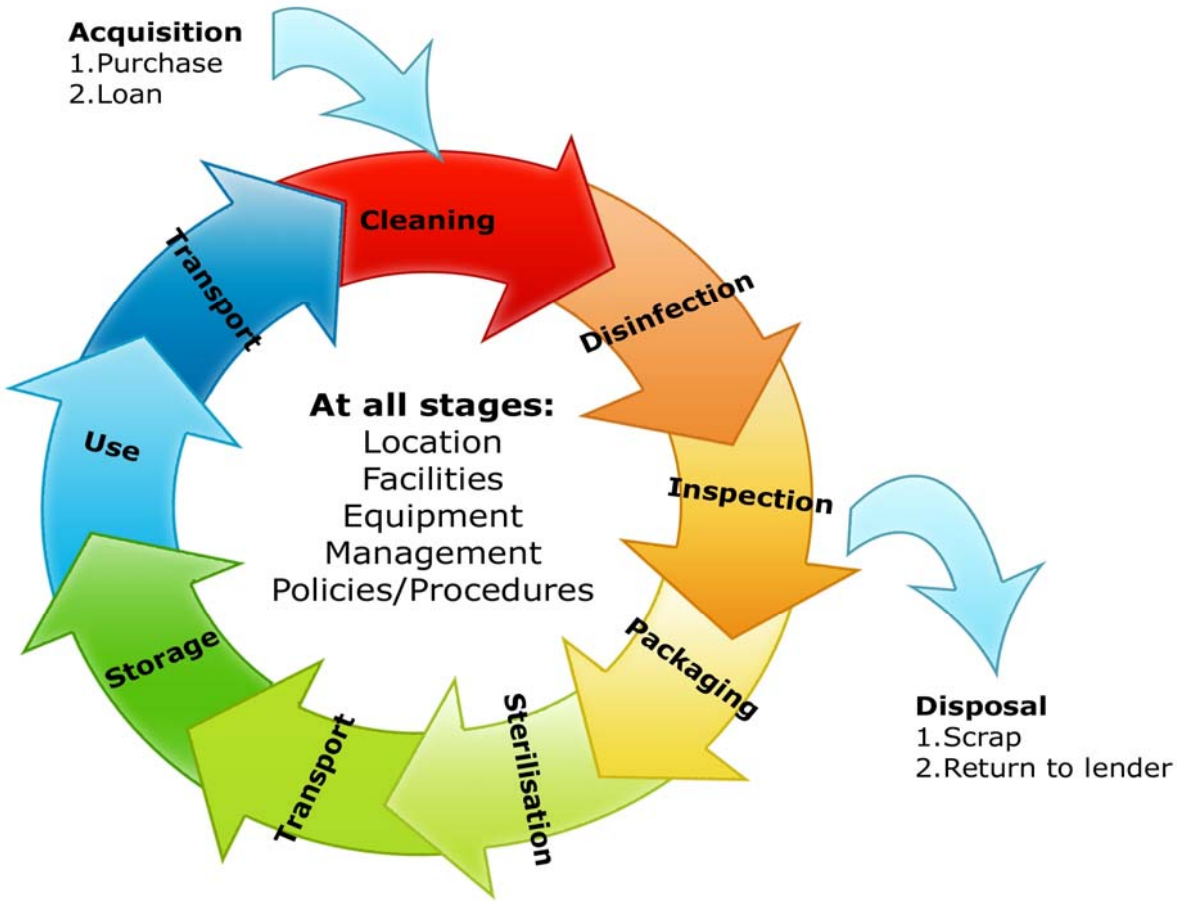
PART 1: BACKGROUND

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



Reader Information

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Superseded Docs:	NA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

Foreword

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

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

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

The Code provides:

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

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

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

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

Contents

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

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

Contents

Contents

Part 3 Recommended Practices for Central Decontamination Units

Contents

Contents

Part 1

Background

Contents – Part 1

Contents

1 Introduction

1.1 Prevention and control of healthcare associated infection

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

1.2 Steering committee

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

1.3 Decontamination process

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

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

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

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

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

1.4 Effectiveness of decontamination

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

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

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

2 Development of decontamination code of practice

2.1 Introduction

The Code of Practice was developed as follows:

- Extensive literature search.
- Consideration of the opinion of experts knowledgeable in the subject.
- Consideration of the available current best practice, both in Ireland and internationally, that may impact on decontamination of RIMD.
- Development of draft Standards and recommended practices for distribution for consultation to key stakeholders.
- Incorporation of feedback, where appropriate into the final version of the Code.

2.2 Definition

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

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

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

Development of decontamination code of practice

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

The Recommended Practices are intended to define correct decontamination practice and to promote patient safety. They are also intended to serve as the basis for policy and procedure development in decontamination services in the Health Service Executive.

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

3 Medical Devices Directive (93/42/EEC)

3.1 Medical Devices Directives

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

The Medical Devices Directive (93/42/EEC) applies to manufacturers placing medical devices on the market. In doing so, it specifies the essential requirements to be met by any medical device. **These essential requirements should be regarded as the minimum acceptable Standard whether or not the decontamination unit qualifies as a 'manufacturer' within the terms of the Directive.**

A Medical Device is defined in the Medical Device Directive (93/42/EEC) as "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with the software necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

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

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

Medical Devices Directive (93/42/EEC)

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

There are four classes of general medical devices as follows:

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

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

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

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

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

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

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

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

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

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

3.3 Placing on the market

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

3.4 In-house manufacture

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

3.5 Particular procedure for systems and procedure packs—Article 12

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

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

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

3.6 CE marking

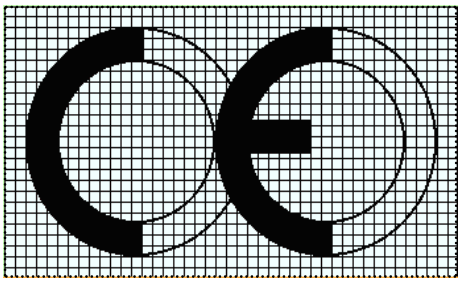
CE stands for: La Conformité Europeénne or European Conformity. The CE mark is not a mark indicating conformity to a Standard but rather a mark indicating conformity to the legal requirements of European Union (EU) Directives. When a product has the CE mark, it can be traded freely in any country within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

3.7 CE symbol

The CE marking symbolises the following:

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

Figure 3-1 CE symbol



Medical Devices Directive (93/42/EEC)

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

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

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

3.8 Notified body

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

4 Spaulding classification

4.1 Classification of infection risk

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

In 1968 Earle Spaulding devised a classification system for infection risk associated with the decontamination of RIMD. Spaulding believed that instruments and equipment should be cleaned and reprocessed according to the level of risk associated with their intended use. The three categories he described were critical, semicritical and noncritical. The appropriate level of decontamination will depend on the procedure for which the device is used (see Table 4-1 below).

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

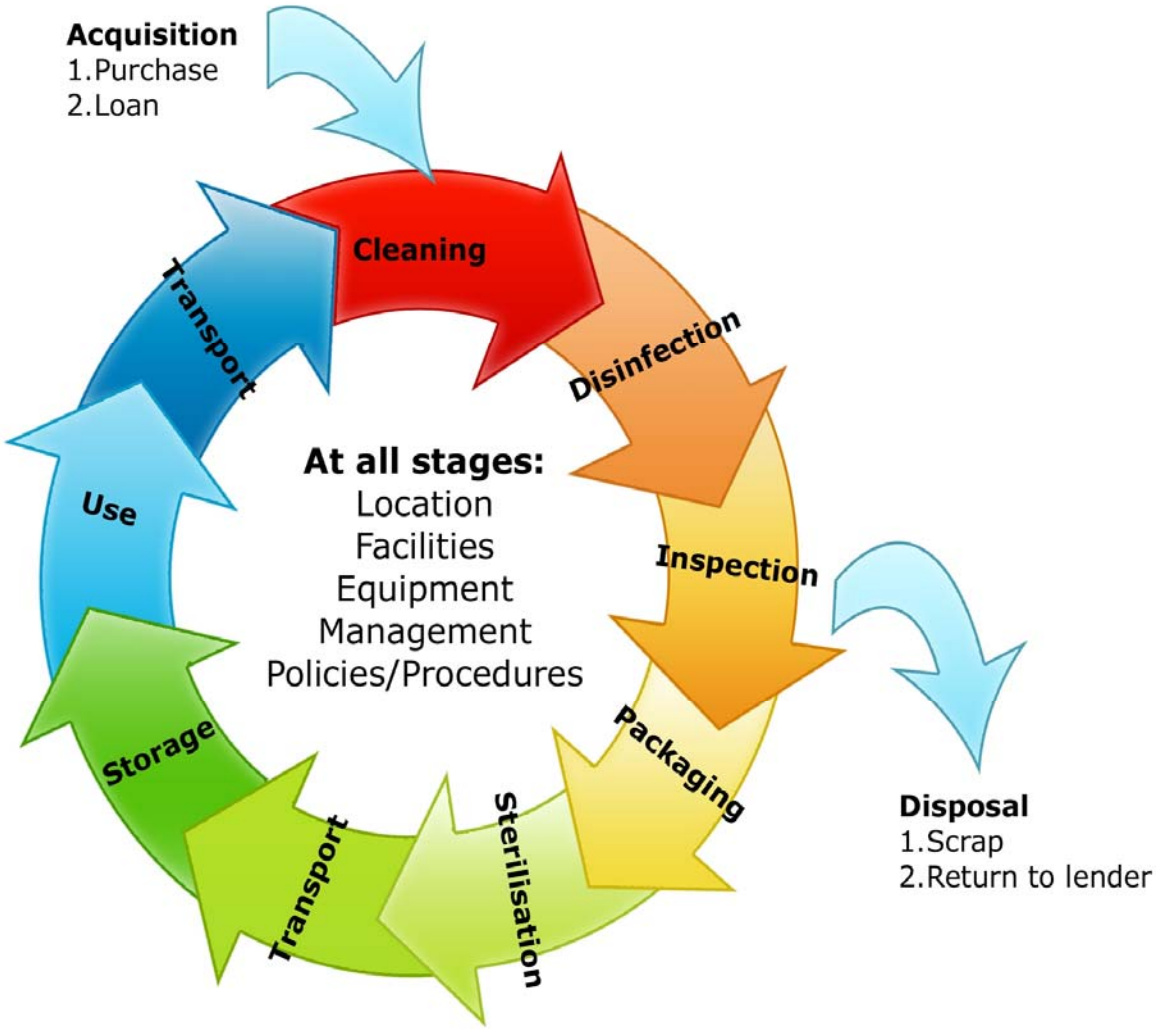
Risk	Application	Recommendation
Critical	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area, e.g. theatre surgi-	Requires Sterilisation
Semi-critical	Items in close contact with intact skin, mucous membranes or body fluids, particularly after use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

5 Life cycle for reusable invasive medical devices

5.1 Introduction

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

Figure 5.1 Decontamination life cycle



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