Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guide to HIQA's programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals

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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*

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. Background

It is recognised internationally that the setting and implementation of standards and monitoring a hospital's compliance with these standards are important levers in promoting improvements in quality and safety in healthcare.

The Health Information and Quality Authority (HIQA) has an established programme of monitoring against the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* (hereafter called the National Standards).[1] These National Standards were first published by HIQA in 2009[2] and revised in 2017.[1] The Standards were developed to reduce the risk of infection in patients undergoing treatment in hospitals - a well-recognised challenge faced internationally. Under the Health Act 2007, part of HIQA's role is to set such standards in relation to the quality and safety of healthcare and to monitor compliance with these Standards.[3]

A recognised area of risk in relation to the transmission of infection in hospitals is the decontamination and reprocessing of reusable medical devices.[4,5,6,7,8] As part of its monitoring programme for 2018, HIQA is commencing a specific programme of inspection in the area of reusable medical device decontamination and reprocessing. This area requires a specialised approach to monitoring under the National Standards.

Endoscopic and other minimally invasive procedures have revolutionised medicine. Endoscopic procedures in surgery for example are generally safer and less likely to result in complications (including surgical site infection) when compared to conventional open surgery. The success of such procedures, and the evolution of new techniques, has and will see an increasing demand for the use of reusable medical devices over time. However, such procedures are not entirely risk free. One such risk is the potential for the transmission of infection if the devices used to complete these procedures are not properly cleaned, decontaminated and reprocessed between patients.

In some instances, there has been a direct correlation between inadequate decontamination and reprocessing methods and transmission of cross infection between patients.[9,10,11,12] Additionally some reusable medical devices have complex structures and sophisticated designs which facilitate bacterial colonisation, thus making decontamination difficult.[13,14,15]

Antimicrobial resistance presents a serious threat to patients with an increasing amount of outbreaks related to multidrug-resistant organisms. Previous outbreaks of infection related to reusable medical devices have been associated with breeches of approved reprocessing guidelines.[16,17] Outbreak reports have highlighted the

importance of adherence to best available evidence, national guidelines and relevant legislation in relation to every stage of the reprocessing cycle.[18,19]

Therefore, reusable medical device pathways from patient use through to the decontamination process and final storage must be planned, controlled, monitored, and validated to provide ongoing assurances of the effectiveness of every element of the reusable medical device life cycle.

2. Purpose of this guide

The purpose of this guide is to provide an understanding of HIQA's approach to monitoring compliance with the National Standards to ensure patient safety in the decontamination and reprocessing of reusable medical devices. This monitoring programme is designed to supplement HIQA's existing inspection programme against the revised *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*, commenced in 2017.

Inspections, as outlined in this guidance document, are intended to start in late quarter 3 of 2018. Inspections will be conducted in a sample of public acute hospitals, with all hospitals still subject to more extensive methodology against the National Standards. Depending on risk identified, HIQA may determine that inspection under both methodologies is warranted in some hospitals.

This guide should be used in conjunction with the previous *Guide to the monitoring programme undertaken against the National Standards for the prevention and control of healthcare-associated infections* [20] sent to all hospitals and published on www.hiqa.ie in May 2017.

Both monitoring guides aim to give service providers and members of the public an overview of HIQA's monitoring programme against these National Standards. The guidance documents include information about the:

- format of HIQA's phased monitoring programme
- format of unannounced hospital inspections
- type of information, documentation and data that HIQA may request during this phase of the monitoring programme.

Explanations of some terms used in this guide are contained in a glossary at the end of this document.

3. Current context

The *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* outline that reusable medical devices should be decontaminated, reprocessed and maintained to minimise the risk of transmitting a healthcare-associated infection. It is important that hospitals have the necessary structures, systems and processes in place to ensure that reusable medical devices are decontaminated and reprocessed appropriately in line with best available evidence,[21,22,23,24,25,26,27] relevant legislation[28,29] and national guidance.[30,31,32,33,34,35,36,37,38]

The monitoring inspection type outlined in this guidance document aims to build on our revised monitoring programme against the updated National Standards, which commenced in 2017. These inspections will assess public acute hospitals to determine if service providers have the necessary structures, systems and processes in place to ensure that the risk of patients acquiring a healthcare-associated infection in relation to reusable medical devices are appropriately mitigated and managed.

3.1 Stakeholder engagement and the voice of the patient

An external advisory group was formed to provide advice to HIQA on the development of the monitoring methodology outlined in this document. Membership of this group and other national and international regulatory organisations and experts that were consulted during the development of this phase of the programme are outlined in Appendix 1 and Appendix 2 of this guidance document. The advisory group includes patient representation, technical experts and relevant nominees from the Health Service Executive (HSE) and the Department of Health. HIQA would like to acknowledge and thank the members of the external advisory group and other individuals who provided advice on this monitoring programme.

4. Monitoring programme plan

HIQA revised its approach to monitoring against the updated National Standards in May 2017. This revised approach is comprised of three different types of monitoring activity. These three parts have been introduced on a phased basis as outlined below.

Phase 1: April to May 2017

In Phase 1 of this revised monitoring approach, 49 public acute hospitals in Ireland completed a self-assessment tool which was devised by HIQA and based on the National Standards. This tool was designed to both provide HIQA with relevant information around the nature of infection prevention and control practice in acute hospitals, and to enable hospitals to assess their own compliance with the

standards. The tool comprised questions about essential elements of infection prevention and control practice.

Section 2.9 of the self-assessment tool asked specific questions around the systems and processes in place in relation to reusable medical devices. The information provided by each hospital in this section has, in part, provided insight into the structures, systems and processes that are in place for decontamination and reprocessing of reusable medical devices in acute hospitals. Furthermore, the information provided was reviewed by HIQA and used to inform Phase 3 of this monitoring programme. A copy of section 2.9 of the self-assessment tool template is included in Appendix 3 of this guidance document.

Phase 2: May 2017 onwards

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. It is intended that this phase will continue throughout 2018, in parallel with Phase 3.

Phase 3: Quarter 3 2018 onwards

In Phase 3 of this monitoring programme and as part of its approach to monitoring against National Standards, HIQA will perform unannounced inspections in public acute hospitals from quarter 3 2018 onwards with a particular focus on the decontamination and reprocessing of critical and semi-critical reusable medical devices.[*] For the purpose of this programme and in line with national guidelines, semi-invasive ultrasound probes and non-invasive ultrasound probes are categorised as semi-critical devices, and therefore included for consideration in this monitoring programme.

Phase 3 is designed to ensure that HIQA inspects the areas of highest risk of microorganism transmission should decontamination and reprocessing practices fail. HIQA will focus, in the first instance, on decontamination facilities[†] outside of

[*]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.

designated controlled decontamination units[‡] (such as Central Decontamination Units and Endoscope Reprocessing Units), to ensure that structures, systems, processes and outcomes in these facilities are aligned to national guidelines. HIQA will use specific lines of enquiry to guide this inspection process. Appendix 4 shows the lines of enquiry for this part of the monitoring programme which are aligned with the National Standards and include the following:

- **Governance and management structures**

The inspection team intends to assess overarching hospital-wide governance and management arrangements in relation to decontamination and reprocessing of reusable medical devices at the hospital. In doing so, HIQA will determine the effectiveness of oversight arrangements for decontamination and reprocessing of reusable medical devices at the hospital.

- **Monitoring and evaluation systems including audit and risk management**

The inspection team will visit a decontamination facility (outside of a designated controlled decontamination unit) and speak with clinical area managers or those delegated to act on their behalf in order to gather information in relation to monitoring, evaluation and audit of decontamination and reprocessing processes, including management of risk.

In addition, the inspection team will observe aspects of the physical environment and local practices around decontamination of reusable medical devices. The team will specifically gather information in relation to the local management and oversight of decontamination and reprocessing of reusable medical devices at the decontamination facility inspected.

- **Training and education of key personnel**

The inspection team will look for evidence in relation to staff education and training to ensure that key personnel have been appropriately trained to the necessary standard of competence in the decontamination facility inspected.

[‡]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.

HIQA will review how staff are supported with ongoing education and training in relation to decontamination and reprocessing of reusable medical devices.

- **Relevant policies, procedures, protocols and guidelines**

The inspection team will review relevant policies, procedures, protocols and guidelines in relation to decontamination and reprocessing of reusable medical devices at the decontamination facility inspected to ensure that staff are supported to implement evidence-based or best practice in decontaminating and reprocessing of reusable medical devices.

It is anticipated that this monitoring programme may be expanded in due course to include on-site inspections of designated controlled decontamination units such as Endoscope Decontamination Units and Central Decontamination Units with a particular focus on validation, maintenance and periodic testing of associated decontamination and reprocessing equipment. This guide may be revised periodically as this monitoring programme progresses or changes. Hospitals will also be informed as and when this expanded focus occurs.

5. Unannounced hospital inspections

This section provides an overview of the unannounced hospital inspection process in phase 3 of the monitoring programme which is due to start in quarter 3, 2018.

5.1 Before an unannounced hospital inspection

Prior to an unannounced hospital inspection, HIQA will review key pieces of information relating to the way the hospital is organised and run to ensure good practice around decontamination and reprocessing of reusable medical devices. Key pieces of information include:

- self-assessment responses and related documents already submitted by the hospital to HIQA
- previous HIQA inspection reports
- relevant unsolicited information received by HIQA in relation to the hospital
- performance indicators in relation to the prevention and control of healthcare-associated infection.

5.2 The day of inspection

Using specified lines of enquiry, the inspection team will gather governance and management arrangement information relating to decontamination and reprocessing of reusable medical devices across the hospital. Information will be gathered by the inspection team from discussions with the:

- hospital's Chief Executive Officer (CEO) or General Manager
- decontamination coordinator or lead and members of the decontamination committee
- local area manager and other relevant staff.

Additional information will be obtained from reviewing documentation and data provided by the hospital and by observing local structures, systems, processes and reviewing outcomes in relation to decontamination and reprocessing of reusable medical devices in the decontamination facility visited.

On arrival at the hospital, the inspection team will arrange a time to meet with the hospital's CEO or General Manager to gather information in relation to governance and management arrangements for the decontamination and reprocessing of reusable medical devices in decontamination facilities at the hospital. Inspectors will request documentation, data and information in relation to decontamination and reprocessing of reusable medical devices at the hospital from the hospital's CEO or General Manager at the start of the inspection (see sample Appendix 5). This request includes an inventory of critical and semi-critical reusable medical devices at the hospital.

The inspection team will then speak with the decontamination coordinator and members of the decontamination committee to find out about oversight arrangements in relation to decontamination and reprocessing of reusable medical devices at the hospital.

Following the first interview the inspection team will visit a decontamination facility at the hospital (outside of a designated controlled decontamination unit) such as a decontamination facility in the:

- out-patient department
- operating theatre
- early pregnancy assessment unit
- intensive care unit
- radiology department
- emergency department.

Inspectors will speak with staff in order to gather information in relation to the decontamination and reprocessing of reusable medical devices at these facilities. HIQA will ask for documentation, data and information from staff (see sample documentation and data request in Appendix 6). In addition, the inspection team will review structures, systems, processes and outcomes in relation to decontamination and reprocessing of reusable medical devices at the decontamination facility

inspected. During the inspection, the inspection team will look for evidence to assess if the following arrangements are in place, as set out in the lines of enquiry:

- **Governance and management structures**

  Does the hospital have formalised leadership, governance and management arrangements in place in relation to decontamination, reprocessing and use of all reusable medical devices at the hospital?

  Does this include formalised and clear lines of accountability and responsibility at all levels of the service?

- **Monitoring and evaluation systems**

  Does the hospital have effective arrangements in place to respond to ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement?

  Does the hospital have 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?

- **Training and education of key personnel**

  Does the hospital ensure 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?

- **Relevant policies, procedures, protocols and guidelines**

  Is the hospital assured that key personnel are implementing evidenced-based best practice in relation to decontamination and reprocessing of reusable medical devices, and are supported with up-to-date policies, procedures, protocols and guidelines aligned with relevant legislation and national guidelines?

The inspection team will use specific monitoring tools to gather information about the management and oversight arrangements in relation to decontamination and reprocessing of reusable medical devices at the decontamination facility visited. HIQA's monitoring tools are aligned to the National Standards, HIQA's lines of enquiry, HSE standards and guidance, relevant legislation and recommended best practice guidance in relation to reusable medical devices. It should be noted that these tools were specifically designed for HIQA monitoring purposes only.

A sample unannounced one-day inspection plan is set out in Figure 1 below.

Figure 1. Sample one-day unannounced hospital inspection plan

- The inspection team meet with the hospital's CEO or General Manager. HIQA will provide an overview of the inspection plan and schedule.
- A list of required documentation and data which will need to be supplied to HIQA during the inspection will be provided to the hospital at the outset of the inspection.

- The first group interview will be conducted with the decontamination lead or coordinator, relevant local area managers and members of the decontamination committee or equivalent.

- The inspection team will then visit a decontamination facility (outside of a designated controlled decontamination unit) such as in an out-patient department, operating theatre, early pregnancy assessment unit, intensive care unit, radiology department, or emergency department.
- Inspectors will speak with staff in order to gather information in relation to decontamination and reprocessing of reusable medical devices at the decontamination facility inspected.
- Inspectors will follow lines of enquiry.
- A documentation and data request will be provided to the area manager in the area inspected.

- The documentation and data requested will be reviewed.

- The second interview will be conducted with the hospital's CEO or General Manager to determine hospital-wide governance and management arrangements in relation to reusable medical device decontamination and reprocessing at the hospital.

- Preliminary feedback will be provided to the hospital's CEO or General Manager at the close of the inspection.

5.3 Practical information about hospital inspections

- Inspections will be unannounced meaning that the hospital will not receive any prior notification of the date of an inspection.
- Inspections will generally be performed within core working hours. However, weekend and out-of-hours inspections may be carried out.
- On the day of inspection, inspectors will:
    - ask to speak to the CEO or General Manager on arrival in the main hospital reception
    - request access to a secure room for the purpose of documentation review
    - carry visitor name badges or door-access cards required to facilitate movement throughout the hospital; these should be made available to the inspection team as soon as possible upon arrival onsite and will be returned at the end of the inspection
    - inform the hospital's CEO or General Manager during the inspection of any high risks which require action to allow them to put the necessary actions in place to address any risks identified
    - provide feedback on the preliminary inspection findings to the hospital's CEO or General Manager at the end of the inspection.

Hospital inspection teams

- Inspectors will be authorised under the Health Act 2017 and work within the powers described in the Act.
- Inspectors are obliged to comply with HIQA's Code of Conduct which is available on www.hiqa.ie.

Confidentiality

In line with current data protection legislation, HIQA requests that unless specifically requested to do so, hospitals do not send named patient information or information that could identify an individual patient to HIQA by email or by post. Hard copy documents provided to inspectors for removal from the hospital should not contain data that identifies individual patients.

Freedom of Information

HIQA is subject to the Freedom of Information Acts[39] and the statutory Code of Practice regarding Freedom of Information.[40]

6. Risk identification and notification process

Risk identified by HIQA during this monitoring programme will be escalated to the hospital's CEO or General Manager in line with HIQA's risk management process as follows:

- High risks identified during a hospital inspection which require immediate mitigation will be brought to the attention of the hospital's CEO or General Manager during the inspection. This is to allow them to immediately implement the actions necessary to mitigate such risks.
- Formal written notification of any identified risk arising during this monitoring programme will be issued to the hospital's CEO or General Manager by email within two working days of identifying the risk, with the requirement to formally report back to HIQA stating how the risk has been mitigated within a further two working days.
- In the case of high risks which do not require immediate mitigation, formal notification of the identified risk will be issued to the hospital's CEO or General Manager by email within two working days of identifying the risk, with the requirement to formally report back to HIQA with an action plan to reduce and effectively manage the risk within a further five working days of receiving correspondence from HIQA.

HIQA's risk escalation process is outlined in a diagram in Appendix 7.

A copy of this correspondence may also be sent to the relevant hospital group Chief Executive Officer, and the HSE's National Director for Operations.

7. HIQA's inspection report

An individual report will be generated for each hospital inspected and published on HIQA's website www.hiqa.ie. Following an unannounced inspection:

- HIQA will send a draft report of inspection findings, together with a factual accuracy and feedback form, by email to the hospital's CEO or General Manager. A copy of the draft report will also be sent by email to the hospital group Chief Executive Officer.
- The report will outline HIQA's findings including areas of good practice and any identified opportunities for improvement. The report will include risks, if any, that were identified during the monitoring process and may include correspondence between HIQA and the hospital's CEO or General Manager in relation to the management of such risk.

- The hospital's CEO or General Manager should complete the factual accuracy and feedback form provided with the draft report, and return this to HIQA within five working days of receipt.

8. Expected hospital response following an unannounced hospital inspection

In the event that the inspection team identifies high risks to patients (either immediate or non-immediate), it is the responsibility of the hospital to respond as previously outlined in this guidance document.

Each CEO or General Manager is accountable for the development of a quality improvement plan that prioritises the improvements necessary to comply with the National Standards. Quality improvement plans must be approved by the hospital's identified individual who has overall executive accountability, responsibility and authority for the delivery of high-quality, safe and reliable services.

During future inspection, the inspection team will check for evidence that hospitals have taken account of the findings of their individual inspection report and, if appropriate, that plans have been put in place to address any required areas of improvement identified by HIQA.

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10. Appendices

Appendix 1: Membership of the External Advisory Group

Member	Representing / Background
Caroline Connelly	Nominee on behalf of the Quality Improvement Division, Health Service Executive National Clinical Lead for the Decontamination Safety Programme, Quality Improvement Division, Health Service Executive
Mr Fiachra Cooke[§]	Nominee on behalf of Forum of Irish Post-Graduate Medical Training Body, Royal College of Physicians Consultant General and Colorectal Surgeon
Maria Egan[**]	Nominee on behalf of the Department of Health
Ronnie Mc Dermott	Nominee on behalf of Quality Assurance and Verification Division, Health Service Executive National Medical Device Equipment Advisor
Hannah Mc Mahon	Nominee of behalf of the Irish Decontamination Institute Vice-chairperson, Irish Decontamination Institute
Stephen Mc Mahon	Irish Patients Association Director, Irish Patients Association
Deirdre McNamara[††]	Nominee on behalf of the Acute Hospitals Divisions Health Service Executive General Manager, Quality and Patient Safety, Acute Hospitals Division, Health Service Executive
John McNamee	Nominee on behalf of the Acute Hospitals Office, Health Service Executive

[§] Mr Fiachra Cooke via teleconference at the first advisory group meeting
[**] Adele Gannon attended on behalf of Maria Egan at the second advisory group meeting
[††] Aideen Quigley attended on behalf of Deirdre McNamara at the second advisory group meeting

	Decontamination Unit Supervisor
Hugh O' Connor	Authorised Decontamination Engineer
Dr Niamh O' Sullivan[‡‡]	Chair Royal College of Physicians Ireland Clinical Advisory Group, Healthcare Associated Infection and Antimicrobial Resistance Clinical Programme Consultant Microbiologist
Jennifer Roche[§§]	Nominee on behalf of the Health Products Regulatory Authority Medical Devices Inspector, Health Products Regulatory Authority

HIQA membership of the External Advisory Group

Sean Egan	Head of Healthcare Regulation, HIQA (Advisory Group Chair)
Joan Heffernan	Programme Lead, Inspector Manager, HIQA
Aileen O'Brien	Healthcare Inspector, HIQA,
Noreen Flannelly-Kinsella	Healthcare Inspector, HIQA

[‡‡] Roisin Breen attended on behalf of Dr Niamh O' Sullivan at the first advisory group meeting
[§§] Mairead Finucane attended on behalf of Jennifer Roche at the second advisory group meeting

Appendix 2: Consultation with international experts and regulatory organisations

Christina Bradley, Laboratory Manager, Hospital Infection Research Laboratory, Queen Elizabeth Hospital, Birmingham, UK
Regulation and Quality Improvement Authority, Northern Ireland (RQIA)
Care Quality Commission England (CQC)
Healthcare Inspectorate Wales (HIW)
Dutch Healthcare Inspectorate (Inspectie voor Gezondheidszorg- IGZ)

Appendix 3: Section 2.9 of the self-assessment tool in relation to device reprocessing

2.9: Device reprocessing			
This section refers to all medical devices that may be reused in the hospital. Device categories include: Critical items (e.g. surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use. Semi-critical items (e.g. endoscopes for upper endoscopy and colonoscopy, laryngoscope blades, ultrasound probes) are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse. Non-critical items (e.g. blood pressure cuffs, point-of-care devices) are objects that may come in contact with intact skin but not mucous membranes and should undergo cleaning and low or intermediate-level disinfection depending on the nature and degree of contamination.			
2.9.1	The hospital has a named decontamination co-ordinator with responsibility for reusable invasive medical device reprocessing.	Yes	No
2.9.2	Decontamination of medical devices at the hospital is overseen by a decontamination committee.	Yes	No
2.9.3	The hospital has an inventory of all **critical and semi-critical devices** used in the facility that identifies areas in the hospital and services provided by the hospital where such devices are used.	Yes	No
2.9.4	Decontamination of critical items and semi-critical items is performed in a designated decontamination area in line with best practice guidelines.	Yes	No
2.9.5	The hospital has up-to-date policies and procedures for the reprocessing of all reusable invasive medical devices used in and by the facility in line with relevant national guidelines.	Yes	No
2.9.6	The hospital has a competency-based training program for reprocessing of **critical and semi-critical** devices.	Yes	No
2.9.7	There is a continuing programme of training and education for personnel involved in device decontamination.	Yes	No

2.9.8	The hospital regularly audits (monitors and documents) adherence to reprocessing procedures for **critical and semi-critical** devices.	Yes	No
2.9.9	The hospital provides feedback from audits to relevant personnel and hospital management regarding adherence to reprocessing procedures for **critical and semi-critical** devices.	Yes	No
2.9.10	Single-use devices (SUDs) labelled by the manufacturer for a single use are not reprocessed.	Yes	No
2.9.11	The hospital allows adequate time for reprocessing to ensure adherence to all steps recommended by the device manufacturer, including drying and proper storage.	Yes	No
2.9.12	The hospital has an adequate supply of instruments for the volume of procedures performed to allow sufficient time for all reprocessing steps.	Yes	No
2.9.13	The hospital has a service level agreement outlining governance and accountability arrangements with respect to external contractor's involvement in device handling and where decontamination services are outsourced.	Yes	No
2.9.14	The hospital has a standard operating procedure in place based on national guidelines if devices are loaned, borrowed or trialled to minimise the risk of infection to patients, personnel and others.	Yes	No
2.9.15	If chemicals used for high-level disinfection are not single use, routine testing for appropriate concentration is performed and replacement of chemicals is documented.	Yes	No
2.9.16	Each step of the decontamination cycle is recorded, including the identity of the person undertaking each step.	Yes	No
2.9.17	The infection prevention and control team is consulted whenever new devices or products are to be purchased or introduced to ensure implementation of appropriate reprocessing policies and procedures.	Yes	No
2.9.18	All reusable invasive medical device sets (e.g. surgical instrument sets) and endoscopes can be traced through the	Yes	No

	decontamination process to the patient.		
2.9.19	The hospital has policies and procedures outlining hospital response (i.e. risk assessment and recall of device, look back) in the event of a reprocessing error or failure.	Yes	No
2.9.20	The hospital central decontamination unit operates a quality management system in line with EN ISO 13485.	Yes	No
2.9.21	Endoscope and local decontamination units operate a quality system in line with the key elements of EN ISO 13485.	Yes	No
2.9.22	Personnel trained in decontamination practice are available to reprocess reusable invasive medical devices for out of hour's unplanned emergency procedures if there is a requirement to decontaminate the device immediately following use e.g. an endoscope.	Yes	No
2.9.23	The hospital has up- to- date policies and procedures to minimise the exposure of patients and employees to transmissible spongiform encephalopathies.	Yes	No

Appendix 4: Lines of enquiry

1. Effective leadership, 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 formalised and clear lines of accountability and responsibility at all levels of the service.

2. Monitoring and evaluation systems in place including audit and risk management

4.1 The hospital has effective arrangements in place to respond to the ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement.

4.2 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.

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.

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.

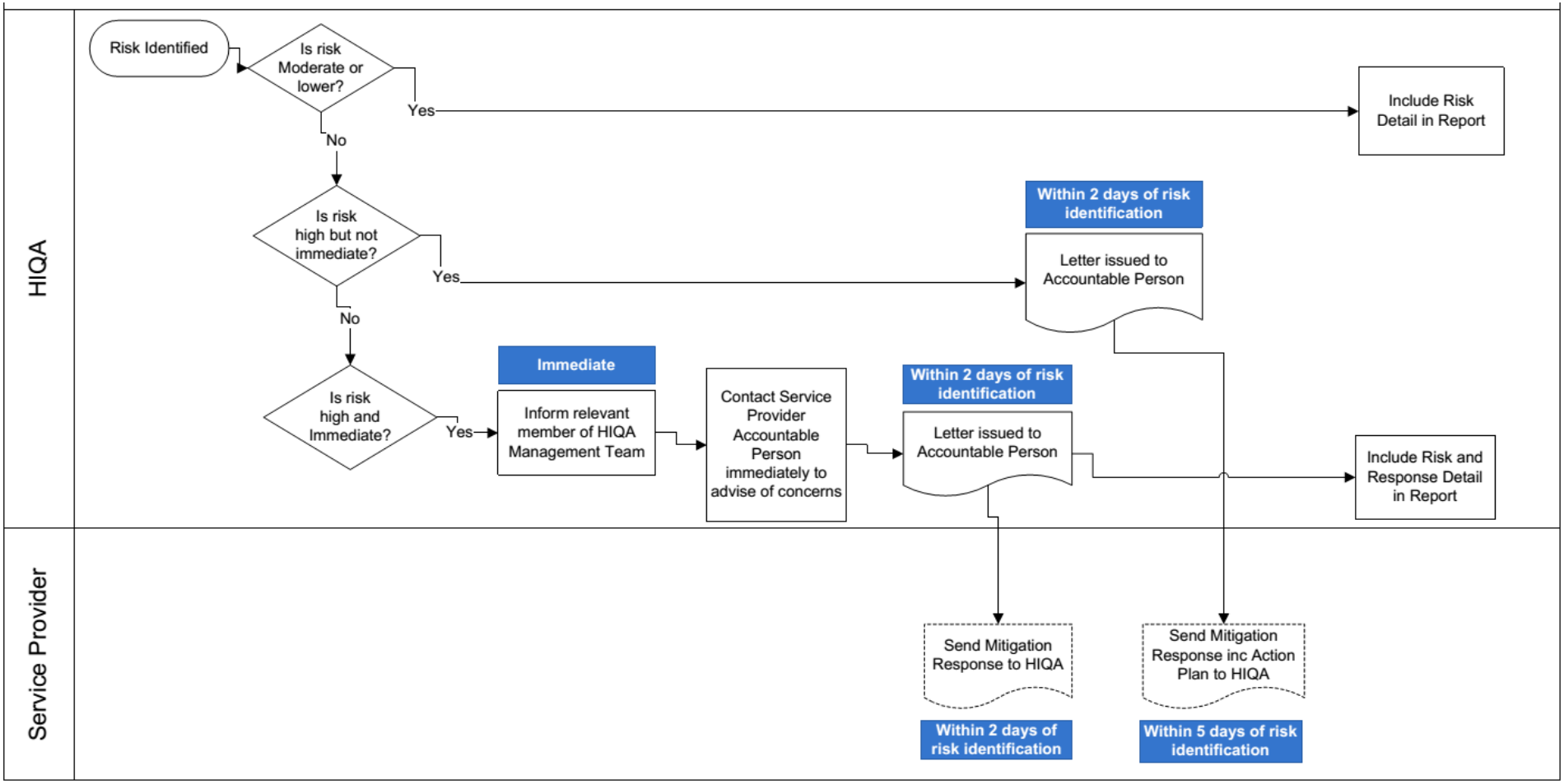
Appendix 5: Sample documentation and data request for Chief Executive Officer and or General Manager

No.	Documentation or data
1	Inventory of critical and semi-critical reusable medical devices at the hospital and the clinical area in which such devices are used
2	List of current policies, procedures and guidelines relating to decontamination and reprocessing of reusable medical devices
3	Terms of Reference and list of members by discipline for the decontamination committee
4	Minutes of decontamination committee meetings for the last three meetings
5	An annual decontamination report submitted to the hospital group CEO
6	Decontamination-related risks on the current hospital risk register
7	Number of decontamination related incidents recorded on the hospital incident management system in the past 12 months
8	Reports of management of individual incidents or look backs in relation to decontamination failures for last 12 months
9	Audits in relation to decontamination and reprocessing of reusable medical devices
10	Examples of action plans to address required improvements identified through monitoring or audit
11	List of content of decontamination education and training programme for staff
12	Number of staff who carry out endoscope decontamination who have received a Fetac Level 6 Minor Award in Decontamination

Appendix 6: Sample documentation and data request for local decontamination facility manager

No	Documentation or data
1	Inventory of critical and semi-critical reusable medical devices used in the facility
2	Number of endoscopy staff employed to work in the facility who have received Fetac Level 6 Minor Award in Decontamination
3	List of content of decontamination education and training programme for staff
4	List of policies, procedures and guidelines in relation to decontamination and reprocessing of reusable medical devices
5	Audit of decontamination and reprocessing processes and results
6	Examples of communication received in relation to medical device alerts
7	Policy for Transmissible Spongiform Encephalopathies risk assessment

Appendix 7 —HIQA's risk escalation process



Note: Accountable Person: identified individual who has overall executive accountability, responsibility and authority for the delivery of high quality, safe and reliable services.

Key: inc= including, days = working days.

Glossary of terms and abbreviations

This glossary details key terms and a description of their meaning within the context of this document.

Assurance: is being sure or certain about systems, processes and procedures and standing over business objectives. It involves monitoring risk and implementing controls to mitigate that risk.

Cleaning: the physical removal of foreign material such as bloody and bodily substances, rust, dust, dirt, debris, spillages, and so on. Cleaning physically removes rather than kills micro-organisms. It is achieved with water, detergents and mechanical action.

Clinical governance: a system through which service providers are accountable for continually improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

Corporate governance: the system by which services direct and control their functions in order to achieve organisational objectives, manage their business processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Critical device: as described in Spaulding's classification is a device and or item that enters sterile tissues and or sterile body areas or the vascular system and must be sterile prior to use for example surgical instruments, biopsy forceps, laparoscopes. See also **Reusable medical device**.

Disinfection: a process used to reduce the number of viable micro-organisms, but which may not necessarily inactivate some infectious agents.

Decontamination: the removal of micro-organisms or foreign matter (or both) from contaminated materials or living tissue. Three processes for decontamination are commonly used: cleaning, disinfection and sterilisation.

Equipment: this consists of a large group of equipment, typically divided into four broad groups including single-use items; single patient-use items; reusable non-invasive communal patient care equipment; and reusable invasive medical devices.

Evaluation: a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.

Governance: in healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for patients. See also **Clinical governance** and **Corporate governance**.

Healthcare-associated infection: infections that are acquired after contact with healthcare services.

Infection: the invasion and reproduction of pathogenic or disease-causing micro-organisms inside the body that may cause tissue injury and disease.

Infection prevention and control: the discipline and practice of preventing and controlling healthcare-associated infection and the spread of infectious diseases in a healthcare service.

Infection prevention and control programme: structures, systems and processes a service has in place to prevent and control healthcare-associated infections.

Infection prevention and control team: a group of people, from within and outside the service, with complementary knowledge and skills relating to infection prevention and control. The structure of the team should be based on current accepted best practice. Below is an example of an infection prevention and control team and is for guidance purpose only:

- consultant medical microbiologist
- infection prevention and control nurse
- antimicrobial pharmacist
- surveillance scientist
- occupational health physician
- senior medical scientist.

Invasive medical device: a device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Medical device equipment decontamination committee: a multidisciplinary group of people from within and outside a hospital or groups of hospitals, which reports to senior management. The committee is responsible for the review and oversight of decontamination of medical devices and equipment in the hospital or hospitals in question. Membership of the decontamination committee may include (where available):

- chief executive, general manager or designated member of senior management team
- infection prevention and control nurse
- central decontamination unit managers
- endoscopy unit managers
- theatre managers
- clinical engineers
- authorising engineer for decontamination
- quality and risk managers
- procurement managers
- HSE estates.

Micro-organism: a living organism, such as bacteria, viruses and fungi too small to be seen with the naked eye but visible under a microscope.

Monitoring: systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.

Multidisciplinary: an approach to the planning of treatment and the delivery of care for a patient by a team of healthcare professionals who work together to provide integrated care.

Outcomes: the impact that a test, treatment, policy, programme or other intervention has on a person, group or population. Depending on the intervention, outcomes could include:

- changes in knowledge and behaviour related to health or in people's health and wellbeing
- the number of patients who fully recover from an illness or the number of hospital admissions
- an improvement or deterioration in someone's health, symptoms or situation.

Policy: a written operational statement of intent which helps staff make appropriate decisions and take actions, consistent with the aims of the service provider, and in the best interests of patients.

Procedure: a written set of instructions that describes the approved and recommended steps for a particular act or sequence of events.

Quality improvement: a systematic approach using specific methods to improve quality through achieving successful and sustained improvement.

Reprocessing: all steps necessary to make a contaminated reusable medical device ready for its intended use. These steps include cleaning, disinfecting, sterilising, functional testing, packaging and labelling.

Reusable medical device: is a device that can be reprocessed and reused on multiple patients. Reusable medical devices can be grouped into one of three categories according to the degree of risk of infection associated with the use of the device:

- **critical devices,** such as surgical forceps, come in contact with blood or normally sterile tissue
- **semi-critical devices,** such as endoscopes, come in contact with mucus membranes
- **non-critical devices**, such as stethoscopes, come in contact with unbroken skin.

Reusable **critical and semi-critical** medical devices are reprocessed by thorough cleaning followed by high-level disinfection or sterilization between patients. They are made of materials that can withstand repeated reprocessing, including manual brushing and the use of chemicals.

Reusable medical device life cycle: involves selection, specification, purchase, transport, storage and eventual disposal of a reusable medical device and includes purchase, validation, maintenance and testing of associated decontamination equipment and processes. All aspects of the life cycle need to be controlled and managed if decontamination is to be fully effective.

Risk: risk is the effect of uncertainty on objectives. It is measured in terms of consequences and likelihood.

Risk management: coordinated activities to direct and control an organisation with regard to risk.

Semi-critical device: as described in Spaulding's classification, is a device and or item that comes in contact with mucous membranes or non-intact skin and requires high-level disinfection at a minimum prior to use although sterilisation is preferred.

Single-use item: a medical device that is intended to be used on an individual patient during a single procedure and then discarded.

Sterilisation: the process to make an object free from viable micro-organisms.

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