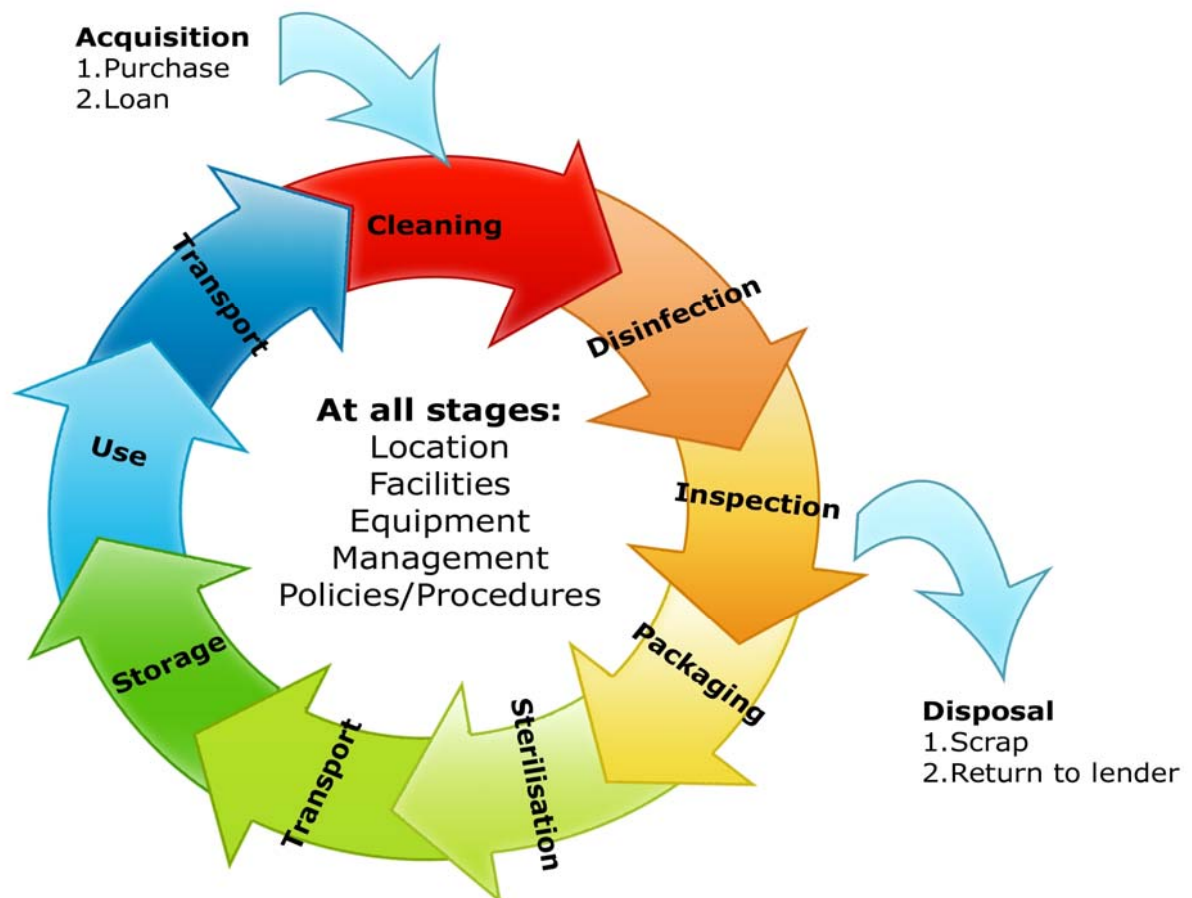


PART 2: STANDARDS

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 2
Author:	Steering Committee for Decontamination of Reusable Invasive Medical Devices
Publication Date:	August 2007
Target Audience:	All 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Superseded Docs:	NA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 2009
Contact Details:	<p>Winifred Ryan, National Hospitals Office, Quality, Risk and Customer Care Directorate, Mid-Western Regional Hospital (Nenagh) Nenagh, Co. Tipperary, Ireland.</p> <p>Email: winifred.ryan1@hse.ie</p> <p>Web: www.hse.ie</p>

Part 2

Part 2
Standards

Contents

Contents – Part 2

	Page
1. Communication and consultation	7
1.1 Standard Statement	
1.2 Rationale	
1.3 Criteria	
2. Organisational structure and accountability	9
2.1 Standard Statement	
2.2 Rationale	
2.3 Criteria	
3. Suitability of decontamination facilities	11
3.1 Standard Statement	
3.2 Rationale	
3.3 Criteria	
4. Decontamination equipment	14
4.1 Standard Statement	
4.2 Rationale	
4.3 Criteria	
5. Procurement of reusable invasive medical devices	19
5.1 Standard Statement	
5.2 Rationale	
5.3 Criteria	

Contents

	Page
6. Decontamination process	21
6.1 Standard Statement	
6.2 Rationale	
6.3 Criteria	
7. Management and key personnel	23
7.1 Standard Statement	
7.2 Rationale	
7.3 Criteria	
8. Education and training	25
8.1 Standard Statement	
8.2 Rationale	
8.3 Criteria	
9. Quality management system	29
9.1 Standard Statement	
9.2 Rationale	
9.3 Criteria	
10. Risk management system	32
10.1 Standard Statement	
10.2 Rationale	
10.3 Criteria	

Contents

	Page
11. Health and safety	34
11.1 Standard Statement	
11.2 Rationale	
11.3 Criteria	
12. Complaints management	36
12.1 Standard Statement	
12.2 Rationale	
12.3 Criteria	
13. Audit and monitoring	38
13.1 Standard Statement	
13.2 Rationale	
13.3 Criteria	
14. Key performance indicators	40
14.1 Standard Statement	
14.2 Rationale	
14.3 Criteria	
15. Procedures relating to transmissible spongiform encephalopathies	46
15.1 Standard Statement	
15.2 Rationale	
15.3 Criteria	
Figures	
6-1 Do not reprocess symbol	22

Communication and consultation

1 Communication and consultation

1.1 Statement

Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD), with key stakeholders within and outside the organisation.

1.2 Rationale

Interactive exchange of information with key stakeholders creates an empowering infrastructure and environment. These are important factors for increasing the level of compliance with the decontamination programme and for continually improving performance.

1.3 Criteria

1. The organisation shall develop a set of shared values, behavioural guidelines and quality principles in support of the Health Service Executive Code of Practice for Decontamination of RIMD that are reflected in job descriptions and vision statements.
2. Healthcare Workers shall be given an opportunity to provide feedback on these values, guidelines and quality principles.
3. These values, guidelines and quality principles shall be reflected in each departments business plans.
4. Regular reviews shall be undertaken to ensure that business plans are translated into action.
5. The organisation shall develop and implement a practical methodology for sharing best practice both internally and with key stakeholders in relation to decontamination of RIMD.
6. The organisation shall inform their staff and patients about the Health Service Executive Code of Practice for Decontamination of RIMD.

Communication and consultation

7. Educational material shall be provided using a variety of different media as required.
8. Staff and key stakeholders shall be encouraged to use feedback procedures to the organisation for any concerns they have in relation to decontamination of RIMD.
9. The decontamination unit and clinical units which it supplies shall have a service level agreement.
10. The decontamination unit shall have in place a formal system for recording and analysing customer complaints.
11. The decontamination unit shall have in place a programme to reduce customer complaints.

Organisational structure and accountability

2 Organisational structure and accountability

2.1 Standard Statement

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

2.2 Rationale

The CEO/Manager through the senior management team is responsible for ensuring that there are effective arrangements for the decontamination of RIMD.

2.3 Criteria

1. Individual responsibility for decontamination of RIMD shall be clearly defined throughout the organization and there shall be clear lines of accountability leading up to the most senior manager or director.
2. The scope of responsibility shall include the competence of contractors where the organisation buys in services and professional liability where the organisation sells services to other organisations.
3. Decontamination of RIMD shall be a standard item on the agenda of the quality and risk management committee (or appropriate committee) in the organisation. The Decontamination Coordinator shall submit regular reports on management of decontamination to the committee.
4. A twice yearly report on the conformity of the decontamination process within the organisation shall be submitted to the quality and risk committee (or appropriate committee) for review. This committee, which shall include in its membership the CEO/Manager or CEO/Manager nominee, shall present the report to the management team.
5. Each organisation shall identify a Decontamination Co-ordinator. The duties of the co-ordinator shall not be confined to any one aspect or decontamination function but shall encompass all decontamination processes wherever they occur within the organisation.

Organisational structure and accountability

6. The Decontamination Coordinator shall have responsibility and authority for developing and monitoring policies, continuous quality improvement and/or strategies for decontamination of RIMD for approval by the quality and risk committee (or appropriate committee).
7. The Decontamination Coordinator shall attend appropriate meetings and conferences local and national, relevant to decontamination of RIMD, which will increase their knowledge and improve their ability to undertake the role.
8. The Decontamination Coordinator shall undertake the dissemination of all information, received from the National Hospitals Office and/or PCCC Directorates/relevant agencies relating to decontamination of RIMD within the organisation.
9. The Decontamination Coordinator shall work with clinicians and decontamination unit managers to develop and improve the systematic approach to decontamination of RIMD.
10. The Decontamination Coordinator shall be responsible for ensuring that the audit activity for decontamination of RIMD, under the responsibility of each decontamination unit manager has been completed.
11. The quality and risk committee (or appropriate committee) shall be responsible for the implementation and monitoring of a decontamination of RIMD audit and monitoring programme in each organisation.
12. Each relevant member of staff shall be made aware of their responsibility in relation to the decontamination process.
13. Each organisation shall have a specific resource provision for decontamination of RIMD related at least in part, to throughput.

Note: Smaller healthcare facilities may decide that the role of the Decontamination Coordinator is best performed as part of the duties of a Coordinator in a larger healthcare facility in the network/PCCC region or as part of the responsibilities of another role. What is important is that:

- The CEO/Manager takes active responsibility for management of decontamination.
- The resources devoted to decontamination of RIMD are adequate.

Suitability of decontamination facilities

3 Suitability of decontamination facilities

3.1 Standard Statement

Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD. For guidance see PD CEN ISO/TR 14969:2005. Additional detailed guidance is available in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities) and Health Building Note 52 (Endoscopy Units).

3.2 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.

3.3 Criteria

1. The department shall be designed so that it is physically separated from all other work areas.
2. The department shall be designed to allow segregation of 'dirty' and 'clean' activities.
3. The department shall be designed to facilitate a unidirectional work flow from the 'dirty' area to the 'clean' area.
4. The department shall not be used for any other purpose.
5. The department shall not be used as a thoroughfare.
6. The department shall not be part of any patient treatment area.
7. All rooms in the department shall be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures shall be controlled between 18-22 degrees Celsius and relative humidity shall be controlled within the range 35-60%).

Suitability of decontamination facilities

8. The environment in which clean non-sterile RIMD are inspected, assembled and packed shall be controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8.
9. The clean area shall be micro-biologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003).
10. Safe storage facilities shall be provided for process chemicals used in decontamination.
11. Storage facilities for bulk items shall be provided external to the clean room and the wash room.
12. Storage facilities shall be provided for sterile product prior to despatch.
13. The shelving in storage facilities shall be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
14. Required personal protective equipment shall be easily accessible in each of the work areas.
15. Entry to the decontamination unit shall be restricted to authorised personnel only.
16. There shall be a changing area for donning work wear which shall include shower facilities, toilet facilities and lockers in proximity to the decontamination area.
17. Access to the wash room and to the clean room shall be through separate dedicated gowning rooms provided with hand hygiene facilities.
18. The area shall be managed by trained staff whose sole or primary responsibility is management of the decontamination unit.
19. The environment in which decontamination of RIMD takes place shall be cleaned in accordance with procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse).
20. Dedicated cleaning provision (both equipment and storage) shall be provided for the clean room and the wash room.
21. There shall be sufficient electricity supply, computer terminal points and work stations in the department.
22. The finishes on the walls and other surfaces shall be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning.
23. The junctions between the walls and floors shall be coved and flush.
24. The fitments (where possible) shall be flush with wall surfaces.

Suitability of decontamination facilities

25. Floors shall be covered in a washable non-slip material which is securely sealed.
26. There shall be adequate lighting available to permit good working practices and visual examination of RIMD.
27. Task lighting and magnification shall be in situ.
28. All work surfaces, fittings, fixtures and furniture shall be made of easily cleanable and robust material and shall be maintained in good condition.
29. The workstations shall be equipped for the preparation of single or composite packs. They shall be of adequate size to accommodate the wrapping material to be used and shall be height adjustable.
30. There shall be adequate space between workstations for equipment and staff movement.
31. The shelving shall be of sufficient depth for all the materials to be held and shall not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.
32. The wash room, clean room and steriliser unloading area shall be free from 'opening' windows, ledges, and uncleanable areas.
33. The wash area and clean room shall be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).
34. Further detailed guidance is given in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities) and Health Building Note 52 (Endoscopy Units).

Decontamination equipment

4 Decontamination equipment

4.1 Standard Statement

All decontamination equipment that does not meet the requirements of current Standards shall be identified and upgraded or replaced in accordance with a planned replacement programme.

All new decontamination equipment shall be procured in conformance with extant harmonized Standards.

All decontamination equipment shall be validated, maintained, periodically tested and monitored to current Standards.

4.2 Rationale

Decontamination equipment that does not meet current Standards cannot be relied upon to meet current requirements for decontamination or to provide the required level of assurance.

Organisations must have a specialist group in place to consider the full implications of procurement of decontamination equipment.

Validation, maintenance, periodic testing and monitoring are required to demonstrate compliance of installed equipment with current Standards.

4.3 Criteria

1. The organisation shall have a specialist group in place to consider the decontamination equipment in the organisation as follows:
 - Ability to meet current Standards.
 - Age and condition of equipment and availability of replacement parts.
 - Cost of maintaining and repairing the equipment.
 - Ability to interface with other equipment in the decontamination facility.
 - Ability to interface with user requirements.

Decontamination equipment

- Ability to meet the requirements of current test methods.
 - Ability to be validated and perform to intended purpose.
 - Energy and water conservation.
 - Ability for self-disinfection for washer-disinfectors and endoscope washer-disinfectors.
2. Key representatives on the specialist group shall include:
- Decontamination Coordinator.
 - Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/Endoscopy Manager.
 - Clinical Unit Manager, e.g. Theatre Manager.
 - Infection Prevention and Control.
 - Bio-medical Engineering/Clinical Engineering/Medical Physics.
 - Procurement.

The group may also include as required:

- Technical Services.
 - Materials Management.
 - Finance Manager/Budget Holder/Business Manager.
 - Other relevant experts (Authorised Person/Sterivigilance Nurse/Microbiologist).
3. The specialist group shall identify all decontamination equipment that needs to be replaced.
4. The specialist group shall formulate a plan to replace or upgrade this equipment.
5. The plan shall be submitted to the senior management team and shall be revised annually by the decontamination coordinator (or designated officer).
6. There shall be sufficient decontamination equipment available to meet the needs of the decontamination unit(s).
7. There shall be clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment.
8. The operational management of each item of decontamination equipment shall be the defined responsibility of a named person (usually the decontamination unit manager).

Decontamination equipment

9. The validation and periodic testing data shall be carried out by qualified personnel.
10. The validation and periodic testing data shall be adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive.
11. The department shall have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

Manual washing

12. Manual washing shall be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector (WD).
13. Dedicated manual cleaning equipment and accessories shall be available for specified RIMD that cannot be cleaned in an automated cleaning process.
14. Separate sinks for washing and rinsing shall be provided.
15. The detergent used shall be one specified by the manufacturer for the manual cleaning of RIMD.
16. Means shall be provided to control the concentration of detergent.
17. A pass-through drying cabinet with inter-locking doors shall be provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector.

Ultrasonic Cleaning

18. A stand-alone ultrasonic cleaner shall be provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers' instructions or as a pre-treatment for RIMD prior to processing through a Washer-Disinfector.
19. The ultrasonic cleaner shall be equipped with the facility for automatic filling and emptying directly to the drain.
20. The ultrasonic cleaner shall be fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
21. The detergent used shall be one specified by the manufacturer for the ultrasonic cleaning of RIMD.
22. Means shall be provided to control the concentration of detergent.
23. The ultrasonic cleaner shall be used in accordance with the manufacturers' instructions.
24. The ultrasonic cleaner shall be validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006.

Decontamination equipment

25. The temperature of the cleaning solution in the ultrasonic cleaner shall be thermostatically controlled.

Washer-Disinfectors

26. The specification of the washer-disinfector shall comply with requirements of EN ISO 15883, parts 1 & 2.
27. Washer-Disinfectors shall be double ended with the clean side discharging into the inspection area of the clean room.
28. Each washer-disinfector shall be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
29. When lumened devices are being reprocessed, the washer-disinfector shall be provided with load carriers that permit the irrigation of the lumened device.
30. Washer-disinfectors and accessories shall be specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1,2 & 5.
31. The Washer-Disinfector shall be subject to planned preventative maintenance.

Steam Steriliser

32. The specification of each steam steriliser shall comply with requirements of EN 285 and the steriliser shall be fitted with an air-detector.
33. Each steam steriliser shall be fitted with a process monitoring system independent of the automatic controller.
34. The sterilisation hold period shall be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
35. Steam Sterilisers shall be double ended with the loading side in the clean room.
36. Sterilisers and accessories shall be specified, installed, commissioned, tested and operated in accordance with the current Standard EN 285 and EN ISO 17665, part 1.
37. The steam sterilisers shall be subject to planned preventative maintenance.

Low temperature sterilisers

38. Low temperature sterilisation methods shall only be used where the manufacturers' instructions do not permit steam sterilisation.
39. Low temperature sterilisation shall be carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes.

Decontamination equipment

40. Low temperature sterilisation methods shall be validated and shall be subject to periodic testing in accordance with ISO 14937.
41. Low temperature sterilisers shall be subject to planned preventative maintenance.

Drying cabinet

42. A pass-through drying cabinet between the wash-room and the clean room shall be provided. The doors of the drying cabinet shall be interlocked to prevent direct connection between the wash room and the clean room.
43. The drying cabinet shall be fitted with a temperature indicator and/or recorder independent of the controller.
44. The drying temperature throughout the cabinet shall be within $\pm 5^{\circ}$ Celsius of the set temperature.
45. The drying cabinet shall be fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than 10° Celsius the heating source is isolated.
46. The air in the cabinet shall be mechanically circulated and items placed throughout the cabinet shall be dried uniformly.
47. The drying cabinet shall be subject to planned preventative maintenance.

Heat sealer

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

Procurement of reusable invasive medical devices

5 Procurement of reusable invasive medical devices

5.1 Standard Statement

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

5.2 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 within the available facilities.

5.3 Criteria

1. The organisation shall have a specialist group in place to consider the procurement of RIMD.
2. Key representatives on the specialist group shall include:
 - Decontamination Coordinator.
 - Decontamination Unit Manager, e.g. Central Decontamination Unit Manager/Endoscopy Manager.
 - Clinical Unit Manager, e.g. Theatre Manager.
 - Infection Prevention and Control.

The group may also include as required:

- Technical Services.
- Procurement.
- Bio-medical Engineering/Clinical Engineering/Medical Physics.
- Materials Management.
- Finance Manager/Budget Holder/Business Manager.
- Other relevant experts (Authorised person/Sterivigilance Nurse/Microbiologist).
- Health and Social Care Professional representative.

Procurement of reusable invasive medical devices

3. The organisation shall have a documented procurement policy.
4. The procurement policy shall comply with the Irish Medicines Board (IMB) recommendations on the procurement of RIMD. SN2006(03)
5. The procurement of RIMD shall be based on agreed specifications and shall comply with the documented procurement policy.
6. There shall be a detailed specification for each RIMD which shall comply with current Standards.
7. Sufficient RIMD and accessories shall be purchased to allow adequate time for reprocessing in the decontamination unit(s) without adversely affecting throughput.
8. A decontamination assessment shall be undertaken prior to the purchase of RIMD to ensure that the organisation has the facilities to reprocess the RIMD in accordance with the manufacturers' instructions.

Note: The procurement group shall carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the processing procedure. This shall require that the manufacturers' validated instructions for the reprocessing of RIMD are available prior to purchase and comply with local policies and procedures.

9. Value for money issues shall be considered when purchasing RIMD.
10. Goods and services shall be purchased from the suppliers in line with the HSE procurement policy.
11. All RIMD and accessories shall be CE marked as this will constitute the manufacturers assurance that a device will be safe and will perform as intended.
12. Suppliers shall be selected based on their ability to supply RIMD in accordance with the specified requirements and provide service support over the lifetime of the RIMD, where applicable.
13. Where parts are single-use or have restricted use this information shall be provided prior to purchasing.

Decontamination process

6 Decontamination process

6.1 Standard Statement

RIMD e.g. surgical instruments, powered devices, rigid and flexible endoscopes, etc. shall 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.

6.2 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.

6.3 Criteria

1. All stages of the decontamination process shall be clearly defined, documented, controlled and recorded.
2. All processes shall be carried out in accordance with documented procedures.
3. All RIMD sets shall be traced through the decontamination process to the patient.
4. Processing data shall be retained for the lifetime of the equipment plus eleven years.
5. There shall be a regular review of all procedures and any necessary changes shall be implemented by a documented change in procedures.
6. RIMD shall be checked and reprocessed in accordance with the manufacturers' instructions.
7. All RIMD shall be visually inspected for cleanliness prior to packaging.
8. All RIMD shall be inspected and/or tested for functionality prior to packaging.
9. There shall be a formal release procedure for sterile product to ensure that only RIMD that have been subjected to a satisfactory sterilisation cycle are released for use.
10. All product released from the decontamination unit shall be labelled with a clear indication of the pack contents, the expiry date and a unique number which shall be used to trace the decontamination processes to which the RIMD was subjected.

Decontamination process

11. Single use devices shall not be reprocessed. Any device with the following symbol shall be deemed single use only.

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

Figure 6-1 Do not reprocess symbol



Management and key personnel

7 Management and key personnel

7.1 Standard Statement

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

7.2 Rationale

To ensure a high quality and safe decontamination of RIMD service.

7.3 Criteria

Key persons and responsibilities shall be as follows:

1. The *CEO/Manager* shall put in place arrangements to ensure effective decontamination of RIMD.
2. A *Decontamination Coordinator* shall be appointed, shall have formally defined responsibilities in accordance with these Standards and shall be provided with the necessary resource to discharge these responsibilities.
3. Each *Decontamination Unit* shall have a person appointed with responsibility for operational management of the unit, which may be in addition to other duties.
4. *Maintenance Personnel* (in-house or sub-contracted) shall be available and shall have documentary evidence to demonstrate competence in the maintenance of the decontamination equipment they will be dealing with.
5. *Test Personnel* (in-house or sub-contracted) shall be available and shall have documentary evidence to demonstrate competence in periodic testing of the decontamination equipment which they will be dealing with.
6. A *Microbiologist* shall be available to advise on microbiological aspects of decontamination.
7. An *Infection Prevention and Control Nurse* shall be available to advise on all aspects of infection surveillance, prevention and control.
8. The *Decontamination Unit Manager* shall have designated *Operatives* to be responsible for each aspect of the decontamination process and shall ensure that these personnel have been trained to the necessary standard of competence.

Management and key personnel

9. A *Biomedical Engineer/Clinical Engineer* shall be available and designated by management for the testing and validation of decontamination equipment.
10. The *Qualified Person (decontamination)* used by the organisation shall be a person registered as an *Authorised Person (Sterilisers)* with the Institute of Healthcare Engineering and Estates management and shall be registered with the Health Service Executive as competent to discharge the duties of a *Qualified Person (decontamination)* in Ireland.

Education and training

8 Education and training

8.1 Standard Statement

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

8.2 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. Staff who are well trained are more likely to provide a high quality, safe service.

8.3 Criteria

1. *General induction training shall include:*

- i. Departmental policies, procedures and Standards, including:
 - Infection Prevention and Control.
 - Safety, Health and Welfare at Work Act, 2005.
 - Occupational Health and Safety.
- ii. Safe operation of equipment.
- iii. Safety Statements (Corporate /Organisation/Departmental) to include specific risk assessments on the physical/chemical/biological hazards and associated protective and preventative measures.
- iv. Fire hazards and regulations.
- v. Moving and Handling.
- vi. First Aid.
- vii. Communications within the Health Service Executive.

Education and training

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

- i. An appreciation of the decontamination process.
- ii. Why processes and procedures take time to give an understanding of the issues faced by decontamination staff.
- iii. Standard Precautions for Infection Prevention and Control.
- iv. Transportation of contaminated equipment/RIMD.
- v. Principles of Cleaning, Disinfection, Inspection, Assembly, Packaging, Sterilisation and Despatch.
- vi. Transportation of sterile RIMD.
- vii. Storage of sterile RIMD.
- viii. Manufacturers' instructions for use of RIMD.
- ix. Identification of RIMD anomalies.
- x. Procurement.
- xi. Quality Management System.
- xii. Risk Management System.
- xiii. Repair/loan equipment.
- xiv. Labelling and single use items and their disposal.
- xv. Symbols associated with sterile RIMD.
- xvi. Roles and responsibilities of management and staff in relation to decontamination of RIMD.
- xvii. Procedures for dealing with contaminated equipment (Transmissible Spongiform Encephalopathies–TSEs).
- xviii. Audit and Monitoring.
- xix. Maintaining environmental cleanliness.

Education and training

3. In particular, the following issues shall 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 Prevention and Control.
- ii. Transportation of contaminated equipment/RIMD.
- iii. Sorting and Disassembly of contaminated RIMD.
- iv. Cleaning.
- v. Disinfection.
- vi. Drying.
- vii. Post Cleaning Inspection and Function Testing.
- viii. Assembly.
- ix. Packaging.
- x. Sterilisation.
- xi. Storage.
- xii. Transportation of sterile equipment and RIMD.
- xiii. Manufacturers instructions for decontamination of RIMD.
- xiv. Identification of RIMD anomalies.
- xv. Clean room technology.
- xvi. Procurement.
- xvii. Testing, maintenance and validation of decontamination equipment.
- xviii. Personal Protective Equipment specific to decontamination of RIMD.
- xix. Quality Management System.
- xx. Risk Management System.
- xxi. Standards and legislation.
- xxii. The build environment (Health Building Notes).
- xxiii. Repair/loan equipment.

Education and training

- xxiv. Labelling and single use items and their disposal.
 - xxv. Roles and responsibilities of management and staff in relation to decontamination of RIMD.
 - xxvi. Procedures for dealing with contaminated equipment (Transmissible Spongiform Encephalopathies—TSEs).
 - xxvii. Audit and Monitoring.
 - xxviii. Maintaining environmental cleanliness.
-
4. *Induction training (see above) shall be provided and recorded in the relevant individuals training record.*
 5. *There shall be a continuing programme of training and education for staff.*
 6. *Training shall be supported with adequate resources and facilities.*
 7. *Individual competencies shall be assessed and records shall be kept in the unit.*
 8. *A formal appraisal system shall be in place to monitor staff performance and to identify individual training needs.*

Quality management system

9 Quality management system

9.1 Standard Statement

Central decontamination units shall operate a quality management system in accordance with EN ISO 13485.

Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.

9.2 Rationale

Formal documented control of decontamination within a quality management system is necessary to monitor each aspect of the decontamination process in order to demonstrate compliance with current legislation and guidance. This reduces risks to patients, staff and to the Health Service Executive.

9.3 Criteria

1. Central Decontamination Units in the organisation shall operate a quality management system in accordance with EN ISO 13485.

Endoscope and local decontamination units operate a quality system in accordance with the following key operational elements of EN ISO 13485.

2. The organisation shall have documented policies, procedures and records for all the key elements of the decontamination process. For each decontamination unit, key policies, procedures and guidelines shall be in place, and where assessed as relevant, include:
 - i. Standard Precautions for Infection Prevention and Control.
 - ii. Transportation of contaminated equipment/RIMD.
 - iii. Sorting and Disassembly of contaminated RIMD.
 - iv. Cleaning.
 - v. Disinfection.
 - vi. Drying.
 - vii. Post Cleaning Inspection and Function Testing.

Quality management system

- viii. Assembly.
 - ix. Packaging.
 - x. Sterilisation.
 - xi. Storage.
 - xii. Transportation of sterile equipment and RIMD.
 - xiii. Manufacturers' instructions for decontamination of RIMD.
 - xiv. Identification of RIMD anomalies.
 - xv. Procurement.
 - xvi. Testing, maintenance and validation of decontamination equipment.
 - xvii. Personal Protective Equipment specific to decontamination of RIMD.
 - xviii. Repair/loan equipment.
 - xix. Labelling and single use items and their disposal.
 - xx. Procedures for dealing with contaminated equipment (Transmissible Spongiform Encephalopathies—TSEs).
 - xxi. Maintaining environmental cleanliness.
 - xxii. Staff training.
3. All policies and procedures associated with decontamination of RIMD shall comply with current Standards, legislation and Health Service Executive guidance.
 4. The quality and risk management committee (or appropriate committee) shall approve policies, procedures and guidelines for decontamination of RIMD in the organisation.
 5. There shall be a system to ensure each department or service has a current copy of the approved decontamination of RIMD policies, procedures and guidelines pertinent to its activities.
 6. All relevant staff shall be required to read the decontamination of RIMD policies and procedures relevant to their area of work and to sign a statement to indicate that they have read, understood and will comply with same.
 7. All policy and procedure documents associated with decontamination of RIMD shall be controlled showing the date of issue and revision number.
 8. Master copies shall be kept in a secure location.

Quality management system

9. Obsolete documents shall be removed from all points of use.
10. A biennial review of all policies, procedures and documents associated with decontamination of RIMD shall be undertaken to check their relevance and issue status.
11. A computerised documentary system shall be available within each decontamination unit to allow the provision of appropriate information to senior management as required. Decontamination unit personnel shall be proficient in the application and operation of such systems.
12. All data (electronic and manual) shall be stored securely. Electronic data shall be backed up and audited in accordance with the organisations policy.
13. Access to data/records shall be restricted to authorised named persons and specified information shall be maintained in line with the Data Protection Acts.
14. All records associated with the decontamination life cycle shall be retained for the life-time of the equipment/RIMD plus eleven years.
15. These records shall be readily accessible to permit traceability when required.

Risk management system

10 Risk management system

10.1 Standard Statement

The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.

10.2 Rationale

Effective risk management is essential for healthcare safety and overall quality improvement. It allows managers to be aware of potential risks and offers the opportunity to deal with them before any loss occurs.

10.3 Criteria

1. The organisation shall compile a list of foreseeable hazards associated with each stage in the decontamination process.
2. The list of hazards shall be maintained in a risk management file.
3. All identified hazards shall be documented as part of a risk register and systematically assessed and prioritised.
4. The organisation shall identify and assess all risks associated with all stages in the decontamination process.
5. The organisation shall institute control measures for identified risks.
6. The organisation shall have a monitoring programme in place to verify compliance with policies and procedures.
7. The organisation shall have documented arrangements for responding to emergencies.
8. The organisation shall identify, record and analyse 'adverse events' and 'near misses'.

Risk management system

9. The organisation shall have a reporting procedure for reporting accidents and incidents to the relevant authorities.
 - i. Reports to the Senior Management Team.
 - ii. Reporting clinical adverse incidents to the Clinical Indemnity Scheme (CIS).
 - iii. Reporting dangerous occurrences to the Health & Safety Authority (HSA) in accordance with organisation policy.
 - 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.
10. The organisation shall have a documented decontamination policy with clear reference to risk management that includes:
 - Health and Safety.
 - Management arrangements for emergencies and untoward incidents.
 - Provision to learn from incidents.
 - Compliance with all relevant legislation, including the Safety, Health and Welfare at Work Act, 2005 and Medical Devices Regulations.
11. The organisation shall have taken measures to ensure that all relevant employees receive adequate information concerning matters relating to the Safety, Health and Welfare at Work Act, 2005.
12. Material Safety Data Sheets shall be made available to all staff who are using potentially hazardous chemicals.
13. Chemical risk assessments shall be completed and brought to the attention of all relevant staff.
14. Each department where decontamination of RIMD takes place shall have a Departmental Safety statement which documents physical, chemical, biological and psychological hazards and associated protective and preventative measures.
15. The organisation shall have a documented staff decontamination training programme to include induction of all new staff through to continual professional development for all other grades.

Health and safety

11 Health and safety

11.1 Standard Statement

Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used devices and process chemicals.

11.2 Rationale

Patient and staff safety, health and welfare is a vitally important issue and there should be an ongoing programme dealing with key issues identified from risk assessment and other processes.

11.3 Criteria

1. Each decontamination unit manager and their staff shall be aware of and shall have access to current health and safety regulations and guidelines as they apply to the decontamination unit.
2. Each decontamination unit shall have a health and safety policy which shall be available and disseminated to staff. This policy shall be up to date and shall be regularly reviewed.
3. Each decontamination unit shall have access to competent health and safety advice.
4. Each decontamination unit shall identify the decontamination processes that may generate substances hazardous to health.
5. These processes shall be contained by appropriate precautions.
6. There shall be regular audits of compliance with the control measures.
7. Each decontamination unit shall have procedures in place to deal with accidents, incidents and emergencies.
8. Flammable liquids and chemicals shall be stored in flame-proof cupboards which are kept locked and closed.
9. Emergency treatment kits for contact with personnel/spillages shall be provided and shall be easily accessible in the work area.

Health and safety

10. There shall be procedures in place to ensure that all decontamination equipment and accessories are specified, installed, commissioned, tested and operated in accordance with current Standards.
11. Personal protective equipment shall be provided and shall be easily accessible in the work area.
12. There shall be a formal, documented release for sterile RIMD to ensure that the RIMD is only returned for use on a patient after it has been decontaminated using validated reprocessing equipment and in line with the manufacturers' instructions.
13. Current copies of approved infection prevention and control policies and procedures in relation to decontamination of RIMD shall be readily accessible to staff in each decontamination unit.
14. Occupational health services shall be provided for all staff.

Complaints management

12 Complaints management

12.1 Standard Statement

All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information.

12.2 Rationale

Complaints, comments and incidents may be linked and are complementary sources of information for improving the safety and quality of the decontamination service.

12.3 Criteria

Complaints System

1. The documented complaint system shall cover the following:
 - 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.
 - Preventative and 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.

Complaints management

Complaints Process

2. Corrective action shall be implemented without undue delay when a finished product is found to be defective or is subject to adverse reports, such action shall 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.
3. Preventative action shall be implemented to ensure as far as practicable that there will be no recurrence of the non-conformance. The efficacy of the preventative action shall be verified.

Audit and monitoring

13 Audit and monitoring

13.1 Standard Statement

Audits shall be carried out to ensure that the procedures for decontamination of RIMD conform to the required Standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

13.2 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.

13.3 Criteria

1. Audit of decontamination of RIMD shall include:
 - 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 shall be responsible for preparing a written agreed programme which shall ensure that all aspects of the decontamination processes and their management within the unit shall be audited at least once a year.
3. Each decontamination unit manager shall be responsible for ensuring that the audit is conducted in accordance with this programme.
4. Each decontamination unit manager shall be responsible for ensuring that remedial actions are carried out for any deficiencies found and for verifying the efficacy of remedial actions undertaken.
5. The quality and risk Committee (or appropriate committee) shall be responsible for ensuring that the audit activity, under the responsibility of the decontamination unit manager has been completed.

Audit and monitoring

6. Audit results shall be fed back to the decontamination coordinator, the quality and risk Committee (or appropriate committee), relevant staff and the senior management team.
7. Audit results shall be included in the quality and risk management annual report (or appropriate annual report).
8. Audit results shall be used to help to inform and improve decontamination of RIMD practices.
9. The audits shall be carried out by appropriately trained auditors.
10. The senior management team shall submit an annual assurance statement on audit findings for consideration and approval by the Network Manager/Assistant National Director Primary Community and Continuing Care (PCCC).
11. The Network Manager/Assistant National Director PCCC shall submit annual assurance statements to the Director of the National Hospitals Office/Director of Primary, Community and Continuing Care.
12. External national audits of decontamination shall be carried out as appropriate under the direction of the Assistant National Directors of Quality, Risk and Customer Care.

Key performance indicators

14 Key performance indicators

14.1 Standard Statement

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

14.2 Rationale

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

14.3 Criteria

Environment

1. All rooms in the department shall be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures shall be controlled between 18-22 degrees Celsius and relative humidity shall be controlled within the range 35-60%).
2. The department shall be designed to allow segregation of 'dirty' and 'clean' activities.
3. The environment in which clean non-sterile RIMD are inspected, assembled and packed shall be controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8.
4. The clean area shall be micro-biologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003).
5. The environment in which decontamination of RIMD takes place shall be cleaned in accordance with procedures and schedules agreed by the decontamination coordinator, with advice when required from the Consultant Microbiologist and Infection Prevention and Control Nurse.
6. Dedicated cleaning provision (both equipment and storage) shall be provided for the clean room and the wash room.

Key performance indicators

7. Access to the wash room and to the clean room shall be through separate dedicated gowning rooms provided with hand hygiene facilities.
8. Safe storage facilities shall be provided for process chemicals used in decontamination.
9. Storage facilities shall be provided for sterile product prior to despatch.
10. All work surfaces, fittings, fixtures and furniture shall be made of easily cleanable and robust material and shall be maintained in good condition.

Equipment

Manual washing

11. Manual washing shall be used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector.
12. Separate sinks for washing and rinsing shall be provided.
13. Means shall be provided to control the concentration of detergent.
14. A pass-through drying cabinet with inter-locking doors shall be provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector.
15. The detergent used shall be one specified by the manufacturer for the manual cleaning of RIMD.

Ultrasonic Cleaning

16. A stand-alone ultrasonic cleaner shall be provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers' instructions or as a pre-treatment for RIMD prior to processing through a Washer-Disinfector.
17. Automatic filling of the ultrasonic cleaner and emptying directly to the drain shall in situ.
18. The detergent used shall be one specified by the manufacturer for the ultrasonic cleaning of RIMD.
19. Means shall be provided to control the concentration of detergent.
20. The ultrasonic cleaner shall be validated and shall be subject to periodic testing and planned preventative maintenance.

Key performance indicators

Washer-Disinfectors

21. The specification of the washer-disinfector shall comply with requirements of EN ISO 15883, parts 1 & 2.
22. The washer-disinfector shall be a pass-through design located between the wash room and the clean room.
23. Each washer-disinfector shall be fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1.
24. When lumened devices are being reprocessed, the washer-disinfector shall be provided with load carriers that permit the irrigation of the lumened device.
25. The washer-disinfector shall be validated and shall be subject to periodic testing in accordance with EN ISO 15883, parts 1, 2 & 5. The Washer-Disinfector shall be subject to a planned preventative maintenance.

Steam Steriliser

26. The specification of each steam steriliser shall comply with requirements of EN 285 and the steriliser shall be fitted with an air-detector.
27. Each steam steriliser shall be fitted with a process monitoring system independent of the automatic controller.
28. The sterilisation hold period shall be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
29. Sterilisers and accessories shall be specified, installed, commissioned, tested and operated in accordance with the current Standard EN 285 and EN ISO 17665, part

Low temperature sterilisers

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

Key performance indicators

Drying cabinet

33. A pass-through drying cabinet between the wash-room and the clean room shall be provided. The doors of the drying cabinet shall be interlocked to prevent direct connection between the wash room and the clean room.
34. The drying temperature throughout the cabinet shall be within $\pm 5^{\circ}$ Celsius of the set temperature.
35. The drying cabinet shall be fitted with a temperature indicator and/or recorder independent of the controller.

Heat sealer

36. Where heat seal packaging is to be used, a rotary heat sealer shall be provided.
37. The heat sealer shall be validated and tested daily to verify the efficacy of the seal.

Utilities

38. Steam sterilisers shall be provided with clean steam, complying with IS EN 285.
39. Washer-disinfectors shall be provided with purified water, for all process stages and purified water for the final rinse stage.
40. The steam supply for sterilisation shall be tested at least annually for dryness value, super-heat and non-condensable gas concentration.
41. Compressed air used for testing power tools shall be medical grade and oil free.

Management and Personnel

42. The CEO/Manager shall put in place arrangements to ensure effective decontamination of RIMD.
43. A decontamination coordinator shall be appointed, shall have formally defined responsibilities in accordance with these Standards and shall be provided with the necessary resource to discharge these responsibilities.
44. Each decontamination unit shall have a person appointed with responsibility for operational management of the unit, which may be in addition to other duties.
45. Maintenance and test personnel shall be available and suitably qualified for the decontamination equipment in use.

Key performance indicators

46. A microbiologist shall be available to advise on the microbiological aspects of decontamination.
47. The decontamination unit manager shall have designated operatives to be responsible for each aspect of the decontamination process and shall ensure that these personnel have been trained to the necessary standard of competence.
48. Test Personnel (in-house or sub-contracted) shall be available and shall have documentary evidence to demonstrate competence in periodic testing of the decontamination equipment which they will be dealing with.
49. An Infection Prevention and Control Nurse shall be available to advise on all aspects of infection surveillance, prevention and control.

Processes

50. The organisation shall have a specialist group in place to consider the procurement of RIMD.
51. All stages of the decontamination process shall be clearly defined, documented, controlled and recorded.
52. All processes shall be carried out in accordance with documented procedures.
53. All RIMD sets shall be traced through the decontamination process to the patient.
54. All RIMD shall be visually inspected for cleanliness prior to packaging.
55. All RIMD shall be inspected and/or tested for functionality prior to packaging.
56. There shall be a formal release procedure for sterile product to ensure that only RIMD that have been subjected to a satisfactory sterilisation cycle are released for use.
57. All product released from the decontamination unit shall be labelled with a clear indication of the pack contents, the expiry date and a unique number which shall be used to trace the decontamination processes to which the device was subjected.

Key performance indicators

Service Quality

58. The decontamination unit and clinical units which it supplies shall have a service level agreement.
59. The decontamination unit shall have in place a formal system for recording and analysing customer complaints.
60. The decontamination unit shall have in place a programme to reduce customer complaints.

Procedures relating to transmissible spongiform encephalopathies

15 Procedures relating to transmissible spongiform encephalopathies (TSEs)

15.1 Standard Statement

The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.

15.2 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.

15.3 Criteria

1. RIMD and equipment used on patients at increased risk of developing a TSE shall be single-use where possible.
2. The organisation shall have written policies and procedures for the identification of patients at increased risk of developing a TSE.
3. These policies and procedures shall be based on Irish TSE Infection Control Guidelines Final Version, Sept 2004.