Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Stakeholder involvement report: development of the 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.

Visit www.hiqa.ie for more information.

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1 Introduction and background

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. Justification is the process of demonstrating that there is a sufficient net benefit associated with a radiation exposure.

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, after consultation with the relevant professional body or bodies, 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, the term 'asymptomatic individual' is used throughout this document. Asymptomatic individuals are defined, for the purposes of these guidelines, as those who have no known disease, signs or symptoms, but who may have risk factors for a disease. Similarly, for the purposes of these guidelines, a health screening programme refers to a national, organised population-based screening programme. As of August 2025 Ireland has several such programmes. BreastCheck is one example of a national, organised population-based screening programme that involves use of a radiological procedure (mammography).

HIQA developed draft guidelines to fulfil its statutory remit. These guidelines were informed by a scoping review of the literature and extensive stakeholder engagement.

The following is a summary of the process and outcome of the two stakeholder consultation stages:

Focus groups, one-to-one interviews & written feedback	May, June and July 2024	19 participants from ten organisations

Targeted and public consultation period	6 November – 18 December 2024	6 written submissions

The feedback received from the focus groups, one-to-one interviews and written feedback from the targeted and public consultation is set out in Sections 2 and 3. Details of the bodies who participated in the development of the draft guidelines are contained in Appendix A. Amendments were made, as appropriate, to the draft guidelines following each stage of consultations. The scoping review and the draft guidelines were presented to HIQA's Medical Exposure to Ionising Radiation EAG for review and feedback in February 2024 and October 2024. The final draft guidelines were circulated to this EAG via email for final comment in July 2025.

This stakeholder involvement report summarises the feedback received at all stages of the stakeholder campaign. It presents the feedback received from the targeted and public consultation and HIQA's responses to suggestions, comments and issues raised, including any changes that were made to the draft guidelines as a result.

2 Focus groups and interviews

This section describes the process of collecting, collating and analysing the responses from the focus groups and one-to-one interviews with stakeholders to inform the refinement of the draft guidelines.

2.1 Overview of the focus group and interview process

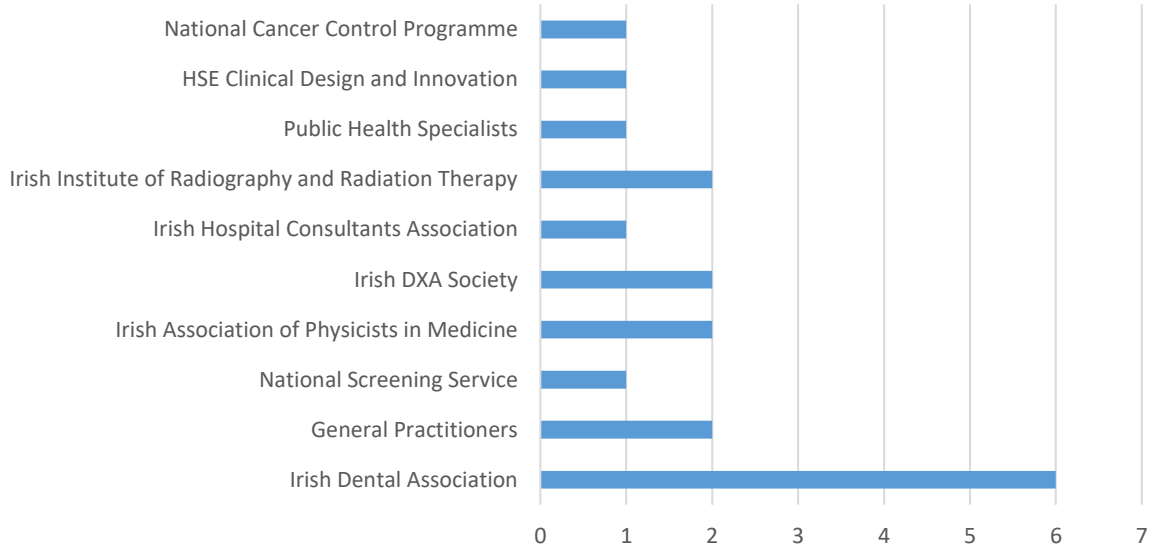
Four focus groups and three one-to-one interviews were carried out during May, June and July 2024. Key stakeholder organisations were contacted and appropriate participants requested. Nominees were sent an email with an invitation to participate in a focus group, a consent form and a briefing document outlining details of why and how the draft guidelines were developed and how they could contribute to their further development and refinement, were provided. Each participant was provided with a draft version of the guidelines document at least one week in advance of the meeting they were scheduled to attend.

A total of 19 participants from 10 organisations took part in a focus group or one-to-one interview. Where a participant agreed to take part, but were not available on the dates chosen for the focus groups, an option for a one-to-one interview and or to provide written feedback were offered as alternatives. The focus groups were hosted online via Zoom. Each focus group was facilitated by a member of the evidence review team and at least one additional team member took notes on the discussion. One-to-one interviews were hosted online via Zoom or Microsoft Teams

depending on the preference of the participant. Two members of the evidence review team attended these meetings, one to interview the participant and one to take notes.

At the start of the focus groups, a brief presentation was given on why and how the draft guidelines were developed before the individual draft guideline statements were discussed in turn. The facilitator asked a small number of pre-set questions to each group, for example, 'did the participants think the order of the guideline statements should be changed?'

Figure 1: Breakdown of participants per organisation for focus groups and interviews



Key: DXA - dual energy X-ray absorptiometry; HSE – Health Service Executive.

2.2 Feedback from focus groups and one-to-one interviews

The evidence review team collated and analysed all the feedback received. Feedback came from three sources: focus groups, one-to-one interviews, and additional written feedback. Each suggestion was listed and fully considered and discussed by the evidence review team. The draft guidelines and introductory sections of the guidelines document were subsequently amended, where appropriate.

The feedback mostly consisted of suggested wording changes for certain guideline statements. No additional guideline statements were suggested and most participants agreed that none of the current statements should be removed. It was suggested that certain statements could be merged; however, this feedback was inconsistent, with different statements suggested for merging and other participants commenting that each statement should be separate. Therefore no merging of

statements was implemented. Wording was changed where there was agreement and or to increase clarity, for example, it was suggested by a number of participants that the use of the word 'screening' in the guideline statements was confusing and should be replaced with a term such as 'medical exposure', or 'medical radiological procedure'; this change was implemented throughout the draft guidelines. The order of the guideline statements was also changed based on feedback. Conflicting feedback was received regarding the level of detail that should be included in the guideline statements and elaborations. The evidence review team took consideration of the feedback received and made a number of adjustments, so as to be consistent in terms of the level of detail provided.

3 Expert Advisory Group (EAG)

The refined draft guidelines were presented to the standing Medical Exposures to Ionising Radiation EAG meeting in October 2024 for discussion and feedback. Additional, minor changes were made to the draft guideline statements based on the discussion. The membership list for the standing Medical Exposures to Ionising Radiation EAG is available here.

4 Targeted and public consultation

The aim of the targeted and public consultation was to seek feedback on the draft guidelines from a wider group of stakeholders and interested parties. The following sections provide details of the consultation process and results.

4.1 Overview of consultation process

The draft guidelines for the justification of medical radiological procedures on asymptomatic individuals report was published on the HIQA website on 6 November 2024, and were available for public consultation until 18 December 2024. To ensure wide accessibility, feedback could be submitted via email, post, or by using the online submission form (Appendix B). The consultation webpage contained a link to the draft report, a link to the online survey (using the Qualtrics platform) for online submission of feedback, a downloadable consultation feedback form, an infographic and a link to the press release.

A press release was issued to a wide range of media outlets at the beginning of the consultation period, and notifications of the public consultation were posted via social media sites (X, Facebook, Instagram and LinkedIn). The public consultation and links were publicised in the media. E-mail requests for feedback were sent to a targeted list of stakeholder organisations and affected individuals with relevant expertise and those who are likely to be affected by the proposed introduction of

these guidelines (Appendix C). All those who participated in the focus groups were also sent an email with a link to the public consultation to allow them to provide further feedback on this version of the draft guidelines.

4.1.1 Feedback form

The template for submission comprised a general request for feedback to allow flexibility for respondents in providing their submission on any aspect of the report. A copy of the submission template is provided in Appendix B.

The consultation included the following questions:

- Are you providing feedback as an individual or as part of an organisation?
    - If individual selected, which best represents you (for example, a member of the public, a person who has used or is currently using healthcare or dental services, etc.)
    - If organisation is selected, select the type of organisation (for example, private dental service, community health service, private healthcare insurer etc.)
- What is your feedback on the draft guidelines?
    - Please provide any general or specific feedback you have on the draft guidelines. Where applicable, please specify the section of the guidelines document to which you are referring.
    - Please outline any issues with the clarity or presentation of the report. In your response, where applicable, please specify the section to which you are referring.

4.1.2 Synthesis

Each submission was recorded (excluding personal information), read in its entirety and, where appropriate, broken down into individual components. In cases where a question was skipped by the respondent, it was assumed that there were no issues of concern specific to that question. Submissions were excluded if the response was incomplete and contained no feedback on guidelines or report. The submissions were stratified according to whether they were from individual members of the general public or stakeholder organisations. Feedback is presented in tabular format alongside direct responses to the feedback (Table 1). Where amendments were made to the guidelines document based on feedback, this is highlighted in the HIQA response section.

4.2 Results of the targeted and public consultation

Overall, six complete submissions containing feedback on the guidelines were received from the targeted and public consultation. Four of these submissions were

received via the online survey and two via email. Two responses were submitted on behalf of a stakeholder organisation and four were submitted by individuals. Their roles included department manager, dentist, dental surgeon and a radiographer. The organisations were the Environmental Protection Agency (EPA) and the Irish Dental Association (IDA).

4.2.1 Summary of general feedback

The four responses from individuals included: a dental surgeon who stated the guidelines seemed reasonable and had no suggestion on the clarity or presentation of the report; a dentist who had no comment on the guidelines but commented that clarification was needed in the report that medical practitioners include dentists; a radiographer who stated they were in favour of the proposed guidelines but queried if there was a possibility to place additional requirements relating to documenting informed consent especially where the overall benefits may not necessarily outweigh the benefits of the radiological examination; and a department manager who had a query regarding a specific population of patients. The EPA submission had specific queries on Guidelines 5 and 8 and suggested adding additional wording around the scope of the guidelines (Table 1). The IDA suggested additional wording to ensure dentists understood how the guidelines applied to them.

4.2.2 Comments on overall clarity and readability

Of the six responses, one stated they had no issues with the clarity or presentation of the report, another stated the report was clear and concise. One respondent did not provide an answer to this question and three suggested changes to increase the clarity of the report. One suggestion was to include wording to clarify that dentists are considered 'practitioners' under the regulations. Another suggested additional wording to ensure it was clear how the guidelines applied to dentists. The final suggestion was that the guidelines should specify that they do not apply to non-medical human imaging exposures.

4.2.3 Specific comments/queries on report content

The feedback received on the report content and the response to this feedback is outlined in Table 1.

Table 1 Comments received on report content and responses

	Comments provided	Comments provided	Response
Question asked	**Please provide any general or specific feedback you have on the draft guidelines.**	**Please outline any issues with the clarity or presentation of the report**	
1	Seems reasonable	None	No response required.
2	Not answered	I couldn't see it clarified that medical practitioner often also included registered dentists as prescribers.	On page 10 of the guideline document it states "These guidelines will also apply to individual professionals involved in the provision of medical radiological procedures in dental and relevant medical settings." For clarity, a line has been added on page 12, Guideline 4, referring to Regulation 5. This regulation identifies the categories of individuals that can act as practitioners and can take clinical responsibility for the individual medical exposure under the regulations.
3	I am in favour of the proposed guidelines to ensure that radiological examinations undertaken on asymptomatic patients are appropriately evaluated. There has been consideration of the wider implications of such screening in particular when incidental findings are identified. Is there a possibility to place additional requirements relating to	Clear and concise	The elaboration for guideline 5, highlights that adequate information must be provided in advance to allow for informed consent. Guideline 7, which relates to documentation, states that the documentation must be commensurate with the risk associated with the medical radiological

	documenting informed consent for these examinations, in particular when the overall benefits may not necessarily outweigh the benefits of the radiological examination?		procedure and the complexity of the organisation or service provider. No changes made as it was felt that the documentation should be appropriate to the procedure that is taking place and take consideration of the other guideline statements.
4	Some patients are given prophylactic cranial irradiation in Radiation Therapy. This is because there is a high chance of cranial metastases, generally from lung cancer. These patients receive CT planning scans and a course of treatment with no confirmed lesions in the brain.	Not answered	No change. Section 1 provides a definition of asymptomatic individuals for the purpose of these guidelines. As only those individuals who have no known disease are considered to be asymptomatic for the purpose of these guidelines, this patient group is considered to be out of scope.
	Comments on draft guidelines from organisations		
EPA	Table 2, guideline 5, page 13: "Potential pathway for follow up of findings (for example, information on additional test(s) that may be required to make a diagnosis)". A CT lung cancer screening programme may indicate the need for repeated thorax scans at various intervals – is there a limit on the number of exposures which an asymptomatic individual may have per annum or per programme?		No change. There are no specific limits based on these guidelines. However, consistent with Guideline 1, any programme, including for example a CT lung cancer screening programme, must be performed in accordance with guidelines from relevant scientific and professional bodies. As outlined in the elaboration for this statement, these guidelines should be evidence-based. If an interval is specified, this should be supported by

			evidence that, on average, the benefit outweighs the harms in this context.
	Table 2, guideline 8, page 14: The EPA's definition of a quality assurance programme in an undertaking's authorisation differs from how a quality assurance programme is referred to here which may possibly cause confusion. Section 6.1.4 of the following Guidance document provides this information: Guidance for undertakings on the application of the Ionising Radiation Regulations (IRR19) | Environmental Protection Agency		Reference to the EPA's guidance document has been added into Guideline 8, page 14.
	Finally, it is stated in the scoping review (page 18) that ionising radiation exposure for non-medical purposes was excluded from the scoping review research question. Has it been considered if the guidelines should also specify that they do not apply to non-medical human imaging exposures?		No change. On page 24 of the guidelines document, under the heading of 'scope' it states that 'these guidelines apply to medical radiological procedures for the purpose of the early detection of disease that takes place outside of these screening programmes.' All other radiological procedures, irrespective of whether medical or non-medical, are therefore considered to be out of scope.
Irish Dental	With regards to the draft guidelines, we would like to reiterate our position that it is		No change.

Association (IDA)	essential that the guidelines are relevant and applicable to dentistry in order to prevent confusion or complication. Perhaps it would be possible to have a short appendix specific to dentistry within the guidelines? Respectfully, we would refer you to the FGDP (UK)'s Selection Criteria for Dental Radiography as a guidance regularly used by Irish-registered dentists, including our Quality and Patient Safety Committee.		Following discussions, it was decided that additional wording specifically for dentists may cause confusion for other professional and stakeholder groups. After the publication of the guidelines, a webinar will be provided specifically for dentists, which will allow any queries to be answered.

*Responses have been slightly amended to ensure anonymity and to correct for minor grammatical errors and or typos.

4.3 Changes to the guidelines from the consultation process

The following changes were made to the draft report in response to comments and feedback received through the consultation process:

- Page 12, Table 2, Guideline statement 4, reference to Regulation 5 was added in order to clarify where details can be found of who can act as a practitioner for justification of a medical exposure.
- Page 14, Table 2, Guideline statement 8, reference added to chapter 6.1.4 of EPA document on Quality assurance "Guidance for undertakings on the application of the Ionising Radiation Regulations (IRR19)'

4.4 Conclusions

Extensive stakeholder engagement was undertaken as part of the preparation of these draft guidelines. All feedback was carefully considered by the ERT and incorporated, as appropriate.

Appendix A – 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 have reviewed 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:

- 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.

Appendix B – Copy of submission feedback form

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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

Public Consultation feedback form

The Health Information and Quality Authority (HIQA) is holding a six-week public consultation to give people an opportunity to provide feedback on the draft guidelines for the justification of medical radiological procedures on asymptomatic individuals.

Your views are important to us. HIQA will carefully assess all feedback received and use it to inform further reports and publications.

The final guidelines and a statement of outcomes report (a summary of the consultation responses) will be published on HIQA's website once the guidelines have been approved.

The closing date for the public consultation is 5pm on Wednesday, 18th December 2024.

How to provide feedback:

- If you are commenting in a personal capacity, there is no need to provide your name or any other personal information.
- If you are commenting on behalf of an organisation, please combine all feedback from your organisation into one submission form. In this case, we will request a name and contact number for a designated representative from your organisation in case we need to verify your feedback.
- If your feedback contains any commercially sensitive or confidential information, please highlight this at the time of submission, so it can be excluded from the summary of feedback that will be published by HIQA.
- When completing this form online, please ensure you scroll down the webpage and complete the form in full.

- Please do not paste other tables into the boxes already provided. Please type directly into the box as the box expands.
- Please spell out any abbreviations that you use.

You can **download** a consultation feedback form at www.hiqa.ie

Then **email** the completed form to consultation@hiqa.ie

OR

Print the consultation feedback form and **post** the completed form to:

Health Information and Quality Authority
Draft asymptomatic guidelines
Health Technology Assessment
Dublin Regional Office
George's Court, George's Lane
Smithfield, Dublin 7
D07 E98Y

Data protection and Freedom of Information

HIQA will only collect personal information, such as the names of individuals who provided feedback or any other personal details during this consultation, for the purposes of verifying your feedback. No personal information will be included in the stakeholder consultation document that will be published by HIQA. All personal information will be deleted once no longer needed, in line with HIQA's record retention policy.

The feedback in your consultation form will be used to help inform the draft guidelines, and in related publications and research. Any feedback you provide will be held securely and anonymised. If included in publications, it will be in an anonymised and summative manner.

To find out more about how HIQA uses personal information, please see our Privacy Notice available here. If you have any concerns regarding your personal information, please contact HIQA's Data Protection Officer on dpo@hiqa.ie

Please note that HIQA is subject to the Freedom of Information (FOI) Act and the statutory Code of Practice in relation to FOI. If we receive a request under FOI for the submissions received under this consultation process, we will contact you and take full account of your views on the release of these records. However, we cannot

give you an assurance that confidentiality can be maintained in all circumstances due to the requirements of the FOI Act.

☐ **I agree to take part in the public consultation**

1. About you

1.1 Are you providing feedback as:

☐ an individual

☐ on behalf of an organisation

1.2. If answer is 'an individual'

Which of the following best represents you?

☐ a person who has used or is currently using healthcare or dental services

☐ a family member of a person who has used or is currently using healthcare or dental services

☐ a member of the public

☐ other (Please specify)

If selected '**other**' above, please give details here:

1.3. If answer is 'an organisation'

Which of the following best represents you?

☐ public hospital

☐ private hospital

☐ community health service (public)

☐ community health service (private)

☐ general practice

☐ private healthcare insurer

☐ public dental service

☐ private dental service

☐ other (Please specify)

If selected '**other**' above, please give details here:

1.4 If answer is 'on behalf of an organisation', please give the name of the organisation:

For verification purposes, please provide your name and your role in the above organisation and your contact details:

2. Your feedback on the draft guidelines

2.1 Please provide any general or specific feedback you have on the draft guidelines. Where applicable, please specify the section of the guidelines document to which you are referring.

2.2 Please outline any issues with the clarity or presentation of the report. In your response, where applicable, please specify the section to which you are referring.

Thank you for taking the time to give us your views

If you have any questions on this document, you can contact the team in HIQA Health Technology Assessment who are working on these draft guidelines:

Emailing: consultation@hiqa.ie

OR

By phoning: (021) 240 9300.

Please ensure that you return your form to us either by email or post, to reach us by Wednesday 18 December 2024.

Appendix C – List of organisations included in the targeted consultation

As part of the public consultation process to develop these guidelines, a list of key stakeholder organisations and affected parties was prepared. These organisations were emailed directly inviting them to participate in the public consultation and providing the link to the consultation website. The organisations included in this targeted group were:

- 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 Cancer Society
- Irish College of General Practitioners
- Irish College of Physicists in Medicine
- Irish Dental Association
- Irish DXA Society
- Irish Hospital Consultants Association
- 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

In addition, all those who took part in the focus groups or one-to-one interviews were emailed directly inviting them to participate in the targeted and public consultation and provided with the link to the consultation website.

Published by the Health Information and Quality Authority (HIQA).

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