Department of Health
An Roinn Sláinte
Männystrie O Poustie
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HEALTH TECHNICAL MEMORANDUM (HTM) 01-01 - MANAGEMENT AND DECONTAMINATION OF SURGICAL INSTRUMENTS (MEDICAL DEVICES) USED IN ACUTE CARE

For Action:
Chief Executives of HSC Trusts for distribution to:

- Medical Directors
- Directors of Dental Services
- Directors of Infection Prevention and Control
- Consultant Microbiologists
- Theatre Managers
- Decontamination Leads
- Risk Managers
- Consultant Surgeons
- Consultant Neurosurgeons
- Governance Leads

Chief Executive RQIA for distribution to:

- Independent Hospitals

For Information:
Distribution as listed at the end of this Circular.

Related documents:
HSS(SC)3/04 – Decontamination of Reusable Surgical Instruments
https://www.health-ni.gov.uk/sites/default/files/publications/health/HSS%20-%20SC%20-%203-04.pdf

NI/HTM 01-01/01 Periodic testing of Sterile Services Department (SSD) Washer Disinfectors (WD), Ultrasonic cleaners (UC) and Porous load sterilizers (PLS), September 2016
https://www.health-ni.gov.uk/sites/default/files/publications/health/NI-HTM%2001-01-01.pdf

NI/Testing Requirements/01: Water testing and Microbial testing requirements for Decontamination equipment, September 2016
https://www.health-ni.gov.uk/articles/dhssps-decontamination-programme-0

Superseded documents:
PEL (12)12 Choice Framework for local Policy and Procedures, CFPP 01-01

Implementation: Immediate

DoH Safety and Quality Circulars including Patient Safety Alerts can be accessed on:
https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

Summary

HTM 01-01 takes account of the changes to the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup's general principals on decontamination. HTM 01-01 replaces the guidance document *Choice Framework for local Policy and Procedures*, CFPP 01-01.

Specific Northern Ireland policy amendments that apply to the revised guidance are outlined in this circular.

Action

Chief Executives of HSC Trusts should:

- Disseminate this circular to all relevant staff
- **By 1 July 2017**, implement *in situ* protein detection methodologies to achieve a ≤5 µg residual protein level for instruments that are likely to come into contact with higher risk tissues, for example neurological tissue.
- **By 1 July 2018**, have implemented the guidance for residual protein levels for other surgical instruments used in acute care to subsequently produce further reductions in protein contamination levels through the optimisation of decontamination processes.

Chief Executive, RQIA should:

- Disseminate this circular to all appropriate Independent Sector providers.

Background

The major change in this latest version of the guidance is taking account of changes to the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup's general principals of decontamination (see ACDP-TSE's Annex C). This establishes a move towards *in situ* testing for residual proteins on instruments. Residual protein is important because of the continuing risks of transmission of prions (the causative agent of transmissible spongiform encephalopathies such as variant Creutzfeldt-Jakob disease (vCJD).

The ACDP-TSE Annex C guidance is available on the gov.uk website:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427855/Annex_C_v3.0.pdf.

Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of health and social care.

The revised HTM 01-01 consists of five parts:

Part A: Management and provision
Part B: Common Elements
Part C: Steam sterilization
Part D: Washer-disinfectors
Part E: Alternatives to steam sterilization of reusable medical devices
The suite of guidance documents is available at:
https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

A summary of the key revisions and specific Northern Ireland policy amendments applicable to the guidance for HSC bodies is detailed at Appendix 1.

The gov.uk website allows users to register to receive announcements on new publications and revisions to guidance such as Health Technical Memorandum guidance on decontamination. To subscribe to announcements, select Announcements at the bottom of the gov.uk webpage (https://www.gov.uk/government/announcements) and use the filter list to select your area of interest before selecting to receive announcements by email or by feed and complete the subscription process.

Enquiries:

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Yours sincerely

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Appendix 1

List of Key Revisions to the HTM 01-01 Guidance

Part A:

- New guidance is included on how to ensure implementation of the ACDP-TSE's Subgroup's recommendations.

- Chapter 5 on prion diseases has been updated to reflect the changes to the ACDP-TSE Subgroup's guidance (2015).

- In the section on "Separation of instruments used on high risk tissues for patients born before and after 1 January 1997", in Chapter 6, the management of instruments for the small number of patients born after 1 January 1997 who have already had past high risk tissue surgery using pre-1997 instruments has been amended (see paragraphs 6.8–6.10) in line with both the views of the Society of British Neurological Surgeons and the ACDP-TSE Subgroup.

  This provides information on how sterile services departments (SSDs) can mitigate the patient safety risk from residual protein with a move towards first achieving this ≤5 µg level and subsequently producing further reductions in protein contamination levels through the optimisation of decontamination processes. The ambition is that all healthcare providers engaged in the management and decontamination of surgical instruments used in acute care will be expected to have implemented this guidance by 1 July 2018. However, providers whose instruments are likely to come into contact with higher risk tissues, for example neurological tissue, are expected to give this guidance higher priority and move to *in situ* protein detection methodologies by 1 July 2017.

Parts B and C: These parts remain unchanged

Part D:

- New periodic in-use test have been included for residual protein including a flowchart.

- New text on the process challenge devices has been inserted and now added as a daily test.

- Previous tests for residual soil using ninhydrin and other alternative methods have been removed as they are no longer applicable.

Part E: This part remains unchanged

Northern Ireland Policy Amendments:

The following Northern Ireland policy amendments apply to the HTM 01-01 suite of documents:

1. Health and Social Care providers in Northern Ireland are required to meet “best practice” requirements as outlined in the suite of documents rather than meeting “essential quality requirements” and having a plan to meet “best practice” as stated. This has been the consistent policy position in Northern Ireland in respect of “Best Practice” requirements as defined in circular HSS (SC) 3/04.

2. In HTM 01-01 Part A, Management of surgical instruments 6.25, the guidance on “Decontamination of surgical instruments that have been dropped preoperatively” is at odds with Department of Health (NI) decontamination policy and is not acceptable in Northern Ireland. This element is replaced by the “Dropped Instrument Risk Assessment and Management (Wales NHS)” model provided at Appendix 2.

3. Health Technical Memoranda 2010 and 2030 are to remain in use in Northern Ireland for laboratory sterilizers and washer-disinfectors for human waste containers respectively, until appropriate HTM 01-01 documents are developed for this range of equipment.

4. Current arrangements for the Department of Health (NI) Authorising Engineer (Decontamination – Assurance) (AE (D-A))) assurance function remain unchanged.

APPENDIX 2

Dropped Instrument Risk Assessment and Management (Wales NHS)