



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the unannounced inspection at Roscommon University Hospital

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

Date of on-site inspection: 12 October 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***

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.
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- **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.
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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 of this monitoring programme began 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 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 in line with national guidelines. It is anticipated 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.

Further 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 Roscommon University Hospital by Authorised Persons from HIQA; Noreen Flannelly-Kinsella and Kathryn Hanly. The inspection was carried out on 12 October 2018 between 09:20hrs and 14:00hrs.

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

During this inspection inspectors spoke with hospital managers and staff, and members of the decontamination committee. Inspectors requested and reviewed documentation and data and observed practice within two satellite decontamination facilities where decontamination of reusable medical devices was carried out:

- Operating Theatre (OT) Department
- Radiology Department.

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 Roscommon University Hospital profile

Roscommon University Hospital is a Model 2 hospital owned and managed by the Health Service Executive (HSE) and is part of the Saolta University Health Care Group.^{††} The hospital has a bed capacity of 63 inpatient beds in addition to 40 day beds providing both day and extended day surgery, selected acute medicine, local injuries, and a range of diagnostic services (including laboratory medicine, point of care testing and radiology), specialist rehabilitation medicine and palliative care services.

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. During this inspection hospital management confirmed that the hospital had ensured the full implementation of this guideline.

Overview of decontamination services

Decontamination and reprocessing of reusable medical devices such as flexible gastro-intestinal (GI) and ENT (Ear Nose and Throat) endoscopes was undertaken centrally in a dedicated endoscope reprocessing unit (ERU) in the Endoscopy Unit.

Procedures for decontamination and reprocessing of surgical instruments and rigid ENT endoscopes performed in a satellite decontamination facility located within the footprint of OT were undergoing a period of transition. As an interim to the hospital's long-term capital development proposal plan, preparations in relation to full outsourcing of this service off-site to an external hospital (part of the same hospital group) was at an advanced stage at the time of inspection.

In addition decontamination of non-critical and semi-critical ultrasound probes used in the Radiology Department, OPD Ambulatory Care and Diagnostic Department (ACAD) and OT were 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.

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"> ▪ Prior to outsourcing of decontamination services to an external provider, surgical instruments and sets used in OT were decontaminated and reprocessed in a satellite decontamination facility located in the OT department. ▪ At the time of inspection outsourcing arrangements were at an advanced stage with the majority of surgical instruments and sets being decontaminated and reprocessed at the external decontamination facility.
<p>Semi-critical items Items in contact with mucous membranes or non-intact skin</p>	<ul style="list-style-type: none"> ▪ GI endoscopes used in the Endoscopy Unit were decontaminated and reprocessed in ERU. ▪ Cystoscopes used in OT were transported, decontaminated and reprocessed in ERU and stored in OT. ▪ Flexible ENT endoscopes used in OPD were transported, decontaminated and reprocessed in ERU. Rigid ENT endoscopes used in OPD were pre-cleaned after use in OPD and transported and sterilised in OT. ▪ Transvaginal probes used in the Radiology Department and vascular ultrasound probes used in ACAD were decontaminated locally by use of automated hydrogen peroxide systems.
<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"> ▪ Vascular ultrasound probes used in ACAD, OPD and OT were decontaminated locally after use in each respective clinical area by use of automated hydrogen peroxide systems.

3.0 Findings at Roscommon University Hospital

As previously identified in HIQA's 2015 and 2016 inspections^{5,6} the infrastructure of the satellite decontamination facility in the Operating Theatre Department at Roscommon University Hospital was not in line with national standards⁷ and relevant guidelines. Findings during this inspection showed that hospital staff had actively endeavoured to address these deficiencies.

3.1 Governance and management

Inspectors found that there were clear lines of accountability and responsibility in relation to management arrangements for decontamination and reprocessing of reusable medical devices at the hospital. Defined management arrangements in relation to decontamination and reprocessing of reusable medical devices at service-delivery level were also in place.

However HIQA found that governance arrangements at Saolta University Health Care Group level could be further strengthened. A hospital group decontamination lead position was in place in line with HSE's recommendations,⁸ and had provided sessional commitments and supported decontamination service provision at the hospital. However since that position had become vacant there had been no onsite presence at the hospital for that period. This deficiency had been escalated by the hospital and had been entered on the hospital's risk register. As outsourcing arrangements with an external hospital was almost finalised, a business case in relation to a joint decontamination co-ordinator position was being advanced by both respective hospitals as appropriate.

The hospital's Decontamination Committee was responsible for overseeing decontamination service provision. This committee, chaired by the general manager met quarterly. Multidisciplinary committee membership included local managers from satellite decontamination facilities and representatives from the infection prevention and control team (IPCT), clinical engineering and risk management. A sub-group of this committee was recently established to oversee the transition from on-site to external off-site decontamination service provision; membership included the general manager from the external hospital providing the decontamination service to the hospital.

The Decontamination Committee reported to the Infection Prevention and Control Committee (IPCC) and to the Hospital Management Team. The IPCC along with other hospitals in the group, also reported to the Saolta University Health Care Group IPCC meeting held quarterly. Inspectors were told that decontamination was a standing agenda item at these meetings.

A Standard Operating Policy in relation to the provision of decontamination services by the external hospital to Roscommon University Hospital was being finalised at the time of this inspection. However formalised agreements defining the scope of service provided and governance, monitoring and quality assurance arrangements should be put in place in line with National Standards.⁹

A service level agreement with the transport company outlining the governance and management arrangements in relation to the transport of reusable invasive medical devices on behalf of the hospital to the external service provider was in place.

3.2 Risk management

Inspectors were informed that a risk management system was in place to identify the hazards associated with decontamination processes, to estimate and evaluate risks and monitor the effectiveness of controls. The Quality and Safety Committee at the hospital was responsible for monitoring and managing incidents and risk and for reporting these to the Hospital Management Team. Risks that could not be effectively mitigated at a local hospital level were escalated to the hospital group through risk management reporting structures. Additionally documentation reviewed showed that decontamination-related risks and incidents were reported to the hospital group IPCC meeting on a quarterly basis.

Risks in relation to decontamination and reprocessing of reusable medical devices on the hospital's risk register^{**} included the risk to patients of infection post procedure as the hospital did not have a dedicated centrally controlled sterile supplies department for reprocessing surgical instruments. The infrastructure of the satellite decontamination facility located in the footprint of the OT did not support the implementation of best practice infection prevention and control practices.

To address this significant risk and as previously identified in section 2.0, hospital management was in the process of finalising arrangements in relation to outsourcing decontamination service provision. A proposal to build a dedicated central sterile supplies department (CSSD) at the hospital was being progressed and escalated to both the hospital group priority capital plan list and HSE estates. Hospital management confirmed that to date approval in relation to this proposal had been obtained from the hospital group. In the interim, other control measures implemented to manage and mitigate this risk are included in section 3.6 of this report.

^{**} 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.

It is acknowledged that significant improvement in relation to centralising decontamination of reusable medical devices at the hospital had been made since HIQA's previous inspections. The facilities for decontamination of flexible ENT endoscopes used in OPD were identified as not being in line with national standards in 2016. Since then such devices were transported, decontaminated and reprocessed in the JAG (Joint Advisory Group) accredited Endoscopy Unit, as appropriate. Additionally, the use of high level disinfectant manual multi-wipe systems across the hospital had been replaced by validated automated system in line with best practice guidance.

The global asset identifier coding and national track and trace programme to support quality assurance of decontamination practices had been implemented in the ERU and satellite decontamination facility in OT. The hospital was currently working towards identifying equipment, interfacing, and trailing track and trace systems with the outsourced external service provider. Staff told inspectors that a specialist committee at the hospital liaised with the group estates department and the national medical device equipment replacement programme; decontamination equipment had been replaced and new equipment installed in the new endoscopy unit opened in 2016. Additionally, to support the transition to outsourcing a considerable supply of reusable medical devices including surgical instruments had been purchased by the hospital. The hospital had an inventory of reusable medical devices and associated decontamination equipment in use however inspectors identified that maintenance of the inventory required improvement.

Decontamination-reported incidents were reported electronically on a group-wide information reporting system. Hospital managers told inspectors that incidents were reviewed and actioned by the risk manager and the Quality and Safety Committee. Documentation reviewed showed that two incidents in relation to decontamination had been reported internally and had been escalated to the National Incident Management System (NIMS).^{§§} However as a consequence of two differing incident reporting systems, hospital managers told inspectors that delays uploading to NIMS were inevitable due to resource deficiencies. Incident reporting across the group needs to be adhered with the national HSE incident management requirements, and statutory reporting obligations.

The national medical devices eAlert system^{***} had been implemented at the hospital. The clinical engineer as the nominated 'designated person', was responsible for

^{§§} 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.

^{***} 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.

internal hospital distribution to the relevant personnel for implementation of the recommended actions where applicable.

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 (TSE).^{†††} A hospital guideline for the management of TSE was reviewed by inspectors. Inspectors were unable to identify if national recommendations in relation to undertaking a pre-operative assessment for identification of service users at increased risk^{†††} of developing a transmissible spongiform encephalopathies (TSEs) had been included.

3.3 Monitoring and evaluation including audit

Although the focus of these inspections was on specific lines of enquiry, inspectors sought assurances in relation to decontamination and reprocessing equipment in OT and ERU. In response, hospital management stated that decontamination and reprocessing equipment was tested, maintained and validated to current standards in all decontamination facilities at the hospital.

An authorised engineer for decontamination (AED)^{§§§} was appointed by the hospital to oversee and audit technical aspects of the programme; a sample of these audit reports were reviewed by inspectors. In preparation for the transition to fully outsourcing of decontamination service provision from OT to the external facility, an independent quality assurance audit by the AED of the outsourced decontamination facility was also undertaken.

3.4 Staff training and education

A number of staff had either completed or were in the process of undertaking an academic qualification in decontamination practices and sterile services in both the ERU and OT in line with HSE recommendations.⁸ All staff responsible for decontamination in these areas had also completed the HSELanD online training in relation to decontamination.¹⁰

^{†††} Transmissible spongiform encephalopathies (TSEs) are a group of progressive, invariably fatal, conditions that affect the brain (encephalopathies) and nervous system of many animals, including humans, cattle, and sheep.

^{†††} 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.

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

Additionally, regular operator training was provided by the manufacturers / suppliers of endoscope and decontamination equipment and training records were maintained. Hospital management told inspectors that chemical safety training was provided to staff in 2018. Technical / user training was also provided by the manufacturers of ultrasound probe decontamination equipment and training records were maintained.

Inspectors were told that individual competencies of staff in ERU and OT were assessed at induction; documentation such as an endoscope decontamination competency assessment framework and operating theatre skills training record was reviewed by inspectors. It was reported to inspectors that staff in ERU were also competency-assessed on an ongoing basis by the unit manager thereafter. The hospital should ensure that training for staff in relation to decontamination is underpinned by a competency assessment framework in all decontamination facilities at the hospital and revalidated at least annually.¹¹

3.5 Policies, procedures, protocols and guidelines

Staff were supported to implement best practice in relation to decontamination and reprocessing of reusable medical devices with up-to-date policies, procedures and guidelines. They were available to staff through an electronic document management system. The hospital had developed policies for key elements of the decontamination and reprocessing processes in the satellite decontamination facility in OT. A policy in relation to a high level disinfection automated system for semi-invasive ultrasound probes used in OT was being finalised at time of inspection.

Hospital policies relevant to decontamination were approved by the Decontamination Committee and ratified by the Quality and Safety Committee at the hospital.

3.6 Decontamination of reusable medical devices at a satellite decontamination facility

Inspectors visited two satellite decontamination facilities located outside of the designated controlled endoscope decontamination unit to ensure that structures, systems, processes and outcomes were aligned to national guidelines.

Operating Theatre Department (OT)

As highlighted in previous HIQA inspections the infrastructure of the satellite decontamination facility located in the footprint of OT did not facilitate segregation of clean and dirty activities and was not compliant with recommended practices for central decontamination units.⁷ A risk assessment was undertaken by the hospital in 2016 and a number of control measures had been implemented in the interim of finalising outsourcing arrangements and proposed capital development:

Evidence of good practice

- a dedicated trained operative whose sole responsibility was management of the decontamination facility during normal working hours was undertaking an academic qualification in decontamination
- quarterly audits of decontamination processes were undertaken
- environmental microbiological testing was performed every fortnight
- weekly environmental hygiene audits were performed and results showed 98-100% compliance with desirable hygiene standards was achieved monthly from January to August 2018
- a pass-through steam steriliser was available
- a six-month pilot surgical site surveillance programme was undertaken in 2017
- an automated system to achieve high level disinfection of a semi-critical ultrasound probe used in the department was in place
- an automatic washer-disinfector (AWD) for cleaning surgical instruments prior to sterilisation was beyond recommended working life; to ensure performance was attained, some examples of additional controls included;
 - instruments were manually washed and rinsed prior to insertion in the AWD
 - cleaning efficacy tests were performed with each cycle
 - periodic testing and validation was undertaken and an annual audit by the AED was performed in line with national guidance
 - maintenance and quality of the water supply was monitored by the maintenance team at the hospital.

The hospital needs to ensure that:

- a manual track and trace system which had been temporarily re-introduced in OT over the transition period to outsourcing, is notified to the national electronic track and trace programme co-ordinator to ensure that a seamless audit trail remains over this period
- cystoscopes used in OT were decontaminated and reprocessed in ERU and returned vacuum-packed for storage in an office in OT; consideration should be given to storage of these items appropriately in ERU, a JAG accredited site
- the decontamination facility in the annex of OT was not mechanically ventilated or under negative pressure; the hospital should ensure that ventilation systems in OT overall are compliant with best practice theatre ventilation guidance.^{12,13}

Radiology department

Evidence of good practice

- an automated process was used to achieve high level disinfection of semi-critical ultrasound probes in a sealed chamber by exposure to hydrogen peroxide mist in line with national standards
- 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
- monthly environmental hygiene audits results reviewed showed that 92-97% compliance with desirable standards was achieved for the previous eight month period; a sample of results showed that areas where decontamination of SIUP's were taking place were also included in these audits as appropriate.

The hospital needs to ensure that:

- a suitable dedicated non-clinical space for decontamination of semi-critical ultrasound probes is identified; decontamination areas should be physically separated from the point-of-use, and allow for segregation of 'dirty' and 'clean' activities and facilitate a unidirectional work flow.

4.0 Conclusion

Overall HIQA found that Roscommon University Hospital was committed to and actively working to improving decontamination and reprocessing practices at the hospital and was endeavouring to fully implement the National Standards and HSE best practice guidance in this regard. Notable areas of good practice observed by HIQA during this inspection included some of the following:

- clear lines of accountability and responsibility and management arrangements in relation to decontamination and reprocessing of reusable medical devices at the hospital
- a risk management system was in place to identify, evaluate, monitor hazards and risks associated with the decontamination process; risks previously identified in relation to decontamination facilities were being actively addressed
- training and education for staff working in decontamination was well established
- up-to-date policies, procedures and guidelines were available to support staff
- validated automated systems for decontamination of all critical and semi-critical reusable medical devices were available at the hospital in line with best practice guidance
- frequency of hygiene audits conducted was appropriate to the risk associated with the functional area; hygiene audit results showed good compliance with desirable standards was achieved in both areas inspected.

Moreover hospital management had almost completed the process of addressing deficiencies in relation to the satellite decontamination facility located in the footprint of OT by outsourcing decontamination service provision to an external service provider in the interim of proposed on-site capital development plans.

Notwithstanding this hospital management should also ensure that:

- a suitable dedicated non-clinical space for decontamination of semi-critical ultrasound probes in the X-ray Department is identified
- ventilation systems in the OT are in line with best practice guidance
- a culture of continuous audit, feedback and quality improvement is embedded
- delays uploading incidents to NIMS is addressed.

At a corporate level and in line with the HSE's own recommendation the hospital needs to be supported in their endeavours to establish a joint decontamination co-ordinator position between the two respective hospitals.

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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	2.1, 2.5, 3.1, 3.6, 3.8, 5.4, 7.2

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