



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Guidance for a review of the
governance arrangements for the
provision of population-based health
screening services by the Health
Service Executive at national level

22 April 2026

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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1. Introduction

The National Screening Service was established in January 2007 by the then Minister for Health and Children. The service was formed in response to the 2006 national cancer strategy, which advocated for a comprehensive cancer control programme. The National Screening Service is now part of the Health Service Executive (HSE). The service delivers four national population-based cancer and non-cancer screening services aimed at reducing morbidity and mortality in the population through prevention and or early recognition of disease and treatment to improve health outcomes. The four population-based health screening services delivered by the National Screening Service are:

- BreastCheck - National Breast Screening Programme
- CervicalCheck - National Cervical Screening Programme
- BowelScreen - National Bowel Screening Programme
- Diabetic RetinaScreen - National Diabetic RetinaScreen Programme.

Following concerns raised around the delivery of services in the CervicalCheck health screening programme in 2018, a number of service reviews were carried out.^{1,2,3,4,5,6} These reviews identified gaps in the programme's governance and accountability arrangements, and practices in relation to open disclosure. The HSE committed to implementing the recommendations from the reviews, and many important changes have been implemented since, including the introduction of primary human papillomavirus (HPV) testing as the primary screening method in CervicalCheck, the introduction of mandatory open disclosure through the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 and a strategic focus on eliminating cervical cancer by 2040.^{7,8}

Furthermore, the National Healthy Childhood Programme delivers two population-based health screening services for newborn babies as part of the HSE's national public health function. The two population-based newborn screening services are:

- National Bloodspot Screening Programme
- National Universal Newborn Hearing Screening Programme.

These population-based health screening services are vital for the early detection and treatment of cancer, diabetic retinopathy and inherited conditions and hearing difficulties in newborn babies.

Early detection and initiation of treatment of disease leads to better treatment outcomes, prevents complications and improves public health. Screening for disease supports a shift from reactive treatment to proactive health management and disease prevention, empowering people to make informed choices about their health, and reduces overall disease burden on people and healthcare systems.⁹

The Health Information and Quality Authority (HIQA), in line with its functions under section 8(1)(c) of the Health Act 2007 as amended, is conducting a review of the governance arrangements for the provision of population-based health screening services in Ireland against the *National Standards for Safer Better Care* (referred to as the national standards).¹⁰ National standards help to protect people using services and aim to drive improvements in the quality, safety and reliability of the services.

HIQA recognises that the population-based health screening services are pursuing measures to improve their services, where necessary, increase participation and to address inequities in access and uptake across screening programmes. The purpose of this review is to provide an independent assurance to the public that required improvements to the way some screening services were provided have been made and sustained across the programmes currently in operation. Such a review is important, not only because of the vital role screening plays in early detection of potential disease in what is a growing and ageing population in Ireland, but also because there is a potential for screening services to grow into the future. The review aims to ensure that any such expansion is built upon strong foundations, and service development is supported by continuous improvement.

1.1 Role of national standards in improving quality and safety in health and social care services

Section 8(1)(c) of the Health Act 2007¹¹ as amended (referred to in this guidance as the Act), confers HIQA with the statutory responsibility for setting standards for health and social care services, and for monitoring the quality and safety of health and social care services against these standards. The national standards promote improvements in the quality and safety of health and social care services in Ireland. They help the public, people who use health and social care services and the people who provide those services to understand what a high-quality, safe health and social care service looks like. Collectively, these national standards describe how a service provides high-quality, safe and reliable care that is centred on people who use health and social services.

The national standards comprise 45 standards presented under eight themes (see Figure 1). Themes one to four describe the dimensions of quality and safety, which are necessary to deliver a person-centred healthcare service. Themes five to eight

describe the capacity and capability dimensions that are necessary to deliver high-quality, safe care.

Figure 1: Themes in the National Standards for Safer Better Healthcare



2. Who should use this guidance document?

This guidance document has been prepared for the providers and staff delivering the population-based health screening services to provide information about HIQA's approach for carrying out the review of the governance arrangements for the provision of population-based health screening services by the HSE at national level. It aims to explain how the review will be carried out, how the findings will be reported and what the service provider and staff can expect during the review.

This guidance document should be read in conjunction with the following documents:

- Terms of Reference for the Review (see appendix 1).
- *National Standards for Safer Better Healthcare Version 2 (2024)*.

All three documents are available online at www.hiqa.ie.

3. What is the purpose of this guidance document?

This guidance document includes information about:

- HIQA's approach to the review

- how information to inform the judgments of compliance with national standards will be collected
- how findings of the review will be reported.

4. Specific objectives of the review

Through this review, HIQA will assess compliance with a number of national standards as relevant to the terms of reference so that the public can be assured the screening services:

- are underpinned by robust governance arrangements that ensures the delivery of high-quality, safe and sustainable services
- are effective in assuring and ensuring the quality and safety, and continued improvement of the services
- have implemented the learning from the reviews and reports into CervicalCheck across the screening services, as relevant
- consider the identified needs and preferences of people who use the screening services
- have arrangements in place to ensure that when things go wrong with the screening services, that the provision of care is person centred in the context of openness, patient communication and open disclosure.

Should HIQA identify any areas for improvement or non-compliance with the national standards in screening services, it will make recommendations for the HSE to support the screening services to come into full compliance with the national standards.

4.1 Scope of the review

The review aims to assess the governance arrangements for the provision of population-based health screening services by the HSE at national level. This includes screening services defined by the HSE as population-based health screening services, which aim to assess the risk of disease, and recognising disease before symptoms appear. The review will assess the corporate and clinical governance arrangements in place governing and supporting the delivery of the four population-based health screening programmes delivered by the National Screening Service and the two population-based newborn screening services delivered by the National Healthy Childhood Programme across the Republic of Ireland.

Screening services for gastric cancer, lung cancer and prostate cancer are not currently provided by the HSE in Ireland so they are not included within the scope of the review.

5. Review methodology

The review will be conducted in accordance with the Health Act 2007 as amended. The review will comprise two parts. Part one comprises a desktop review of relevant information, documentation and data submitted to HIQA about the governance and performance of the population-based health screening services delivered by the HSE at national level. Documentation, data and information requests will be issued to the service provider as per section 73 of the Act.

The review team will review, analyse and evaluate the information submitted to HIQA to identify the specific lines of enquiry that will be explored during the conduct of part two of the review. Lines of enquiry support the review team in gathering evidence when assessing the screening services' governance and oversight arrangements in line with the Terms of Reference for the review. Part two of the review will involve the review team meeting people with responsibility for the governance of and those delivering the population-based health screening services at HSE, National Screening Service, National Healthy Childhood Programme and specific screening programme levels. This aims to confirm, validate and clarify how the screening services are governed and how the quality and safety of the services is assured and ensured. Meetings will focus on confirming, validating and clarifying:

- the structures in place to provide effective and robust governance and oversight of the population-based health screening services as delivered by the HSE at national level
- the safety systems and processes that have been implemented to assure the delivery and monitoring of the quality and safety of the screening services
- any issues raised from the review and analysis of the information submitted to HIQA.

Meetings will be conducted face-to-face and or remotely using videoconferencing technology. Details in relation to these meetings will be communicated to the screening service provider in advance so that the necessary arrangements can be made to ensure people's availability to meet.

A targeted inspection of the screening services (or aspects of the screening services) for example, colposcopy clinic, endoscopy unit, breast clinic may be carried out if a potential risk(s) or particular issue(s) is identified during the review and analysis of

the information submitted to HIQA and or meetings with people involved in the governance and delivery of the services. The inspection will be designed to align to the risk(s) or issue(s) to be explored (see section 5.1).

HIQA aims to protect people that use healthcare services and to drive improvements in the quality and safety of services provided to them. The screening service provider should put the needs and preferences of people who use the screening services at the centre of all their activities. The review team will review how feedback from people using the screening services is taken into account and used to continually support and improve the planning, delivery and coordination of high-quality, safe screening services.

A report on the findings will be shared with the screening service provider and published on completion of the review on HIQA's website.

5.1 Targeted inspection of population-based health screening services

The review team may conduct a targeted inspection of the population-based health screening services (or an element of the screening services) if needed to obtain further information about governance and oversight arrangements and the systems and structures in place to support the operational performance of the services. During the announced inspection, the review team will collect evidence of compliance with the seven national standards deemed most relevant to the review (see section 5.2 for more information on these seven national standards). Evidence of compliance will be collected through inspection and observation of the service area, review of documents, data and information, and meetings with management and staff delivering the service (or aspects of the screening service).

On arrival to the service area, the review team will meet with the person with overall accountability and responsibility for the service.

- The review team will:
 - request that the service nominate a liaison person who will be responsible for engaging with the review team during the course of the inspection
 - request to review specific documentation, data and information during the inspection
 - speak with members of staff involved in the governance and delivery of the service

- request an office for use during the inspection to accommodate scheduled meetings and on-site documentation review.

5.2 National standards to be monitored during the review

The review will monitor compliance with seven national standards (see Table 1).

Table 1: National Standards to be assessed during the review

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 5.8: Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services.
Standard 5.9: The quality and safety of services provided on behalf of healthcare service providers are monitored through formalised agreements.
Theme 7: Use of Resources
Standard 7.2: Service providers have arrangements in place to achieve best possible quality and safety outcomes for service users for the money and resources used.
Quality and Safety Dimension
Theme 1: Person-Centred Care and Support
Standard 1.1: The planning, design and delivery of services are informed by service users' identified needs and preferences.
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 3.5: Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known, and continue to provide information and support as needed.

While the review will focus on the above, in line with HIQA's functions under Section 8 1(c) of the Health Act (2007) as amended, the review team may assess compliance with any of the national standards from the *National Standards for Safer Better Healthcare* as required.

5.3 Confidentiality

The review team and HIQA will be guided by and adhere to relevant data protection legislation throughout the review.

6. Assessment-judgment framework

Under section 8(1)(c) of the Health Act as amended, HIQA is responsible for assessing whether the screening service provider comply with the national standards. In order to carry out its functions as required by the Act, HIQA has adopted a common 'Authority Monitoring Approach' (AMA). The approach does not replace or take away from the screening service provider's responsibility to ensure that they comply with the national standards and provide safe and high-quality screening services. AMA aims to:

- ensure a consistent and timely assessment and monitoring of compliance with national standards
- ensure a responsive and consistent approach to the assessment of risk within health and social care services
- contribute to the improvement of the service being inspected through the application of the inspection process.

During the review of screening services, the review team will adhere to the policies, procedures and protocols of AMA. While the approach provides the review team with a range of steps, approaches and tools to assist them in carrying out their functions, it does not replace their professional judgment.

The review team will use an assessment-judgment framework to guide them in assessing and judging compliance with the seven national standards to be assessed during the review. The assessment approach and assessment-judgment framework will help ensure that the assessment of the screening services' compliance with the national standards is timely, consistent and responsive to any risks identified within the services.

The assessment judgment framework will be applied in conjunction with the Health Act 2007 as amended and is informed by the national standards developed by HIQA.

It sets out the lines of enquiry to be explored by the review team in order to assess compliance with the national standards to be assessed during the review. When the evidence is gathered and reviewed, the review team will make a judgment on the screening services' compliance with the national standards. Assessment of compliance with the national standards will be determined across the totality of evidence gathered during the entirety of the review. The judgment descriptors in Table 2 will be used when describing compliance with the seven national standards to be assessed as part of the review.

Table 2: Descriptors of compliance

Compliant: A judgment of compliant means that the service is in compliance with the relevant national standard.
Substantially compliant: A judgment of substantially compliant means that the service meets 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 the service meets some of the requirements of the relevant national standard while other requirements are 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 one or more findings indicate that the relevant national standard is not being met, and that this deficiency is such that it represents a significant risk to people using the service.

7. Risk identification, assessment and notification

During the review, the review team may identify specific issues that it believes may present a risk(s) to the health and or welfare of people using the population-based health screening services. If a risk(s) is identified, the review team will use HIQA's risk matrix (see appendix 2) to assess the likelihood and the impact of the identified risk(s). The risk-rating will be based on the severity of impact on people using the screening services and the likelihood of occurrence or recurrence. Moderate and or significant risk(s) will be raised with the head of the screening service or the provider, the HSE, in line with HIQA's escalation process.

Moderate and or significant risk(s) that require immediate mitigation will be brought to the attention of the designated accountable person for the service to allow them to implement the action(s) necessary to mitigate the risk(s). In the case of moderate and or significant risk(s), where immediate mitigation may not be reasonably achievable, formal notification of the identified risk(s) will be issued to the accountable person by email within two working days of the risk(s) being identified. The accountable person will be required to formally report back to HIQA with an action plan detailing how the identified risk(s) will be managed.

8. The report of the review

HIQA will prepare a draft report in relation to its findings. The draft report is issued to the healthcare service provider to enable it to provide feedback, including any perceived factual inaccuracies and feedback on the review findings. The final report will be provided to the service provider and will be published on HIQA's website at www.hiqa.ie. The purpose of the report is to:

- provide an assurance to the people who use the population-based health screening services and wider public, that the screening services delivered by the HSE at national level:
 - are compliant with the relevant national standards
 - are organised and led appropriately to ensure service quality and safety
 - are effective in assuring and ensuring the quality and safety, and continued improvement of the screening services
 - has implemented learning from the reviews and reports into CervicalCheck across the screening services, as relevant
 - considers the needs and preferences of people who use the screening services
 - use their resources to achieve best possible quality and safety outcomes for people who use the screening services
 - protect people using the screening services from the risk of harm
 - have arrangements in place to ensure that when things go wrong with the screening services, that the provision of care is person centred in the context of openness, patient communication and open disclosure

- provide information and share learning across screening services to inform the governance and delivery of those services.

9. Escalation

If a risk(s) is identified, it may be escalated at any stage of the review in line with HIQA's procedures and the Authority's Monitoring Approach. Escalation is defined as increased activity up to and including the decision to take further action as a result of concerns regarding the quality and safety of care being delivered by the screening services.

Formal written notification of any moderate and or significant identified risk(s) will also be issued to the accountable person for the screening service by email within two working days of HIQA identifying the risk. The accountable person will be required to formally report back to HIQA with an action plan to reduce and effectively manage the risk.

10. Governance of the review

HIQA will carry out the review in line with its functions under section 8(1)(c) of the Act, monitoring compliance with the national standards. In conducting the review, HIQA notes the provisions of section 8(2) of the Act that apply when it is conducting compliance monitoring pursuant to the Section 8(1)(c) of the Act. HIQA has internal governance and oversight arrangements in place to support the implementation of a robust assessment approach for the review.

A review team, appointed in accordance with the Health Act 2007 as amended, will carry out the review. The team may exercise all of the statutory powers available to HIQA pursuant to the Health Act 2007 as amended. Members of the review team have extensive experience in the governance of healthcare services, reviews into the safety and quality of healthcare services and inspection of healthcare services. The team may exercise all of the statutory powers available to HIQA pursuant to the Act. Members of the review team will comply with the HIQA's Code of Conduct, available on HIQA's website, www.hiqa.ie.

In the conduct of the review, HIQA will, where necessary, seek advice and expertise external to HIQA to fully inform the conduct and findings of this work. This may involve the provision of technical and or clinical advice and support of a subject matter nature and is provided through an Expert Advisory Group (EAG). To support the review, HIQA has convened an EAG with expertise in the governance and operational delivery of population-based health screening services and public health, and with a patient representative. Its advice and input will reflect national and

international evidence and best practice. HIQA may seek additional external expertise as needed throughout the review, depending on the requirements of the review.

Notwithstanding the input of external expertise to inform the review, the conduct and methodology of the review and its outputs remain the full responsibility of HIQA, and governance oversight and sign off will be provided by HIQA.

11. How to contact HIQA

General queries or questions in relation to the information contained within this guidance document can be sent by email to screeningservicesreview@hiqa.ie.

12. Freedom of Information

Please note that HIQA is subject to the Freedom of Information (FOI) Act 2014. HIQA may receive a request under the FOI Act for access to records that concern you. If HIQA receives an FOI request that relates to the population-based health screening services delivered by the HSE at national level, HIQA will consider the request in line with the provisions of the FOI Act and may consult with the service provider to seek their views on the release of this information.

12. Data Protection

HIQA collects and processes personal data for the performance of its functions under the Act. For more detailed information on how HIQA uses personal data and information about the rights of data subjects, please see its online Privacy Notice: <https://www.hiqa.ie/reports-and-publications/corporate-publication/hiqa-privacy-notice>.

If you have any queries about the processing of personal data, please contact HIQA's Data Protection Officer at dpo@hiqa.ie.

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Appendix 1: Terms of Reference for a review of the governance arrangements for the provision of population-based health screening services by the Health Service Executive at national level

The following terms of reference have been determined for the conduct of this review.

1. To assess the governance, leadership and management arrangements in place for the provision of high-quality, safe population-based health screening services by the HSE at national level.
2. To assess the screening services' compliance with the national standards, cognisant of the learnings from the reviews and reports into CervicalCheck.
3. In assessing the *capacity and capability* of the population-based health screening services, HIQA will:
 - review the effectiveness and sustainability of the governance and oversight arrangements in place to support the ongoing delivery of high-quality, safe population-based health screening services. This will include a review of the arrangements in place for:
 - providing assurances regarding the quality and safety of screening services
 - risk management and reporting
 - formalised agreements for the provision and quality of services provided externally on behalf of the HSE
 - ensuring learnings from the reviews and reports into CervicalCheck have been implemented across the screening services, where relevant
 - screening services to use their resources to achieve the best possible quality and safety outcomes for people who use the services.
4. In assessing the *quality and safety* of the population-based health screening services, HIQA will:

- review the extent to which the governance and oversight arrangements support a person-centred approach to care and the delivery of high-quality, safe and effective services. This will include a review of:
 - how the screening services considers the identified needs and preferences of people who use the services
 - how the screening services protects people using the services from the risk of harm
 - the screening services' compliance with the policies and procedures to support open disclosure
 - how people using the screening services or who have used the services are informed and supported after an adverse event.

While the review will focus on the above, in line with our functions under Section 8 1(c) of the Health Act (2007) as amended, the review team may assess compliance with any of the national standards from the *National Standards for Safer Better Healthcare* as required.

5. To prepare and publish a report of the findings of the review to ensure transparency and promote quality in the delivery and safety of screening services for the benefit of the health and welfare of the public.
6. Where HIQA identifies gaps in the service and or non-compliance with the national standards, it will make recommendations in the review report for the purposes of quality improvement and to support the screening services to come into full compliance with the national standards. HIQA will make recommendations to the HSE that will reflect best practice and the future vision for screening services in line with standards, policy and legislation.
7. If, in the course of the review, it becomes apparent that there are reasonable grounds to believe that there are wider areas of concern or risks to people using the population-based health screening services, HIQA may recommend that these terms be extended to include further evaluation or that a new body of work should be undertaken, as appropriate.

Appendix 2: Risk Matrix

Regulatory risk is the identification and assessment of risk caused by non-compliance with relevant legislation, regulations and national standards by the service provider and the impact of this risk on people using the service.

In a risk based approach to regulation risk is assessed as the product of both the likelihood and impact of risk within a service that HIQA monitors. Authorised persons will assess risk by estimating the likelihood (scores 1-5) and impact of the risk (scores 1-5) and calculate an aggregate score using the matrix below.

Risk Rating	1	2	3	4	5
<i>Likelihood impact</i>	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic					
4 Major					
3 Moderate					
2 Minor					
1 Negligible					

The calculated score indicates if risk is low, moderate or significant

Low risk - Risk levels 1-6

Risk levels 1-6 are deemed low risk and this falls within the 'trusted' and 'right-touch' regulation.

Moderate risk - Risk levels 8-12

This level of risk is not acceptable and a regulatory response in line with HIQA's policy on risk escalation will be considered.

Significant risk - Risk level 15-25

This level of risk is unacceptable and a regulatory response in line with HIQA's policy on risk escalation will be considered and requires an immediate regulatory response. This level of risk will result in an immediate review by HIQA with a recommendation on escalation action as part of the regulatory plan for the service.

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