

# Guidelines for the justification of medical radiological procedures on asymptomatic individuals



Health  
Information  
and Quality  
Authority

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

**Dr Kirsty O'Brien**  
**Health Services Researcher,**  
**Health Technology Assessment Directorate**



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# Overview

- Background
- Development of the guidelines
- Guideline statements
- Other relevant HIQA documents

# Background

The background features a light teal gradient. Overlaid on this are several overlapping geometric shapes in various shades of teal and light green. These shapes include triangles, trapezoids, and rectangles, some of which are oriented diagonally. The shapes are semi-transparent, creating a layered effect. A prominent feature is a large, dark teal triangle pointing downwards on the left side, which overlaps with other shapes. To its right, there are several horizontal bands of different shades of teal, some of which are also overlapped by other shapes. The overall composition is abstract and modern.

# Legal framework for ionising radiation in Ireland



# HIQA's role

## **Healthcare Regulation Directorate**

- Some competent authority roles commenced in January 2019
- Functions include:
  - Inspections (monitoring compliance, escalate and enforce as necessary)
  - Receipt of significant events related to accidental and unintended exposures & sharing of lessons learned
  - Diagnostic reference levels including establishment and review of national DRLs
  - Population dose estimation from medical exposures
  - Dose constraints for carers and comforters
  - Criteria for acceptability of equipment
  - National procedures for clinical audit

# HIQA's role

## Healthcare Regulation Directorate

- Some competent authority roles commenced in January 2019
- Functions include:
  - Inspections (monitoring compliance, escalate and enforce as necessary)
  - Receipt of significant events related to accidental and unintended exposures & sharing of lessons learned
  - Diagnostic reference levels including establishment and review of national DRLs
  - Population dose estimation from medical exposures
  - Dose constraints for carers and comforters
  - Criteria for acceptability of equipment
  - National procedures for clinical audit

## Health Technology Assessment (HTA)

- Commenced in Feb 2023
- Functions include:
  - Level 2 (generic justification) of new types of practices
  - Review of existing classes or types of practice
  - Justification of medical radiological procedures which are part of health screening programmes
  - **Publication of the asymptomatic guidelines**

# Why did HIQA develop these guidelines?

**Regulation 8(6) SI 256 of 2018, as amended,  
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”

# Regulation 8(5)

## **Regulation 8(5) SI 256 of 2018, as amended:**

“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)”

# Definitions

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.

A *health screening programme*, for the purpose of these guidelines, refers to a national, organised, population-based screening programme. BreastCheck is an example of such a programme.

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.

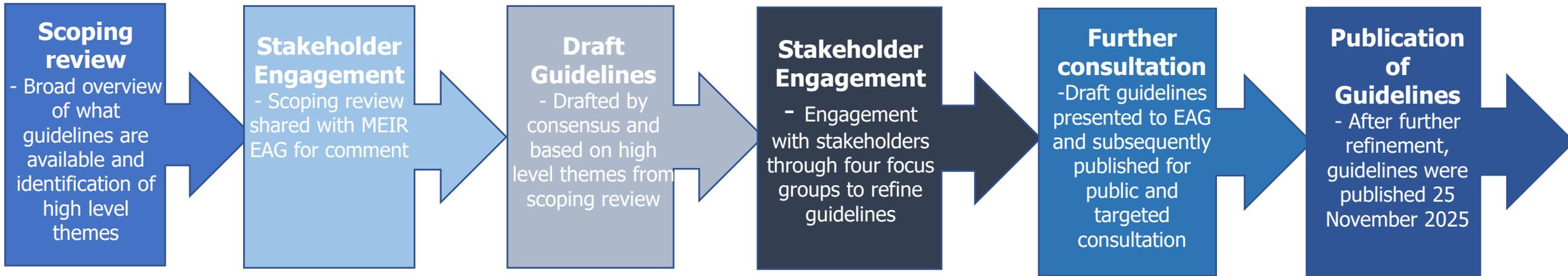
# Purpose, scope, & use of the guidelines

- **Purpose** — to outline the principles and essential criteria for the specific justification of medical radiological procedures on asymptomatic individuals and to provide stakeholders with a clear understanding of the guidelines and how they were developed.
- **Scope** — These guidelines apply to medical radiological procedures for the purpose of the early detection of disease that take place outside of 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. 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** — there are eight 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.

# Development of the guidelines

The background features a light teal gradient. Overlaid on this are several overlapping geometric shapes in various shades of teal and light green. These shapes include triangles, rectangles, and trapezoids, some of which are oriented diagonally. The shapes are semi-transparent, creating a layered, architectural effect. A prominent diagonal line runs from the bottom left towards the top right, intersecting several of the other shapes.

# Developing the guidelines



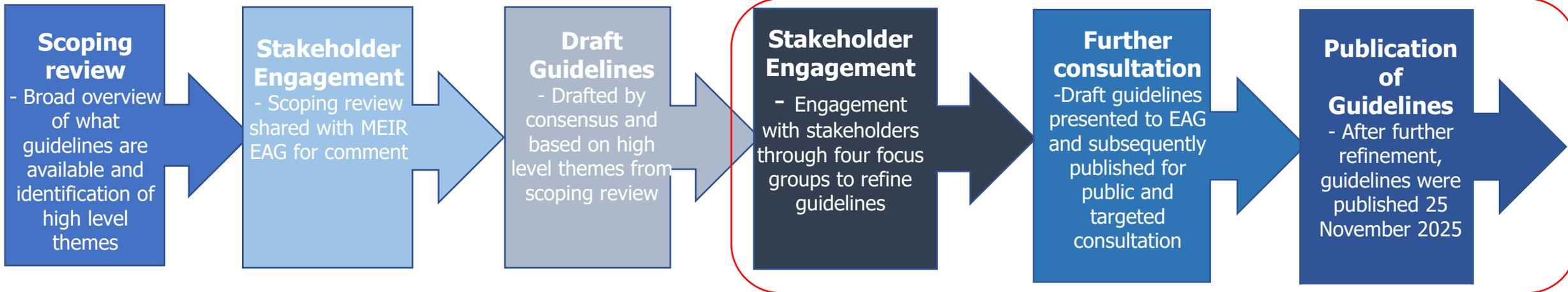
- To inform the development of these guidelines, we undertook a scoping review to determine if any guidelines, recommendations or guidance documents existed nationally or internationally that would be relevant to Irish context.
- After review by our Expert Advisory Group (EAG), the guidelines were drafted based on the high level themes identified in the scoping review.

# Developing the guidelines



- To inform the development of these guidelines, we undertook a scoping review to determine if any guidelines, recommendations or guidance documents existed nationally or internationally that would be relevant to Irish context.
- After review by our Expert Advisory Group (EAG), the guidelines were drafted based on the high level themes identified in the scoping review.

# Refining the draft guidelines



- Three rounds of stakeholder engagement:
  - Expert Advisory Group (EAG)
  - Focus groups and 1:1 interviews
  - Public and targeted consultation
- The guidelines underwent refinement based on feedback after each round of engagement

# Focus group & 1:1 interviews

- Organisations and individuals that participated:
  - 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

# Organisations: targeted consultation

- Organisations contacted included:

- Age Action Ireland
- CORU
- Dental Council
- Environmental Protection Agency
- Faculty of Radiologists and Radiation Oncologists, Royal College of Surgeons in Ireland
- Faculty of Sports and Exercise Medicine, Royal College of Physicians of Ireland
- Health Products Regulatory Authority
- Health Protection Surveillance Centre
- Irish Association of Physicists in Medicine (IAPM)
- Irish Cardiac Society
- Irish College of General Practitioners
- Irish College of Physicists in Medicine
- Irish Dental Association
- Irish Hospital Consultants Association
- Irish DXA Society
- Irish Institute of Radiography and Radiation Therapy
- Irish Medical Council
- Irish Medical Organisation
- Irish Nuclear Medicine Association
- National Cancer Control Programme
- National Clinical Effectiveness Committee
- National Radiation Protection Office
- National Screening Advisory Committee
- National Screening Service
- Nursing and Midwifery Board of Ireland
- Office of the nursing and midwifery services director, Health Service Executive
- Patients for Patient Safety
- Private Hospitals Association
- Royal College of Physicians Ireland
- SAGE advocacy

# Guidelines

The background features a light teal gradient. Overlaid on this are several overlapping geometric shapes in various shades of teal and light green. These shapes include triangles, rectangles, and trapezoids, some of which are oriented diagonally. The shapes are semi-transparent, creating a layered effect. A prominent feature is a large, dark teal triangle pointing downwards on the left side, which overlaps with other shapes. To its right, there are several horizontal bands of different shades of teal, some of which are also overlapped by other shapes. The overall composition is abstract and modern.

# Guideline statement 1

	<b>Guideline</b>	<b>Elaboration and examples</b>
1	Medical radiological procedures carried out on asymptomatic individuals must be performed in accordance with guidelines from relevant scientific and professional bodies.	<p>Elaboration:</p> <ul style="list-style-type: none"><li>■ Guidelines should be evidence-based (with this evidence clearly documented) and relevant to the Irish context.</li><li>■ Guideline recommendations should conclude that the medical radiological procedure is justified, that is, on average, it results in a sufficient overall net benefit.</li></ul>

# Guideline statement 2

	<b>Guideline</b>	<b>Elaboration and examples</b>
2	There must be a risk profile* of those expected to benefit from the medical radiological procedure.	<p>Elaboration:</p> <ul style="list-style-type: none"><li>■ The risk profile should be underpinned by a clearly defined evidence-base. The evidence base may include information provided through clinical guidelines.</li><li>■ Prospective assessment of individuals must be carried out against this risk profile.</li></ul> <p>Examples:</p> <p>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 nonmodifiable (for example, age, sex).</p>

\* One or more risk factors

# Guideline statement 3

	<b>Guideline</b>	<b>Elaboration and examples</b>
3	Benefits of a medical radiological procedure must outweigh the risk; the assessment of these benefits and risks must take into account available alternative techniques which involve no or less exposure to ionising radiation.	<p>Justification of medical radiological procedures must be carried out in line with <a href="#">Regulation 8</a>.</p> <p>Elaboration:</p> <ul style="list-style-type: none"><li>■ 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).</li><li>■ The assessment must include consideration of:<ul style="list-style-type: none"><li>■ <b>Benefits:</b> 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.</li><li>■ <b>Risks:</b> 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).</li></ul></li><li>■ Ideally these benefits and risks should be quantified.</li><li>■ 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.</li></ul>

# Guideline statement 4

	<b>Guideline</b>	<b>Elaboration and examples</b>
4	Medical radiological procedures for asymptomatic individuals must be individually justified by a practitioner	<p>Elaboration:</p> <ul style="list-style-type: none"><li>■ As per Regulation <a href="#">10(3) and 8(5)</a>, 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 <a href="#">Regulation 5</a> can act as a practitioner and only those defined in <a href="#">Regulation 4</a>, can refer a service user for a medical exposure to ionising radiation.</li><li>■ As per <a href="#">Regulation 8(8)</a>, 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.</li></ul>

# Guideline statement 5

	Guideline	Elaboration and examples
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.	<p>Elaboration:</p> <ul style="list-style-type: none"><li>Information must be provided by the referrer or practitioner in advance of the medical radiological procedure.</li><li>Provision of information must be consistent with the requirements of the regulations.</li><li>The information provided must be commensurate with the risk associated with the medical radiological procedure.</li><li>Information provided should be accessible and sufficient for the individual or their representative, parent or legal guardian to provide informed consent.</li></ul> <p>Information provided must include:</p> <ul style="list-style-type: none"><li><b>Benefits:</b> 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.</li><li><b>Risks:</b> 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).</li><li>Ideally the identified benefits and risks should be quantified.</li><li>Potential pathway for follow up of findings (for example, information on additional test(s) that may be required to make a diagnosis).</li></ul>

# Guideline statement 6

	<b>Guideline</b>	<b>Elaboration and examples</b>
6	There must be a defined process for how results of examinations are integrated into care pathways** or treatment plans	<p>Elaboration:</p> <ul style="list-style-type: none"><li>■ The results of the medical radiological procedure must be communicated to the referrer and the asymptomatic individual.</li><li>■ For each test result (for example, positive, negative or indeterminate) there must be a defined pathway or treatment plan.</li><li>■ Consideration must be given to the management of incidental findings.</li></ul>

\*\*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.

# Guideline statement 7

	<b>Guideline</b>	<b>Elaboration and examples</b>
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.	<p>Elaboration:</p> <ul style="list-style-type: none"><li>■ Documentation showing how each guideline statement has been considered must be in place.</li><li>■ 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.</li><li>■ Documentation must include the referral for the medical radiological procedure (in line with <a href="#">Regulation 8(10)</a>), the justification of the individual exposure, adherence to the assessment of risk profiles, and relevant clinical guidelines.</li><li>■ In addition to other factors, this will provide evidence of compliance with the requirements of the regulations. <a href="#">HIQA's Guidance on the assessment of undertakings providing medical exposure to ionising radiation</a> provides information to undertakings about how compliance with the regulations will be assessed.</li></ul>

# Guideline statement 8

	<b>Guideline</b>	<b>Elaboration and examples</b>
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.	<p>Elaboration:</p> <ul style="list-style-type: none"><li>■ 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.</li><li>■ The quality assurance programme must meet the requirements of the regulations, for example, <a href="#">Regulation 14</a> Equipment and <a href="#">Regulation 13(4)</a> Procedures for Clinical Audit. The <a href="#">national procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation</a> detail the requirements.</li><li>■ In addition, consideration should be given to Section 6.1.4 - Quality Assurance in the EPA document; '<a href="#">Guidance for undertakings on the application of the Ionising Radiation Regulations</a>'.</li></ul>

# Other relevant HIQA documents

The background features a decorative pattern of overlapping, semi-transparent geometric shapes in various shades of teal and light green. These shapes, which include triangles and polygons, are arranged in a way that creates a sense of depth and movement, primarily concentrated in the lower half of the page.

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## Safer Better Care

HIQA is an independent authority that exists to improve health and social care services for the people of Ireland.



Healthcare Services



Children's Services



Disability Services



Older People's Services



International Protection  
Accommodation



Ionising Radiation



Health Information



Health Technology  
Assessment



National Immunisation  
Advisory Committee



National Standards

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## Safer Better Care

HIQA is an independent authority that exists to improve health and social care services for the people of Ireland.



Healthcare Services



Children's Services



Disability Services



Older People's Services



International Protection  
Accommodation



Ionising Radiation



Health Information



Health Technology  
Assessment



National Immunisation  
Advisory Committee



National Standards

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

Ionising Radiation ▶

Justification of practices

Regulation of Medical Exposure

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

Ionising Radiation ▶

Justification of practices

Regulation of Medical Exposure

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## Ionising Radiation

Justification of practices

Regulation of Medical Exposure

### How to apply for generic justification

To apply for the generic justification please see information below

### Medical Exposure to Ionising Radiation (MEIR) Expert Advisory Group

See information on HIQA's EAG which advises on its medical exposure to ionising radiation functions

### Applications in progress

See list of applications for generic justification currently in progress:

### Generic justification decisions

Published reports on the justification of practices involving medical exposure to ionising radiation

### Asymptomatic guidelines

Read HIQA's guidelines on the use of medical radiological procedures in asymptomatic individuals

### Information Events

See below details of information events held by HIQA

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## Ionising Radiation

Justification of practices

Regulation of Medical Exposure

### How to apply for generic justification

To apply for the generic justification please see information below

### Medical Exposure to Ionising Radiation (MEIR) Expert Advisory Group

See information on HIQA's EAG which advises on its medical exposure to ionising radiation functions

### Applications in progress

See list of applications for generic justification currently in progress:

### Generic justification decisions

Published reports on the justification of practices involving medical exposure to ionising radiation

### Asymptomatic guidelines

Read HIQA's guidelines on the use of medical radiological procedures in asymptomatic individuals

### Information Events

See below details of information events held by HIQA

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## How to apply for generic justification

To apply for the generic justification please see information below



## Medical Exposure to Ionising Radiation (MEIR) Expert Advisory Group

See information on HIQA's EAG which advises on its medical exposure to ionising radiation functions



## Applications in progress

See list of applications for generic justification currently in progress:



## Generic justification decisions

Published reports on the justification of practices involving medical exposure to ionising radiation



## Asymptomatic guidelines

Read HIQA's guidelines on the use of medical radiological procedures in asymptomatic individuals



## Information Events

See below details of information events held by HIQA



## Read HIQA's guidelines on the use of medical radiological procedures in asymptomatic individuals



HIQA has developed guidelines for justifying medical radiological procedures for early detection of disease in people who have no known disease or symptoms and not as part of a health screening programme. Justification means making sure that the benefits outweigh the risks involved.

These guidelines apply to any person or organisation conducting medical radiological procedures. This includes individual professionals involved in the provision of medical radiological procedures in dental and medical settings.

The guidelines were developed following the completion of a scoping review and engaging with relevant stakeholders.

- Asymptomatic guidelines
- Scoping review
- Stakeholder involvement report

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

Ionising Radiation ▶

Justification of practices

Regulation of Medical Exposure

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

Ionising Radiation ▶

Justification of practices

Regulation of Medical Exposure

# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## Ionising Radiation

Justification of practices

Regulation of Medical Exposure

### The legislation

The primary regulations.



### Inspections

Inspections are carried out to seek assurance that undertakings are in compliance with the regulations.



### Radiation incidents



### Dental services

See information for dental services.



### National Diagnostic Reference Levels (DRLs)

The role of HIQA and undertakings in DRLs.



### Clinical Audit

National procedures for clinical audit of radiological procedures involving medical exposures to ionising radiation.



### Getting the Right Image for My Patient



# HIQA website: [www.hiqa.ie](http://www.hiqa.ie)

## Ionising Radiation

Justification of practices

Regulation of Medical Exposure

### The legislation

The primary regulations.

### Inspections

Inspections are carried out to seek assurance that undertakings are in compliance with the regulations.

### Radiation incidents

### Dental services

See information for dental services.

### National Diagnostic Reference Levels (DRLs)

The role of HIQA and undertakings in DRLs.

### Clinical Audit

National procedures for clinical audit of radiological procedures involving medical exposures to ionising radiation.

### Getting the Right Image for My Patient

# Thank you



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte