA SN 9701 Reporting adverse incidents relating to medical devices

MDB 9801 Medical Device and Equipment Management for Hospitals and Community based Organizations

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

MDB 2000(05) Purchasing, etc of benchtop vacuum sterilizers

MDB 2000(04) Re-use of single-use devices

MDB 2003(05) Management of medical devices prior to repair, service or investigation

The Joint Transmissible Spongiform Encephalopathy (TSE) Working Group of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee Joint Working Group http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm

56 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 of foreign matter (or both) from contaminated materials or living tissue. Three processes of decontamination are commonly used; cleaning, disinfection and sterilisation
Disinfectant	A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms; and that is not represented by the manufacturer to be suitable for internal use
Disinfection	The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation
Hazard	A source of potential harm or a situation with a potential to cause loss
Healthcare associated infection.	Infection contracted as a result of health care. Includes iatrogenic infections resulting from medical procedures and nosocomial infections resulting from the patient's presence in a health care establishment.
Health care workers	Refers to all health care professionals, including students and trainees, and employees of health care establishments, who have contact with patients or with blood or body substances from patients.
Incidence (of infection)	Rate at which new cases occur
Invasive procedure	Any procedure that pierces skin or mucous membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities or organs, or repair of traumatic injuries

Medical device	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of: ▪ diagnosis, prevention, monitoring, treatment or alleviation of disease; ▪ diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap; ▪ investigation, replacement or modification of the anatomy or of a physiological process; or ▪ control of conception and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means
Monitor	To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change
Prion	The small proteinaceous infectious unit that appears to cause TSEs
Primary Care	HSE healthcare provision 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 objects capable of inflicting penetrating injury, including needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware
Stakeholders	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity
Standard	Required level of quality
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)

57 Abbreviations

AORN	Association of periOperative Registered Nurses
CE	La Conformité Européenne
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
COSSH	Control of Substances Hazardous to Health
EC	European Community
EN	European Norm
HAS (H&S)	Health and Safety
HBN13	Health Building Note 13
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
MSDS	Material Safety Data Sheets
NHO	National Hospitals Office
NSAI	National Standards Authority of Ireland
PPE	Personal Protective Equipment
RIMD	Reusable Invasive Medical Devices
SSD	Sterile Services Department
TSE	Transmissable Spongiform Encephalopathies
TSSU	Theatre Sterile Services Unit

Part Five

Appendices

Contents – Part 5

Appendix One - Membership of the Steering Committee

Name	Address	Title
Dr. Ronnie Russell	Moyne Institute of Preventative Medicine Trinity College Dublin (Joint Chair)	Applied Microbiologist and Immunologist
Winifred Ryan	National Hospitals Office Health Service Executive (Joint Chair)	Quality Risk & Customer Care
Ann O'Connor	IMB, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2	Medical Devices Director
Sheila Sheahan	Health Service Executive Mid Western Regional Hospital Limerick	Chairperson of the Irish Association of Sterile Services Managers
Mary Owens	Mallow General Hospital Cork	Chairperson of the Irish Association of Directors of Nursing and Midwifery
Caroline Dolan	Portiuncula Hospital, Ballinasloe, Co. Galway	Chairperson of Irish Association of Theatre Managers
Tracy Doherty	Beaumont Hospital, Dublin	Infection Control Nurse representing the ICNA
Donna Roche	Bons Secours Hospital, Co. Cork	Chairperson of the Irish Society of Endoscopy Nurses
Dr Robert Cunney	Health Protection Surveillance Centre, Dublin	Consultant Microbiologist
Dr Anne Gilleece	Connolly Hospital Blanchardstown Dublin	Consultant Microbiologist
Gerry Clerkin	Health Service Executive North East Management Dept Kells, Co. Meath	Risk Advisor
Oonagh Ryan (In attendance)	St Vincents Private Hospital Dublin	Sterile Services Manager
Niall Creggy (In attendance)	Mater Private Hospital Dublin	Sterile Services Manager
Sandra Kehoe (Secretariat)	Health Service Executive	Quality Risk & Customer Care NHO

Appendix Two - Membership of Standards Sub-Group

Name	Address	Title
Winifred Ryan	National Hospitals Office Health Service Executive (Chair)	Quality Risk & Customer Care
Sheila Sheahan	Health Service Executive Mid Western Regional Hospital Limerick	Sterile Services Manager
Caroline Dolan	Portiuncla Hospital, Ballinasloe, Co.	Theatre Manager
Tracy Doherty	Beaumont Hospital, Dublin	Infection Control Nurse
Donna Roche	Bons Secours Hospital, Co. Cork	Chairperson of the Irish Society of Endoscopy Nurses
Alan Cherryman	Health Service Executive Mid Western Regional Hospital Limerick	Technical Services Department
Hugh O'Connor, MBB	St. James' Hospital, Dublin	Authorised Person (Sterilisers)
Wilf Higgins	Department of Health and Children	
Dr Anne Gillecce	Connolly Hospital Blanchardstown	Consultant Microbiologist
Sandra Kehoe (Secretariat)	Health Service Executive	Quality Risk & Customer Care NHO

Appendix Three – List of Consultees

Name	Title	Organisation
Paul Barron	Assistant Secretary	Department of Health & Children
Dr Jim Kiely	Chief Medical Officer	Department of Health and Children
Dr. Anna T Clarke	Dean	RCPI Faculty of Occupational Health
Michael Horgan	Registrar	Royal College of Surgeons of Ireland
Dr. Anna T Clarke	Dean	Royal College of Physicians of Ireland
Dr. Anna T Clarke	Dean	RCPI Faculty of Public Health
Dr Niamh O'Sullivan	President	Irish Society of Clinical Microbiologists
Barbara Fitzgerald	President	Irish Directors of Nursing and Midwifery Association
Sheila Sheahan	Chairperson	Irish Association of Sterile Services Managers
Professor John Crowe	President	Irish Society of Endoscopy Nurses
Caroline Dolan	Chair	Irish Association of Theatre Managers
Marena Burd	Co-ordinator	Infection Control Nurses Association
Professor Hilary Humphries	Chairperson	SARI National Committee
Mr Phil Caffery	Chair	Maintenance Management Association
Cora McGaughan	Quality and Risk Co-ordinator	Health Care Risk Managers Forum
Michael Lyons	Chairperson	DATHs Risk Management Forum
Dr Ailis Quinlan	Head of Clinical Indemnity Scheme	Clinical Indemnity Scheme
Yvonne Finorde	Chairperson	Association of Occupational Therapists in Ireland
Joyce Worrell	Chairperson	Irish Society of Chartered Physiotherapists
Una O'Shiel	Chairperson	Irish Association of Speech & Language Therapy
Paddy Gilligan	Chairperson	Association of Physical Scientists in Medicine
Ann O'Connor	Medical Devices Director	Irish Medicines Board

Appendix Four – Regulations and Guidance

Medical Device

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

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

Medical Devices Directive

Medical Devices are regulated by three main Directives

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

These three Directives:

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

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

Irish Medicines Board

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

Legislation

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

- S.I. No. 253 of 1994 European Communities (Active Implantable Medical Devices) Regulations, 1994which 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.

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'.

Control of Substances Hazardous to Health Regulations (COSHH) 2002

The COSHH Regulations 2002 (COSHH) help protect people in the workplace against health risks from hazardous substances. The substances may be used directly in the work (e.g. cleaning chemicals, chemical reagents) or may arise from work activities (e.g. dusts, fumes and waste products).

COSHH requires the following:

- Assessment of the risks.
- Deciding what precautions are needed.
- Prevention or control of the risks.
- Ensuring that control measures are used and maintained.
- Monitoring exposure and health surveillance, where necessary.
- Informing, instructing and training employees about the risks and precautions needed.

The risk will depend on a number of factors, such as the hazard presented by the substance, how it is used, how exposure is controlled, the degree and extent of exposure etc.