### REPORT SUMMARY SHEET

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<th>Meeting:</th>
<th>SMT and Trust Board</th>
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<td>Date:</td>
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<tr>
<td>Title:</td>
<td>Decontamination of Reusable Medical Devices Annual Report 2013/14</td>
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<td>Lead Director:</td>
<td>Director of Acute Services</td>
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| Corporate Objective: | • Provide safe, high quality care.  
• Make the best use of resources. |
| Purpose: | For approval/assurance.  
This report sets out the Trust’s position with regard to the decontamination of reusable medical devices during the year 1 April 2013 to 31 March 2014 as required by the Decontamination of Reusable Medical Devices Controls Assurance Standard. |
| Summary of key areas: | • The Trust’s 2013/14 self-assessment score against the Decontamination of Reusable Medical Devices Controls Assurance Standard was substantive at 88%.  
• Both Sterile Services Departments at Craigavon Area Hospital and Daisy Hill Hospital were successfully re-accredited to the BS EN ISO 13485:2003 Quality Management Standard and the Medical Devices Directive (MDD) 93/42/EEC.  
• The new purpose built endoscope decontamination facility, which was part of the Theatres refurbishment at Daisy Hill Hospital, was completed in December 2013.  
• The Trust received a capital allocation of £3,072,000 for new/replacement decontamination equipment and accompanying remedial works. An installation and commissioning programme is in progress with completion planned for August 2014.  
• From April 2014 the decontamination of instruments from Community Dental transferred to Sterile Services Departments.  
• Estates Department has implemented a fully compliant testing and maintenance service of all decontamination equipment. The Trust now complies with all DHSSPSNI validation and testing standards and guidance.  
• The decontamination of ENT flexible endoscopes used in Banbridge Polyclinic and Armagh Community Hospital has transferred to the endoscope decontamination unit at Craigavon Area Hospital Theatres. All ENT flexible endoscopes used throughout the Trust are now being decontaminated in endoscope washer disinfectors between each patient use as recommended by DHSSPSNI standards and guidance. |
DECONTAMINATION OF REUSABLE MEDICAL DEVICES

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1.0 **STRATEGIC CONTEXT**

The Department of Health in Northern Ireland (DHSSPSNI) has issued the following standards and guidance in relation to the decontamination of reusable medical devices:

- DHSS Circular HSS (MD) 16/99, Controls assurance in infection control: decontamination of medical devices
- DHSS Circular HSS (MD) 15/99, Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission
- DB 9904 (NI) Medical Device and Equipment Management for Hospitals and Community-based Organisations NIAIC
- HSS (SC) 3/04 – Decontamination of Reusable Surgical Instruments
- Hine Review 2004
- DB 2002 (NI) (05) Decontamination of Endoscopes
- EN ISO 15883 Washer Disinfectors Parts 1 – 4
- BS EN 285 Sterilisation – Steam Sterilisers – Large Sterilisers
- BS EN ISO 17665 Sterilisation of Healthcare Products – Moist Heat
- PEL(12)12 Choice Framework for Local Policies and Procedures (CFPP) 01-01: Management and Decontamination of Surgical Instruments (medical devices) used in Acute Care: Parts A, B, C, D, E for use in Northern Ireland
- NI/CFPP/01 Northern Ireland addendum to CFPP 01-01 and CFPP 01-06: Water Testing Requirements
- NI/CFPP/02 Northern Ireland addendum to CFPP 01-01: Periodic testing of Sterile Services Department (SSD) Washer Disinfectors (WD), Ultrasonic Cleaners (UC) and Porous Load Sterilisers (PLS)
- PEL(13)15 Choice Framework for local Policies and Procedures (CFPP) 01-06: Reprocessing of flexible endoscopes; for use in Northern Ireland
- NI/CFPP/03 Northern Ireland addendum to CFPP 01-06: Periodic testing of Endoscope Washer Disinfectors (EWD) and Endoscope Drying Cabinets (EDC).
- PEL(13)16 Northern Ireland Addenda To Choice Framework For Local Policies And Procedures (CFPP) 01-01: Management And Decontamination Of Surgical Instruments (Medical Devices) Used In Acute Care And Cfpp 01-06: Reprocessing Of Flexible Endoscopes.
2.0 OPERATIONAL CONTEXT

There are two Sterile Services Departments (SSDs) located at Craigavon Area Hospital (CAH) and Daisy Hill Hospital (DHH). Reusable surgical instruments used in CAH, DHH, South Tyrone Hospital (STH) and G.P. surgeries throughout the Southern Trust are decontaminated within these SSDs. In addition, the decontamination of instruments from Community Dental clinics transferred to Sterile Services Departments in April 2014. The SSDs employ 50 staff and decontaminate approximately 184,000 sets of instruments per annum.

Flexible endoscopes are decontaminated in Endoscope Washer Disinfectors (EWDs) in four locations throughout the Trust, i.e. Day Surgery Units in CAH and STH, Theatres in CAH and DHH endoscope decontamination unit.

Bedpans are decontaminated in bedpan washer disinfectors at ward / department level.

Re-usable instruments used in Podiatry clinics in the various community facilities throughout the Trust are decontaminated in benchtop sterilisers within these facilities.

3.0 GOVERNANCE ARRANGEMENTS

3.1 Roles and Responsibilities

The Chief Executive in accordance with Choice Framework for local Policy and Procedures 01-01 - Management and Decontamination of Surgical Instruments used in Acute Care Part A is the Executive Manager and is defined as the person with ultimate management responsibility.

The Director of Acute Services in accordance with Choice Framework for local Policy and Procedures 01-01 - Management and Decontamination of Surgical Instruments used in Acute Care Part A is the nominated Decontamination Lead at Trust Board level with responsibility for Decontamination.

The Assistant Director of Acute Services, Functional Support Services has operational responsibility for the management of the decontamination service provided by SSDs including the decontamination of flexible endoscopes at Theatres, CAH. The Head of Decontamination Services has responsibility for the provision of decontamination services within the Trust and is accountable to the Assistant Director of Acute Services, Functional Support Services.

The Assistant Director of Cancer and Clinical Services has operational responsibility for the decontamination of flexible endoscopes at Day Surgery Units in CAH and STH and DHH endoscope decontamination unit.

The Director of Older People and Primary Care has responsibility for the decontamination of Community Podiatry instruments.
3.2 **Trust Decontamination Committee**

The Decontamination Committee ensures that appropriate arrangements are in place throughout the Trust for the management of decontamination of reusable medical devices.

The Committee meets three times a year and includes representatives from Support Services, Infection Prevention and Control, Estates, Nursing, Podiatry and Dental. Meetings are chaired by the Assistant Director of Acute Services, Functional Support Services.

The Decontamination Committee is a sub-committee of Senior Management Team (SMT) and any decontamination issues will be reported to SMT by the Director of Acute Services and escalated on to Trust Board if appropriate.

3.3 **Trust Policy for the Decontamination of Reusable Medical Devices**

The Trust Policy for the Decontamination of Reusable Medical Devices was approved by SMT on 30 January 2008. It was last reviewed in August 2012 and it is next due for review in August 2014.

3.4 **Trust Policy for the Decontamination of Flexible Endoscopes**

The Trust Policy for the Decontamination of Flexible Endoscopes was approved by SMT on 23 December 2009. It was last reviewed in August 2012 and it is next due for review in August 2014.

4.0 **MONITORING AND AUDIT ARRANGEMENTS**

4.1 **Internal Arrangements**

4.1.1 **Decontamination of Reusable Medical Devices Controls Assurance Standard**

The DHSSPSNI published a Controls Assurance Standard on Decontamination of Reusable Medical Devices in 2006, with a requirement for Trusts to achieve ‘substantive’ compliance. During 2013/14, a self-assessment of the Trust’s position against the Decontamination of Reusable Medical Devices Controls Assurance Standard was undertaken. The overall score for the self-assessment was substantive at 88%.

An action plan has been developed which identifies the work required to be undertaken to maintain and further improve compliance with the Controls Assurance Standard.


Both SSDs at CAH and DHH are accredited to the BS EN ISO 13485:2003 Quality Management Standard and the Medical Devices Directive (MDD) 93/42/EEC. As part of the Quality Management System the SSDs are required to undertake the following:-
• **Internal departmental audits**
  Internal departmental audits are conducted to ensure continued compliance. The frequency of the audits is dependent on the risk categorisation of the particular process.

  The outcomes of the departmental audits are reviewed at the SSD Management Review Meetings and action plans are developed and implemented if appropriate.

• **Satisfaction Surveys**
  A satisfaction survey is carried out annually by both SSDs. In August 2013 surveys were issued to all service users i.e. Theatres, Day Surgery Units, Delivery Suites, Outpatient Departments, Trust wards / departments and GP clinics. There was a 57% response rate and the results of the survey were very positive with all service users being either satisfied or very satisfied with the standard of service provided.

• **Complaints**
  SSDs monitor complaints received from service users. During 2013/14 the SSDs decontaminated approximately 15,333 instrument sets per month and received on average 6 complaints per month (equates to approximately 0.04%) from their service users.

  The complaints related to dirty instruments, missing instruments or damaged packaging but they did not have an adverse effect on any patients or led to the cancellation of any theatre sessions. All of the complaints were analysed for root causes and corrective / preventive measures were actioned where applicable.

4.2 **External Audit Arrangements**

4.2.1 **British Standards Institution (BSI) Audits**
  The SSDs at CAH and DHH are externally audited by the British Standards Institute (BSI) on a six monthly basis to ensure compliance with BS EN ISO 13485:2003 and the Medical Devices Directive (MDD) 93/42/EEC.

  Both SSDs were externally audited in September 2013 and April 2014 and BSI recommended continuation of the ISO and MDD registration.

5.0 **TRAINING**

  All Sterile Services staff receive extensive induction training and also complete a refresher decontamination e-learning package as required.
6.0 **KEY ISSUES DURING 2013/14**

6.1 **New Endoscope Decontamination Unit, DHH**

DHH - The new purpose built endoscope decontamination facility, which was part of the Theatres refurbishment, was completed in December 2013. The area is currently managed and staffed by Nursing staff but plans are in place to transfer the management to SSD. The new endoscope decontamination unit at DHH now meets all of the required DHSSPSNI standards and recommendations.

6.2 **New / Replacement Decontamination Equipment**

The Trust received a capital allocation of £3,072,000 for new / replacement decontamination equipment and accompanying remedial works. The following is a breakdown of the main equipment purchased:-

- CAH SSD - 3 replacement and 3 additional washer disinfectors, 1 additional steriliser
- DHH SSD - 2 replacement and 1 additional washer disinfecter and 1 additional steriliser
- DHH Endoscope Decontamination Unit – 1 additional endoscope washer disinfecter
- Trust wide - 21 endoscope drying cabinets
- Trust wide – 50 bedpan washer disinfecters
- Upgrade of Independent Monitoring Systems for Lancer endoscope washer disinfecters and for SSD sterilisers

An installation and commissioning programme is in progress with completion planned for August 2014. On completion of the installation and commissioning programme the Trust will comply with all DHSSPSNI decontamination standards and guidance with the exception of the following areas:-

- **Centralised Endoscope Decontamination Unit on the CAH Site**
  New endoscope decontamination facilities have been identified in phase 1 of the Capital Priorities and Strategic Outline Case for the Redevelopment of Craigavon Area Hospital which was approved by SMT on 8 January 2014 and then submitted to the DHSSPSNI on 10 January 2014.

- **Community Podiatry Decontamination**
  Reusable Podiatry instruments are still decontaminated in bench top sterilisers in the various community clinics throughout the Trust.

  The Department has approved funding for the purchase of single use Podiatry instruments and this will be progressed by Older People and Primary Care Directorate during 2014/15.

6.3 **Maintenance & Testing of Decontamination Equipment**

During 2013/14 Estates Department implemented a fully compliant testing and maintenance service of all decontamination equipment. The Trust now complies with all DHSSPSNI validation and testing standards and guidance.
6.4 **Bedpan Washer Disinfectors**

During 2013/14 the Trust purchased 50 new / replacement bedpan washer disinfectors that comply with DHSSPSNI standards and guidance.

The daily testing of bedpan washer disinfectors is undertaken by wards and departments and during 2013/14 audits were conducted to ensure compliance. The quarterly and annual testing and maintenance service is provided by Estates Department.

6.5 **ENT Flexible Endoscopes**

The decontamination of ENT flexible endoscopes used in Banbridge Polyclinic and Armagh Community Hospital has transferred to the endoscope decontamination unit at Craigavon Area Hospital Theatres.

All ENT flexible endoscopes used throughout the Trust are now being decontaminated in endoscope washer disinfectors between each patient use as recommended by DHSSPSNI standards and guidance.

7.0 **ACTION PLAN FOR 2014/15**

7.1 Work collaboratively with Estates and suppliers to progress the installation and commissioning programme for all new decontamination equipment which is due for completion by August 2014.

7.2 Continue to maintain the BS EN ISO 13485:2003 Quality Management Standard and the Medical Devices Directive (MDD) 93/42/EEC accreditation at both SSDs.

7.3 Transfer the management of the DHH Endoscopy Decontamination Unit to Sterile Services.

7.4 Older People and Primary Care Directorate to progress the procurement of single use Podiatry instruments and then de-commission the Community Podiatry bench top sterilisers.