Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

# OVERVIEW REPORT OF Healthcare Services IN 2024

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## About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Visit www.hiqa.ie for more information.

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## A Message from the Director of Healthcare Regulation

I am pleased to introduce HIQA's overview report of our monitoring and regulation of healthcare services in 2024. This report builds on the findings of our previous overview reports of monitoring and regulating healthcare services, as well as our findings in relation to the monitoring in emergency departments.

Notwithstanding the changes we have seen since the COVID-19 pandemic, demands are increasing and the landscape is evolving rapidly. In 2024, Ireland's health service underwent a significant period of change. Governance changes in the Health Service Executive (HSE), aligned to the Sláintecare reform programme, reconfigured the singular health service into six health regions. These regions were established to integrate public hospital and community care, supporting a more coordinated approach to care delivery.

Since 2022, HIQA has progressed an inspection approach focused on assessing hospitals and emergency departments across the country against the *National Standards for Safer Better Healthcare*. In parallel, our regulatory function in relation to medical exposure to ionising radiation aims to drive improvements in the care and service delivered in imaging and treatment facilities.

While we have seen challenges in healthcare delivery through our inspections and monitoring activity, our inspections have found examples of improved compliance in healthcare services in 2024. For example, the level of non-compliance identified in medical ionising radiation facilities has decreased from 12% to 5% since 2023. In addition, further inspections of hospitals against the national standards demonstrate that healthcare services are making improvements, with over 41% of standards assessed on re-inspection showing higher levels of compliance. These are very positive findings, showcasing both the value of inspection and regulation, and the willingness and commitment of service providers make improvements to the quality of care delivered.

Similarly, more recent inspections of healthcare services have generally demonstrated positive findings with compliance in some healthcare services, with

patients in these hospitals often speaking highly of, and expressing pride in, the services provided locally.

While we continue to find examples of good performance, a number of key areas require ongoing improvement across the healthcare sector, including:

- ensuring clinical leadership, governance and oversight arrangements are in place to support robust and sustainable governance and effective leadership of healthcare services
- ensuring that service providers plan, organise and manage their workforce to achieve high-quality, safe and reliable healthcare
- strengthening risk management processes to identify, monitor and respond appropriately to actual and potential risks of harm, and protect patients
- continuing to improve the physical environment and infrastructure so they support the delivery of high-quality, safe care and protect the privacy, dignity and welfare of people who use the services
- systematically monitoring, evaluating and continuously improving the effectiveness of healthcare through a variety of outcome measures, shared learning from incidents, complaints, concerns and compliments
- taking account of demographic changes and Ireland's growing and ageing population, continuing to build additional inpatient capacity in the healthcare services.

Throughout this report, we include patients' voices, and their feedback shows that they generally hold healthcare staff in high regard and recognise the busy environment in which care is delivered. Inspectors have observed healthcare workers that consistently demonstrate an unwavering commitment, often in difficult working circumstances, to provide person-centred care to patients and a willingness to improve systems of care.

We also recognise the work carried out to improve workforce numbers over recent years, particularly efforts to implement the Department of Health's *Framework for Staff Nurse Staffing and Skill Mix in General and Specialist Medical and Surgical Care Settings*, as well as the introduction of public-only consultant contracts for hospital consultants. Despite this progress, our monitoring and inspection activities continue to identify some deficits in front-line staffing, highlighting some continued reliance on agency or temporary staff. This reliance is both unsustainable and insufficient to support the delivery of patient care.

We also continue to fulfil our function as the competent authority in medical exposure to ionising radiation through regulating and overseeing radiation safety in

the public interest. In 2024, alongside the Environmental Protection Agency, we published the first report in 10 years on typical radiation doses received by the public. The report demonstrated that such radiation doses have reduced since the previous report, showing that services are considering how best to use equipment to achieve diagnostic goals while keeping exposure of the patient as low as reasonably possible.

HIQA's regulatory role in healthcare also continues to evolve. The commencement of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the Patient Safety Act) on 26 September 2024 marked an important milestone. This legislation introduced mandatory notification of incidents from healthcare services to HIQA for the first time, and expanded our monitoring remit to private hospitals. In line with this, we also conducted our first inspection of compliance with the *National Standards for Safer Better Healthcare* in a private hospital in 2024. We look forward to monitoring both public and private hospitals in line with our new expanded remit.

Furthermore, the European Union (Resilience of Critical Entities) Regulations 2024 (S.I. No. 559 of 2024), which came into effect on 17 October 2024, aims to strengthen the resilience of essential services across EU member states. Healthcare services and providers will be required to implement resilience-enhancing measures to ensure essential healthcare services can withstand disruptions and continue to withstand and recover from disruptions like public health emergencies and natural disasters, thereby safeguarding public health and safety. HIQA's role in this respect will be further progressed in 2025 and 2026. Additional legislation supporting HIQA's oversight of healthcare includes:

- Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024
- Patient Safety (Licensing) Bill.

In addition to this work, HIQA has a statutory function under the Health Act 2007, as amended, to conduct reviews. Throughout 2024, we progressed a review into governance and oversight of the use of surgical implants and implantable medical devices in Children's Health Ireland (CHI), including at CHI at Temple Street. This review commenced in 2023 following a request from the Minister for Health, with the final review and recommendations published in April 2025.

During the year, the Minister also requested that HIQA conduct an independent statutory review to inform the delivery of safe, high-quality urgent and emergency care in the HSE's Mid West region of Ireland. The review aims to inform decision-making on the design and delivery of urgent and emergency healthcare services, including consideration of the case for a second emergency department in the region with the final review and recommendations published in September 2025.

Finally, as we reflect on the findings of 2024, while many improvements are being progressed in healthcare services, strategic planning must continue to take a whole-system view of health and social care. Resourcing and capacity requirements, particularly in acute hospitals, must be addressed to reduce persistent shortfalls in inpatient bed capacity relative to service demand — shortfalls that directly affect both patients and the workforce on a daily basis. HIQA welcomes the additional capacity committed to in the Acute Hospital Inpatient Capacity Expansion Plan 2024-2031. When delivered, the plan will increase inpatient capacity across healthcare services while noting that additional investment in inpatient capacity will required to meet the projected healthcare requirements in the longer term. This is especially relevant in the context of organisational change and the development of new services and models of care delivery to progress integrated care. At the same time, healthcare itself is changing rapidly, with technological innovations offering both opportunities and challenges. Regular review and evaluation of governance and management arrangements, together with ensuring adequate capacity to balance service provision and change, are essential to enable the health service to adapt effectively while maintaining the delivery of safe, high-quality care to patients.

In planning for improvements to urgent and emergency care, it is also critical to recognise the interdependence of the hospitals and community health systems. Given Ireland's ageing and growing population, progress on bed capacity and associated resourcing requirements must continue year-on-year to meet both current and future healthcare needs. HIQA, through its statutory role and functions, will continue to work with Government and the Department of Health to support and strengthening patient safety in Ireland.

**Sean Egan**

*Director of Healthcare Regulation*
Health Information and Quality Authority

# 1. Introduction

The Health Information and Quality Authority (HIQA) is the independent authority established to monitor the safety and quality of health and social care services and drive continuous improvement of those services. Under Section 8 of the Health Act 2007, as amended, HIQA:

- monitors compliance with the *National Standards for Safer Better Healthcare* Version 2 (2024), (referred to in this report as the 'national standards') in publicly and privately-funded healthcare services.[1]
- conducts statutory reviews or investigations into healthcare services where there are potential serious patient safety concerns impacting on the health and welfare of patients using those services.

HIQA is also the competent authority in Ireland with responsibility for inspecting against and enforcing the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations, as amended in Ireland.[*2]

This overview report summarises the key findings from HIQA's monitoring programmes in these areas in 2024. It builds on findings from previous overview reports published in 2022[3] and 2024.[4]

Inspections that monitored compliance with the *National Standards for Safer Better Healthcare* were carried out through the lens of the four key areas of known risk in healthcare — infection prevention and control; medication safety; deteriorating patient (including sepsis management)[†] and transitions of care.[‡] This report presents a summary of the findings from those inspections and keys areas identified for targeted improvements to support the consistent delivery of high-quality, safe healthcare. These findings will guide healthcare service providers' understanding of what compliance with the *National Standards for Safer Better Healthcare* looks like. The report also summarises the key findings from HIQA's programme of inspection of medical and dental services which provide medical exposure to ionising radiation.

[*] Medical exposure to ionising radiation means a radiation exposure received by patients or other individuals as part of their own medical or dental diagnosis or treatment such as X-rays, radiotherapy and so on.
[†] The National Deteriorating Patient Improvement Programme is a priority patient safety programme for the Health Service Executive. Using Early Warning Systems in clinical practice improve recognition and response to signs of patient deterioration. A number of Early Warning Systems, designed to address individual patient needs, are in use in public acute hospitals across Ireland.
[‡] Transitions of Care include internal transfers, external transfers, patient discharge, shift and interdepartmental handover. World Health Organization. *Transitions of Care. Technical Series on Safer Primary Care*. Geneva: World Health Organization. 2016. Available online from https://apps.who.int/iris/bitstream/handle/10665/252272/9789241511599-eng.pdf

# 2. Findings from monitoring activity assessing compliance with the *National Standards for Safer Better Healthcare*

## National context

HIQA's inspections in 2024 were carried out during a period of very significant change and reform as a new landscape for the delivery of healthcare services in Ireland evolved. The Patient Safety Act commenced on 26 September 2024 which expanded HIQA's monitoring remit to private hospitals.[6] As a result, HIQA now monitors an additional 23 hospitals, bringing the total number of public and private healthcare service providers under HIQA's remit to 116 services, assessing the quality of care across public and private healthcare services. The monitoring of compliance in private healthcare services against *the National Standards for Safer Better Healthcare* began in late 2024. Prior to this, an extensive stakeholder engagement occurred with the private hospital providers in Ireland to inform them of HIQA's role and monitoring approach. The engagement with private healthcare services was positive, collaborative and informative. It enabled HIQA to promote awareness of its work, gathered feedback to inform decision-making, and ensured that HIQA's standards and guidance supported the drive to improve the quality and safety of healthcare services. This is further discussed in Section 4 of the report.

In addition, changes were underway to restructure the HSE and to align the delivery of health and social care services with the Sláintecare reform programme. Six health regions were being established to facilitate and support the integration of hospital and community care under one governance structure and to provide a more localised, integrated approach to care delivery. The health regions replaced the earlier configuration of nine Community Healthcare Organisations (CHOs) and six hospital groups. Each health region have its own governance structure and comprise substructures called Integrated Healthcare Areas (IHAs). Each IHA has a designated manager who will report to and be accountable to the health region's Regional Executive Officer (REOs). The REO is the overall accountable person who is responsible for the safety and quality of health and social care services within their respective health region and the REO reports directly to the HSE's Chief Executive Officer (CEO). During 2024, while the HSE reforms were being implemented, governance and oversight of the quality and safety of healthcare services remained the responsibility of the assigned accountable person at local healthcare service provider level and the hospital group or CHO structures at HSE level.

## HIQA's monitoring approach

HIQA uses a standardised approach to monitoring — the 'Authority Monitoring Approach'. This approach ensures consistency and transparency throughout the inspection process and supports the process to be impartial, efficient, proportionate,

consistent and clear. HIQA's standard monitoring approach to assessing compliance with the national standards comprises at least two inspections for each healthcare service in a three-year cycle. The inspections could be unannounced or announced. Inspections occur over one or two days, depending on the scope and size of the healthcare service, the type of services provided and the findings on the day(s) of inspection. HIQA's approach to monitoring compliance with the national standards and regulations is risk based. In fulfilling this function, two types of inspections — monitoring inspections and targeted (focused risk) inspections (Table 1) were carried out in 2024.

Table 1: Type of inspections to monitor compliance with national standards in 2024

| Types of inspection used to monitor compliance with national standards |
|---|
| Monitoring inspections: These inspections were routine inspections that monitored the quality of the healthcare service provided and the level of compliance with the national standards and regulations. They can be announced or unannounced. |
| Targeted (focused risk) inspections: These inspections were in addition to routine inspections and were carried out when information was received about a healthcare service that indicated that there may be a risk posed to people who receive care and treatment in the service. A targeted risk-based inspection could be carried out to monitor compliance with any of the 45 national standards from the *National Standards for Safer Better Healthcare* Version 2 (2024). |

Monitoring activities were tailored, responsive and proportionate to the regulatory risk determined from the information HIQA reviewed in relation to a service. Decisions regarding the type, frequency and focus of monitoring activity were based on information gained from a variety of sources, these included:

- findings from previous HIQA inspections
- statutory notifications made under the Patient Safety Act
- unsolicited information[§]
- publicly reported compliance with quality and safety performance metrics relevant to healthcare services
- findings from the National Care Experience Programme, where relevant.[**]

[§] Unsolicited information is information not requested by HIQA, but is received by HIQA from people who use healthcare services, their relatives, staff in the service or any member of the public. All information received is reviewed and risk rated. The information is used alongside the other information gathered about a healthcare service to monitor the quality and safety of care, to inform and prompt monitoring activity and to inform regulatory judgments.
[**] The National Care Experience Programme currently collects information on patients' experience of receiving care in publicly-funded healthcare services only.

In order to consistently carry out its functions as required by the Health Act 2007 as amended, HIQA appoints 'authorised persons', or inspectors, under the Act to monitor compliance with national standards. To support healthcare service providers to be compliant with the *National Standards for Safer Better Healthcare* Version 2 (2024), HIQA published the following regulatory guidance documents in 2024:

- Guide to Assessment-Judgment Framework to monitor against the *National Standards for Safer Better Healthcare.*[7]
- A guide to healthcare inspections against the *National Standards for Safer Better Healthcare.*[8]

Forty-one inspections of 40 healthcare services were carried out in 2024 and published reports relating to HIQA's inspection activities are listed in Appendix 1. The majority (95%) of these inspections focused on monitoring compliance with a core set of 11 national standards drawn from five themes (Appendix 2). The selection of the core standards was informed by previous preparatory work carried in 2022 where the approach to monitoring against the *National Standards for Safer Better Healthcare* was revisited. Two (5%) of the 41 inspections focused on emergency departments only, where compliance with four national standards drawn from four themes of the *National Standards for Safer Better Healthcare* Version 2 (2024) was monitored (Appendix 3).

Information collected during inspection, informed the judgment about healthcare service providers' level of compliance with the national standards (Table 2).

Table 2: Compliance descriptors used by HIQA

| |
|---|
| **Compliant:** A judgment of compliant means that on the basis of this inspection, the service is in compliance with the relevant national standard. |
| **Substantially compliant:** A judgment of substantially compliant means that on the basis of this inspection, the service met most of the requirements of the relevant national standard, but some action is required to be fully compliant. |
| **Partially compliant:** A judgment of partially compliant means that on the basis of this inspection, the service met some of the requirements of the relevant national standard while other requirements were not met. These deficiencies, while not currently presenting significant risks, may present moderate risks, which could lead to significant risks for people using the service over time if not addressed. |
| **Non-compliant:** A judgment of non-compliant means that this inspection of the service has identified one or more findings, which indicate that the relevant national standard has not been met, and that this deficiency is such that it represents a significant risk to people using the service. |

The following sections of this overview report presents a summary of the findings from the inspection reports published in 2024. It was also used to familiarise and

support staff working in the private healthcare service to understand HIQA's role, remit and approach to monitoring healthcare services.

The findings of compliance with the national standards monitored are presented under the two dimensions of *Capacity and Capability* and *Quality and Safety*. Healthcare services judged to be partially or non-compliant with the national standards were required to submit a compliance plan to HIQA outlining the actions, with timelines they plan to introduce to bring the service into full compliance with the national standards. HIQA continues to engage with those healthcare services who have submitted compliance plans to ensure the actions are implemented and that the service is coming into compliance with the national standards.

## Overview of healthcare services inspected in 2024

In 2024, 26 (65%) of the inspections carried out were in HSE-funded acute or specialist healthcare services (Model 2, Model 3, Model 4 and specialist hospitals), 13 (33%) inspections were carried out in rehabilitation and community inpatient healthcare services (RCIHS) and one (2%) pilot inspection was carried out in a private hospital (Figure 1).

Figure 1: Breakdown of all healthcare services inspected in 2024

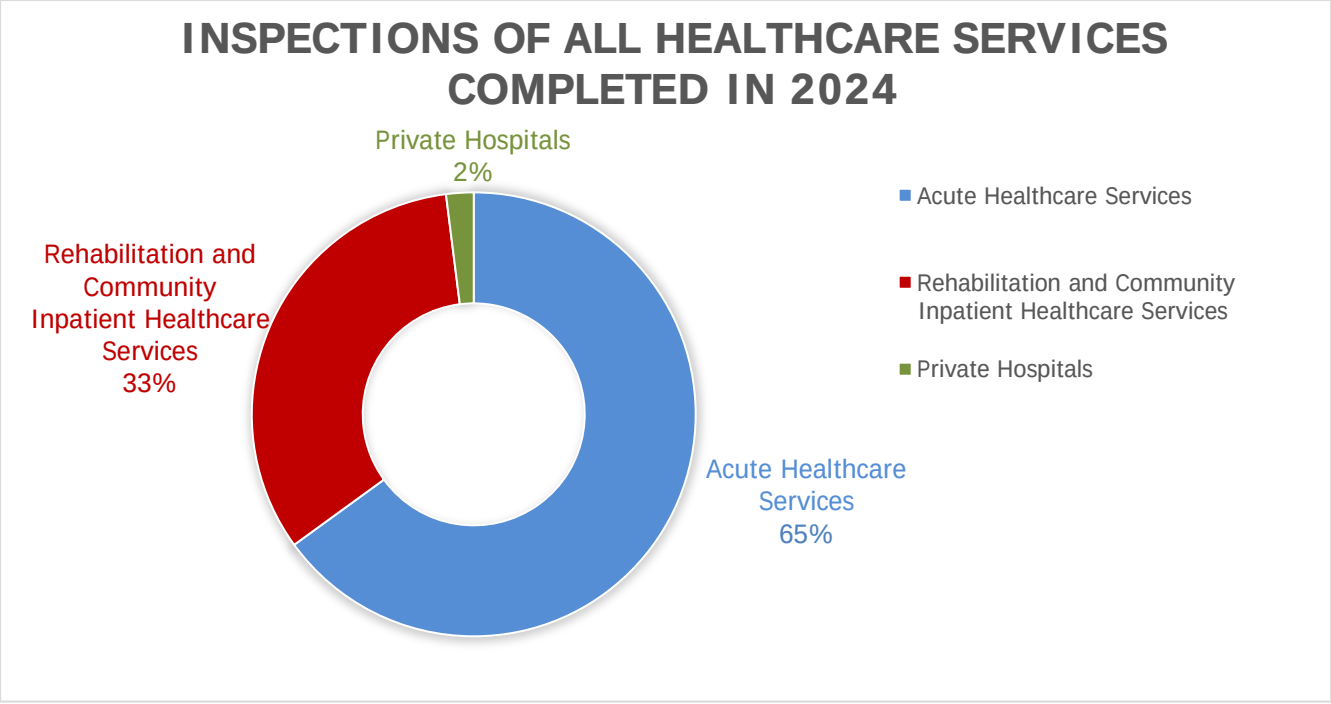
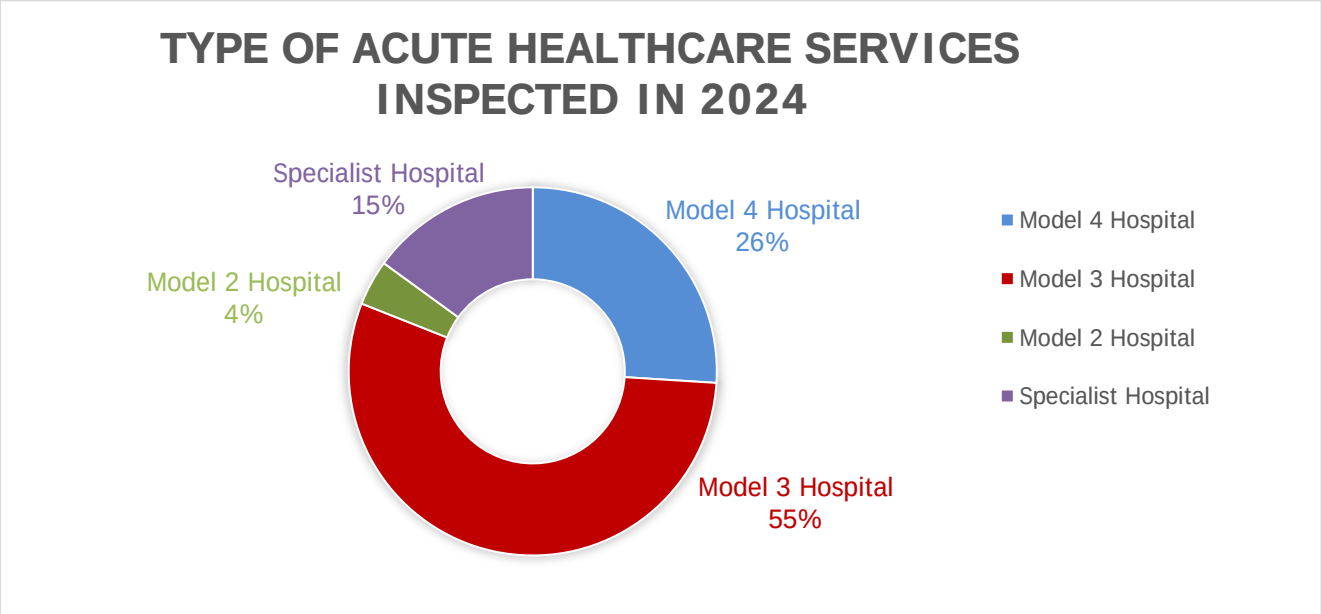



Figure 2 provides a breakdown of the models of acute and specialist healthcare services inspected in 2024, 26% of the acute healthcare services were Model 4

hospitals,[††] 55% were Model 3 hospitals,[‡‡] 4% were Model 2 hospitals[§§] and 15% were specialist hospitals.[***] Appendix 1 details the model in each healthcare service inspected.

Figure 2: Category of acute and specialist healthcare services inspected in 2024




Just over half (55%) of the inspections carried out in 2024 were announced and 45% of inspections were unannounced. With an announced inspection, healthcare service providers were given advance notice, to ensure that arrangements could be made for relevant staff to meet with inspectors during the inspection. Inspectors also requested information on performance metrics of the quality and safety of healthcare services over time in advance of the inspection. This information informed and guided the areas and issues to be explored during the inspection. With an unannounced inspection, healthcare services were not notified by HIQA in advance of the inspection. A summary of the compliance judgments for the 40 healthcare services inspected in 2024 is included in Appendices 4 to 6.

[††] Model 4 hospitals provide tertiary care and, in certain locations, supra-regional care. They have a category 3 or speciality level 3(s) intensive care unit (ICU) onsite, a Medical Assessment Unit open on a continuous basis (24/7) and an emergency department that may include a Clinical Decision Unit.
[‡‡] Model 3 hospitals admit undifferentiated acute medical patients, provides 24/7 acute surgery, acute medicine and critical care services. They typically have a category 1 or 2 ICU and may have a high dependency unit (HDU).
[§§] Model 2 hospitals provide the majority of hospital activity including extended day surgery, selected acute medicine, local injuries, a large range of diagnostic services, including endoscopy, laboratory medicine, point-of-care testing and radiology - computed tomography (CT), ultrasound and plain-film X-ray, specialist rehabilitation medicine and palliative care.
[***] A specialist hospital provides care for specific health conditions, often with dedicated facilities and expertise for those conditions.

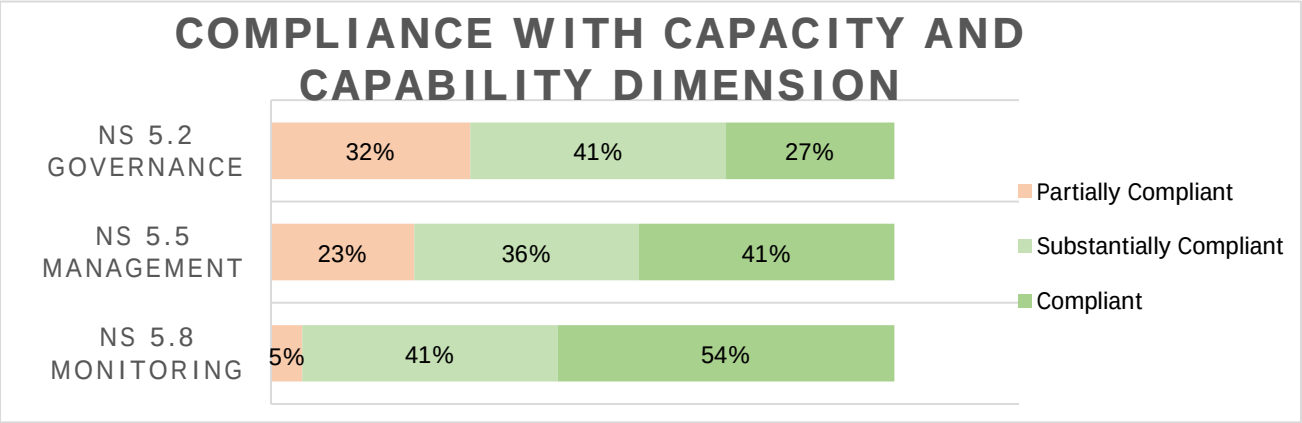
## 2.1 Capacity and Capability Dimension

This section of the overview report presents the composite findings from published inspection reports of the compliance with four national standards (5.2, 5.5, 5.8 and 6.1) from two themes in the *Capacity and Capability* dimension — Leadership, Governance and Management; and Workforce. It is an evaluation of how effective the leadership, governance and management arrangements were in healthcare services in supporting and ensuring that the services provided a high-quality, safe and reliable service consistently and sustainably. It indicates whether there were appropriate oversight and assurance arrangements in place to ensure the sustainable delivery of safe, effective person-centred care and support, and how people who worked in the service were managed and supported to deliver high-quality, safe care. Figures 3 to 9 and Appendix 6 shows how overall there was a good level of compliance, either at substantially compliant or compliant level with the four national standards monitored under the *Capacity and Capability* dimension. Achieving compliance with the national standard monitored under the Workforce theme was a challenge for all healthcare services inspected in 2024. It was particularly challenging for over a quarter (26%) of the acute and specialist healthcare services inspected. Improvements were needed to bring healthcare services into full compliance with the four national standards monitored under the *Capacity and Capability* dimension.

### Theme 5: Leadership, Governance and Management

A well-governed healthcare service has corporate and clinical accountability and reporting structures, with clear lines of accountability at individual, team and service level for the quality and safety of the service. Figure 3 presents the level of compliance with the three national standards (5.2, 5.5 and 5.8) monitored from the Leadership, Governance and Management theme.

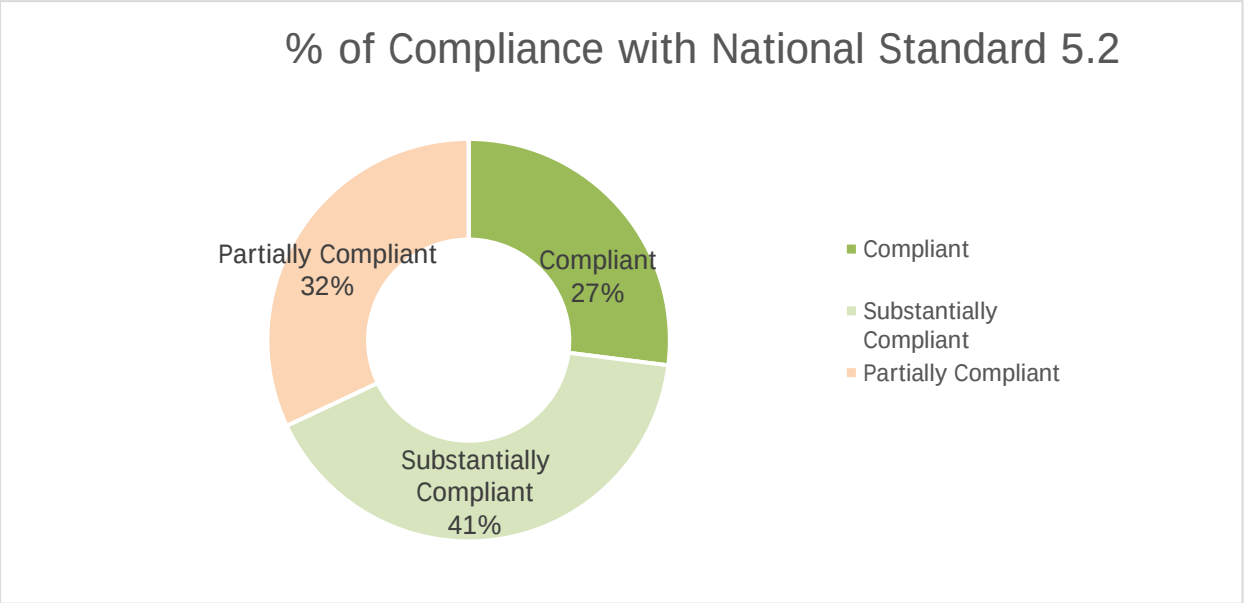
Figure 3: Compliance with three national standards in Leadership, Governance and Management theme all healthcare services



Standard 5.2 Service providers have formalised governance arrangements for assuring the delivery of high-quality, safe and reliable healthcare.

Monitoring compliance with national standard 5.2 focused on the corporate and clinical governance arrangements that assured and ensured the delivery of high-quality, safe and reliable healthcare services. Good governance arrangements were found in 68% (25) of healthcare services inspected in 2024. Actions were needed in the remaining 32% (12) of healthcare services to improve and strengthen the governance arrangements and to bring services into compliance with the national standard. None of the healthcare services inspected in 2024 were non-compliant with national standard 5.2 (Figure 4).

Figure 4: Compliance with the national standard 5.2 all healthcare services




Ten (27%) healthcare services were **compliant** with national standard 5.2. In these services, the governance arrangements:

- were appropriate for the size, scope and complexity of the service
- were integrated and robust for assuring the delivery of safe, high-quality services
- identified the person with overall accountability and responsibility for the healthcare service
- clearly defined the roles, accountability and responsibilities throughout the service for assuring the quality and safety of the service
- identified the senior person onsite with responsibility for operational management of the healthcare service at corporate and clinical levels 24/7

- monitored the quality and safety of services in the four areas of focus — infection prevention and control, medication safety, deteriorating patient and transitions of care.

Fifteen (41%) healthcare services were **substantially compliant** with national standard 5.2.

Actions that will support healthcare services come into full compliance with national standard 5.2 include:

- filling the CEO position on a permanent basis
- allowing new governance committees time to embed into the overall corporate and clinical governance structures
- evaluating new governance committees to ensure they functioned as intended
- updating and ratifying terms of reference for governance structures regularly
- ensuring governance committees function and meet as specified in the terms of reference, with good attendance at meetings of all committee members
- formally documenting agreed actions from committee meetings and ensuring there is a person(s) assigned with responsibility to implement the actions
- ensuring the governance arrangements are effective in promoting and supporting adequate patient flow through the service.

Twelve (32%) healthcare services were **partially compliant** with national standard 5.2.

Other improvements identified from the inspections of **acute and specialist healthcare services** were:

- ensuring there is clarity about who is the responsible and accountable person for the healthcare service
- strengthening and improving the quality function and governance structures
- filling gaps in the executive and senior management team to support and sustain effective corporate and clinical governance of the healthcare service
- continuing to implement reforms to improve the governance and clinical leadership structures
- improving the governance and oversight of medication safety practices
- documenting the frequency of committee meetings in all governance committee's terms of reference.

Other improvements identified as required from the **rehabilitation and community inpatient healthcare services (RCIHS)** inspections were:

- filling vacant core managerial and leadership positions, such as the director of nursing position
- strengthening the governance arrangements at healthcare service and community levels
- implementing and strengthening the governance, management and robust monitoring of medication practices, while also ensuring that there is an effective escalation process in place to promote safe medication practices
- ensuring committees function in line with their terms of reference and that the upwards reporting relationships to corporate governance structures are documented and formalised
- improving the integration between acute and community healthcare services
- ensuring robust governance and oversight of the development of policies, procedures, protocols and guidelines that inform clinical practice and standards.

The governance and oversight of medication practices was identified as a specific area requiring focused improvement in one acute healthcare service and 46% (six) of RCIHS.

Eight healthcare services[†††] inspected in 2024 were also inspected between 2021 and 2023. Subsequent inspections of these services enabled HIQA to monitor ongoing compliance with national standards and to follow up on earlier findings and progress in implementing compliance plan actions. The inspection findings and compliance levels from previous inspections allowed for comparison in compliance levels from inspection to inspection. A comparison of the compliance levels from 2024 with the compliance levels from 2021 and 2023 for the eight healthcare services showed the compliance level with national standard 5.2:

- remained the same for four healthcare services, at:
  - substantially compliant for two healthcare services (Naas General Hospital and Midland Regional Hospital Portlaoise)
  - partially compliant for two healthcare services (Regional Hospital Mullingar and St Columcille's Hospital)
- improved for four healthcare services, from
  - non-compliant to partially compliant in one healthcare service (University

[†††] The eight healthcare services were Cavan Monaghan General Hospital; Connolly Hospital; Naas General Hospital; Midland Regional Hospital Portlaoise; Regional Hospital Mullingar; St Columcille's Hospital; St Vincent's University Hospital and University Hospital Kerry.

Hospital Kerry)

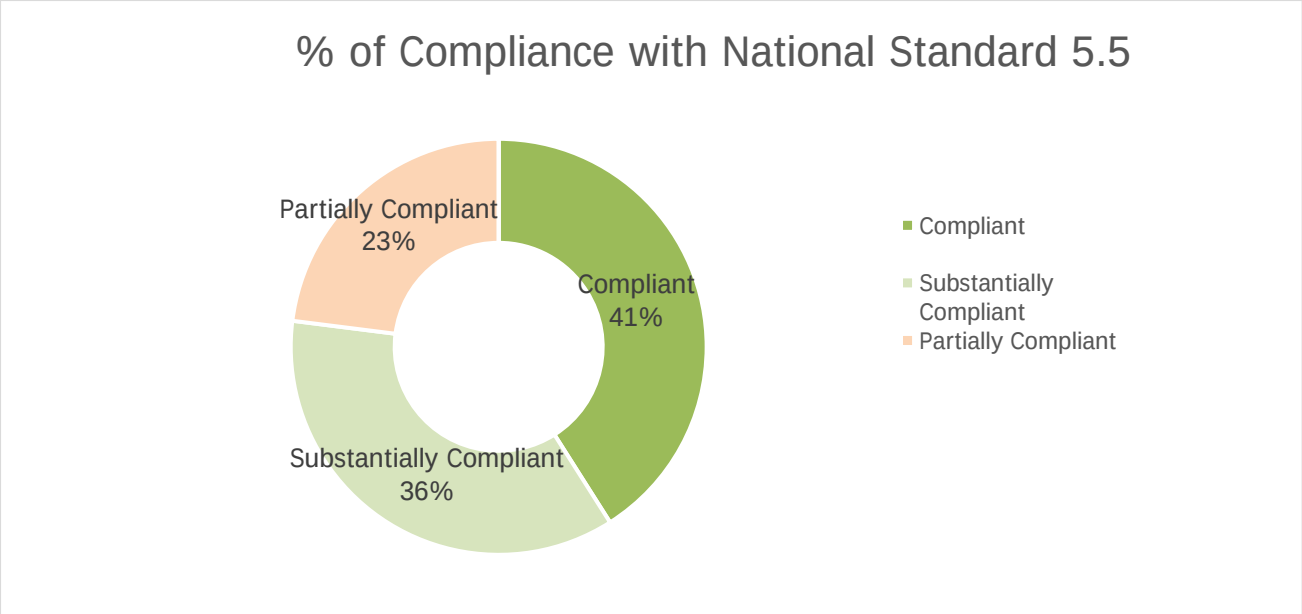
- partially compliant to substantially compliant in one healthcare service (St Vincent's University Hospital)
- substantially compliant to compliant for two healthcare services (Cavan Monaghan General Hospital and Connolly Hospital).

**Standard 5.5 Service providers have effective management arrangements to support and promote the delivery of high-quality, safe and reliable healthcare services**

Effective and efficient operational management structures ensures the healthcare service fulfils its purpose by planning, governing and organising the service and resources to achieve its outcomes and ensure the delivery of high-quality, safe and reliable healthcare. A well-managed healthcare service should have management arrangements that effectively and efficiently support and promote the delivery of high-quality, safe and reliable services.

Overall, in the healthcare services inspected in 2024, there was a good level of compliance with national standard 5.5. Thirty healthcare services (77%) were compliant or substantially compliant with the national standard. In these services, there was evidence of good, robust leadership and effective management arrangements, structures and mechanisms to manage, support and oversee the delivery of high-quality, safe and reliable healthcare services. Nine services (23%) were partially compliant with the national standard. No healthcare service was found to be non-compliant with national standard 5.5 (Figure 5).

Figure 5: Compliance with the national standard 5.5 all healthcare services



Sixteen healthcare services (41%) were **compliant** with national standard 5.5. In these healthcare services, there was robust and sustainable governance and effective leadership at corporate and clinical level. The executive or senior management team had good operational grip and were responsive in ensuring and assuring the quality and delivery of services. Clear, responsive and effective management arrangements, controls and processes supported the effective management and operational functioning of the healthcare services. Robust management arrangements supported and promoted the delivery of high-quality, safe and reliable healthcare services in the four areas of focus — infection prevention and control, medication safety, deteriorating patient and transitions of care.

### Infection prevention and control

The healthcare services who complied with national standard 5.5 had an overarching infection prevention and control programme or annual plan that set out the specific objectives to be achieved in relation to infection prevention and control over the duration of the programme or plan. The infection prevention and control programme or plan was implemented by the infection prevention and control team with oversight by the infection prevention and control governance committee, and executive or senior management team. Compliant healthcare services also had a defined antimicrobial stewardship (AMS) programme that was implemented by an antimicrobial stewardship team. Staff working in the services had access to advice and support from a consultant microbiologist 24/7 either onsite or offsite with the arrangements formalised when other healthcare services in the hospital group provided microbiologist support. Periodic and annual reports conveyed the progress in meeting the objectives of the infection prevention and control and AMS programmes or plans. These reports provided the executive and senior management teams with information and assurances about infection prevention and control and AMS practices, infection prevention and control and AMS surveillance and monitoring and on compliance with relevant infection prevention and control and AMS standards and key performance indicators (KPIs).

### Medication safety

Healthcare services who complied with national standard 5.5 had management arrangements to support the promotion of safe medication practices, this included a medication strategy or plan that set out the specific objectives to be achieved in relation to medication safety over the duration of the strategy or plan. There was a designated lead for the pharmacy services and there was adequate staff resourcing to provide a comprehensive clinical pharmacy service to all clinical areas and to undertake pharmacy-led medication reconciliation for patients on admission and discharge. The medication strategy or plan was implemented with oversight by the

relevant governance committee with defined reporting arrangements to the executive or senior management team. Periodic and annual reports provided the executive and senior management team with information and assurances on the progress in implementing the medication strategy or plan.

### Deteriorating patient

Healthcare services who complied with national standard 5.5 had implemented a deteriorating patient improvement programme under the clinical leadership of a consultant physician. In four acute healthcare services (15%), this programme was supplemented by a critical care outreach team which was seen as good support within services to aid the timely recognition and management of the clinically deteriorating patient. There was governance and oversight of the effectiveness of management arrangements in place to recognise and manage the deteriorating patient. Relevant early warning systems[‡‡‡] were used for the appropriate cohorts of patients with ongoing staff education and training provided by an early warning system coordinator or another staff member to support staff to promptly recognise and manage a clinically deteriorating patient. Compliance with national guidance on the early warning systems was monitored with oversight by the relevant governance committee who in turn provided assurances to the executive or senior management team.

### Transitions of care

Healthcare services that were compliant with national standard 5.5 had effective management arrangements to manage patient flow and the safe transitions of care. The effectiveness of these arrangements along with the issues that impacted on patient flow such as the number of delayed transfers of care, the average length of stay for medical and surgical patients and emergency department related patient experience times (PETs) were monitored by the executive or senior management team. There was good integration between acute and community services and the service resourcefully used transitional beds and rehabilitation beds in the RCIHS to support efficient patient flow. There were effective arrangements and plans to manage any increase for service demand. Plans to manage any increase in demand for services was formalised in the healthcare service's escalation policy that aligned with the national escalation framework and the full capacity protocol procedures. Findings from inspection activity confirmed that the actions introduced in the service to manage the increase demand for healthcare services during times of escalation

[‡‡‡] Using Early Warning Systems in clinical practice improve the recognition and response to signs of patient deterioration. A number of Early Warning Systems, designed to address individual patient needs, are in use in public acute hospitals across Ireland - Irish Early Warning System (INEWS), Irish Maternity Early Warning System (IMEWS), Irish Paediatric Early Warning System (PEWS) AND Emergency Medicine Early Warning System (EMEWS).

aligned with the actions for specific level of escalation with their escalation policy.

Fourteen (36%) healthcare services were **substantially compliant** with national standard 5.5.

Actions that will support healthcare services come into full compliance with national standard 5.5 include:

- ensuring there is a formalised up-to-date escalation policy to support efficient patient flow within and from the healthcare service during times of increased demand for services
- developing and implementing a medication safety strategy or annual plan to support safe mediation practices
- providing a comprehensive clinical pharmacy service and pharmacy-led medication reconciliation
- formalising arrangements to support infection prevention and control practices, where such support is obtained from another healthcare service
- ensuring the management arrangements are effective in promoting and supporting adequate patient flow through the service
- ensuring policies, procedures, protocols and guidelines guiding inter-hospital patient transfer policies are up to date.

Nine (23%) healthcare services were **partially compliant** with national standard 5.5. None of the RCIHS inspected in 2024 were partially compliant with the national standard. No healthcare service (acute and specialist healthcare services or RCIHS) inspected in 2024 were non-compliant with national standard 5.5.

Other improvements identified from the inspections of **acute or specialist healthcare services** were:

- ensuring management arrangements are effective and responsive in managing increases for demand for healthcare services and support efficient and effective patient flow, especially during times of escalation
- ensuring there is a designated lead clinician assigned with responsibility for the quality and safety of clinical services 24/7
- ensuring the on-call arrangements for medical consultants and non-consultant hospital doctors (NCHDs) are formalised, available for and known to staff 24/7.

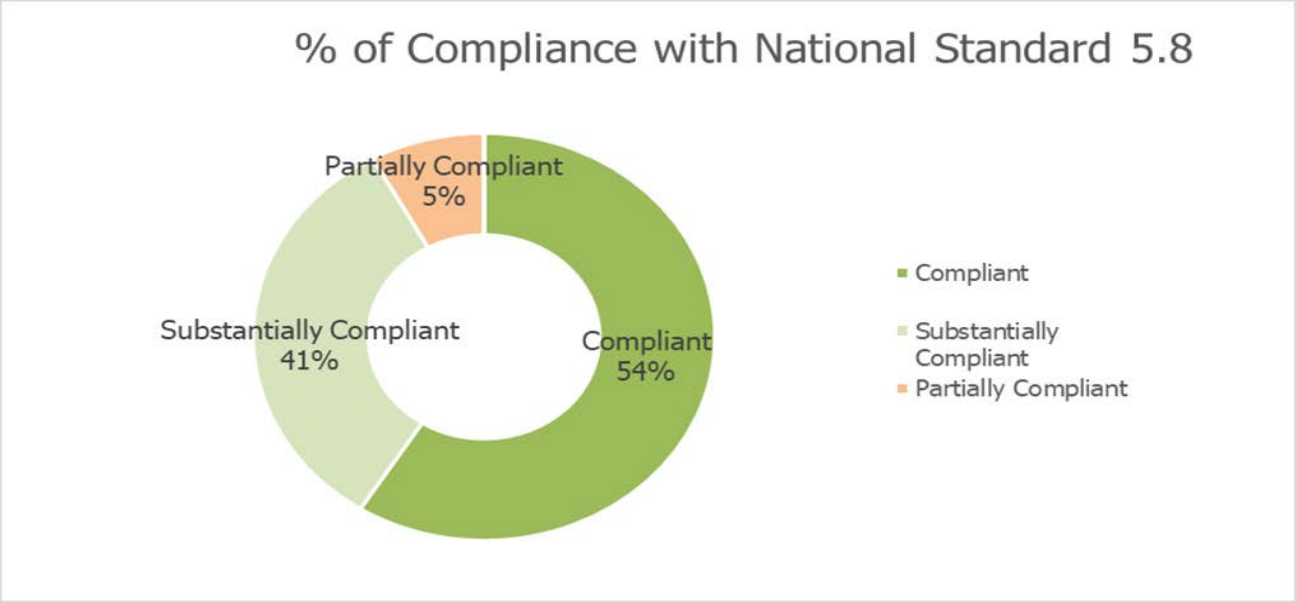
A comparison of the compliance levels from 2024 with the compliance levels from 2021 and 2023 for eight healthcare services showed the compliance level with national standard 5.5:

- remained the same at substantially compliant for one healthcare service (Cavan Monaghan General Hospital)
- improved for six healthcare services from:
  - non-compliant to partially compliant for one healthcare service (University Hospital Kerry)
  - partially compliant to compliant for three healthcare services (Connolly Hospital, St Columcille's Hospital and St Vincent's University Hospital)
  - partially compliant to substantially compliant for one healthcare service (Regional Hospital Mullingar)
- substantially compliant to compliant for one healthcare service (Naas General Hospital)
- regressed from compliant to substantially compliant for one healthcare service (Midland Regional Hospital Portlaoise).

Standard 5.8 Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services.

A well-governed and managed healthcare service monitors performance to ensure the services and care they provide are safe and of a consistently high quality. Arrangements to monitor healthcare services' performance and quality should be systematic with information from the monitoring activity used to improve the quality and safety of services. In 2024, there was a very good level of compliance with national standard 5.8 in the healthcare services inspected (Figure 6).

Figure 6: Compliance with the national standard 5.8 all healthcare services



Thirty-five (95%) healthcare services had systematic arrangements to identify, monitor and act on opportunities to continually improve the quality, safety and reliability of healthcare services. 5% of healthcare services were partially compliant. No healthcare services were non-compliant with national standard 5.8 (Figure 6).

54% of healthcare services were **compliant** with national standard 5.8. These healthcare services:

- systematically and continually monitored performance against KPIs in the areas of infection prevention and control, medication safety, deteriorating patient and transitions of care
- collected, collated, analysed and published information from a range of different clinical and quality data sources in line with the HSE's reporting requirements
- had formalised risk management structures that supported the proactive identification, analysis, management, regular monitoring and escalation of reported clinical and non-clinical risks
- reported, monitored and analysed patient safety incidents
- collected and analysed feedback from the people who used the healthcare services
- implemented time-bound quality improvements initiatives to improve the quality and safety of services, and patients' experiences of using the services
- proactively shared learnings from the review of patient-safety incidents and feedback received from people who used the healthcare services
- implemented findings and recommendations of reviews and investigations of healthcare services to improve the quality and safety of their services.

41% of healthcare services were **substantially compliant** with this national standard.

Actions that will support healthcare services come into full compliance with national standard 5.8 include:

- ensuring there is a comprehensive approach to and framework for the effective management of risk to protect the people who use the healthcare services and staff who work in the services from the risk of harm
- using a range of sources, including national and international KPIs to assess the quality, efficiency and effectiveness of healthcare services
- where national or international KPIs are not available, healthcare services should develop or adopt performance indicators with the best available evidence

- resourcing and promoting a coordinated approach to monitoring and auditing of clinical and non-clinical services
- implementing quality improvement initiatives to improve the quality and safety of healthcare services, and patient's experiences of using the services
- quality improvement plans should be time bound with a person assigned with the responsibility to ensure the action(s) in the plan are implemented
- proactively share learnings from the review of patient safety incidents
- ensuring the timely implementation of recommendations and sharing of learnings from reviews to support patient safety.

5% of healthcare services inspected were **partially compliant** with national standard 5.8.

Other improvements identified as required from inspections of **acute and specialist healthcare services** were:

- ensuring there is sufficient resources to operationally support the proactive monitoring and evaluation of healthcare services, and to act on opportunities to continually improve the quality, safety and reliability of healthcare services.

A comparison of the compliance levels from 2024 with the compliance levels from 2021 and 2023 for eight healthcare services showed the compliance level with national standard 5.8:

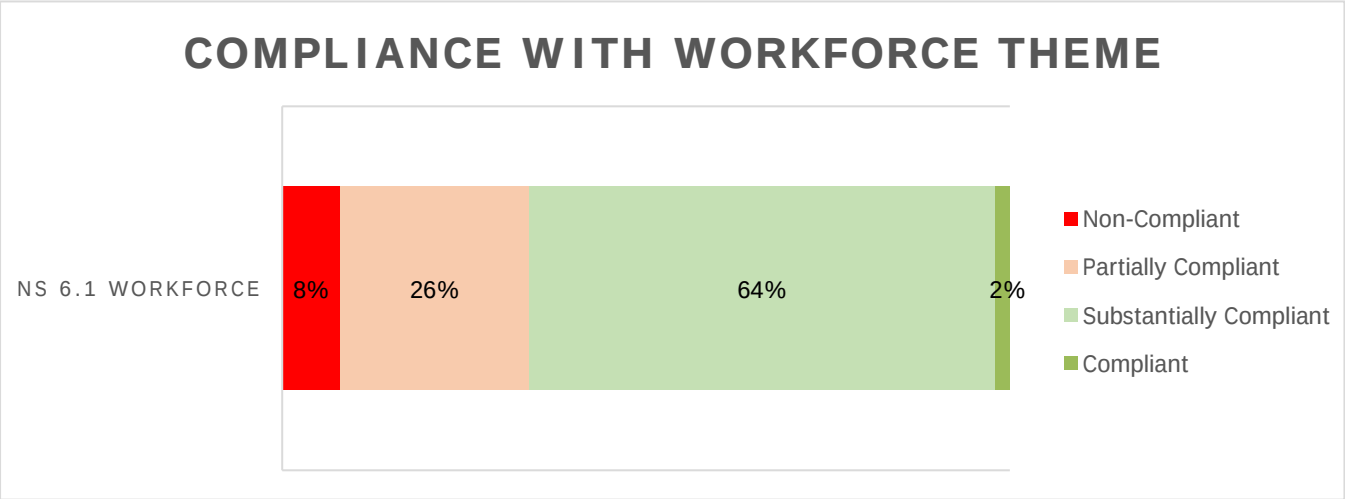
- remained the same for five healthcare services:
  - compliant for three healthcare services (Cavan Monaghan General Hospital, Connolly Hospital and Naas General Hospital)
  - substantially compliant for one healthcare service (Midland Regional Hospital Portlaoise)
  - partially compliant for one healthcare service (University Hospital Kerry).
- improved for three healthcare services from:
  - partially compliant to substantially compliant for one healthcare service (Regional Hospital Mullingar)
  - partially compliant to compliant for one healthcare service (St Columcille's Hospital)
  - substantially compliant to compliant for one healthcare service (St Vincent's University Hospital).

## Theme 6: Workforce

The healthcare services inspected in 2024 planned, organised and managed their workforce to maintain patient safety and support the delivery of high-quality and safe services in line with national policy, where applicable. This was done against a backdrop of a pause on healthcare staff recruitment arising from the recruitment moratorium implemented by the HSE in late 2023, which continued until July 2024. The moratorium led to significant challenges in ensuring adequate staffing levels in healthcare services across the medical, nursing and health and social care professions (pharmacy, physiotherapy, occupational therapy, speech and language therapy and medical social workers). Staffing numbers were further impacted by the HSE's 2024 pay and numbers strategy, which set out the maximum number of employees that could be employed in HSE funded healthcare services.

Challenges and difficulties in recruiting clinical and allied staff, as well as other core staff positions such as the quality patient safety manager or clinical risk manager, impacted on some healthcare services' ability to function effectively and efficiently. It also affected the service's ability to respond in a timely manner to changes in workload and resources available to deliver high-quality, safe services. This resulted in a number of partial or non-compliances with national standard 6.1 (Figure 7 and Appendix 6). Workforce was a high risk recorded on many healthcare services' corporate risk registers. This risk was been actively managed by the majority of services at the time of inspection.

Figure 7: Compliance with a national standard under workforce theme for all healthcare services

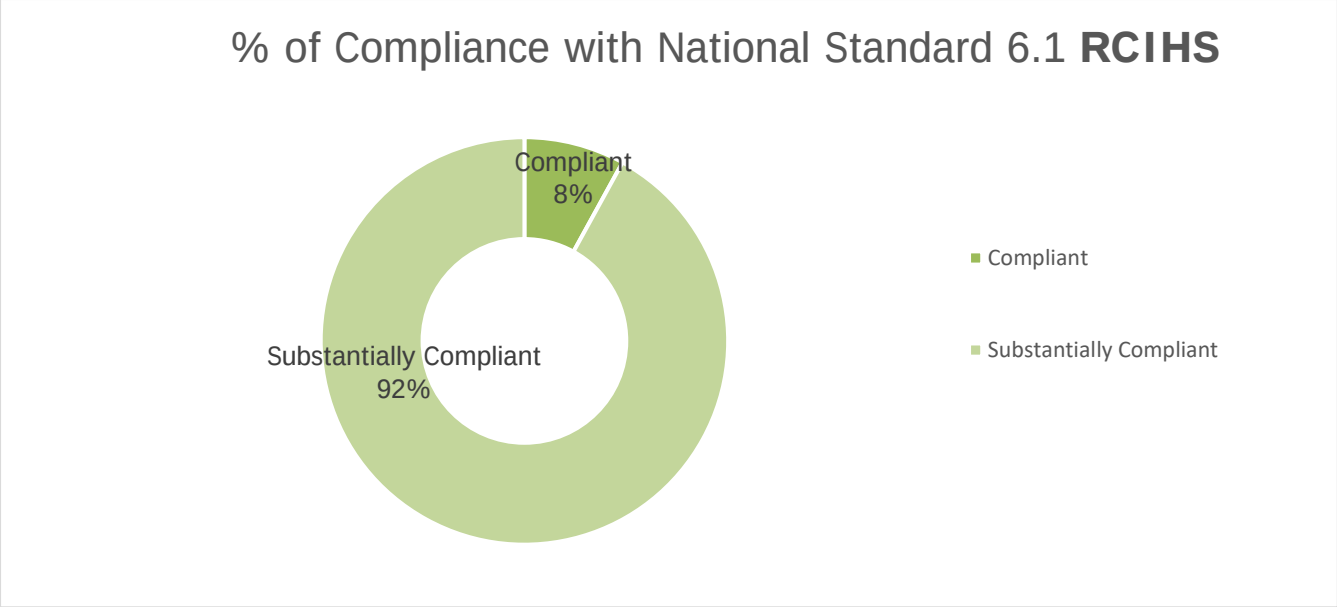


Standard 6.1 Service providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare.

Figure 7 shows the overall compliance with the national standard (NS 6.1) monitored in the Workforce theme. One (2%) healthcare service inspected in 2024 was fully compliant with the national standard. Twenty-five (64%) healthcare services were substantially compliant, 10 (26%) healthcare services were partially compliant and three (8%) services were non-compliant with national standard 6.1.

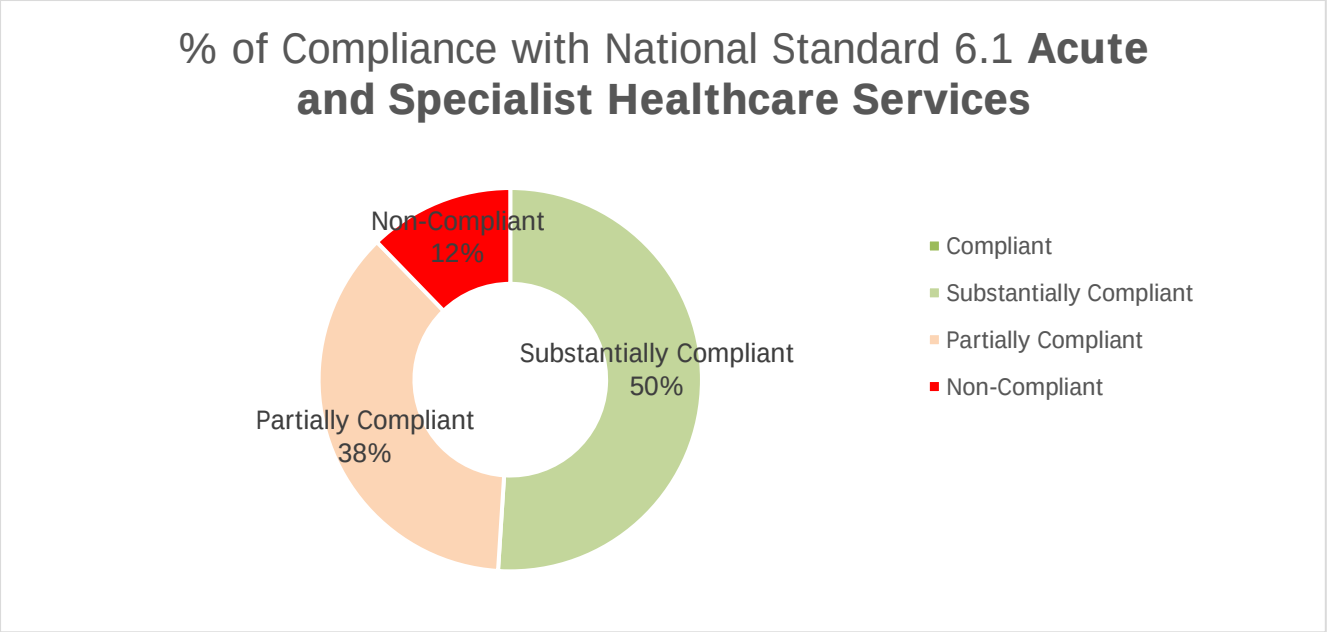
When compared to the acute and specialist healthcare services, RCIHS had a better level of compliance with national standard 6.1 (Figures 8 and 9). One (8%) RCIHS was compliant and the remaining 12 (92%) were substantially compliant with the national standard (Figure 8).

Figure 8: Compliance with national standard 6.1 RCIHS




Thirteen (50%) acute and specialist healthcare services were substantially compliant with the national standards. Ten (38%) acute and specialist healthcare services were partially compliant and the remaining three (12%) services were non-compliant with national standard 6.1. None of the acute or specialist healthcare services inspected in 2024 were fully compliant with national standard 6.1 (Figure 9).

Figure 9: Compliance with national standard 6.1 acute and specialist healthcare services




Shortfalls in medical, nursing and health and social care professionals such as pharmacy staff, physiotherapists, speech and language therapists, occupational health therapists and medical social workers providing front-line care was a common finding across all healthcare services inspected in 2024. Three acute healthcare services (Wexford General Hospital, Midland Regional Hospital Portlaoise and University Hospital Kerry) reported staffing shortfalls in the areas of quality and patient safety. The Regional Hospital Mullingar had a number of vacancies in senior management and leadership positions, with four of the nine (44%) vacant senior management positions in the quality and patient safety and midwifery corporate governance areas.

Improvements in varying degrees were needed in 98% of the healthcare services inspected, which were **substantially compliant** (64%), **partially compliant** (26%) and **non-compliant** (8%) with national standard 6.1. Non-compliances related to shortfalls in staffing and the sub-optimal completion of relevant mandatory and essential training by staff.

### Medical staff

The majority of the acute and specialist healthcare services had their approved complement of medical consultants and NCHDs to support the delivery of medical care across a range of specialties 24/7. Three healthcare services (University Hospital Kerry, University Hospital Waterford and Midland Regional Hospital Tullamore) reported a shortfall in the approved number of medical consultants (across specialties), in a range between 4 and 7.65 whole-time equivalents (WTEs). Shortfalls in approved NCHDs positions, ranging between 1% and 12% were

reported in five acute healthcare services (Wexford General Hospital, University Hospital Waterford, Mater Misericordiae University Hospital, Naas General Hospital and University Hospital Kerry). Recruitment campaigns to fill unfilled medical positions were underway in most healthcare services at the time of inspection, with recruitment at an advanced stage in some services. The majority of medical consultants who were employed permanently in the healthcare services inspected were on the relevant specialist division of the register of the Irish Medical Council. For consultants progressing to specialist registration or those not on the specialist division of the register, there were arrangements in place, in line with HSE guidance and with appropriate oversight by senior management, to support medical consultants.

Despite the reported shortfalls in medical staffing, on-call rosters were maintained to support the delivery of medical care 24/7 in all the healthcare services inspected, however some on-call arrangements were irregular, onerous and not sustainable in the long term. Some healthcare services relied on locum medical staff to support the delivery of 24/7 services, which is not a sustainable long-term solution. Medical officers or the local general practitioner (GP) services provided medical cover in RCIHS during core working hours. Outside those hours, medical cover was provided by the local out-of-hours GP services.

### Nursing staff

Half of all the healthcare services inspected in 2024 reported shortfalls in the approved nurse staffing levels, ranging between 2.5% (University Hospital Waterford) and 15% (Wexford General Hospital). Four acute healthcare services reported nursing shortfalls of 14% (Mater Misericordiae University Hospital, Naas General Hospital, Regional Hospital Mullingar and Tallaght University Hospital). Reported nurse staffing shortfalls in RCIHS, ranged between 10% (Ballina District Hospital) and 22.8% (Swinford District Hospital). The shortfall in the overall approved nurse staffing numbers for all healthcare services was further compounded by additional shortages arising from short-term absenteeism rates. Staffing shortfalls impacted on the ability to deliver optimal care but the exact impact was difficult to quantify because care undone, incomplete or delayed was not routinely quantified by all healthcare services. Healthcare services employed a number of measures to manage nursing shortfalls, including use of agency staff, staff redeployment or staff working extra shifts (bank staff), but these arrangements were not sustainable in the long term.

### Pharmacy staff

Twenty-one (53%) healthcare services inspected in 2024 reported shortfalls in their approved WTE pharmacy staff numbers (81% were acute healthcare services and 19% were RCIHS). The reported shortfall in the number of approved pharmacist

positions ranged between 14% (Naas General Hospital) and 30% (Midland Regional Hospital Portlaoise). In addition, three (14%) of these 21 healthcare services reported shortfalls in their approved WTE pharmacy technician positions — 24% (University Hospital Kerry), 17% (Tallaght University Hospital) and 12.5% (Cavan Monaghan General Hospital). The shortfall in pharmacy staff numbers was further compounded by additional shortages arising from annual and statutory leave, with some healthcare services unable to recruit to fill short-term absences. The shortfalls impacted on these services' ability to deliver a comprehensive clinical pharmacy service and pharmacy-led medication reconciliation service to all people receiving care and treatment. Recruitment campaigns to fill unfilled pharmacist and pharmacy technician positions were underway in most healthcare services inspected.

### Infection prevention and control staff

All acute and specialist healthcare services inspected had established multidisciplinary infection prevention and control teams. The size of the infection prevention and control team corresponded to the size and scope of the healthcare service, with core members being an infection prevention and control clinical nurse specialist, infection prevention and control nurse, consultant microbiologist, surveillance scientist and antimicrobial stewardship pharmacist. All clinical staff in all healthcare services had access to support and advice from a consultant microbiologist 24/7, some with on-site presence and others provided support remotely, off site. All acute and specialist healthcare services inspected in 2024 had an antimicrobial stewardship programme that coordinated and optimised the use of antimicrobials to decrease healthcare-associated infections, reduce antimicrobial resistance and improve patient outcomes. Infection prevention and control support for staff in RCIHS and surveillance of practice in those services was coordinated through the HSE's CHO, with input and support from the acute healthcare services. Staff in RCIHS could avail of infection prevention and control specific support and advice from infection prevention and control link nurses.

### Staff absenteeism rates

All healthcare services monitored staff absenteeism rates and reported those rates monthly to the HSE. None of healthcare services inspected in 2024 were compliant with the HSE's target of less than or equal to 4%. The level of staff absenteeism reported by healthcare services during the inspections in 2024 ranged between 4.28% and 10%. This variation in staff absenteeism rates warrants further analysis by the healthcare services and the HSE, especially for healthcare services with higher rates and greater deviations from the HSE's target.

### Staff uptake of mandatory and essential training

Staff attendance and uptake of mandatory and essential training in relation to

infection prevention and control, medication safety and the deteriorating patient varied across all the healthcare services inspected in 2024. While a small number of services performed well in this area, it was an area identified for targeted improvement in the majority of healthcare services inspected in 2024. This finding was consistent with the inspection findings from 2021 and 2023. A higher level of compliance with staff uptake of mandatory and essential training, appropriate to their service and scope of practice was found in the 66% of healthcare services which were compliant or substantially compliant with national standard 6.1. Significant gaps in staff uptake of mandatory and essential training was identified in the remaining 34% of healthcare services that were partially or non-compliant with the national standard. Areas where the uptake of training needed to improve included training in:

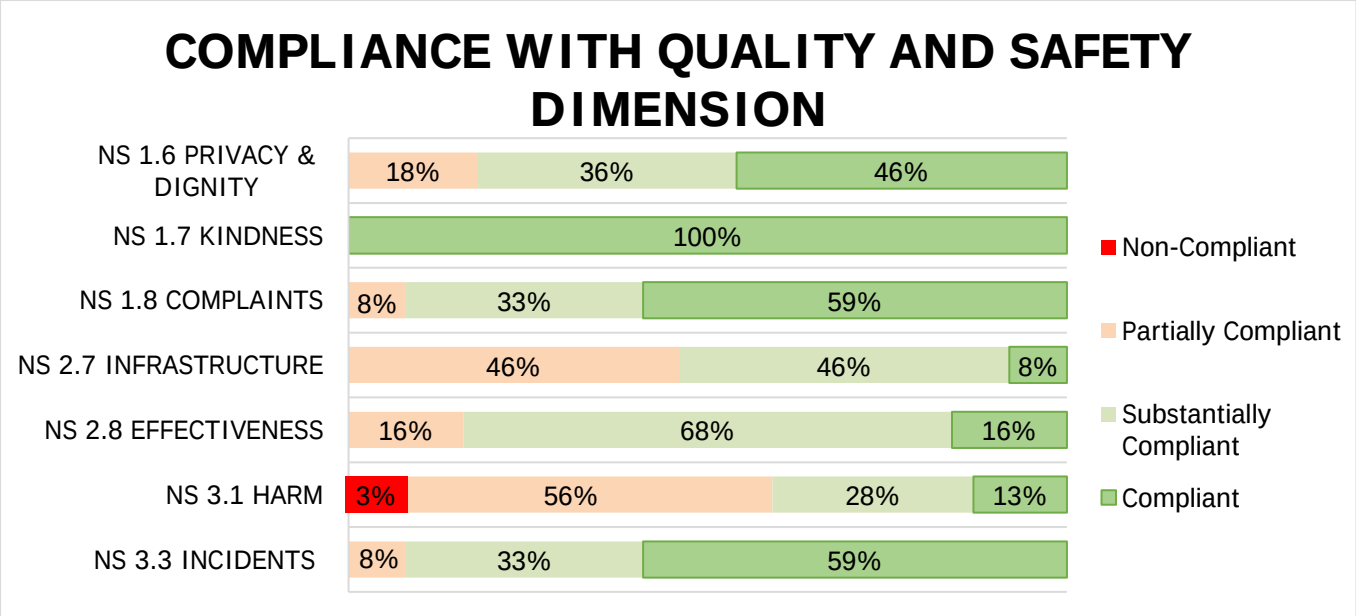
- standard and transmission-based precautions
- hand hygiene
- basic life support
- early warning systems
- obstetric emergencies.

Senior management awareness and oversight of staff uptake of mandatory and essential training varied across the healthcare services inspected in 2024. This awareness was further impacted by difficulties in recording and monitoring staff attendance and uptake of mandatory and essential training centrally, but a number of the healthcare services inspected were working towards introducing measures to improve this. Clinical managers monitored the uptake of mandatory and essential training for nursing and support staff (healthcare assistants, multi-task assistants) at local clinical area level and were aware of the staff training needs in their clinical areas. However, this information was not always collected and collated centrally making it challenging for more executive or senior managers to have oversight of staff uptake of mandatory and essential training. NCHDs attendance at essential and mandatory training was recorded on the National Employment Record system, which allowed for the centralised monitoring of NCHD training attendance.

## 2.2 Quality and Safety Dimension

This section of the report presents the composite findings of compliance with seven national standards (NS 1.6, 1.7, 1.8, 2.7, 2.8, 3.1 and 3.3) drawn from three themes in the *Quality and Safety* dimension — Person-Centred Care and Support; Effective Care and Support; Safe Care and Support. It is an evaluation of the care and support people using the services received on a day-to-day basis and if the service was a good quality and caring one that was person centred and safe.

Figure 10: Compliance with seven national standards in Quality and Safety dimension all healthcare services




Figures 10 to 18 and Appendix 6 shows how there was a varied level of compliance with the seven national standards monitored under the *Quality and Safety* dimension. All healthcare services were compliant with the national standard that focused on the promotion of a culture of kindness, respect and consideration (NS 1.7). There was also good levels of compliance with the national standards concerned with:

- the promotion of dignity, privacy and autonomy (NS 1.6)
- the promotion of a culture of kindness, consideration and respect (1.7)
- complaints management (1.8)
- the reporting, responding and management of patient-safety incidents (3.3).

Further work in respect of compliance was identified in the other three national standards monitored in the *Quality and Safety* dimension. Areas for improvement were needed to ensure that:

- the physical environment supported the delivery of high-quality, safe, reliable care and protects the health and welfare of people using the services (2.7)
- the effectiveness of healthcare services was systematically monitored, evaluated and continuously improved (2.8)
- people who use the healthcare services were protected from the risk of harm associated with the design and delivery of the services (3.1) (Figure 11).

## Theme 1: Person-Centred Care and Support

The Person-Centred Care and Support theme promotes and respects the dignity, privacy and autonomy of people attending for care and treatment. Compliance with three national standards (1.6, 1.7 and 1.8) from this theme was monitored in 2024 (Figures 12, 13 and Appendix 6).

### Standard 1.6: Service users' dignity, privacy and autonomy are respected and promoted.

People have a right to expect that their dignity, privacy and confidentiality is respected and promoted when attending healthcare services for care and treatment. As part of each inspection, inspectors met and spoke with patients to ascertain their experience about the care received. The majority of patients who spoke with the inspectors were complimentary of the staff. Examples include:

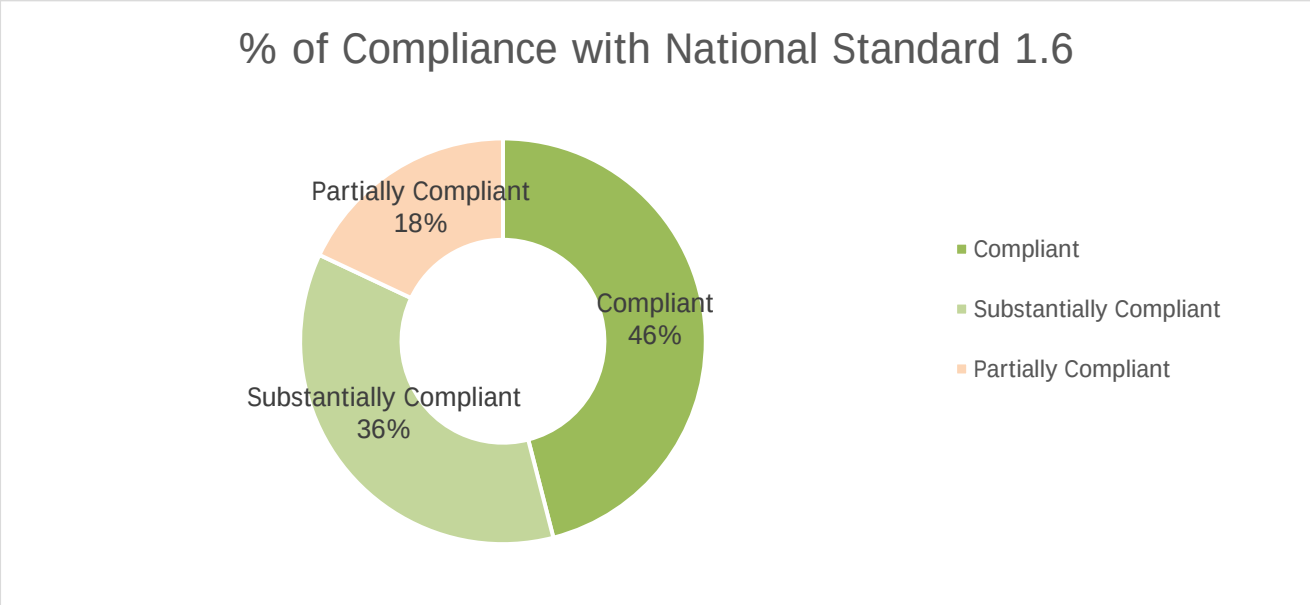
Patients gave positive feedback to inspectors when describing their experience of care received in healthcare services. These include:


When asked what could be improved, patients remarked how there was not enough staff, how staff were busy and how the physical environment did not protect their dignity, privacy and confidentiality. Examples of feedback include:


Good levels of compliance were found with national standard 1.6, with 32 (82%)

healthcare services compliant or substantially compliant with the national standard. Eight (18%) healthcare services were partially compliant and no services were non-compliant with national standard 1.6 (Figure 11).

Figure 11: Compliance with national standard 1.6 in all healthcare services




Eighteen (46%) healthcare services were **compliant** with national standard 1.6. In these services:

- there was a focus on protecting patients' dignity and privacy, which was consistent with the human rights-based approach to care promoted by HIQA
- staff were focused and committed to promoting a person-centred approach to care
- staff were motivated to do their best for the people receiving care and to deliver high-quality care
- staff were kind and caring, and interacted with people receiving care in a reassuring way
- measures were implemented to support and ensure patients were appropriately supported with their individual needs
- the placement of older and vulnerable patients and patients with specific care needs, such as those at the end of life was prioritised.

Fourteen (36%) healthcare services were **substantially compliant** and seven (18%) services were **partially compliant** with national standard 1.6. The protection and promotion of people's dignity and privacy was very challenging in healthcare services where the demand for urgent and emergency healthcare services overtook inpatient bed capacity. This mismatch manifested in overcrowding in different clinical areas, with more pronounced overcrowding seen in emergency

departments. As a result, patients were regularly accommodated in non-designated patient areas or on trolleys in corridors, with their dignity, privacy and confidentiality constrained and compromised. It was not aligned with the human rights-based approach in healthcare services promoted by HIQA.

Actions that will support healthcare services to come into full compliance with national standard 6.1 include:

- ensuring that the environment and areas where patients receive care and treatment protects and meaningfully promotes the patient's privacy, dignity and confidentiality
- ensuring the environment supports and enables the confidential exchange of private and sensitive information during interactions with healthcare staff
- implementing processes to support efficient patient flow and egress to mitigate overcrowding of emergency departments and across healthcare services
- ensuring patients' personal information is protected at all times and that systems and processes are in place to ensure compliance with relevant data protection legislation.

A comparison of the compliance levels from 2024 with 2021 and 2023 for eight healthcare services showed the compliance level with national standard 1.6:

— remained the same at substantially compliant for three healthcare services (Naas General Hospital, Midland Regional Hospital Portlaoise, Connolly Hospital and University Hospital Kerry)
— improved from substantially compliant to compliant for two healthcare services (St Columcille's Hospital and St Vincent's University Hospital)
— regressed from substantially compliant to partially compliant for three healthcare services from (Cavan Monaghan General Hospital and Regional Hospital Mullingar).

Standard 1.7 Service providers promote a culture of kindness, consideration and respect.

All healthcare services inspected in 2024 were compliant with national standard 1.7. Across all healthcare services inspected, staff promoted a culture of kindness, consideration and respect with the inspectors observing considerate and respectful interactions between staff and patients. Staff were observed interacting with patients in a kind and respectful manner. Staff listened actively and communicated with patients in an open and sensitive manner, in line with their expressed needs

and preferences. Where appropriate, validated assessment tools were used to assess patients' individual needs and to determine the supports needed in areas such as geriatric assessment, nutrition and hydration, falls and dementia.

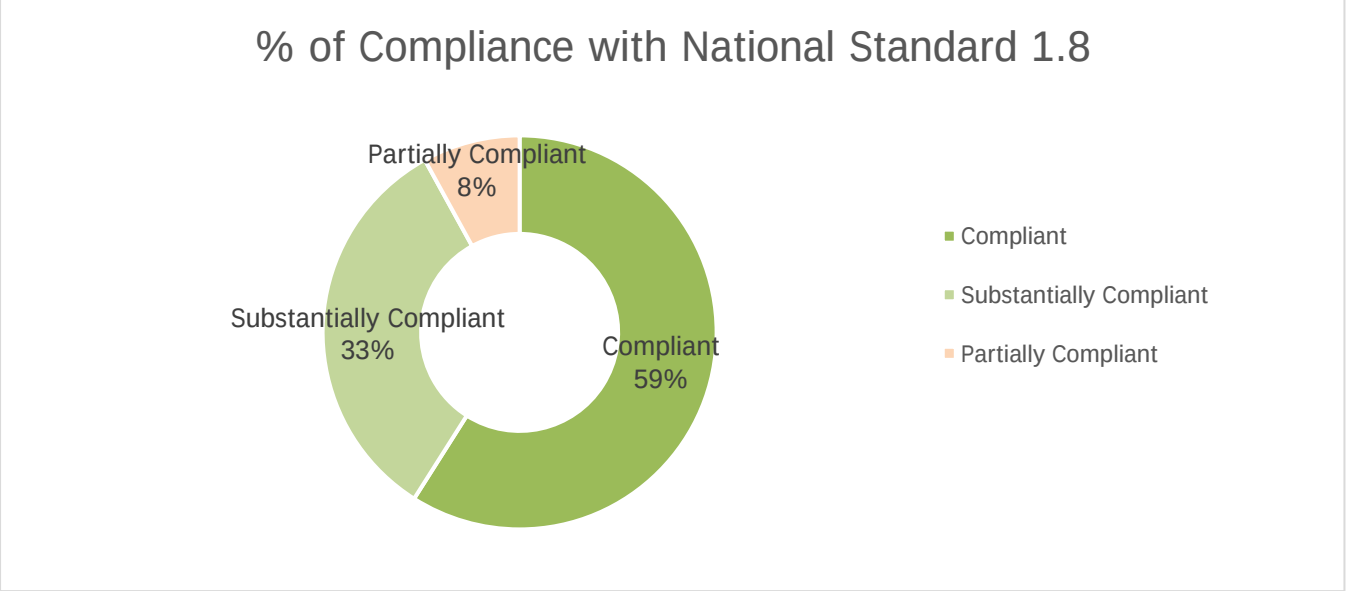
Initiatives such as 'Just a Minute' (JAM) supported people with a hidden disability or communication barrier to highlight to others that they needed extra time and understanding when communicating with staff. Some healthcare services had implemented the hospice friendly hospital programme to support end-of-life care. Some healthcare services had an end-of-life coordinator to support patients receiving end-of-life care and their families. Nurses specialising in dementia care helped support the delivery of patient-centred care for patients with dementia. Some healthcare services had a designated area designed to reduce the environmental stressors for patients with dementia. Enhanced care and supervision was provided for vulnerable patients. Patient information leaflets were available and accessible on a range of health-related issues and conditions, but they were in English and were not always available in a range of languages. Translation services were provided for patients who did not speak English. Information about the patient advisory liaison service was available in some healthcare services. Two healthcare services inspected had a volunteer support programme to 'meet, greet and guide' patients and families when they arrived to the service. One healthcare service had a sensory room located in the paediatric emergency department, to support and comfort paediatric patients when they felt anxious. Another healthcare service had a hairdresser onsite who was available to patients and staff.

Compared to the inspections findings from 2021 and 2023, compliance levels with national standard 1.7 remained the same (compliant) for six healthcare services and improved from substantially compliant to compliant for two healthcare services (Regional Hospital Mullingar and University Hospital Kerry).

### Standard 1.8 Service users' complaints and concerns are responded to promptly, openly and effectively with clear communication and support provided throughout this process

Patient experiences and feedback is an important outcome for healthcare services. Having a robust complaints resolution process provides people who use healthcare services with the opportunity to express their views when their experiences have not been optimal and allows healthcare service providers to identify and act on areas for improvement. Very good levels of compliance were generally found with national standard 1.8. Thirty-four (92%) healthcare services were compliant or substantially compliant with the national standard. Three (8%) healthcare services were partially compliant. No services were non-compliant with the national standard (Figure 12).

Figure 12: Compliance with national standard 1.8 all healthcare services




Twenty-two (59%) healthcare services were **compliant** with national standard 1.8. In these services:

- there were clear, transparent, open and accessible complaints procedures that enabled and supported a coordinated approach to the management of complaints received from patients and families
- there was a culture of complaints resolution
- there was a designated complaints officer to receive and handle complaints, with the name of the complaints officer readily available to patients and their families
- senior management had oversight and monitored the timeliness of response and management of complaints
- staff received training on complaints management
- staff were knowledgeable about the healthcare service's complaint resolution process
- there was a formalised complaints management policy
- point of contact complaint resolution was promoted and supported by executive or senior management in line with national guidance with formal and informal complaints recorded
- there was a coordinated response to people who made a complaint
- complaints were responded to in a timely way, in line with national or local targets (the HSE target is that 75% of complaints are resolved within 30 working days)

- complaints were tracked and trended to identify emerging themes, categories and the departments involved, with information and learnings from this process shared with senior management and clinical staff
- time-bound quality improvement plans were devised to implement recommendations from the complaints resolution process, with the implementation of these plans monitored by senior management
- arrangements were in place to provide and or facilitate access to independent advocacy services for patients and their families, ensuring that the patient's voice was heard either through the patient directly or through a nominated representative. The Patient Advocacy Liaison Service (PALS) was available to support patients, their families and carers to provide feedback or make a compliant about the care received.

Twelve (33%) healthcare services were **substantially compliant** and three (8%) services were **partially compliant** with national standard 1.8. None of the 15 healthcare services that were substantially or partially compliant with national standard 1.8 were compliant with the HSE national target of 75% for complaint resolution. Shortfalls in staffing in the quality and risk department impacted the timeliness and responsiveness of the complaints resolution process in the three healthcare services that were partially compliant with this national standard. The complexity of complaints and the resulting time it took to ensure a comprehensive coordinated response was a key contributing factor impacting on the timeliness of the complaints resolution process. A small number of patients who spoke with the inspectors during inspections were aware of the service's complaints management procedures. Patients talked to staff if they had any issues, complaints or concerns.

Actions that will support healthcare services come into full compliance with national standard 1.8 include:

- appointing a designated complaints officer who will receive and handle complaints
- establishing a culture of complaints resolution, with local point-of-contact complaint resolution promoted and supported
- ensuring there is adequate staff resources to enable the timely and responsive resolution of complaints in line with national and local targets
- ensuring senior management oversee and monitor the effectiveness of the complaints resolution process
- continuously track and trend complaints and use the information to identify areas for improvement
- ensuring feedback from the complaints resolution is shared with staff and

learnings are applied to improve experiences for people receiving care and treatment

- ensuring the timely implementation of actions and recommendations from the complaints resolution process to improve the experiences of people who receive care in healthcare services
- providing information on the healthcare service's complaint resolution process to people who use the services
- facilitating access to support services, such as independent advocacy services for patients and their families to ensure that the patient's voice is heard.

A comparison of the compliance levels from 2024 with 2021 and 2023 for eight healthcare services showed the compliance level with national standard 1.8:

— remained the same at compliant for one healthcare service (Regional Hospital Mullingar)

— improved for five healthcare services from:

  — substantially compliant to compliant for three healthcare services (Cavan Monaghan General Hospital, Connolly Hospital and St Columcille's Hospital)

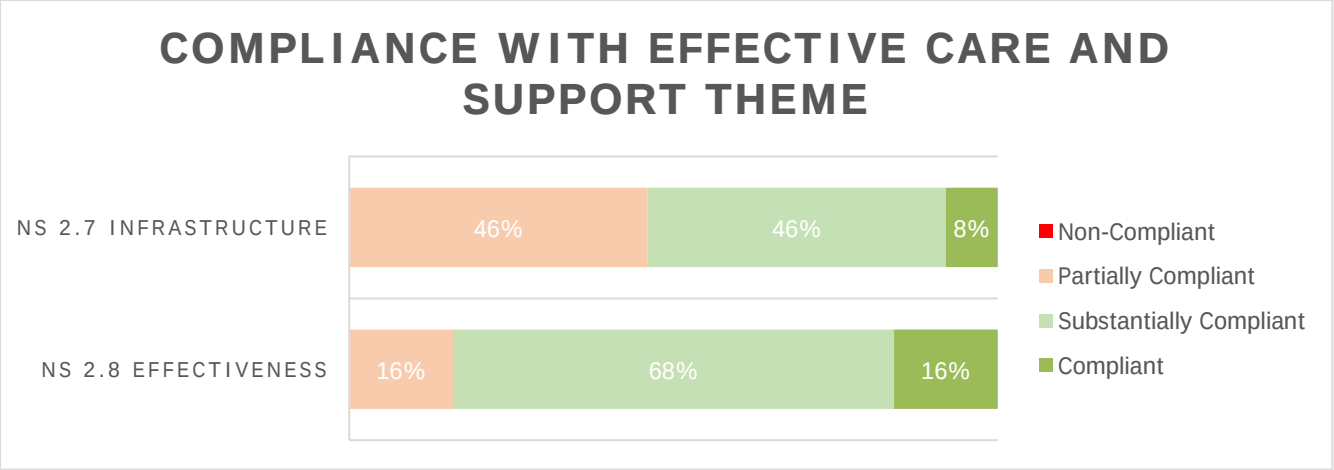
  — partially compliant to substantially compliant in two healthcare services (Midland Regional Hospital Portlaoise and University Hospital Kerry)

— regressed from compliant to substantially compliant in two healthcare services (Naas General Hospital and St Vincent's University Hospital).

## Theme 2: Effective Care and Support

The fundamental principle of effective care and support is that it consistently delivers the best available outcome for people using the healthcare service within the context of the service and the resources available. Compliance with two national standards (2.7 and 2.8) from the Effective Care and Support theme was monitored in 2024 (Figure 13 and Appendix 6).

Figure 13: Compliance with two national standards in Effective Care and Support theme all healthcare services

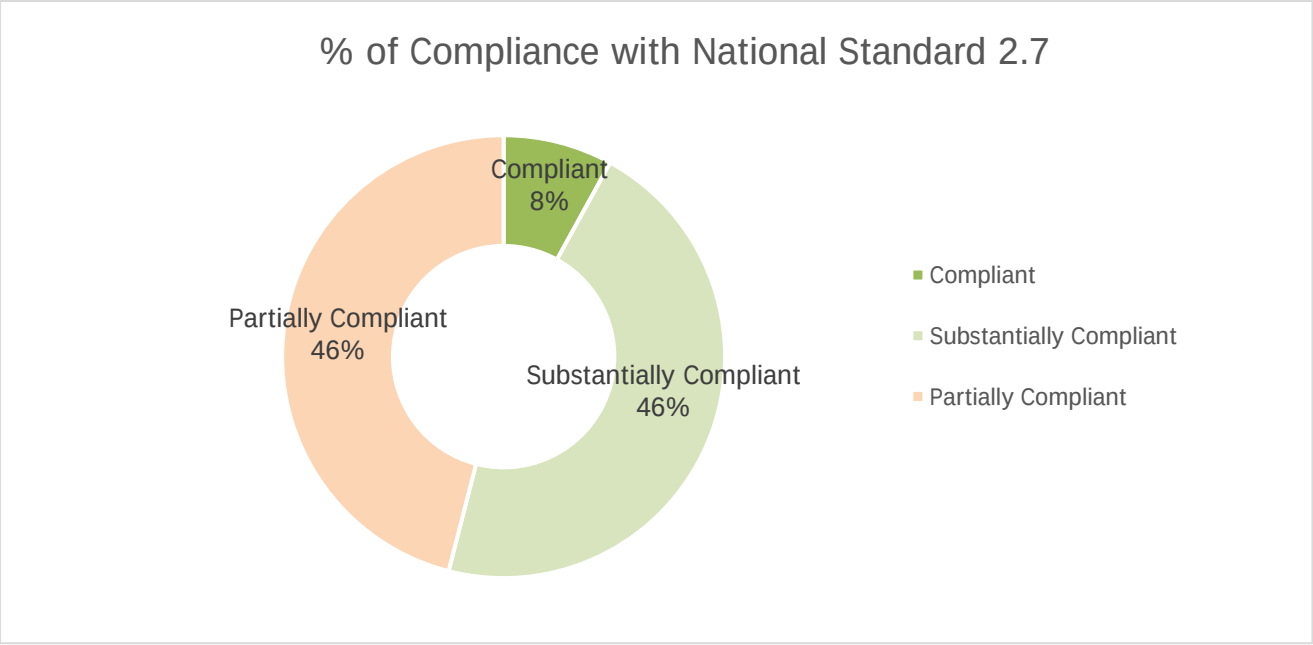



Standard 2.7 Healthcare is provided in a physical environment which supports the delivery of high quality, safe, reliable care and protects the health and welfare of service users.

The effectiveness of care is supported by the environment in which healthcare is delivered. Effective healthcare is provided in a safe and secure environment that is responsive to patients' physical and sensory needs and supports their health and wellbeing. Just over half (54%) of the healthcare services inspected in 2024 were compliant or substantially compliant with national standard 2.7.

Seventeen (46%) healthcare services were partially compliant and no service was non-compliant with national standard 2.7 (Figure 14).

Figure 14: Compliance with national standard 2.7 all healthcare services



Three (8%) healthcare services were **compliant** with national standard 2.7. In these services:

- the physical environment, premises and facilities complied with relevant legislative and best standard requirements
- premises and facilities were accessible and responsive to the physical and sensory needs of people using the healthcare services
- the physical environment was developed and managed to minimise risks of acquiring a healthcare-associated infection
- there was appropriate management, which included the safe handling, storage, use and disposal of hazardous materials and waste
- there are appropriate measures to ensure the security of the premises
- risks associated with changes to the physical environment where care was provided were identified, evaluated and the necessary actions taken to eliminate or minimise any risks to patient safety.

Seventeen (46%) healthcare services were **substantially compliant** with national standard 2.7. The ageing physical infrastructure adversely impacted compliance with national standard 2.7 and compromised the delivery of safe, high-quality care in 17 (46%) healthcare services judged to be **partially compliant** with the national standard.

In the majority of healthcare services inspected, the physical environment was clean and well maintained but there was wear and tear of woodwork and floor surfaces, which did not facilitate effective cleaning. Some areas, for example, bathroom and shower facilities were in need of refurbishment. Refurbishment works were underway in a number of healthcare services at the time of inspection. Patient equipment was observed to be clean in majority of healthcare services and the majority of healthcare services had a system to identity clean patient equipment. However, the identification system was not used consistently in some services. Storage space was a challenge for some healthcare services, resulting in the inappropriate storing of supplies and patient equipment on corridors or in patient areas, causing cluttering and congestion. This presented a risk to patient safety, especially for patients with mobility issues and potentially could impact the timely response in the case of an emergency. In the majority of healthcare services inspected, the physical environment was a high risk recorded on local or corporate risk registers, with appropriate controls applied to mitigate the potential and actual risks to patient safety.

Actions that will support healthcare services come into full compliance with national standard 2.7 include:

- assessing and mitigating any potential or actual risks to patient safety arising from a challenging physical environment
- ensuring hand hygiene sinks conform and are compliant with specified requirements
- ensuring there are sufficient number of single rooms with en-suite bathroom facilities for the size and scope of the service, and to support the placement of patients requiring transmission-based precautions
- increasing the number of en-suite bathroom facilities in multi-occupancy rooms to support appropriate placement of patients
- ensuring there are sufficient negative pressure rooms with ante rooms appropriate to the size and scope of the healthcare service
- ensuring adequate infection prevention and control signage that aligns with national guidance and specifies the appropriate type of precautions to be used when transmission-based precautions are in use
- using the correct use of personal protective equipment when applying transmission-based precautions
- storing clean patient equipment in line with national guidance and good practice standards
- ensuring sufficient cleaning staff 24/7 to support the routine and terminal cleaning of healthcare services when needed
- promoting and maintaining adequate physical spacing between beds in multi-occupancy rooms
- auditing hand hygiene practices frequently. Implementing time-bound quality improvements when hand hygiene practices fall below expected standards to ensure compliance with best practice and national standards
- auditing the cleanliness of the physical environment and patient equipment frequently
- implementing time-bound quality improvements when hygiene standards fall below expected standards to ensure compliance with best practice and national standards
- storing and segregating used and clean linen in line with national guidance and good practice standards
- ensuring adequate security arrangements where and when required.

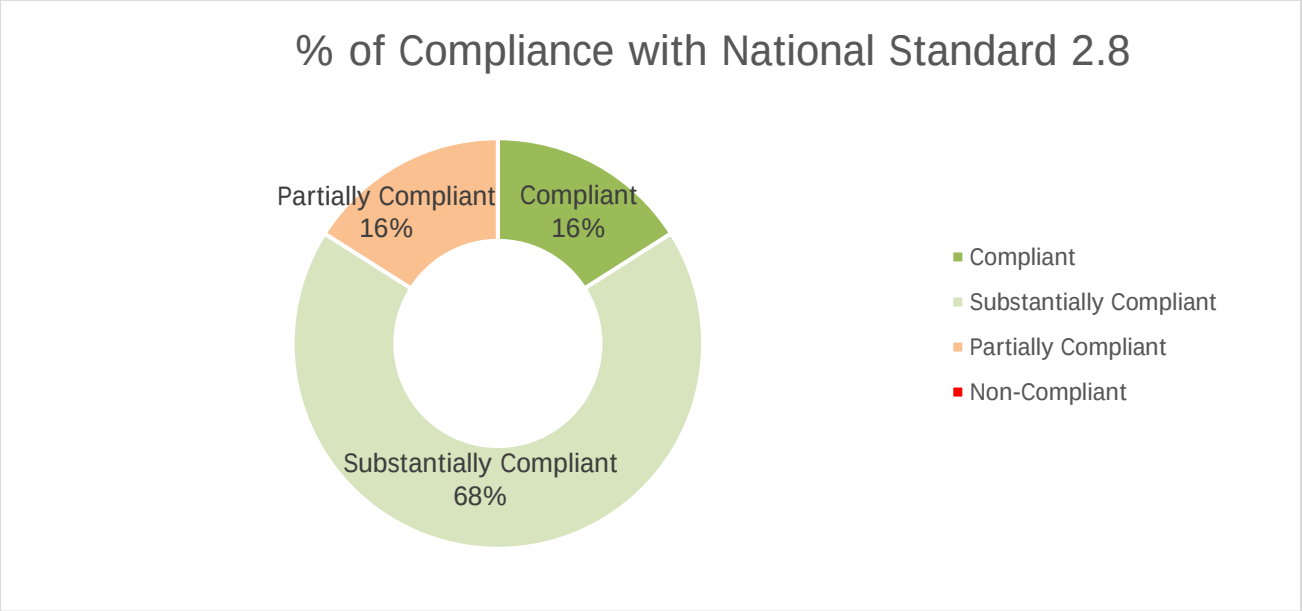
A comparison of the compliance levels from 2024 with the compliance levels from 2021 and 2023 for eight healthcare services showed the compliance level with national standard 2.7:

- remained the same for four healthcare services at:
  - partially compliant for three healthcare services (Midland Regional Hospital Portlaoise, Naas General Hospital and St Vincent's University Hospital)
  - substantially compliant for one healthcare service (Cavan Monaghan General Hospital)
- improved from partially compliant to substantially compliant for four healthcare services (Connolly Hospital, Regional Hospital Mullingar, St Columcille's Hospital and University Hospital Kerry).

**Standard 2.8 The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.**

An effective healthcare service continually looks for opportunities to improve how it cares for and supports people receiving care in the service. Auditing and evaluating healthcare processes, practices, and outcomes against established standards, provides healthcare service managers with assurances about the quality of services. It also helps identify areas where improvements are needed and ensures healthcare services are delivered safely, effectively, in line with best practices and standards. Overall there was a good level of compliance with national standard 2.8 (Figure 15).

Figure 15: Compliance with national standard 2.8 all healthcare services




Thirty-one healthcare services (84%) were compliant or substantially compliant with the national standard. Six (16%) healthcare services were partially compliant. None of the healthcare services inspected were non-compliant with national standard 2.8 (Figure 16).

Six (16%) healthcare services were **compliant** with national standard 2.8. These services:

- systematically monitored and measured the quality and safety of the care and its outcomes using relevant national performance indicators and benchmarks for infection prevention and control, medication safety, deteriorating patient and the transitions of care
- used a variety of outcome measures to evaluate the effectiveness of healthcare services and reported on theme publicly
- used information from the monitoring and evaluation process to improve the care delivered
- had an agreed annual audit plan that incorporated participation in national audit programmes, and local targeted audits based on the service's requirements and priorities
- had robust clinical governance arrangements to ensure findings from clinical audits were reported and monitored effectively
- used findings and information from clinical and non-clinical audit activity to monitor, evaluate and benchmark service performance with other similar healthcare services
- had good levels of compliance (over 90%) with national guidance and best practice standards in the four areas of focus — infection prevention and control, medication safety, deteriorating patient and transitions of care
- implemented quality improvements to improve practices and standards
- shared findings and learning from audit activity to improve practice and standards.

Monitoring and evaluating the structures and processes to support the safe transitions of care was an area identified for targeted improvement in the 84% of healthcare services. Six (16%) healthcare services were **compliant**, 25 (68%) services were **substantially compliant** and six (16%) services were **partially compliant** with national standard 2.8.

Audit findings related to the four areas of focus — infection prevention and control, medication safety, deteriorating patient and transitions of care showed varied levels of compliance with best practice standards and guidance. The frequency of carrying out audits depended on the scope and size of the healthcare service, with the majority of services carrying out environmental and patient equipment hygiene audits, and hand hygiene audits on a monthly basis. Compliance with environmental and patient equipment hygiene standards varied across the healthcare services, with some services performing very well (above 90%) and others less positively. Compliance with environmental and patient equipment hygiene standards ranged

between 65.10% and 97.9%. Varying levels of compliance were also found with hand hygiene standards, with the services' compliance ranging between 58.3% and 100%. The national target or benchmark for hand hygiene standards was 90%. The majority of healthcare services screened patients for known multidrug-resistant organisms (MDROs), such as *Carbapenemase-Producing Enterobacterales* (CPE), in line with national guidance, with a wide variance in the services' level of compliance with CPE screening ranging between 18% and 100%. Quality improvement initiatives were implemented to improve hygiene standards and screening for MDROs where needed.

Medication safety practices were audited by healthcare services. The focus and topic of the audits were informed by the scope and size of the service. Some services audited prescribing actions for specific medications, while others focused on administration and storage of medications or the effectiveness of strategies used to manage high-risk medications. Services' compliance levels with safe medication practices ranged between 58% and 100%. Five Model 3 and 4 healthcare services had participated in the European Centre for Disease Prevention and Control point prevalence of the hospital-acquired infections and antimicrobial use.[§§§]

Healthcare services' compliance with the monitoring and surveillance of a patient's clinical condition was evaluated through the nursing and midwifery quality care metrics in all healthcare services inspected. Services' compliance with the nursing and midwifery quality care metrics varied between 75% and 90%. Compliance with the early warning systems' response and escalation protocol for patients experiencing clinical deterioration was also audited in the majority of healthcare services inspected in 2024. Similar to other audit findings, there was a varied level of compliance with the protocol, with the range between 37.5% and 100%. Not all healthcare services audited compliance with national guidance on the use of Identify, Situation, Background, Assessment, Recommendation/Read Back/Risk ($ISBAR_3$) communication tool or clinical handover practices. Where $ISBAR_3$ use was audited, there was a high level of compliance, ranging between 90% and 100%. Compliance with guidance on sepsis management was audited in a small number (three) of healthcare services inspected in 2024, with compliance levels ranging between 45% and 100%.

Other audits carried out included the auditing of care bundles, venous thromboembolism (VTE), falls and 'Skip the Dip' quality improvement initiative.[****]

[§§§] The European Centre for Disease Prevention and Control (ECDC) is an agency of the European Union aimed at strengthening Europe's defences against infectious diseases. It provides scientific advice, data analysis, and support for disease prevention and control measures across EU member states.

[****] The 'Skip the Dip' quality initiative promotes best practices for assessing urinary tract infections in people aged 65 years and over in healthcare services. It highlights that not using antibiotics for

Findings and learnings from monitoring and evaluation activity were shared with staff. In some services, this process was structured and formalised occurring through staff meetings, quality boards and quality newsletters. While in other services, it was unplanned, unstructured and more informal.

Actions that will support healthcare services come into full compliance with national standard 2.8 include:

- ensuring that there is regular auditing of compliance with national guidance on the early warning system(s), sepsis management, clinical handover and the ISBAR$_3$ use to support continuous quality improvement
- ensuring the findings and scores from audit activities are calculated to facilitate comparisons and benchmarking with similar healthcare services
- ensuring time-bound quality improvement plans are developed and implemented when findings from the monitoring and evaluation of processes, care, standards and services identify a need to improve healthcare services
- monitoring and tracking the implementation of quality improvement initiatives to improve the quality and safety of healthcare services
- evaluating the effectiveness of the quality initiatives implemented to ensure planned improvements are achieved
- proactively sharing findings and learnings from monitoring and evaluation activities.

A comparison of the compliance levels from 2024 with the compliance levels from 2021 and 2023 for eight healthcare services showed the compliance level with national standard 2.8:

— remained the same for five healthcare services:
  — partially compliant for one healthcare service (University Hospital Kerry)
  — substantially compliant for four healthcare services (Cavan Monaghan General Hospital, Connolly Hospital, St Columcille's Hospital and St Vincent's University Hospital)
— increased for two healthcare services from:
  — substantially compliant to compliant for one healthcare service (Midland Regional Hospital Portlaoise)
  — partially compliant to substantially compliant for one healthcare service (Regional Hospital Mullingar)

bacteria in urine without symptoms is safe and helps prevent antibiotic resistance, based on best-practice guidelines and evidence.

— regressed from substantially compliant to partially compliant for one healthcare service (Naas General Hospital).

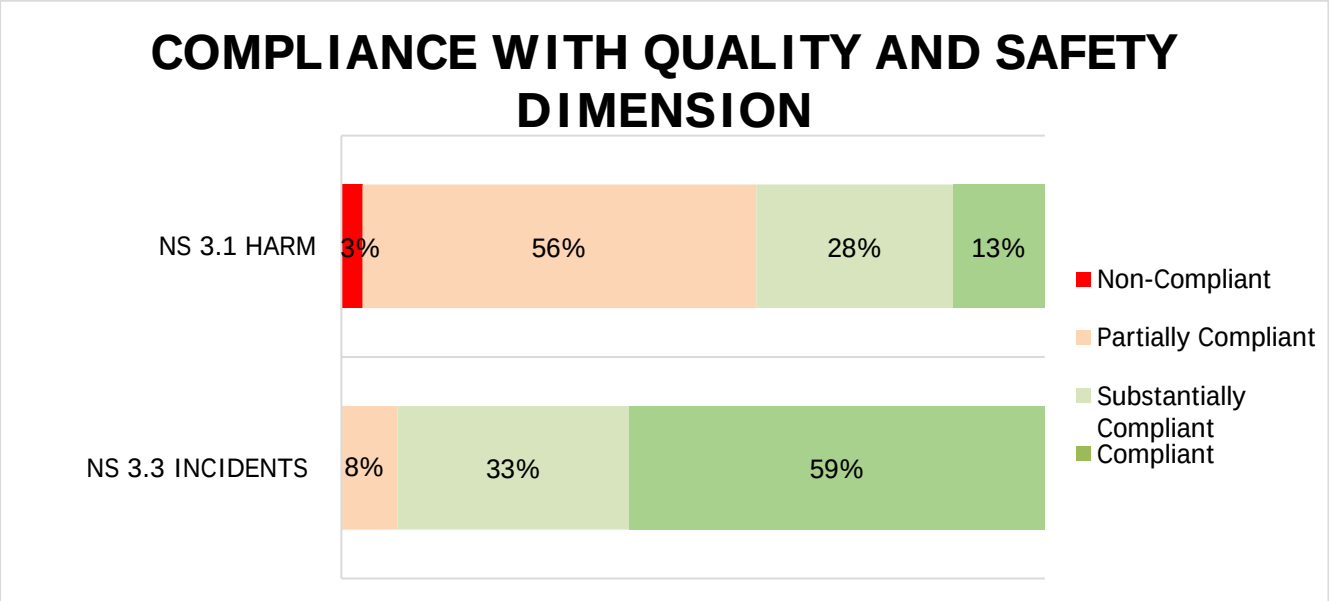
## Theme 3: Safe Care and Support

The Safe Care and Support theme recognises that the safety of people who use healthcare services is paramount. The theme is focused on identifying, preventing or minimising unnecessary or potential harm to people who use healthcare services. Care delivery has some associated element of risk of harm for people who use healthcare services. Therefore, actual and potential risks to people who use healthcare services should be proactively identified and managed.

Healthcare services that focus on safe care continually look for ways to improve the quality and safety of the service it delivers. Quality and safety improvements require service providers to plan, implement and evaluate necessary changes to improve the quality and safety of services.

Compliance with two national standards (3.1 and 3.3) from this theme was monitored during the monitoring of healthcare services in 2024 (Figure 16 and Appendix 6).

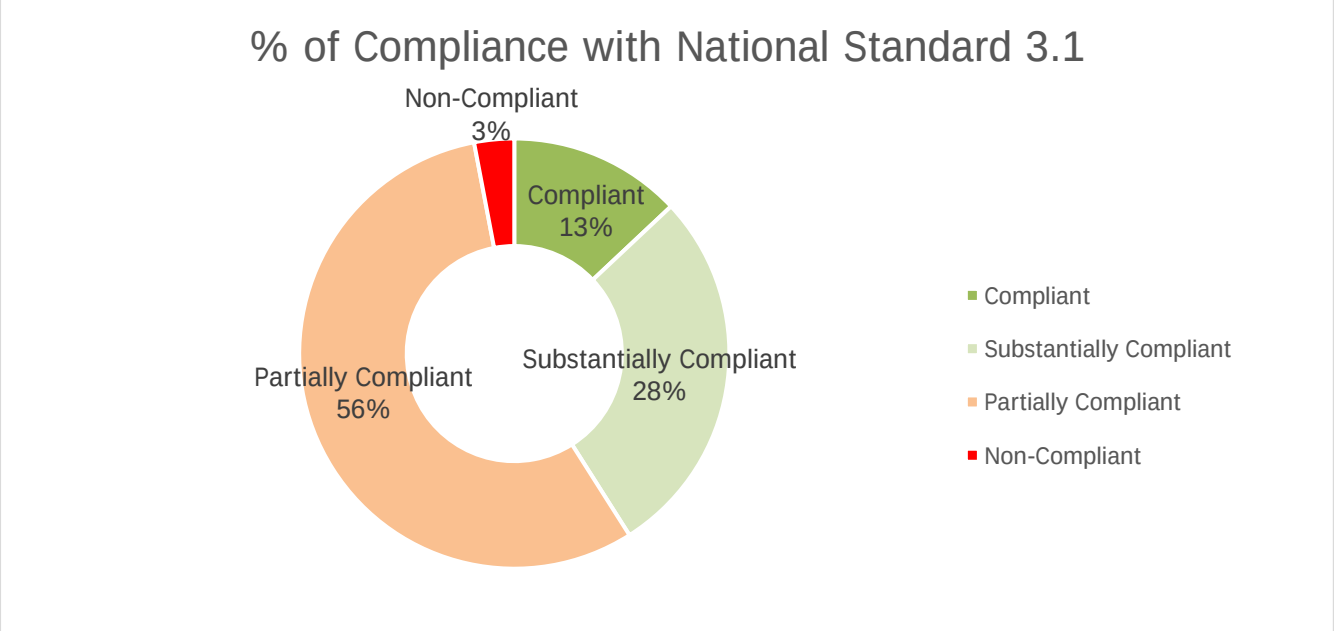
Figure 16: Compliance with two national standards in Safe Care and Support theme all healthcare services



Standard 3.1 Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

All healthcare services inspected in 2024 had structures and processes in place to monitor, manage and escalate risk(s) associated with the four areas of focus — infection prevention and control, medication safety, the deteriorating patient and transitions of care. The effectiveness of these systems varied across the healthcare services inspected. When compared to the other core national standards monitored in 2024, the level of compliance with national standard 3.1 was the lowest levels of all the national standards monitored (Figure 17).

Figure 17: Compliance with national standard 3.1 all healthcare services




Sixteen (41%) healthcare services were compliant or substantially compliant with national standard 3.1. The majority (59%) of healthcare services were partially compliant or non-compliant with national standard 3.1. This indicated that the risk management processes in 59% of healthcare services inspected in 2024 needed improvement and or strengthening in order to provide adequate oversight of the management of any actual or potential risks to people using the healthcare services (Figure 18).

Five (13%) healthcare services were **compliant** with national standard 3.1. These services had:

- arrangements to ensure there was proactive monitoring, analysis and response to information significant to the delivery of safe healthcare services
- governance, structures and processes to ensure:

  - any immediate and potential risks to people using the healthcare service were proactively identified, evaluated and managed
  - necessary actions were taken to eliminate or minimise immediate and potential risks
  - evaluated actions taken to eliminate or minimise risks and reported these through appropriate governance structures
- governance, structures, processes, policies and procedures to identify, assess, monitor, manage and review the risk of harm in relation to:
  - the prevention and control of healthcare associated infections
  - medication management
  - people using the service whose condition acutely deteriorates
  - the transitions of care
- a well-organised, planned and managed infection prevention and control programme that was coordinated and integrated with an antimicrobial stewardship programme
- access to specialist infection prevention and control advice 24/7
- systems and processes to facilitate the prevention, prompt identification and management of and learning from infection outbreaks
- systems and processes to ensure the risks of harm and potential for errors from medication safety incidents were used to inform and implement a medication safety programme or plan
- risk reduction strategies that when implemented reduced the risk of medication-related error, including the identification of high-risk medicines
- good compliance with the emergency department PETs, were applicable
- up-to-date policies, procedures, protocols and or guidelines that guided the:
  - management and practice of infection prevention and control
  - the safe use of medications
  - early detection and emergency response for patients whose clinical condition deteriorates
  - effective sharing of information during transitions of care.

Eleven (28%) healthcare services were **substantially compliant**, 22 (56%) services were **partially compliant** and one (3%) service was **non-compliant** with national standard 3.1. Healthcare services with outstanding compliances had systems and process to reduce risks to patients in the four different areas of focus, but there were some shortfalls in the processes that resulted in a judgment of substantially, partially or non-compliance.

### Infection prevention and control

All healthcare services had access to specialist infection prevention and control advice. Services had multidisciplinary teams that advised on, supported and promoted best practice standards in relation to infection prevention and control. This team was onsite in the acute and specialist healthcare services and were community based for RCIHS. Services had access to microbiology support and advice 24/7. All services had a process to identify patients presenting with a previous history of MDROs and screened patients for MDROs. However, in some services the screening for MDROs was not always in line with national guidance. As discussed previously under national standard 2.8, all services evaluated environmental, patient equipment and hygiene standards with varying degrees of compliance with best standards and guidance. Outbreak management teams were convened to manage infection outbreaks when they occurred. While the management of infection outbreaks were in line with national guidance, the implementation of recommendations and sharing of learning from infection outbreak reviews was an area identified for targeted improvement. The 'Sepsis 6' care bundle was used to enable the timely recognition and management of sepsis in some of healthcare services inspected.

### Medication safety

A comprehensive clinical pharmacy service was not available in the majority of healthcare services inspected in 2024. Shortfalls in pharmacy staff was the main barrier to the delivery of a comprehensive clinical pharmacy service. Pharmacy-led medication reconciliation was not carried out for all patients at all transition of care points. Medication reconciliation was prioritised for specific, identified groups such as those receiving critical care services or patients on multi-pharmacy. Strategies, like high-risk and sound alike-look alike drugs (SALAD) lists, were used to support the use and administration of high risk medications. There were coordinated measures in the acute and specialist healthcare services to improve and measure the appropriate use of antimicrobials. A repository of up-to-date policies, procedures, protocols or guidelines was not readily available to staff at point of medication preparation in all healthcare services inspected in 2024.

### Deteriorating patient

Appropriate early warning systems for the different groups of patients were used in line with the scope and size of the healthcare service. Compliance with the response and escalation protocol for patients experiencing clinical deterioration could be improved. The $ISBAR_3$ communication tool was used but the effectiveness of the tool was not audited by all healthcare services inspected in 2024. The national clinical handover guideline was not adapted or implemented by all healthcare services. Healthcare services that did not have the scope to provide a higher level of observation or critical care services had formalised clinical pathways and

arrangements in place to support the timely transfer of patients needing that level of care to the most appropriate healthcare setting.

### Transitions of care

All healthcare services had arrangements and processes in place to support the safe transition of care. In the acute and specialist healthcare setting, this included the use of a management system that identified and minimised delays in a patient's inpatient stay, patients having a predicated date of discharge. Multiple operational meetings were held daily to support patient flow and egress, and the use of multiple clinical pathways and or hospital admission avoidance pathways enabled some patients to receive the most appropriate care for their individual needs in the most appropriate settings. The effectiveness of these arrangements and processes in supporting the safe transition of care was not evaluated by all healthcare services inspected.

Model 3 and 4 healthcare services provided undifferentiated urgent and emergency care in emergency departments. There is a known relationship between longer waiting times in emergency departments and increased mortality rates, particularly for patients waiting over five hours.[9] Delays in admission to an inpatient bed from the emergency department are also associated with higher rates of mortality. This risk informed the level of compliance with national standard 3.1, for the 73% of acute healthcare services who had emergency departments. In the majority of these services, the demand for urgent and emergency care outpaced bed capacity. The number of patients admitted and lodging in emergency departments while waiting for an inpatient bed ranged between 15% and 41%. In the emergency departments, the average waiting times from:

- registration to triage ranged between 5 minutes and 34 minutes (national target for triage is 15 minutes), with an average wait of 28 minutes
- triage to medical assessment ranged between 3 minutes and 5 hours for non-urgent patients, with an average wait of 1 hour 25 minutes
- decision to admit to actual admission in an inpatient bed ranged between 1 hour and 59 hours.

Three (16%) of the emergency departments inspected in 2024 were fully compliant with all emergency department PETs during inspection. The remaining 84% healthcare services were partially or non-compliant with all or some of the PETs. Most healthcare services performed well in the PETs related to patients aged 75 years and over.

Actions that will support healthcare services come into full compliance with national standard 3.1 include:

- increasing single-room capacity to enable the appropriate placement of patients with communicable infectious diseases who may require isolation within 24 hours of admission or diagnosis as per national guidance
- ensuring people using healthcare service are screened for MDROs in line with national guidance
- ensuring infection outbreaks are managed in line with national guidance
- ensuring learnings from reviews of infection outbreaks are shared and applied to support good infection prevention and control practices and standards
- implementing risk-reduction strategies for high-risk medicines (such as anticoagulants, insulins and opioids) that are in keeping with the scope and size of the healthcare service. This includes controls and high-leverage strategies, like the rationalisation of multiple strengths of infrequently used medications, a high-risk medication list and a sound-alike look-alike medications (SALADs) list
- providing a comprehensive pharmacy-led clinical pharmacy service to all clinical areas that would support prescription monitoring, clinical auditing, adverse drug reaction detection and prevention
- carrying out pharmacy-led medication reconciliation on all patients during transitions of care, including admission and discharge
- providing up-to-date medicine information where medications are prepared to support safe and appropriate prescribing and administration of medication practices
- fully implementing the appropriate early warning systems for the different cohorts of people who may use healthcare services in line with national guidance, including the emergency medicine early warning system (EMEWS), where appropriate
- fully implementing the ISBAR$_3$ communication tool in line with national guidance
- fully implementing clinical handover in line with national guidance
- ensuring there are effective systems and process in place to support the timely issuing of discharge summaries with accurate and up-to-date information to primary healthcare services
- ensuring management and operational processes are efficient and effective to enable compliance with defined timelines or KPIs for scheduled and unscheduled care, such as attendance and admissions from the emergency department, PETs, inpatient length of stay for medical and surgical patients, delayed transfer of care
- ensuring up-to-date policies, procedures, protocols and or guidelines are available and accessible to staff to guide the:
    - management and practice of infection prevention and control
    - safe use of medications

- early detection and timely emergency response for patients whose clinical condition deteriorates
- safe transitions of care.

A comparison of the compliance levels from 2024 with the compliance levels from 2021 and 2023 for eight healthcare services showed the compliance level with national standard 3.1:

- remained the same for three healthcare services:
  - partially compliant for two healthcare services (Regional Hospital Mullingar and Midland Regional Hospital Portlaoise)
  - substantially compliant for one healthcare service (St Columcille's Hospital)
- increased for one healthcare service from partially compliant to substantially compliant (Cavan Monaghan General Hospital)
- regressed for four healthcare services from:
  - substantially compliant to partially compliant for three healthcare services (Connolly Hospital, Naas General Hospital and St Vincent's University Hospital)
  - partially compliant to non-compliant for one healthcare service (University Hospital Kerry).

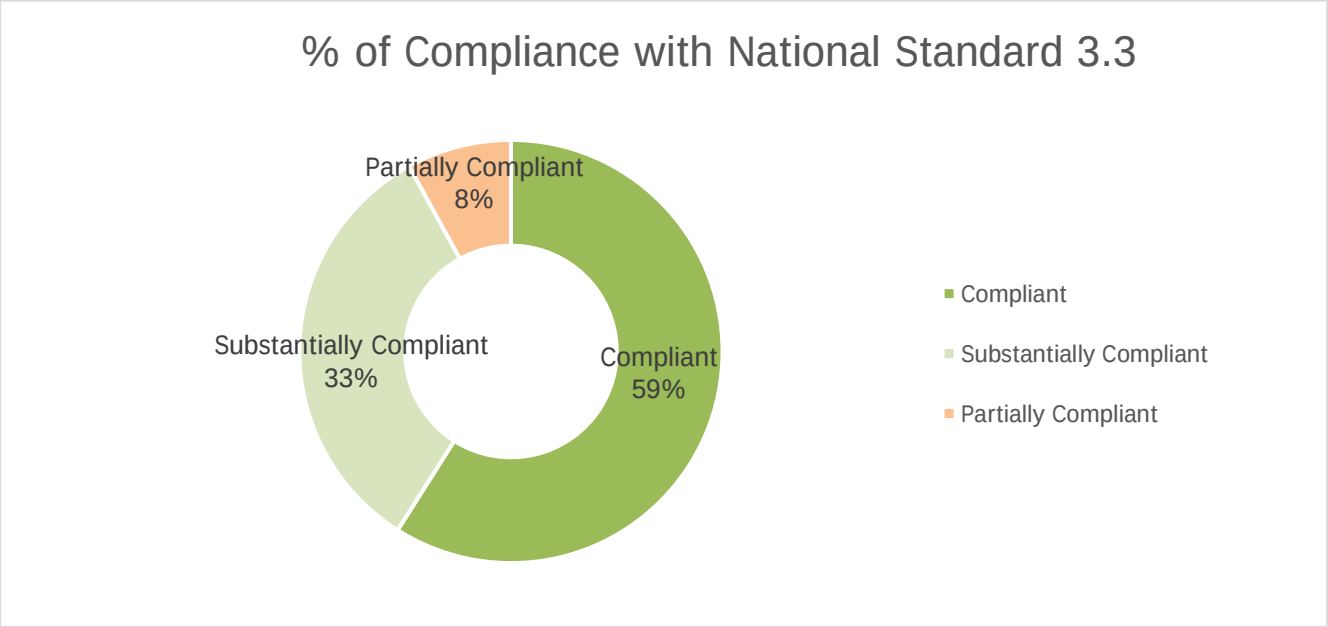
**Standard 3.3 Service providers effectively identify, manage, respond to and report on patient-safety incidents.**

A high-quality, safe service learns from all information relevant to the delivery of safe services and particularly from situations where things have gone wrong. Patient safety incidents and adverse events can happen in any healthcare service. When they occur or when something does go wrong, services should have policies and procedures in place to report, manage, review and investigate what happened. Services should learn from what happened and make changes to reduce the likelihood of the same thing happening again. Learnings from reviews of patient safety incidents should improve the quality and delivery of healthcare services.

There was a high level of compliance (92%) with national standard 3.3 in the healthcare services inspected in 2024 (Figure 18 and Appendix 6). All healthcare services inspected in 2024, had formal arrangements in place to respond to adverse events that harm people who use the service and to support those people and their family. Services managed patient safety incidents in line with the Incident Management Framework. All healthcare services used the web-based database — National Incident Management System (NIMS), hosted by the Clinical Indemnity

Scheme, to report and manage patient safety incidents and improve the safety of healthcare services. A number of healthcare services used the online system within NIMS — NIMS Electronic Point of Entry to directly enter incident reports on to the system.

Figure 18: Compliance with national standard 3.3 all healthcare services




Twenty-two (59%) healthcare services were **compliant** with national standard 3.3. These services:

- had arrangements in place to identify, manage, respond to and report patient safety incidents in line with applicable national legislation, policy and guidelines. These arrangements:
    - included a structured incident reporting mechanism
    - ensured patient safety incidents were reported in a timely manner through the appropriate reporting system
    - classified patient-safety incidents using an agreed categorisation such as those in the Incident Management Framework and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) categories for medication errors
- supported staff training to ensure they knew what to report and how to identify, manage, respond to and report on patient-safety incidents
- had robust and effective governance and oversight of the reporting and management of patient-safety incidents
- reported patient safety incident on to the National Incident Management System (NIMS) in line with the prescribed timelines in the Incident

Management Framework

- regularly reviewed the effectiveness of the patient-safety incident arrangements, systems and processes
- implemented measures to improve the reporting and management of patient-safety incident arrangements, systems and processes
- tracked and trended patient-safety incidents and used the information from that process to improve healthcare services
- implemented recommendations from investigations of patient-safety incidents and monitored the effectiveness of any action(s) taken.

Twelve (33%) healthcare services were **substantially compliant** and three (8%) services were **partially compliant** with national standard 3.3. Non-compliances mainly related to the timeliness of reporting patient safety incidents (the HSE target is reporting within 30 days or less from the date the healthcare service becomes aware of the incident), delays in completing comprehensive reviews of category 1 patient safety incidents (the HSE target is a time frame of 125 days for the completion of the review) and delays in implementing the learning and recommendations from patient safety incidents reviews. The complexity of the case and or availability of subject matter experts were the main reasons given by healthcare service management that contributed to the non-compliance with the 125 days' timeline for review of category 1 patient safety incidents. Delays in implementing learnings and recommendations from patient safety incident reviews had the potential to impact the continual improvement of practice and services for people using healthcare services.

Actions that will support healthcare services come into full compliance with national standard 3.3 include:

- ensuring there is effective robust governance and oversight of the reporting and management of patient safety incidents
- ensuring patient safety incidents are reported to NIMS within 30 days or less from the date the healthcare service becomes aware of the incident
- ensuring comprehensive reviews of category 1 patient safety incidents are completed within the time frame of 125 days
- timely implementation of the learning and recommendations from patient safety incidents reviews
- sharing findings and learnings from patient safety incidents reviews in a planned, structured and formalised way.

A comparison of the compliance levels from 2024 with 2021 and 2023 for eight healthcare services showed the compliance level with national standard 3.3:

- remained the same for four healthcare services:
  - compliant for two healthcare services (Cavan Monaghan General Hospital and Midland Regional Hospital Portlaoise)
  - substantially compliant for one healthcare service (St Vincent's University Hospital)
  - partially compliant for one healthcare service (University Hospital Kerry)
- increased for four healthcare services from:
  - substantially compliant to compliant for three healthcare services (Connolly Hospital, Naas General Hospital and St Columcille's Hospital)
  - partially compliant to substantially compliant for one healthcare service (Regional Hospital Mullingar).

## 2.3 Overall summary of compliance findings against the *National Standards for Safer Better Healthcare* in 2024

In 2024, 40 healthcare services were inspected to monitor compliance the *National Standards for Safer Better Healthcare*. Findings from the monitoring activity showed that healthcare services generally:

- achieved a high level of compliance with four national standards (5.8, 1.7, 1.8 and 3.3)
- were moderately compliant with three national standards (5.2, 5.5 and 1.6)
- further improvements are required to bring healthcare services into full compliance with four national standards (6.1, 2.7, 2.8 and 3.1).

In situations where findings from previous inspections facilitated comparison on re-inspection in 2024, 41% of national standards assessed on re-inspection showed improvements. Services maintained compliance levels for 45% of the national standards re-inspected and 14% had dis-improved since the previous inspection.

Key areas identified for ongoing vigilance in services include:

- ensuring corporate and clinical leadership and governance arrangements are in place to support robust and sustainable governance and effective leadership of healthcare services
- ensuring that service providers plan, organise and manage their workforce to achieve high-quality, safe and reliable healthcare
- ensuring effective robust risk management processes to identify, monitor and appropriately respond and protect patients from actual and potential risks of harm

- continuing to improve the physical environment so that it supports the delivery of high-quality, safe care and protects the privacy, dignity and welfare of people who use the services
- ensuring the effectiveness of healthcare is systematically monitored, evaluated and continuously improved through a variety of outcome measures, shared learning from incidents, complaints, concerns and compliments.

### Leadership, governance and management

Good, robust, effective and responsive leadership and governance is vital to the delivery of high-quality, safe healthcare services and this is especially important when reform and change is occurring. Findings from the monitoring of healthcare services in 2024 indicated that there was a good level of compliance with the three national standards monitored under the Leadership, Governance and Management theme. The majority of healthcare services inspected had good and effective leadership at corporate and clinical level, with robust and sustainable operational and management arrangements that were in keeping with the size and complexity of the service. The robust leadership and management arrangements were effective in promoting, supporting and facilitating the delivery of high-quality, safe and reliable healthcare services. They enabled services to identify, prepare, respond to and manage increases or decreases in service demand, including short-term changes, predictable changes and sudden or unexpected changes. Escalation procedures were enacted to support the demand for healthcare services, especially urgent and emergency services. These escalation procedures were in line with the national escalation framework and full capacity protocol, where appropriate. However, despite implementing escalation measures, the demand for urgent and emergency healthcare services was greater than the available bed capacity in many services. The resultant mismatch between service demand and bed capacity manifested in overcrowding, and this was especially pronounced in healthcare services that provided urgent and emergency care. The overcrowding led to patients accommodated, albeit temporarily, in non-designated clinical areas and increased patient experience times. The practice directly impacted on the care delivered and on the wider health and safety of those using or working in healthcare services. This manifested in a number of different risks, including infection control risks, obstruction and fire safety risks and delayed emergency response.

Governance arrangements to assure and ensure the delivery of high-quality, safe and reliable healthcare services was an area identified for targeted improvement in almost a third of healthcare services monitored in 2024. Areas requiring improvement included—governance and oversight of the effective management of risk, safe use of medications and the timely management of patients experiencing clinical deterioration.

## Workforce

Many healthcare services inspected had mechanisms in place to plan, organise and manage their workforce, but further work is needed to address staff shortfalls, especially those in the medical and nursing professions, pharmacy staff and health and social care professionals. The uplift in nurse staffing numbers found in acute and specialist healthcare services corresponded with the implementation of phase 1 of the *Framework for Staff Nurse Staffing and Skill Mix in General and Specialist Medical and Surgical Care Settings*. However, the healthcare staff recruitment moratorium implemented by the HSE from the end of 2023 until mid-2024 led to significant challenges in ensuring and maintaining adequate staffing levels across the medical, nursing and health and social care professions. The shortfall in staffing numbers found in healthcare services were further impacted by the HSE's pay and number strategy introduced in 2024, which set out the maximum number of employees that could be employed in HSE-funded healthcare services.

Maintaining approved pharmacy staffing levels was particularly challenging for 21 (53%) of the healthcare services inspected in 2024. The reported shortfalls in the number of approved pharmacist positions ranged between 14% and 30%. Three of the 21 healthcare services (33%) also reported shortfalls in their approved WTE pharmacy technician positions ranging between 12.5% and 17%. The shortfall in pharmacy staff numbers impacted on the healthcare service's ability to deliver a comprehensive clinical pharmacy service and pharmacy-led medication reconciliation service to all people receiving care and treatment. Recruitment campaigns to fill unfilled staff positions were underway in most healthcare services inspected.

HIQA welcomes the HSE's plans to progress with the implementation of phase two of the *Framework for Safe Nurse Staffing and Skill Mix* with a focus on safe nurse staffing and skill-mix in adult emergency care settings. Safe staffing frameworks, increased recruitment and retention efforts, and improved working conditions are some of the measures needed to adequately and sustainably tackle staffing shortfalls. Sufficient staff with the necessary qualifications, skills and experience is a fundamental prerequisite for the delivery of safe, high-quality care, positive patient outcomes, and mitigate staff burnout.

## Privacy, dignity and confidentiality

All healthcare services inspected promoted a culture of kindness, consideration and respect for patients and there was good overall compliance with the two national standards concerned with privacy, dignity and confidentiality. Staff and management of healthcare services were aware and used measures to promote the dignity, privacy and autonomy of people receiving care in line with the human rights-based approach to care promoted by HIQA. As per previous HIQA reports, the physical infrastructure of some healthcare services—together with the persistent

overcrowding in emergency departments and wider service level—compromised the privacy, dignity and confidentiality of people receiving care and treatment in some services.

### Complaint resolution and management of patient safety incidents

Two out of three (66%) healthcare services inspected in 2024 had effective arrangements in place to respond to complaints and to support the timely reporting and management of patient safety incidents were in place. The majority of healthcare services were compliant with the national standards on complaints resolution and the management of patient safety incidents. However, areas for improvement were identified during the inspection activity, these included ensuring compliance with national timelines related to the resolution of complaints and the timely completion of reviews of patient safety incidents, ensuring there is a planned, structured, multi-faceted approach to the sharing of recommendations and learning from the review of complaints and patent safety incidents. Sharing learning from patient safety incidents is crucial to prevent recurrence of the incident and to improve patient safety.

### Monitoring and evaluation

The monitoring and evaluation of healthcare services is central to ensuring effectiveness, efficiency, and accountability in delivering safe, high-quality services and care. Monitoring and evaluation provides vital information on the impact of healthcare services, supports informed decision-making and optimal and efficient resource allocation. The majority (82%) of healthcare services inspected in 2024 had robust and effective arrangements in place to evaluate the infection prevention and control standards, medication safety practices and compliance with the response and escalation protocol for the early warning systems. Evaluating the processes that support the safe transitions of care was identified as an area for targeted improvement. Further mitigation was also needed in regard to the timely escalation and management of the deteriorating patient, safe medication practices, which include the delivery of a comprehensive clinical pharmacy service and pharmacy-led medication reconciliation for all people receiving care and treatment in all clinical areas. Information from monitoring and evaluation activities helped identify what was working well, what was not working, and where improvements were needed. Quality improvement initiatives were developed to improve healthcare services but the implementation of these initiatives could be improved to ensure planned improvements are realised in a time-bound manner.

### Risk management

Findings from inspection activity in 2024 showed that a just over a third (39%) of healthcare services inspected had comprehensive arrangements and systems in

place to manage the risk of harm to people receiving care in the services. These arrangements were well established and embedded in some healthcare services, but in 61% of services they required further strengthening to support the effective identification, management and mitigation of risks to people who use the services. Insufficient bed capacity and delays in transitions of care was a common risk identified in the acute and specialist healthcare services, especially those providing undifferentiated urgent and emergency care. Delays impacted on the efficient flow of patients through and from the healthcare service. Consequently, this manifested in overcrowding of emergency departments and other clinical areas. Caring for admitted patients in emergency departments adversely impacted compliance with PETs and was a patient safety risk. The correlation of increased waiting times in emergency departments and increased mortality was a risk and a cause of avoidable harm. Many healthcare services had implemented short, medium and long-term measures to address healthcare service overcrowding, improve patient flow and surge or escalation capacity. However, as the numbers of people attending for urgent and emergency care continues to increase and outpace capacity development, the competing demands between unscheduled and scheduled care continued and inevitability led to the disproportionate focus on managing unscheduled care within healthcare services.

## Conclusion

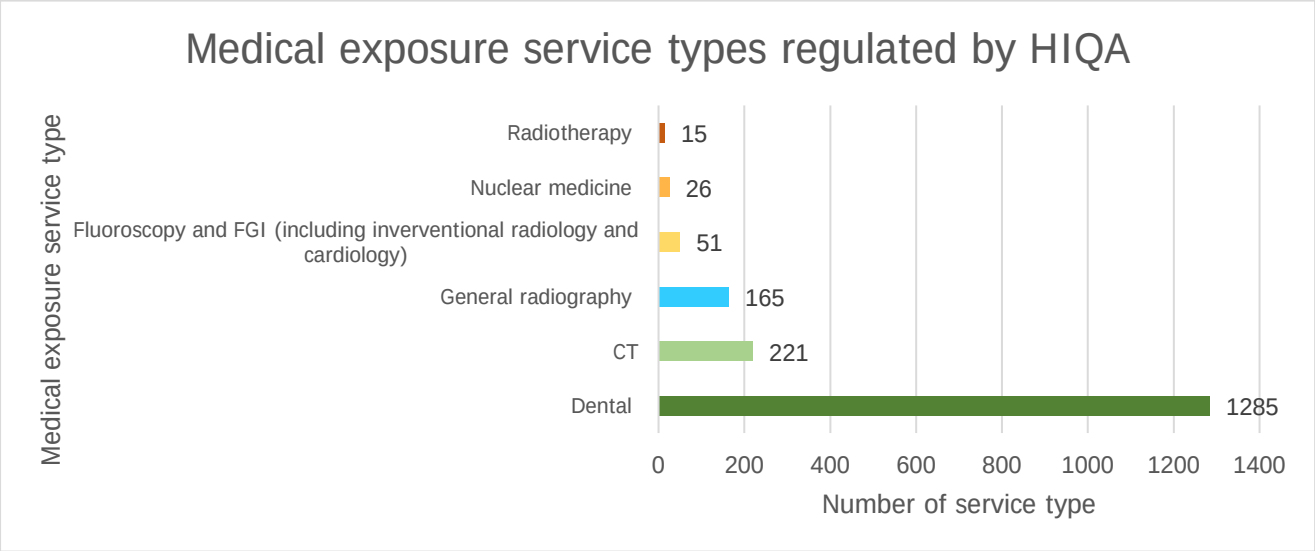
The Sláintecare reform programme will replace the hospital-centric model of care with a more integrated model of care, where care is provided closer to the patient in the most appropriate location. This, with alternative care pathways, increased step-down bed capacity in communities, improved access to primary care services, enhanced access to diagnostic services and dedicated elective care services will help support and improve the current imbalance in meeting the demand for scheduled and unscheduled care. It is also imperative that the Government's planned expansion of inpatient bed capacity is progressed to increase the bed stock across the healthcare sector up to 2031 and beyond. Over 86% of the national standards assessed in 2024, had improved or maintained compliance levels on re-inspection. While this is positive, healthcare services must continue to focus on the essential elements of capacity and capability in order to be responsive and to effectively manage the demand for healthcare services, and ensure there is a sufficiently trained and skilled workforce to support current and future expansion of healthcare services. Processes that robustly manage risks, patient incidents and complaints, together with the continuous monitoring of service's performance will ensure that the safety and voice of patients remain central to the delivery of healthcare services.

# 3. Regulation of Medical Exposure to Ionising Radiation 2024

HIQA is the designated competent authority with responsibility for monitoring against and enforcing the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations, as amended, in Ireland. HIQA fulfils its regulatory functions through inspection and desktop monitoring. Under these regulations, HIQA also has a number of other functions, which contribute to the radiation protection of people using the service. These functions include receiving notifications of accidental and unintended exposures and establishing diagnostic reference levels (DRLs) for medical exposure to ionising radiation.

Since 8 January 2019, under Regulation 6 (Undertakings) of S.I. No. 256 of 2018, as amended, an undertaking[††††], that intends carrying out medical radiological procedures, must notify HIQA of its existence no later than one month before its proposed commencement. This is known as declaring to HIQA. From these declarations, HIQA is currently responsible for regulating 1,430 medical radiological facilities across Ireland, which provide a range of medical exposure service types (Figure 19).

Figure 19: Medical exposure service types regulated by HIQA




## 3.1 Regulation of facilities conducting medical exposures to ionising radiation

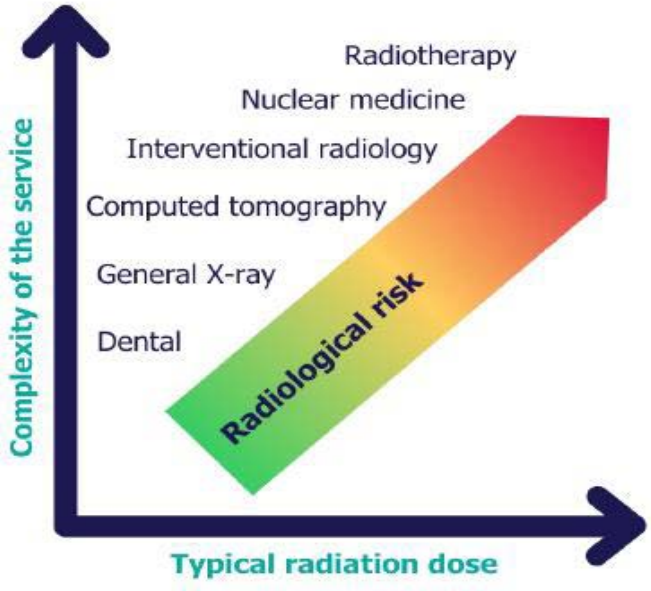
HIQA regulates facilities that conduct medical exposure to ionising radiation through inspections and monitoring of information received from both the facilities and the

[††††] An undertaking is defined in the regulations as 'a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure'.

public, and has escalation and enforcement powers to enforce compliance under law.

HIQA's inspection programme follows a graded, risk-based approach which is informed by the International Atomic Energy Agency's (IAEA) guidance on the *Application of a Graded Approach in Regulating the Safety of Radiation Sources*[10]. Each facility undergoes regular risk assessment that considers the service type and associated risks (Figure 20), compliance history and, where relevant, other information including information HIQA requests from the facility (solicited information), for example, incident notifications and self-assessment questionnaires (SAQ). HIQA also annually inspects a sample of lower radiological risk facilities that have self-assessed as compliant with the regulations, in order to validate information such as the SAQ.

Figure 20: Types of radiological facilities and associated radiological risk



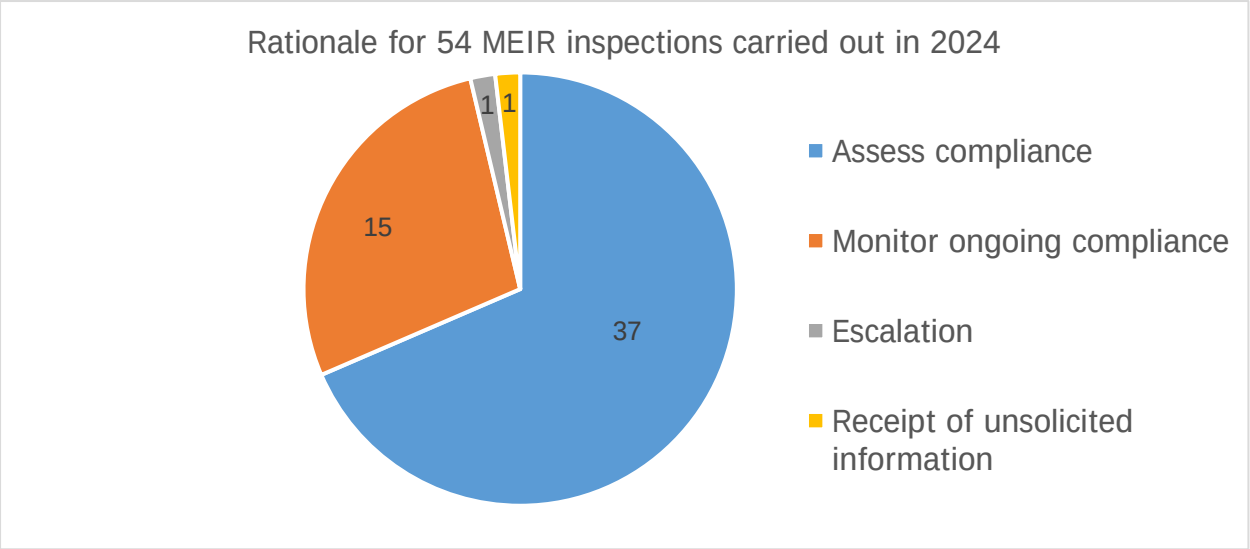

Each undertaking providing medical exposures to ionising radiation must ensure that it is delivering a safe service that complies with the regulations. The regulations set the minimum standard of safe, high-quality care to be provided to people who use healthcare services, and undertakings should continually seek to improve the service provided. While some regulations attribute individual responsibility to a defined person or persons along the patient's pathway, overall responsibility for compliance lies with the undertaking.

For each regulation reviewed during an inspection, the undertaking is found to be compliant, substantially compliant or not compliant with the regulation. Undertakings that are found to be either not compliant or substantially compliant with the regulations are required to take action within a reasonable time frame to address the

issues identified and to comply with the regulations. The level of action required and the time frame is dependent on the risk associated with the non-compliance.

In 2024, HIQA conducted 54 inspections of facilities conducting medical exposures to ionising radiation in Ireland. These inspections were announced to ensure that relevant staff were available to facilitate the inspection. Of the 54 inspections, 44 were carried out in imaging and hospital facilities (including five which provide radiotherapy exposures) and 10 in dental facilities. Fifteen of these facilities had been inspected previously, enabling HIQA to monitor their ongoing compliance with the regulations and to follow up on earlier findings and compliance plans. As discussed in Sections 3.2 and 3.2.2 below, overall, undertakings demonstrated high levels of compliance with the regulations during these inspections. Additionally, one inspection was prompted by receipt and review of information not requested but received by HIQA from the public (unsolicited information) and one was prompted by HIQA's escalation process due to unresolved previous non-compliance, which required urgent action and which had not been addressed within defined timelines (Figure 21).

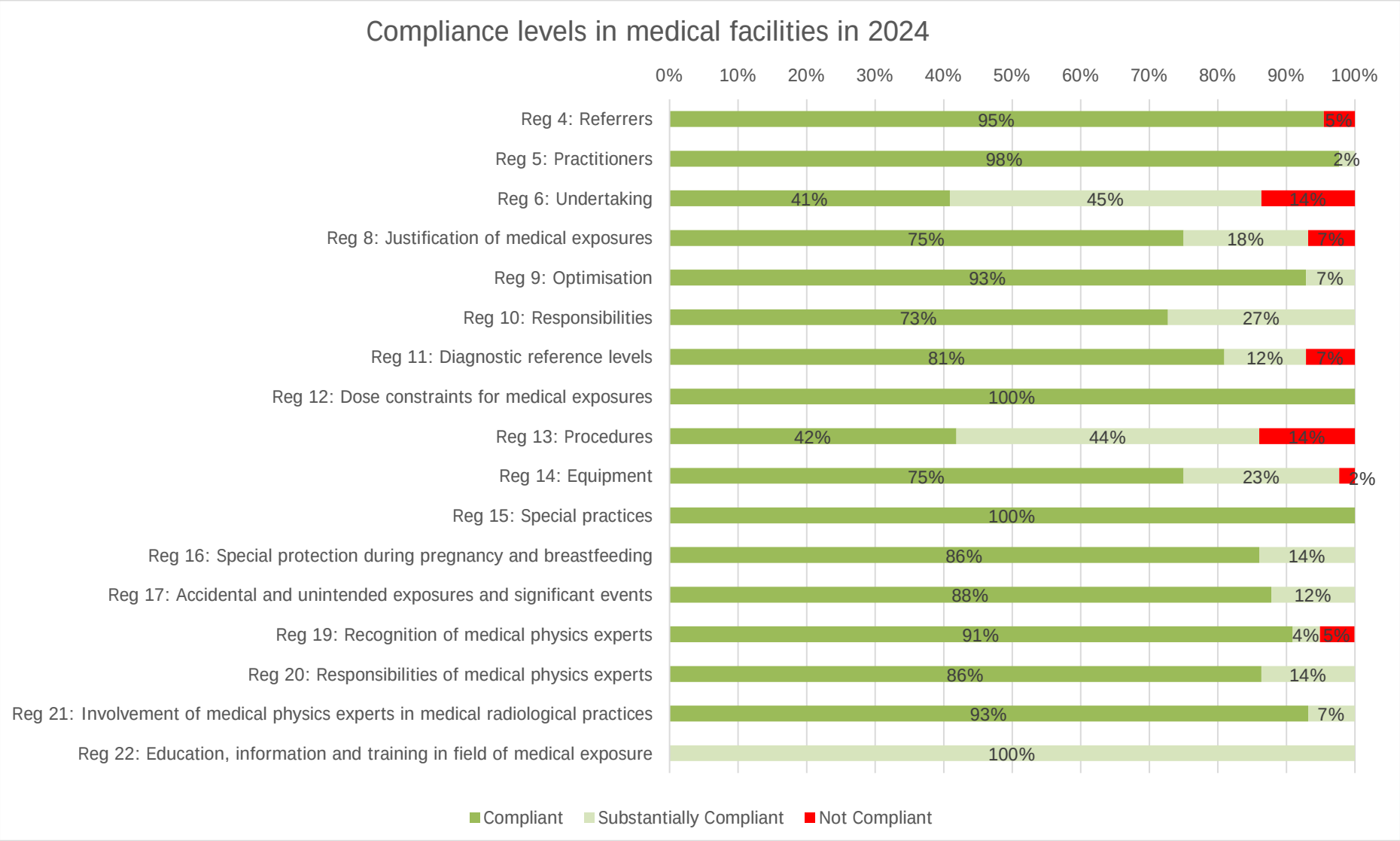
Figure 21: Frequency for rationale for initiating inspections in 2024




## 3.2 Medical facilities: Summary of regulatory compliance in 2024

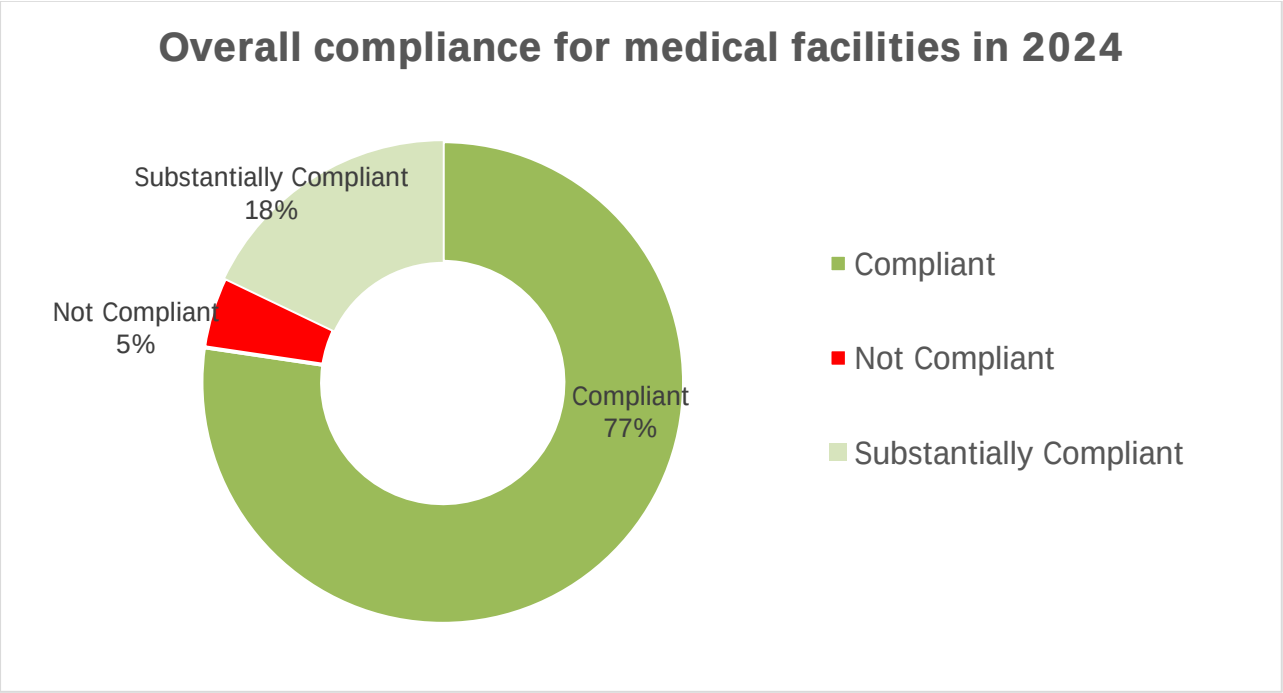
This section summarises HIQA's findings of regulatory compliance in medical facilities (non-dental facilities) conducting medical exposures to ionising radiation in 2024. Figure 22 below summarises the compliance levels for the regulations assessed during the inspection of medical facilities in 2024.

Figure 22: Compliance level for regulations assessed on inspections of medical facilities in 2024



Across medical facilities, overall compliance remained strong. In 2024, 77% of regulations assessed were fully compliant, 18% substantially compliant, and only 5% not compliant which is significantly lower than the 12% identified between 2021 and 2023. This improvement in compliance is a positive finding and may indicate a greater awareness of regulatory responsibilities and stronger radiation protection practices in facilities due to HIQA's inspection programme and other stakeholder activities. Ultimately this improvement in compliance has enhanced the safety of people using the services.

Figure 23: Compliance levels in medical facilities in 2024




### *3.2.1 Positive findings from inspections in 2024*

Similar to findings from previous years, undertakings continued to demonstrate good levels of compliance with:

- Regulation 4: Referrers
- Regulation 5: Practitioners
- Regulation 9: Optimisation
- Regulation 17: Accidental and unintended exposures and significant events
- Regulations 19, 20 and 21 which pertain to Medical Physics Experts.

Compliance with these regulations provided assurances that the allocation of key radiation protection responsibilities, such as referring, optimisation, and clinical responsibility are appropriately assigned by undertakings to recognised professionals, as defined in the regulations. Notably, compliance with Regulation 11

(Diagnostic Reference Levels) improved to 81% (from 64% in 2021–2023), and Regulation 16 (Protection during pregnancy and breastfeeding) improved to 86% (from 68%).

Regulation 9 relates to optimisation, which is one of the fundamental principles of radiation protection, and which must be applied to each medical exposure of ionising radiation carried out. Optimisation helps to minimise unnecessary radiation dose to people using the service, while ensuring that an appropriate dose is delivered to achieve the required clinical outcome, for example, in the diagnosis of a disease or treatment of a tumour. During the inspection programme in 2024, many undertakings were seen to implement multiple, appropriate optimisation measures in their facilities, such as the development, implementation and monitoring of an optimisation policy and comprehensive quality assurance programmes. Optimisation, as a principle, is applicable under many other regulations.

Regulation 15 (Special Practices) recognises that certain groups of people using the service require special radiation protection to ensure that they are appropriately protected when exposed to high doses of ionising radiation, or due to particular circumstances, such as young age. Notably, where high doses of radiation are delivered, for example in radiotherapy, interventional radiology and nuclear medicine, undertakings had implemented strong radiation protection measures. Examples of good measures observed during inspections of radiotherapy and nuclear medicine facilities, included appropriate quality assurance programmes to evaluate the radiological equipment used and programmes to assess and verify the dose delivered and or the administered activity. In many high-dose interventional radiology facilities, systems were in place to alert staff to threshold doses, beyond which tissue reactions could occur. When these higher doses were unavoidable, methods to manage this complication were also in place. Across many of these facilities, inspectors noted that appropriate training and education of staff involved in the justification, optimisation and carrying out of such exposures had been provided.

High levels of compliance were also found under Regulation 12 (Dose constraints for medical exposures). This regulation requires that undertakings ensure that the dose constraints established by HIQA are used in the protection and safety of carers and comforters who are exposed to a radiation dose. A carer and comforter is a person who receives an exposure of ionising radiation, other than through their work, when supporting and comforting a service user having a medical exposure. For example, they may be a parent supporting a child having an X-ray at a dental practice. The awareness and use of dose constraints ensures that the doses received by these groups are kept as low as reasonably achievable. During the 2024 inspection programme, it was observed that many undertakings had good measures, such as policies and guidelines on the use of dose constraints, and good monitoring systems

to record dose and frequency of exposure to persons acting as carers and comforters.

Further examples of good practice found in inspected facilities in 2024 included:

- The recording of dose information on medical exposure reports, which is a requirement of Regulation 13(2). In many re-inspected facilities, considerable improvements in compliance was identified with respect to this particular regulation.
- Ongoing training of medical physics staff to ensure the continuity of medical physics expert involvement in facilities.
- Numerous undertakings had shared learning across facilities, which contributed to minimising the likelihood of incidents for patients undergoing medical exposures.
- DRLs had been established for both adult and paediatric procedures and were displayed in clinical areas in clear, visible formats such as colour-coded posters.
- Strong commitment was shown by staff towards improving the radiation protection of people using facilities, in particular the neonatal population in the facilities inspected in 2024.

### *3.2.2 Areas for improvement*

Improvements in compliance were required under a number of regulations assessed in 2024, in particular under Regulation 6: Undertakings and Regulation 13 (Procedures), specifically Regulation 13(4).

Regulation 6 (Undertaking) requires that the undertaking clearly allocates roles and responsibilities for radiation protection to appropriate personnel along the medical exposure pathway. Regulatory guidance developments in 2023 in relation to the justification of new practices (Regulation 7 (Justification of new practice)) and the publication of HIQA's *National Procedures for Clinical Audit of Medical Radiological Procedures* in November 2023[11] meant that undertakings were required to allocate particular responsibilities for these aspects. However, as routine assessment of these regulations formed part of HIQA's 2024 inspection programme, it was found that key roles and responsibilities in these areas had not been considered and or allocated by many undertakings, which contributed to poor compliance levels under Regulation 6. As part of the inspection process, inspectors discussed these gaps with the services to ensure improved understanding and clarity on what was required to comply with this regulation. The allocation of roles and responsibilities, including allocation for the justification of new practices, and for clinical audit, will continue to be a focus in our inspection programme.

Additionally in some facilities, non-compliance with Regulation 6 was identified because clinical evaluation of the outcome of each medical exposure was not being carried out by a recognised practitioner. This was mainly evident for a particular sub-set of interventional radiology procedures in theatre departments, which are conducted outside the main radiology departments. Although inspectors were satisfied that this gap did not result in any urgent risk to people using the service, it was an area that required attention by undertakings.

Regulation 13 (Procedures) has four sub-regulations, each covering separate and distinct areas of radiation protection. In previous years, poor compliance levels were identified with Regulation 13(2), which states that the undertaking should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure. Although many facilities demonstrated improvements under this sub-regulation in 2024, gaps were identified for particular sub-sets of exposures in some facilities, as detailed in individual inspection reports and addressed in satisfactory compliance plans subsequently submitted by undertakings.

Additionally, while many facilities had made good efforts to comply with Regulation 13(4) since the publication of HIQA's national procedures for clinical audit further work was required in some facilities to fully align with the procedures. In particular, undertakings should ensure that a clinical audit strategy is developed which encompasses the principles set out in the national procedures and ensures that clinical audit topics span the full patient journey, covering the structures, processes and outcomes relating to medical exposures.

## 3.3 Dental facilities: Summary of regulatory compliance in 2024

HIQA currently regulates over 1,200 dental facilities which carry out medical exposure to ionising radiation in Ireland. In general, these facilities use low dose radiation (low radiological risk) and, in accordance with HIQA's graded approach to inspection, are inspected less frequently than facilities with higher radiological risk. However, other methods to monitor these facilities are used, including the receipt and review of self-assessment questionnaires (SAQs) and by inspection when required, or as part of random sampling.

### *3.3.1 Self-assessment questionnaires*

As part of HIQA's monitoring programme, dental undertakings are issued with a self-assessment questionnaire (SAQ) shortly after they declare to HIQA. HIQA has devised two distinct self-assessment questionnaires for dental facilities, depending on the facility type.

When completing the SAQ, the undertaking is required to self-assess their level of compliance with a number of the regulations. HIQA inspectors then review the

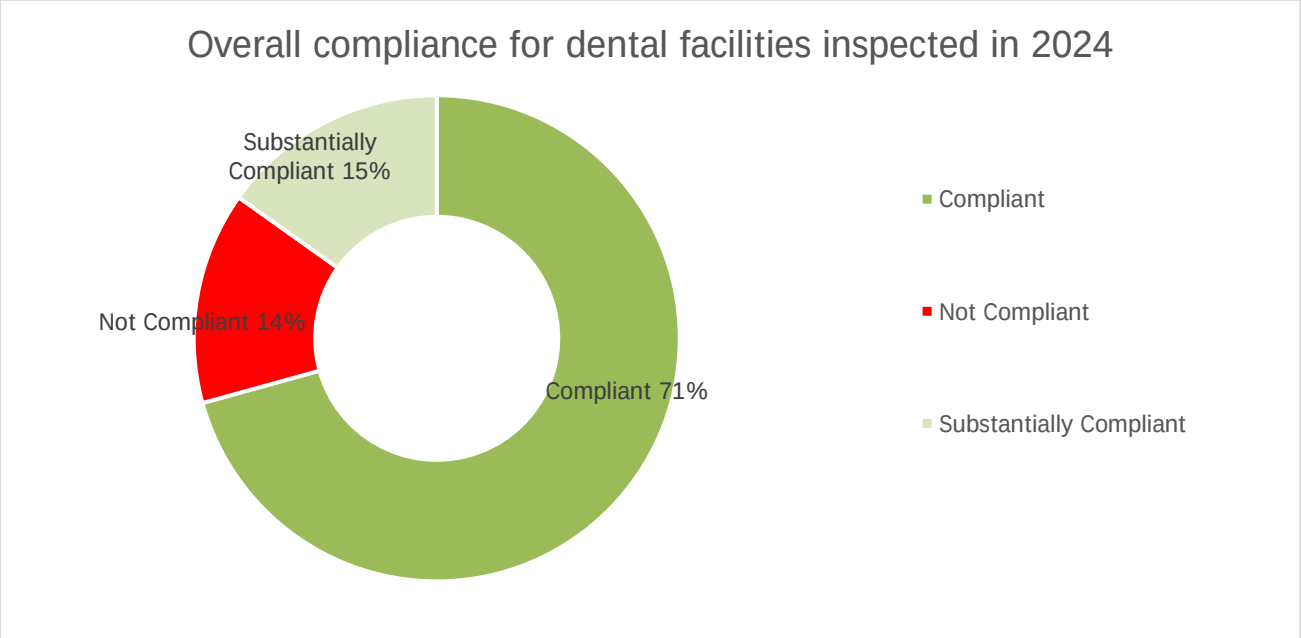
undertaking's response to the SAQ, and use this information to determine the level of regulatory risk in the facility and its potential impact on people using the service. Inspectors may also communicate further with the undertaking following the receipt of the completed SAQ. When satisfactory assurances are received from the undertaking, the SAQ is recorded and retained for future information, and some of these facilities may be inspected through HIQA's random sampling of dental facilities. Where undertakings fail to communicate with HIQA, or gaps in compliance are identified in the SAQ, further regulatory action is prompted, such as an inspection.

In 2024, 29 self-assessment questionnaires were received and processed by HIQA. Each SAQ submitted by the undertaking was self-assessed as compliant with the regulations.

### *3.3.2 Inspections of dental facilities in 2024*

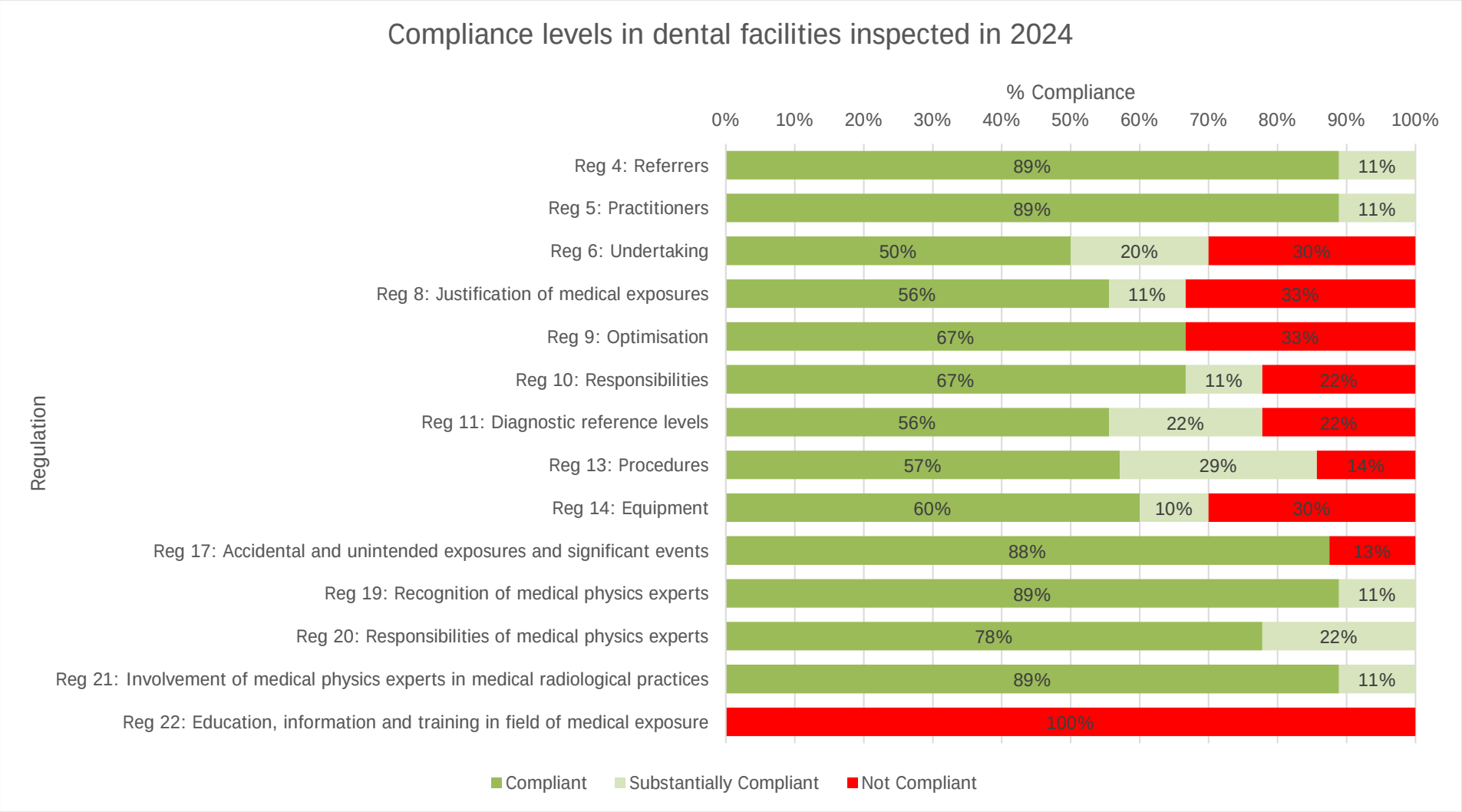
In 2024, 10 dental facilities were inspected. This included facilities identified through an annual risk assessment of all declared facilities and also a random sample of facilities. An annual risk assessment is completed for each dental undertaking and facility, with SAQs, unsolicited information and known compliance history considered during this assessment.

Figure 24: Overall compliance with the regulations in dental facilities inspected in 2024




An inspection checks the validation of information received and enables HIQA to assess the level of compliance with the regulations. In 2024, 29% of the regulations assessed were found to be non-compliant in dental undertakings, as illustrated in Figure 24.

Figure 25: Compliance level for each regulation assessed in dental facilities in 2024



As shown in Figure 25 above, dental undertakings had generally good compliance with many of the regulations assessed in 2024, while poor compliance was observed with a number of regulations including:

- Regulation 22: Education, information and training in the field of medical exposure
- Regulation 14: Equipment
- Regulation 13: Procedures
- Regulation 11: Diagnostic Reference Levels
- Regulation 9: Optimisation
- Regulation 8: Justification of medical exposures
- Regulation 6: Undertaking.

It is important to note that not all regulations are assessed during every dental facility inspection and certain regulations may be prioritised due to information received by HIQA prior to the inspection or gathered during the inspection.

In 2024, for example, Regulation 22 (Education, information and training in the field of medical exposure) was only assessed when gaps in compliance with the training requirements for cone beam CT imaging, as prescribed by the Irish Dental Council, were identified.

Under Regulation 14 (Equipment), dental undertakings remain responsible for ensuring that each piece of radiological equipment is kept under strict surveillance. While medical exposure procedures conducted in dental facilities carry a lower level of radiological risk, it is important that undertakings ensure that quality assurance testing is performed in line with manufacturers' guidelines and in accordance with the medical physics expert's advice.

Additionally, undertakings must demonstrate compliance with Regulation 13 (Procedures), which includes ensuring that written protocols are in place for common examinations, referrer guidelines are available to referrers, and that clinical audit is carried out in line with the national procedures established by HIQA.

Regulation 11 (Diagnostic Reference Levels), requires that undertakings establish DRLs at local facility level, regularly review and compare these with national levels and apply local DRLs in daily practice. Through regular reviews, doses which consistently exceed relevant local and national DRLs are identified and addressed. Furthermore, the undertaking must ensure that staff are educated on, and aware of the use of DRLs for protection of people using the service.

In a dental facility, all referrer and practitioner responsibilities may lie solely with the dentist. However, in order to comply with Regulation 6 (Undertakings), the undertaking must ensure that there is a clearly documented allocation of responsibility for radiation protection in its organisation. This ensures that each dentist working in the facility is aware of and understands their individual and collective responsibilities when carrying out medical exposures to ionising radiation. It also ensures that there is a clear allocation of responsibilities for the medical physics expert and those delegated the practical aspects for all medical exposures. The undertaking must also ensure that the allocation of responsibility is only assigned to professionals who have completed training requirements, as specified by the Irish Dental Council,[12] for standard dental radiographs and the additional training requirements for referrers and practitioners involved in cone beam CT medical radiological procedures. The latter has been identified as an area of improvement in some inspections and has resulted in escalation and increased monitoring by HIQA, as required.

## 3.4 Other Competent Authority functions

Under the regulatory framework of the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations, as amended, HIQA is responsible for carrying out a number of functions, in addition to our inspection programme, which contribute to and enhance the radiation protection of people using the service. These functions include the receipt and review of information from undertakings and the development of guidance to direct and assist undertakings in the radiation protection of people using the service.

### *3.4.1 Overview of lessons learned from receipt of statutory notifications of accidental and unintended exposures in 2024*

Under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 as amended, undertakings have a statutory responsibility to submit notifications to HIQA on significant events arising from accidental or unintended medical exposure to ionising radiation, as they occur in their facilities. Under these same regulations, HIQA is required to analyse notifications received and to share the lessons learned from the associated incident investigations.

In September 2024, HIQA published its annual report of lessons learned from the statutory notifications and associated investigation reports, on accidental and unintended exposures to ionising radiation, processed in 2023. A supporting poster and infographic, available in both Irish and English, were also published to clearly communicate the lessons learned to undertakings and their staff.[13]

This report of lessons learned outlined a number of key findings from analysing the incident and investigation reports submitted to HIQA in 2023. For example, fewer facilities reported to HIQA in 2023 than in 2022, however the total number of notifications submitted increased by 18% from the previous year. This year-on-year increase in the number of incidents reported to HIQA is a positive development and highlights the greater awareness that undertakings have of their responsibility to report incidents to HIQA. The first notification submitted by a dental facility was also received in 2023.

A separate annual report is also available on the lessons learned from the statutory notifications of accidental and unintended exposures to ionising radiation that were submitted to HIQA in 2024.

### *3.4.2 Significant event review*

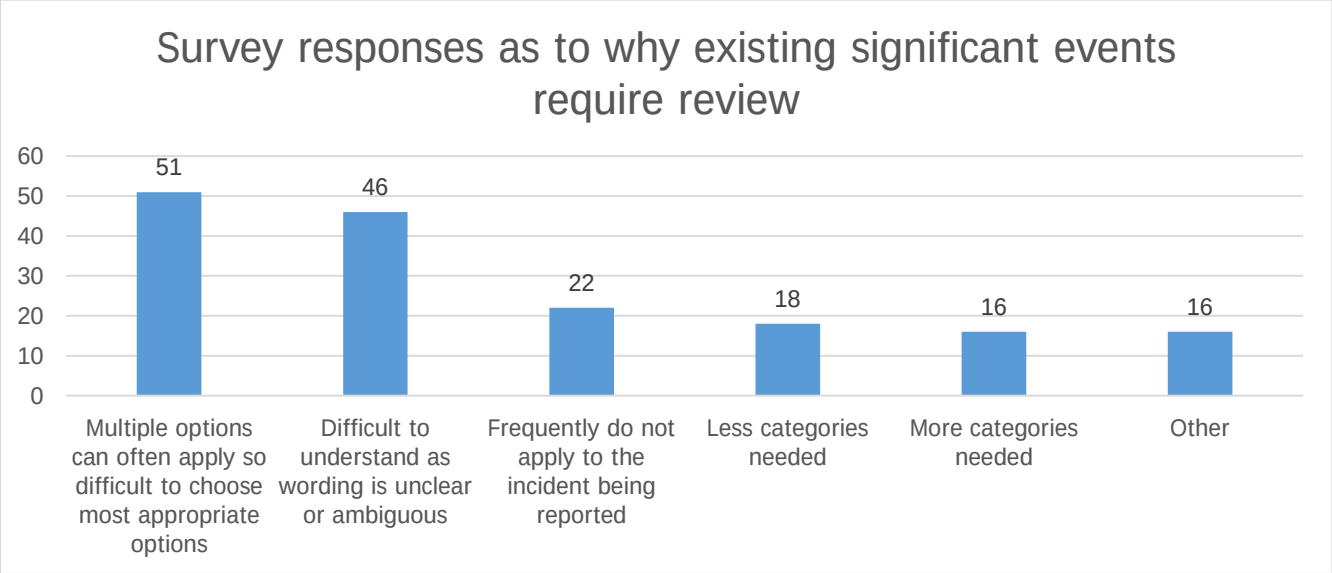
Under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to ionising Radiation) Regulations 2018, as amended, HIQA is responsible for defining significant events that undertakings are required to notify to the Authority, as they occur in their facilities.

On commencement of the regulations, HIQA adopted, with minor changes, the significant events in place under the previous competent authority. After five years of regulation in 2024, it was deemed timely to conduct a review of, and where necessary revise, current significant events. This review aims to improve awareness on the reporting and investigating of such events, and thereby improve the learning and corrective actions implemented to mitigate the risk of such events recurring in services.

The review began in 2024 with a literature review that considered significant event types that are notifiable to competent authorities internationally. This literature review was then complemented by a survey on the existing significant events that was issued to designated managers of medical radiological facilities, with a request to disseminate to key personnel in their services. A total of 74 responses were received from those involved in the radiation protection of people using the service, such as radiographers, radiation therapists, medical physics experts, radiologists and radiation oncologists.

Figure 26 highlights the various reasons that almost 75% of respondents agree that a review is warranted. Based on survey feedback, revised significant events have been drafted and will be presented to key stakeholders at selected events and focus groups throughout 2025, for review and discussion.

Figure 26: Rationale for significant event review




### *3.4.3 National Diagnostic Reference Levels for Fluoroscopy and Fluoroscopically Guided Interventions*

Under Regulation 11, HIQA has a statutory responsibility to establish and review national Diagnostic Reference Levels (DRLs) for ionising radiation procedures. DRLs are typical radiation dose values established for common medical imaging procedures, which support medical radiological facilities by allowing them to compare and optimise their local imaging doses to a national standard.

In 2024, HIQA published its scientific paper "Establishing national diagnostic reference levels in fluoroscopy and fluoroscopically guided interventions in Ireland and comparing these with national diagnostic reference levels in Europe and internationally" in *The European Journal of Radiology.*[14]

Fluoroscopy is a procedure that uses ionising radiation to produce real-time imaging of the body; while fluoroscopically guided interventions (FGI) use this imaging method to help guide devices and equipment used for medical diagnostic or treatment purposes. Over 120,000 adult fluoroscopy and FGI procedures are carried out every year in Ireland, with coronary angiogram being the most common. The scientific paper followed up on the work completed and published by HIQA on its website in 2022. This work established national adult and paediatric DRLs for an extensive range of fluoroscopy and FGI procedures, many for the first time.

Nationally established DRLs aid undertakings in keeping radiation doses as low as reasonably achievable for people using the service, minimising their exposure to radiation while still providing the required diagnostic information. Scientific publication helps to disseminate new research findings, facilitate peer review and evaluation, and foster a collaborative environment for knowledge advancement.

### *3.4.4 National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation*

Under Regulation 13(4), undertakings must ensure that clinical audits are carried out in accordance with the HIQA National Procedures for Clinical Audit of Medical Radiological Procedures, as established by HIQA in 2023, following an amendment to S.I. 256 of 2018. These national procedures provide guidance to undertakings on the approach to implementing clinical audit in medical radiological facilities.

HIQA recognises that there is a wide spectrum of radiological risks associated with different types of medical exposures, and therefore has provided specific examples of approaches to be taken by different undertaking types, such as dental imaging, nuclear medicine, radiotherapy and so on. The development of the national procedures involved an extensive stakeholder engagement campaign with a broad range of affected parties.[11]

In 2024, through its inspection programme, HIQA began monitoring undertakings' compliance with Regulation 13(4), and saw that many had made good efforts to implement the national procedures in their facilities. Examples of good compliance included the development of local clinical audit strategies, identification of clinical audit topics that focused on multiple aspects of radiation protection of people using the service, and the incorporation of audit report templates into local audit processes.

However, inspectors also identified that improvement was required in some facilities to ensure that:

- the principles and essential criteria, as set out in the national procedures, are included in local clinical audit documents
- appropriate oversight structures are in place for clinical audit
- radiology departments' clinical audit programmes are incorporated into hospitals' established clinical audit programmes.

For clinical audit to be meaningful, sustainable and achievable, it should align with regulatory requirements and be integrated into the facility's overall audit programme.

### *3.4.5 The Ionising Radiation National Dose Report*

In 2024 the Environmental Protection Agency (EPA) and HIQA jointly published an assessment of the average radiation doses received by the Irish population. *The Ionising Radiation – National Dose Report*[15] assessed the radiation exposure over the last five years received from the air, medical exposures, diet, and exposures to radiation in the environment.

This report is an update of a 2014 assessment, and the current assessment found that the average dose remains similar to that found a decade ago. The assessment found medical exposures account for just over 10% of a person's average annual exposure or dose. Additionally, the assessment found that:

- nearly 60% of the dose is due to the radioactive gas radon in indoor air, with more than 8% coming from exposure to thoron, another radioactive gas
- just over 10% of the dose comes from medical exposures, mainly from medical imaging
- nearly 9% comes from cosmic radiation, of which 2% is due to exposure received during flights
- just over 7% comes from our food and drinking water
- nearly 6% comes from radiation from the ground, as gamma radiation.

People in Ireland receive a slightly higher average radiation dose than the European average, mainly due to radon exposure in the home and in the workplace. Radioactivity from artificial sources, such as discharges from international nuclear facilities, fallout from historic nuclear weapons testing, and past nuclear accidents comprise less than 1% of overall exposure.

The dose contribution from medical exposure was estimated mainly from surveys issued by HIQA to health facilities providing medical exposures to ionising radiation. The surveys established that the largest contributor to the average annual dose from medical exposure was from CT scans.

However, the assessment by HIQA also established that the average amount of radiation from medical exposure has decreased over the last 10 years. This may be partly due to the use of new technologies and improvements in procedure optimisation. This decrease demonstrates that patients are typically receiving less radiation dose on a population basis from imaging when compared to the previous report in 2014.

### *3.4.6 International Atomic Energy Agency Integrated Regulatory Review Mission*

In 2024, HIQA commenced preparations for the International Atomic Energy Agency (IAEA) Integrated Regulatory Review Facility (IRRS) Mission. An IRRS mission is an international peer review process during which an expert team of radiation protection experts formed by the IAEA, will visit Ireland in January 2026 to assess Ireland's regulatory framework for nuclear and radiation safety against IAEA Safety standards. The aim of an IRRS mission is to strengthen and enhance the effectiveness of the national regulatory infrastructure for radiation safety, radioactive waste and transport safety, and the security of radioactive sources.

Ireland hosted its first IRRS Mission in 2015, with one of the key findings being the lack of an effective legal framework in Ireland for the regulation of patient protection from ionising radiation. This led to HIQA being assigned as the competent authority in Ireland for patient protection in relation to medical exposure to ionising radiation. Within HIQA, a cross-directorate project team was established and overseen by HIQA's Executive Management Team.

HIQA will have the opportunity to demonstrate its regulatory and health technology assessment programmes relating to medical exposures that have been developed and implemented since the previous mission to promote better, safer practice across all facilities using medical exposures in Ireland. It will also provide HIQA with an opportunity to learn from the experiences of other regulators, and to contribute to a harmonised regulatory approach across numerous states.

Preparation for the mission was led by a national project management team and involved collaboration and input from key external stakeholders. The main organisations involved in preparing for this mission are the two regulatory bodies – the EPA and the HIQA – along with their parent departments, the Department of Climate, Energy and the Environment and the Department of Health, respectively.

## 3.5 Conclusion

In 2024, as the competent authority in Ireland with responsibility for monitoring compliance in medical radiological facilities in Ireland, HIQA continued to fulfil its regulatory functions and engage with relevant external stakeholders to further enhance the radiation protection of service users.

Throughout the year, HIQA found that overall compliance with the regulations was good in the inspected services. Inspectors identified many examples of good practice by undertakings that ensured the radiation protection of people using the service, for example appropriate and effective optimisation practices. However, inspectors also identified areas that continue to show higher levels of non-compliance with the regulations, such as gaps in the allocation of responsibilities in radiation protection and in information relating to patient exposure forming part of the report of the medical radiological procedure. Where non-compliances, such as these, were identified, compliance plans outlining the actions to be taken were submitted by undertakings.

Through monitoring, inspection and continued stakeholder engagements, HIQA ensures undertakings seek to improve compliance in these areas. As clinical audit, in line with the national procedures, is further developed and embedded in medical radiological facilities, undertakings should continue to assess their own regulatory compliance and take the necessary actions to ensure regulatory compliance.

Going forward, HIQA will continue to engage with and support undertakings through inspection programmes and ongoing work relating to other statutory functions including:

- sharing lessons learned from incident investigations
- continued work on the review and revision of reportable significant events
- continued development of national DRLs
- management of self-assessment questionnaires submitted by dental undertakings.

In addition, HIQA will continue to engage with external stakeholders through a number of fora at local, national and international level, with details of some of the engagement completed in 2024 included in section 4.3. In addition, HIQA will continue to collaborate with key regulatory bodies including the EPA and the Dental Council.

HIQA looks forward to demonstrating its regulatory programme and approach to generic justification relating to medical exposures to ionising radiation to the International Atomic Energy Agency (IAEA) Integrated Regulatory Review (IRRS) Mission in early 2026, and to considering any recommendations that may result from this review.

# 4. What people told us about services and how we engaged with stakeholders in 2024

HIQA receives information about healthcare services from a variety of sources. This information is categorised as solicited and unsolicited information. Unsolicited information is defined as information that is not requested by HIQA but is received from people, including people who use the healthcare services. In addition, throughout 2024, HIQA engaged with various external national and international stakeholders, to consult and share information on the work we do. This is further described under Section 4.3.

## 4.1 Overview of unsolicited information received by HIQA

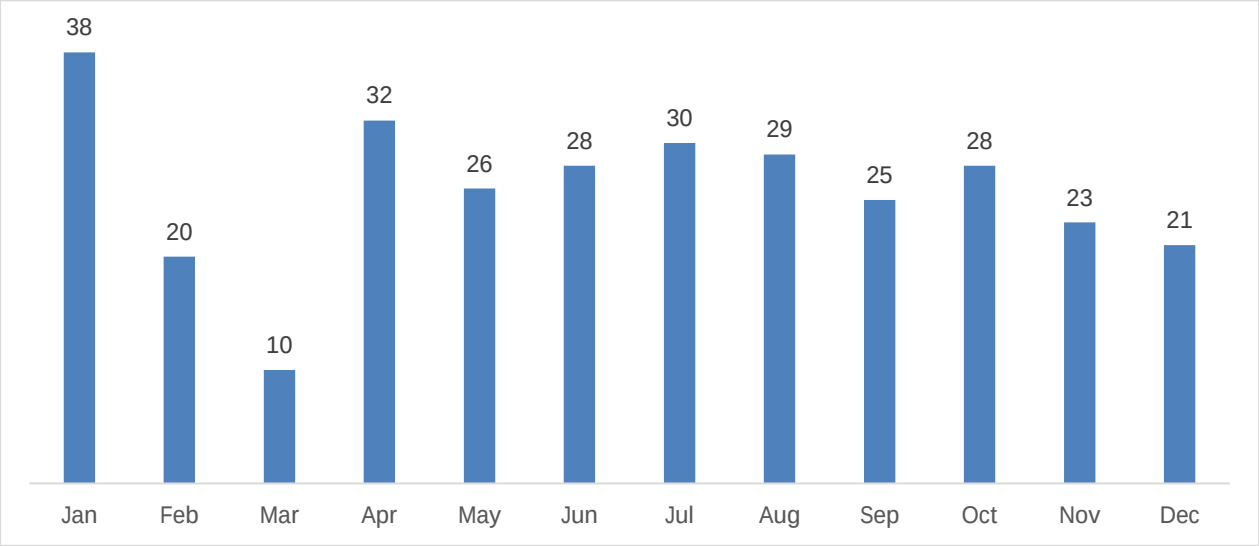
HIQA welcomes feedback about people's experiences of services to inform the assessment of the quality of care received within healthcare services. This information is referred to as unsolicited information and can be received from people who use the healthcare services, their family members or advocates, health and social care professionals, employees, and the general public.

While HIQA currently has no legal remit to investigate an individual complaint about care under the Health Act 2007, it uses this information to monitor the quality and safety of care. All information received is reviewed and risk rated and used alongside the other information gathered about a healthcare service to inform and prompt monitoring activity that informs regulatory judgments.

This section of the overview report sets out a detailed analysis of the 310 pieces of feedback HIQA received in 2024 about healthcare services under HIQA's remit. This includes data on who has contacted us in relation to unsolicited information, a breakdown and analysis of unsolicited information and how HIQA used this information to inform our work.

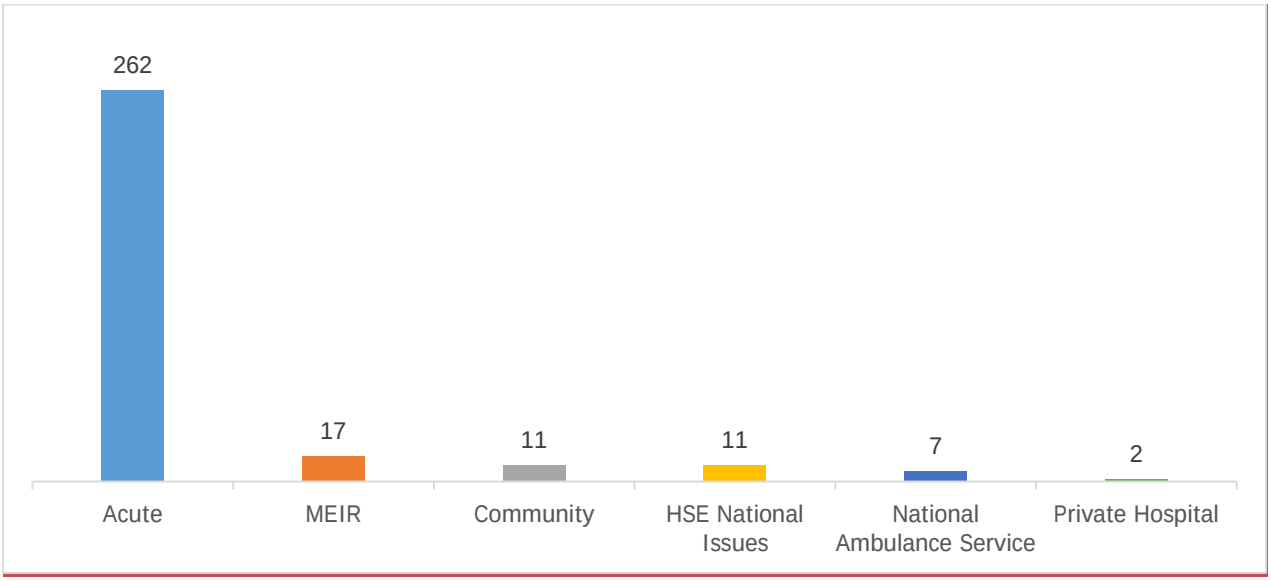
In 2024, HIQA received 1,769 pieces of feedback for all services within its remit. Feedback about acute and specialist, community and private hospitals, medical exposure to ionising radiation services, and HSE national services accounted for 17.5% (310 pieces of information) of the feedback received (Figure 27). Compared to the 352 unsolicited information received in 2023, this represents a 12% decrease in the volume of feedback received in 2024. In 2024, six pieces of complimentary feedback were received.

Figure 27: Number of healthcare unsolicited information received per month during 2024




Of the 310 pieces of information received, 262 (84.5%) related to acute hospitals, 17 (5.5%) related to medical exposure to ionising radiation services, 11 (3.5%) related to community or rehabilitation hospitals, 11 (3.5%) related to HSE national issues, seven (2%) related to the National Ambulance Service and two related to private hospitals‡‡‡‡ (Figure 28).§§§§

Figure 28: Unsolicited information received by service type for healthcare services in 2024

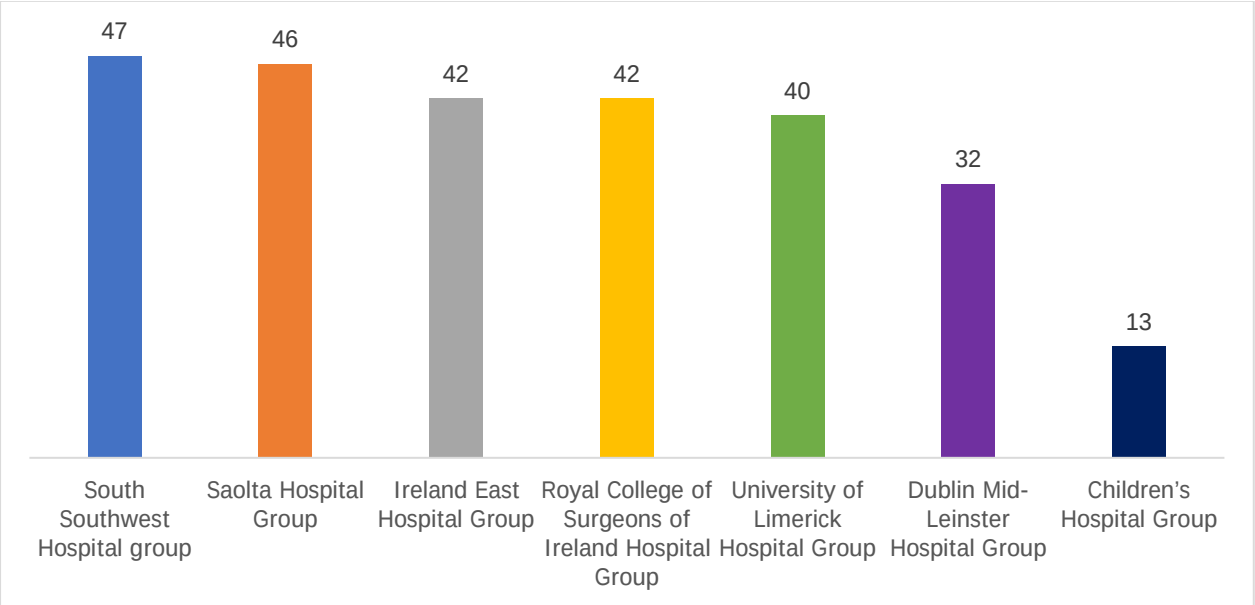



Acute and specialist hospitals accounted for 84.5% (262) of the unsolicited information received. At the beginning of 2024, acute hospitals were organised into

‡‡‡‡ The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 came into effect on 26 September 2024 and this brought a number of private healthcare providers under HIQA's remit.

hospital groups led by a Group CEO and community services were provided separately through a structure of nine CHOs. By the end of 2024, the HSE had progressed reform by introducing regional heath areas. With this change, hospital groups and CHOs were integrated in the new HSE Health Region in their area, with the management of hospital groups and CHOs being stood down on a planned basis. For the purposes of this overview report, we have set out a breakdown of the number of pieces of unsolicited information received for acute and specialist hospitals within their respective hospital groups in 2024 (Figure 29).

Figure 29: Breakdown of acute hospitals into their respective groups

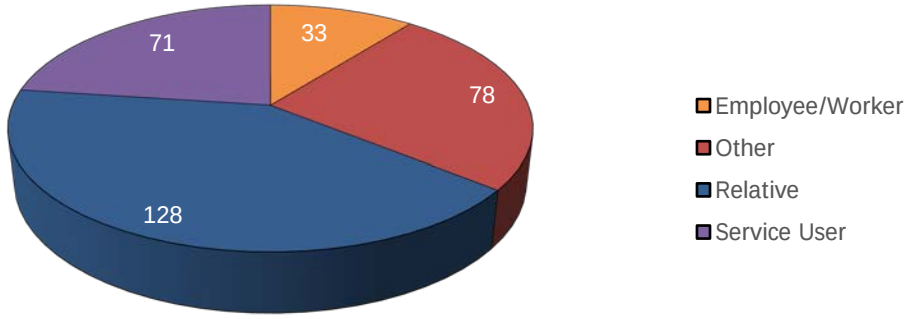



### *4.1.1 Who contacted HIQA about healthcare services?*

People[*****] using healthcare services accounted for 23% (71) of the 310 pieces of information received about healthcare services. Relatives[†††††] accounted for 41% (128) and 10.5% (33) were from employees of services (Figure 31). HIQA also managed 40 (13%) externally sourced unsolicited information from 'others' including members of the public, health and social care professionals and the national confidential recipient (Figure 30). This figure is higher than the information received from people using any other services within HIQA's remit.

Figure 30: Breakdown of origin of contact persons for healthcare unsolicited information received in 2024

[*****] One piece of information from a service user was received via the National Care Experience Programme.
[†††††] Four pieces of information from a relative were received via the National Care Experience Programme.




HIQA collates and classifies information raised through internal surveillance of data, key national reports and other sources including published literature, coroner's reports and media articles. Of the 310 unsolicited information raised about healthcare services in 2024, 38 (12.5%) of these were created by HIQA inspectors in response to internal surveillance.

### *4.1.2 Qualitative assessment of information received by HIQA*

Across all feedback received in 2024 about healthcare services, the five most common themes[‡‡‡‡‡] under the *Quality and Safety* dimension were:

- safeguarding[§§§§§]
- rights
- the quality of care
- risk management
- infection prevention and control measures
- complaints handling.

The breakdown of the quality of care theme included assessment and care planning, healthcare, personal care, nutrition and hydration and medicines management.

The five most common themes of feedback received under the *Capacity and Capability* dimension included:

- governance and management
- communication
- staffing
- information governance.

[‡‡‡‡‡] A piece of feedback can include more than one theme.
[§§§§§] Safeguarding is the measures that are put in place to reduce the risk of harm, promote and protect people's human rights and their health and wellbeing, and empowering people to protect themselves (National Standards for Adult Safeguarding, HIQA/MHC 2019).

### *4.1.3 How HIQA manages unsolicited information*

All unsolicited information received is acknowledged, logged and examined by HIQA. The information is reviewed by an inspector to establish if the information received indicates a risk to the safety, effectiveness, and management of the service, and the day-to-day care people using the service receive. Unsolicited information allows HIQA to:

- ensure services continue to meet high standards of care for people using the service
- consider how well services handle complaints and use them as opportunities to improve care for people using the service
- identify any trends or patterns that could indicate that something unacceptable is happening in a service.

If HIQA considers that the healthcare service provider may not be compliant with the national standards, we can respond by:

- asking the healthcare service provider to submit additional information on the issue
- requesting a plan from the healthcare service provider outlining how the issue will be investigated and addressed
- using the information on inspection
- carrying out an unannounced inspection to assess the quality and safety of the care being provided in the healthcare service.

In addition, where the information indicates that people may be at immediate risk, HIQA will use its full legal powers and report the incident, where appropriate, to other relevant agencies.

### *4.1.4 What has happened with the feedback provided about healthcare services?*

All feedback received by HIQA is brought to the attention of the inspector. The inspector reviewed the feedback in line with the information they already had about the service, risk rated the information and determined the appropriate action to take.

Inspectors have a variety of regulatory actions that they can take in response to feedback received. This is informed by their regulatory intelligence about a service, which would include other feedback received, solicited information including statutory notifications and the regulatory compliance history of the service. The regulatory actions available to the inspector include using the information to inform lines of enquiry for the next scheduled inspection of the centre, seeking an updated compliance plan, seeking a provider assurance report or triggering a risk inspection.

Of the feedback received during 2024, 78.5% was used to inform the ongoing monitoring of the respective healthcare services and were included as lines of enquiry at the next inspection. A further 3% contained similar information to a previous piece of feedback received. Of the remaining information, inspectors sought assurances for 54 pieces of information (17.5%) and used both the feedback and the assurances provided in the provider assurance report to inform lines of enquiry at the next inspection.

## 4.2 Overview of solicited information received by HIQA as statutory notifications under the Patient Safety Act

The Patient Safety Act requires that certain incidents are notified to HIQA by healthcare service providers. The Patient Safety Act commenced on 26 September 2024. These notifiable incidents relate to very serious adverse events resulting in unanticipated and unintended deaths or outcomes of traumatic births. Unfortunately, these types of adverse events can and sometimes do occur in healthcare services. The occurrence of an accident or adverse event in a health service is not necessarily an indication of poor care. For healthcare providers, the Patient Safety Act facilitates:

- mandatory open disclosure, by healthcare service providers of certain incidents occurring in the course of the provision, to a person, of a health service
- apologies made in the course of such disclosures and the use of any other information relating to the open disclosure provided
- provisions for procedures in respect of clinical audit, and the data obtained in clinical audits.

The requirement for healthcare service providers to notify HIQA on the occurrence of a notifiable incident is a patient safety measure which will enable HIQA to obtain and use information about incidents for the purposes of monitoring patient safety. These notifiable incidents are set out in Appendix 8. Based on the context of the incident types, it was expected that these events will predominantly happen in a surgical or obstetric setting. However, in principle, a notifiable incident may occur in any healthcare service provider setting where a health practitioner such as a doctor or nurse provides a health service.

### *4.2.1 HIQA process for managing notifiable incidents*

Following submission of the initial notification, the notification will be reviewed and assessed by an inspector. When the completed notification is received, the information will be risk-assessed within five days of receipt and an inspector will decide on an appropriate response. Possible responses include:

- Requesting additional or further information under Section 31 of the Patient Safety Act. Such information may be requested if it is required and or necessary for the performance of HIQA's functions, having had regard for the nature of incident and the safety of patients. The information provided on foot of a request under this section shall be provided in such manner as HIQA specifies in the request.
- Seeking further assurance from healthcare service providers for which HIQA has a monitoring role under Section 8 of the Health Act 2007.
- Referring the information to an appropriate agency or body if required.
- Carrying out other regulatory activity such as an inspection of the service for which HIQA has a monitoring role under Section 8 of the Health Act 2007.
- Closure and retention of the notification in line with HIQA's data retention policies.

### Notifications received from September 2024 to December 2024

Section 27 (1) of the Patient Safety Act requires that, *"where a health services provider… is satisfied that a notifiable incident, specified in subsection (2) has occurred in the course of the provision by the health services provider of a health service to a patient, it shall notify the Authority of that notifiable incident—(a) as soon as practicable, and (b) in any event, not later than 7 days from the day on which the provider was satisfied the incident had occurred*. This means that notifications must be reported as soon as possible and in any event, not later than seven days from the day on which the healthcare service provider was satisfied the incident had occurred.

Between the 26 September and 31 December 2024, HIQA received 32 notifiable incidents from healthcare service providers. Of the 32 notifications received by HIQA, eight notifications were cancelled following further investigation and or clinical assessment by the healthcare service provider that the original notification did not constitute a notifiable incident (Table 3). Of the remaining 24 notifications, 22 were received from public, acute and specialist settings and two were submitted by private hospitals.

Table 3: Number of notifications received from September to December 2024

| Type of Notifiable Incident | Total |
|---|---|
| 1.5 Unintended, unanticipated death in a healthy patient undergoing elective surgery | 3 |
| 1.6 Unintended, unanticipated death directly related to any medical treatment | 3 |
| 1.8 Patient death associated with a medication error | 1 |
| 1.9 Unanticipated death of a woman while pregnant or within 42 days of the end of pregnancy | 1 |
| 1.10 An unanticipated and unintended stillborn child | 2 |
| 1.11 An unanticipated and unintended perinatal death | 1 |
| 1.12 An unintended death of a patient where the cause is believed to be suicide | 1 |
| 2.1 (a) A baby who is referred for therapeutic hypothermia | 12 |
| Total | **24** |

### *4.2.2 Open disclosure*

The Patient Safety Act also requires that when a notifiable incident occurs, the open disclosure process should occur. In 2023, the Department of Health published the National Open Disclosure Framework to promote a clear and consistent approach, by health and social care service providers and other organisations where appropriate, to open communication with people using the service and any relevant support person following a patient safety incident or an adverse event. The framework developed a core set of principles with the aim of improving the health and social care culture where open disclosure is integral to everyday practice. It also sets out the responsibilities of healthcare service providers and health practitioners and considerations that should support information sharing. It proposed that open disclosure must be considered as an ongoing journey as information becomes available, rather than a one-off event. Of the notifiable incidents submitted in 2024, HIQA has received assurances through all notifications received from healthcare service providers that open disclosure had either commenced, or there was a plan to commence it at the time of notification with families affected by the outcomes and impact of notifiable incidents.

Standard 3.5 of the *National Standards for Safer Better Healthcare* requires service providers to fully and openly inform and support people using the service as soon as possible after an adverse event affecting them has occurred, or becomes known, and continue to provide information and support as needed. Ensuring that communication after a patient safety incident or adverse event is open, honest, and

timely is important to improving overall patient safety. It is intended to enhance the current monitoring programme and include national standard 3.5 as part of routine monitoring of healthcare services.

### *4.2.3 Learning for healthcare service providers*

HIQA's risk-based approach to regulation means that HIQA makes decisions based on the information it has about healthcare services and prioritises its regulatory activities accordingly. Request for information are made to prove assurances that the incident is appropriately investigated by the healthcare service providers and that HIQA is aware of the necessary facts in the early stages through the lifetime of such a review.

When notifying HIQA, the healthcare service provider should provide a sufficiently detailed description of the incident, having regard to the causes of the notifiable incident insofar as they are known at the time of the notification. In addition, the healthcare service provider should detail the actions taken in response to that incident, or proposes to be taken, to prevent recurrence, or mitigate the consequences of any similar such incident.

The Patient Safety Act provides that the Freedom of Information Act 2014 does not apply to records of, or relate to notifications of notifiable incidents to HIQA, including any additional or further information about the notifiable incident that a healthcare service providers supplies to HIQA. Additionally, the 2014 Act does not apply to records of, or relate to information obtained from a notification that is shared by HIQA with another relevant body and held by that body. The intentions of these provisions is to support open and transparent communications between health practitioners and healthcare service providers when incidents happen. It also aims to facilitate open and transparent engagement between healthcare service providers and HIQA so that any such information or assurances can be provided under the protections of the Patient Safety Act.

Healthcare service providers should be aware that it is an offence under section 77(4) of the Patient Safety Act to fail to comply with their statutory obligation to notify the relevant authority (HIQA, the Chief Inspector, and Mental Health Commission) of the occurrence of a notifiable incident, and a person who fails to comply with section 27, 28 or 29 shall be guilty of an offence and shall be liable on summary conviction to a class A fine. For healthcare service providers within HIQA's monitoring remit under Health Act 2007, HIQA inspectors will continue to report on compliance with the amended *National Standards for Safer Better Healthcare*, Version 2 (2024) in relation to mechanisms that healthcare service providers have in place to effectively identify, manage, respond to and report on patient safety incidents.

## 4.3 Stakeholder engagement

Throughout 2024, HIQA engaged with various external national and international stakeholders to consult and share on relevant matters for healthcare and radiation protection. Through such engagements, HIQA aims to build on the safe delivery of services in dental and healthcare facilities in Ireland.

### *4.3.1 Preparing for Patient Safety (Notifiable Patient Safety Incidents) Act 2023 commencement*

In preparation for the commencement of the Patient Safety Act, HIQA developed and implemented a stakeholder engagement strategy to support the commencement of the Act. HIQA's statutory responsibilities were adapted by amendments to the Health Act 2007 by:

- extending HIQA's monitoring functions into the private health sector
- adapting the threshold for Section 9 statutory investigations for the Minister for Health
- requiring healthcare service providers to notify HIQA and the Chief Inspector where relevant of statutorily defined notifiable events.

The stakeholder project to support the commencement was informed by analysis of stakeholders, which included:

- Department of Health
- State Claims Agency
- Currently monitored services, including public acute and community services already under HIQA's monitoring role
- New services to be monitored, including private hospitals
- Other healthcare service providers that were required to notify HIQA should an notifiable incident occur
- The public.

To support stakeholders and the public in understanding the implications of the Patient Safety Act, HIQA developed a number of resources. These were intended to support providers in understanding the actions required of them, and the general public in knowing how these changes would impact them. In September 2024, upon commencement of the Patient Safety Act, the HIQA website was updated to provide providers and the general public with information on the Act.

Guidance on Reporting Notifiable Incidents to HIQA and the Chief Inspector of Social Services was published on HIQA's website and updates to the Healthcare Monitoring guidance webpage were made with updated links to guide to assessment judgment framework and guide to inspection. HIQA also published the updated *National*

*Standards for Safer Better Healthcare Version* 2 on its website and archived previous standards. Through a series of short explanation videos, HIQA raised awareness on its social media platforms of how the Patient Safety Act would affect different stakeholders.

### *4.3.2 SINC International Innovation Network for Health and Care Regulators Congress 2024*

On 19 and 20 September 2024, HIQA organised and hosted the Supervision and Regulation Innovation Network for Care (SINC) Congress 2024. SINC is an international network for health and care regulators. Several senior leaders from health and social care regulators from nine countries across Europe gathered in Dublin attended. The meeting discussed health and social care regulation in a rapidly changing world, while adding greater societal value and supporting our staff through this change. The discussions ranged from sharing quality improvements; to artificial intelligence (AI) considerations for our approach to regulation; to innovation in whole-system inspections. Several HIQA staff members were involved in chairing sessions, or presenting across the two days. HIQA CEO Angela Fitzgerald delivered the closing remarks for the conference.


*Pictured above are colleagues from across HIQA and members of the SINC Network taking part in the SINC Congress 2024.*

### *4.3.3 HIQA engagement on medical exposure to ionising radiation*

#### Heads of the European Radiological Protection Competent Authority (HERCA)

At European level, HIQA continued to represent Ireland as the competent authority for medical exposure to ionising radiation on the Heads of the European Radiological Protection Competent Authority (HERCA) Working Group on Medical Applications (WGMA).[16] The focus of HERCA's WGMA is to develop a common understanding and approaches, where possible, regarding the implementation of radiation protection regulations in Europe, including those related to new medical applications and requirements.

In 2024, HERCA published a position paper titled *HERCA's View on Patient Radiation Protection in Medicine,* which HIQA was involved in preparing, advising on and reviewing. The purpose of the position paper is to help to harmonise, within European countries, the use of contact shielding, which is the use of a protective layer of radiation absorbing material during medical exposures. HIQA advocates that undertakings implement the position paper's general recommendations on the use of patient contact shielding in their radiological facilities.


*HIQA's Regional Manager Dr Agnella Craig is currently a member of HERCA's WGMA (pictured above).*

HIQA inspector, Lee O'Hora presented on ongoing work on considerations in interventional radiology at the European Conference of Radiology in Vienna in March. This presentation highlighted the work of the team in establishing national diagnostic reference levels in interventional radiology as well as their role in the identification of patients who may have incurred high skin doses after these procedures.


In June 2024, Inspectors Lee O'Hora and Kirsten O'Brien participated at the European Commission's Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA), Diagnostic Reference Levels Workshop in Luxembourg (HIQA inspectors pictured below with staff from the European Commission).

On a national level HIQA Inspector, Kirsten O'Brien presented on at the Irish Association of Medical Physicists (IAPM) Annual Scientific Meeting workshop on 'Dealing with Incidents involving Ionising Radiation' in April. The presentation focused on the analysis of notifiable significant events to HIQA and associated corrective actions to ensure compliance with the regulations.

HIQA staff Kirsty O'Brien, Andrew Dullea, Kirsten O'Brien and Margaret Keaveney presented at the National Radiation Protection Study Day in Dublin on 16 May 2024.


HIQA staff also participated at the National Patient Safety Office conference in September 2024 to promote the launch of HIQA's annual report on lessons learned from receipt of statutory notifications of accidental and unintended medical exposures to ionising radiation in 2023.

### Joint webinar for dental practices using X-ray and CBCT units

HIQA recognises that effective communication regarding regulatory requirements, radiation risks, and significant regulatory decisions is key to the radiation protection of people using the service. HIQA and the EPA have a memorandum of understanding that allows relevant information to be shared as deemed necessary and also to collaborate on some areas where competent authority responsibilities are linked. On 17 October 2024, HIQA held a joint webinar with the EPA for dental undertakings.


*Pictured above are colleagues from across HIQA and EPA taking part in a joint webinar for dental undertakings.*

This joint webinar sought to highlight to dental undertakings, and personnel working in these facilities, that HIQA and the EPA are separate and independent competent authorities that, under their respective regulations and remit, regulate different aspects of ionising radiation in dental practices providing medical exposures to ionising radiation, such as X-ray and Cone Beam Computed Tomography. The webinar content was designed to support dental undertakings to understand and comply with their regulatory responsibilities, under the distinct pieces of legislation monitored independently by HIQA (European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposures to Ionising Radiation) Regulations 2018, as amended and the EPA (Radiological Protection Act, 1991) and to build on basic compliance levels by encouraging best practice for radiation protection within their facilities. Throughout 2024, members of the Healthcare Regulation Directorate presented at a number of forums and participated in a number of the European Commission's projects (Table 5).

Table 4: Presentations by HIQA in relation to its healthcare functions in 2024

| **Presentations by HIQA's healthcare functions in 2024** |
|---|
| Agnella Craig presented at the Continuing Professional Development Event, Office of the Nursing and Midwifery Director on *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation.* |
| Margaret Keaveney and Kirsten O'Brien and presented at the National Radiation Protection Day on *Lessons learned from receipt of statutory notifications of accidental and unintended medical exposures to ionising radiation in 2023.* |
| Lee O'Hora presented at the Irish DXA Society Annual Meeting 2024 on *HIQA update* and on *Clinical Audit.* |
| Kirsten O'Brien presented at the Irish Association of Medical Physicists (IAPM) Annual Scientific Meeting workshop on *Analysis of significant events reported to HIQA.* |
| Lee O'Hora presented at the Irish Institute of Radiographers and Radiation Therapists (IIRRT) webinar on *HIQA's approach to the inspection of diagnostic imaging services.* |
| John Tuffy presented a webinar organised by the Irish Association of Directors of Nursing and Midwifery on HIQA's role under Patient Safety Act in September 2024. |
| Sean Egan presented at the Bon Secours Nursing & Quality Conference in October 2024. |
| John Tuffy presented at the RCPI National Specialty Quality Improvement Annual Conference in November 2024. |

Table 5: HIQA's participation in European Commission's projects in 2024

| **Participation in European Commission's Medical Exposure to Ionising Radiation Projects in 2024 under the Strategic Agenda for Medical ionising Radiation Applications (SAMIRA)** |
|---|
| Steering Group on Quality and Safety (SGQS) of medical applications of ionising radiation:<br>▪ presented on HIQA's project which established the *National Procedures for Clinical Audit of Medical Radiological Procedures* at the 6th plenary meeting of the SAMIRA SGQS. |

| |
|---|
| SAMIRA Medical Applications of Radiation – Learning from Incidents and Near Misses (MARLIN) project:<br>▪ represented HIQA and HERCA on the advisory board throughout the lifecycle of this project<br>▪ attended the results and recommendations workshop in Brussels and presented on behalf of HERCA on the WGMA's perspective on this project. |
| SAMIRA working group on Diagnostic Reference Levels, a sub-group of the SGQS:<br>▪ participated at the SAMIRA Diagnostic Reference Levels (DRLs) Workshop in Luxembourg in June 2024<br>▪ chaired the Working Group on DRLs in December 2024, having prepared a Position Paper on Diagnostic Reference Levels. |
| SAMIRA study on the definition of KPIs on Quality and Safety of medical applications of ionising radiation<br>▪ represented HIQA on the advisory board that aims to develop a proposal for a set of common quality and safety indicators for medical applications of ionising radiation. |

# 5. Independent statutory reviews and HIQA's expanding remit

In 2024, HIQA continued to engage with relevant stakeholders on the expansion of its remit and work progressed on two independent statutory reviews.

HIQA undertook reviews of two healthcare services in line with its powers under section 8(1)(c) of the Health Act 2007 (as amended).

## 5.1 Independent statutory review of governance and oversight of processes for surgical implants in Children's Health Ireland

In September 2023, it emerged publicly that non-CE-marked equipment (in the form of metal springs) had been surgically implanted into a number of children who underwent spinal surgery at CHI at Temple Street. This led to concern among the families of the children affected and the wider public. This issue emerged alongside wider public concerns around the quality and safety of orthopaedic services at the hospital.

As a result of these concerns, the Minister for Health requested that HIQA carry out an independent review to monitor compliance with national standards, in accordance with HIQA's remit under section 8(1)(c) of the Health Act 2007 (as amended), into the end-to-end processes around the use of non-CE marked springs at CHI at Temple Street. The request also incorporated a review of the governance and oversight of processes in place within CHI on the use of surgical implants and or implantable medical devices.[17] HIQA undertook the review in 2024 in line with the Terms of Reference, including an assessment of compliance at CHI and CHI Temple Street against relevant *National Standards for Safer Better Healthcare*. This review concluded with the publication of a report in early 2025.[18]

## 5.2 Independent review to inform decision-making around the design and delivery of urgent and emergency healthcare services in the Mid West region of Ireland

Overcrowding at University Hospital Limerick (UHL) has been an ongoing issue for many years, as identified in a number of HIQA inspections at the hospital. This overcrowding has occurred because the demand for urgent and emergency healthcare services in the Mid-West region has outpaced and the capacity development at UHL. Significant investment to increase bed capacity across the Mid-West region is underway and UHL has been subject to several external interventions aimed at supporting its internal capability to manage the issue of overcrowding at the hospital.

In May 2024, the Minister for Health requested HIQA to conduct a review, with the primary objective of providing advice to the Minister for Health on the appropriate action to ensure optimal quality and safety of future urgent and emergency

healthcare services for the population of the Mid-West region. As part of this review, HIQA was requested to consider the case for a second emergency department within HSE Mid West in the context of the population changes and ongoing demand for urgent and emergency healthcare services at UHL. In conducting this review, HIQA was also requested to consider the recommendations of an HSE-commissioned review by former Chief Justice Frank Clarke into the circumstances surrounding the death of Aoife Johnston from sepsis at UHL in December 2022. The review of urgent and emergency healthcare services in the Mid-West region was undertaken by HIQA's Health Technology Assessment and Healthcare Regulation Directorates. The review concluded with the publication of a report in September 2025.[19]

## 5.3 Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024

In 2024, HIQA continued to engage with the Department of Health about the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022. The Bill was enacted to become the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024. The Act has a broad scope and amongst other functions, makes provision for the donation by living persons of their bodies after death for the purposes of anatomical examination or public display, to provide for the establishment of a licensing system in respect of persons undertaking anatomical examinations or public display activities. From a HIQA perspective, the Act is intended to mandate HIQA to regulate certain elements of post-mortem practices, for which we will have enforcement powers. The Department of Health's priority has been placed on commencement of the functions as it relates to transplantation, which commenced in June 2025. It is expected that regulations pertaining to post-mortem practice will be further advanced in 2025.

## 5.4 The Critical Entities Resilience (CER) Directive

In 15 October 2024, the Minister of Defence signed the European Union (Resilience of Critical Entities) Regulations 2024 (S.I. No. 559 of 2024). The regulations transpose EU Directive 2022/2557 (Critical Entities Resilience Directive), which came into effect on 17 October 2024.

The Resilience of Critical Entities Regulations are part of a European Union-wide effort to increase the resilience of essential services that provide vital societal functions in all member states. The regulations will apply to the following sectors of the economy: energy, transport, banking, financial market infrastructure, health, drinking water, wastewater, digital infrastructure, public administration, space, and large-scale food production, processing, and distribution. HIQA is designated as the competent authority in the State on resilience in respect of healthcare providers. Further information will be provided to potential critical entities in the healthcare

sector as this function is progressed by HIQA.

## 5.5 Patient Safety (Licensing) Bill

The Department of Health has prepared legislative systems for a mandatory licensing of public and private hospitals, and other providers of high-risk healthcare activities. The Bill is designed to improve and enhance patient safety by ensuring that healthcare providers do not operate below core standards, which are applied in a consistent and systematic way. It is part of a broader range of measures to enhance patient safety and when enacted will ensure that healthcare services meet certain standards to optimise patient safety and patient rights. When enacted, the Bill will introduce a licensing requirement for all hospitals, both public and private, and certain services in the community that are considered potentially high-risk if not provided to the appropriate standard. The general scheme of the Patient Safety (Licensing) Bill was approved by Government on 12 December 2017 and underwent pre-legislative scrutiny at the Oireachtas Joint Committee of Health on 13 June 2018. The Bill was subsequently referred to the Attorney General's Office for drafting to be undertaken and is currently actively progressed by the Department of Health.

# 6. Conclusion

2024 was a year of significant change in healthcare services with the continued implementation of Sláintecare reforms, the restructuring of the HSE into health regions, and the implementation of new legislation to support open disclosure and expand HIQA's monitoring function into private hospitals through the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023. The commencement of the Patient Safety Act was an important milestone for the entire health sector. It mandated the notification of incidents from healthcare services to HIQA for the first time, expanded HIQA's monitoring remit to private hospitals and further supports the promotion of quality and safety across healthcare services, both public and private.

Ireland's health service continues to be challenged by capacity, staffing and infrastructural issues which highlight the need for resilient services that can meet the needs of the population now and into the future. Following the COVID-19 pandemic, the health system has responded to increasing demands and HIQA is committed to ensuring the way it monitors and regulates adapts with these changes to ensure the best possible outcomes for people using services.

With these changes and challenges, HIQA maintained its monitoring, regulating and statutory review functions to provide assurances on the safety and quality of care. The findings outlined in this report show that HIQA inspections have been key driving factors in delivering sustained improvement in healthcare services for the benefit of people using services. HIQA has seen a continued effort and dedication from many service providers to use the findings from inspections to drive positive outcomes for patients.

As the competent authority in Ireland with responsibility for monitoring against and enforcing the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations, HIQA continued a regulatory inspection programme along with other statutory regulatory functions, such as receiving notifications of significant events of accidental and unintended exposures and establishing diagnostic reference levels (DRLs) and continued to publish content in relation to our work.

Throughout the year, HIQA found that overall compliance with the regulations was good in the inspected medical radiological facilities. Through our monitoring and inspection programme of these services and continuing our stakeholder engagements, as outlined in Chapter 4, HIQA will ensure undertakings seek to improve compliance. In addition, the publication of a joint report with the EPA provides valuable information on the average radiation doses received by the Irish population in 2024. This report, which found that medical exposure accounts for just

over 10% of a person's average annual exposure or dose, established that the average amount of radiation from medical exposure has decreased over the last 10 years. Having worked collaboratively also with a number of organisations in 2024 in preparing for the Integrated Regulatory Review (IRRS) Mission, HIQA also looks forward to demonstrating its regulatory and health technology assessment programmes relating to medical exposures to the International Atomic Energy Agency (IAEA) in early 2026. HIQA will continue to collaborate with key regulatory bodies and stakeholders.

In 2024, HIQA continued its programme to monitor compliance in 40 healthcare services inspected across the acute, specialist and post-acute settings including the first inspection of a private hospital against the *National Standards for Safer Better Healthcare.* The monitoring approach for healthcare services was a continuation of the revised methodology, introduced in 2022, to ensure HIQA remaind responsive and agile as its role and remit in healthcare regulation and monitoring expanded with the enactment of the Patient Safety Act. HIQA's findings demonstrate the ability for regulation to act as a catalyst for positive change in services and the willingness and commitment from service providers to improve patients' experiences and safety. In situations where findings from previous inspections facilitated comparison on follow-up inspections in 2024, 41% of standards assessed showed improvements, showing a commitment from service providers to learn from and improve on inspection findings. Services maintained compliance levels for 45% of standards on follow-up inspections; however, 14% of standards had dis-improved since the previous inspection. HIQA will continue to engage with and support service providers through inspection programmes and seek to improve compliance in these areas.

Findings on follow-up inspections indicated improvements in compliance levels were focused on leadership, governance and leadership, the delivery of person-centred care, complaints management, monitoring, evaluating and improving service performance and the management of patient safety incidents. In contrast, areas that showed dis-improvement were focused on respecting and promoting patients' dignity, privacy and autonomy, and comprehensive arrangements to protect people using the healthcare services from the risk of harm. HIQA is committed to promoting a person centred and a human rights-based approach to care across healthcare services. This approach is underpinned by the national standards, which place an emphasis on protecting service users' rights, and respecting their autonomy, privacy and dignity. HIQA's programmes will continue to focus on this going forward to ensure better experiences for patients.

HIQA's remit will extend further to post-mortem practices with the commencement of the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024. The enactment and commencement of new regulations and legislation — European Union (Resilience of Critical Entities) Regulations 2024 (S.I.

No. 559 of 2024) confer new functions on HIQA. The regulations under the transposed EU Directive 2022/2557 (Critical Entities Resilience Directive), came into effect on 17 October 2024 and designate HIQA as the competent authority in the State on resilience in respect of healthcare providers and will plan towards commencing a programme of monitoring to monitor compliance with the regulations in 2025. Patient Safety (Licensing) Bill will, when enacted, form part of a broader range of measures to enhance patient safety and when enacted will ensure that healthcare services meet certain standards to optimise patient safety and patient rights. The Bill will introduce a licensing requirement for all hospitals, both public and private, and certain services in the community that are considered potentially high-risk if not provided to the appropriate standard. These important legislative changes will drive improved safety in our health service and HIQA will continue to engage with relevant stakeholders as they progress.

## Next steps

The context in which healthcare services are required and delivered changed in 2024 and this will continue into 2025 and beyond. Services are re-organising in line with the Sláintecare reform programme, with the growth in population and aging driving increased demand for healthcare services. Healthcare itself is also changing, both in the ways in which it is delivered and with technological innovation advancing at an ever-increasing pace, offering both new opportunities and challenges. It is imperative that the health system is agile, resilient and responsive to anticipate and meet the projected demand for healthcare services. A purposeful response will require adjustments to the healthcare infrastructure including increased inpatient bed capacity, resource allocation and a skilled workforce to ensure healthcare service providers can meet the projected increase in demand for healthcare services.

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# Appendices

## Appendix 1: Published inspection reports for which the 2024 compliance data with *National Standards for Safer Better Healthcare* is based

| Hospital | Model | Date(s) of Inspections |
|---|---|---|
| University Hospital Kerry | Model 3 | 23/01/2024 |
| Midland Regional Hospital Tullamore (ED) | Model 3 | 01/02/2024 |
| Tallaght University Hospital | Model 4 | 14/02/2024 |
| Wexford General Hospital | Model 3 | 05/03/2024 |
| Kilcreene Regional Orthopaedic Hospital | Specialist | 25/03/2024 |
| St Luke's General Hospital Kilkenny | Model 3 | 09/04/2024 |
| Mercy University Hospital | Model 3 | 18/04/2024 |
| Our Lady of Lourdes Hospital, Drogheda | Model 3 | 25/04/2024 |
| University Hospital Galway | Model 4 | 08/05/2024 |
| St Colmcille's Hospital | Model 2 | 15/05/2024 |
| Cavan and Monaghan Hospital | Model 3 | 21/05/2024 |
| Midland Regional Hospital, Portlaoise | Model 3 | 28/05/2024 |
| University Hospital Waterford | Model 4 | 05/06/2024 |
| Mater Misericordiae University Hospital | Model 4 | 02/07/2024 |
| Naas General Hospital | Model 3 | 17/07/2024 |
| Ballina District Hospital | Community | 17/07/2024 |
| Wicklow District Hospital | Community | 01/08/2024 |
| Our Lady's Hospice and Care Services | Community | 31/07/2024 |
| Castlecomer District Hospital | Community | 30/07/2024 |
| Gorey District Hospital | Community | 07/08/2024 |
| The Royal Hospital, Donnybrook | Community | 14/08/2024 |
| Royal Victoria Eye and Ear Hospital | Specialist | 21/08/2024 |
| Peamount Hospital | Community | 28/08/2024 |
| Bantry General Hospital | Model 2 | 04/09/2024 |
| St James's Hospital | Model 4 | 18/09/2024 |
| St Finbarr's Hospital, Cork | Community | 18/09/2024 |
| Beaumont Hospital | Model 4 | 24/09/2024 |
| Sligo University Hospital | Model 3 | 08/10/2024 |
| Lisdarn Transitional Care Unit | Community | 09/10/2024 |
| Regional Hospital Mullingar | Model 3 | 09/10/2024 |
| Connolly Hospital, Dublin | Model 3 | 17/10/2024 |
| St. Patrick's Hospital Waterford | Community | 22/10/2024 |
| Midland Regional Hospital Tullamore | Model 3 | 05/11/2024 |
| Swinford District Hospital | Community | 11/11/2024 |
| St Vincent's University Hospital | Model 4 | 13/11/2024 |
| National Orthopaedic Hospital Cappagh | Specialist | 20/11/2024 |
| St. Theresa's Hospital, Tipperary | Community | 09/12/2024 |
| Incorporated Orthopaedic Hospital of Ireland, Clontarf | Specialist | 10/12/2024 |
| Clifden District Hospital | Community | 11/12/2024 |

## Appendix 2: National standards monitored during inspections of healthcare services in 2024

| **Capacity and Capability Dimension** |
|---|
| Theme 5: Leadership, Governance and Management |
| Standard 5.2: Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare. |
| Standard 5.5: Service providers have effective management arrangements to support and promote the delivery of high quality, safe and reliable healthcare services. |
| Standard 5.8: Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services. |
| Theme 6: Workforce |
| Standard 6.1: Service providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare. |
| **Quality and Safety Dimension** |
| Theme 1: Person-Centred Care and Support |
| Standard 1.6: Service users' dignity, privacy and autonomy are respected and promoted. |
| Standard 1.7: Service providers promote a culture of kindness, consideration and respect. |
| Standard 1.8: Service users' complaints and concerns are responded to promptly, openly and effectively with clear communication and support provided throughout this process. |
| Theme 2: Effective Care and Support |
| Standard 2.7: Healthcare is provided in a physical environment which supports the delivery of high quality, safe, reliable care and protects the health and welfare of service users. |
| Standard 2.8: The effectiveness of healthcare is systematically monitored, evaluated and continuously improved. |
| Standard 2.7: Healthcare is provided in a physical environment which supports the delivery of high quality, safe, reliable care and protects the health and welfare of service users. |
| Theme 3: Safe Care and Support |
| Standard 3.1: Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services. |
| Standard 3.3: Service providers effectively identify, manage, respond to and report on patient-safety incidents. |

## Appendix 3: National standards monitored during inspections of emergency departments in 2024

| **Capacity and Capability Dimension** |
| --- |
| Theme 5: Leadership, Governance and Management |
| Standard 5.5: Service providers have effective management arrangements to support and promote the delivery of high quality, safe and reliable healthcare services. |
| Theme 6: Workforce |
| Standard 6.1: Service providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare. |
| **Quality and Safety Dimension** |
| Theme 1: Person-Centred Care and Support |
| Standard 1.6: Service users' dignity, privacy and autonomy are respected and promoted. |
| Theme 3: Safe Care and Support |
| Standard 3.1: Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services. |

# Appendix 4: Compliance with national standards monitored during inspections of Acute and Specialist Healthcare Services (published inspection reports)

| Healthcare Directorate Inspections Completed in 2024 | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Acute Healthcare Services | Capacity and Capability | | | | | | Quality and Safety Dimension | | | | | | | | |
| Hospital Name | Date(s) of Inspection | Type of Inspection | National Standards | | | | | | | | | | | | |
| | | | NS 5.2 | NS 5.5 | NS 5.8 | NS 6.1 | | NS 1.6 | NS 1.7 | NS 1.8 | NS 2.7 | NS 2.8 | NS 3.1 | NS 3.3 |
| Bantry General Hospital | 04 and 05 September 2024 | Announced | Partially Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| Beaumont Hospital | 24 and 25 September 2024 | Announced | Compliant | Partially Compliant | Compliant | Partially Compliant | | Partially Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Compliant |
| Cavan Monaghan Hospital | 22 and 23 May 2024 | Unannounced | Compliant | Substantially Compliant | Compliant | Substantially Compliant | | Partially Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Compliant |
| Connolly Hospital | 17 and 18 October 2024 | Announced | Compliant | Compliant | Compliant | Partially Compliant | | Substantially Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Compliant |
| Clontarf Hospital | 10 and 11 December 2024 | Announced | Substantially Compliant | Partially Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Substantially Compliant | Compliant | Partially Compliant | Compliant |
| Kilcreene Regional Orthopaedic Hospital | 25 and 26 March 2024 | Announced | Substantially Compliant | Compliant | Compliant | Partially Compliant | | Substantially Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Compliant | Compliant |
| Mercy University Hospital | 18 and 19 April 2024 | Unannounced | Substantially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | | Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| Mater Misericordiae University Hospital | 02 and 03 July 2024 | Unannounced | Substantially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | | Substantially Compliant | Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| Midland Regional Hospital Portlaoise | 28 and 29 May 2024 | Unannounced | Partially Compliant | Compliant | Substantially Compliant | Partially Compliant | | Substantially Compliant | Compliant | Partially Compliant | Partially Compliant | Compliant | Partially Compliant | Compliant |
| Midland Regional Hospital Tullamore | 01 February 2024 (Emergency Department only) | Unannounced | | Substantially Compliant | | Substantially Compliant | | Compliant | | | | | Substantially Compliant | |
| Midland Regional Hospital Tullamore | 05 and 06 November 2024 | Unannounced | Substantially Compliant | Substantially Compliant | Compliant | Partially Compliant | | Compliant | Compliant | Partially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Partially Compliant |
| Naas General Hospital | 17 and 18 July 2024 | Unannounced | Substantially Compliant | Compliant | Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Substantially Compliant | Partially Compliant | Partially Compliant | Partially Compliant | Compliant |
| National Orthopaedic Hospital, Cappagh | 20 and 21 November 2024 | Announced | Substantially Compliant | Partially Compliant | Compliant | Partially Compliant | | Compliant | Compliant | Compliant | Partially Compliant | Compliant | Partially Compliant | Compliant |

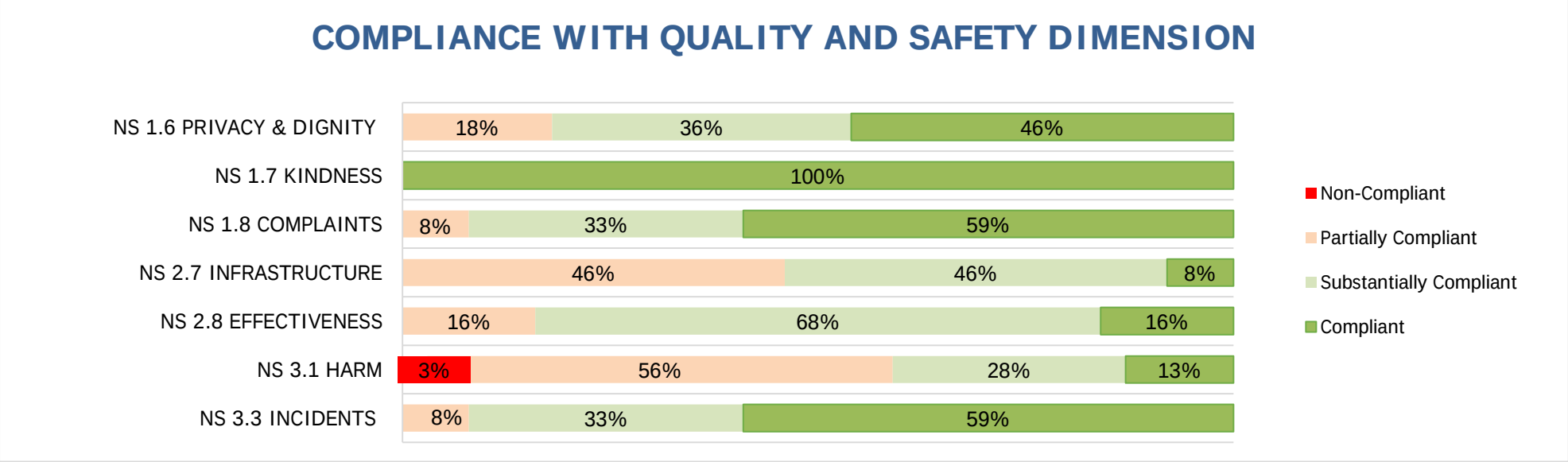
# Appendix 4: Compliance with national standards monitored during inspections of Acute and Specialist Healthcare Services (published inspection reports) Continued

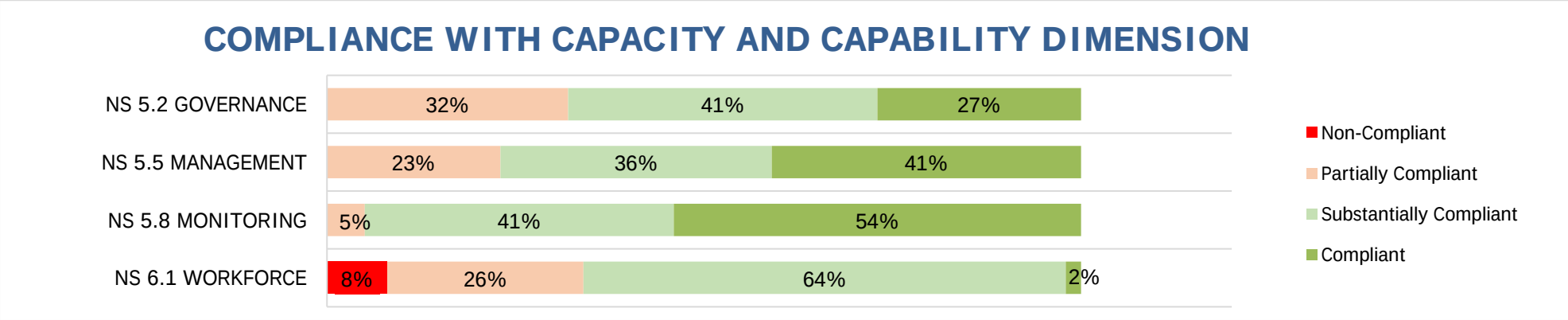
| Healthcare Directorate Inspections Completed in 2024 | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Acute Healthcare Services | | | Capacity and Capability | | | | | Quality and Safety Dimension | | | | | | |
| Hospital Name | Date(s) of Inspection | Type of Inspection | National Standards | | | | | National Standards | | | | | | |
| | | | NS 5.2 | NS 5.5 | NS 5.8 | NS 6.1 | | NS 1.6 | NS 1.7 | NS 1.8 | NS 2.7 | NS 2.8 | NS 3.1 | NS 3.3 |
| Our Lady of Lourdes Hospital Drogheda | 25 April 2024 (Emergency Department only) | Unannounced | | Partially Compliant | | Substantially Compliant | | Partially Compliant | | | | | Partially Compliant | |
| Regional Hospital Mullingar | 01 and 10 October 2024 | Unannounced | Partially Compliant | Substantially Compliant | Substantially Compliant | Non-compliant | | Partially Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| Royal Victoria Eye and Ear Hospital | 21 and 22 August 2024 | Announced | Partially Compliant | Compliant | Partially Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant |
| Sligo University Hospital | 08 and 09 October 2024 | Announced | Substantially Compliant | Partially Compliant | Compliant | Partially Compliant | | Partially Compliant | Compliant | Substantially Compliant | Partially Compliant | Partially Compliant | Partially Compliant | Compliant |
| St Columcille's Hospital | 15 and 16 May 2024 | Unannounced | Partially Compliant | Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Compliant |
| St James's University Hospital | 18 and 19 September 2024 | Unannounced | Compliant | Compliant | Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Compliant |
| St Luke's General Hospital Kilkenny | 09 and 10 April 2024 | Unannounced | Substantially Compliant | Partially Compliant | Substantially Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant |
| St Vincent's University Hospital | 13 and 14 November 2024 | Unannounced | Substantially Compliant | Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| Tallaght University Hospital | 14 and 15 February 2024 | Unannounced | Substantially Compliant | Partially Compliant | Substantially Compliant | Substantially Compliant | | Partially Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| University Hospital Galway | 08 and 09 May 2024 | Unannounced | Substantially Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | | Partially Compliant | Compliant | Partially Compliant | Partially Compliant | Partially Compliant | Partially Compliant | Substantially Compliant |
| University Hospital Waterford | 05 and 06 June 2024 | Unannounced | Compliant | Substantially Compliant | Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Substantially Compliant | Compliant | Compliant | Substantially Compliant | Compliant |
| University Hospital Kerry | 23 and 24 January 2024 | Unannounced | Partially Compliant | Partially Compliant | Partially Compliant | Non-compliant | | Substantially Compliant | Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Non-compliant | Partially Compliant |
| Wexford General Hospital | 05 and 06 March 2024 | Unannounced | Substantially Compliant | Compliant | Substantially Compliant | Non-compliant | | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Partially Compliant | Substantially Compliant |

# Appendix 5: Compliance with national standards monitored during inspections of Rehabilitation and Community Inpatient Healthcare Services (published inspection reports)

| Healthcare Directorate Inspections Completed in 2024 | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Rehabilitation and Community Inpatient Healthcare Services | Capacity and Capability | | | | | | Quality and Safety Dimension | | | | | | | |
| Hospital Name | Date(s) | Type of Inspection | National Standard | | | | | National Standard | | | | | | |
| | | | NS 5.2 | NS 5.5 | NS 5.8 | NS 6.1 | | NS 1.6 | NS 1.7 | NS 1.8 | NS 2.7 | NS 2.8 | NS 3.1 | NS. 33 |
| Ballina District Hospital | 17 and 18 July 2024 | Announced | Partially Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Compliant | Substantially Compliant | Compliant | Partially Compliant | Substantially Compliant |
| Castlecomer District Hospital | 30 and 31 July 2024 | Announced | Partially Compliant | Compliant | Substantially Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Compliant |
| Clifden District Hospital | 11 and 12 December | Announced | Partially Compliant | Substantially Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant |
| Gorey District Hospital | 07 and 08 August 2024 | Announced | Partially Compliant | Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Compliant |
| Lisdarn Transitional Care Centre | 09 and 10 October 2024 | Announced | Substantially Compliant | Substantially Compliant | Compliant | Substantially Compliant | | Substantially Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Substantially Compliant | Compliant |
| Our Lady's Hospice and Care Services, Harold's Cross | 31 July and 01 August 2024 | Announced | Compliant | Compliant | Compliant | Compliant | | Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Compliant | Compliant |
| Peamont Healthcare | 27 and 28 August 2024 | Announced | Compliant | Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Compliant | Compliant |
| St Finbarr's Rehabilitation Unit | 18 and 19 September 2024 | Announced | Substantially Compliant | Compliant | Substantially Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Compliant |
| St Teresa's Hospital | 11 and 12 December | Announced | Compliant | Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Substantially Compliant | Compliant | Compliant | Compliant |
| Swinford District Hospital | 12 and 14 November 2024 | Announced | Partially Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | | Compliant | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | Partially Compliant | Substantially Compliant |
| The Royal Hospital Donnybrook | 14 and 15 August 2024 | Announced | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Partially Compliant | Substantially Compliant | Partially Compliant | Compliant |
| Waterford Residential Care Centre – Rehabilitation Unit | 22 and 23 October 2024 | Announced | Partially Compliant | Compliant | Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Compliant | Compliant | Partially Compliant | Compliant |
| Wicklow Community Unit | 01 and 02 August 2024 | Announced | Compliant | Substantially Compliant | Substantially Compliant | Substantially Compliant | | Compliant | Compliant | Compliant | Partially Compliant | Partially Compliant | Compliant | Compliant |

## Appendix 6: Compliance with national standards in *Capacity and Capability* and *Quality and Safety* Dimensions



## Appendix 7: Key documents published in 2024

| Key Documents Published | Date published | Link |
|---|---|---|
| Inspection reports of 9 inspections of medical radiological facilities | 11 January 2024 | here |
| Inspection reports against the *National Standards for Safer Better Healthcare* in:<br>▪ Mayo University Hospital<br>▪ Sligo University Hospital<br>▪ The Rehabilitation Unit, St Mary's Care Centre, Regional Hospital Mullingar<br>▪ Clontarf Hospital<br>▪ Carlow District Hospital<br>▪ National Rehabilitation Hospital. | 27 March 2024 | here |
| Inspection reports against the *National Standards for Safer Better Healthcare* in:<br>▪ University Hospital Limerick<br>▪ Letterkenny University Hospital<br>▪ Rotunda Hospital<br>▪ Belmullet Community Hospital<br>▪ Nenagh Hospital<br>▪ Coombe Women and Infants University Hospital. | 2 May 2024 | here |
| Inspection reports of 26 inspections of medical radiological facilities | 3 May 2024 | here |
| Joint report from the EPA and HIQA on the average ionising radiation doses received by the Irish population | 25 June 2024 | here |
| Inspection reports of 10 inspections of medical radiological facilities | 18 Jul 2024 | here |
| Inspection reports against the *National Standards for Safer Better Healthcare* in:<br>▪ University Hospital Kerry<br>▪ Midland Regional Hospital Tullamore<br>▪ Kilcreene Orthopaedic Hospital<br>▪ Tallaght University Hospital. | 25 Jul 2024 | here |
| Terms of Reference: Independent Review to Inform Decision-making around the Design and Delivery of Urgent and Emergency Healthcare Services in the Mid-West Region of Ireland | 21 Aug 2024 | here |

| Key Documents Published | Date published | Link |
|---|---|---|
| Lessons learned from receipt of statutory notifications of accidental and unintended medical exposures to ionising radiation in 2023 | 16 September 2024 | here |
| Inspection reports against the *National Standards for Safer Better Healthcare* in:<br>▪ Wexford General Hospital<br>▪ St. Luke's General Hospital Kilkenny<br>▪ Mercy University Hospital<br>▪ Our Lady of Lourdes, Drogheda<br>▪ University Hospital Galway<br>▪ University Hospital Waterford<br>▪ Our Lady's Hospice and Care Services, Harold's | 23 October 2024 | here |
| Inspection reports of 17 inspections of medical radiological facilities | 12 November 2024 | here |
| Press release on launching engagement to inform review into urgent and emergency care in the mid-west region of Ireland | 4 December 2024 | here |
| Academic publication on establishing national diagnostic reference levels in fluoroscopy and fluoroscopically guided interventions in Ireland and comparing these with national diagnostic reference levels in Europe and internationally | 18 December 2024 | here |

## Appendix 8: Schedule of notifiable incidents reportable to HIQA under the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

| Item | Notifiable Incident |
|---|---|
| 1.1 | Surgery performed on the wrong patient resulting in unintended and unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness. |
| 1.2 | Surgery performed on the wrong site resulting in unintended and unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness. |
| 1.3 | Wrong surgical procedure performed on a patient resulting in an unintended and unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness. |
| 1.4 | Unintended retention of a foreign object in a patient after surgery resulting in an unanticipated death which did not arise from, or was a consequence of an illness or an underlying condition of the patient, or, having regard to any such illness or underlying condition, was not wholly attributable to that illness. |
| 1.5 | Any unintended and unanticipated death occurring in an otherwise healthy patient undergoing elective surgery in any place or premises in which a health services provider provides a health service where the death is directly related to a surgical operation or anaesthesia (including recovery from the effects of anaesthesia) and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient. |
| 1.6 | Any unintended and unanticipated death occurring in any place or premises in which a health services provider provides a health service that is directly related to any medical treatment and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient. |
| 1.7 | Patient death due to transfusion of ABO incompatible blood or blood components and the death was unintended and unanticipated and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient. |

| Item | Notifiable Incident |
|---|---|
| 1.8 | Patient death associated with a medication error and the death was unintended and unanticipated as it did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient. |
| 1.9 | An unanticipated death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to, or aggravated by, the management of the pregnancy, and which did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the patient. |
| 1.10****** | An unanticipated and unintended stillborn child where the child was born without a fatal foetal abnormality and with a prescribed birthweight or has achieved a prescribed gestational age and who shows no sign of life at birth, from any cause related to or aggravated by the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the patient or an underlying condition of the child. |
| 1.11 | An unanticipated and unintended perinatal death where a child born with, or having achieved a prescribed gestational age and a prescribed birthweight who was alive at the onset of care in labour, from any cause related to, or aggravated by, the management of the pregnancy, and the death did not arise from, or was a consequence of (or wholly attributable to) the illness of the child or an underlying condition of the child. |
| 1.12 | An unintended death where the cause is believed to be the suicide of a patient while being cared for in or at a place or premises in which a health services provider provides a health service whether or not the death was anticipated or arose from, or was wholly or partially attributable to, the illness or underlying condition of the patient. |

### Part 2

| Item | Notifiable Incident |
|---|---|
| 2.1 | A baby who — (a) in the clinical judgment of the treating health practitioner requires, or is referred for, therapeutic hypothermia, or (b) has been considered for, but did not undergo therapeutic hypothermia as, in the clinical judgment of the health practitioner, such therapy was contraindicated due to the severity of the presenting condition. |

****** The term “prescribed” has the meaning given to it in section 2 of the Patient Safety Act as meaning “prescribed in regulations made by the Minister under this Act”.

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