Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guide to HIQA's consolidated programme of monitoring against the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* in 2019

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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.

Contents

1. Purpose of this guide

The purpose of this guide is to provide an understanding of the Health Information and Quality Authority's (HIQA) 2019 consolidated approach to monitoring compliance with the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*[1] (hereafter called the National Standards) to ensure patient safety in the prevention and control of infection in acute hospitals.

This guidance document includes information about the:

- background to HIQA's prevention and control of healthcare-associated infection monitoring programme
- the 2019 monitoring programme
- format of HIQA unannounced hospital inspections
- risk identification and notification processes
- HIQA inspection reports
- HIQA's revised Submission policy 2019.

This guide replaces the previous documents sent to all hospitals and published on www.hiqa.ie:

- Guide to the monitoring programme undertaken against the National Standards for the prevention and control of healthcare-associated infections. May 2017.[2]
- Guide to HIQA's programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals July 2018.[3]

The guide may be revised periodically as this monitoring programme progresses and or changes. Explanations of some terms used in this guide are contained in a glossary at the end of this document.

2. Background to HIQA's prevention and control of healthcare-associated infection monitoring programme

Preventing and controlling healthcare-associated infections continues to be a significant challenge to healthcare systems throughout the world, including Ireland. These infections affect on average 1 in 20 people in the acute healthcare service setting, rising in patient care areas with high numbers of vulnerable patients and complex activity. Protecting patients from infection becomes more challenging when hospitals are operating in circumstances where there are high bed-occupancy rates. Healthcare-associated infections can result in serious illness, prolonged hospital stays and potentially long-term disability or death.

However, a significant proportion of healthcare-associated infections are avoidable if effective structures, systems and processes are in place to manage the potential risks arising from the environment and activities within the hospital. Effective prevention and control of healthcare-associated infections requires a multi-targeted approach. This is best achieved through a well-organised, planned and managed infection prevention and control programme which is integrated with an antimicrobial stewardship programme to effectively coordinate efforts within an acute healthcare service.

Effective infection prevention and control programmes depend on effective leadership, governance and management. Hospital staff need to consistently implement evidence-based best practice in relation to the prevention and control of healthcare-associated infection, and this implementation needs to be overseen at local level by hospital managers. Managers with overall responsibility for the delivery of high-quality, safe care in hospitals need to be assured that the people using their services and staff working in these services are protected in as far as possible from developing healthcare-associated infections.

The National Standards provide a framework for service providers to assess and improve infection prevention and control practices. 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.[4] Since 2012, HIQA has engaged in a rolling programme of inspections against the 2009 Standards in order to promote improvement in infection prevention and control practices across Irish hospitals. These inspections are publicly reported on HIQA's website to allow and enable transparent sharing of findings and provide assurances to the public that service providers have implemented the National Standards.

Previous HIQA inspections of acute hospitals have identified many good areas of practice. However, these inspections have also highlighted areas for improvement

including the prevention and control of multidrug-resistant organisms and reducing medical-device-related infection.

HIQA revised the monitoring approach in parallel with the publication of updated National Standards published in May 2017. The revised monitoring approach was developed with consideration of:

- the key infection risk factors for patients associated with the hospital environment
- previous HIQA inspections and findings
- increasing antimicrobial resistance in Ireland.

The revised monitoring programme aimed to determine each hospital's compliance against the revised National Standards, with a particular focus on how each hospital worked to establish and embed an effective infection prevention and control programme. The revised monitoring programme was implemented in three phases, with the second and third phases building on the findings from the first phase (Appendix 1).

In 2018 HIQA implemented phase three of the revised monitoring programme with a specific focus on decontamination of reusable medical devices.

3. Monitoring programme 2019

During 2019 HIQA will continue to monitor infection prevention and control services in areas known to represent a high potential risk to patient safety.

Using a consolidated monitoring programme, HIQA's focus will include a detailed evaluation of how hospitals organise themselves to minimise the spread of healthcare-associated infections, with a particular focus on systems to detect, prevent, and manage multidrug-resistant micro-organisms, and the approach taken to reduce the risk of device-related infection. These two areas are internationally recognised as being major contributors to potentially preventable patient harm as a consequence of healthcare provision.

3.1 Prevention and control of multidrug-resistant organisms

While MRSA* rates have fallen in Ireland in recent years, the incidence of infections caused by multi-drug resistance Gram-negative organisms are increasing and may

* Methicillin-resistant Staphylococcus aureus

also be more difficult to treat. This includes the emergence of CPE[†] in Ireland - a strain of bacteria which are very resistant to antibiotics, harder to treat, and therefore carry a very high risk to patient safety in our hospitals.

In Ireland, over the last five years, we have seen a rapid increase in the incidence of infection and colonisation by CPE. Numerous clusters and outbreaks have been reported, some of which have been successfully contained. This evidenced that, when the appropriate and multifaceted control measures are implemented, clusters and outbreaks can be managed effectively.

In October 2017, the Minister for Health activated a Public Health Emergency Plan and convened a National Public Health Emergency Team as a public health response to the increase of CPE in Ireland.

The focus of planning, preparation and prevention for the control of organisms of significance, such as CPE, requires an effective infection control program. Therefore the 2019 inspections will continue to examine the systems in place to detect, prevent and respond to multidrug-resistant bacteria in hospital settings in line with national guidelines. [5,6,7]

3.2 Decontamination and reprocessing of reusable medical devices

Another recognised area of risk in relation to the transmission of infection in hospitals is the decontamination and reprocessing of reusable medical devices.[8,9,10,11,12] In some instances, there has been a direct correlation between inadequate decontamination and reprocessing methods and transmission of cross infection between patients.[13,14,15,16] Additionally some reusable medical devices have complex structures and sophisticated designs which facilitate bacterial colonisation, thus making decontamination difficult.[17,18,19] Previous outbreaks of infection related to reusable medical devices have been associated with breeches of approved reprocessing guidelines.[20,21]

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 in line with national standards and recommended practices. [22,23,24,25]

Monitoring of the decontamination and reprocessing of reusable medical devices may be expanded in due course to include on-site inspections of designated controlled

[†] Carbapenemase producing Enterobacteriaceae

decontamination units such as Endoscope Decontamination Units and Central Decontamination Units. Hospitals will be informed of programme revisions in advance.

3.3 Lines of enquiry (LOE) 2019 monitoring programme

Using specified lines of enquiry that are aligned with the National Standards, the inspection team will gather information in relation to the governance and management of the prevention and control of healthcare-associated infections at the hospital during unannounced one-day inspections in public acute hospitals. Lines of enquiry are:

LOE 1: Governance and management structures

- The hospital has formalised governance arrangements with clear lines of accountability and responsibility around the prevention and control of healthcare-associated infections and the decontamination and reprocessing of reusable medical devices.

LOE 2: Monitoring and evaluation systems including risk management

- The hospital has effective arrangements in place to respond to the ongoing monitoring, evaluation, audit and outcome measurement in relation to the prevention and control of healthcare-associated infection programme and the decontamination and reprocessing of reusable medical devices.
- The hospital has a risk management system in place to identify, manage and report all hazards, adverse events, near misses and risks in relation the prevention and control of healthcare-associated infections and the decontamination and reprocessing of reusable medical devices.

LOE 3: Implementation of evidence-based best practice

- The hospital has the structures, systems and processes to detect, prevent, and manage multidrug-resistant organisms.
- The hospital has the structures, systems and processes in relation to decontamination and reprocessing of reusable medical devices in satellite decontamination facilities.
- 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.
- The hospital ensures that key personnel are implementing evidenced-based best practice with up to date policies, procedures, protocols and guidelines in line with relevant legislation and national guidelines.

4. 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. The following section provides an overview of the unannounced hospital inspection process.

Using specified lines of enquiry, the inspection team will gather information relating to the prevention and control of healthcare-associated infection and decontamination and reprocessing of reusable medical devices across the hospital. Information will be gathered by the inspection team through:

- speaking with the hospital's CEO or general manager
- speaking with members of clinical area managers and other hospital staff
- reviewing documentation and data
- observing clinical environments and local practices.

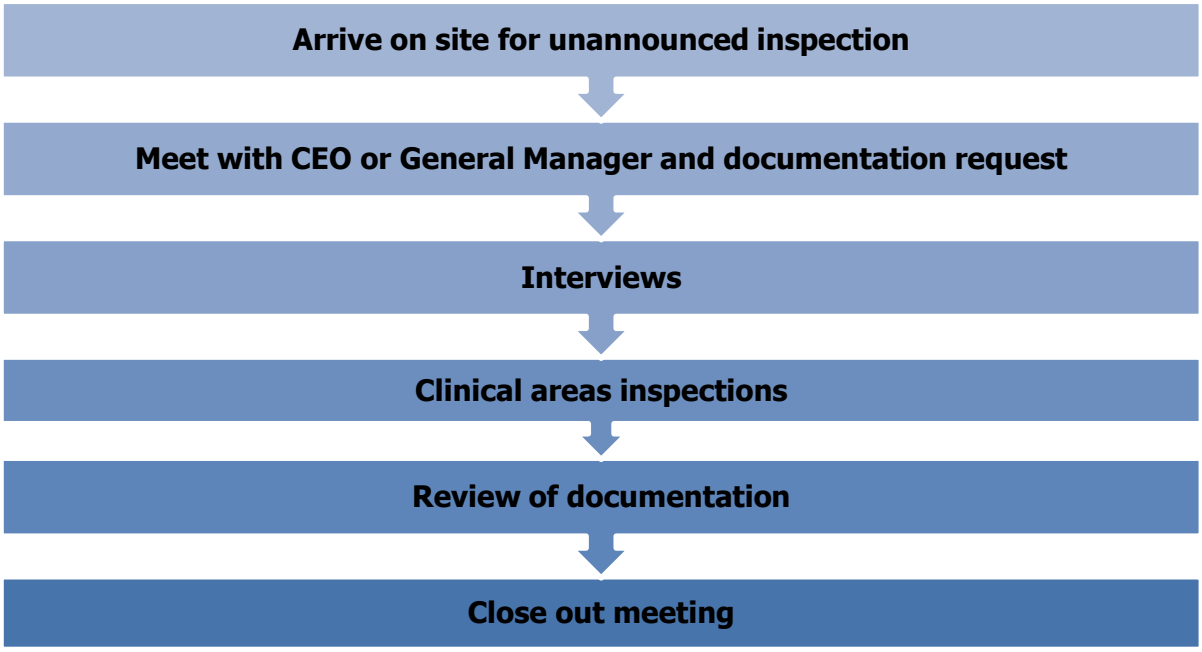
Before an unannounced hospital inspection:

HIQA will review key pieces of information relating to the way the hospital is organised and operated. Key pieces of information include:

- 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.

The day of inspection

Table 1. Sample one-day unannounced hospital inspection schedule[‡]



On arrival at the hospital, the inspection team will meet with the person with overall accountability and responsibility for the hospital, for example, the hospital's CEO or General Manager. Hospitals will be asked to nominate a liaison person who will be responsible for engagement with HIQA during the course of the inspection.

Practical information about hospital inspections

During the inspection, inspectors will:

- request access to a secure room for the purpose of interviews and documentation review
- request visitor name badges or door-access cards to facilitate movement throughout the hospital. These should be made available to the inspection team as soon as possible following arrival onsite and will be returned at the end of the inspection.

[‡] This is a sample inspection plan. The schedule may vary on the day of inspection for operational reasons

Documentation, data and information request

HIQA will request documentation data and information on the day of inspection (Appendix 2: sample documentation request). If any piece of documentation is not available on the day of the inspection, the hospital should submit this after the inspection in electronic format as requested to qualityandsafety@hiqa.ie.

Interviews

The inspection team will arrange a time to meet with key personnel. Interviews will be held with:

1. the hospital's CEO or General Manager to determine hospital-wide governance and management arrangements in relation to infection prevention and control and reusable medical device decontamination and reprocessing at the hospital.
2. the decontamination lead or representative from the Decontamination Committee.
3. a representative from the Infection Prevention and Control Team or Committee.

The purpose of the interviews is to gather information about:

- how infection prevention and control and decontamination services are led and managed
- how risks are identified and managed
- how the management team is assured that the service provided is safe and effective.

Clinical area inspections

The inspection team will visit two to three clinical areas including;

- in-patient wards or units
- decontamination facilities (outside of a designated controlled decontamination unit) such as decontamination facilities in the:
    - out-patient department
    - operating theatre
    - early pregnancy assessment unit
    - intensive care unit
    - radiology department
    - emergency department.

Inspectors will gather information in relation to:

- the structures, systems and processes to detect, prevent, and manage multidrug-resistant organisms
- the structures, systems and processes in relation to decontamination and reprocessing of reusable medical devices in satellite decontamination facilities.

- systems and processes in place for risk management and incident reporting
- access to and use of relevant policies, procedures and guidelines
- monitoring arrangements in place for infection prevention and control
- staff training and sharing of learning.

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

Documentation review

Inspectors will review the documentation and data provided.

Close-out meeting

When the inspection has been completed, the inspection team will conduct a close-out meeting with the hospital's CEO or General Manager. The purpose of this meeting is to provide preliminary findings of the inspection and identify any high-risks which require immediate action have been identified, to allow them to rapidly address such risks.

Inspection teams

Inspection teams comprise of HIQA staff who have been appointed by HIQA as 'authorised persons' under the Health Act 2007 and work within the powers described in the Act to monitor compliance with standards. Inspectors are obliged to comply with HIQA's Code of Conduct for staff, which is available at 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[26] and the statutory Code of Practice regarding Freedom of Information.[27]

5. Risk identification and notification processes

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:

- 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 matrix and risk escalation process map is outlined in a diagram in Appendix 3 and 4.

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

6. 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 inspection.

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. Therefore HIQA recommends that the hospital does not include individual staff names in high risk correspondence.

In 2019, HIQA has revised its approach to receipt of feedback from hospitals on reports progressing through the drafting process. Under this new and enhanced process, each inspection report goes through three main stages as they are prepared for publication.

Stage 1 Inspection Report

A stage 1 inspection report will be issued with a 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 CEO.

Preliminary findings will have been given during the close-out meeting. However, following review of the Stage 1 report the hospital's CEO or General Manager can return the feedback form to include any factual accuracy detail along with feedback on receipt of the stage 1 inspection report.

The hospital's CEO or General Manager is encouraged to engage with the lead inspector if deemed necessary and in advance of completion of the formal written documentation, to discuss specific concerns or queries they may have regarding the judgments in this stage 1 inspection report. This can be completed by phone and/or email.

To complete the feedback process, (and having engaged via telephone call or email with the lead inspector, if deemed necessary), the hospital's CEO or General Manager should formally complete the factual accuracy and feedback form provided with the draft report, and return this to HIQA within **15 working days of receipt.**

Stage 2 Inspection Report

On receipt of feedback from the hospital on a stage 1 report, HIQA will consider the feedback in the context of evidence gathered on inspection. Consequently, a stage 2 inspection report will be produced which will include any required amendments made by the inspector resulting from the feedback process. This stage 2 report will then be again issued to the hospital for review.

If the hospital's CEO or General Manager believes that the judgment(s) contained in the stage 2 inspection report are not based on the evidence made available to inspectors at the time of the inspection, or if they believe that the judgment(s) are disproportionate to the evidence reviewed, they may decide to make a formal submission to HIQA to challenge a regulatory judgment or judgments contained in the stage 2 report.

Should a hospital's CEO or General Manager decide on making a formal submission this must be made within **10 working days of receipt of the stage 2 report.** The process for making a formal submission is detailed in the next section (section 7). Should 10 days elapse without receipt of submission on a regulatory judgement, reports will proceed to stage 3 and publication as detailed below.

Stage 3 Inspection Report

A stage 3 inspection report is issued to the hospital's CEO or General Manager prior to publication. The stage 3 report is the version of the report that will be published and if a submission has been received the stage 3 inspection report will have taken into consideration any decisions of the Submissions Decision Panel.

The stage 3 inspection report will be sent to the hospital's CEO or General Manager **five working days** before publication. A copy of the draft report will also be sent by email to the hospital group CEO, and other relevant personnel as formally agreed with the HSE and Department of Health.

Making a submission on judgments contained in a Stage 2 Inspection Report

The hospital's CEO or General Manager can make a formal submission if they believe that the judgment(s) contained in the stage 2 inspection report are not based on the evidence made available to inspectors at the time of the inspection or the judgment(s) are disproportionate to the evidence reviewed.

As part of this process, the hospital's CEO or General Manager may formally submit comments, evidence or descriptors of circumstances that supports their case.

A hospital's CEO or General Manager wishing to make a submission on a regulatory judgment must first engage in the feedback process with the lead inspector as described in the section above on page 25 'Stage 1 Inspection report'.

Further information on HIQA's submissions procedure and how to make a submission can be found on the HIQA website (www.hiqa.ie).

7. Expected hospital response

Each hospital's 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 inspections, 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.

8. Contact HIQA

General queries or questions in relation to this programme or the information contained within this guide can be sent by email to qualityandsafety@hiqa.ie.

Such queries will be referred to a member of the healthcare team involved in the programme for reply. It should be noted however that specific queries about an inspection can only be accepted from the hospital's CEO or General Manager.

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10. Appendices

Appendix 1: Phased monitoring approach

Phase One	Commenced in April 2017 ▪ All public acute hospitals were requested to complete and return a self-assessment tool to HIQA.
Phase Two:	Commenced in May 2017 ▪ Unannounced inspections in public acute hospitals focusing on elements of the prevention and control of healthcare-associated infection in line with National Standards. ▪ In light of the ongoing national public health emergency[4] in relation to Carbapenemase-Producing *Enterobacteriales* (CPE)[5] the focus of these inspections was on systems to detect, prevent and respond to healthcare-associated infections and multidrug-resistant organisms.
Phase Three:	Commenced in August 2018 ▪ HIQA's monitoring programme focussed on decontamination and reprocessing of critical and semi-critical reusable medical devices.[6]
2019	**Commencing in January 2019** ▪ A consolidated inspection approach comprising phase two and three.

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

[5] 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.

[6] 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).

Appendix 2: Sample inspection documentation and data request

Sample documentation / data request (subject to change)
Organisational diagrams outlining the corporate and clinical governance structures including lines of accountability and reporting relationships up to hospital group level for: ▪ infection prevention and control and / or ▪ decontamination services at the hospital.
Terms of reference and minutes of committee meetings for: ▪ infection prevention and control and / or ▪ decontamination services at the hospital.
An annual report submitted to the hospital's / group CEO from the: ▪ Infection prevention and control committee and ▪ Decontamination committee.
Risks on the current hospital risk register (corporate risk register) that relate to the: ▪ infection prevention and control and ▪ decontamination services.
Inventory of critical and semi-critical reusable medical devices at the hospital.
Audit reports and action plans in relation to: ▪ infection prevention and control and ▪ decontamination and reprocessing of reusable medical devices.
Staff training and education records

Appendix 3: Risk matrix

Risk assessment process: the authorised persons will assess the consequence of the risk to patients and the probability of reoccurrence to determine the level of risk, using the tables below. The consequence of the risk, and the probability of occurrence are both assessed and given a score from 1 to 5. The risk matrix is then used to give an overall risk score. This score then corresponds with the classification of risk table.

Consequence of the risk: what is the actual impact of the risk?

Consequence category	Impact on individual/future patients
1 Negligible	No obvious harm No injury requiring treatment
2 Minor	Minor injury No permanent harm
3 Moderate	Significant injury or ill health Some temporary incapacity
4 Major	Major injuries or long-term incapacity or disability Major permanent harm as result of clinical or non-clinical incident injuries or long-term incapacity or disability Major permanent harm
5 Catastrophic	Death

Probability of reoccurrence: what is the chance of this event occurring or reoccurring? Identify the 'probability rating' for reoccurrence from the following table:

Probability Score	Descriptor	Frequency
1	Rare	This will probably never happen/reoccur
2	Unlikely	Do not expect it to happen/reoccur again but it is possible
3	Possible	Might happen or reoccur occasionally
4	Likely	Will probably reoccur, but it is not a persistent issue
5	Almost certain	Will undoubtedly reoccur, possibly frequently

The lead authorised person classifies the risk using the risk matrix below and documents the findings that indicate the risk.

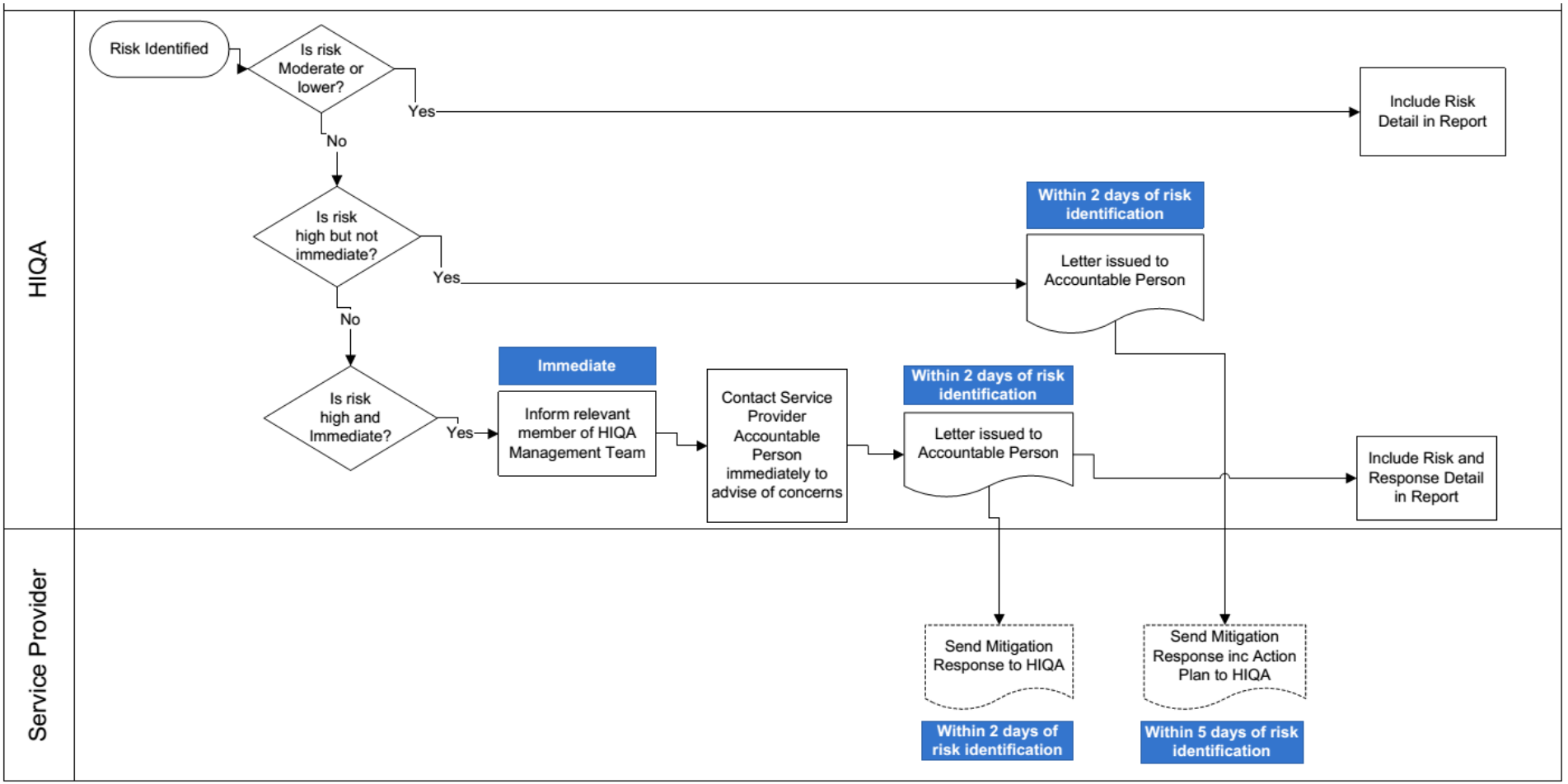
Risk Matrix

Probability ↓	**Consequence category** →				
	Negligible (1)	**Minor (2)**	**Moderate (3)**	**Major (4)**	**Catastrophic (5)**
Almost certain (5)	**5**	**10**	**15**	**20**	**25**
Likely (4)	**4**	**8**	**12**	**16**	**20**
Possible (3)	**3**	**6**	**9**	**12**	**15**
Unlikely (2)	**2**	**4**	**6**	**8**	**10**
Rare (1)	**1**	**2**	**3**	**4**	**5**

The risk is then classified as high, moderate, low or very low as per the risk matrix score. See classification of risk table below.

Classification of risk	**Risk matrix score**
High risk (red)	**15, 16, 20 or 25**
Moderate risk (orange)	**8, 9, 10 or 12**
Low risk (yellow)	**4, 5 or 6**
Very low risk (green)	**1, 2 or 3**

Appendix 4: HIQA's risk escalation process map



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

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.

Infection prevention and control 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 the service to prevent and control infection in the hospital or hospitals in question.

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 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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