Continuing Professional Development
For
Referrers of Medical Radiological Procedures

Live Online Study Day One

Thursday 8th June 2023

S.I. 256 Overview
Duty Holder Responsibilities
Legislative Requirements to Refer

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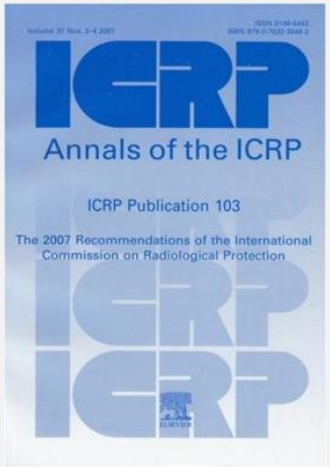
Legislative Framework For Radiation Protection



The Basic Safety Standard


Official Journal of the European Union L 13

English edition Legislation Volume 57 17 January 2014

Contents

II Non-legislative acts

DIRECTIVES

★ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom 1

Regulation of Worker/Public Exposures

S.I. 30 of 2019 (IRR19)

Environmental Protection Agency

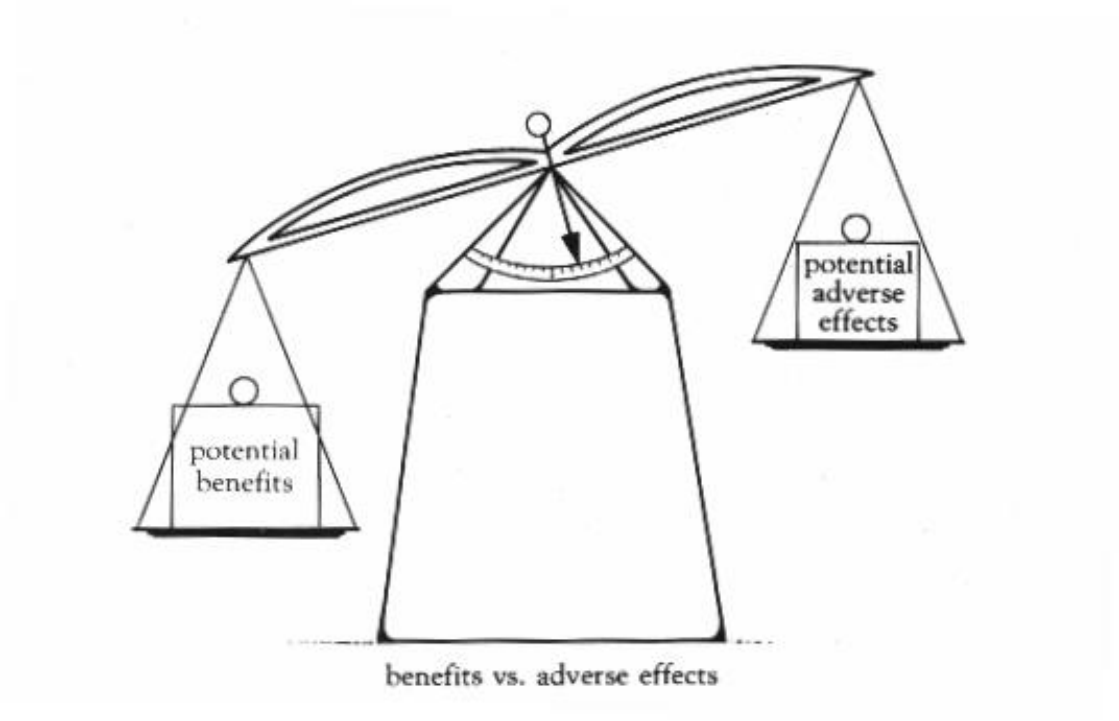
Regulation of Medical Exposures

S.I. 256 of 2018

Health Information and Quality Authority

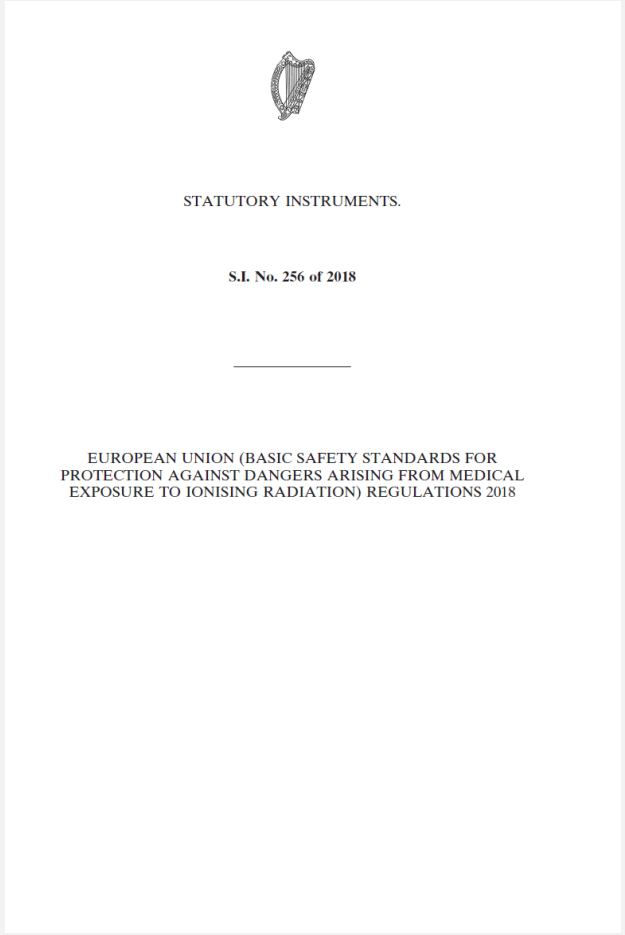
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

System of Radiological Protection



- *Limitation*
- *Justification*
- *Optimisation (or ALARA)*

S.I. No. 256/2018 - European Communities (Medical Ionising Radiation Protection) Regulations 2018



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

- The Referrer
- The Undertaking
- The Practitioner
- Persons Authorised to Take Exposures
- The Medical Physics Expert (MPE)
- **Justification & Optimisation**
- Referral Criteria & DRLs
- The Pregnant Patient
- Equipment
- Clinical Audit
- Etc., etc.

S.I. No. 256 of 2018

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

ARRANGEMENT OF REGULATIONS

THE UNDERTAKING

Definition: a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure.

Undertaking

6. (1) Subject to paragraph (2), an undertaking shall notify the Authority, no later than one month before commencing practices, of the proposed commencement, in such form and manner as may be prescribed by the Authority from time to time.

(2) An undertaking which, on the commencement of these Regulations, is carrying out practices shall notify the Authority, no later than 3 months after the commencement of these Regulations, of such activity, in such form and manner as may be prescribed by the Authority, and may continue such activity pending said notification.

(3) An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.

(4) An undertaking is responsible for the failure of any person employed or engaged by it to comply with a requirement of these Regulations.

Business types that may be categorised as an undertaking in line with the regulations;

- Sole Trader
- Partnership
- Company
- Unincorporated Body
- Body Corporate

The Undertaking Representative;

Undertaking business type	Appropriate undertaking representative
Sole trader	The sole trader
Partnership	A partner of the partnership
Company	A director of the company
Unincorporated body	A member of the committee of management or other controlling authority of the unincorporated body
Body corporate	A person with delegated authority as per a scheme of delegation provided for or by the relevant Act for the statutory body, or a member of the board, directorate or other governance structure of the body.
HSE	**Deputy Director General and Chief of Operations***

*Governance of Radiation Protection in Hospitals and Community Healthcare Organisations' (National Radiation Protection Office of the HSE -August 2019 v3)

Declaration of Undertaking to HIQA (NF200)

Medical Radiological Installations

Service Type (Dental, General Radiography, Nuclear Medicine, Radiotherapy, IR, CT)

Designated Manager

Undertaking business type	Example of a designated manager
Sole Trader	The sole trader or practice manager
Partnership	A named partner or practice manager
Company	Practice manager
Unincorporated body	Operational manager
Body corporate	General manager
HSE	**Hospital GM or CHO Chief Officer**

The Practitioner

Responsibilities

10. (1) An undertaking shall ensure that all medical exposures take place under the **clinical responsibility** of a practitioner.

"clinical responsibility" means responsibility of a practitioner for individual medical exposures, in particular,

- justification;
- optimisation;
- clinical evaluation of the outcome;
- cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures;
- obtaining information, if appropriate, on previous examinations;
- providing existing medical radiological information or records to other practitioners or the referrer, as required;
- and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;

NOTES:

- A Referral for a Medical Exposure must be made to a Practitioner.
- The Practitioner can reject referral or request further information to assist in justification.
- Justification of routine referrals is generally delegated to the Radiographer

Who can be the practitioner

- Must have adequate education, information, theoretical and practical training as well as relevant competence in radiation protection

- Dentist
  - Training as prescribed by the Dental Council

- Radiographer
  - Subject to Scope of Practice

- Medical practitioner defined by Medical Practitioners Act 2007
  - Training as prescribed by a Training Body approved by the Medical Council
  - E.g. faculty of radiologists
  - ALL other medical doctors with the appropriate training

The Medical Physics Expert (MPE)

20. (1) An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (*c*) of Article 22(4) of the Directive.

Definition; "an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the Minister

Currently recognised by membership of the Irish College of Physicists in Medicine, but transition to more formal system of recognition by the DoH&C is in progress.

Responsibilities of the MPE (20(2))

- Patient Dosimetry (& Comforters/Carers) & Surveillance of Installations.
- Advice on Medical Radiological Equipment (Specifications, Acceptance Testing, QA, Optimisation, Measuring Equipment, etc).
- Optimisation of Radiation Protection of Patients inc. use of DRLs.
- Analysis of Accidental or Unintended Medical exposures.
- Selection of Radiation Protection Equipment
- Radiation Protection Training of Practitioners & Others.
- Liaise with the Radiation Protection Adviser (RPA) where appropriate.

Practical Aspects of Medical Radiological Procedures

Definition; the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing;

10 (4) Practical aspects of a medical radiological procedure may be delegated by—
(a) the undertaking, or
(b) the practitioner,

as appropriate, to one or more individuals, who are registered or recognised by—
(i) the Dental Council,
(ii) the Minister,
(iii) the Nursing and Midwifery Board of Ireland
(iv) the Radiographers Registration Board *(CORU/IIRRT)*, or
(v) the Medical Council,

and have completed a course in radiation safety as prescribed by the appropriate body, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (**Radiation Protection No. 175**).

The Referrer

- a member of one of the classes of persons referred to in Regulation 4(1), who is entitled to refer an individual for medical radiological procedures to a practitioner;
  - Nurse or Midwife

    (subject to meeting standards & requirements of the NMBI)

    Bord Altranais agus Cnáimhseachais na hÉireann
    Nursing and Midwifery Board of Ireland
  - Dentist

    Dental Council
    Comhairle Fiaclóireachta
  - Medical Practitioner

    (IMC or GMC (NI) Registered)

    Comhairle na nDochtúirí Leighis
    Medical Council
  - Radiographer

    Irish Institute of Radiography and Radiation Therapy

Responsibilities of the Referrer

8(10) A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral—
(a) is in writing, (*E-ordering; password = signature*)
(b) states the reason for requesting the particular procedure, and
(c) is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment.

8(12) The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposure.

8(13) Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that … the patient or his or her representative (*parent, legal guardian, intervener*) ……
is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.

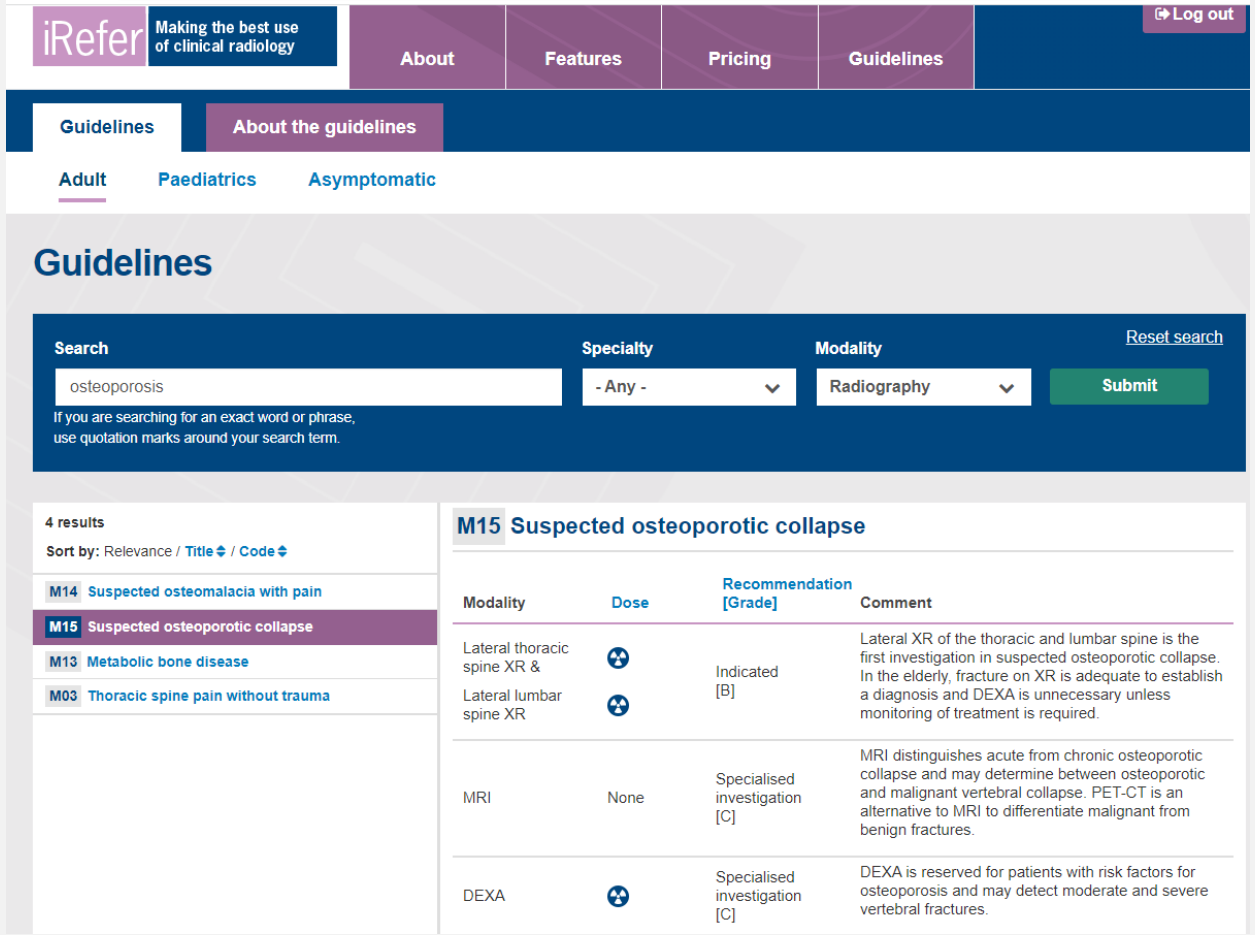
Justification of Medical Exposures

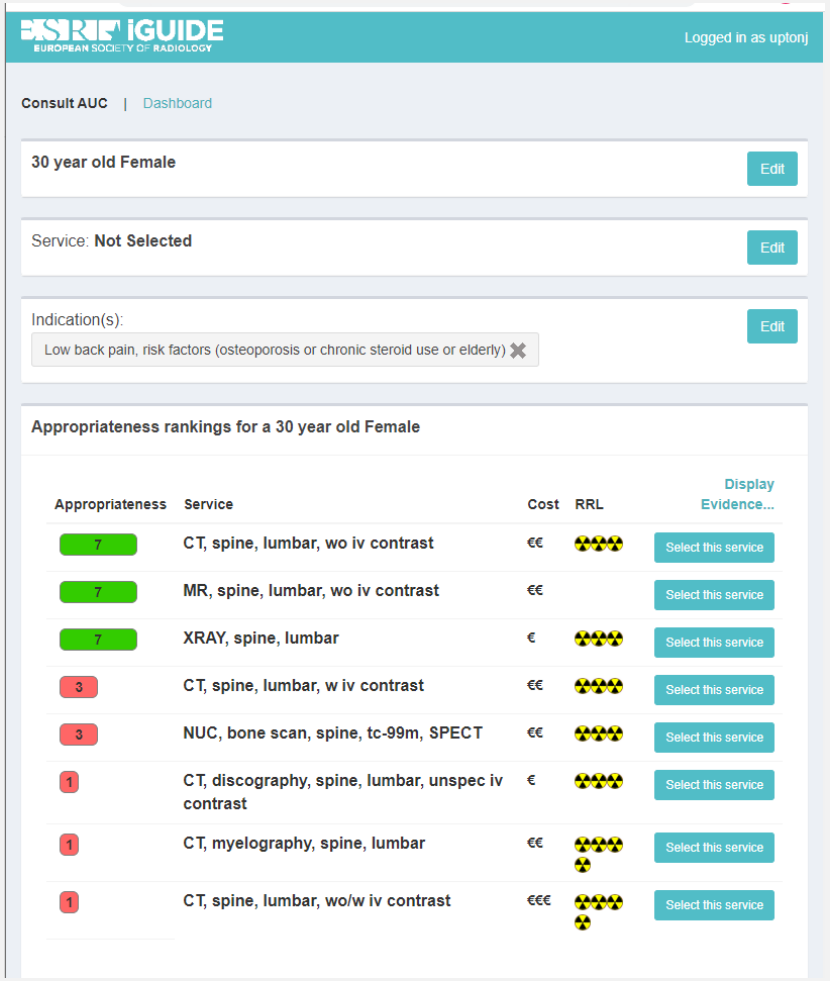
- 8. (1) A person shall not carry out a medical exposure unless it—
- (*a*) shows a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment 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.

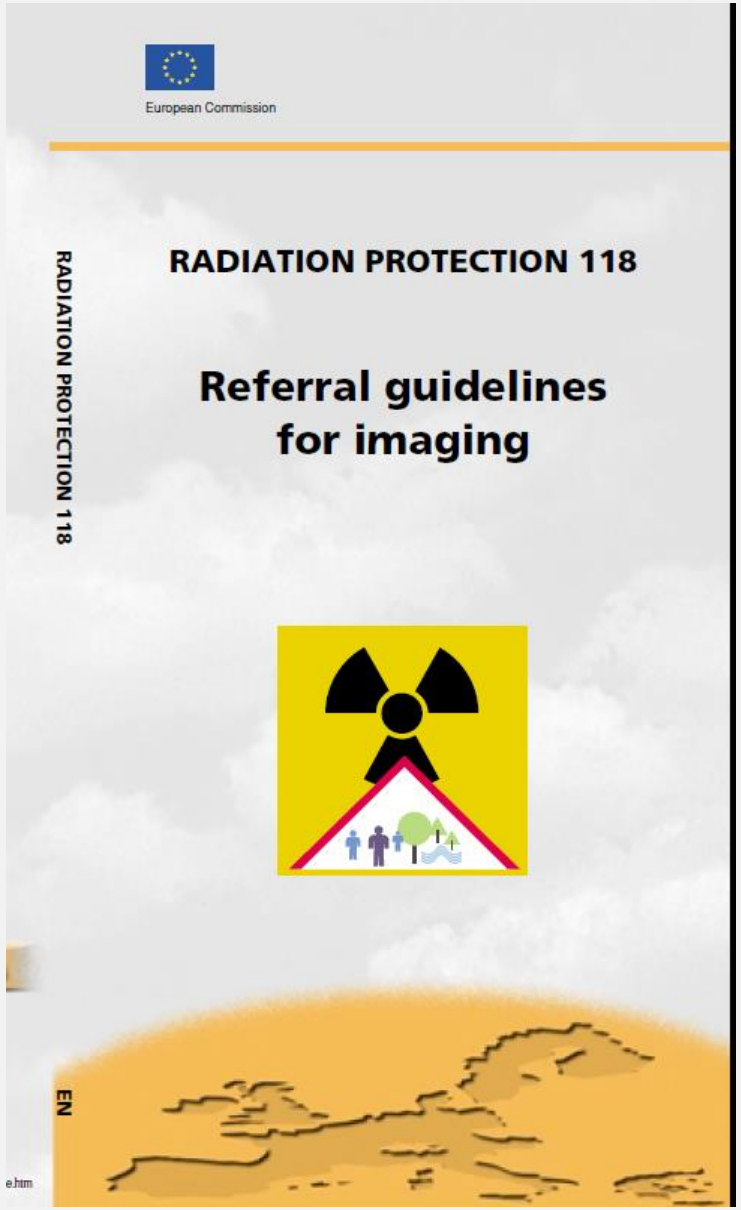
(9) Where a type of practice involving medical exposure is not justified in general, an undertaking shall ensure that a specific individual exposure of this type is justified, where appropriate, in special circumstances, to be evaluated by the practitioner on a case-by-case basis and documented.

Referral Guidelines

13 (3) An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.







Introduction

Why are guidelines and referral criteria needed?

A useful investigation is one in which the result — positive or negative — will alter management or add confidence to the clinician's diagnosis. A significant number of radiological investigations do not fulfil these aims and may add unnecessarily to patient irradiation (14). The chief causes of the wasteful use of radiology are:

(1) **Repeating investigations which have already been done:** e.g. at another hospital, in an outpatient department, or in the accident and emergency department. HAS IT BEEN DONE ALREADY? Every attempt should be made to get previous films. Transfer of digital data through electronic links may assist in this respect in future years.

(2) **Investigation when results are unlikely to affect patient management:** because the anticipated 'positive' finding is usually irrelevant, e.g. degenerative spinal disease (as 'normal' as grey hairs from early middle age) or because a positive finding is so unlikely. DO I NEED IT?

(3) **Investigating too often:** i.e. before the disease could have progressed or resolved or before the results could influence treatment. DO I NEED IT NOW?

(4) **Doing the wrong investigation.** Imaging techniques are developing rapidly. It is often helpful to discuss an investigation with a specialist in clinical radiology or nuclear medicine before it is requested. IS THIS THE BEST INVESTIGATION?

(5) **Failing to provide appropriate clinical information and questions that the imaging investigation should answer.** Deficiencies here may lead to the wrong technique being used (e.g. the omission of an essential view). HAVE I EXPLAINED THE PROBLEM?

(6) **Over-investigating.** Some clinicians tend to rely on investigations more than others. Some patients take comfort in being investigated. ARE TOO MANY INVESTIGATIONS BEING PERFORMED?

What advice is available?

In some clinical situations firm guidelines have been established. Guidelines are:

> *systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances... (Field & Lohr 1992, 15).*

Just as the term implies, a guideline is not a rigid constraint on clinical practice, but a concept of good practice against which the needs of the individual patient can be considered. So while there have to be good reasons for ignoring them they are not absolute rules. No set of recommendations will command universal support and you should discuss any problems with your radiologists.

The preparation of guidelines has become something of a science, with numerous papers emerging within the evolving guidelines discipline. In particular, experts have provided detailed methodology as to how guidelines should be developed, produced and appraised (8, 15–21). Using such methodology, the development of a single scientifically robust guideline represents a major piece of academic endeavour. For the 280 clinical problems in this booklet, such expenditure of time and resources is somewhat impractical. Nevertheless much of the philosophy of the methodology for the preparation of guidelines has been

Training

22(1) … an undertaking shall ensure that—
(a) practitioners, and
(b) individuals to whom the practical aspects of medical radiological procedures are delegated

have adequate education, information and theoretical and practical training for that purpose, as well as relevant competence in radiation protection.

22(3) … as prescribed by;

(a) the Dental Council,

Dental Council
Comhairle Fiaclóireachta

DUBLIN DENTAL UNIVERSITY HOSPITAL
OSPIDÉAL DÉADACH OLLSCOILE ÁTHA CLIATH

(b) the Irish College of Physicists in Medicine,

ICPM

(c) the Nursing and Midwifery Board of Ireland,

(d) the Radiographers Registration Board, or

CORU
Ag Rialáil Gairmithe Sláinte agus Cúraim Shóisialaigh
Regulating Health + Social Care Professionals

Irish Institute of Radiography and Radiation Therapy

(e) a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course,

RCSI FACULTY of RADIOLOGISTS and RADIATION ONCOLOGISTS

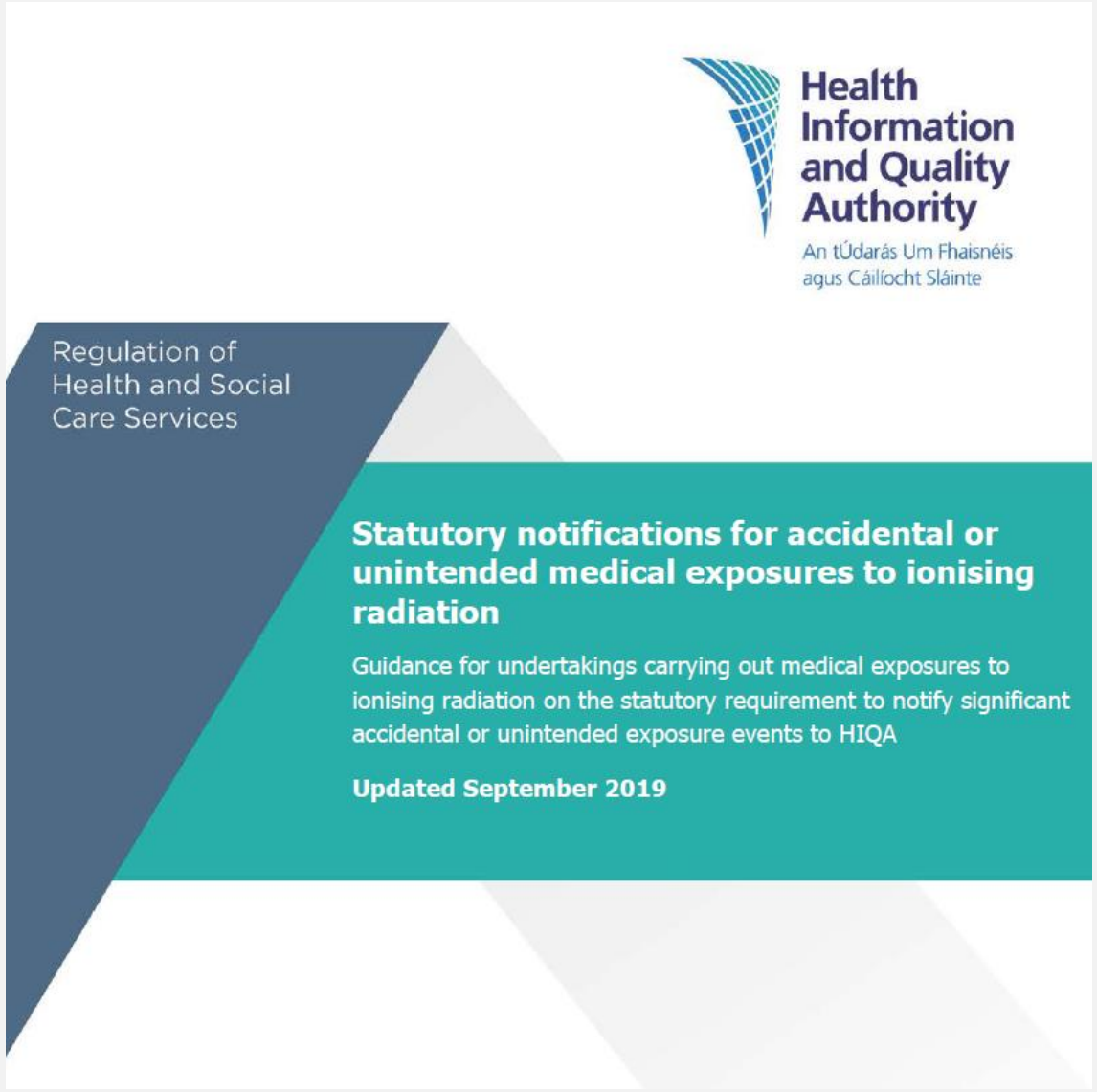
Hospital Radiation Safety Courses

Radiation Incidents

17. (1) An undertaking shall ensure that—

(c) for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,

(e) the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose, and



Radiation Incidents – HIQA Categorisations

Table 1. Significant events of accidental or unintended exposures that are notifiable to HIQA

1	Administration of a Reference Point Air Kerma (Ka,r) of 15 Gray (Gy) or greater as a result of a single interventional radiological procedure (including interventional cardiology) or a cumulative Ka,r dose of 15 Gy arising from a series of interventional radiological procedures carried out over a six month period
2	Tissue reactions (deterministic effects) as a result of interventional radiology/cardiology
3	Diagnostic overexposure of an adult of more than twice the exposure intended that leads to a dose that is greater than 10 millisievert (mSv) or 20 times the dose intended
4	Diagnostic overexposure of a child of more than twice the exposure intended that leads to a dose that is greater than 3 millisievert (mSv) or 15 times the dose intended
5	Dose given to comforters and carers greater than 3 millisievert (mSv) for adults under 60 years of age and 15 millisievert (mSv) for those over 60 years of age
6	Dose to a breastfed child greater than 1 millisievert (mSv)
7	Inadvertent dose to a foetus greater than 1 milligray (mGy)
8	Incorrect anatomy greater than 1 millisievert (mSv)

9	Incorrect procedure greater than 1 millisievert (mSv)
10	Incorrect radiopharmaceutical
11	Therapeutic dose given instead of diagnostic dose, for example, in the use of radioiodine
12	Administered activity variation of 20% from intended dose during use of therapeutic nuclear medicine
13	No dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)
14	Radiotherapy dose or volume variation of 10% or greater from the total prescribed
15	Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed
16	Unexpected tissue reactions (deterministic effects) as a result of radiotherapy treatment
17	Any other radiation exposure incident considered to have serious service user safety implications, for example, multiple non-notifiable incidents of a similar nature

Radiation Incident Management

- If an x-ray exam is incorrectly ordered for a patient and they receive it – it is a radiation incident. Clinically Significant unintended exposures should be reported to the Referrer, Practitioner & Patient (Policy of open disclosure and/or commumication to the patient).
- Reviewed - magnitude of exposure / type of mistake determines if reportable to HIQA (Role of the MPE & Clinical Risk Management).
- If it is a near miss, whereby a radiographer intercepts an actual radiation incident from occurring, it must be recorded as per regulator guidelines.
- Corrective Measures & Dissemination of Information

Should significant events be reported to other competent authorities?

Some incidents may be notifiable to more than one competent authority. HIQA and the EPA have a dual and collaborative role in the regulation of ionising radiation in Ireland under their respective legislation.

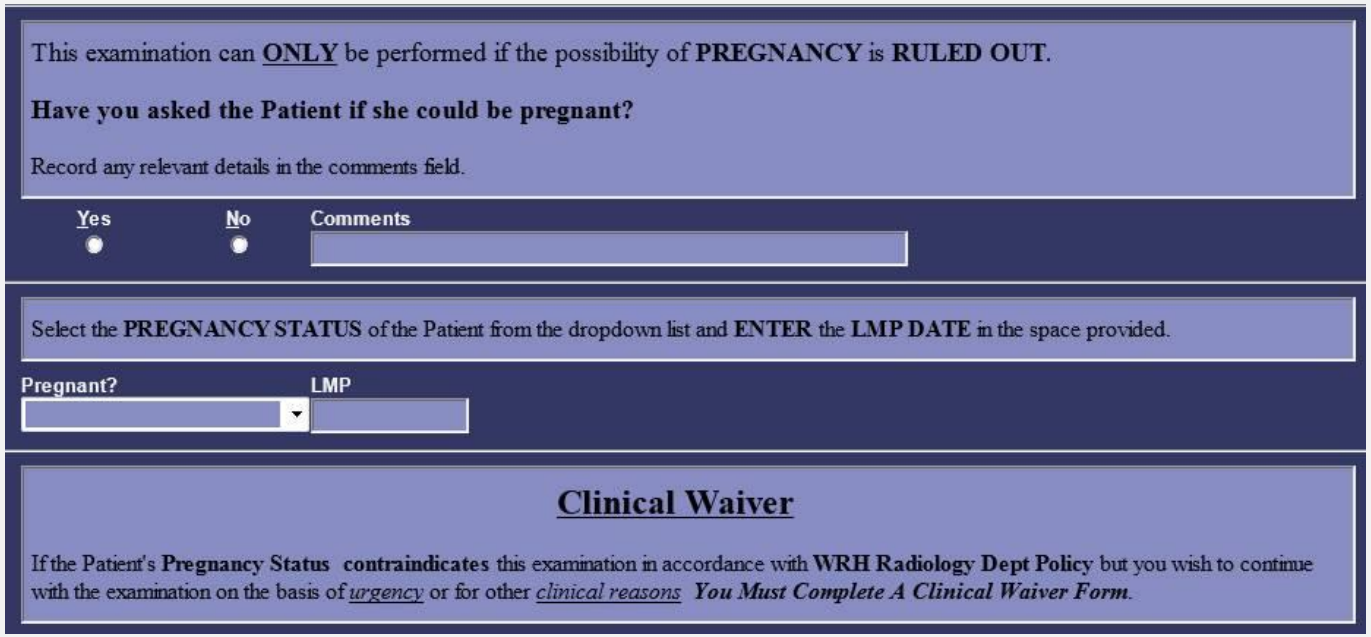
The Pregnant Patient

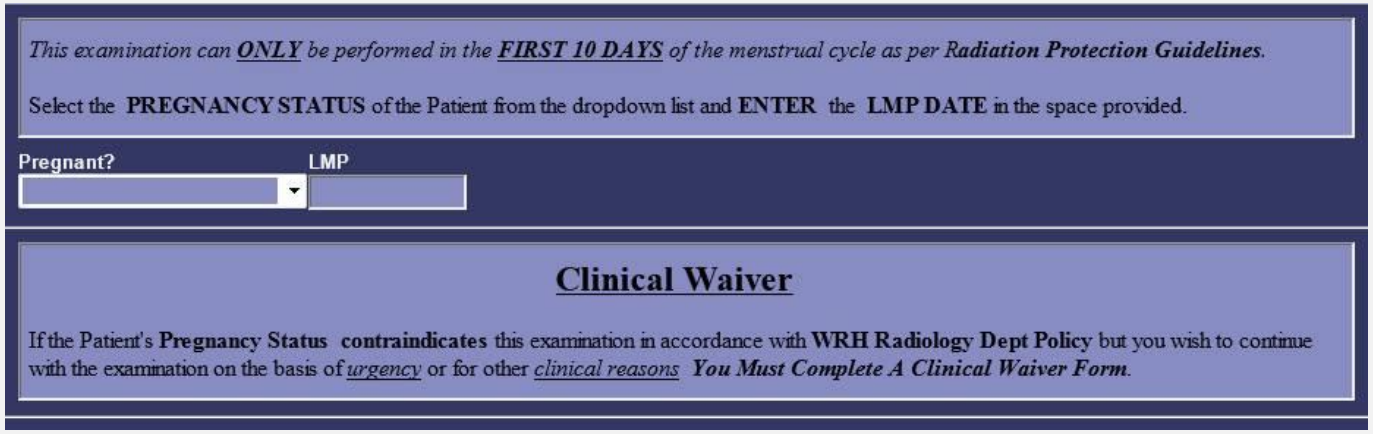
16. (1) An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall—

(a) inquire as to whether an individual subject to the medical exposure is pregnant …. , unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned,
and
(b) record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.

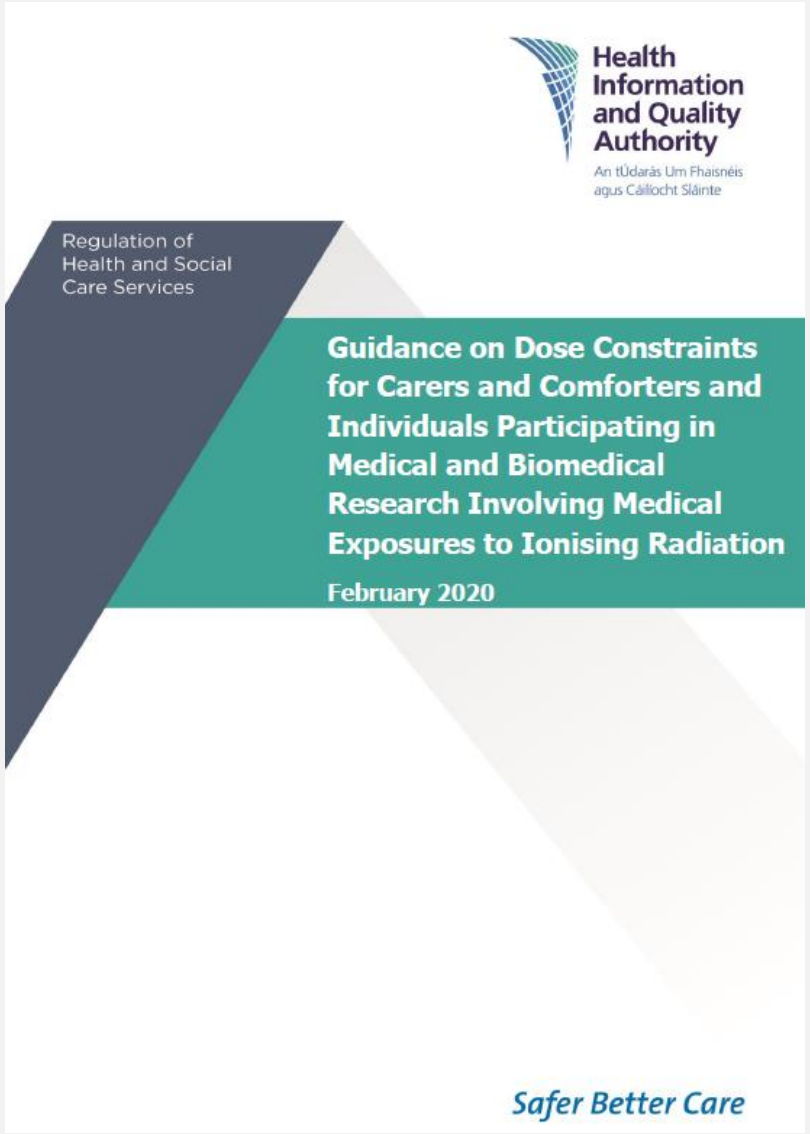
(2) If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the medical radiological procedure involved, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

Referral Procedures for Patients of Reproductive Capacity





Biomedical Research/Comforters & Carers



9(6) An undertaking shall ensure that, wherever practicable and prior to the exposure taking place, the practitioner or the referrer provides the carers and comforters with—
(*a*) adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure, and
(*b*) the guidance established under paragraph (5).

9(3)(b) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, individual dose levels are considered by the practitioner or the referrer, or both, prior to the exposure taking place.

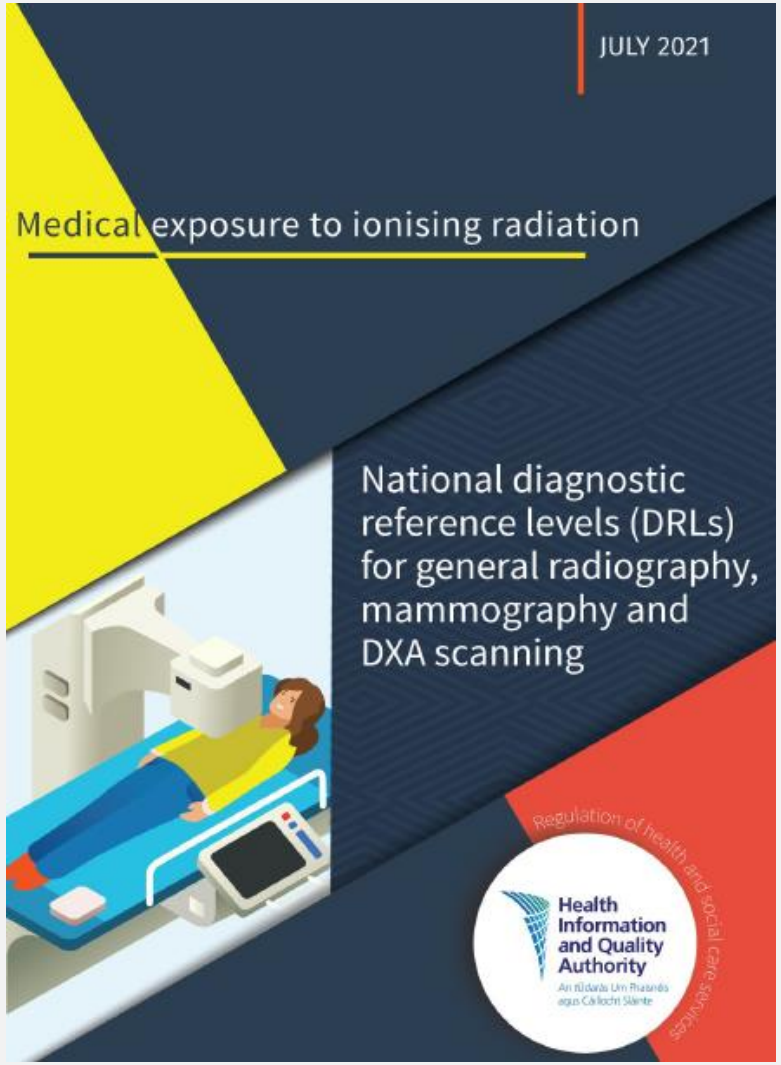
Asymptomatic Referrals & Health Screening Programmes

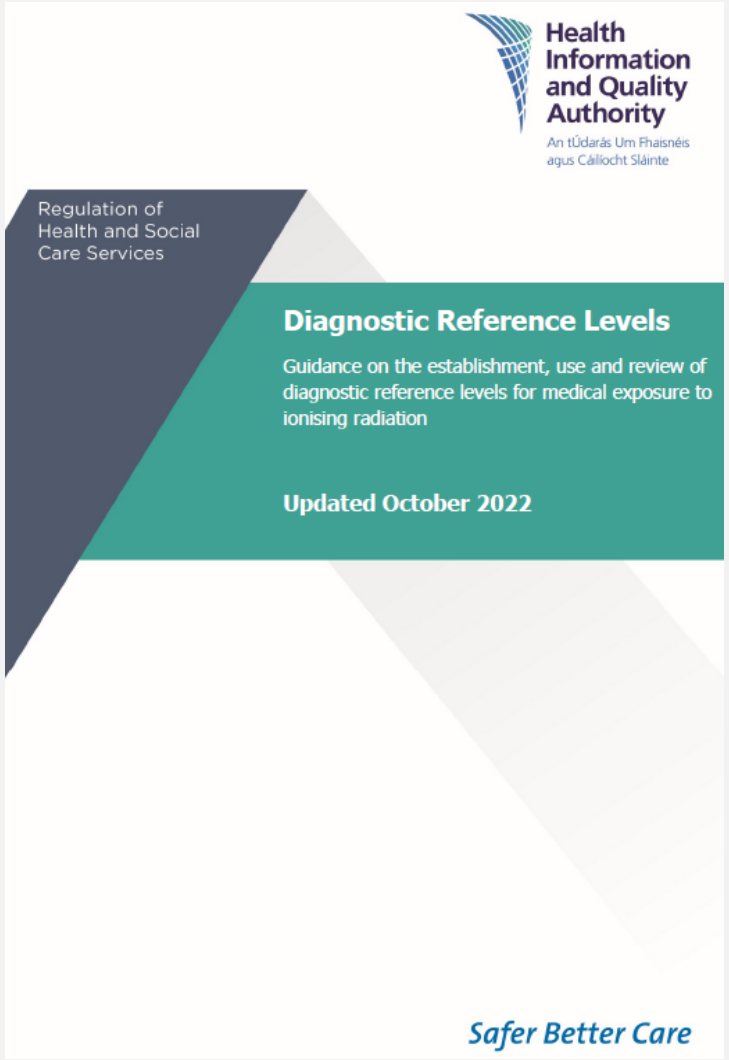
8(5a) An undertaking shall ensure that, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease— the procedure is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer

Note – Exposures for Non-Medical imaging to be regulated by the EPA under SI 30 of 2019

Diagnostic Reference Levels (DRLs)

11. (1) The Authority *(HIQA)* shall, after consultation with the relevant professional body or bodies, establish national diagnostic reference levels for radiodiagnostic examinations, ….





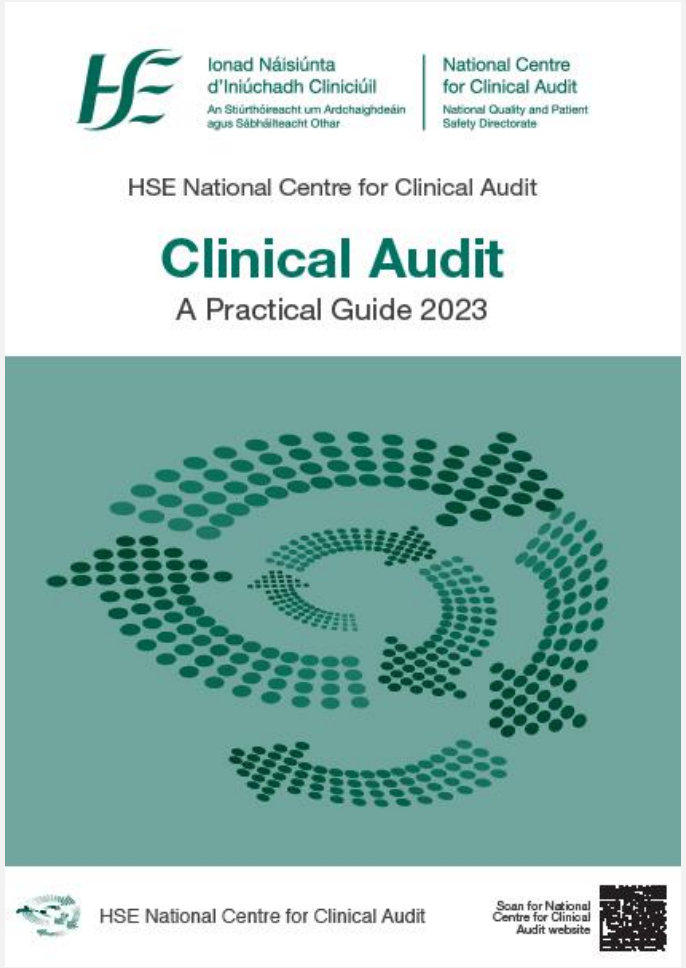
Local Diagnostic Reference Levels (LDRLs)

11 (5) An undertaking shall ensure that diagnostic reference levels …. are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1)

11 (6) An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.

Clinical Audit

13 (4) An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Minister.



Examples of Medical Exposure Audits

- Patient Dose – DRLs
  Opitmisation Measures
  Exposure Incidents/Accidents
  Referral Errors

- Justification – Efficacy of a Diagnostic Procedure
  Appropriate Referral Criteria/Clinical Indications
  Qualifications/Scope of practice of the Referrer
  Appropriate Clinical Information on referrals

- Procedure – Prior justification.
  Patient Exposure on Reports
  Patient ID
  Referrals for Patients of Reproductive Capacity (LMP etc)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"Still, let's do an x-ray just to be sure."

END