Report of the unannounced inspection at Connolly Hospital.

Monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals.

Date of on-site inspection: 23 August 2018

A programme designed to additionally supplement HIQA’s approach to monitoring against the National Standards for the prevention and control of healthcare-associated infections in acute healthcare services.
Report of the unannounced inspection of the prevention and control of healthcare associated infection at Connolly Hospital
About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA’s role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA’s mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

- **Regulation** — Registering and inspecting designated centres.

- **Monitoring Children’s Services** — Monitoring and inspecting children’s social services.

- **Monitoring Healthcare Safety and Quality** — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.

- **Health Information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland’s health and social care services.
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1.0 Introduction

HIQA monitors the implementation of the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*¹ in public acute hospitals in Ireland to determine if hospitals have effective arrangements in place to protect patients from acquiring healthcare-associated infection. The *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* will be referred to as the *National Standards* in this report.

In 2017, HIQA commenced a revised monitoring programme against the National Standards. The aim of this revised monitoring programme is to assess aspects of the governance, management and implementation of designated programmes to prevent and control healthcare-associated infections in hospitals. This monitoring programme comprises Phases One, Two and Three:

**Phase One**

All public acute hospitals were requested to complete and return a self-assessment tool to HIQA during April and May 2017.

**Phase Two**

Phase 2 commenced in May 2017 and involved unannounced inspections in public acute hospitals, focusing on elements of the prevention and control of healthcare-associated infection in line with the *National Standards.*²

In light of the ongoing national public health emergency* in relation to Carbapenemase-Producing *Enterobacteriales* (CPE)† the focus of these inspections was on systems to detect, prevent and respond to healthcare-associated infections and multidrug-resistant organisms. It is anticipated that this phase will continue throughout 2018 and 2019 in parallel with Phase 3.

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¹ A National Public Health Emergency Plan was activated on 25 October 2017 by the Minister for Health in response to the increase and spread of CPE in Ireland. As a result a National Public Health Emergency Team was convened and they have been meeting on a weekly basis since 02 November 2017. Please refer to the Department of Health webpage for further details: http://health.gov.ie/national-patient-safety-office/patient-safety-surveillance/antimicrobial-resistance-amr-2/public-health-emergency-plan-to-tackle-cpe/nphet-press-releases-minutes-of-meetings/.

² Carbapenemase-Producing *Enterobacteriales* (CPE), are Gram-negative bacteria that have acquired resistance to nearly all of the antibiotics that would have historically worked against them. They are therefore much more difficult to treat.
Phase Three

From quarter 3 2018 onwards the programme focussed on decontamination and reprocessing of critical and semi-critical reusable medical devices. HIQA will focus, in the first instance, on decontamination facilities outside of designated controlled decontamination units to ensure structures, systems, processes and outcomes in these facilities are aligned to the National Standards and guidelines.

Additional information can be found in the Guide to HIQA’s programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals which was published in July 2018 and is available on HIQA’s website: www.hiqa.ie

Information about this inspection

This inspection report was completed following an unannounced inspection carried out at Connolly Hospital by Authorised Persons from HIQA; Kathryn Hanly and Noreen Flannelly Kinsella. The inspection was carried out on 23 August 2018 between 09.30hrs and 14.40hrs.

Prior to this inspection, authorised persons reviewed the hospital’s completed self-assessment tool and related documentation submitted to HIQA earlier in May 2017.

Inspectors spoke with hospital managers and staff, and the decontamination lead. Inspectors requested, reviewed documentation and data and visited two clinical areas where reusable medical device decontamination was carried out:

- Radiology Department
- Theatre Department.

HIQA would like to acknowledge the cooperation of the hospital management team and all staff who facilitated and contributed to this unannounced inspection.

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1The Spaulding classification, dating back to the 1950s, is a widely used classification system which is used to determine the level of decontamination a reusable medical device requires. The level of decontamination required is dependent on the equipment’s purpose, and ranges from cleaning, through disinfection to a requirement for sterilisation. Devices may be classified as ‘critical’ (presenting a high risk of infection transmission if not fully cleaned, disinfected and sterilised), ‘semi-critical’ or ‘non-critical’ (presenting a low risk).

2Decontamination facilities refers to the physical infrastructure where decontamination of reusable medical devices is provided.

**A controlled decontamination unit, such as a Central Decontamination Unit or Endoscope Reprocessing Unit, is a designated unit which has defined governance arrangements and is designed, constructed, maintained and controlled with structures, systems, processes and outcomes that are continuously monitored, measured and validated to provide assurances that reusable medical devices are safely and effectively reprocessed consistently in accordance with legislation, manufacturer’s instructions, national decontamination standards and guidelines, National Standards and best practice guidance.
2.0 Profile

Connolly Hospital is a major teaching hospital providing a range of services to a diverse population covering the communities of West Dublin, North Kildare and South County Meath. These services include a 24 hour Emergency Department, acute medical and surgical services, long-stay residential care, day care, out-patient care plus diagnostic and therapeutic and support services.

Table 1.0 Overview of decontamination facilities

<table>
<thead>
<tr>
<th>Spaulding risk categorisation</th>
<th>Reusable medical device and location of decontamination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical items</strong></td>
<td>• Surgical instruments used in the general theatre department were decontaminated and reprocessed by an external out-sourced provider.</td>
</tr>
<tr>
<td>Items that enter sterile tissues/ sterile body areas or the vascular system</td>
<td></td>
</tr>
<tr>
<td><strong>Semi-critical items</strong></td>
<td>• Flexible endoscope decontamination was undertaken centrally in the Endoscopy Decontamination Unit (EDU) and in a satellite decontamination facility within the footprint of the operating theatre department.</td>
</tr>
<tr>
<td>Items in contact with mucous membranes or non-intact skin.</td>
<td></td>
</tr>
<tr>
<td>• Transoesophageal Echocardiogram (TOE) scopes were decontaminated in the EDU</td>
<td></td>
</tr>
<tr>
<td>• Nasopharyngeal endoscopes from the Outpatients Department were decontaminated and reprocessed in a satellite decontamination facility in the operating theatre department.</td>
<td></td>
</tr>
<tr>
<td>• Ultrasound probes used in the radiology department were decontaminated at point of care in radiology department.</td>
<td></td>
</tr>
<tr>
<td>• Disposable bronchoscopes for bronchoscopy procedures undertaken outside of the central endoscopy unit were available at the hospital.</td>
<td></td>
</tr>
<tr>
<td><strong>Non-critical items</strong></td>
<td>• An ultrasound probe used in the general theatre for vascular access was decontaminated after use within the operating theatre department.</td>
</tr>
<tr>
<td>Items in contact with intact skin but not mucous membranes or not in contact with the patient</td>
<td></td>
</tr>
</tbody>
</table>
3.0 Findings at Connolly Hospital

3.1 Risk identified

**Carbapenemase Producing Enterobacteriaceae**

On review of supplementary documentation requested after the inspection, inspectors identified that the hospital was not in compliance with the Health Service Executive guideline around screening patients for CPE.\(^4\)

Considering this in the context of the activation of the National Public Health Emergency Plan to address CPE in our health system, HIQA sought assurance regarding arrangements that were in place to ensure compliance with the national guidelines on screening\(^{††}\) for CPE at Connolly Hospital.

In its response to the high risk letter sent by HIQA to the Connolly Hospital, the hospital communicated that a Quality Improvement Plan for CPE had been implemented to ensure implementation of the screening guidelines as set by the National CPE Expert Group.

3.2 Governance and management

The hospital had an established Decontamination Committee with formalised governance arrangements and lines of accountability in place for decontamination of reusable medical devices. The governance arrangements and decontamination activity were clearly outlined in the organogram provided to inspectors (Appendix 3).

Inspectors were informed that the Decontamination Committee reported to the Infection Prevention and Control Committee who in turn reported to the Quality and Safety Executive Committee.

The Decontamination Committee was co-chaired by a consultant microbiologist and the perioperative directorate assistant director of nursing (ADON). The peri-operative ADON was designated as the hospital decontamination lead in May 2015. Multidisciplinary membership of the committee included representatives from satellite decontamination facilities, the infection prevention and control team and the clinical engineer. The Decontamination Committee also formally reported to the Quality and Safety Executive on an annual basis.

Individual responsibility for decontamination of reusable medical devices was clearly defined throughout the organisation. Each area where reusable medical device decontamination was undertaken had personnel appointed with responsibility for operational management of the area.

\(^{††}\) Performing active surveillance cultures, active screening tests or contact screening of at-risk patients to detect colonisation with Carbapenemase Producing Enterobacteriales.
The hospital had a comprehensive inventory of reusable medical device and decontamination equipment used.

Semi-invasive ultrasound probes were decontaminated locally within the radiology department.

Recent efforts had been made to reduce the number of satellite facilities carrying out endoscope decontamination. Decontamination of flexible endoscopes was undertaken both centrally within the endoscopy unit and in decontamination facilities located within the operating theatre department. To comply with national guidance the hospital should continue to work towards a centralised model of endoscope service delivery.  

Sterilisation of critical items including surgical instruments was outsourced to an external contractor. Inspectors found evidence of clear oversight of and accountability for this externally contracted decontamination service. A service-level agreement was in place and included the scope of service provided and governance arrangements for the quality and safety of services delivered. Inspectors were also informed that an annual audit of external decontamination facilities was undertaken by the hospital and that procedures were in place for the recall of nonconforming surgical instruments and sets in line with national guidelines.

The Rotunda Hospital’s ambulatory hysteroscopy clinic was located at Connolly hospital. A service level agreement outlined that governance and management of the service was provided by the Rotunda hospital. Hysteroscopes, surgical sets and transvaginal ultrasound probes were transported to and decontaminated in the Rotunda Hospital’s central sterile services department.

Inspectors were informed that there was no decontamination lead within the HSE RCSI Hospital’s Group. In the absence of such structures, hospital managers told inspectors that support was provided by the HSE’s National Decontamination Lead.

### 3.3 Risk management

A risk management system was in place to identify the hazards associated with the decontamination process, to estimate, evaluate the risks and monitor the effectiveness of the control. Issues which were considered to potentially compromise safe decontamination of reusable medical devices were included in local departmental risk registers. Senior management told inspectors that there were no active or open decontamination risks on the hospital’s corporate risk register.

The hospital had identified a lack of appropriate facilities for surgical instrument decontamination a number of years ago. In order to mitigate the identified risk, in 2016 the hospital began outsourcing all decontamination of surgical instruments to an external company.
The national medical devices eAlert system‡‡ had been implemented in the hospital. The clinical engineer, as the nominated "designated person", was responsible for internal hospital distribution to the relevant personnel for implementation of the recommended actions where applicable.

The hospital had a procedure for reporting decontamination accidents and incidents. Incidents were discussed at quarterly decontamination committee meetings. A draft policy regarding the management of decontamination incidents had been developed and was awaiting sign off.

The hospital had developed draft guidelines for the identification of service users at increased risk§§ of developing transmissible spongiform encephalopathies (TSEs). Inspectors were informed at interview that TSE risk assessments were not routinely undertaken as “high risk” surgery, endoscopy or invasive procedures where contact with high/medium risk TSE tissue was likely were not undertaken within the hospital.

**Monitoring and evaluation including audit**

In order to identify areas for improvement the Decontamination Committee had conducted a gap analysis of the decontamination programme at the hospital at the beginning of 2018. An action plan was developed to address issues identified.

An annual audit of flexible endoscope decontamination facilities was undertaken in 2017 by the Authorised Engineer (Decontamination)*** in line with national guidelines.10 However audits of facilities used for reprocessing of semi-critical ultrasound probe decontamination had not been undertaken.

Environmental hygiene audits were carried out by the Hygiene Services Department and formed part of the management of environmental cleaning. However inspectors noted that frequencies of hygiene audits for very high and moderate risk functional areas such as operating theatres and the radiology department were not carried out in line with national guidance.9

Audits of reusable medical device decontamination practices and processes were not undertaken. Front-line staff responsible for performing high level disinfection should

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‡‡ The national eAlert system receives notification directly from the HPRA of all medical device safety / hazard notifications or any internally generated HSE safety notifications for distribution.

§§ Critical and semi critical medical devices contaminated with high-risk tissue (i.e., brain, spinal cord, and eye tissue) from high-risk patients—those with known or suspected infection with Transmissible Spongiform Encephalopathies require special treatment. Patients who are due to undergo a procedure involving high-infectivity or medium-infectivity tissues must be questioned pre-operatively and have their medical records searched to determine if they are at increased risk of developing a TSE. High/medium risk tissue includes brain, spinal cord, posterior/anterior eye, olfactory epithelium and lymphoid tissue

*** The role of the AE(D) is fully independent of the healthcare facilities' structure for maintenance, testing and management of the decontamination equipment. The AE(D) is defined as a person designated by Management to provide independent auditing and technical advice on decontamination procedures, washer-disinfectors
be initially and routinely monitored to assure that all steps are being conducted thoroughly and accurately.

Although the focus of inspections was on decontamination facilities outside of a designated controlled decontamination unit, inspectors sought assurances in relation to monitoring and evaluation systems implemented in the central EDU.\textsuperscript{10} The endoscopy unit was externally validated and inspected to the standards developed by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG). Inspectors were informed that the endoscopy decontamination unit (EDU) was designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities.

Staff in the satellite decontamination facility within the operating theatre department informed inspectors that daily and weekly testing of endoscope decontamination equipment was performed and documented; a sample of checklists was viewed by the inspector.

Validation, routine monitoring and control on endoscope washer disinfectors in the central endoscope decontamination unit and in the theatre department were carried out in accordance with documented procedures as recommended by the manufacturers’ instructions.\textsuperscript{10,11}

A formalised system to trace nasopharyngeal endoscopes used in the outpatients department was not in place at the time of the inspection. A record showing that the decontamination process had taken place was kept with reprocessed nasopharyngeal endoscopes. However systems were in place to record the decontamination process used on all other endoscopes and accessories (tracking) linking them with service users on which they had been used (tracing).

A manual track and trace system was in place for surgical instruments. Inspectors were informed that the hospital was currently working toward implementing the national electronic track and trace system for reusable medical devices. The hospital must ensure that externally contracted decontamination services are fully integrated and compatible with Health Service Executive (HSE) surgical instrument traceability systems to ensure the traceability chain is maintained throughout the decontamination process.

### 3.4 Staff training and education

A HSE review of surgical instrument decontamination (2015) identified the need for a formalised academic training programme to enhance safe practice and support personnel involved in the management or decontamination of surgical instruments. Technical/user training was provided by the manufacturers of endoscope and ultrasound probe decontamination equipment and training records were maintained.
In addition, individual competencies of staff in the EDU were assessed by the unit manager.

One staff member in the satellite decontamination facility in the theatre department had completed an academically recognised decontamination training course. The manager of the sterile services department had completed a degree in decontamination sciences.\(^5\)

Material safety data sheets were available to all staff used potentially hazardous chemicals. Staff also completed the HSELaND online Chemical Safety eLearning Programme.\(^{12}\)

### 3.5 Policies, procedures, protocols and guidelines

The hospital had developed a number of multidisciplinary policies procedures and guidelines to support the decontamination and reprocessing of reusable medical devices. However, a number of guidelines reviewed by inspectors were still in draft format and had not been formally approved for use at the hospital.

Inspectors identified a lack of standardisation of policy and procedures folders within the hospital. The hospital did not have a controlled document control system to ensure that staff had access to the most up-to-date versions of hospital policies, procedures and guidelines. Policies and guidelines were available on the hospital intranet.
3.6 Decontamination of semi-critical medical devices in satellite decontamination facilities.

Inspectors visited two decontamination facilities††† outside of designated controlled decontamination units‡‡‡ to ensure that structures, systems, processes and outcomes in these facilities are aligned to national guidelines. HIQA Inspectors visited the radiology department and theatre department.

**Radiology Department**

**Evidence of good practice**

Inspectors found that processes for the decontamination of reusable invasive devices used within the radiology department were in line with national standards.⁰¹³

- An automated process was used to achieve high level disinfection (HLD) of semi-critical ultrasound probes in a sealed chamber by exposure to hydrogen peroxide mist.
- Maintenance and service contracts covering validation, testing and maintenance of the equipment were in place.
- A system was in place to ensure probes were tracked through the decontamination process and linked to the patient on whom the devices had been used.

**Areas for improvement**

- National guidelines recommend that semi invasive ultrasound probes should placed into a solid-walled container for transfer to the decontamination area and transported in a manner that avoids dissemination of contamination.¹³
- A suitable dedicated non-clinical space for decontamination of semi-critical ultrasound probes be identified. The hydrogen peroxide decontamination system used for probe decontamination was located in an open area within the department.
- Storage of decontaminated semi invasive ultrasound probes in the hydrogen peroxide decontamination system between uses was not in line with best practice.

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††† Decontamination facilities refers to the physical infrastructure where decontamination of reusable medical devices is provided.

‡‡‡ A controlled decontamination unit is a designated unit which has defined governance arrangements and is designed, constructed, maintained and controlled with structures, systems, processes and outcomes that are continuously monitored, measured and validated to provide assurances that reusable medical devices are safely and effectively reprocessed consistently in accordance with legislation, manufacturer’s instructions, national decontamination standards and guidelines, National Standards and best practice guidance.
Theatre Department

Decontamination of flexible endoscopes was undertaken both centrally in the endoscopy unit and in a local decontamination facilities located within the theatre department. Nasopharyngeal endoscopes from the outpatients department were also decontaminated and reprocessed in this satellite facility in the theatre department. An ultrasound probe used in the general theatre for vascular access was decontaminated after use in the department.

Surgical instruments and surgically-invasive endoscopes used in the department were decontaminated and reprocessed by an external provider.

Evidence of good practice

Inspectors found that decontamination processes for the decontamination of endoscopes within the operating theatre department were undertaken in line with national standards.  
10,13

- Automated reprocessing of endoscopes took place in an automated endoscope reprocessor (AER).
- A dedicated trained operative whose sole responsibility was management of the facility during normal working hours was in place.
- Staffing arrangements were in place to support out-of-hours decontamination in the department.
- There was a clear flow of work within the decontamination facilities in the department distinct and separate dirty and clean areas.
- Electronic track and trace was in place for endoscopes in place with the exception of tracing for nasopharyngeal endoscopes.
- Staff reported that an (non-critical) ultrasound probe used for vascular access was cleaned with a disinfectant wipe and alcohol. Inspectors were informed that if the transducer came in contact with broken skin, blood, mucosal membranes or bodily fluid a high-level disinfection process was used.

Opportunities for improvement

- Recent efforts had been made to reduce the number of satellite facilities carrying out endoscope decontamination. The centralisation of all endoscope decontamination activity within the JAG accredited endoscopy unit at the hospital should be progressed to ensure that standards are centrally controlled and meet national and international best practice guidance.  
5
- Ongoing microbiological monitoring of the decontamination facility environment including air and contact surfaces was not performed in line with national guidelines and European legislation.  
10,6
- Access and egress to the decontamination facility was through a minor operating theatre which was not appropriate.

- The facility provided unidirectional flow from 'dirty' area to 'clean' area. However the design of the decontamination facilities did not ensure the complete physical separation of dirty and clean activities as rooms were not separate from each other; there was no separate gowning room between washroom and clean area.

- Endoscope Washer Disinfectors (EWD) were not pass-through models as recommended in national guidelines.¹⁰

- Ventilation systems within the satellite endoscope decontamination facility in the theatre department were not in line with best practice and relevant legislation.

- Open shelving in the clean area should be replaced with enclosed cupboards to avoid cross contamination of clean items and to facilitate cleaning.
4.0 Conclusion

Overall HIQA found that Connolly Hospital was committed to improving decontamination and reprocessing practices at the hospital and were endeavouring to fully implement the National Standards and HSE best practice guidance in this regard.

During the course of this inspection areas of good practice observed by HIQA included the following:

- The hospital had identified a lack of appropriate facilities for surgical instrument decontamination a number of years ago. In order to mitigate the identified risk, in 2016 the hospital began outsourcing all decontamination of surgical instruments to an external company.
- Clear lines of accountability and responsibility in relation to governance and management arrangements for decontamination and reprocessing of reusable medical devices were in place at the hospital.
- A risk management system was in place to identify, evaluate, control and monitor hazards and risks associated with the decontamination process.
- Staff were supported to implement best practice in relation to decontamination and reprocessing of reusable infection prevention and control with policies, procedures and guidelines; some were due to be updated.
- Monitoring, testing and evaluation systems, outcome measures had been implemented; the hospital had a comprehensive inventory of reusable medical devices and decontamination equipment.
- An automated validated process for decontaminating semi-critical transvaginal and transrectal ultrasound probes had recently been introduced in line with national guidelines.\(^{13}\)

However HIQA also identified opportunities for improvement which included:

- To concur with national guidance, the hospital must continue to work towards a centralised model of endoscope decontamination.
- The infrastructure in the interventional radiology department should support the implementation of best infection prevention and control practices for semi-critical ultrasound probes.
- The frequency of hygiene audits conducted should be appropriate to the risk associated with the functional area and the cleanliness levels already achieved.

The hospital should also further explore the potential to collaborate within its hospital group structure, to share and develop good practice pertaining to decontamination of reusable medical devices. There was no dedicated hospital group
decontamination lead within the Royal College of Surgeons in Ireland (RCSI) Hospital Group. Mechanisms should be progressed to support continuous monitoring and assessment of the safety of decontamination service delivery within the hospital group.
5.0 References


### 6.0 Appendices

**Appendix 1: Lines of enquiry for the monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals**

<table>
<thead>
<tr>
<th>Lines of Enquiry</th>
<th>Relevant national standards</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Governance and management structures</strong></td>
<td>2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 5.2, 5.3, 5.4, 6.1, 7.1</td>
</tr>
<tr>
<td>The hospital has effective leadership, governance and management structures in place in relation to decontamination and reprocessing of reusable medical devices and has formalized and clear lines of accountability and responsibility at all levels of the service.</td>
<td></td>
</tr>
<tr>
<td><strong>2 Monitoring and evaluation systems including audit and risk management</strong></td>
<td>2.1, 2.3, 2.5, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.8,</td>
</tr>
<tr>
<td>The hospital has effective arrangements in place to respond to the ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement.</td>
<td></td>
</tr>
<tr>
<td>The hospital has a risk management system in place to identify, manage and report all hazards, adverse events, near misses and risks in relation to decontamination and reprocessing of reusable medical devices.</td>
<td></td>
</tr>
<tr>
<td><strong>3 Education and training of key personnel</strong></td>
<td>2.1, 2.8, 3.1, 3.2, 3.3, 3.6, 6.1, 6.2</td>
</tr>
<tr>
<td>The hospital ensures that key personnel have been appropriately trained to the necessary standard of competence and are supported with ongoing education and training reflecting national and international evidence in relation to decontamination and reprocessing of reusable medical devices.</td>
<td></td>
</tr>
<tr>
<td><strong>4 Relevant policies, procedures, protocols and guidelines</strong></td>
<td>2.1, 2.5, 3.1, 3.6, 3.8, 5.4, 7.2</td>
</tr>
<tr>
<td>The hospital ensures that key personnel are implementing evidenced-based best practice in relation to decontamination and reprocessing of reusable medical devices with up to date policies, procedures, protocols and guidelines in line with relevant legislation and national guidelines.</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 2: Spaulding risk categorisation table

<table>
<thead>
<tr>
<th>Risk</th>
<th>Application</th>
<th>Recommendation</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical</strong></td>
<td>Items that enter sterile tissues / sterile body areas or the vascular system</td>
<td>Cleaning followed by Sterilization</td>
<td>surgical instruments</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>biopsy instruments</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>forceps, laparoscopes, arthroscopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>surgical dental instruments</td>
</tr>
<tr>
<td><strong>Semi-critical</strong></td>
<td>Items in contact with mucous membranes or non-intact skin</td>
<td>Sterilisation preferred but at minimum, requires high level disinfection</td>
<td>flexible endoscopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>specula</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>respiratory therapy equipment</td>
</tr>
<tr>
<td><strong>Non-critical</strong></td>
<td>Items in contact with intact skin but not mucous membranes or not in contact with the patient</td>
<td>Can be processed by cleaning (and low level disinfection where necessary)</td>
<td>blood pressure cuffs, oximeters, ecg leads, etc.</td>
</tr>
</tbody>
</table>
Appendix 3: Organogram of decontamination activities and governance
Report of the unannounced inspection at Connolly Hospital

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