Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

HIQA

@HIQA

Welcome to HIQA's Ionising Radiation Information Event

June 2019

Sean Egan

Head of Healthcare

Safer Better Care

Programme		
Topic	Speaker	Time
Chair and facilitator	Sean Egan, Head of Healthcare	
Introduction to HIQA	John Tuffy, Regional Manager	20 mins
Introduction to the regulations	Maeve McGarry/ Lee O'Hora, Inspector	25 mins
HIQA's outline regulatory plan	Agnella Craig, Inspector	25 mins
Demonstration of HIQA's portal system	Kirsten O'Brien, Inspector	15 mins
Q&A	Panel	30 mins

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

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Presentation 1: Introduction to HIQA

June 2019

John Tuffy

Regional Manager

Safer Better Care

Topics

- About HIQA
- Areas we work in
- Role of HIQA in regulating medical exposure to ionising radiation
- HIQA's competent authority functions

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

Health Information and Quality Authority (HIQA)

- An independent authority
- Formed under the Health Act 2007
- Offices in Mahon in Cork (Head Office), Smithfield in Dublin and Galway.

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

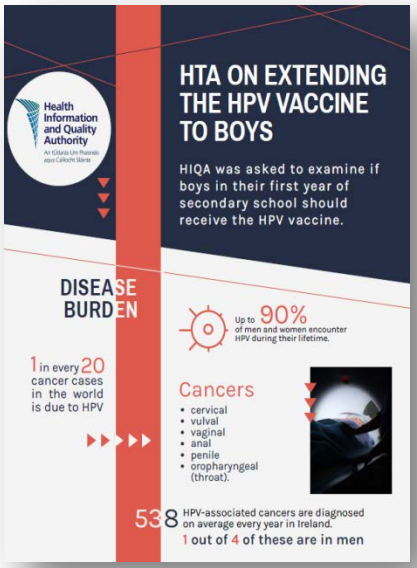
Areas we work in

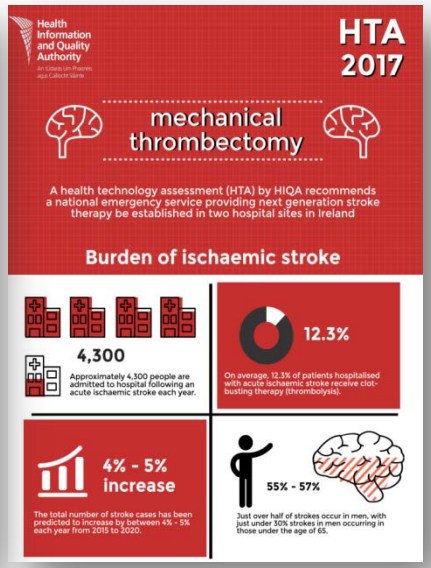
- Current mandate across public, private and voluntary sector services

- Functions:
  - develop standards
  - inspect and review health and social care services
  - support informed decisions on how services are delivered

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

Other directorates relevant to Ionising Radiation: HTA





- Provide guidance on assessment of **health technologies**:
  - Cost effectiveness
  - Place in therapy
  - Ethical considerations etc.
- Recent work includes:
  - Point of care testing to inform antibiotic prescribing
  - Mechanical thrombectomy
  - Extending HPV vaccine to boys

Regulation

Regulation Directorate to include the Office of Chief Inspector

- Largest directorate in HIQA
- Approx. 70% of the workforce
- Experience across four pillars

- **Acute and Community Healthcare Services**
- **Children's Services**
- **Disability Services**
- **Older People's Services**

2018 Activity

Office of the Chief Inspector

Older People's Services

- Monitoring, inspection and registration of designated centres for older people, such as nursing homes
- HIQA regulating since 2009
- >580 designated centres registered

Disability Services

- Monitoring, inspection and registration of designated centres for adults and children with a disability
- HIQA regulating since 2013
- >1,300 designated centres registered

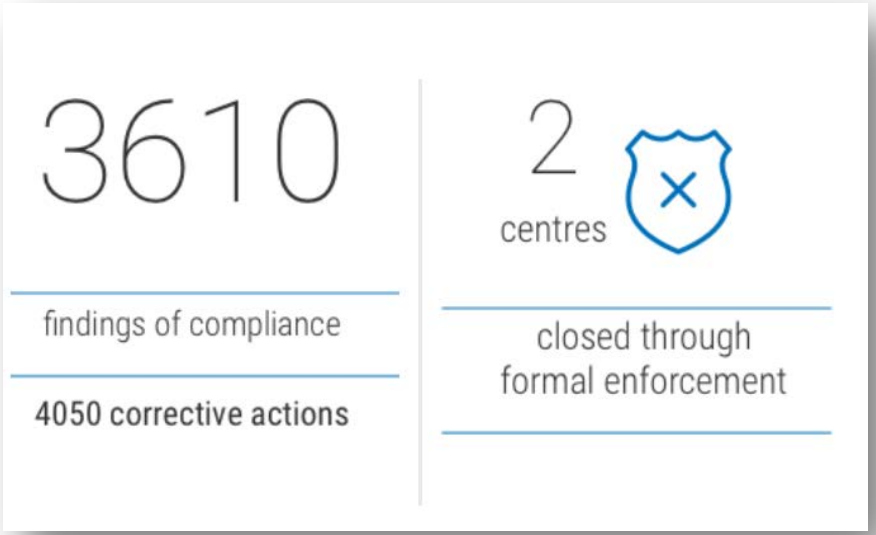
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Office of the Chief Inspector

Older People's Services

- Monitoring, inspection and registration of designated centres for older people, such as nursing homes
- HIQA regulating since 2009
- >580 designated centres registered

Regulatory activity



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

Formal regulatory powers

- The new regulation give HIQA **enforcement** powers
  - Compliance notice
    - Do or refrain from doing an act or acts
  - Prohibition order (cessation of practice)
    - Serious risk to patients, carers or volunteers in medical or biomedical research
    - Failure to comply with a compliance notice
- Order to cease carrying out a particular procedure or practice

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

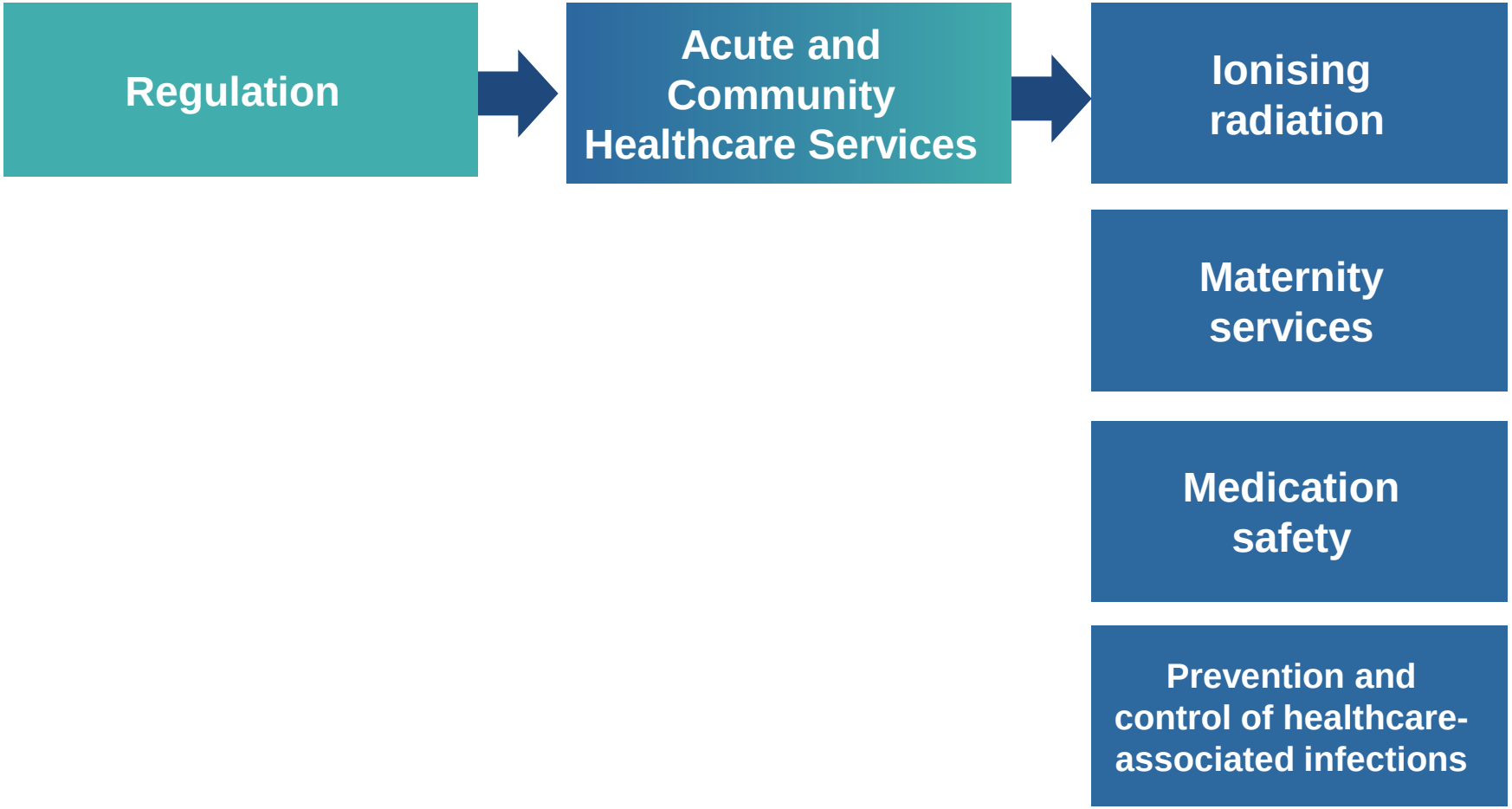
Healthcare

- Section 8(1) Health Act 2007
  - **HIQA sets standards** on safety and quality
  - **HIQA monitors compliance** with the standards (thematic monitoring programmes)
  - HIQA can **escalate concerns** directly to the Minister for Health

- Section 9(1) of the Act:
  - HIQA can undertake a **statutory investigation**

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

Healthcare and ionising radiation



HIQA's role in ionising radiation

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

Legislation

European Commission

Official Journal of the European Union

ISSN 1977-0677

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

- 2013/59/EURATOM
- 5 December 2013
- Basic safety standards for protection against the dangers arising from exposure to ionising radiation
- Directives repealed
  - 89/618/Euratom
  - 90/641/Euratom
  - 96/29/Euratom
  - 97/43/Euratom
  - 2003/122/Euratom

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Legislation

Official Journal of the European Union

L 13

ISSN 1977-0677

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

Competent authority

1. Member States shall designate a competent authority to carry out tasks in accordance with this Directive. They shall ensure that the competent authority:

(a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of practices under this Directive, in order to ensure effective independence from undue influence on its regulatory function;

(b) is given the legal powers and human and financial resources necessary to fulfil its obligations.

International Atomic Energy Agency (IAEA) in 2015 recommended:

- Governments establish a regulatory body for patient protection
- Body should not have responsibilities or interest in providing medical exposure to ionising radiation

Transposition to Irish law


Official Journal
of the European Union
L 13
ISSN 1977-0677
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

S.I. No. 256/2018
Patients

S.I No. 30/2019
Staff/Public

- In Ireland, the BSS was transposed into two documents
- Each new S.I. with different competent authorities

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

epa
Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Competent authority

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

Competent authority

- 8 January 2019: S.I. 256 of 2018
- HIQA is the competent authority for **patient protection** in relation to **medical exposure to ionising radiation** in Ireland
- Amendment of Health Act 2007 Section 8(1)(n)

Amendment of Health Act 2007

32. Section 8(1) (as amended by section 97 of the Child and Family Agency Act 2013 (No. 40 of 2013)) of the Health Act 2007 (No. 23 of 2007) is amended—

(*a*) in paragraph (*m*)(ii), by substituting "Disability Act 2005;" for "Disability Act 2005.", and

(*b*) by inserting the following paragraph after paragraph (*m*):

"(*n*) to exercise such powers and perform such functions of the State and the competent authority under Council Directive 2013/59/Euratom of 5 December 2013 as are conferred on the Authority by the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018).".

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

Competent authority

- Role in regulating **public and private** facilities providing medical exposures
- Services involving medical exposures including:
  - dental
  - research
  - radiation therapy
  - diagnostic imaging
  - interventional procedures
- **Not** for the purpose of regulating **community standards**

Take home messages

- HIQA has a range **functions** and extensive experience in health and social care regulation
- Remit now includes regulation of **medical exposure to ionising radiation** and **competent authority functions**
- Key purpose of the regulations is for patient protection and help drive quality improvements

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Presentation 2: Introduction to the Regulations

June 2019

Maeve McGarry/
Lee O'Hora
Inspector

Safer Better Care

Topics

- Regulation overview
- Undertaking
  - Regulatory notice
  - Undertaking information handbook
- Incident reporting
  - Guidance for reporting to HIQA
- Navigating the website

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

Regulation overview

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


Official Journal
of the European Union
L 13
ISSN 1977-0677
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

S.I. No. 256/2018
Patients

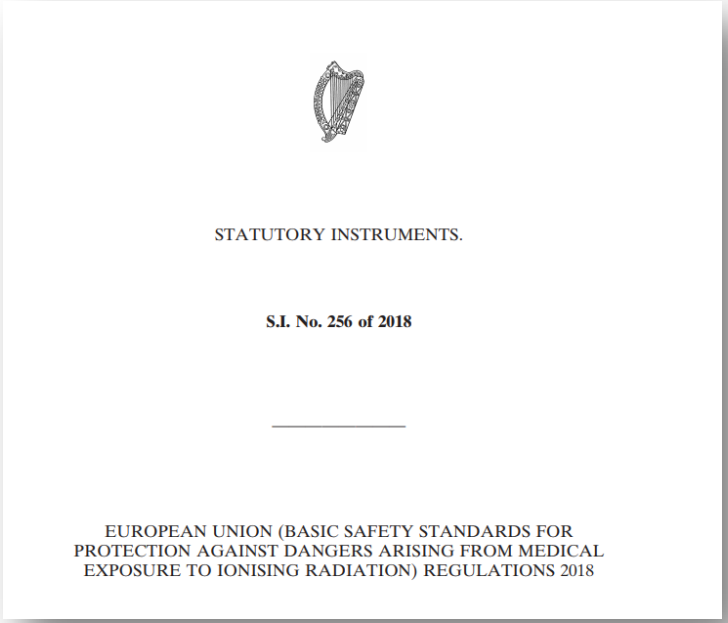
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

S.I. No. 30/2019
Staff/Public

epa
Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Regulations 2018 and 2019

- S.I. 256 of 2018 was enacted 8 January 2019
- Part 1 - Interpretation
- Part 2 - Requirements for medical exposures
- Part 3 - Medical physics experts



STATUTORY INSTRUMENTS.

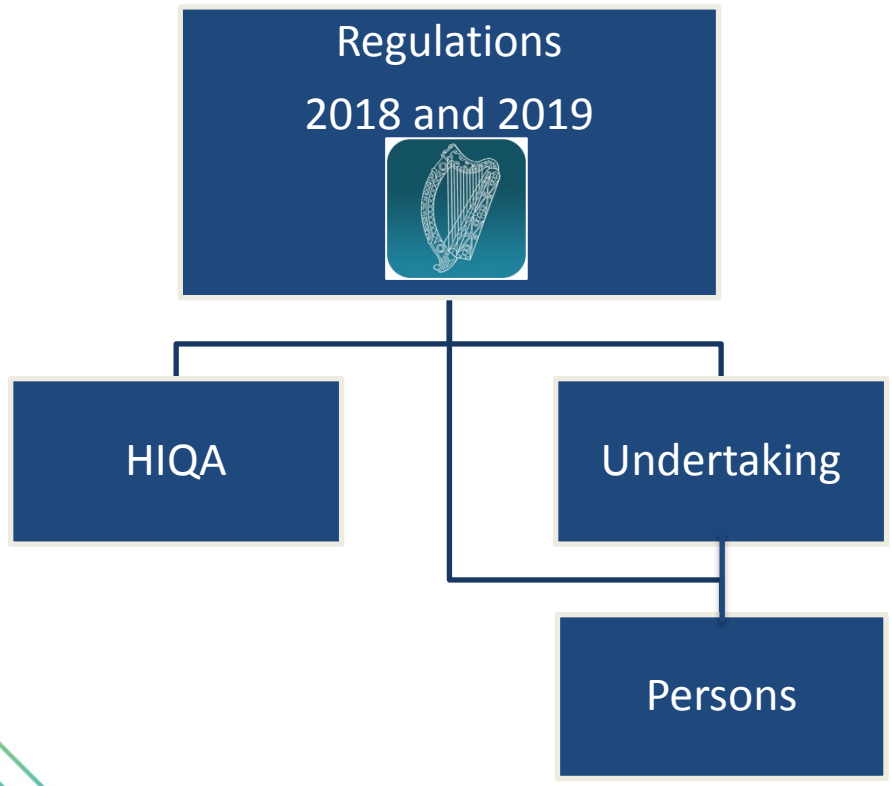
S.I. No. 256 of 2018

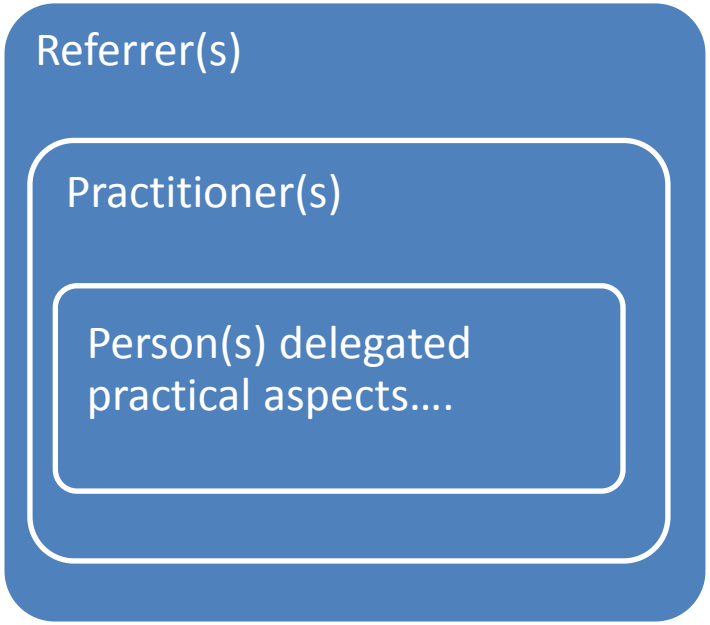
EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO IONISING RADIATION) REGULATIONS 2018

- Part 4 - Education and training
- Part 5 - Compliance and enforcement
- Part 6 - Offences and penalties
- Part 7 - Amendments

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

Responsibilities





Competent authority functions

- Regulatory and non-regulatory functions
- System of inspection taking into account the risks associated with different practices
- Justification: types of medical practice (new/old)
- Establishment and review of national diagnostic reference levels
- Receipt of significant events related to accidental and unintended exposures
- Population dose estimation from medical exposures
- Measures to ensure adequacy of equipment

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

Undertaking

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

Notification of undertaking

"undertaking" means 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 definition in the legislation

  (Regulations 2018 and 2019)
- Requirement for HIQA to know who is responsible for the conduct of medical exposures for regulatory purposes
- Declaration closed - 8 April 2019
- Any new declaration to declare one month in advance

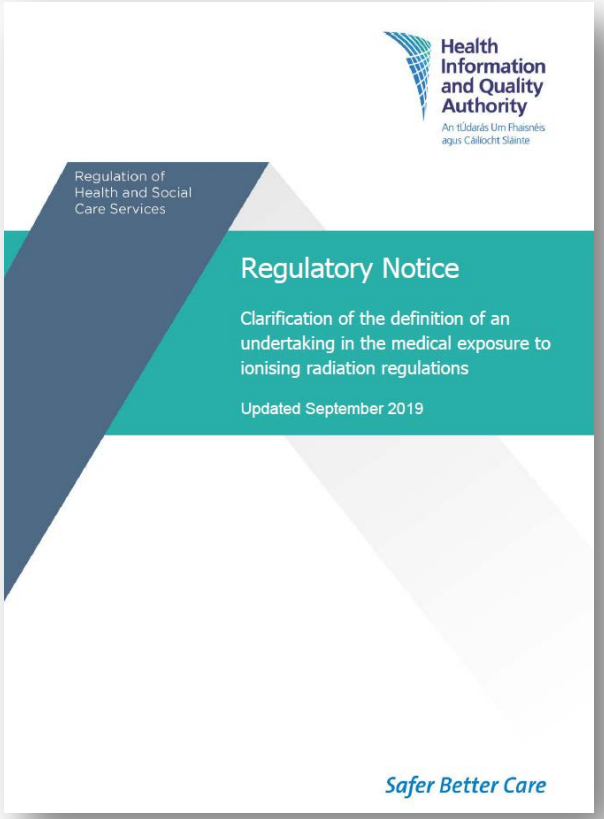
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

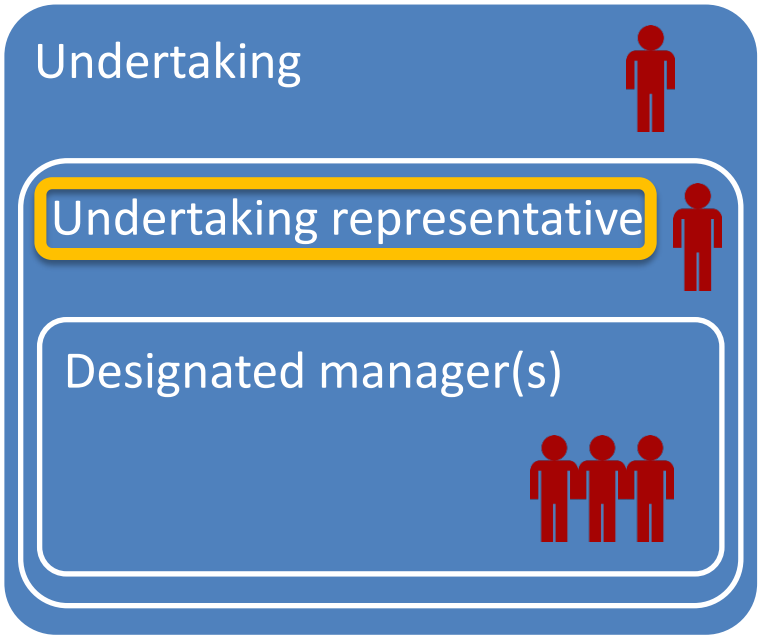
Notification of undertaking

"undertaking" means 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.

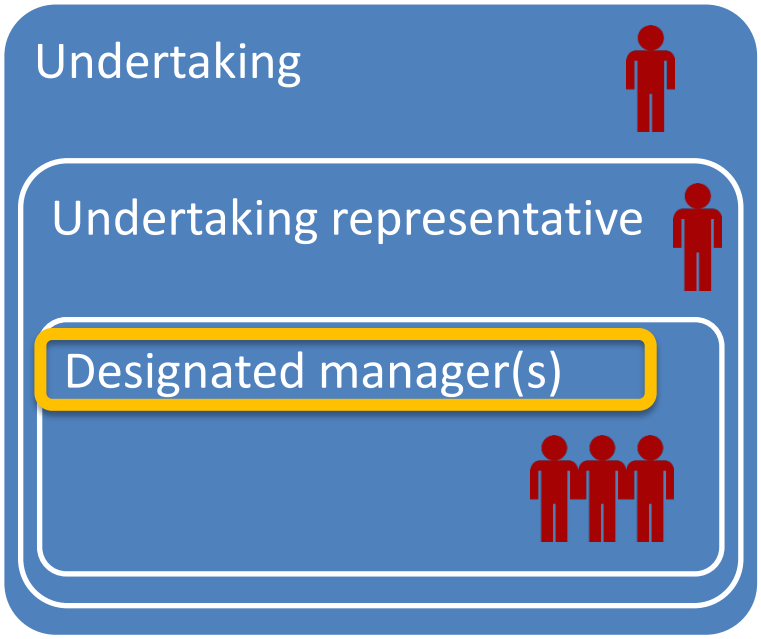
- Clarification of the definition
- Two undertaking scenarios

Regulatory Notice updated September 2019

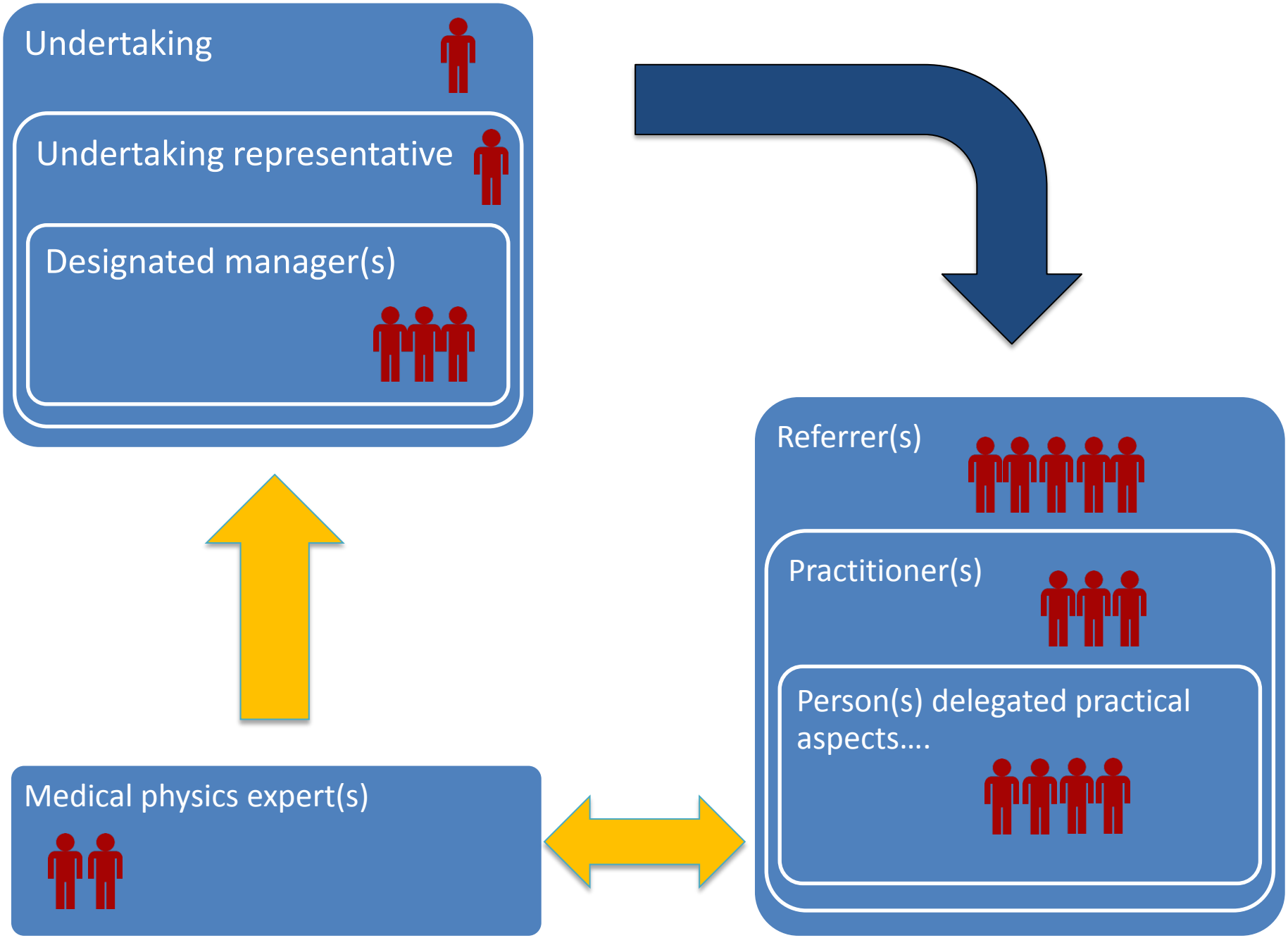


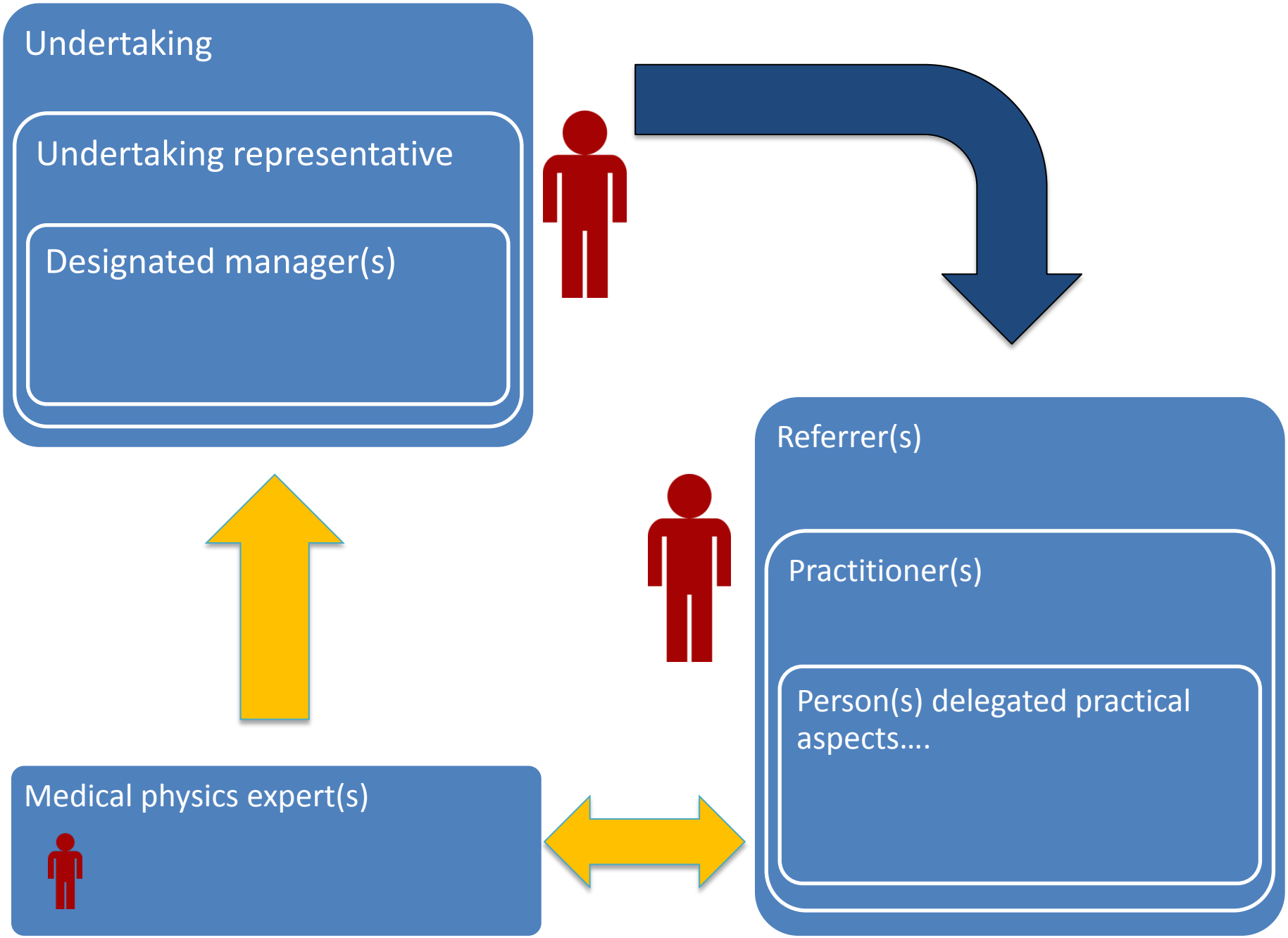


- Must hold a senior position within the undertaking
- Must be involved in the executive governance and management of the service
- Example: director of the company
- Will engage with HIQA in response to escalated or significant concerns or risks



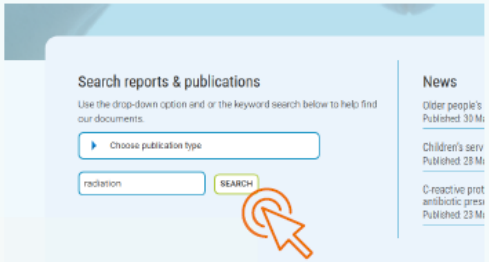
- HIQA requires all undertakings to nominate a designated manager of each medical radiological installation
- This is to facilitate communications between HIQA and the undertaking for operational matters, such as the scheduling of an inspection


Undertaking
Undertaking representative
Designated manager(s)
Referrer(s)
Practitioner(s)
Person(s) delegated practical aspects….
Medical physics expert(s)

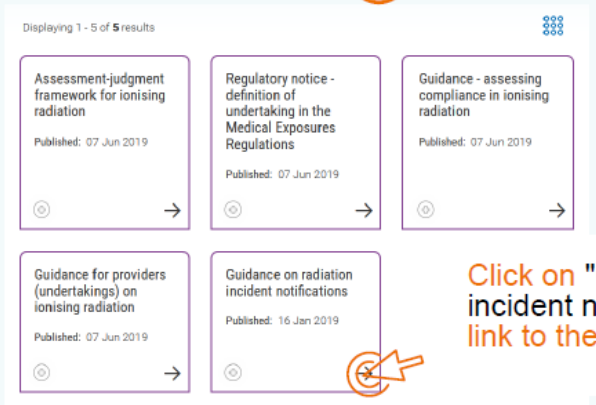

Undertaking
Undertaking representative
Designated manager(s)
Referrer(s)
Practitioner(s)
Person(s) delegated practical aspects….
Medical physics expert(s)

Where to find key documents and information

From the hiqa.ie home page scroll down to search reports & publications

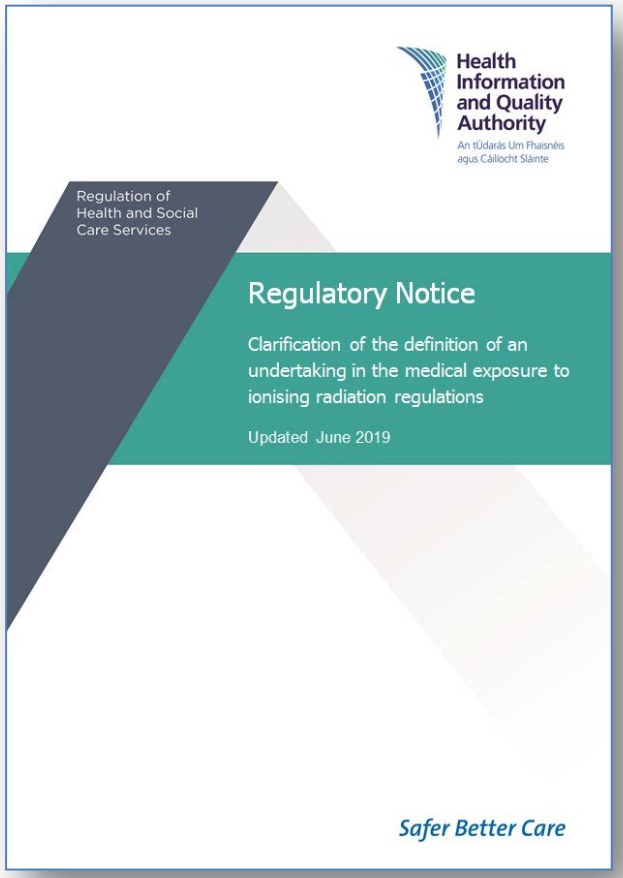


Search for "radiation"



Click on "Guidance on radiation incident notifications" to get a link to the notification forms

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



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

Incident reporting

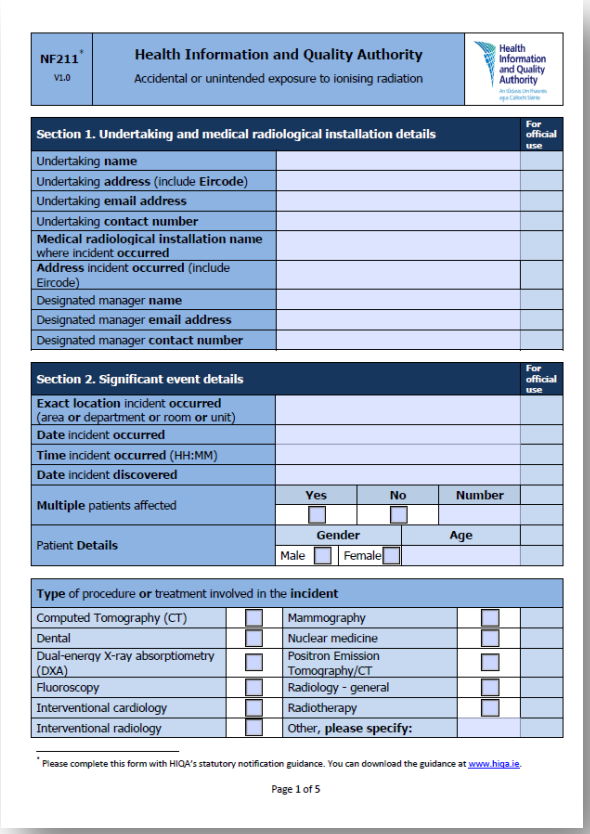
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Notification of accidental and unintended exposures

HIQA to be notified of a significant event within **3 working days** of discovery

Notification forms are available at

www.hiqa.ie



NF211* V1.0

Health Information and Quality Authority

Accidental or unintended exposure to ionising radiation

Section 1. Undertaking and medical radiological installation details		**For official use**
Undertaking **name**		
Undertaking **address** (include **Eircode**)		
Undertaking **email address**		
Undertaking **contact number**		
Medical radiological installation name where incident **occurred**		
Address incident **occurred** (include Eircode)		
Designated manager **name**		
Designated manager **email address**		
Designated manager **contact number**		

Section 2. Significant event details				**For official use**
Exact location incident **occurred** (area **or** department **or** room **or** unit)				
Date incident **occurred**				
Time incident **occurred** (HH:MM)				
Date incident **discovered**				
Multiple patients affected	**Yes** ☐	**No** ☐	**Number**	
Patient **Details**	**Gender** Male ☐ Female ☐		**Age**	

Type of procedure **or** treatment involved in the **incident**				
Computed Tomography (CT)	☐	Mammography	☐	
Dental	☐	Nuclear medicine	☐	
Dual-energy X-ray absorptiometry (DXA)	☐	Positron Emission Tomography/CT	☐	
Fluoroscopy	☐	Radiology - general	☐	
Interventional cardiology	☐	Radiotherapy	☐	
Interventional radiology	☐	Other, **please specify:**		

* Please complete this form with HIQA's statutory notification guidance. You can download the guidance at www.hiqa.ie.

Page 1 of 5

Notification of accidental and unintended exposures

HIQA to be notified of a significant event within **3 working days** of discovery

- Undertaking/representative and designated manager to be aware of notifications submitted
- Adopted former criteria for significant events
- Events below thresholding for reporting to HIQA should be managed internally
  - Recorded and analysed
  - Includes ‘near misses’

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

Results of investigation

HIQA to receive **results of investigation** into significant event within **120 calendar days** from receipt of initial notification

- Oversight
  - Designated manager
  - Undertaking representative
- Persons included in investigation
  - Medical physics expert
  - Persons notified
- Causation and contributing factors
- Corrective actions
- Recommendations (specific and time bound)
- Incident close-out details

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

Results of investigation

Not required

- Personally identifiable information
  - No patient names or identifiers
- Supplementary or third party information
  - Such external engineers reports
- Investigation results will be returned
- Will need to be resubmitted

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

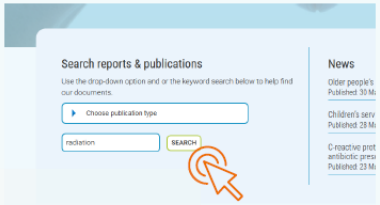
Dissemination of learning

- Incident learning is about patient safety
- Non-punitive
- HIQA encourage a healthy incident reporting culture
- HIQA will publish overview report to disseminate learning

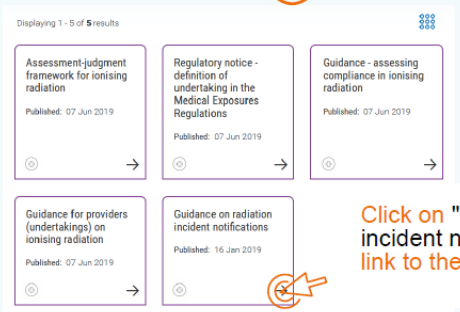
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Where to find key documents and information

From the hiqa.ie home page scroll down to search reports & publications



Search for "radiation"



Click on "Guidance on radiation incident notifications" to get a link to the notification forms

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

Take home messages

- Overall responsibility for radiation safety of the patient or service user lies with the ‘undertaking’

- This is a new relationship for both HIQA and the radiological community and time will be required to become accustomed to the totality of the new regulations

- HIQA will carry out open bilateral communications in order to be proportionate and fair in our regulatory approach and judgments

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

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Presentation 3: HIQA's Outline Regulatory Plan

June 2019

Agnella Craig

Inspector

Safer Better Care

Topics

- Methods used to assess compliance
- Timelines
- Details of inspection
- How we make judgments
- Reporting process

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

Assessing compliance

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

Assessing compliance

Who?

- Inspectors –

authorised person appointed by HIQA under Regulation 24 of S.I 256 of 2018 for the purpose of ensuring compliance with the regulations

How?

- Declaration of undertaking (NF200)
- The self-assessment questionnaire
- Inspections

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

Declaration of undertaking (NF200)

NF200	**Notification Form** Declaration of undertaking To be completed in conjunction with guidance published at www.hiqa.ie	Health Information and Quality Authority An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Definition of an undertaking
An "undertaking" means a person or body, in the course of a trade, business or other undertaking, who carries out (other than as an employee), or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure.[1]

Section A. Undertaking information			
A1. Undertaking details			**For official use**
Undertaking **name**			
Undertaking **address**	Address line 1		
	Address line 2		
	County		
	Eircode		
Undertaking **email address**			
Undertaking **contact number**			
Number of medical radiological installations[2] under the undertaking's remit			

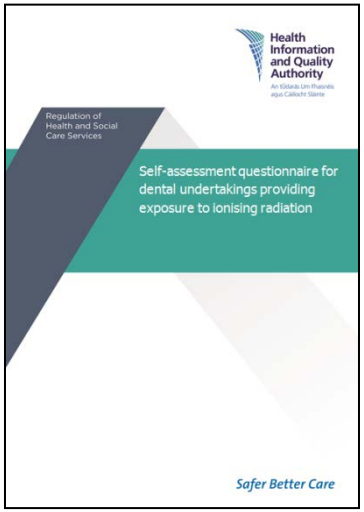
When?

Existing practices 8 April 2019

New practices 1 month before commencing practice

The self-assessment questionnaire

- HIQA will issue a self-assessment questionnaire
- Each undertaking/facility will self-appraise compliance
- A tool for the facility and the regulator
- Aim:
  - Identifies risks/perceived gaps in practice
- Format - Yes/No questions



When?

- Larger installations - **2019**

(e.g. general radiography, radiotherapy, dental cone beam CT)

- Dental installations (without cone beam CT facilities) - **2020**

Inspections

- The aim of the on-site inspection is to gather evidence to assess compliance with the regulations
- A **risk-based and graded approach** to regulation across a range of medical radiological services:
  - radiology, radiotherapy, dental services
- Information used to devise this approach will include:
  - The types of services provided:
    - Size and scale of activities
    - Results of the self-assessment questionnaire
    - Significant event notifications (NF211)
    - Unsolicited information received by HIQA

When?

Begins: 4th quarter 2019*

Larger installations first

*unless a specific risk is identified

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

Details of inspections

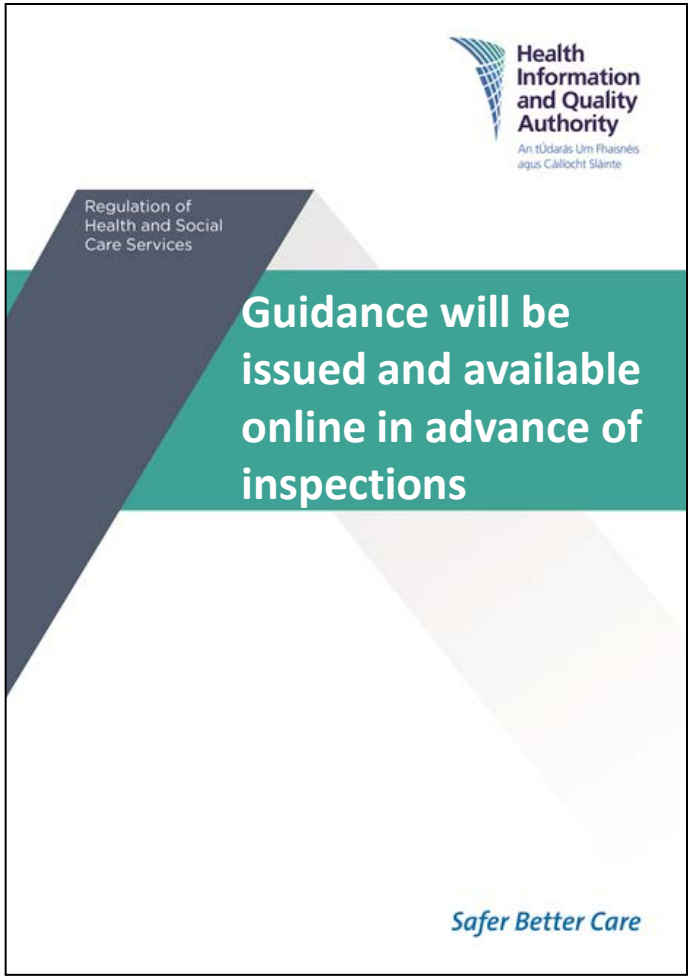
Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Inspections

- On-site inspections may be:
  - **announced inspections**
  - **a short notice announced inspection**
  - **unannounced inspection**

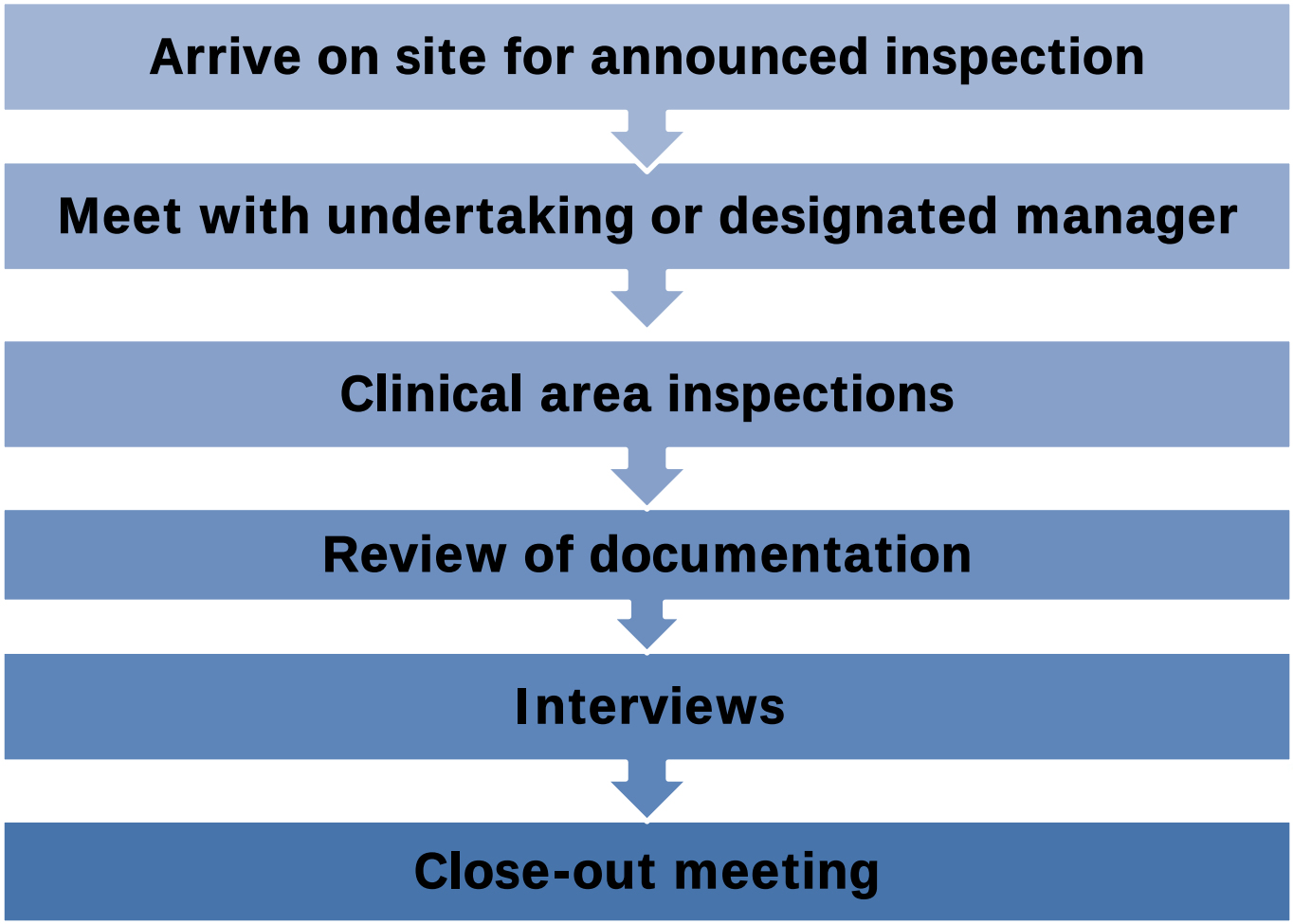
- Pre-inspection
  - Request for information
  - Specific to the installation type and services
  - Communicated in advance

- Duration:
  - larger facilities - one day
  - smaller facilities - less than one day



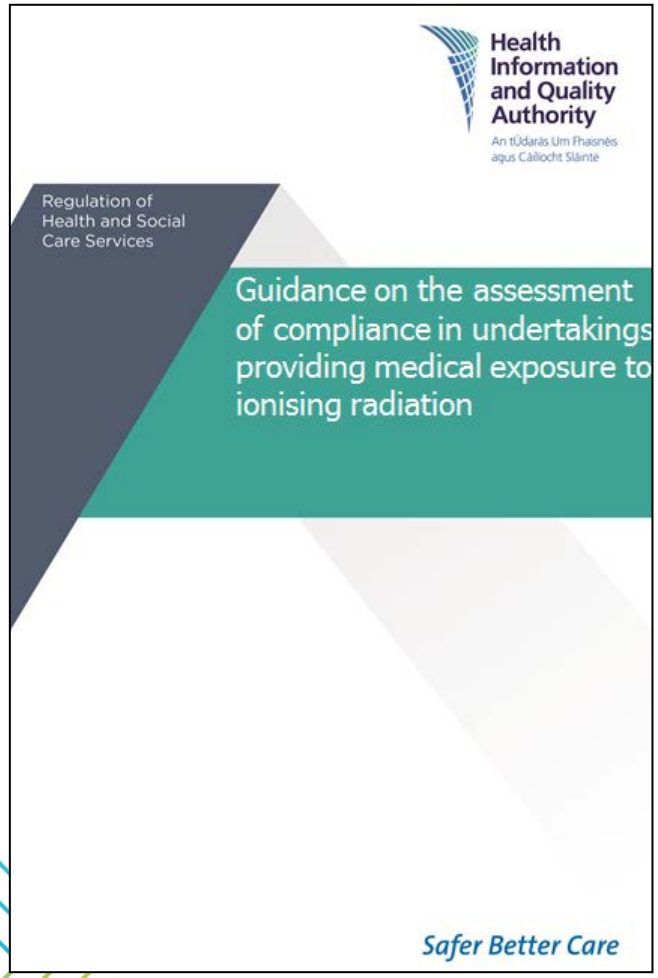
Inspections

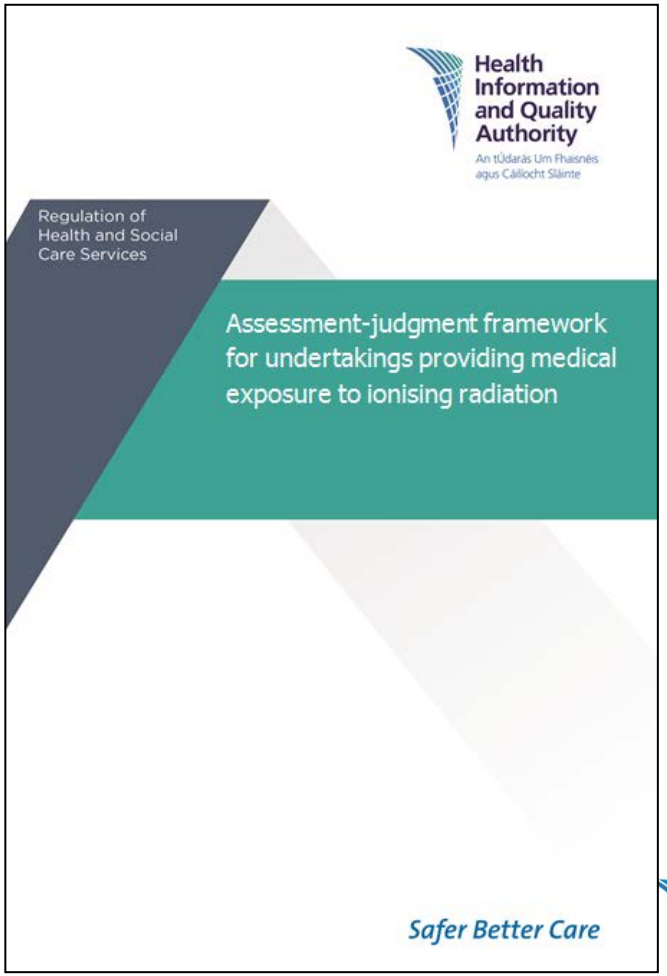
Sample outline of an on-site inspection schedule



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

Supporting documentation





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

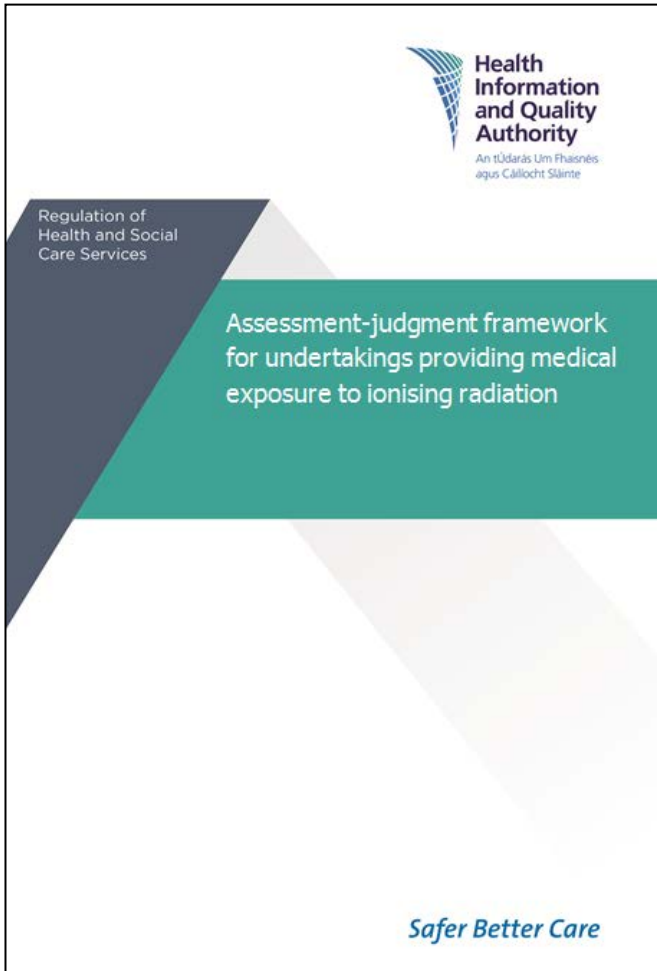
www.higa.ie

Assessment-judgment framework

Purpose:

- support inspectors in gathering evidence when monitoring or assessing an undertaking and making judgments on compliance

- set out the lines of enquiry (questions) to assess compliance with the regulations being monitored or assessed



Assessment-judgment framework

Example

Regulation 4. Referrers

What this regulation means for the service user

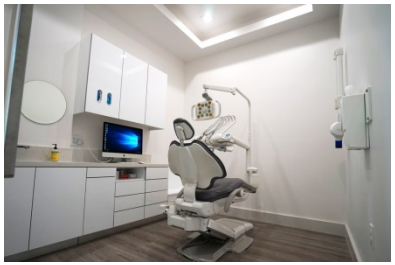
This regulation helps assure service users that only recognised healthcar professionals with appropriate knowledge and expertise have the entitler refer an individual for a medical exposure.

Only appropriately trained and recognised professionals, as defined in Re can refer an individual for a medical exposure. Those carrying out medic must ensure that people have only been referred for radiological procedu appropriate individual.

Dimension: Governance and management arrangements for medical exposures	
Regulation 4	**Referrers**
Line of enquiry	1. Is the person making a referral for medical radiological procedures to a practitioner one of the following: (a) a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives (b) a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985) (c) a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007) (d) a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005) or (e) a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner? 2. Does a person only carry out a medical radiological procedure on the basis of a referral from a referrer?
Judgment	**Compliant:** a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

On inspection

Observe



Evidence

Read

Hear

Example

Regulation 4. Referrers

What this regulation means for the service user

This regulation helps assure service users that only recognised healthcare professionals with appropriate knowledge and expertise have the entitlement to refer an individual for a medical exposure.

Only appropriately trained and recognised professionals, as defined in Regulation 4, can refer an individual for a medical exposure. Those carrying out medical exposures must ensure that people have only been referred for radiological procedures by an appropriate individual.

Observe:

- process for accepting referrals
- if medical exposures are based on a referral from a recognised professional

Example

Regulation 4. Referrers

What this regulation means for the service user

This regulation helps assure service users that only recognised healthcare professionals with appropriate knowledge and expertise have the entitlement to refer an individual for a medical exposure.

Only appropriately trained and recognised professionals, as defined in Regulation 4, can refer an individual for a medical exposure. Those carrying out medical exposures must ensure that people have only been referred for radiological procedures by an appropriate individual.

Hear:

- from practitioners about how they ensure they only accept referrals from recognised professionals

Example

Regulation 4. Referrers

What this regulation means for the service user

This regulation helps assure service users that only recognised healthcare professionals with appropriate knowledge and expertise have the entitlement to refer an individual for a medical exposure.

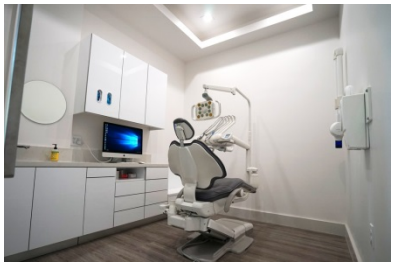
Only appropriately trained and recognised professionals, as defined in Regulation 4, can refer an individual for a medical exposure. Those carrying out medical exposures must ensure that people have only been referred for radiological procedures by an appropriate individual.

Review:

- referrals for medical exposures to assess if the referral is from a healthcare professional entitled to act as a referrer as defined in Regulation 4
- the processes and procedures in place for accepting referrals
- written policies, procedures and guidelines defining who is entitled to refer

How do inspectors assess compliance?

Observe



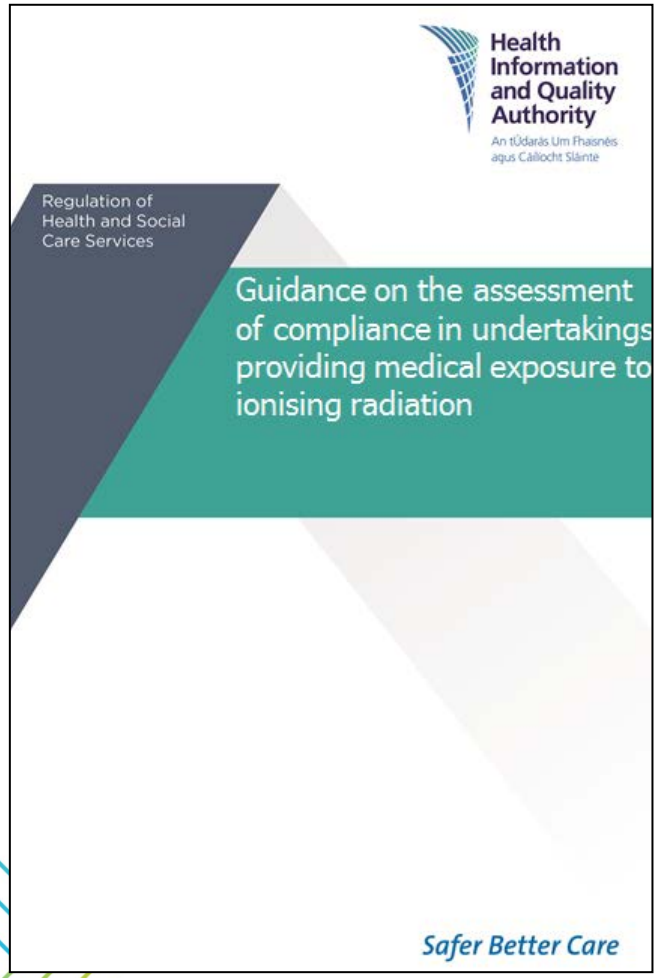
Read

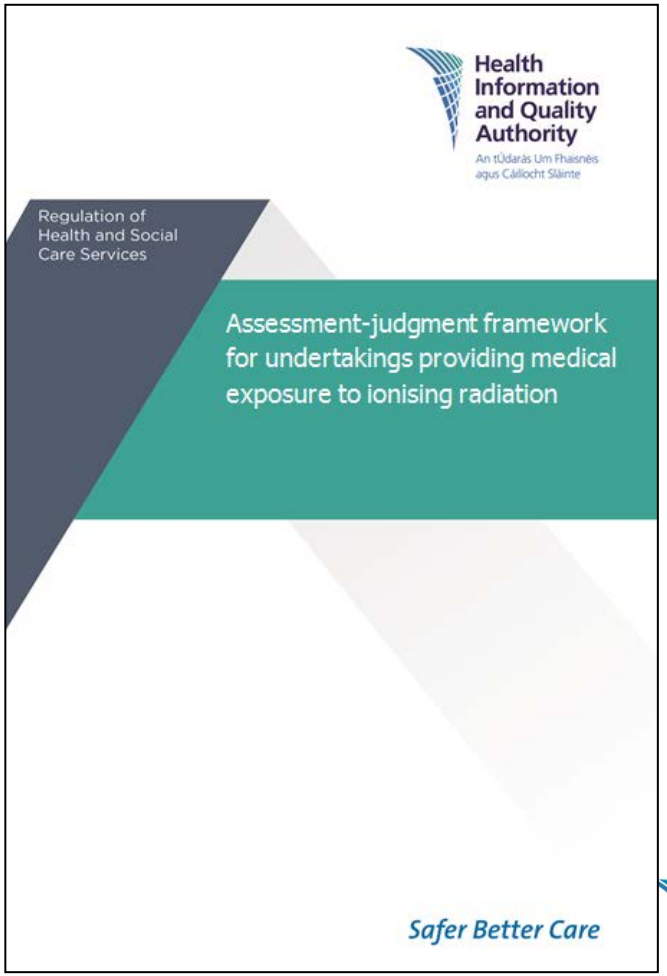
Evidence

Hear

Judgment

Supporting documentation





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

www.higa.ie

Judgment

- A judgment about the level of compliance is made for each regulation
- Some regulations attribute **individual responsibility** to a defined person or persons along the service user's pathway

But

- **Overall responsibility** for compliance is with the undertaking

- Following assessment, an undertaking will be found to be:
  - **compliant**
  - **substantially compliant**

  or
  - **not compliant.**

Compliance descriptors

- **Compliant:**
  - the undertaking or other person is in **full compliance** with the relevant regulation
- **Substantially compliant:**
  - the undertaking or other person has generally met the requirements of the regulation but **some action is required** to be fully compliant
- **Not compliant:**
  - the undertaking or other person has not complied with a regulation and that **considerable action is required** to come into compliance

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

Reporting process

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

Reporting process

- An individual report will be generated and published for each inspected medical radiological installation
- Three stage process

Stage 1 Inspection report

Feedback and factual accuracy

Stage 2 Inspection report

Complete the feedback stage

Stage 3 Inspection report

Final report

Formal submission

Reporting risk

- If a judgment of non-compliance is made, inspectors review the risk to service users
- Inspectors will report on this risk as being:
  - **Red**: there is **high risk** associated with the non-compliance
  - **Orange**: there is **moderate risk** associated with the non-compliance
  - **Yellow**: there is **low risk** associated with the non-compliance
  - **Green**: there is **very low risk**

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

Non-compliance

- Powers of enforcement under the regulations
- Priority to aid undertaking to come into compliance
- The report will include a compliance plan
  - HIQA will outline:
    - which regulations the undertaking must take action on to comply
    - the time frame associated with the “take action”
  - Undertaking:
    - set out what action they will take to comply with the regulation

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

Take home messages

Compliance of the regulations will be assessed by **inspectors** using a number of methods:

- **Declaration of undertaking** (NF200)
  - Existing practices - 8 April 2019
  - New practices - one month before commencing practice
- **The self-assessment questionnaire**
  - Larger installations - 2019
  - Dental installations (without cone beam CT facilities) - 2020
- **Inspections**
  - Begin - 4th quarter 2019
  - Dental facilities - proposed timeframe 2020

- Online documentation
  - Guidance document
  - Assessment-judgment framework

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

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Presentation 4: HIQA Portal

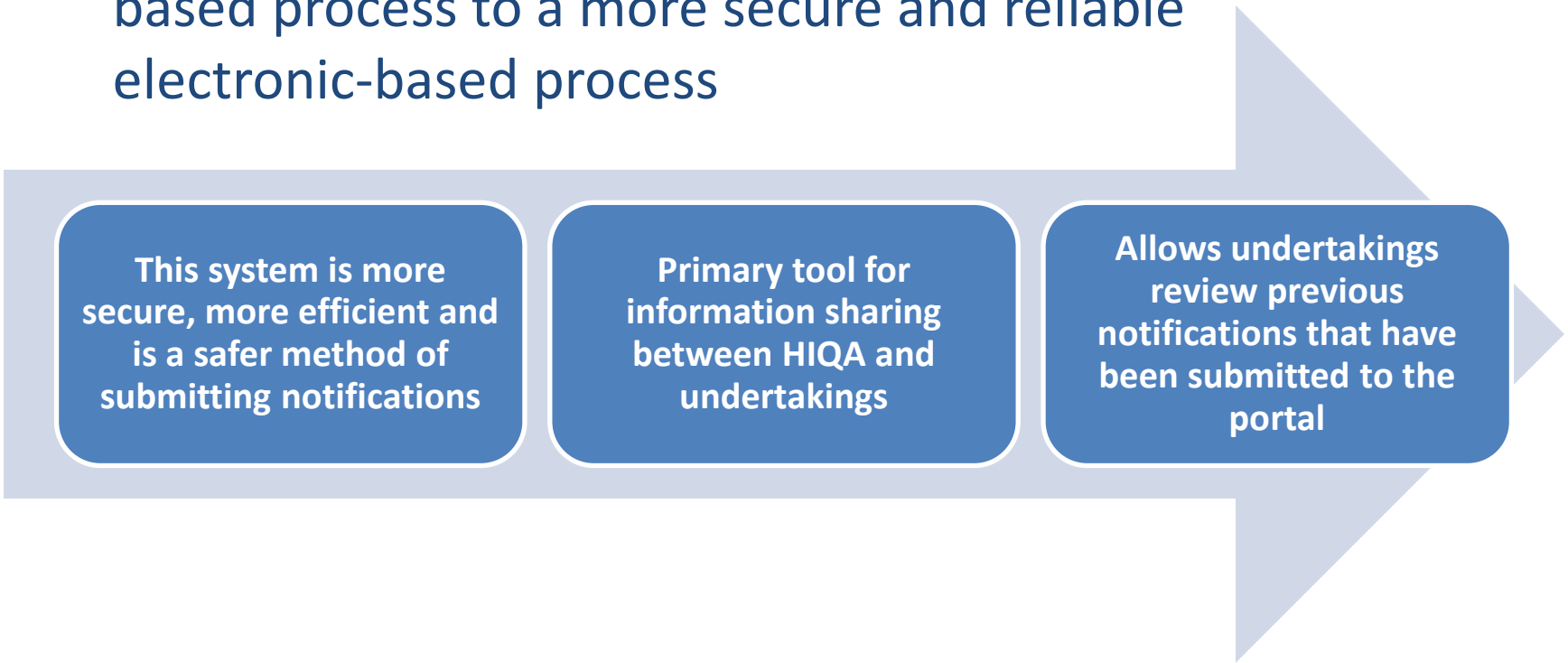
June 2019

Kirsten O'Brien
Inspector

Safer Better Care

HIQA Portal

- The portal supports HIQA's regulatory process
- The portal allows us to move from a paper-based process to a more secure and reliable electronic-based process



Notifications

- Notifications are the most common forms of solicited information HIQA receive from undertakings
  - Changes to undertaking details (undertaking level)
  - Submission of a Significant Event notification (undertaking/facility level)

Undertaking level notifications

Changes to undertaking details (undertaking level)

Notification	Title
NF200	Declaration of undertaking
NF201A	Change of undertaking details
NF201B	Change of undertaking representative details
NF201C	Change of medical radiological installation service type
NF201D	New medical radiological installation
NF201E	Change of medical radiological installation designated manager
NF201F	Change of partnership details
NF201G	Change of unincorporated body details
NF202A	Cessation of undertaking practice
NF202B	Cessation of medical radiological installation

Installation/facility level notifications

Submission of Significant Event notification (installation/facility level)

Notification	Title
NF211A	Significant event notification – Radiology, Dental, Nuclear Medicine
NF211B	Significant event notification - Radiotherapy
NF211C	Significant event notification - Other

Benefits of HIQA Portal

- **Accuracy -** all mandatory fields must be completed
- **Efficiency -** no requirement to complete undertaking details for each submission/information is stored in the portal
- **Record keeping -** readily available in notification history
- **Reliability -** once submitted it has been sent to HIQA successfully
- **Security -** information is transmitted securely to HIQA.
- **Version control -** forms on the HIQA Portal will always be the most up-to-date versions

Super user portal access

The **Super-User**:

- can nominate sub-account users who can also access the portal
- is responsible for managing all sub account users for the facility (for example, dental practice/hospital)
- is responsible for deactivating portal access for any sub-account user who has left the practice or hospital (failure to do so may result in this person accessing notification history for the facility)

Most frequent queries

I am locked out of my account

I had access earlier but now portal is stating my password is incorrect

Health Information and Quality Authority

I am getting this message: This account has no Portal access role(s). Account not validated

I missed the 24 hour access deadline to set up my account; please re-send the activation email

Who do I contact if I need assistance?

portalsupport@hiqa.ie

Access to HIQA Portal for Undertakings

- Time frame for deployment of HIQA Portal for undertakings is to be determined as the portal is under development

- Roll out of the HIQA Portal will be introduced for **larger undertakings** (such as hospitals) in the first instance

- Undertakings will be communicated with by HIQA and **invited to register** on the HIQA Portal when available

Contact us:

radiationprotection@hiqa.ie

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte