Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Draft guidelines for the justification of medical radiological procedures on asymptomatic individuals

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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.
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- **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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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 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.

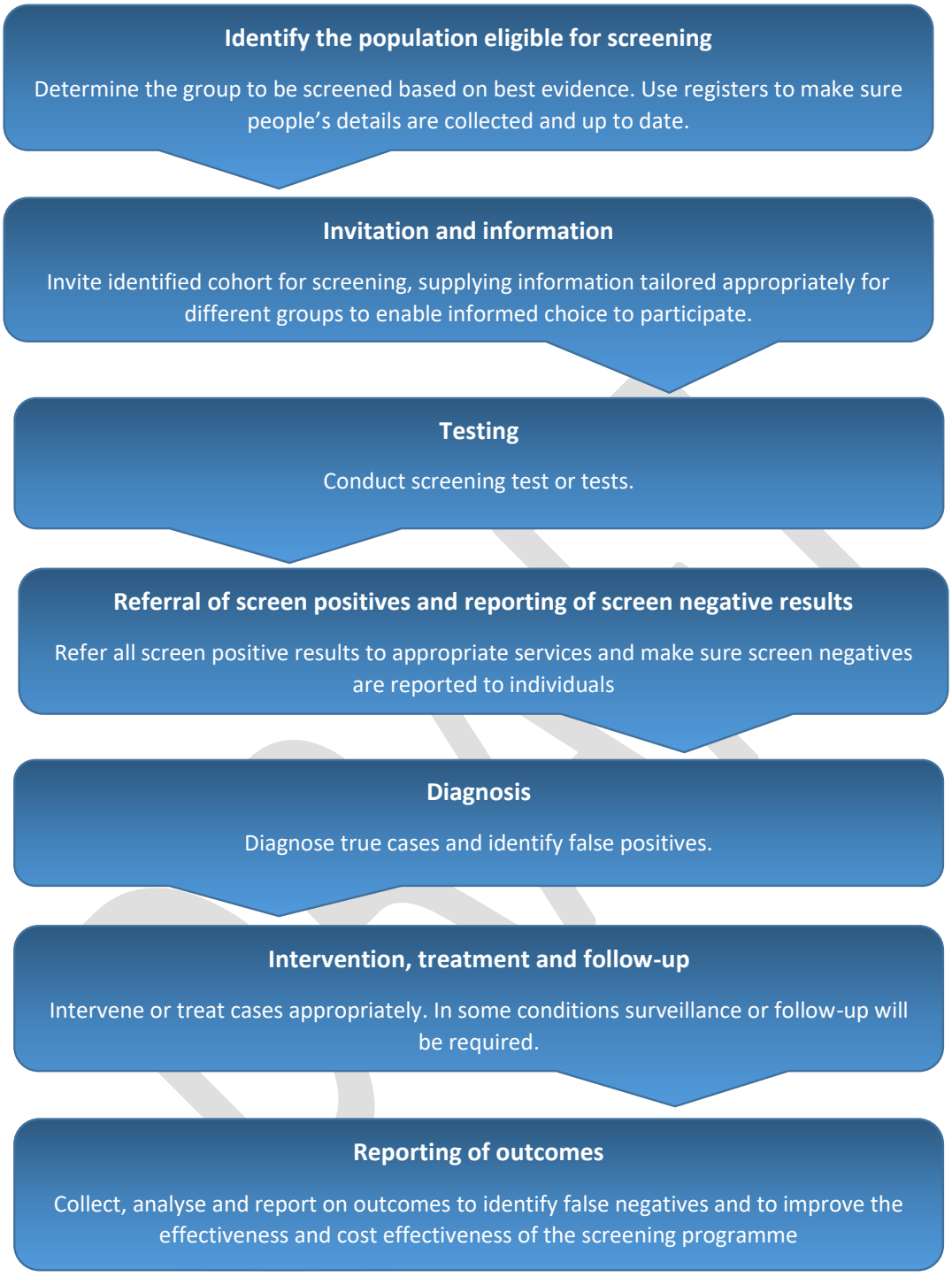
This document describes the background to and regulations underpinning these guidelines as well as the steps taken to date in their development. Draft guideline statements are presented.

1.1 Screening

Screening is a process which separates the people who probably have the 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 population groups at risk.

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 possible detrimental impact for the individual of misleading or inaccurate results, as well as the healthcare resource use and opportunity cost to the healthcare system for 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. These state 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' and 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, either for diagnostic or therapeutic purposes, in symptomatic individuals. 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 to be performed as part of a health screening programme prior to the commencement of such 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 develop guidelines on 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 draft guidelines that have been developed in line with HIQA's remit under Regulation 8(6).

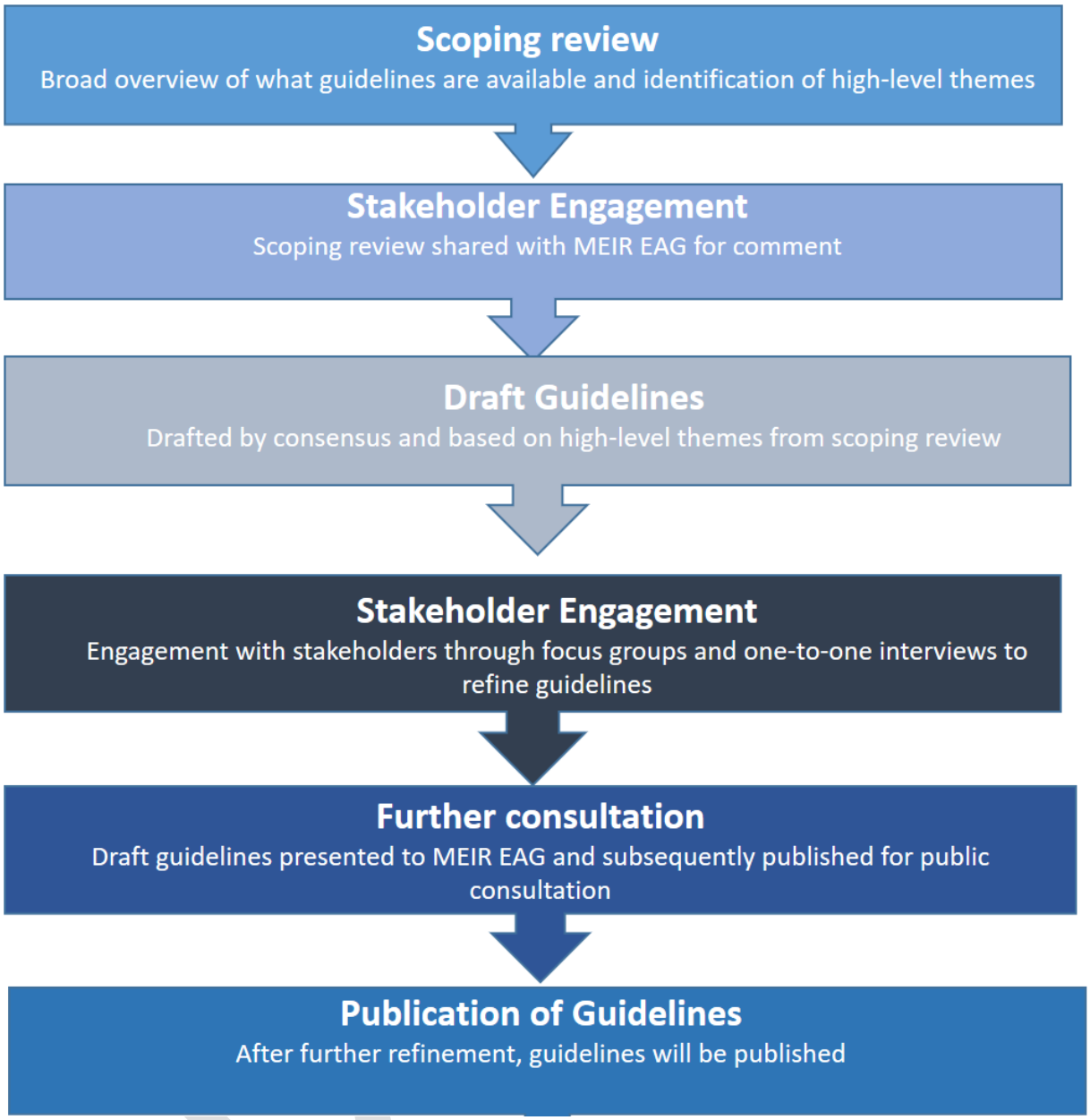
> Regulation 8(6) of the regulations requires that:
>
> "The Authority shall, after consultation with the relevant professional body or bodies, publish guidelines on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease 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 October 2024, Ireland has several such programmes. Specifically, the National Screening Service (NSS) in the HSE has programmes that screen for breast, cervical and colorectal cancers and diabetic retinopathy. The HSE's National Healthy Childhood Programme includes the National Newborn Bloodspot Screening Programme (NNBSP) and the National Newborn Hearing Screening Programme (NNHSP).[9]

1.4 Process steps for the development of the guidelines

Figure 2 below outlines the steps that have or that will be 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 with 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 to three sets of one-to-one interviews. 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 is now publishing the draft guidelines on its website along with the scoping review that informed their development. The draft guidelines will be available for a six-week public consultation, with this consultation publicised through media and social media sites. Targeted consultation with a range of identified key stakeholder organisations and bodies will also be undertaken. After further refinement, the revised draft guidelines will be presented again to the EAG for further comment. Feedback will be implemented, as appropriate, before the guidelines are reviewed and approved 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 draft guidelines and how they are being developed.

Scope — this document includes the draft 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 Draft guidelines

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

Table 2 Draft 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

	Draft 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 procedures.	Elaboration: ▪ There must be a clearly defined evidence base underpinning the risk profile for the proposed group to be screened. 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 should outweigh the risk; the assessment of these benefits and risks should take into account available alternative	Elaboration: ▪ This assessment must be carried out in advance of the medical radiological procedure and should be commensurate with the level of risk (see section below).

	techniques which involve no or less exposure to ionising radiation.	▪ 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 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 or other investigations). ▪ 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 medical 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 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 should take place under the clinical responsibility of a practitioner(defined in the regulations).

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 provided must be accessible and sufficient for the individual or their representative, parent or legal guardian to provide informed consent. ▪ Information must be provided in advance of the medical radiological procedure. ▪ Provision of information must be consistent with the regulations. ▪ The information provided must be commensurate with the risk associated with the medical radiological procedure. Information provided must include, where applicable: ▪ 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 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 or other investigations). ▪ Ideally these 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 are integrated into care pathways** or treatment plans.	Elaboration: ▪ The results of the medical radiological procedure should be communicated to the referrer and the 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	Elaboration:

	aspects of the process, including the medical radiological procedure and care pathway or treatment plan.	▪ Documentation showing how each guideline statement has been considered must be in place as per HIQA's Guidance on the assessment of undertakings providing medical exposure to ionising radiation.*** ▪ 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, the justification of the individual exposure, adherence to the assessment of risk profiles, and relevant clinical guidelines.
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 be consistent with the regulations, for example, Regulation 14 equipment and Regulation 13(4) clinical audits. See also HIQA's national procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation.

* 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.(10)
*** This will be updated once these asymptomatic guidelines are finalised.

3 Other regulatory requirements

These guidelines do not replace or take away from undertakings' responsibility to comply with the regulations. The requirements of the regulations apply to all medical exposures; however, as per Regulation 8(5), medical radiological procedures carried out on asymptomatic individuals outside of a health screening programme must also adhere to these guidelines. Regulation 8(5) states, that for these medical radiological procedures, 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 is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following 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 and guidance by HIQA. 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, with particular regard for exposures carried out on asymptomatic individuals. 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 radio-sensitivity 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 during 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 SI 256/2018 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 draft guidelines please contact HIQA at radiationjustification@hiqa.ie.

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Appendix 1 — 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 will review draft 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:

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

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