Overview of decontamination in the UK – legislation, compliance, guidance and training

Thursday 3rd December 2020

"Proper decontamination of medical recycling equipment - what is required by management?"
Who am I?

Worked in Public Health England for 30 years

Research Microbiologist with a specific interest in waterborne microorganisms

Worked on wide range of decontamination projects including the potential transmission of prions through dental care

Close collaboration with the Department of Health and subsequent work on a number of the more recent guidance documents including Health Technical Memorandums.

Currently involved in a number of BSI committees

Conflict of Interests:
Current chair of the Central Sterilising Club
Consultancy: Walker on Water
What is the Central Sterilising Club?

Oldest and original Decontamination and Sterilisation Club
Founded in 1960 by a small group of enthusiastic individuals working in central sterile supply departments, or solving sterilising problems.

Multidisciplinary membership that is open to Sterile Service staff, Medical and non-medical microbiologists, Infection Prevention nurses, Authorized persons (sterilizers) and others

Membership £20 (approx. 237 NOK) per year

Here to serve our members and we look forward to you joining: https://centralsterilisingclub.org/membership/

Contributed to and published guidance e.g. National audit of decontamination standards in English hospitals 2000.


And provide certificates of “Continuing Professional Development” for our study day and annual scientific meetings

“Cleanliness is next to Godliness”

Legislation - Health and Safety at Work Act

Guidance documents (HTMs, HBN etc.) and Standards (EN/ISO)

How DH policy is implemented in NHS hospitals/Trusts and other healthcare providers

Compliance to quality systems, certification, accreditation for different sectors, for centralised and local decontamination units in hospitals.

Audits and inspections, Notified Bodies, JAG and CQC

Training/qualifications for staff and engineering services e.g. AE(D)
Legislation

- **Consumer Protection Act 1987:**
  - Part 1 implements EU Council Directive 85/374/EEC (product liability) providing compensation to be paid to persons injured by a defective product. There may also be civil liability violations with payment for damages.

- **Health and Safety at Work Act 1974**
  - Section 3 makes it a criminal offence if a Trust fails to conduct its undertaking in such a way as to ensure that patients are not exposed to health or safety risks. This is a very high standard of care with a reverse burden of proof (i.e. it is for the Trust to prove that it did take all reasonably practicable steps). (Sanction: Unlimited maximum fine).
  - Section 7 also makes it a criminal offence for any employee to fail to take reasonable care for the health and safety of himself and of other persons (e.g. patients) who may be affected by his acts or omissions at work. This could apply from front line staff right up to chief executive level. (Sanction: £5,000 maximum fine).

- **Criminal Offence of Manslaughter:**
  - If a patient dies as a result of an infection passed on through inadequately decontaminated surgical instruments, then the criminal offences of manslaughter (for individuals) and corporate manslaughter (for Trusts) could also apply.
  - Although a very high hurdle - “defendant's conduct was so bad, in all the circumstances, as to amount to a criminal act or omission”
Health and Safety at Work Act 1974
Anyone entering these premises must comply with regulations covered by the above act.
Cleaning up Chemical Spills

1. Call Public Safety at 609-258-5300 for advice on handling chemical spills.
2. For spills less than one gallon, use this spill kit.
3. Collect contaminants in a properly labeled bag.
4. Protect nearby floor with absorbent pads.
5. Pour absorbent from the bag of the spill to the floor.
6. Cover the spill with a clean cloth.
7. Collect contaminated spill pads in the same bag.
8. Call the appropriate environmental health and safety office to report spills to your supervisor.

EHS PRINCETON UNIVERSITY ENVIRONMENTAL HEALTH + SAFETY
Between 1974 and 2015:
- Fatal injuries to employees have fallen by 85%
- Non-fatal injuries have fallen by 77% (to 2011/12)
- Self-reported non-fatal injuries have fallen (since 2000/01)
- However - deaths from asbestos-related diseases have increased almost constantly year-on-year with about 10 times as many deaths in 2012 than in 1974, mainly due to exposure to asbestos prior to 1980
How do the different structures interact?
Regulation and codes of Practice

European Legislation (eg European Directives)
- Medical Devices Directive 93/42/EEC
- In-Vitro Diagnostic Devices Directive
- Active Implantable Medical Devices Directive

English Legislation (this is not an exclusive list)
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Care Quality Regulations 2009
- Health Act 2000
- Health and Safety at Work etc Act 1974
- Consumer Protection Act 1997

Regulations and Codes of Practice relating to the manufacture and supply of medical devices and reprocessing equipment
- Medical Devices Regulations 2002
- Pressure Systems Safety Regulations 2000 (as amended)
- Control of Substances Hazardous to Health Regulations 2002 (as amended)
- Personal Protective Equipment at Work Regulations 1992 (as amended)
- The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance
Role of Standards

- British, European and International Standards
- Healthcare Standards

- Regulatory bodies
  - Medicines and Healthcare products Regulatory Agency (MHRA)
  - Notified bodies
- Regulatory bodies
  - Care Quality Commission
Guidance documents

- DH Guidance (HTMs and Health Building Notes such as HBN 13)
- MHRA guidance (safety notices, alerts and bulletins)
- NICE guidance (e.g., NICE196)
- ACDP-TSE guidance

Notes
1. The In-Vitro Diagnostic Devices and Active Implantable Medical Devices Directives have been included for completeness although these devices are usually supplied sterile and are single-use.
Guidance in the UK

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care
Part A: Management and provision

Health Building Note 00-01
General design guidance for healthcare buildings
Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care

Part A: Management and provision
Why is Guidance Produced?

In the 1958 “the standards of sterilizing practice are open to criticism”. The imperfections of sterilizing technique may be a contributing factor to the...high incidence of infection in hospitals (7/8).

HSC 2000/032
A snapshot survey of current decontamination practices in a small number of healthcare premise has been carried out. More comprehensive survey..... Some immediate steps......to manage risks

DH 2009 Survey
- Migration of instruments between sets still occurring.
- Single instruments used to supplementaries still used.
- Single instruments tracking only implemented in a small number of centres.
Why has the guidance been updated?

HTM 01-01 has been updated to take account of recent changes to the ACDP-TSE Subgroup’s general principles of decontamination (Annex C). In relation to the decontamination of surgical instruments, this principally relates to paragraphs C21 and C22:

**Protein detection**

C21. Work commissioned by the Department of Health indicates the upper limit of acceptable protein contamination after processing is 5μg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments.

C22. It is necessary to use protein detection methods to check for the efficient removal of protein from surgical instruments after processing. Protein levels are used as an indication of the amount of prion protein contamination. Ninhydrin swab kits are commonly used for this purpose, but recent evidence shows that ninhydrin is insensitive. Furthermore, proteins are poorly desorbed from instruments by swabbing. Other commonly used methods have also been shown to be insensitive.
Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues
All surgical instruments in contact with high-risk tissues must be kept moist and separated from other instruments.

Rigid neuroendoscopes (rather than flexible neuroendoscopes) should be used if possible.

Instruments that come into contact with high-risk tissues must not be moved from one set to another and must remain within their individual sets.

Supplementary instruments in contact with high-risk tissues must remain within the individual set to which they have been introduced.
Decontamination
Health Technical Memorandum
01-05: Decontamination in primary care dental practices
Test chamber VHP and FFP3 set up

- HSE 34m³ controlled environment test chamber;
- ProteQ VHP machine set to hospital parameters adjusted for room configuration.
- FFP3s suspended in chamber to maximise potential VHP penetration.
How is Guidance Produced?

HTM 0101
Overall Project Team
Resources
Finances
Project Plan
Time Scale
Public consultation
Publishing and implementation
Health Technical Memorandum (England)

- HTM 01-01 Management of Decontamination of Medical Devices
  - Part A Local Policy and Choices
  - Part B Common Elements (equipment)
  - Part C Steam Sterilization including Steam Quality
  - Part D Washer-Disinfectors & Ultrasonic cleaners
  - Part E Low Temperature Sterilization

- HTM 01-04 Disinfection of Linen

- HTM 01-05 Primary Care Dentistry

- HTM 01-06 Decontamination of Flexible Endoscopes
  - Part A Policy and management
  - Part B Design and installation
  - Part C Operational management
  - Part D Validation and verification (including storage/drying cabinets)
  - Part E Testing methods
Wales participates in the production of the English HTM’s, either directly as part of the DH peer group or as external consultants.

NHS Wales Shared Services Partnership (NWSSP) /Specialist Estates Services act as primary leaders on Welsh Health Technical Memorandum’s on behalf of Welsh Government and NHS Wales

Adapts the content based upon their own regulatory framework and technical requirements.

For Decontamination, acceptance of any HTM revision into a WHTM is accepted through the All Wales Decontamination and Sterilization Advisory Group

Training is based upon IDSC and other frameworks across the UK, however Wales are setting up our own education pathway based on the National Vocational Qualification (NVQ) system, to be managed through an All Wales education framework – Agored Cymru – but this is not near implementation and is based upon a cost effective solution.

Endoscopy has traditionally been covered as part of the All wales endoscopy nurse competency framework, this covers the principles of decontamination, but are moving away from this as standards are being raised and Endoscopy Decontamination is now becoming more common in dedicated Decontamination Centres such as Hospital Sterilisation and Decontamination Unit.
Devolved Nations - Scotland (Scottish, SHTMs)

Health Facilities Scotland:

- Participates in the production of the English HTMs (DH England) and adapts the content for HFS
- Responsible for compliant requirements for decontamination units e.g. Central DU, Local DU, Endoscopy DU.
- Documents specific requirements for compliant facilities – physical facility, equipment, management and process.
- Support the boards to achieve compliance to the above requirements
  1. Various guidance documents
  2. National training framework and e-learning
  3. National procurement framework
  4. Assurance – independent annual validation test and certification of equipment, all CDUs are subjected to the notified body audit
  5. Helpline and support: enquiry services, support/advise on Boards projects and incident investigation
  6. Quality improvement projects

- Provides leadership and coordination on decontamination agenda in Scotland.
- 24 people in HFS, supporting 14 regional and one special boards decontamination facilities.
- Authorised Engineers are employed by HFS

http://www.hfs.scot.nhs.uk/home/
How is DH policy implemented in NHS hospitals/Trusts and other healthcare providers

Chief Executive is responsible for the management and safe operation of the premises, including decontamination.

Decontamination Lead is responsible for the effective, and technically compliant, provision of decontamination services in the organisation (operational policies, defines the roles and responsibilities and monitoring & implementation of the policy).

Surgical instruments (medical devices) decontamination manager is responsible for coordinating activity between the theatre, decontamination and supply/purchase teams.

User is responsible for the day-to-day management of the decontamination of reusable surgical instruments.

Authorised Engineer (Decontamination) provides independent auditing and technical advice on decontamination procedures, washer disinfectors, sterilizers and sterilization and to review and witness documentation on (re)validation i.e. monitoring and auditing all test results.
Compliance and accreditation in the UK is through a quality management system such as BS EN ISO 13485 across all areas of the decontamination cycle.

Centralised, local and endoscopy decontamination units in hospitals and others.

Requirements for the quality management system
• Life cycle of reusable medical devices and related services.
• Meet regulatory requirements.
• Implement reusable medical device regulatory requirements for quality management systems.
How are those DH Policies implemented by Third Party Providers?

Where decontamination services are provided by a third party, all parties should work together to develop and implement local policies and procedures.

Third-party providers of decontamination services come under the Medical Device Directive (directive 93/42/EEC has been superseded by directive 2007/47/EC).

They will use existing British and European Standards to demonstrate compliance with the essential requirements of the MDD and will have a quality system against which they are independently audited.

The development and implementation of new local policies and procedures may require a variation to the contract and changes to quality systems to accommodate.
HTM01 Requirements

• Requires that:
  • facilities designed to minimise the risks
  • procedures for acquisition, maintenance and validation of decontamination equipment
  • training in cleaning and decontamination processes (competences)
  • record-keeping to ensure decontamination processes fit for purpose and use the required quality systems

• Instruments/Endoscopes should be decontaminated in accordance with manufacturers’ recommendations

• Medical Devices should be reprocessed using a validated automated process (where possible)
HTM01 Requirements

- Policies and guidelines on the minimisation of recontamination or recolonisation should be in place.
- Production, maintenance and use of written procedures for each stage in the management,
- Reprocessed devices should be inspected so they are clean and safe for reuse.
- Manual or computer-based instrument track and trace system should be in place.
- Procedure for the withdrawal of devices from service should be in place.
Regulation of Decontamination in the UK

Figure 4 Regulation and audit of decontamination services and the respective responsibilities of MHRA and CQC

- Decontamination carried out on-site
  (for example, sterile services super centre, a trust carrying out decontamination on behalf of another trust or trusts)

  - Regulation by MHRA
  - Audit by a notified body

- Decontamination carried out on-site
  (for example, a trust or other healthcare organisation has its own sterile services department on-site)

  - Regulation by CQC
  - Local self-audits by provider with judgement about compliance by CQC
Notified Body

- Examine the products
- Assess technical information
- Verify batches
- Assess the quality system
- Conduct unannounced audits

BSI, SGS, IL International
Care Quality Commission (CQC)

Independently regulates all providers of regulated health and adult social care activities in England.

Providers must comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations (2009)

Maintain appropriate levels of cleanliness and hygiene in relation to reusable medical devices and the provision of a safe decontamination service that generates a clean and sterile product.
Who Audits Endoscopy Units?

Infection Prevention Society Audit Quality Improvement Tool
A local annual internal infection control audit and risk assessment is carried out within the decontamination area. We recommend that this is undertaken for the endoscopy unit.

IHEEM audit of Endoscopy
The Authorised Engineer (Decontamination) AED must carry out the audit and this should not be completed by endoscopy staff or on the AED’s behalf.

Joint Advisory Group on Gastrointestinal Endoscopy (JAG 1995) provides a framework for the quality improvement and assurance of endoscopy services

Assesses performance, and it supports units in planning and developing their services.

JAG helps with improving:
- Peoples focus on meeting users’ needs
- Workforce focus on meeting the team’s needs
- Awareness and understanding of endoscopy, so building confidence and credibility both within the organisation and among the public
- Performance – the standard serves as an authoritative benchmark for assessing performance, rewarding achievements in the service and driving quality improvement
Training in Decontamination
Possibly no formal qualifications

Healthcare Science Support Worker (Apprentice)

Healthcare Science Support Worker

Healthcare Science Support Worker Higher (Decontamination Technician)

Healthcare Science Assistant/Associate Practitioner (Decontamination Technician Supervisor)
Decontamination support worker - BTEC Level 2 Diploma in Healthcare Science

Apprenticeship
• competence-based qualification to give learners the opportunity to develop and demonstrate their competence.

• describe the knowledge, skills and behaviours (KSBs) required to undertake a specific occupation well, and to operate confidently within a sector.

• demonstrates mastery of an occupation, and meet professional registration requirements in sectors, where these exist.

Qualifications are outcome-based with no fixed learning programme, therefore allowing flexible delivery to meet the individual needs of learners and their employers.

Learners will work towards their qualification in the workplace or in settings that replicate the working environment as specified in the assessment requirements. (Taken from the BTEC specification)
Minimum number of credits that need to be achieved 4.

This course is assessed by the National School of Healthcare Science (Health Education England)
My experience as a Decontamination Science apprentice by John Allen

31st January 2020

Listen to John as he talks about what it’s like to be a Decontamination Science apprentice.

Decontamination Technician - Technical Certificate (TC) credit rated at a 3 England (6 Scotland, 4 EU) by Scottish Qualifications Authority

Course has 34 credits with 230 hours learning and is aimed at supervisory level with staff learning the theory behind the practice allowing them to make informed decisions on decontamination putting equipment out of use etc. and highlighting issues to senior staff.

This is an exam based course with exams twice a year in May and October, candidates are required to score 55 on both papers or over to obtain a pass.
Module 1
INFECTION PREVENTION & CONTROL - CONTAINMENT, TRANSPORTATION AND RISK MANAGEMENT

Introduction

This module introduces you to the environment and the resources that a technician will require when transporting reusable medical devices to and from the Decontamination department. It will include environmental requirements necessary in the Decontamination department for the prevention and control of potential infection as well as an explanation of Protective Personal Equipment (PPE) and importance of using this.

This module covers activities that you either perform yourself, or the measures you take to protect the equipment that you are transporting, patients, colleagues, visitors and anyone who may become involved. It will explain the importance of complying with risk management, so that you or any other people are not exposed to hazard, infection or any other risk from your actions or inactions.
<table>
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<tr>
<th>General</th>
<th>WI reference</th>
<th>Trainee</th>
<th>Trainer</th>
<th>Assessment: Discussion Observation Other</th>
<th>Date</th>
<th>Review Date</th>
<th>Review Date</th>
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<tr>
<td>Staff understand the QMS &amp; can find the Quality Manual, WIs and forms and relevance to ISO</td>
<td>Quality Manual WIs &amp; Forms</td>
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<td>Staff understand COSHH issues around working in the decontamination wash room</td>
<td>COSHH folder / risk assessments</td>
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<td>Chemical spills and spillage kit</td>
<td>WI-40</td>
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<td>Staff understand the different dress code of the specific areas in the decontamination unit</td>
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<td>Staff understand the need for different Personal Protective Equipment PPE</td>
<td>WI-1 WI-10</td>
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<td>Staff understand the importance of hand washing in the decontamination areas</td>
<td>Infection control e-learning</td>
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<td>Understand the different stages of the decontamination process Cleaning / Disinfection / Sterilisation</td>
<td>WI-4 WI-13 WI-37</td>
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<td>Understand the track and trace process and its importance</td>
<td>WI-11</td>
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Apprenticeships come in a number of levels with an academic equivalent as below:

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<tr>
<th>Level</th>
<th>Classification</th>
<th>Academic equivalent</th>
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<td>Level 2</td>
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<td>Level 5</td>
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<td>HND</td>
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<td>Diploma in higher education</td>
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<td>Level 6</td>
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<td>Masters’ Degree</td>
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• **Decontamination Technician Supervisor - Apprenticeship level 4** Pearson BTEC Level 4 Diploma in Healthcare Science.

The apprenticeship can be run by any college registered with Pearsons. Currently run at Eastwood Park as the decontamination experts or at an appropriate college with in-house teaching of decontamination.

• Work is continuing with HEE on higher qualifications but due to Covid have been delayed

Leading Excellence in Endoscopy Decontamination

Location: Leeds
Venue: The Queens (Hotel)
City Square
Leeds LS1 1PJ

Attendance is free of charge

To book your place, please email enquiries@interceptmed.com
with your:
- Full name
- Title
- Hospital Trust
- Department
- Telephone Number
- Email Address

This study day is aimed at staff with lead and management responsibility for endoscope decontamination.

The day will focus on the management skills required to lead teams to deliver excellence in endoscopy decontamination.

The expert speakers will be providing an essential overview from legislative requirements, microbiological facts to practical advice to ensure your department is effective and compliant.

The day will be headed by Mr Dan Simmons of Metris Leadership, former officer in the Special Air Service, presenting on leading teams in high pressured environments.

Speakers also include:
Dr Helen Griffiths,
Decontamination Advisor,
British Society of Gastroenterology
Mr Wayne Spencer,
Device Reprocessing

*Free Online Courses*

View our free CE courses on device processing related topics. While topics in this category focus on reprocessing medical devices, other topics include cleaning chemistries, sterility assurance, equipment maintenance and the role you play in preventing infections in hospitals.
Becoming an IHEEM registered Authorising Engineer (Decontamination)

All AE(D)s wishing to register with IHEEM are being assessed under a competency framework developed and agreed with IHEEM and managed by Eastwood Park Training. This is a unique programme with IHEEM that involves a rigorous assessment of competencies and skills. Here are the steps in the process:

Step 1 Initial assessment

There will be a full assessment interview to discuss the process in some detail, review your existing competencies and knowledge. This will involve an experienced decontamination Authorising Engineer (Decontamination) and Eastwood Park’s Learning & Development Manager.

You will be taken through the six assessment modules:
1. Management Skills
2. Equipment processes
   a. Sterilisation
   b. Washer disinfectors
   c. Water standards
   d. Environmental controls
   e. Purchasing and specifications
   f. Packaging methods
3. Roles and responsibilities and legal aspects
4. Decontamination and microbiology fundamentals
5. Standards and guidance
6. Validation, calibration, periodic testing and maintenance

Step 2 Individual development plan

At a meeting Eastwood Park will work with you to identify your existing knowledge in the context of the above modules and where there might be gaps or training and development requirements.

This will be supported by a detailed personal development plan and the next steps to achieving your AE(D) registration.

This might well include additional training, some of which may be met by Eastwood Park and would be part of the programme fee. Other needs may be fulfilled by other sources and may be in addition to the price outlined here. However we cannot identify these until after your initial assessment interview.

Price:
Programme registration is £5,895, excluding any specialist training requirements identified.
Summary

Legislation and the role of Health and Safety at Work Act

Breadth of guidance documents (HTMs, HBN etc.) and Standards (EN/ISO)

Implementation of policy in NHS hospitals/Trusts and other healthcare providers

Compliance and importance of quality systems, certification, accreditation for different sectors, for centralised and local decontamination units in hospitals.

The role of audits and inspections, AE(D), NB, JAG and CQC

The importance of training/qualifications for key staff, management and engineering services AE(D), AP Decontamination etc
Acknowledgement

Val O’Brien
Wayne Spencer
Karen Tweed
Gill Ellis-Pow
Sulisti Holmes
Helen Campbell

Decontamination in Dentistry – impact of COVID-19
10\textsuperscript{th} February 2021
Zoom

CSC Study Day
4\textsuperscript{th} October 2021
Stratford Upon Avon

CSC Annual Scientific Meeting 2022
Spring 2022
Stratford Upon Avon

FREE to CSC members