Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guidelines for the justification of medical radiological procedures on asymptomatic individuals

25 November 2025

About the Health Information and Quality Authority (HIQA)

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 the Minister for Children, Equality, Disability, Integration and Youth, 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.

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Plain language summary

While the risks are generally considered to be low, all medical exposures to ionising radiation (for example, X-rays or CT scans) carry some risk. Under Irish law, the Health Information and Quality Authority (HIQA) must publish guidelines for justifying procedures that involve medical exposure to ionising radiation in people who have no known disease or symptoms and where they are not part of a national health screening programme. Justification means making sure that the benefits outweigh the risks involved. Justification is particularly important when the person has no known disease or symptoms (that is, they are asymptomatic) and the medical exposure to ionising radiation is for screening purposes. BreastCheck, the National Breast Screening Programme in Ireland, is an example of where ionising radiation is used within an approved national screening programme. National screening programmes are government-funded services that look for early signs of disease in people who have no known disease or symptoms, and include screening services such as BreastCheck.

The guidelines were developed based on principles found as part of a scoping review, with the support of an expert advisory group brought together by HIQA. This group includes patients and patient advocates, health care professionals and experts in radiation protection. HIQA also carried out a series of focus groups and a public consultation to gain feedback from a broad range of stakeholders.

These guidelines set out eight requirements for the screening of asymptomatic individuals involving ionising radiation, outside of a screening programme. Under Irish law, undertakings must follow these guidelines. An undertaking is a person or body who carries out, employs others to carry out, or engages others to carry out a medical radiological procedure (for example, an X-ray or CT scan) or the practical aspects of a medical radiological procedure. Examples of healthcare professionals who will be required to follow these guidelines include dentists, doctors, nurses and radiographers.

1 Introduction

The European Union Basic Safety Standards for the Protection Against Dangers from Medical Exposure to Ionising Radiation (Euratom) were initially transposed into Irish law under SI 256 in January 2019.[1] These regulations named HIQA as the competent authority for medical exposure to ionising radiation. This legislation, and subsequent amendments, will be referred to as 'the regulations' from this point on in this document. The regulations require HIQA to publish guidelines on the specific justification of medical radiological practices on asymptomatic individuals for the early detection of disease, but not as part of a health screening programme. As an asymptomatic person presenting for a radiological procedure is not always a patient in the traditional sense, in these guidelines the term 'asymptomatic individual' is used throughout. Asymptomatic individuals include, for example, those who may have an increased risk of a disease due to a risk factor or a combination of risk factors.

A *medical exposure* means an exposure incurred as part of an individual's own medical or dental diagnosis or treatment, and intended to benefit their health.

Asymptomatic individual: for the purpose of these guidelines, an asymptomatic individual is defined as a person with no known disease, signs or symptoms, but who may have risk factors for a disease.

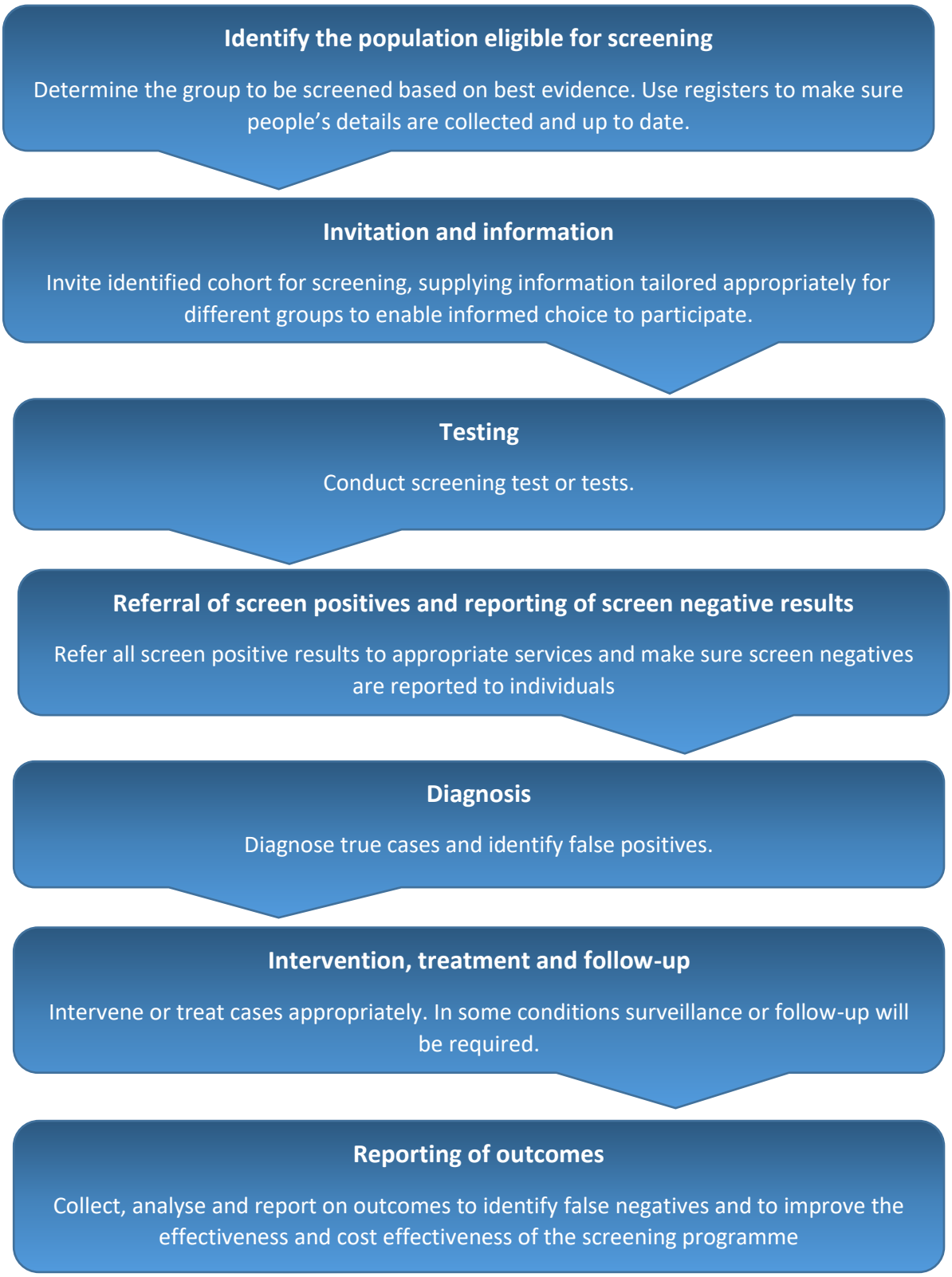
This document describes the background to and regulations underpinning these guidelines as well as the steps taken to date in their development. Guideline statements are presented.

1.1 Screening

Health screening is a process that separates the people who probably have a condition from those who probably do not. The purpose of health screening is to identify people in an asymptomatic population who are at higher risk of a health problem or a condition, so that early treatment or intervention can be offered.[2] Health screening in the context of medical exposure to ionising radiation refers to procedures using medical exposures for early diagnosis in at-risk population groups. Further information about the benefits and risks of screening are outlined in a document published by the World Health Organization ('Screening programmes: a short guide').[2]

A screening programme is not just a single procedure or test, but is part of a pathway. Figure 1 shows the steps involved in a screening pathway. The first step in the pathway is to identify people who are eligible for screening based on the best evidence. The pathway ends when the outcomes are reported.[2]

Figure 1: Steps in a screening pathway§



§ **Source:** Modified from Screening programmes: a short guide by the World Health Organization[2]

1.2 Justification

Ionising radiation is used in both the diagnosis and treatment of disease. Technological developments in ionising radiation have led to improved patient outcomes due to better, faster diagnosis and more effective treatment. However, there are concerns that certain technologies are overused, with the potential that, for some individuals, the harms exceed the potential for benefit.[3-5] All medical exposures to ionising radiation carry some risk. One of the main risks is the increased risk of developing cancer for the individual. When considering the use of ionising radiation to support screening and diagnosis of disease, the risks are generally considered to be low. However, other risks to consider include the potential for a negative impact for the individual due to misleading or inaccurate results, as well as the healthcare resource use and opportunity cost to the healthcare system associated with additional investigations.

Justification is the process of demonstrating that there is a sufficient net benefit associated with a radiation exposure.[6, 7] This takes into account the efficacy and potential benefits of the exposure, the possible risks associated with the exposure, and any alternatives that may be available. Table 1 outlines the three levels of justification of a radiological practice recognised internationally.

Table 1: Levels of justification of radiological practices

Level	Consideration
1	**Considers the use of radiation in medicine in general.** The proper use of radiation in medicine is accepted as doing more good than harm to society, since, in general, the net benefits outweigh the harms. General level of justification is now taken for granted.
2	**Undertaken at a population level for a type of practice.** Level 2 justification considers whether, in general, for a specified practice with a specified objective, the benefits outweigh the risks. At a population level, the practice should be judged to usually improve the diagnosis or treatment, or to provide necessary information about the exposed individuals. For example, chest X-rays for patients showing relevant symptoms, or a group of individuals at risk for a condition that can be detected and treated.
3	**Considers the diagnostic or therapeutic outcome at an individual patient level.** This is assigned to the healthcare professionals involved in the patient's care. All individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved. That is, the particular application should be judged to provide more good than harm for the individual patient.

Source: International Commission on Radiological Protection[6, 7]

Level 2 justification is outlined in Regulation 7 of the regulations. This states that HIQA, as the competent authority, must justify new types or classes of practice prior to them being generally adopted. This is known as 'generic justification'; further guidance in relation to the requirements for generic justification is available in HIQA's Methods document on the HIQA website.[8]

Level 3 justification considers justification at the individual patient level. As per Regulation 8, each individual medical exposure must be justified in advance by a practitioner taking into account medical information about the service user and their individual characteristics, such as their pregnancy status, if relevant.

Regulation 8(1) of the regulations requires that:

"A person shall not carry out a medical exposure unless it (a) shows a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, and (b) takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation."

1.3 Justification for asymptomatic individuals

Medical radiological procedures are typically used in symptomatic individuals for either diagnostic or therapeutic purposes. However, they can also be used to screen asymptomatic individuals who are at risk of developing disease, with the intention of early diagnosis, thereby enabling earlier treatment and improved outcomes. BreastCheck, the National Breast Screening Programme in Ireland, is an example of where ionising radiation is used within an approved national screening programme. Under Regulation 8(3) HIQA must justify medical radiological procedures that are being performed as part of a health screening programme prior to the commencement of such a programme.

Regulation 8(3) of the regulations requires that:

"8(3) The Authority shall, after consultation with the relevant professional body or bodies, carry out specific justification for medical radiological procedures to be performed as part of a health screening programme prior to the commencement of such programme."

However, the regulations recognise that medical radiological procedures can also occur outside of organised population-based health screening programmes. Under Regulation 8(6) HIQA is required to publish guidelines for the specific justification of medical radiological procedures on asymptomatic individuals, performed for the early detection of disease, outside of a health screening programme. This document sets out guidelines that have been developed in line with HIQA's remit under Regulation 8(6).

Regulation 8(6) of the regulations requires that:

"The Authority shall, after consultation with the relevant professional body or bodies, publish guidelines on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease but not as part of a health screening programme."

For the purpose of these guidelines, a health screening programme refers to a national, organised population-based screening programme. As of November 2025, the only national, population-based screening programme in Ireland that involves ionising radiation as the primary screening tool is BreastCheck.

1.4 Process steps for the development of the guidelines

Figure 2 below outlines the steps that have been undertaken to develop these guidelines.

Figure 2: Steps taken to develop the guidelines

Key: EAG – Expert Advisory Group; MEIR – Medical Exposure to Ionising Radiation

A scoping review was carried out to gather any relevant guidelines, guidance or recommendations available nationally or internationally on the use of medical ionising radiation in asymptomatic individuals for the purpose of the early detection of disease, but not as part of a health screening programme. A number of high-level themes were identified from the literature. The findings of the scoping review were presented to HIQA's Medical Exposure to Ionising Radiation Expert Advisory Group (EAG).

The themes identified in the scoping review were subsequently used to prepare draft guidelines (Table 2); this was done through consensus by HIQA's evidence review team following discussion.

A stakeholder engagement campaign was carried out after identification of relevant stakeholders; details of the bodies included in this campaign are contained in Appendix 1. As part of the stakeholder engagement, four separate focus groups were convened with key stakeholders for these guidelines. In addition, three sets of one-to-one interviews were conducted. Feedback was incorporated, as appropriate, into the draft guidelines. These updated draft guidelines were presented to HIQA's Medical Exposure to Ionising Radiation EAG for review and feedback.

HIQA published the draft guidelines on its website along with the scoping review that informed their development. The draft guidelines were available for a six-week targeted and public consultation, with this consultation publicised through media and social media sites. Targeted consultation with a range of identified key stakeholder organisations and bodies was also undertaken. After further refinement, the revised draft guidelines were presented again to the EAG for further comment. Feedback was implemented, as appropriate, before the guidelines were submitted for approval by HIQA, and published on the HIQA website.

HIQA will review and update these guidelines, as required and in line with best practice and legislative change.

1.5 Purpose, scope and use of this document

Purpose — the purpose of this document is to outline the principles and essential criteria for the specific justification of medical radiological procedures on asymptomatic individuals. It also aims to provide stakeholders with a clear understanding of the guidelines and how they were developed.

Scope — this document includes the guidelines for the specific justification of medical radiological procedures on asymptomatic individuals, performed for the early detection of disease, outside of a health screening programme. For the purpose of these guidelines, a health screening programme refers to the organised population-based screening programmes named in Section 1.3 above. Therefore, these guidelines apply to medical radiological procedures for the purpose of the early detection of disease that take place outside of these screening programmes. These guidelines also apply to medical radiological procedures on asymptomatic individuals who have a history of a treated condition and have completed treatment and follow-up.

Applies to — undertakings must follow the principles outlined in these guidelines to ensure compliance with the requirements of the regulations. An undertaking is a person or body who carries out, employs others to carry out, or engages others to carry out a medical radiological procedure or the practical aspects of a medical radiological procedure. These guidelines will also apply to individual professionals involved in the provision of medical radiological procedures in dental and relevant medical settings.

Using this document — this document has been developed in the form of a series of guideline statements; equal consideration should be given to each statement. Each statement is followed by an elaboration of what that statement means and an example, where appropriate. Where regulations are quoted, a hyperlink has been provided to S.I. 256 of 2018, as amended.

2 Guidelines

Table 2 includes eight guideline statements. These statements are then elaborated upon, with examples included, where appropriate.

Table 2 Guidelines for the justification of medical radiological procedures on asymptomatic individuals for the purpose of the early detection of disease outside of health screening programmes

	Guideline	Elaboration and examples
1	Medical radiological procedures carried out on asymptomatic individuals must be performed in accordance with guidelines from relevant scientific and professional bodies.	Elaboration: ▪ Guidelines should be evidence-based (with this evidence clearly documented) and relevant to the Irish context. ▪ Guideline recommendations should conclude that the medical radiological procedure is justified, that is, on average, it results in a sufficient overall net benefit.
2	There must be a risk profile* of those expected to benefit from the medical radiological procedure.	Elaboration: ▪ The risk profile should be underpinned by a clearly defined evidence-base. The evidence base may include information provided through clinical guidelines. ▪ Prospective assessment of individuals must be carried out against this risk profile. Examples: The risk profile may contain one or a number of risk factors or referral criteria. These risk factors can be modifiable (for example, diet, smoking) or non-modifiable (for example, age, sex).
3	Benefits of a medical radiological procedure must outweigh the risk; the assessment of these benefits and risks must take into account available alternative	Justification of medical radiological procedures must be carried out in line with Regulation 8. Elaboration: ▪ This assessment must be carried out in advance of the medical radiological procedure and should be

	techniques which involve no or less exposure to ionising radiation.	commensurate with the level of risk (see section below). ▪ The assessment must include consideration of: ➢ Benefits: for example, the potential, at a population level, to reduce mortality and morbidity by early detection and early treatment of disease, reduce incidence of a condition by identifying and testing for its precursors, or to increase choice by identifying a condition or its risk factors at an earlier stage when more options may be available. ➢ Risks: risks associated with the medical radiological procedure (that is, the biological effects of radiation) and other risks (for example, the potential for diagnostic error and or overdiagnosis; the likelihood of further investigations being required; risks associated with subsequent imaging, other investigations or treatments). ▪ Ideally these benefits and risks should be quantified. ▪ Consideration must be given to the effectiveness, benefits and risks of available alternative techniques having the same objective, but involving no or less exposure to ionising radiation.
4	Medical radiological procedures for asymptomatic individuals must be individually justified by a practitioner	Elaboration: ▪ As per Regulation 10(3) and 8(5), to protect the service user, both the practitioner and the referrer must be involved in the justification process for each medical exposure. Each medical exposure requires a written referral which must state the reason for requesting the particular procedure. Sufficient clinical data must be provided to enable the practitioner to carry out a justification assessment. Only appropriately-trained and recognised healthcare professionals, as defined in Regulation 5 can act as a practitioner and only those defined in Regulation 4, can refer a service user for a medical exposure to ionising radiation. ▪ As per Regulation 8(8), all individual medical exposures must be justified by a practitioner in advance of the exposure, and taking account of the objectives of the exposure and the specific characteristics of the individual involved.

		▪ As per Regulation 10(1), all medical exposures must take place under the clinical responsibility of a practitioner. ▪ As per Regulation 8 (15), a record of this justification should be available.
5	Adequate information must be provided to the individual by the referrer or practitioner about the potential benefit and harm of the medical radiological procedure, including the implications of possible findings.	Elaboration: ▪ Information must be provided by the referrer or practitioner in advance of the medical radiological procedure. ▪ Provision of information must be consistent with the requirements of the regulations. ▪ The information provided must be commensurate with the risk associated with the medical radiological procedure. ▪ Information provided should be accessible and sufficient for the individual or their representative, parent or legal guardian to provide informed consent. Information provided must include: ▪ Benefits: for example, the potential, at a population level, to reduce morbidity and mortality by early detection and early treatment of disease, reduce incidence of a condition by identifying and testing for its precursors, or to increase choice by identifying a condition or its risk factors at an earlier stage when more options may be available. ▪ Risks: risks associated with the medical radiological procedure (that is, the biological effects of radiation) and other risks (for example, the potential for diagnostic error and or overdiagnosis; the likelihood of further investigations being required; risks associated with subsequent imaging, other investigations or treatments). ▪ Ideally the identified benefits and risks should be quantified. ▪ Potential pathway for follow up of findings (for example, information on additional test(s) that may be required to make a diagnosis).
6	There must be a defined process for how results of examinations	Elaboration: ▪ The results of the medical radiological procedure must be communicated to the referrer and the

	are integrated into care pathways** or treatment plans.	asymptomatic individual. ▪ For each test result (for example, positive, negative or indeterminate) there must be a defined pathway or treatment plan. ▪ Consideration must be given to the management of incidental findings.
7	Adequate measures must be in place to document the key aspects of the process, including the medical radiological procedure and care pathway or treatment plan.	Elaboration: ▪ Documentation showing how each guideline statement has been considered must be in place. ▪ Documentation must consider both the processes and adherence to the processes. This must be commensurate with the risk associated with the medical radiological procedure and the complexity of the organisation/service provider. ▪ Documentation must include the referral for the medical radiological procedure (in line with Regulation 8(10)), the justification of the individual exposure, adherence to the assessment of risk profiles, and relevant clinical guidelines. ▪ In addition to other factors, this will provide evidence of compliance with the requirements of the regulations. HIQA's Guidance on the assessment of undertakings providing medical exposure to ionising radiation provides information to undertakings about how compliance with the regulations will be assessed.
8	There must be a quality assurance programme, along the whole care pathway, including technical equipment, the performance and interpretation of images, and the management of findings.	Elaboration: ▪ Quality assurance is defined as all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. ▪ The quality assurance programme must meet the requirements of the regulations, for example, Regulation 14 Equipment and Regulation 13(4) Procedures for Clinical Audit. The national procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation detail the requirements. ▪ In addition, consideration should be given to Section 6.1.4 - Quality Assurance in the EPA document;

		'Guidance for undertakings on the application of the Ionising Radiation Regulations'.

Key: EPA – Environmental Protection Agency.
* One or more risk factors.
** Care pathways describe the process involved in managing a clinical condition. They typically include details on what to do, when to do it, who does it, and where.[9]

3 Other regulatory requirements

These guidelines do not replace or take away from an undertaking's responsibility to comply with the regulations, the requirements of which apply to all medical exposures. Additionally, as per Regulation 8(5), for medical radiological procedures carried out on asymptomatic individuals outside of a health screening programme, specific documented justification should be carried out by the practitioner, in consultation with the referrer. Special attention must be given to the provision of adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure in accordance with Regulation 8(13).

Regulation 8(5) of the regulations requires that:

"An undertaking shall ensure that, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease — (a) the procedure – (i) is part of a health screening programme, or (ii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer, in accordance with guidelines published by the Authority in accordance with paragraph (6), and (b) special attention is given to the provision of information to the individual, as required by paragraph (13)."

All medical exposures must be optimised to ensure the dose is kept as low as reasonably achievable, to maximise radiation protection to the asymptomatic individual in line with the regulations. An essential part of ensuring medical exposures are optimised is the establishment, use and regular review of diagnostic reference levels (DRLs) for medical radiological procedures. Undertakings must establish local facility DRLs, and ensure that these are regularly reviewed and used by persons conducting medical radiological procedures, while having regard also for national DRLs established by HIQA.

Particular attention must be given to the radiation protection of asymptomatic persons, especially children as they have greater radiosensitivity than adults. Regulation 15 identifies special practices including exposures of children, and high dose procedures such as computed tomography. This regulation requires that special attention must be given to the use of appropriate equipment including ancillary

equipment, practical techniques, quality assurance programmes and the assessment or verification of dose. Regulation 16 also mandates special protections in relation to pregnancy and breastfeeding in relation to medical exposures.

4 Conclusions

This document has been developed to fulfil HIQA's statutory remit under Regulation 8(6) of S.I. 256 of 2018, as amended to publish guidelines on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease, but not as part of a health screening programme.

If you have any queries in relation to these guidelines please contact HIQA at radiationjustification@hiqa.ie.

References

1. SI No. 256. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 as amended. Dublin: The Stationary Office (2019). Ireland: 2019 [Available from: http://www.irishstatutebook.ie/eli/2018/si/256/made/en/print.
2. World Health Organization. Screening programmes; a short guide. Increase effectiveness, maximise benefits, minimise harms. Copenhagen: 2020 [Available from: https://www.who.int/europe/publications/i/item/9789289054782.
3. Smith-Bindman R, Kwan ML, Marlow EC, Theis MK, Bolch W, Cheng SY, et al. Trends in Use of Medical Imaging in US Health Care Systems and in Ontario, Canada, 2000-2016. JAMA. 2019;322(9):843-56.
4. Rao VM, Levin DC. The overuse of diagnostic imaging and the Choosing Wisely initiative. Annals of internal medicine. 2012;157(8):574-6.
5. Hong J-Y, Han K, Jung J-H, Kim JS. Association of Exposure to Diagnostic Low-Dose Ionizing Radiation With Risk of Cancer Among Youths in South Korea. JAMA Network Open. 2019;2(9):e1910584-e.
6. International Commission on Radiological Protection The 2007 Recommendations of the International Commission on Radiological Protection Publication 103. Ann ICRP. 2007;37:1-63.
7. International Commission on Radiological Protection The 2007 Recommendations of the International Commission on Radiological Protection Publication 105. Ann ICRP. 2007;37(2-4).
8. Health Information and Quality Authority (HIQA). Methods for Generic Justification of New Practices in Ionising Radiation. 2022.
9. Health Service Executive (HSE). Dementia Pathways, Care Pathways: [Available from: https://www.hse.ie/eng/dementia-pathways/care-pathways/.

Appendix — Engagement with key stakeholders

The Medical Exposure to Ionising Radiation expert advisory group (EAG) provided feedback on the scoping review used to underpin these guidelines and reviewed versions of the guidelines. The membership list and the terms of reference for the Medical Exposure to Ionising Radiation EAG can be found here.

As part of the consultation process to develop these guidelines, a list of key stakeholder organisations and affected parties was prepared. Of those identified, the following took part in either focus groups or one-to-one interviews:

- General practitioners
- HSE Clinical Design and Innovation
- Irish Association of Physicists in Medicine
- Irish Dental Association
- Irish DXA Society
- Irish Hospital Consultants Association
- Irish Institute of Radiography and Radiation Therapy
- National Cancer Control Programme
- National Screening Service
- Public health specialists.

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