

INTRODUCTION:

To provide a detailed core programme to member countries who wish to provide training to decontamination personnel based on European and International Standards.

1. Aims:

- Indicate the depth and scope of knowledge and required training for each syllabus within each training programme.
- Assist those who will be involved either as trainers or trainees to understand the range of skills and depth of knowledge that successful trainees should achieve.
- Encourage the use of European Norms (EN) and International Standards (ISO) as the basis for quality in all member countries.
- Encourage member countries to include their own national regulatory aspects.
- Review EFHSS core syllabus and those of listed member organisations educational programmes on a regular basis to ensure they still meet legal requirements.
- The educational group of EFHSS will ensure that information on the web site is accurate and it is member organisations responsibility to incorporate such information into their educational programmes as required

2. Target population:

Technical and Management Personnel working within Central Sterile Services Departments (CSSD) and other Decontamination Facilities:

The Medical Device Directive (93/42EEC) became effective within the European Union on 1st January 1995. It was assumed throughout the Union, that all manufacturers of medical devices (including hospital based CSSD) were required to comply with the principals of the Directive by no later than 14th June 1998. To verify compliance with the essential requirements of the Directive, each manufacturer is required to demonstrate that their devices have been produced in accordance with approved technical specifications and in quality controlled circumstances.

The need for trained and qualified management and technical staff is self apparent: companion programmes for training basic grade technicians, supervisory grades and managers have been developed to meet their particular requirements.

3. Methods:

We recommend that in general, teaching should be provided by lectures/presentations, personal tuition and practical demonstrations undertaken by qualified trainers.

Following training, employee performance should be evaluated and further training needs identified so that they can be met all listed countries will identify their preferred training evaluation method.

It is a management responsibility to train and supervise others. Training professional managers requires skill and application. It is important to maintain the trainee's interest and to remind them of the relevance to their daily work. Some of the content will be background knowledge that adds meaning and understanding to current practises.

4. Listed Member Organisations Training Programmes:

All courses which comply with the requirements of EFHSS will be listed by the Educational Working Group; following request from the member organisations

Requirements are given within this document:

Notes:

1. Training records must be retained for each trainee detailing training undertaken and an assessment of performance achieved as required by the Quality System.

5. Member countries should remember that different aspects of the syllabus may apply to different levels of staff depending on the size of the CSSD, therefore some local interpretation may be required.

TRAINING PROGRAMMES AVAILABLE

Level I Training (Basic grade technician)

Training for all staff that begin working in CSSD without previous experience.

Admission requirements:

- Employed within a CSSD
- Literate and numerate

Suggested syllabus content:

Module 1	Departmental organisation & basic quality procedures
Module 2	Anatomy and Physiology
Module 3	Basic microbiology and infection control procedures
Module 4	Cleaning and Disinfection of Medical Devices
Module 5	Inspection, Assembly and Packaging
Module 6	Sterilization
Module 7	Storage and Distribution
Module 8	Teambuilding and Teamcoaching

Level II Training (Supervisory grade)

Training course for the occupational designation of ‘Supervisor, CSSD’ with extended responsibilities (e.g. shift supervisor)

Admission requirements:

- Successful completion of Level I

The programme should last at least 80 hours so that all of the syllabus can be covered in adequate depth

Suggested syllabus content:

Module 1	Statutory legal requirements/directives, recommended standards
Module 2	Quality Management System
Module 3	Human Resource and Staff Management
Module 4	Communication and Team Coaching
Module 5	Qualification and Validation of Work Processes
Module 6	Building design and technical equipment
Module 7	Knowledge of Instruments
Module 8	Product release, tracking and traceability
Module 9	Infection prevention



Level III Training (Management grades)

Training courses for all grades of CSSD and Decontamination Facility Manager.

Admission requirements:

- Successful completion of Level I & Level II
- A minimum of two years experience in a supervisory position within a CSSD

The programme should last at least 60 hours so that all the syllabus can be covered in adequate depth

Suggested syllabus content:

Module 1	General Management
Module 2	Total Quality Management
Module 3	Economic and Financial Business Management
Module 4	Personnel Management Issues
Module 5	Other resources

DETAILED INDIVIDUAL PROGRAMME CONTENTS**Level I**

Level I - Module 1	Departmental organisation & basic quality procedures
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- Training objectives:

To ensure the trainee understands the aims and objectives of the service provided, this will include organisation and work-flow; a general understanding of the disciplines and procedures that are required in each work area, the maintenance of the working environment and how personal protection is afforded to each worker; and they will be able to identify the systems and personnel involved.

- Topics to be covered:

Role of the department: layout, basic environmental requirements, workflows, basic operational policies, staffing organisational chart, responsibilities of various staff members, health and safety regulations, personal protective equipment, safe lifting and handling, electrical safety, health surveillance, first aid, emergency action drill, accident/incident reporting, customer service and basic quality assurance practices.

- Performance criteria:

After module completion; trainees must be able to show that in each work area they understand their own role, that of their team or group, can identify work-flows, the functions of each area, their own responsibilities for personal safety and that of others. Trainees must also demonstrate a clear knowledge of 'standard operating procedures' and all other aspects of an integrated quality system.

Level I - Module 2	Anatomy & Physiology
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- Training objectives:

To give an appreciation of the structure and working of the human body enabling the trainee to understand clinical procedures, medical terminology and the purpose of medical devices in the diagnosis, treatment and after-care of patients.

- Topics to be covered:

Anatomy of the body (skeleton, muscles, joints, organs), physiology-body systems (cardiovascular, respiratory, digestive, lymphatic, endocrine, reproduction, nervous, special senses); basic medical terminology and appropriate definitions.

- Performance criteria:

The trainee must be able to identify the major organs responsible for each bodily function and the terminology used to describe routine surgical procedures

Level I - Module 3	Basic microbiology and infection control procedures
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- Training objectives:

To understand the life cycles and functions of micro-organisms; identify the risks some micro-organisms pose to human health and the environment. To illustrate the effectiveness of preventative measures and good personal and communal hygiene.

- Topics to be covered:

Microbiology – pathogens (micro-organisms) – definition (bacteria, spores, viruses, fungi, protozoa), prion protein types, reproducibility (growth) conditions, movement patterns; infection control – sources of infection, infection spread, routes of infection, nosocomial infection and cross infection. The prevention and control of infection; the control of infection team and their relevance to decontamination departments; basic hygiene procedures; dress codes and the importance of decontamination processes and procedures.

- Performance criteria:

At the conclusion of this module, the trainee should be able to demonstrate a basic knowledge of micro-organisms and their potential for causing harm to human beings.

They should also have knowledge of infection control procedures used within the hospital. Hazards associated with handling and transporting used devices back to the re-processing area, and the requirements for staff protection.

Level I - Module 4	Cleaning and Disinfection of Medical Devices
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- Training objectives:

To understand the skills required to practise; and the importance of following the procedures in the functional areas. Show how to clean and disinfect, medical devices by using both manual and automated processes.

- Topics to be covered:

Collection, handling, reception, sorting of medical devices, decontamination (cleaning, disinfecting) processes (methods and equipment).

- Performance criteria:

The trainee should be able to clean and disinfect medical devices using either a manual or automated process. Load and un-load processing equipment; understand cycle stages and be able to monitor the process. The trainee should also demonstrate competence in batch labelling and recording processing data as well as carrying out “load acceptance” procedures.

Level I - Module 5	Inspection, Assembly and Packaging
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- Training objectives:

To understand the practices and procedures necessary to work in the inspection and packaging area of the SSD. (Decontamination, inspection, function testing, and packaging)

- Topics to be covered:

Clean room procedures: Sorting of used medical devices, recognition of devices, inspection, testing and assembly of packs, packaging materials used, sealing and labelling, documentation and record keeping.

- Performance criteria:

On completion of this module, trainees must be able to demonstrate their competence in understanding the safe operation of mechanical equipment and the action required if the equipment is faulty. Inspection, function testing, assembly, packaging, sealing and labelling techniques for packaging products.

Level I - Module 6	Sterilization
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- Training objectives:

To identify the essential characteristics and the indications for use of the different sterilization processes available; why different process are needed and when they would be selected. Identify the material properties of devices needing sterilization; to understand and practice sterilizer loading and unloading techniques, cycle stages and performance criteria of terminal processes including the care of devices prior to; and immediately after, sterilization.

- Topics to be covered:

Steam sterilization, Ethylene Oxide Gas sterilization, Low Temperature Steam/Formaldehyde sterilization and Gas Plasma sterilization Systems.

- Performance criteria:

The trainee should be able to prepare a load for sterilization, to load and unload a sterilizers, understand cycle stages and monitoring. The trainee should also demonstrate competence in documenting and recording data as well as undertaking load acceptance procedures.

Level I - Module 7	Storage and Distribution
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- Training objectives:

To develop skills in the receipt, handling, storage and distribution of raw materials and processed devices; including all relevant documentation.

- Topics to be covered:

Storage requirements; identification of devices/products; distribution policy; shelf life; documentation and record keeping; action to be taken for non-conforming products.

- Performance criteria:

The trainee should be competent to receive, identify, store and issue raw materials and processed medical devices and/or equipment. They must understand the importance of organisation in the storage environment of medical devices. Additionally, the trainee should be familiar with the “first in and first out” (FIFO) principles of storage and distribution.

Level I - Module 8	Teambuilding and Teamcoaching
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- Training objectives:

To understand the impact of an individuals contribution to the department as one person; and to place it in relationship to working alone and when working with other team members.

- Topics to be covered:

Through communication assignments and forms of psychodrama (role play), to observe how individuals behave in different ways within a group.

Understand that verbal as well as non-verbal (body language) communication is important. By using the recognised scientific interpretation of behaviour, and using examples from the exercises, corrective exercises can be given if required.

The group as well as the individual come to change through own understanding. Opportunity for emotional release can be created in some cases but only if group members offer enough emotional security to each other, but it is not always necessary to do so.

- Performance criteria:

If work is being done in a climate of trust and security, the group will communicate better. A team that communicates will improve the quality of the work assignments and will contribute to an optimal quality of the finished product.

Level II

Level II - Module 1	Statutory legal requirements/directives, recommended standards
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- Training objectives:

To provide the supervisor with an understanding of the practical aspects of Directives, regulations, standards both national and local recommendations as they affect CSSD and how they affect all aspects of the service.

- Topics to be covered:

To gain understanding of International, European and National legislation; European standards and recommended practises affecting Sterile Service departments; including the essential requirements of the Medical Devices Directive 93/42/EEC.

- Performance criteria:

On module completion, supervisors should be able to organize and monitor staff performance to ensure compliance with statutory and other requirements. They should also be able to handle and respond to routine inquiries and be able to take action to ensure that all safety requirements are followed and any non-conformances reported and resolved.

Level II - Module 2	Quality Management System
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- Training objectives:

To provide knowledge that will lead to improved practical understanding of the quality system, good manufacturing practise and other essential documentation requirements and their contribution towards maintaining a successful system

- Topics to be covered:

Quality management programme for CSSD; good manufacturing practice requirements, monitoring, control and documentary requirements including standard operating procedures, non conformities, document retention, commissioning data etc.

- Performance criteria:

The supervisor should be able to monitor quality processing/production systems within the department and ensure that accurate documentary evidence of compliance with written procedures is retained. They should be capable of informing other personnel of quality management system requirements and identifying areas in need of review.

Level II – Module 3	Human Resource and Staff Management
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- Training objectives:

To understand the management responsibilities for personnel working in CSSD and to recognise the connections with other hospital departments. To be aware of the basic principals of human resource allocation and control.

- Topics to be covered:

Basic employee rights and responsibilities; Health & Safety at work regulations; planning staff rotas, skill mix and work allocation; departmental workflows and basic production management techniques; priority work assessment; monitoring and control procedures; basic financial planning and implications; basic accounting procedures; supervisory skills including in-service technician training.

- Performance criteria:

Following this module, the supervisor should be able to demonstrate effective management principals which ensure that all workplace resources are used correctly resulting in reduced waste of both time and materials. An understanding of employee entitlements, responsibilities and expectations as well as practical methods of staff training and evaluation

Level II - Module 4	Communication and Team Coaching
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- Training Objectives:

To understand alternative communication methods, motivation techniques and how to influence people in order to meet user requirements and how to interact with others

- Topics to be covered:

Verbal, written and body language communication, different motivational methods, performance evaluation interviews, goal setting and qualification interviews with identified completion dates,

- Performance criteria:

Following completion of this module, the participant should be able to understand, use and apply alternative communication methods

Level II - Module 5	Qualification and Validation of Work Processes
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- Training objectives:

To develop an understanding of cleaning, disinfection, inspection, function testing, assembly of medical devices, packaging and sterilizing processes and contribute to the development of written instructions for qualification and validation criteria to understand the impact and interaction of all components of the process including water quality, steam quality, product specification and mechanical equipment function

- Topics to be covered:

Mechanical equipment care and maintenance; characteristics and chemical interaction including compatibility with devices (material composition, design) to be processed; reactions to chemical and physical influences; testing of utilities for quality and chemical composition; different test and measurement methods and how to interpret their results; developing and retaining outcomes; bio-burden and microbiological tests and understanding of parametric release

- Performance criteria:

The supervisor should understand the effects of the supporting utilities and their impact on the final product produced Which tests should be used to access the efficiency of the water/steam quality etc and they will be able to assist the manager to ensure that the all mechanical equipment is performing according to specification and commissioning data

Level II - Module 6	Building design and technical equipment
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- Training objectives:

Basic knowledge of building design, location and logistics; ergonomics of the working place; equipment, services and utilities;

- Topics to be covered:

Building standards and regulations; space allocation; evaluation of equipment requirements; air quality and pressure within the department; maintenance of building of equipment.

- Performance criteria;

The participant should understand the legal requirements of building design and equipment maintenance and the impact of having an appropriate working environment on staff and final product;

Level II - Module 7	Knowledge of Instruments
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- Training objectives:

Optimal handling practice and preservation of the medical devices

- Topics to be covered:

Composition materials, corrosion, types of corrosion, care, design, classification and risk management, ISO 17664 and the manufacturers responsibilities

Storage

- Performance criteria:

The supervisor should understand how to maintain instruments in optimum condition and be aware of the causes of corrosion and how to prevent it

Level II - Module 8	Product release, tracking and traceability
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- Training objectives:

To understand European and international standard requirements for packaging, labelling and sealing of medical devices; to implement approved pack traceability /product recall systems in accordance with quality system requirements.

- Topics to be covered:

Use of biological and chemical monitors (integrators and indicators); parametric release; sterility assurance; storage and distribution; monitoring, control and documentation procedures.

- Performance criteria:

The supervisor should be able to release processed medical devices with confidence and be able to initiate a product recall procedure should it be required.

Level II - Module 9	Infection prevention
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- Training objectives:

To understand the necessity for policies and procedures in relation to cleaning and disinfection of the working environment; continuing training and control of hand hygiene and disinfection and the impact of departmental processes on the control of infection within the hospital environment and his impact on patients.

- Topics to be covered

Microbiology of the environment, floor cleaning, general wall washing, surface cleaning and disinfection, sinks and toilets, cleaning protocols and disinfection methods, frequency, detergents and disinfectants.

- Performance criteria

The supervisor should understand how failure to follow procedures may lead to infection. He should be able to contribute to appropriate instructions to insure compliance with the above.

Level III

Level III - Module 1	General Management
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- Training objectives:

To be aware of the general requirements that apply to managing any service including planned work demands and organising work flows to meet user demand; to include employment law; Health and Safety; MDD 94/42EEC; European Norms and International Standards; Liability, personal accountability; European Contract Law; total quality management; project planning and how to evaluate changing clinical trends or demands.

- Topics to be covered:

Legal requirements both local employment law and international standards; training and continuous education of self and staff; the use of Personal Protective Equipment and how to protect staff from any potentially hazardous chemicals or equipment; time management and personal organisation and strategic service planning.

- Performance criteria:

Upon completion of this module, the manager should be able to plan effective and practical strategies and options for change within legal requirements. They should be able to modify practises to meet new practise standards and to accommodate new demands on the service safely.

Level III - Module 2	Total Quality Management
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- Training objectives:

To fully explore all the processes and requirements of a total quality management system, its implementation, accreditation, maintenance, auditing and monitoring.

- Topics to be covered:

Quality system ISO 13485 and ISO 9000/2000 series ISO14971; essential requirements for compliance with Medical Device Directive (EEC 93/42).

- Performance criteria:

The manager should be able to introduce and effectively monitor a total quality management system and assist others working in the organisation to understand and comply with the principals and practises necessary for effective compliance with the Medical Device Directive (EEC 93/42).

Level III - Module 3	Economic and Financial Business Management
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- Training objectives:

To set the provision of CSSD in the financial context of health care; financing, costing, accounting and budget control for the present and future activities of the department at national and local level. How to cost your service; compare commercial financial tenders and prepare a financial business plan to demonstrate cost benefits analysis.

- Topics to be covered:

Healthcare funding; hospital finance and budget setting procedures; costing of service and cost containment practises; accountancy practises; contract/service level agreements; procurement policies and materials management /inventory control procedures; bench marking; financial record maintenance and retention.

- Performance criteria:

The manager should be able to understand how financial health service provision and CSSD provision in particular are organised and funded at national and local levels. They should be able to produce costs benefits analysis for their service and demonstrate ability in maintaining, planning control systems which will lead to competence in responding to changes in the organisation.

Level III - Module 4	Personnel Management Issues
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- Training objectives:

To improve awareness of Human Resource Management; to learn personnel management tools (selection & recruitment, motivation, retention, development, training, education and team building) to facilitate their self development. To be aware of changing relationships between employees and employers and the possible impact on production.

- Topics to be covered:

Human resources management – recruitment and selection procedures; personnel and job specifications; training and educational aspects (planning and implementation of in-house and external programmes); management and staff development programmes; team building and development; health and safety issues; employee/employer contractual obligations/expectations; inter personal skills.

- Performance criteria:

The manager should be able to demonstrate effective staff management, development and retention which will lead to improved service provision and better inter active relationships with other departments.



Level III – Module 5	Other Resources
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- Training objectives:

To be aware of other resources which impact on the manager role, including the use of information technology; manufacturers courses; the internet as reference library; professional organisations both local and international.

- Topics to be covered:

The use of modern office software; designated CSSD operational systems including traceability;

- Performance criteria:

The manager will be able to identify a preferred operational system; use computers for service benefit and be aware of the positive benefits of contact with their professional peers at home and abroad,