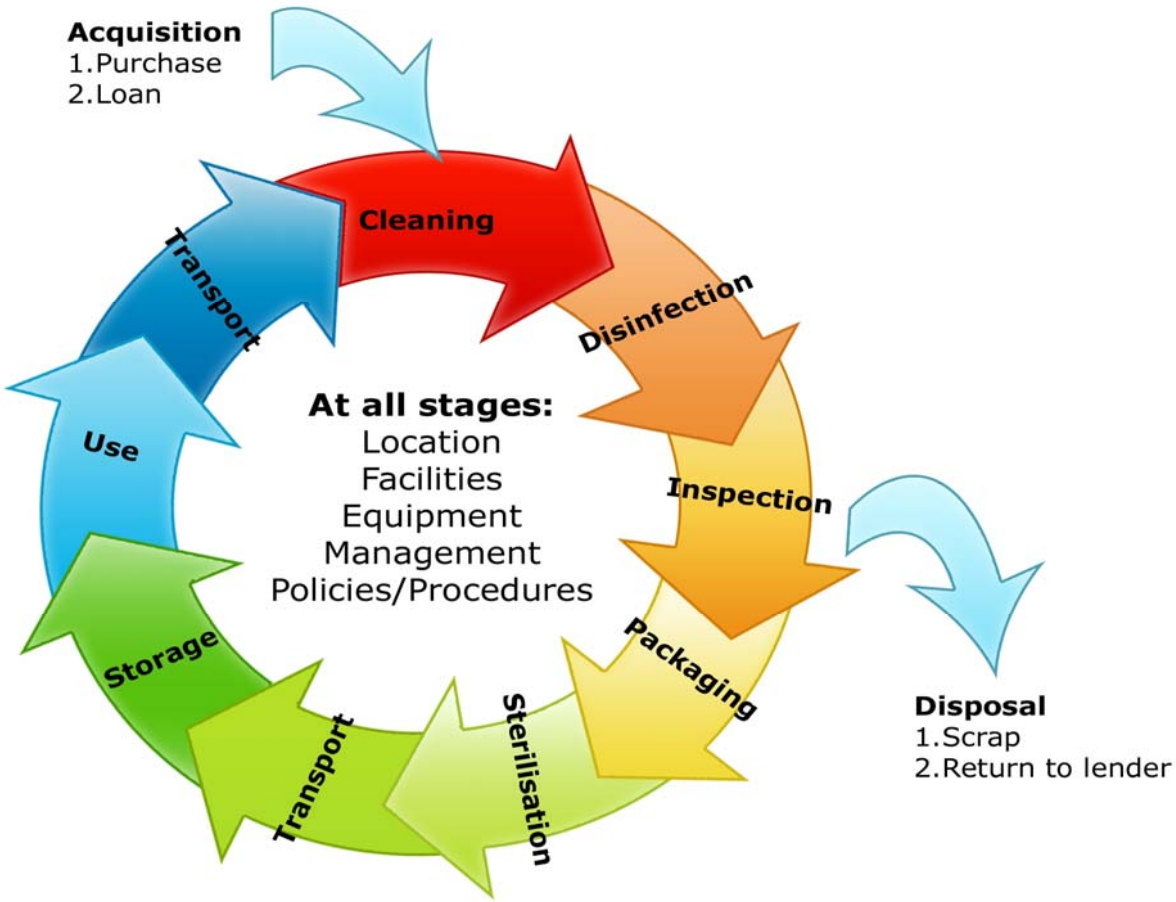
PART 7: ADDITIONAL RESOURCES AND APPENDICES

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



Reader Information

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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
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Part 7
Additional Resources and Appendices

Contents

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2. Abbreviations

AORN	Association of periOperative Registered Nurses
AER	Automated Endoscope Reprocessor
CE	La Conformité Européenne
CDU	Central Decontamination Unit
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
EEC	European Economic Community
EN	European Norm
EU	European Union
EDU	Endoscopy Decontamination Unit
EWD	Endoscope Washer-Disinfector
HAS (H&S)	Health and Safety
HBN	Health Building Note
HAI	Healthcare Associated Infection
HCW	Health Care Worker
HIQA	Health Information Quality Authority
HSE	Health Service Executive
IMB	Irish Medicines Board
ISO	International Standards Organisation
LCD	Liquid Chemical Disinfector
MSDS	Material Safety Data Sheets
NHO	National Hospitals Office
NSAI	National Standards Authority of Ireland
PCCC	Primary, Community and Continuing Care
PPE	Personal Protective Equipment
RIMD	Reusable Invasive Medical Devices
TSE	Transmissible Spongiform Encephalopathies
WD	Washer-disinfector

3. Glossary

Adverse event	An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.
Cleaning	The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning removes microorganisms and the organic material on which they thrive. It is a necessary pre-requisite of effective disinfection or sterilisation.
Clinical Governance	Corporate accountability for clinical performance.
Decontamination	The removal of microorganisms 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.

3. Glossary

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.

3. Glossary

Risk Reduction	A selective application of appropriate techniques and management principles to reduce either likelihood or an occurrence or its consequences, or both.
Reprocessing	All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation.
Reusable item	An item designated or intended by the manufacturer to be suitable for reprocessing and reuse.
Sharps	Any object capable of inflicting penetrating injury, including needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.
Stakeholders	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.
Standard	Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
Statutory	Required by law.
Sterilisation	A process used to render an object free from viable microorganisms including viruses and bacterial spores.
TSEs	TSEs are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans.
Validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications. Validation broadly encompasses three activities — commissioning, verification of a process specification and performance qualification.
Verification	Checking or confirmation of the truth or accuracy of something (e.g., self-assessment).

Appendix 1: Membership of Decontamination of RIMD Steering Committee

Name	Title	Address
Dr. Ronnie Russell	Applied Microbiologist and Immunologist	Moyne Institute of Preventative Medicine Trinity College Dublin (Joint Chair)
Winifred Ryan	Quality Risk & Customer Care	National Hospitals Office, Health Service Executive (Joint Chair)
Ann O'Connor	Medical Devices Director	IMB, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2
Sheila Sheahan	Chairperson of the Irish Association of Sterile Services Managers	Health Service Executive, Mid Western Regional Hospital, Limerick
Mary Owens	Vice-President of the Irish Association of Directors of Nursing and Midwifery	Mallow General Hospital Cork
Caroline Dolan	Chairperson of Irish Association of Theatre Managers	Portiuncula Hospital, Ballinasloe, Co. Galway
Tracy Doherty—Replaced in February 2007 by Michelle Bergin	Infection Control Nurse representing the ICNA	Beaumont Hospital, Dublin/ Midland Regional Hospital, Tullamore
Donna Roche—Rotated with Mary Fogarty	Chairperson of the Irish Society of Endoscopy Nurses	Bons Secours Hospital, Co. Cork/ Mater Hospital, Dublin
Dr Robert Cunney	Consultant Microbiologist	Health Protection Surveillance Centre, Dublin
Dr Anne Gilleece	Consultant Microbiologist	Connolly Hospital Blanchardstown Dublin
Gerry Clerkin	Risk Advisor	Health Service Executive, North East Management Dept, Kells, Co. Meath
Hugh O'Connor, MBB	Authorised Person (Sterilisers)	St. James' Hospital, Dublin
Wilf Higgins	Principal Engineering Advisor	Hospital Planning Office, Department of Health and Children
Oonagh Ryan (In attendance)	Sterile Services Manager	St Vincents Private Hospital Dublin
Niall Creggy (In attendance)	Sterile Services Manager	Mater Private Hospital Dublin
Sandra Kehoe (Secretariat)	Quality Risk & Customer Care NHO	Health Service Executive

Appendix 2: Membership of Standards Sub-Group

Name	Title	Address
Winifred Ryan	Quality Risk & Customer Care	National Hospitals Office Health Service Executive (Chair)
Sheila Sheahan	Sterile Services Manager	Health Service Executive Mid Western Regional Hospital Limerick
Caroline Dolan	Theatre Manager	Portiuncla Hospital, Ballinasloe, Co. Galway
Tracy Doherty–Replaced in February 2007 by Michelle Bergin	Infection Control Nurse representing the ICNA	Beaumont Hospital, Dublin/ Midland Regional Hospital, Tullamore
Brid Lennon	Irish Society of Endoscopy Nurses	South Tipperary General Hospital
Alan Cherryman	Technical Services Department	Health Service Executive Mid Western Regional Hospital Limerick
Hugh O'Connor, MBB	Authorised Person (Sterilisers)	St. James' Hospital, Dublin
Wilf Higgins	Principal Engineering Advisor	Department of Health and Children
Dr Anne Gillecce	Consultant Microbiologist	Connolly Hospital, Blanchardstown
Professor David C. Coleman	Professor of Oral & Applied Microbiology	Dublin Dental School & Hospital, University of Dublin, Trinity College, Lincoln Place, Dublin 2.
Nick Armstrong	Senior Administrative Dental Surgeon	HSE Eastern Area.
Dr Jane Renehan	Principal Dental Surgeon	HSE Dublin North West
Mary O'Donnell	Dublin Dental School & Hospital	University of Dublin, Trinity College, Lincoln Place, Dublin 2.
Joy Markey	Sterile Services Manager	Dublin Dental School & Hospital, University of Dublin, Trinity College, Lincoln Place, Dublin 2.
Sandra Kehoe (Secretariat)	Quality Risk & Customer Care, NHO	Health Service Executive

Appendix 3: List of hospitals who participated in the consultation process

Waterford Regional Hospital, Co. Waterford
St Luke's General Hospital, Kilkenny
Lourdes Orthopaedic Hospital, Kilcreene, Kilkenny
Wexford General Hospital, Wexford
South Tipperary General Hospitals, Clonmel, Co.Tipperary
Cork University Hospital, Wilton Road, Cork
Cork University Maternity Hospital, Cork
St. Finbarr's Hospital, Douglas Road, Cork
St Mary's Orthopaedic Hospital, Gurranbraher, Cork
Mallow General Hospital, Mallow, Co. Cork
Kerry General Hospital, Tralee
Bantry General Hospital, Bantry, Co. Cork
Mercy University Hospital, Grenville Place, Cork
South Infirmary-Victoria University Hosp., Old Blackrock Rd, Cork
Our Lady of Lourdes Hospital, Drogheda, Co. Louth
Louth County Hospital, Dundalk, Co. Louth
Cavan General Hospital, Cavan
Monaghan General Hospital, Co. Monaghan
Our Lady's Hospital, Navan, Co. Meath
Sligo General Hospital, Sligo
University College Hospital, Galway
Merlin Park Reg. Hospital, Galway

Appendix 3: List of hospitals who participated in the consultation process

Mayo General Hospital, Castlebar, Co. Mayo
Roscommon County Hospital, Roscommon
Portiuncula Hospital, Portiuncula, Ballinasloe, Co. Galway
Letterkenny General Hospital, Letterkenny, Co. Donegal
Midland Regional Hospital, Mullingar, Co. Westmeath
Midland Regional Hospital, Tullamore, Co. Offaly
Adelaide & Meath Incorp National Children's Hospital, Tallaght, D24
Naas General Hospital, Naas, Co. Kildare
Coombe Women's Hospital, Dolphins Barn, Dublin 8
Our Lady's' Hospital for Sick Children, Crumlin, Dublin 12
Midland Regional Hospital Portlaoise
Mid Western Regional Hospital Limerick, Dooradoyle, Limerick City
Mid Western Regional Orthopaedic, Croom, Co. Limerick
Mid Western Regional Maternity Hospital, Limerick City
Mid Western Regional Hospital, Ennis, Co. Clare
Mid Western Regional Hospital, Nenagh, Co. Tipperary
St John's Hospital, Limerick City
St Vincent's University Hospital, Elm Park, Dubiln 4
St Michaels Hospital, Lower George's St., Dun Laoghaire, Co. Dublin
St Columcille's Hospital, Loughlinstown, Co. Dublin
National Maternity Hospital, Holles St., Dublin 2

Appendix 3: List of hospitals who participated in the consultation process

St Luke's Hospital, Highfield Rd., Rathgar, Dublin 6
Royal Victoria Eye & Ear, Adelaide Road, Dublin 2.
St James's Hospital, James's St., Dublin 8
Mater Misericordiae University Hospital, Eccles St., Dublin 7
Beaumont Hospital, Beaumont Road, Dublin 9
Connolly Hospital, Blanchardstown, Dublin 15
Cappagh National Orthopaedic Hospital, Cappagh, Finglas, Dublin 1
Children's University Hospital, Temple Street, Dublin 1
Rotunda Hospital, Parnell St., Dublin 1
Dublin Dental School and Hospital, University of Dublin, Trinity College

Appendix 4: List of External Consultees

Consultees (External)	Consultees (External)
Department of Health and Children	SARI National Committee
RCPI Faculty of Occupational Health	Maintenance Management Association
Royal College of Surgeons of Ireland	Health Care Risk Managers Forum
Royal College of Physicians of Ireland	DATHs Risk Management Forum
RCPI Faculty of Public Health	Clinical Indemnity Scheme
Irish Society of Clinical Microbiologists	Association of Occupational Therapists in Ireland
Irish Directors of Nursing and Midwifery Association	Irish Society of Chartered Physiotherapists
Irish Association of Sterile Services Managers	Irish Association of Speech & Language Therapy
Irish Society of Endoscopy Nurses	Association of Physical Scientists in Medicine
Irish Association of Theatre Managers	Irish Medicines Board
Infection Control Nurses Association	

Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is 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.

Legislation

Directive 42/93/EEC.

European and International Standards

i. Cleanroom standards

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

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

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

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

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

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

Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based

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.

Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based

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.

Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based

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.

Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based

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.

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.

Appendix 5: Standards and Guidance on which the Decontamination Code of Practice is based

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.

Appendix 6: 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.

Appendix 6: Regulations and Guidance

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.

Appendix 6: Regulations and Guidance

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'.

Appendix 7: Suggested Membership of Decontamination Advisory Group

Group Membership	Group Membership
Chair	Health & Safety Personnel
Senior Medical Staff/Consultant Surgeon	Quality Manager
Consultant Microbiologist	Procurement Personnel
Senior Administrative Staff/ Business Manager	Bio-Medical Engineering Personnel/ Clinical Engineering Personnel/Medical Physics
Senior Nursing Staff	Dangerous Goods Safety Advisor
Decontamination Unit Manager – CDU Operatives	Porter
Decontamination Unit Manager - Endoscopy	Technical Services Personnel
Decontamination Unit Manager - Theatre	Risk Manager
Dentist/Orthodontist	Union Representative
Infection Prevention and Control Nurse	Links to local partnership committee
Health & Social Care Professional	