# ANNEX C

## GENERAL PRINCIPLES OF DECONTAMINATION AND WASTE DISPOSAL

**Summary of advice**
Annex C provides information on the general principles of decontamination and waste disposal for transmissible spongiform encephalopathies (TSEs).

**Previous revision date: November 2009**
**Changes new to this edition:**

| Date | Change | Notes |
|---|---|---|
| February 2015 | Change of terminology from “infection control” to “infection prevention and control”. | Changed throughout the document as appropriate. |
| February 2015 | Decontamination cycle diagram updated, to allow for new prion deactivation technologies. | This change affects paragraph C2. |
| February 2015 | Addition of advice to clean instruments as soon as possible after use. | Paragraphs C4 and C5 have been added and the numbering of subsequent paragraphs changed accordingly. |
| February 2015 | Clarification that the use of sodium hypochlorite is at ambient temperature. | This change affects paragraph C8. |
| February 2015 | Additional advice on the use of formic acid. | This change affects paragraph C10. |
| February 2015 | Expansion of the section on ‘Other processes’. | This change affects paragraph C17, and paragraphs C18-C20 have been added. |
| February 2015 | Addition of a section on ‘Protein detection’. | Paragraphs C21-C23 have been added. |
| February 2015 | Addition of a table with details of recent research projects relating to protein detection and decontamination, funded by the Department of Health. | Table C2 has been added. |
| February 2015 | Update of the references to other relevant guidance. | These changes affect Table C3. |

## Introduction

C1. This annex provides information on the general principles of decontamination and waste disposal for transmissible spongiform encephalopathies (TSEs). A list of selected guidelines and standards related to decontamination and waste disposal is included as Table C3. Guidance on decontamination and waste disposal in a healthcare setting can be found in Part 4 of this guidance. Guidance on decontamination and waste disposal in a laboratory setting can be found in Part 3 of this guidance.

## The Decontamination Cycle for reusable medical equipment

C2.

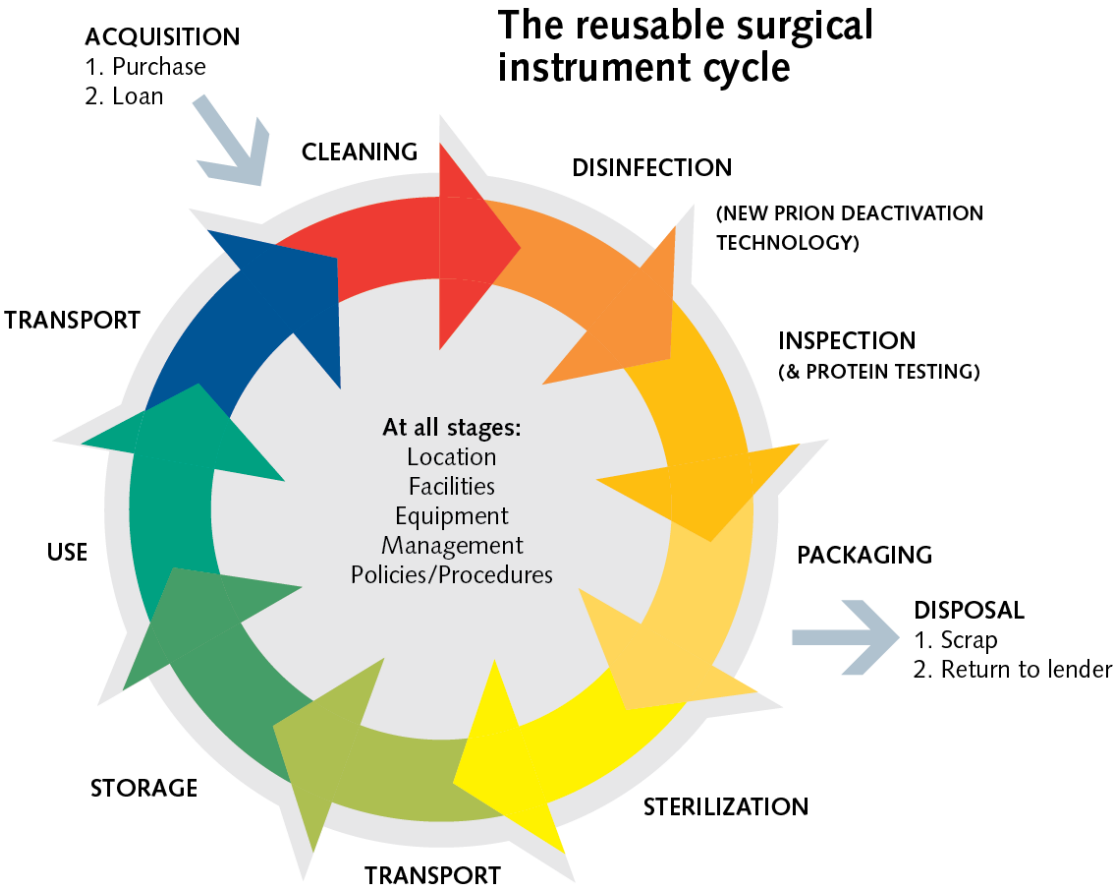


Diagram from Department of Health CFPP 01-01

## Decontamination and TSE agents

C3. TSE agents are particularly resistant to standard physical and chemical methods of inactivation and decontamination. **Therefore, effective cleaning is of great importance in the removal of these agents.**

C4. Research demonstrates that allowing surgical instruments to dry for more than fifteen minutes before reprocessing greatly increases the amount of

residual protein contamination[1,2,3,4]. Therefore instruments should be transported to the sterile services department (SSD) immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible. This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD.

C5. For endoscopes, the bedside clean should take place immediately after the procedure has been carried out, and it is recommended that the endoscopes should be manually cleaned according to the manufacturer's recommendations and passed through an Endoscope Washer Disinfector as soon as possible after use. See Annex F for further guidance about decontamination of endoscopes.

C6. Details of chemical and gaseous disinfectants and physical processes commonly used for decontamination, and their effectiveness at reducing infectivity, are outlined below. **It should be noted that combinations of some agents and/or processes could be effective, for example, physical/chemical combinations such as autoclaving with sodium hydroxide.**

**Chemical decontamination**

C7. **Most chemical disinfectants are ineffective at reducing infectivity and some, acting as protein fixatives, may stabilise the agent** (see Table C1).

**Sodium hypochlorite**

C8. Sodium hypochlorite is considered to be effective at reducing infectivity but only at concentrations (20,000ppm available chlorine for 1 hour at ambient temperature) that pose certain practical constraints. The following should be taken into account when considering the use of sodium hypochlorite:

- It must not be used on open surfaces *i.e.* benches due to the possible release of chlorine gas
- It corrodes metal and steel
- It is incompatible with formaldehyde, alcohols and acids
- It is rapidly inactivated by protein residues

[1] Lemmer *et al*. 2004. Decontamination of surgical instruments from prion proteins: in vitro studies on the detachment, destabilization and degradation of $PrP^{Sc}$ bound to steel surfaces. *Journal of General Virology*, 85; 3805-3816.

[2] Rutala and Weber 2001. Creutzfeldt-Jakob disease: recommendations for disinfection and sterilization. *Clinical Infectious Diseases*, 32; 1348-1356.

[3] Lipscomb *et al*. 2007. Effect of drying time, ambient temperature and pre-soaks on prion-infected tissue contamination levels on surgical stainless steel: concerns over prolonged transportation of instruments from theatre to central sterile service departments. *Journal of Hospital Infection*, 65; 72-77.

[4] Secker *et al.* 2011. Adsorption of prion and tissue proteins to surgical stainless steel surfaces and the efficacy of decontamination following dry and wet storage conditions. *Journal of Hospital Infection*, 78; 251-255.

- Concentrated stock dilutions last for only approximately 2-3 weeks
- Diluted solutions are not stable and should be made up daily

**Sodium hydroxide**

C9. Sodium hydroxide (2M for 1 hour) has a substantial effect, and will reduce infectivity to an acceptable level when used at ambient temperature. An increase in temperature will increase effectiveness. The following should be taken into account when considering the use of 2M sodium hydroxide:

- It should not be used on aluminium or zinc
- It will not cause fumes but is damaging to body tissue
- It is an irritant and harmful as dust

**Formic acid**

C10. Formic acid (96% for 1 hour) may be used for histological samples of human or animal tissue that have previously been fixed in formalin. For material not treated with formic acid prior to processing, the immersion of formalin-fixed tissue sections (5µm or less) in undiluted formic acid (*i.e.* 96% or above) for at least 5 minutes is considered appropriate as a risk reduction measure. However, it should not be used on tissue that has previously been exposed to phenol, as this interacts deleteriously with formic acid.

**Table C1: Ineffective chemical disinfectants**

| **Chemical disinfectants commonly used for decontamination that are INEFFECTIVE at reducing infectivity** |
|---|
| Alcohols[1] |
| Ammonia |
| ß-propiolactone |
| Chlorine dioxide |
| Ethylene oxide |
| Formaldehyde and related compounds[1] |
| Glutaraldehyde and related compounds[1] (e.g. orthophthalaldehyde [OPA]) |
| Hydrochloric acid (Not reliably effective for practicable use) |
| Hydrogen peroxide |
| Iodophors |
| Peracetic acid |
| Aqueous solutions of phenol (≤10% phenol) |
| Sodium dichloroisocyanurate (e.g. 'Presept')[2] |
| 10,000ppm sodium hypochlorite (Not reliably effective for practicable use) |

[1]These agents are strong fixatives, may stabilise infectivity and thereby decrease the efficiency of the decontamination process

[2]The rate of release of chlorine from this product is insufficient to ensure complete inactivation of the agent

**Phenol**

C11. Phenol (≥ 90% phenol) is highly effective at eliminating infectivity. Phenol is a toxic, corrosive and irritant chemical which can be absorbed through mucous membranes, wounds and intact skin, and should be used cautiously and with the appropriate personal protective clothing.

## Physical processes

**Incineration**

C12. Incineration is effective at removing the infectious agent and eliminating infectivity. Temperatures over 600ºC are likely to be practically effective, and 850ºC is commonly used in practice. Temperatures ≥1000 ºC can produce sterility. The particle size of material to be combusted should be suitably small to ensure efficient heat penetration to the centre.

**Autoclaving**

C13. Autoclaving remains an important method of reducing infectivity. Different strains of TSE are known to vary in their sensitivity to heat.

C14. The following methods will reduce infectivity but cannot be relied upon to completely eliminate infectivity (either porous load or gravity displacement).

- 121°C for 15 minutes
- 134-137°C for 3 minutes
- 134-137°C for 18 minutes
- Six successive cycles of 3 minutes

C15. The 'Prion Cycle' found on some benchtop vacuum autoclaves will also reduce infectivity **but will not eliminate infectivity entirely**. See MHRA Safety Notice 'SN 2002(11): Benchtop vacuum steam sterilizers – the 'prion cycle', available here.

**Radiation**

C16. Ionising, UV or microwave radiation at conventional doses are not effective at reducing infectivity.

## Other processes

C17. A number of anti-prion technologies are in development. In 2008 the Engineering and Science Advisory Committee into the Decontamination of Surgical Instruments including Prion Removal (ESAC-Pr) produced a report on prion inactivating agents. This report provides advice on various anti-prion technologies then available or in development, their applicability to the current decontamination process for reusable medical equipment, and the direction of future research needs. The report can be accessed here.

C18. Many products developed for prion inactivation have only been available as a pre-soak. There are problems associated with the soaking of instruments, and the ESAC-Pr report specifically notes that:

*"It is apparent that there needs to be greater discussion between the disinfectant product manufacturers, washer disinfector manufacturers and the end users,*

*particularly the Decontamination Leads and the Sterile Services Managers. The overwhelming conclusion of these professionals is that using these products, as a manual pre-soak is not a viable option in operating departments or in SSDs. It is not possible to validate reliably the soaking of instruments in open containers of chemical. Further, the question of penetration of chemical into serrations and box joints cannot be guaranteed. Therefore, it is vital that chemicals intended for this purpose are incorporated into the existing decontamination cycle practices i.e. as part of the washer disinfector process."*

C19. A Working Group of the Advisory Committee on Dangerous Pathogens TSE Subgroup was convened in 2014 to assess the outputs of Department of Health funded research projects aimed at improving the evidence base for the decontamination of reusable surgical instruments and protein detection. The Working Group reviewed several novel technologies then in development for protein detection and decontamination. It is hoped that these technologies will make decontamination practices even more effective in the future.

C20. New technologies being developed need to reflect the operational requirements of the service. The Engineering Research Group has suggested that a routine test for washer disinfectors could be developed to measure the cleaning efficacy at validation and routine testing, such as daily or weekly tests. This method could be based on a process challenge device system that will monitor the optimised wash cycles; the results must be quantifiable and objective. This method should be sensitive to the requirements of this document and be able to deliver a consistent and accurate set of results that can be assessed by the unit management and Notified Bodies.

**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[5,6]. Furthermore, proteins are poorly desorbed from instruments by swabbing[6]. Other commonly used methods have also been shown to be insensitive[7].

[5] Lipscomb *et al.* 2006. The sensitivity of approved Ninhydrin and Biuret tests in the assessment of protein contamination on surgical steel as an aid to prevent iatrogenic prion transmission. *Journal of Hospital Infection*, 64; 288-292.

[6] Nayuni *et al.* 2013. Critical evaluation of ninhydrin for monitoring surgical instrument decontamination. *Journal of Hospital Infection,* 84, 97-102.

[7] Nayuni and Perrett 2013. A comparative study of methods for detecting residual protein on surgical instruments. *Medical Device Decontamination (incorporating the IDSc Journal),* 18, 16-20.

C23. New technologies are required on the market that can detect protein on instruments *in situ*, in nanogram quantities.

**Table C2: Research projects relating to protein detection and decontamination recently funded by the Department of Health**

| Project | Topic | Publications arising to date |
|---|---|---|
| 007/0194 Cold Gas Plasma Decontamination of Flexible Endoscopes | Novel technology for decontamination of endoscopes. | |
| 007/0196 Endoscope Decontamination: defining the problem | Decontamination of endoscopes | Hervé, R.C. and Keevil, C.W. 2013. Current limitations about the cleaning of luminal endoscopes. *Journal of Hospital Infection* 83, 22-29. |
| 007/0200 Optimisation of Automated Washer Disinfector Performance | Parameters contributing to optimised automated washer disinfector performance. | Nayuni, N. and Perrett, D. 2014. Valipro tags for the monitoring of washer disinfector efficiency. *Medical Device Decontamination (incorporating the IDSc Journal)* 18, 16-20. |
| 007/0201 Meta and cluster analysis on Animal Models Used for TSE Decontamination Research | Literature review of animal models used in decontamination research. | |
| 007/0202 Protein Detection Trial in SSDs | High sensitivity protein detection in SSD environments. | Perrett D and Nayuni N 2014. Assessing protein contamination on surgical and dental instruments Chapter 23 *in Decontamination in Hospitals and Healthcare*. Edited by Dr J.T. Walker, Woodhead Publishers<br><br>Perrett D,*et al.* 2014. The *in-situ* detection of residual protein on surgical instruments: Development of the ProReveal system. *Medical Device Decontamination (incorporating the IDSc Journal)* 18, 8-17<br><br>Nayuni N, *et al.* 2013. A critical evaluation of ninhydrin as a protein detection method for monitoring surgical instrument decontamination in hospitals. *J Hospital Infection* 84, 97-102<br><br>Nayuni N. and Perrett D. 2013. A comparative study of methods for detecting residual protein on surgical instruments*. Medical Device Decontamination (incorporating the IDSc Journal)* 18, 16-20 |
| 007/0203 Protein Detection Trial | Detection of residual protein on instruments. | *Continued overleaf* |

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|---|---|---|
| 007/0204<br>Evaluation of EFSCAN Protein Detection for Monitoring Decontamination | Detection of residual protein on instruments. | Smith, A., *et al.* 2014. Dental handpiece contamination: a proteomics and surface analysis approach. *Biofouling*, 30, 29-39 |
| 007/0208<br>Selection and Preclinical Evaluation of Coatings for Surgical Instruments | Coating surgical instruments to minimise protein attachment. | |

**Table C3: Selected guidelines and standards related to decontamination and waste disposal**

| Name | Date published | Brief description |
|---|---|---|
| **93/42/EEC The Medical Devices Directive** | 1993 UK law since 1998 | This Directive under European Law covers the placing on the market and putting into service of Medical Devices (other than active implantable and *in vitro* diagnostic devices). Available here. Essential requirements in the Directive are listed under Annex 1. Two essential requirements under section 8 – Infection and microbial contamination – are particularly relevant: "8.4: Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate validated method." "8.5: Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions." |
| **Medical Devices Regulations** | 2002 | These UK Regulations are drawn from the Medical Devices Directive 93/42/EEC |
| **Department of Health NHS Estates and Facilities Policy (formerly NHS Estates) Health Building Notes (HBNs)** HBNs provide advice to project teams designing and planning new buildings and adapting/extending existing buildings. HBNs are available at: https://www.gov.uk/government/collections/health-building-notes-core-elements | | |
| **Department of Health Estates and Facilities Policy (formerly NHS Estates) Engineering Health Technical Memoranda (HTM) and Choice Framework for local policy and procedures (CFPP)** HTMs and CFPPs provide evidence-based policy and guidance on the management and decontamination of reusable medical devices and other aspects of decontamination in healthcare settings. | | |
| **CFPP 01-01 Management and decontamination of surgical instruments (medical devices) used in acute care** | 2013 | This CFPP offers best practice guidance on the whole decontamination cycle including the management and decontamination of surgical instruments used in acute care. It is in four parts: Part A – Formulation of local policy and choices Part B – Common elements Part C – Steam sterilization Part D – Washer disinfectors Part E - Alternatives to steam for the sterilization of reusable medical devices https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care |
| **CFPP 01-04 Decontamination of linen for health and social care** | 2013 | This CFPP amalgamates earlier versions of laundry guidance. Earlier documentation incorporated in and superseded by this guidance includes HSG(95)18 and parts of Health Building Note 25 – 'Laundry'. https://www.gov.uk/government/publications/decontamination-of-linen-for-health-and-social-care *Continued overleaf* |

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|---|---|---|
| **CFPP 01-06 Management and decontamination of flexible endoscopes** | 2013 | This CFPP covers flexible endoscope management and decontamination. It is divided into five volumes:<br>• Policy and management<br>• Design and installation<br>• Operational management<br>• Validation and verification<br>• Testing methods<br>https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes |
| **HTM 01-05 Dental Decontamination** | 2013 | This guidance has been produced to reflect a reasonable and rational response to emerging evidence around the effectiveness of decontamination in primary care dental practices, and the possibility of prion transmission through protein contamination of dental instruments.https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170689/HTM_01-05_2013.pdf |
| **HTM 07-01 Safe management of healthcare waste** | 2013 | This document is a best practice guide to the management of healthcare waste. Healthcare waste refers to any waste produced by, and as a consequence of, healthcare activities. For the purposes of this document, this guidance also applies to offensive/hygiene and infectious waste produced in the community from non-NHS healthcare.<br>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167976/HTM_07-01_Final.pdf |
| **Technical requirements and Guidance in Scotland** | | |
| **The Glennie framework** | 2001 | This document specifies the requirements for sterile service provision across NHS Scotland.<br>http://www.scotland.gov.uk/Publications/2001/10/10106/File-1 |
| **Compliant Dental Local Decontamination Units in Scotland (Primary Care)** | 2013 | This document specifies the requirements for compliant reprocessing of dental devices in Local Decontamination Units (Primary Care).<br>http://www.hfs.scot.nhs.uk/publications-1/decontamination/ |
| **Provision of Compliant Podiatry Instruments** | 2014 | This document specifies the requirements for compliant provision of podiatry instruments.<br>http://www.hfs.scot.nhs.uk/services/decontamination-services/guidance/ |
| **Other relevant decontamination guidance** | | http://www.hfs.scot.nhs.uk/services/decontamination-services/guidance/<br>*Continued overleaf* |

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| **Welsh Health Technical Memoranda (WHTMs)** **http://www.wales.nhs.uk/sites3/page.cfm?orgid=254&pid=64101** | | |
| **WHTM 01-01 Decontamination of medical devices within acute services** | 2013-2014 | This document gives guidance on the whole decontamination cycle in the management and decontamination of surgical instruments used in acute care. It is in five parts:<br>Part A – Management and environment<br>Part B – Common elements<br>Part C – Steam sterilization and steam for sterilization<br>Part D – Washer disinfectors<br>Part E - Alternatives to steam for the sterilization of reusable medical devices |
| **WHTM 01-05 Decontamination in primary care dental practices and community dental services** | 2014 | This guidance relates to locally conducted decontamination in primary care dental services |
| **WHTM 01-06 Decontamination of flexible endoscopes** | 2014 | This guidance allows local decisions to be made in the formulation of an appropriately developed, risk controlled, operational environment within the healthcare facilities that decontaminate flexible endoscopes. It is in five parts:<br>Part A - Policy and management<br>Part B - Design and installation<br>Part C - Operational management<br>Part D - Testing methods<br>Part E - Validation and verification |
| **Guidance in Northern Ireland** | | |
| **PEL (13) 12*: Choice Framework for Local Policies and Procedures (CFPP)01-01*** | 2013 | Management and Decontamination of Surgical Instruments (Medical Devices ) Used in Acute Care: Parts A, B,C,D, and E for use in Northern Ireland. http://www.dhsspsni.gov.uk/pel_13_12_part_1.pdf |
| **PEL (13) 15: *Choice Framework for Local Policies and Procedures (CFPP)01-06*** | 2013 | Reprocessing of Flexible Endoscopes: For use in Northern Ireland. http://www.dhsspsni.gov.uk/pel-13-15.pdf |
| **PEL (13) 16: *Northern Ireland Addenda to Choice Framework for Local Policies and Procedures (CFPP) 01-01*** | 2013 | Management and Decontamination of Surgical Instruments (Medical Devices) Used in Acute Care and CFPP 01-06: Reprocessing of Flexible Endoscopes. NI/CFPP/01, NI/CFPP/02 and NI/CFPP/03 : Testing Requirements. http://www.dhsspsni.gov.uk/pel-13-16.pdf |
| **HSS(MD)4/01** | 2001 | Protocol for local decontamination of surgical instruments |
| **HSS(MD)4/01** | 2001 | Decontamination of reusable medical devices Addendum 3 |

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|---|---|---|
| **HSS(MD)16/99** | 1999 | Controls Assurance in Infection Control: Decontamination of Medical Devices. (and accompanying Decontamination Guidance CD-ROM) |
| **HSS(MD)12/2007** | 2007 | Decontamination of Surgical Instruments in light of National Institute for Health and Clinical Excellence (NICE) Guidance – Patient Safety and Reduction of Risk of Transmission of CreutzfeldtJakob Disease (CJ) via Interventional Procedures |
| **PEL (13) 13** | 2013 | Updated Northern Ireland Guidance on Decontamination in Primary Care Dental Practices: Health Technical Memorandum 01:05 2013 Edition http://www.dhsspsni.gov.uk/pel_13_13.pdf |
| **Other relevant guidance** | | |
| **Standards and Practice** | 2012 | The Institute of Decontamination Sciences (IDSc), formerly the Institute of Sterile Services Management, has produced a revised third edition of this guidance, which sets out in detail the operational, technical and managerial requirements of decontamination services and provides a useful resource for anyone working in or around decontamination. The revised 3rd edition has been extensively updated to include the latest legislative framework referencing the work of the Healthcare Commission, ISO 13485 and the revised HBN13.<br>A hardcopy of 'Standards and Practice' is free to full members of the Institute. Non-members can purchase hardcopies of the guidance. More information available at http://www.idsc-uk.co.uk/publications.php |
| **Standards and Recommendations for Safe Perioperative Practice** | 2015 | The Association for Perioperative Practice (AfPP), formally NATN, has produced the fourth edition of their perioperative standards and recommendations. The Decontamination Section is found within chapter 6 providing direction and guidance on all aspects of the decontamination life cycle processes, including direct links to all UK regions, National and International standards. The book is available to purchase via AfPP's website (www.afpp.org.uk/books-journals/afpppublication) |