



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the unannounced inspection at St Michael's Hospital, Dun Laoghaire

**Phase 3: Monitoring of decontamination and reprocessing of
reusable medical devices in public acute hospitals**

Date of on-site inspection: 11 September 2018

**A programme designed to 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 St Michael's Hospital, Dun Laoghaire

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 National Standards.²

In light of the Public Health Emergency Plan* in relation to Carbapenemase-Producing *Enterobacteriales* (CPE)[†] in Ireland the focus of these inspections was on systems to detect, prevent and respond to healthcare-associated infections and multidrug-resistant organisms. It is intended that this phase will continue throughout 2018 and 2019 in parallel with Phase 3.

* 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 Carbapenemase-Producing *Enterobacteriales* (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/>

† 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 focussed, in the first instance, on decontamination facilities[§] outside of a designated controlled decontamination unit^{**} to ensure structures, systems, processes and outcomes in these facilities are aligned to national 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*³ 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 St Michael's Hospital, Dun Laoghaire by Authorised Persons from HIQA; Noreen Flannelly-Kinsella and Kathryn Hanly. The inspection was carried out on 11 September 2018 between 09:25hrs and 14:00hrs.

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

During this inspection inspectors spoke with hospital managers and staff and the interim decontamination lead. Inspectors requested and reviewed documentation and data and observed practice within the clinical environment in the:

- Out-Patient Department (OPD).

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

[‡] The 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).

[§] Decontamination 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 St Michael's Hospital profile

St Michael's Hospital is a voluntary acute general hospital and is part of the Ireland East Hospital Group.^{††} The hospital is also a member of the St Vincent's Healthcare Group (incorporating St Vincent's University Hospital, St Vincent's Private Hospital and St Michaels Hospital, Dun Laoghaire).

The hospital has a bed capacity of 130 inpatient beds including day care facilities with a range of diagnostic and support services and a 12-hour emergency service.^{‡‡}

In light of the National Public Health Emergency in relation to CPE inspectors sought assurance regarding arrangements that were put in place to ensure compliance with the latest national guideline⁴ on screening for CPE at the hospital. Hospital management confirmed that the hospital had ensured the full implementation of this guideline.

Overview of decontamination services

Decontamination of reusable medical devices was undertaken centrally in the Central Sterile Supplies Department (CSSD), and in local decontamination facilities located in the Endoscopy Unit, General Theatre (GT), Radiology Department and the Out-Patients Department (OPD).

Decontamination of non-critical items used in clinical areas was performed locally in each respective clinical area (see table 1.0 overleaf).

^{††} Hospital groups: The hospitals in Ireland are organised into seven hospital groups: 1. Ireland East Hospital Group. 2. Dublin Midlands Hospital Group. 3. South/South West Hospital Group. 4. Saolta University Health Care Group. 5. University Limerick Hospitals Group. 6. RCSI Hospitals Group. 7. National Children's Hospital Group.

^{‡‡} The hospital profile information contained in this section has been obtained on the hospitals website and has not been verified by HIQA.

Table 1.0: Decontamination facilities and reusable medical devices decontaminated and reprocessed at the hospital

Spaulding risk categorisation	Reusable medical device and location of decontamination
<p>Critical items Items that enter sterile tissues/sterile body areas or the vascular system</p>	<ul style="list-style-type: none"> ▪ Surgical instruments and surgical sets used in the General Theatre (GT) and in local clinical areas were decontaminated and reprocessed in CSSD.
<p>Semi-critical items Items in contact with mucous membranes or non-intact skin</p>	<ul style="list-style-type: none"> ▪ Gastro-intestinal endoscopes, cystoscopes and bronchoscopes used in the Endoscopy Unit were decontaminated and reprocessed in a decontamination facility located within the unit. ▪ Non-channelled fiberoptic nasendoscopes (Ear Nose and Throat (ENT) endoscopes) used in OPD were decontaminated and reprocessed after use in OPD. ▪ An endo-anal probe used in the OPD was decontaminated and reprocessed after use in OPD. ▪ Transrectal ultrasound probes and ultrasound probes for vascular access used in GT were decontaminated after use locally in GT.
<p>Non-critical items Items in contact with intact skin but not mucous membranes or not in contact with the patient</p>	<ul style="list-style-type: none"> ▪ Non-invasive ultrasound probes, bladders scanners and doppler devices used in the OPD, GT, Physiotherapy Department, Radiology Department and local clinical areas were decontaminated locally after use in each respective clinical area.

3.0 Findings at St Michael's Hospital

3.1 Risk identified

Decontamination facilities should have systems in place to record the decontamination process for reusable critical and semi-critical medical devices and to link the decontaminated device with service users, in line with national standards.^{5,6,7,8} Track and trace systems verify that reusable medical devices have been decontaminated effectively and permits retrospective tracing of the service user on which it was used in the event of exposure to potential risk.

During the course of this inspection HIQA found that the hospital had not implemented a track and trace system for ENT endoscopes used in OPD and considered this a high risk. HIQA acknowledges that the hospital had identified this as an area of concern and had entered this risk on the hospital risk register. HIQA sought assurances regarding arrangements put in place following this inspection to mitigate this risk. In response the general manager outlined key actions implemented to address this risk.

A copy of the letter issued by HIQA to the general manager to seek further assurance regarding the risk and a copy of the response, and associated assurance and action plan received from the general manager are shown in Appendices 2 and 3 respectively.

3.2 Governance and management

Inspectors found that there were clear lines of accountability and responsibility in relation to governance and management arrangements for decontamination and reprocessing of reusable medical devices at St Michael's Hospital. In addition defined management arrangements at service-delivery level were also in place.

At a hospital group level and in line with the HSE's own recommendation⁹ a group decontamination lead position to lead, support and drive the effective implementation of best practice guidance in relation to decontamination service provision across the Ireland East Hospital Group should be progressed.

The hospital had recently appointed a dedicated decontamination lead (0.5 WTE)^{§§} position. Prior to this appointment the Infection Prevention and Control Clinical Nurse Manager 3 (IPC CNM3) undertook this role.

^{§§} Whole-time equivalent (WTE): allows part-time workers' working hours to be standardised against those working full-time. For example, the standardised figure is 1.0, which refers to a full-time worker. 0.5 refers to an employee that works half full-time hours.

The Medical Device and Equipment Decontamination Committee, established in February 2016 was responsible for overseeing and monitoring the implementation of and compliance with the national standards for decontamination of reusable medical devices. The IPC CNM3 was current chair of meetings held quarterly.

Committee membership included the general manager, consultant microbiologist and an authorised engineer for decontamination (AED).^{***} Local managers from central and satellite decontamination facilities also attended. A member of the Medical Devices Group at the hospital was due to attend the next scheduled committee meeting. The committee reported to the hospital's Patient Safety Committee and Executive Council.

Decontamination was also a standing agenda item at Infection Prevention and Control Committee meetings held monthly, and chaired by the hospital manager.

Hospital management told staff that the hospital had devised a proposed plan and presented it to the hospital group in relation to centralising decontamination service provision at the hospital subject to capital funding approval.

3.3 Risk management

Inspectors were informed that a risk management system was in place to identify the hazards associated with the decontamination process, to estimate and evaluate risks, and monitor the effectiveness of controls. A risk in relation to decontamination on the hospital risk register^{†††} included:

- ENT endoscopes in the OPD.

To address this risk control measures documented included changing from a high level decontamination (HLD) soakage system to a HLD manual multi-wipe system in the interim of implementation of automated validated reprocessing systems. In line with national standards^{6,6,7} non-channelled ENT endoscopes should be reprocessed in automated validated endoscope washer disinfectors (EWD). A quality improvement and business plan had been completed by the AED and IPC CNM3 supporting advancing to a dedicated local decontamination unit and automated endoscope reprocessors in OPD.

In the interim of these plans and as an additional risk control measure whilst using HLD manual multi-wipe systems, the hospital could consider reprocessing ENT

^{***} A suitably qualified person designated by management to provide testing, advice and review validation records and is suitable qualified to graduate level.

^{†††} A risk register is a database of assessed risks that face any organisation at any one time. Always changing to reflect the dynamic nature of risks and the organisation's management of them, its purpose is to help hospital managers prioritise available resources to minimise risk and target improvements to best effect. The risk register provides management with a high level overview of the hospital's risk status at a particular point in time and becomes an active tool for the monitoring of actions to be taken to mitigate risk.

endoscopes in an EWD in the Endoscopy Unit at the end of each list, if the ability to interface equipment is possible, in line with international recommendations;¹⁰ this measure would also facilitate more appropriate storage in the shorter term. However inspectors were informed following this inspection that this option was not compatible with manufacturer's instructions.

Other risk assessments undertaken and control measures implemented in relation to decontamination and reprocessing-related issues included for example:

- use of HLD manual multi-wipe systems to decontaminate semi-critical ultrasound probes; as manual disinfection is the least preferred option, a risk assessment was undertaken in line with national guidance; staff education and training in the use of manual systems was also rolled-out
- decontamination of semi-critical ultrasound probes in General Theatre using a HLD soakage system; the hospital was changing to HLD manual multi-wipe systems in line with national guidance.

Inspectors were informed that facilities for decontamination in the endoscopy unit were not in line with national HSE standards;^{6,7} the hospital therefore needs to undertake an infection prevention and control risk assessment of this facility.

Notwithstanding that the quality and risk manager attended the decontamination committee meetings, risk management should be included as a standing agenda item. Incidents were reported through the hospital incident management system and uploaded to the National Incident Management System.^{***} The quality and risk manager reported on hospital incidents at the Patient Safety Committee meetings. Staff told inspectors that there were no recent decontamination-related incidents reported.

The hospital had a comprehensive inventory of reusable medical device and decontamination equipment used hospital-wide however all items in relation to decontamination and reprocessing of equipment including endoscope drying cabinets for storing endoscopes should be included. The inventory showed that some equipment varied between 9-13 years old. As equipment that goes beyond the minimum technical life expectancy puts additional pressure on service provision due to possible downtime for repairs, it is recommended that replacing and upgrading of this equipment is prioritised. Inspectors were told by management that contingency plans in the event of decontamination equipment failure were available during working hours, and due to the elective nature of surgical procedures at the hospital

^{***} The State Claims Agency National Incident Management System is a risk management system that enables hospitals to report incidents in accordance with their statutory reporting obligation.

they were not required 'out of hours'.^{§§§} The global asset identifier coding and national track and trace programme to support quality assurance of decontamination practices had been rolled-out at the hospital.

The national medical devices eAlert system^{****} had been implemented at the hospital. The asset manager as the nominated 'designated person', was responsible for internal hospital distribution to the relevant personnel whose responsibility was to implement recommended actions.

HIQA also sought assurance during this inspection regarding arrangements that were in place to ensure compliance with national guidance on minimising the risk of transmission of developing a transmissible spongiform encephalopathies (TSEs). Staff told inspectors that the hospital was in the process of reviewing and updating nursing assessment documentation; a risk assessment for the identification of service users at increased risk⁺⁺⁺ of developing a TSEs in line with recommended practice was due to be included in these updates.

3.4 Monitoring and evaluation including audit

Although the focus of inspections was on decontamination facilities outside of a designated controlled decontamination unit, and inspections were guided by specific lines of enquiry, inspectors sought assurances in relation to monitoring and evaluation systems implemented in the CSSD and decontamination facility in the Endoscopy Unit at the hospital.

In response hospital management stated that decontamination and reprocessing equipment was tested, maintained, and validated to current standards in both decontamination facilities. An AED was appointed by the hospital to oversee and audit technical aspects of the programme. In addition microbiological monitoring and testing of the environment within controlled areas including air, contact surfaces and water had been implemented.

Documentation reviewed showed that an independent audit of decontamination and reprocessing practices in the CSSD were undertaken in 2017 and 2018. Hospital management also undertook an audit of decontamination of critical and semi-critical

^{§§§} "Out of hours" was defined as after 18.30 hours on weekdays and 24 hours on the weekends and Bank Holidays.

^{****} 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.

ultrasound probes and endoscopes in satellite decontamination facilities at the hospital in 2018.

3.5 Staff training and education

In line with HSE's recommendations, a number of staff in both the Endoscopy Unit and CSSD had completed or were in the process of undertaking an academic third level qualification in decontamination practices and sterile services.

Appropriate staff had received manufacturers' training and completed online training in relation to HLD manual multi-wipe systems in satellite decontamination facilities. Staff in OPD satellite decontamination facilities were also due to undertake the online HSELand training in relation to decontamination.¹¹

In addition, regular operator training was provided by the manufacturers / suppliers of endoscope and decontamination equipment. Staff told inspectors that chemical safety training was mandatory for staff at induction and every two years thereafter.

Inspectors were told that assessment of staff competencies in relation to decontamination and reprocessing of reusable medical devices was monitored informally. The hospital should ensure that training for staff in relation to decontamination is underpinned by a competency assessment framework and revalidated at least annually in decontamination facilities at the hospital.¹²

3.6 Policies, procedures, protocols and guidelines

Policies in relation to decontamination and reprocessing of reusable medical devices in the satellite decontamination facility inspected were in draft format and awaiting sign-off at the time of inspection. These documents were available to staff in both hard copy and electronic format. Hospital staff told inspectors that local managers were responsible for control of local documents; a formalised document control management system was not in place as recommended.

Hospital management reported that a policy for the management of patients with CPE was due to be updated to reflect the latest national screening guidance in relation to CPE.

3.7 Decontamination of semi-critical medical devices in satellite decontamination facilities

Out-patient department (OPD)

Inspectors visited a satellite decontamination facility in OPD to ensure that structures, systems, processes and outcomes were aligned with national guidelines.

A transrectal ultrasound probe was decontaminated at point-of-use using a HLD manual multi-wipe system. While manual HLD complies with national guidelines for this device, it is the least preferred option. A validated automated system for decontaminating reusable medical devices is best practice.

The decontamination of ENT endoscopes was also carried out at point-of-use within the ENT OPD; inspectors observed that the configuration of these facilities did not facilitate the implementation of effective infection prevention and control measures.

Many of the issues identified during this inspection showed that structures, systems and processes were not aligned to national guidance in relation to ENT endoscope decontamination,^{6,7,7} for example:

- There was no system in place to record the decontamination process used on ENT endoscopes (tracking) and link them with service users on which they have been used (tracing); as identified by HIQA as a high risk in section 3.1.
- Point of care decontamination represented a chemical hazard to staff and patients; access to chemical agents used in the disinfection of these probes was not restricted.
- The hand hygiene sink was inappropriately used for rinsing of these endoscopes.
- There was no separate dirty and clean area to ensure that fully decontaminated endoscopes cannot be confused with non or partially decontaminated endoscopes.
- Storage and transport of ENT endoscopes was not in line with national guidance.
- Manufacturers' transport cases were inappropriately stored on a floor surface; floor covering did not facilitate effective cleaning and needed to be replaced.
- There were insufficient work surfaces and insufficient storage for consumables used during the decontamination procedure.

HIQA acknowledge that the hospital had identified similar risks and had included these risks in the hospital's risk register. Inspectors were informed that plans were in place to reconfigure the department to include a dedicated decontamination facility. However there was no agreed timeframe for completion of these minor capital works.

Additionally inspectors noted the following opportunities for improvement which could be addressed in the shorter term:

- Audit of practices had not taken place; regular audits and improvement plans should be embedded into routine practice; for example auditing of disinfection activation and contact times with HLD manual multi-wipe system to provide assurance that times are in line with manufacturer's instructions.
- Recent local environmental hygiene audits reviewed did not specifically identify decontamination facilities as having been audited; this should be included as part of the ongoing auditing schedule and management of decontamination facilities.¹³
- Standard operating procedures (SOP's) should be available at point-of-use, in particular where non-automated processes are used, to control variables that affect processes.

4.0 Conclusion

Overall HIQA found that St Michael's Hospital was endeavouring to improving decontamination and reprocessing practices at the hospital. However hospital management will need to be fully supported at hospital group and national level in their endeavours to fully mitigate risks identified in relation to decontamination service provision in the satellite decontamination facility inspected.

It was identified during the course of the inspection that the hospital had not implemented a track and trace system in relation to ENT endoscopes in OPD. HIQA sought assurances from hospital management in relation to managing this risk and such assurances had been provided.

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

- clear lines of accountability and responsibility in relation to governance and management arrangements for decontamination and reprocessing of reusable medical devices at the hospital; the hospital had appointed a dedicated decontamination lead
- a risk management system was in place to identify, evaluate, monitor hazards and risks associated with the decontamination process
- training and education for staff working in decontamination was well established
- hospital management was in the process of addressing deficiencies in relation to decontamination facilities across the hospital; consideration was also given to centralising decontamination activity.

However HIQA also identified opportunities for improvement which included:

- a need to embed a culture of continuous audit, feedback and quality improvement in relation to decontamination and reprocessing structures, processes and outcomes
- implementation of automated validated processes for decontamination of ENT endoscopes and semi-invasive ultrasound probes
- equipment that goes beyond expected lifecycles need to be addressed by hospital management.

At a corporate level and in line with the HSE's own recommendation a dedicated hospital group decontamination lead position with overall executive accountability and responsibility for decontamination service provision to support all decontamination services in the hospital group should be progressed.

5.0 References

1. Health Information and Quality Authority. National Standards for the prevention and control of healthcare-associated infections in acute healthcare services. Dublin: Health Information and Quality Authority; 2017. [Online]. Available online from: <https://www.hiqa.ie/sites/default/files/2017-05/2017-HIQA-National-Standards-Healthcare-Association-Infections.pdf>
2. Health Information and Quality Authority. Guide to the monitoring programme undertaken against the National Standards for the prevention and control of healthcare-associated infections. Dublin: Health Information and Quality Authority; 2015. [Online]. Available online from: <https://www.hiqa.ie/sites/default/files/2017-05/Guide-monitor-National-Standards-healthcare-associated-infections.pdf>
3. Health Information and Quality Authority. Guide to HIQA's programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals. Dublin: Health Information and Quality Authority; 2018. [Online]. Available online from: <https://www.hiqa.ie/sites/default/files/2018-07/HIQA-reusable-medical-devices-guide.pdf>
4. Health Service Executive. Requirements for screening of Patients for Carbapenemase Producing Enterobacteriaceae (CPE) in the Acute Hospital Sector. February 2018. [Online]. Available online from: <http://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/strategyforthecontrolofantimicrobialresistanceinirelandsari/carbapenemresistantenterobacteriaceae/guidanceandpublications/>
5. Health Service Executive Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes. November 2016. [Online]. Available online from: <https://www.hse.ie/eng/about/Who/qualityandpatientsafety/Medical-Devices/decontamination/Ultrasound-Probe-Decontamination-Guidance-Feb-17.pdf>
6. Health Service Executive Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Units. Dublin: Health Service Executive; 2017. [Online]. Available online from: <http://www.hse.ie/eng/about/Who/QID/nationalsafetyprogrammes/decontamination/HSE-Standards-and-Recommended-Practices-for-Facility-Design-and-Equipping-of-EDUs-QPSDD022.pdf>
7. Health Service Executive Standards and Recommended Practices for Commissioning, Validation and Testing in Endoscope Decontamination Facilities. Dublin: Health Service Executive; 2018. [Online]. Available online from: <https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/>

[standard-and-recommended-practices-for-commissioning-validation-and-testing-in-endoscope-decontamination-facilities.pdf](#)

8. Health Service Executive National Decontamination of Reusable Invasive Medical Devices Advisory Group. Health Service Executive Standards and Recommended Practices for Central Decontamination Units. Dublin: Health Service Executive; 2011. [Online]. Available online from:

http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/Decontamination/HSE_Standards_Recommended_Practices_CDUs.html

9. Health Service Executive. Quality Improvement Division. Review of Endoscope Decontamination in Acute Hospitals. Dublin: Health Service Executive; 2015.

10. Joint Advisory Group (JAG) on GI endoscopy. [Online]. Available online from: <https://thejag.zendesk.com/hc/en-us/articles/360001646414-Can-Tristel-wipes-be-used-to-clean-nasoendoscopes->

11. Health Service Executive. HSELand. Available online from: <http://www.hseland.ie/dash/Account/Login>

12. British Society of Gastroenterology (BSG). The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee; 2016. [Online]. Available online from: <https://www.bsg.org.uk/resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy-2017-edition.html>

13. National Hospitals Office, Quality, Risk and Customer Care. HSE Cleaning Manual Acute Hospitals. Dublin: Health Service Executive; 2006. [Online]. Available online from:

http://hse.ie/eng/services/publications/Hospitals/HSE_National_Cleaning_Standards_Manual.pdf

6.0 Appendices

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

Lines of Enquiry			Relevant national standards
1	Governance and management structures	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.	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
2	Monitoring and evaluation systems including audit and risk management	<p>The hospital has effective arrangements in place to respond to the ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement.</p> <p>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.</p>	2.1, 2.3, 2.5, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.8
3	Education and training of key personnel	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.	2.1, 2.8, 3.1, 3.2, 3.3, 3.6, 6.1, 6.2
4	Relevant policies, procedures, protocols and guidelines	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.	2.1, 2.5, 3.1, 3.6, 3.8, 5.4, 7.2

Appendix 2: Copy of the letter issued to St Michael's Hospital regarding the high risk identified during HIQA's inspection at St Michael's Hospital



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13 September 2018

Ref: PCHCAI 2018/74

Dear Seamus

National Standards for the prevention and control of healthcare-associated infections in acute healthcare services – monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals

During the course of the Health Information and Quality Authority (HIQA) unannounced inspection on 11 September 2018, inspectors identified a risk in relation to the absence of a track and trace system for decontamination processes of rhino-laryngo fiberscopes in the Out-Patient Department (OPD).

We consider this to be a high risk as it does not permit retrospective tracing of the endoscopes through the decontamination process and linked to the patient on whom the devices have been used in line with national guidance.

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Please outline how the hospital intends to address this high risk following this inspection. Details of the risk identified, and proposed mitigating actions will be included in the report of this inspection.

Please provide this information to HIQA by close of business on **20 September 2018** to qualityandsafety@hiqa.ie. Should you have any queries, please do not hesitate to contact me at qualityandsafety@hiqa.ie.

Yours sincerely,

A handwritten signature in black ink, which appears to read 'Noreen Flannelly-Kinsella', is positioned above a horizontal line.

Noreen Flannelly-Kinsella
Authorised Person

CC: Mary Day, CEO, Ireland East Hospitals Group

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Appendix 3: Copy of the response letter received from St Michael's Hospital regarding the high risk identified during HIQA's inspection at St Michael's Hospital



Ms Noreen Flannelly-Kinsella
Authorised Person
Health Information and Quality Authority
Head Office
Unit 1301 City Gate
Mahon
Cork

Ref: PCHCAI 2018/74

18th September 2018

Dear Noreen

Thank you for your letter dated 13th September 2018 detailing the high risk identified during the inspection of procedures relating to decontamination and reprocessing of RIMDs in St. Michael's Hospital undertaken by HIQA on 11th September. As discussed with HIQA auditors at the time of the audit, a number of interventions to mitigate this risk had been initiated, which have now been completed.

Risk identified:

Absence of a track and trace system for the decontamination processes of rhino-laryngo fiberscopes in the OPD.

Mitigating actions:

Each of the three rhino-laryngo fiberscopes in the outpatient department has been identified by the following method:

1. Each rhino-laryngo fiberscopes, with its corresponding serial number, has been assigned a unique identifying number.
2. Track and trace of each rhino-laryngo fiberscope used is recorded in the Tristel traceability log book. Each rhino-laryngo fiberscope is linked to the individual patient on whom the device has been used via its unique identifying number, to ensure that retrospective tracing of the endoscope is possible.
3. Cleaning and decontamination of each rhino-laryngo fiberscope is undertaken using the Tristel Trio Wipe System.

4. A standard operating procedure detailing all processes and procedures around this new pathway has been written and is awaiting ratification.
5. A programme of education and training has been commenced for all staff involved in decontamination of rhino-laryngo fiberscopes.

Please contact me should you require further information.

Kind regards


Seamus Murtagh

CC: Mary Day, CEO, Ireland East Hospitals Group.

For further information please contact:

**Health Information and Quality Authority
Dublin Regional Office
George's Court
George's Lane
Smithfield
Dublin 7**

**Phone: +353 (0) 1 814 7400
Email: qualityandsafety@hiqa.ie
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