Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Welcome

Webinar:

Justification of practices

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Webinar:
Justification of practices

Lydia O'Sullivan

Senior Health Technology Assessment Analyst

Overview

- Introduction to HTA and the Ionising Radiation Team
- Ionising radiation activities at HIQA
- Justification of medical exposure
- Generic justification in Ireland
- HIQA's approach to generic justification

What is health technology assessment (HTA)?

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Health technology assessment (HTA):
a multidisciplinary process that summarises information about the **medical, social, economic and ethical** issues related to the use of a health technology in a **systematic, transparent, unbiased, robust** manner.

Its aim is to **inform** the formulation of **safe, effective, health** policies that are **patient focused** and seek to achieve **best value**.
(EUnetHTA)

Examples of HIQA HTA outputs

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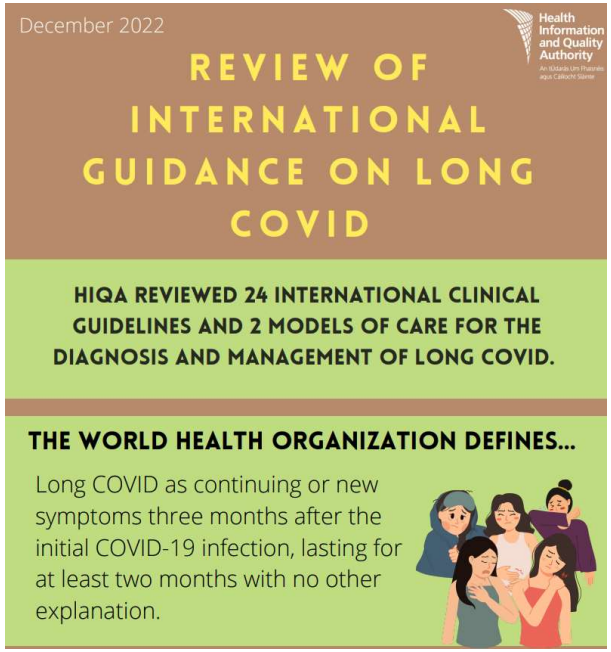

Evidence Synthesis

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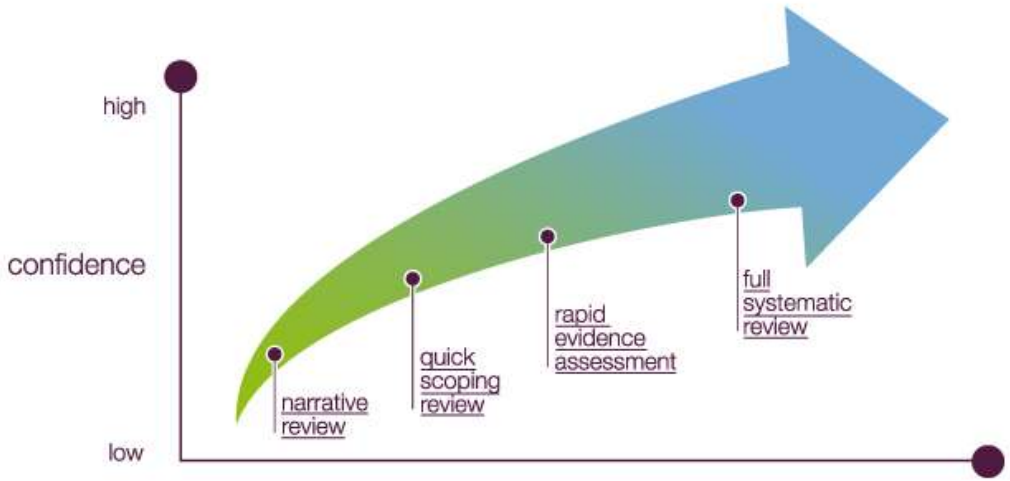
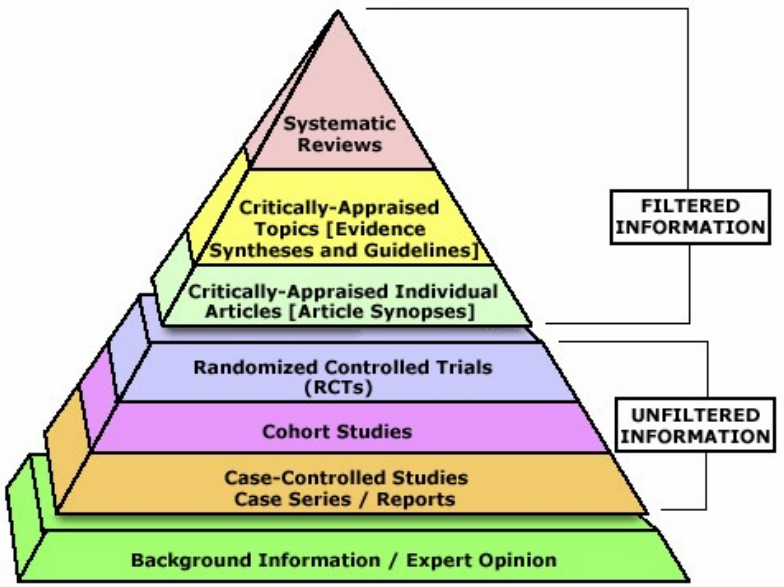
- Evidence Synthesis is a way of combining information from multiple studies that have investigated the same thing, to come to an overall understanding of what they found. Evidence synthesis helps determine how effective a certain treatment or drug is, or how people have experienced a particular health condition or treatment.





Ionising Radiation team in HTA

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Dr. Kirsty O'Brien, Health Services Researcher
Mr. Andrew Dullea, Health Services Researcher
Ms. Maeve McGarry, Health Services Researcher
Dr. Lydia O'Sullivan, Senior HTA Analyst

Ms. Marie Carrigan, Librarian/Information Scientist

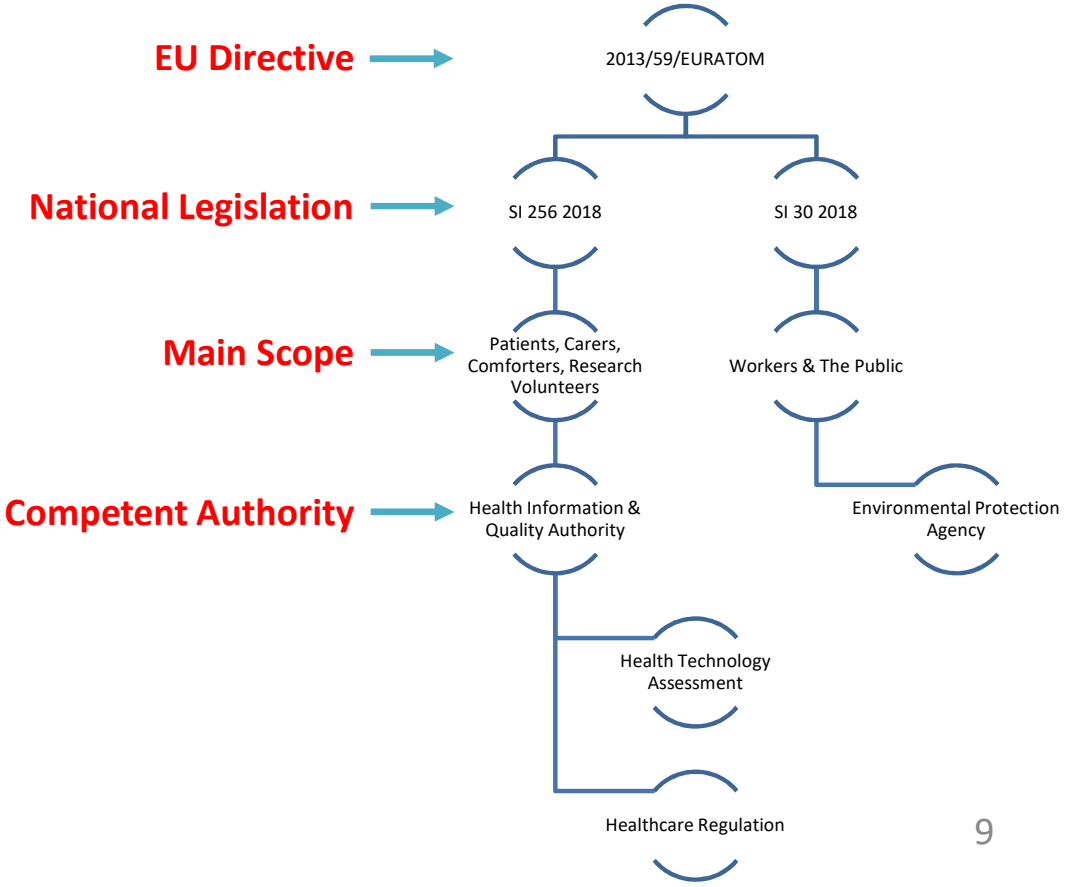
Dr. Patricia Harrington, Deputy Director of Health Technology Assessment
Dr. Susan Spillane, Deputy Director of Health Technology Assessment
Dr Máirín Ryan, Director of HTA & Deputy CEO

Ionising radiation activities at HIQA

Maeve McGarry
Health Services Researcher

Framework

- Transposition of EU BSS (basic safety standards) for the protection against the dangers arising from exposure to ionising radiation in 2019
- EPA: regulation of workers & the public
- HIQA: competent authority for patient safety
  - Healthcare regulation
  - Heath technology assessment



Competent Authority

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Regulation

- Healthcare Regulation directorate
- Functions include:
  - Monitoring and **inspection** of services
  - Receipt of **notifications** of accidental and unintended exposures
  - Establishing national diagnostic reference levels **(DRLs)**
  - Development of **guidance** including:
    - Guidance on Dose Constraints in Medical Exposures to Ionising Radiation
    - Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy

Health Technology Assessment (HTA)

- Regulation 8(6)
  - Development of guidelines on the specific justification of medical radiological practices on an asymptomatic individual for the early detection of disease, but not as part of a health screening programme
- Regulation 8(3)
  - Specific justification of medical radiological procedures as part of screening programmes
- Regulation 7
  - Justification of practices (generic justification)

Justification of medical exposure

Justification

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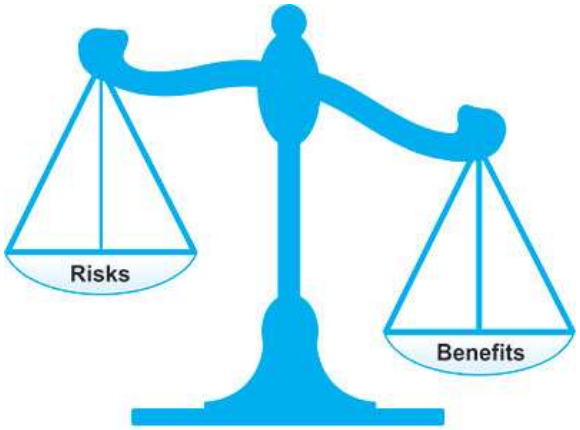
- The principle of justification: any decision that alters the existing radiation exposure situation should do more good than harm
- Considers both the benefits to an individual person and to society, and the harms to the exposed individual
- Considers the effectiveness, advantages and risks associated with the available alternative practices which expose the individual to less or no ionising radiation
- ICRP 103 & 105 outlines 3 levels of justification



Levels of Justification

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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 benefit outweighs 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. That is, that the practice will usually improve the diagnosis or treatment, or will 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 do more good than harm to the individual patient.

Generic justification in Ireland

Responsibilities of HIQA

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- Under Regulation 7(1) HIQA must justify new types of practices involving medical exposure in advance of these being generally adopted

- Under Regulation 7(3) & 7(4) HIQA shall consider a review of any existing class or type of practice should:
  a. new and important evidence about their efficacy or potential consequences be obtained
  b. New and important information about other techniques and technologies be obtained

- Under Regulation 7(6) HIQA shall take into account medical and where relevant associated occupational and public exposures

STATUTORY INSTRUMENTS.

S.I. No. 256 of 2018

EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO IONISING RADIATION) REGULATIONS 2018

Responsibilities of persons

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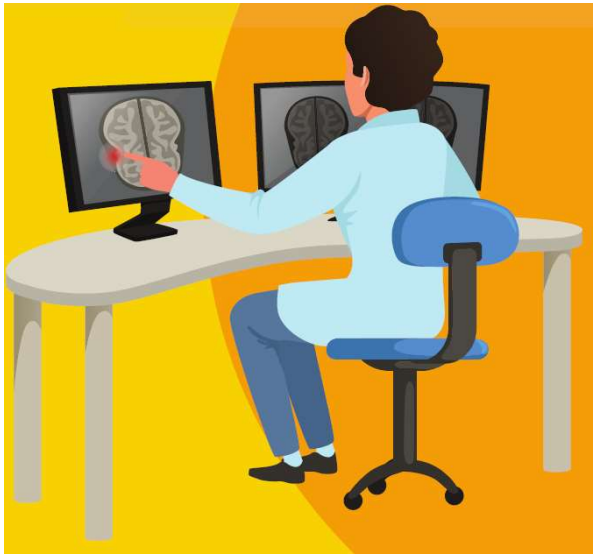
- Under Regulation 7(2) a person shall not carry out a new type of practice unless such new type of practice has been justified in advance by HIQA

- Under Regulation 7(5) a person shall not carry out a class or type of practice which has been reviewed by HIQA and found not to be justified

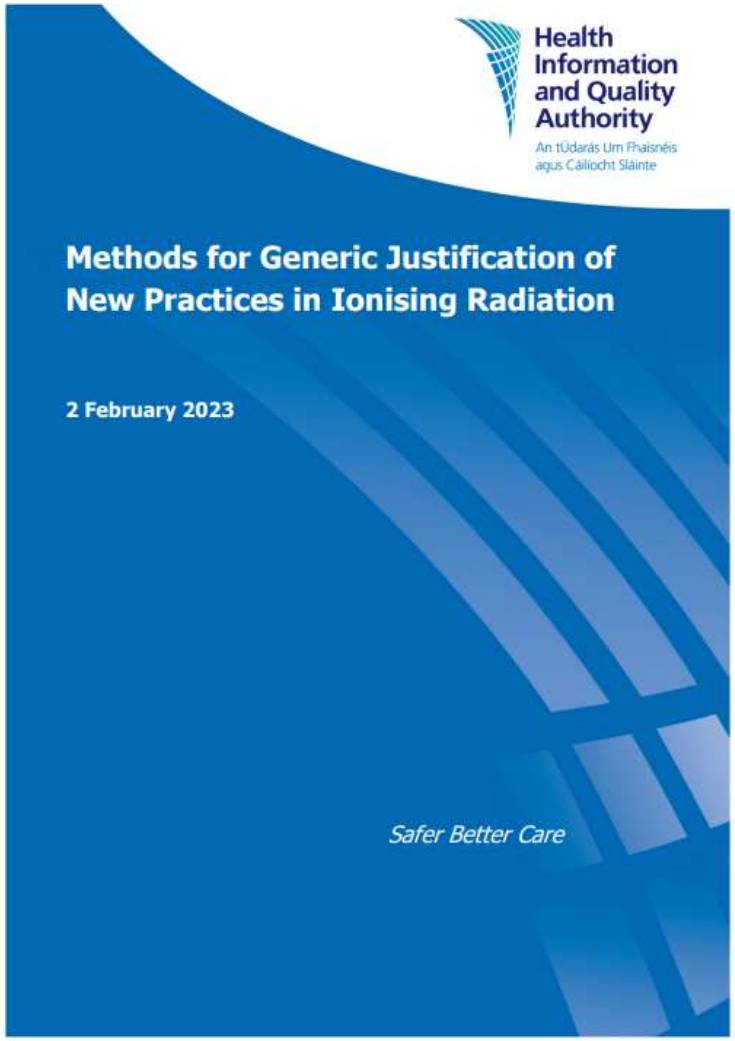
- Under Regulation 8(9) where a type of practice involving medical exposure is not justified in general, an undertaking shall ensure that a specific individual exposure of this type is justified, where appropriate, in special circumstances, to be evaluated by the practitioner on a case-by-case basis and documented



HIQA's approach to generic justification

HIQA's approach

- HIQA's approach outlined in published methods document (see www.hiqa.ie)
- Now open for applications
- Justification of practice in progress for:
  - ^{177}Lu oxodotreotide for the treatment of metastatic and/or inoperable gastroenteropancreatic neuroendocrine tumours (GEP-NETs)



What is a new practice?

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- HIQA defines a ‘new’ practice as a class or type of radiological procedure which was not used prior to the introduction of the Regulations, that is, before 8 January 2019
- The term ‘class or type of practice’ refers broadly to both the technology (that is, the radiopharmaceutical, device or technique) and the objective to be achieved by using that technology, that is, the clinical indication
- Varying approaches have been adopted across the EU

What is a new practice

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In the Irish context, a new class or type of practice will **typically** mean:

- **New technologies**
  - (that is, sealed or unsealed sources, a radiopharmaceutical, device or technique)
- **Use of an existing technology for a new indication**
  - (that is, a new clinical condition(s) or anatomical region(s) under investigation or treatment)
- **New combinations of existing technologies for a specific indication**
  - (for example, mammography and tomosynthesis for breast cancer screening)
- **New intended populations**
  - (for example, change from an adult to a paediatric population, or from a symptomatic to an asymptomatic population)
- **In radiation oncology:** a new indication, site or population for hypo- or hyper fractionation

Dose optimisation

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- Regulatory requirements under Regulation 9

- In general, dose optimisation is a separate concept and does not represent a new class or type of practice e.g.

    - In diagnostic imaging, changes to planning parameters
    - In radiation oncology, changes to beam orientation using the same RT technique

Figure 1: Simplified Schematic of the Generic Justification Process

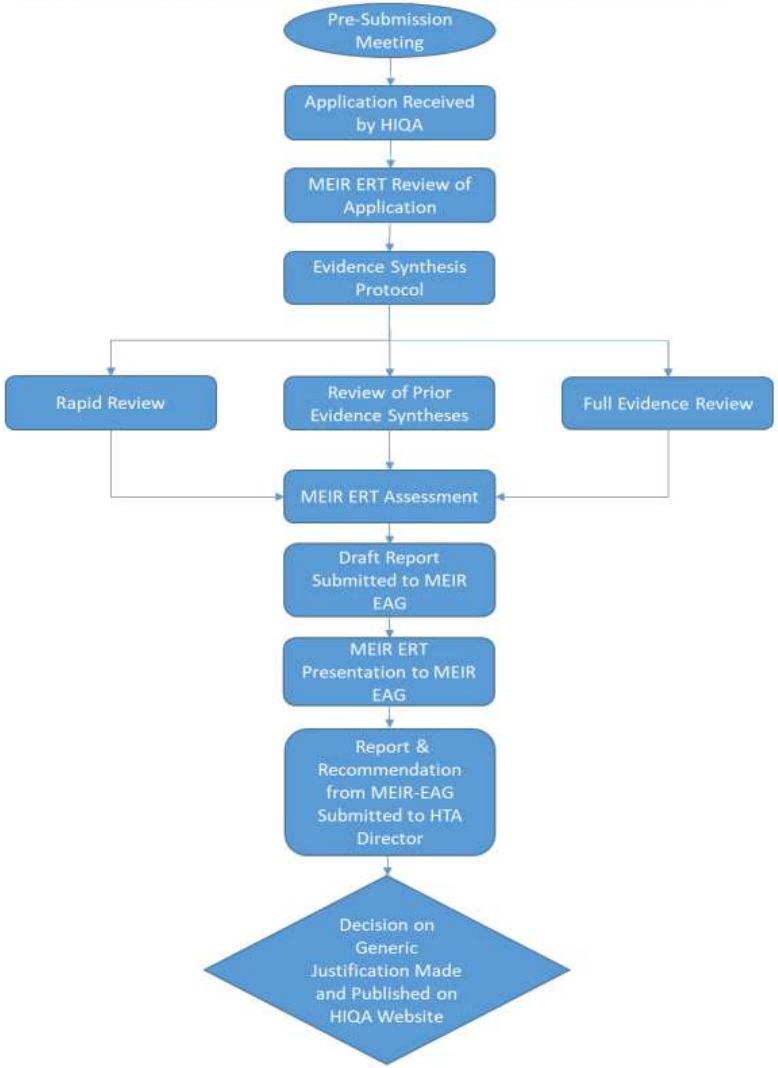
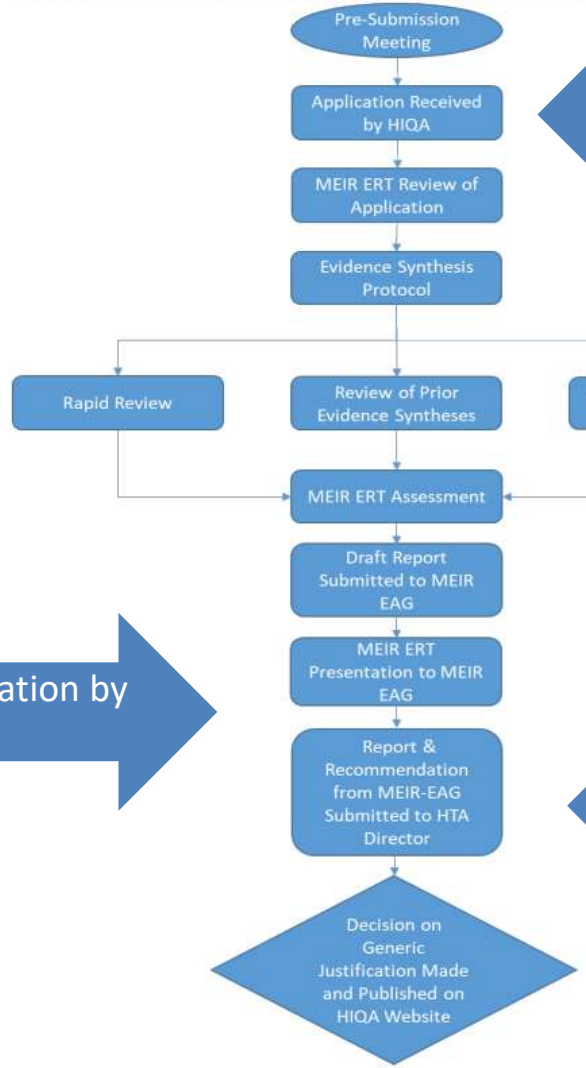


Figure 1: Simplified Schematic of the Generic Justification Process



Application received by HIQA

Varying levels of review

Evidence synthesis carried out by HIQA

Recommendation by EAG

Decision by HIQA's HTA Director

Evidence Synthesis Matrix - Draft

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Risk/Dose

International experience

	Dose significantly increased compared with current practice	Existing technology/methodology, but focus is a different anatomical region and there is no significant increase in dose	Practice decreases dose compared with current practice and *decreases* the diagnostic performance or clinical benefit of the practice	Changes to fractionation schedules at population level (e.g. hypo- or hyperfractionation)	Practice decreases dose compared with current practice but *does not decrease* the diagnostic performance or clinical benefit of the practice	Number or type of sources of radiation has changed, but there is no significant increase in dose
1.Completely new practice	Full Evidence Review	Full Evidence Review	Full Evidence Review	Full Evidence Review	Full Evidence Review	Full Evidence Review
2. New practice to Ireland, but is undertaken elsewhere with limited evidence available	Full Evidence Review	Full Evidence Review	Full Evidence Review	Review of Prior Evidence Syntheses	Rapid Review	Rapid Review
3. New practice to Ireland, but is undertaken elsewhere (EU or non EU), or generically justified by another EU country, with a good availability of evidence	Review of Prior Evidence Syntheses	Review of Prior Evidence Syntheses	Review of Prior Evidence Syntheses	Rapid Review	Rapid Review	Rapid Review

This matrix is provided for guidance purposes and should be read in the context of the typical definition of a new type or class of practice, as outlined in this document. Please consult HIQA if the practice does not fit the description of any of the categories described.

Expert advisory group

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- EAG membership & terms of reference on HIQA website
- Includes:
  - patient advocacy group and representatives
  - Regulatory bodies
  - Representatives from professional bodies
  - Representatives from national clinical programmes

2023 meetings:

- Thursday, 23rd February at 2pm
- Thursday, 1st June at 2pm
- Thursday, 19th October at 2pm

Expert advisory group: current membership

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Name	Organisation
Prof Mary Coffey, Chairperson	Independent Chairperson
Dr Jennie Cooke	Irish Association of Physicists in Medicine, *Principal Physicist (Diagnostic Radiology), Children's Health Ireland*
Dr Agnella Craig	HIQA Healthcare Directorate, *Regional Manager, Ionising Radiation Regulation Team, HIQA*
Prof Clare Faul	HSE National Cancer Control Programme, *Consultant Radiation Oncologist*
Dr Eva Godske Friberg	International Expert, *Senior Medical Application Advisor, Department of Radiation and Environmental Safety Section for Medical Appliances, Norwegian Radiation and Nuclear Safety Authority*
Mr Anthony Heaphy	Patients for Patient Safety *Patient Advocate*
Ms Patricia Heckman	HSE National Cancer Control Programme, *Chief Pharmacist & NCCP lead on radionuclides licensed as medicines*
Ms Geraldine Jolley	SAGE Advocacy, *Patient Advocate*
Dr Peter Kavanagh	HSE National Clinical Programme for Radiology and Faculty of Radiologists, Royal College of Surgeons in Ireland *Consultant Radiologist*
Prof Ronan Killeen	Irish Nuclear Medicine Association *Consultant Radiologist*

Name	Organisation
Dr Emer Lahiff	Health Products Regulatory Authority, *Technology Group Lead, Assessment & Surveillance, Medical Devices Department*
Mr Aodh MacGairbhith	Irish Association of Physicists in Medicine, *Medical Physicist (Radiation Oncology)*
Ms Michele Monahan	Irish Institute of Radiography and Radiation Therapists (Diagnostic Radiography), *Radiography Services Manager*
Ms Collette O'Connor	Environmental Protection Agency, *Senior Inspector*
Dr Maria O'Grady	Irish Dental Association, *Dentist*
Ms Edel O'Toole	Irish Institute of Radiography and Radiation Therapists (Radiation Therapy), *Radiation Safety Officer/Radiation Protection Officer*
Mr Niall Phelan	National Screening Service, HSE, *Chief Physicist, BreastCheck*
Prof Susan Smith	Methodology Expert, *Professor of General Practice, Public Health and Primary Care*
To be confirmed	HSE National Heart Programme *Consultant Cardiologist*

Guidelines for asymptomatic individuals: Regulation 8(6)

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- Guidelines for MEIR exposures in asymptomatic individuals outside of screening programmes, e.g., Individual Health Assessments
- Scoping Review completed – high level principles identified from the literature
- Planning for focus groups
- Draft guidelines – stakeholder engagement

Key points

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- HIQA as the competent authority must generically justify new types of practices (post-January 2019) before they are generally adopted
- HIQA can review existing practices if new or important evidence emerges
- Includes medical exposures in screening programmes
- Where a type of practice involving medical exposure is not justified in general, an undertaking shall ensure that a specific individual exposure of this type is justified, where appropriate, in special circumstances, to be evaluated by the practitioner on a case-by-case basis and documented
- In most cases, dose optimisation is a separate concept under the regulations and does not represent a new class or type of practice

Website

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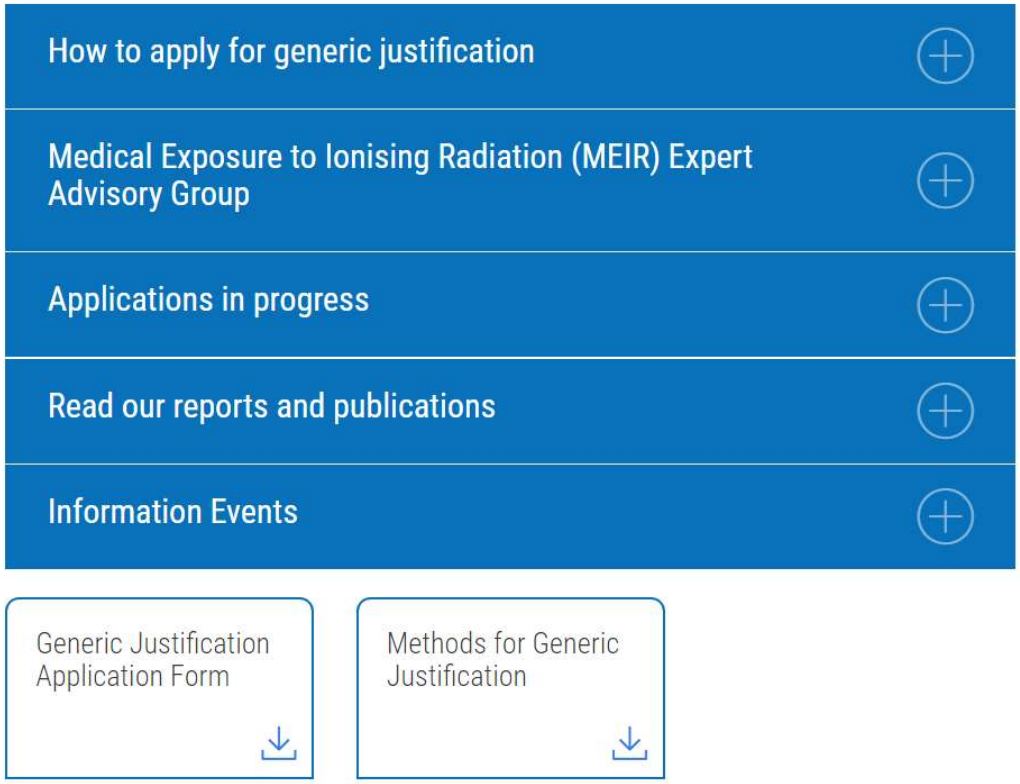

Thank you

Contact information:

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Phone: 01 828 6700

Website: Justification of practices | HIQA

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