

# HIQA webinar for dental services providing medical exposure to ionising radiation

September 2020

*Safer Better Care*



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# Presentation 1: Work to date and planned approach to inspection in dental sector

September 2020

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*Safer Better Care*

# Transposition to Irish law



Official Journal  
of the European Union

L 13



English edition

Legislation

Volume 57  
17 January 2014

Contents

II - New 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, 90/443/Euratom, 96/29/Euratom, 97/43/Euratom and 2001/20/Euratom



S.I. No. 256/2018  
Patients



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



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



epa

Environmental Protection Agency  
An Gníomhaireacht um Chaomhú Comhshaoil



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# 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.

- Requirement for HIQA to know who is responsible for the conduct of medical exposures for regulatory purposes
- Required Notification by 8 April 2019 (NF200)
- Any new undertaking to declare one month in advance
- An example is a dentist who runs his or her own service. The dentist could be assisted by a dental nurse or other staff.

**Top Tip:** See the *Undertaking information handbook* for more information about undertakings

# Other examples of undertaking types

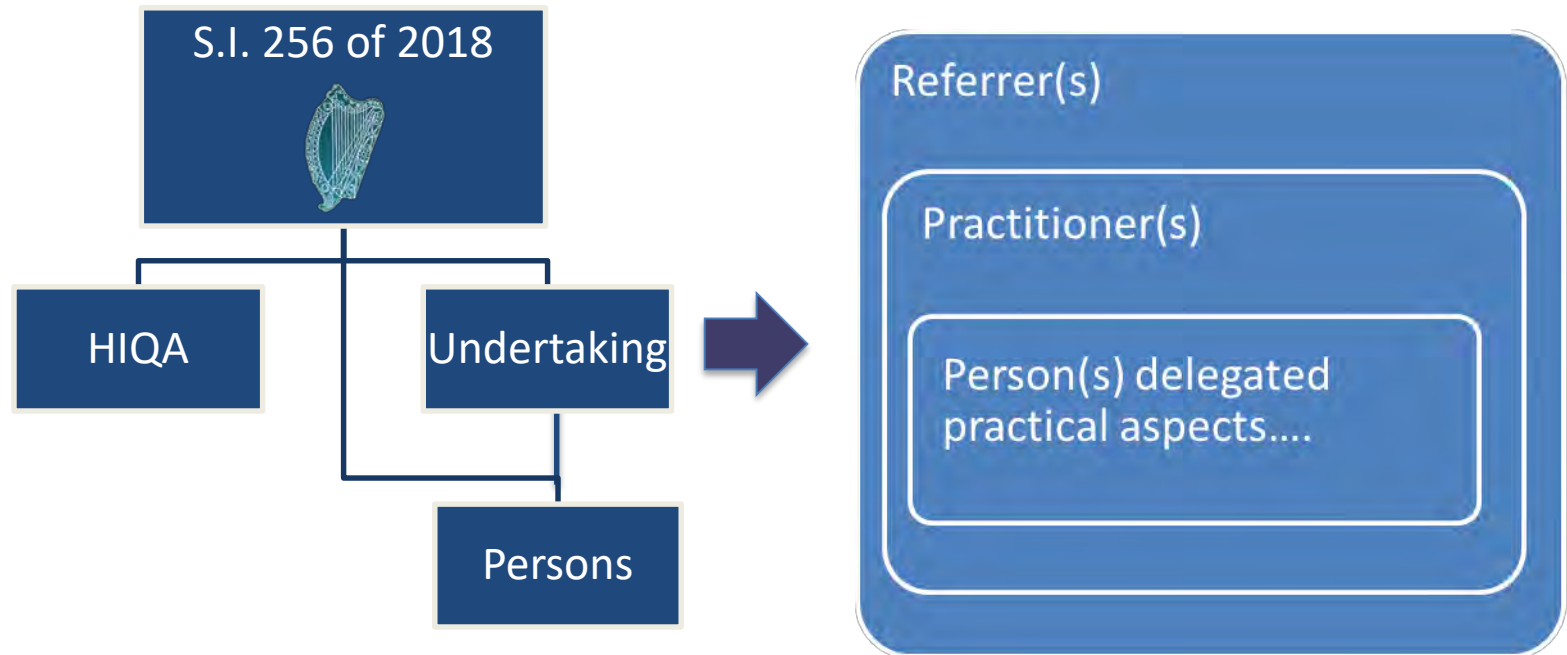
## — Partnership

- A family run dental practice has been in business for 30 years. The dental practice is run as a partnership by a father and daughter. The partnership is the undertaking in this scenario, with each partner being legally responsible for the undertaking.

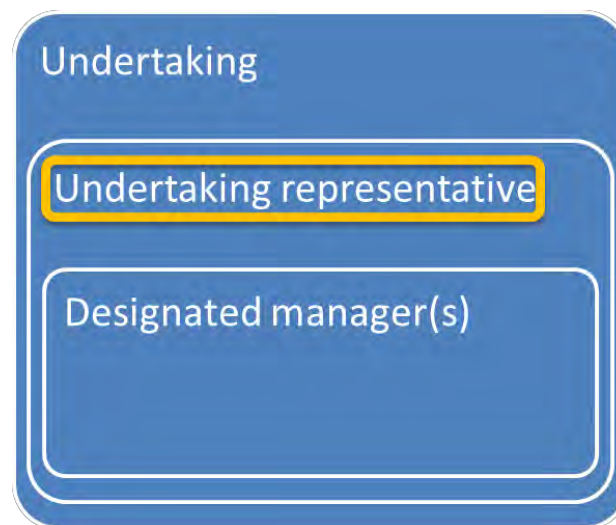
## — Company

- X-Ray Ltd. provides a nationwide diagnostic imaging service to the general public and specialises in computed tomography (CT) imaging. It has eight sites throughout Ireland, and each site has its own manager. The company is the undertaking responsible for the service

# Responsibilities



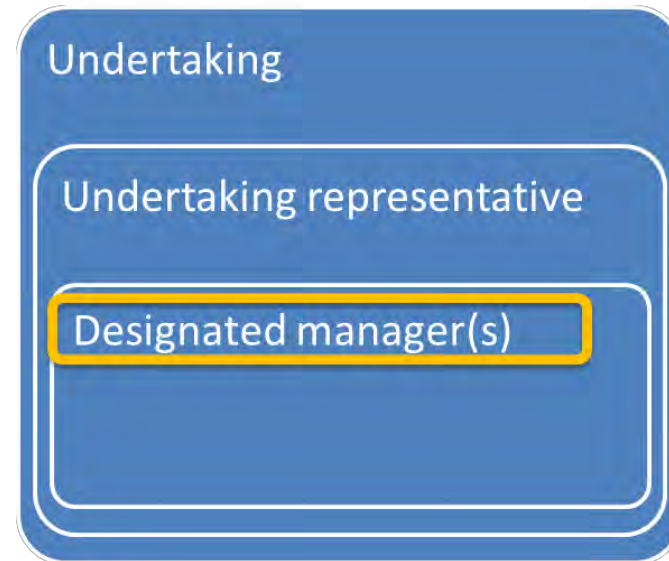
# Undertaking representative



- Must hold a senior position within the undertaking legal entity
- 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



# Designated manager



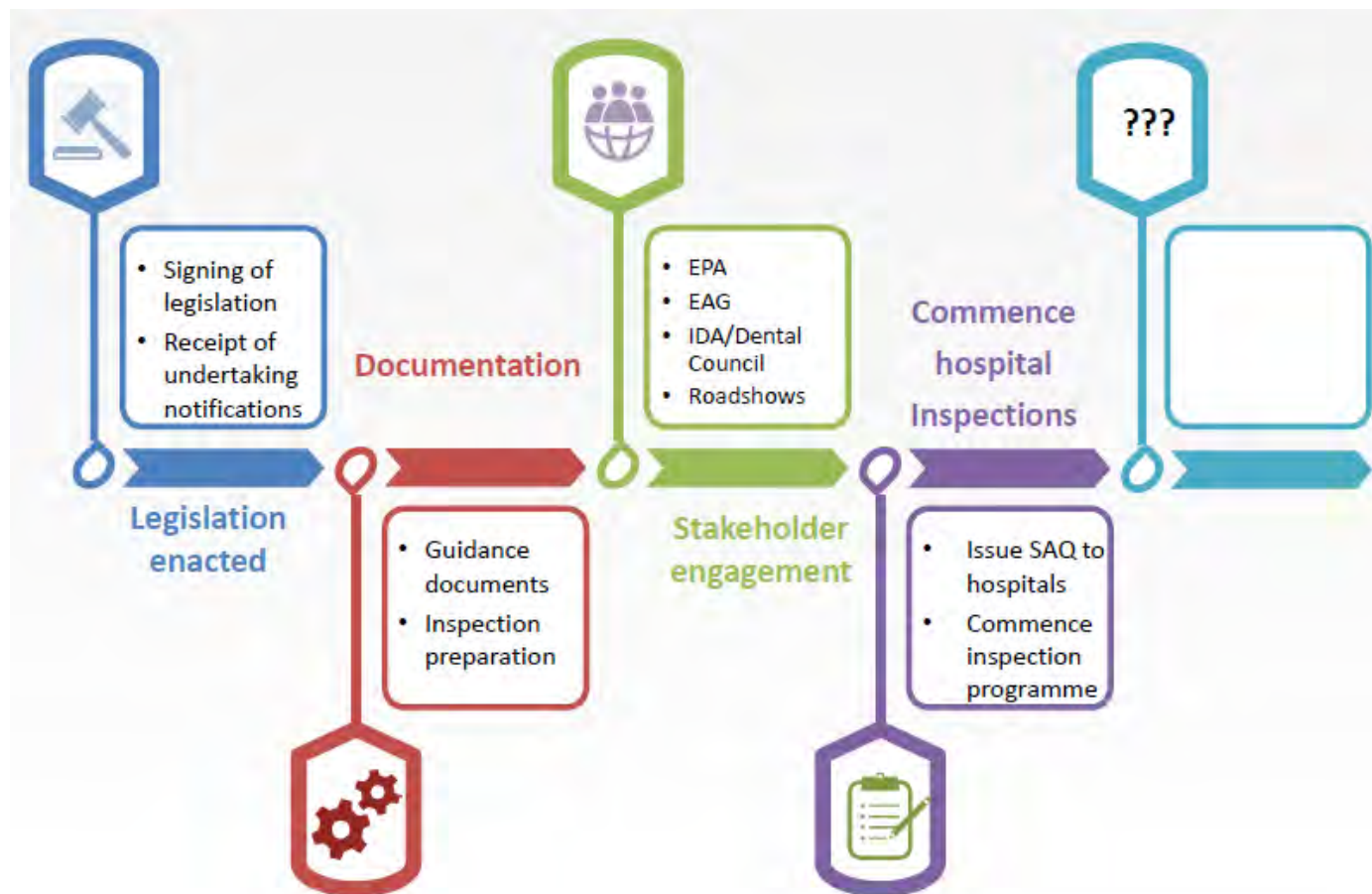
- HIQA requires all undertakings to nominate a designated manager of each medical radiological installation
- This is to facilitate communications between HIQA and the undertaking for operational matters, such as the scheduling of an inspection



# Work to date

- 20 Ionising Radiation (IR) Inspections from January to September 2020
- Publication of:
  - Assessment Judgement Framework - June 2019
  - Guide to the assessment of compliance - June 2019
- Publication of further Guidance Documents in February 2020
  - Diagnostic Reference Levels
  - Dose constraints
  - Criteria for acceptability of equipment
- Publication of first 10 inspection reports in June 2020
- Annual report from accidental or unintended exposures 2019 published in September 2020
- **Guide to the inspection of dental services providing medical exposure to ionising radiation published in September 2020**

# Work to date



# Responsibility of HIQA

## 25. (1) The Authority shall establish—

- (a) a system or systems of inspection to enforce the provisions of these Regulations and to initiate surveillance and corrective action where necessary, and
- (b) an inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with these Regulations.

# Proposed rollout (dental)

- The aim of the on-site inspection is to gather evidence to assess compliance with the regulations
- A **risk-based, graded approach** to regulation across a range of medical radiological services including dental practices starting with those with CBCT
- 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



# Phase One – Organising portal access

- HIQA are planning to rollout access to an online portal system to dental services that will facilitate and streamline information sharing.
- The rollout of access will be carried out in a phased manner during the coming months to coincide with the release of the regulatory self-assessment questionnaire.
- In order to facilitate this transition to our online system, the HIQA Portal Support Team will be contacting designated managers over the coming months to activate your “super-user” access rights to Portal Account for designated manager.

# Phase Two – Self-assessment questionnaire

- Over the coming months, HIQA will begin to issue undertakings with a self-assessment questionnaire (SAQ) to assess regulatory compliance.
- This SAQ is a tool that allows you to self-appraise your level of compliance and helps to identify any possible risks or perceived gaps in your practice.
- As it is a regulatory requirement to provide information to HIQA when requested, we will be setting up your portal system access that will facilitate communications between HIQA and your undertaking.
- A tool for the facility and the regulator
- Format - Yes/No questions

# 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

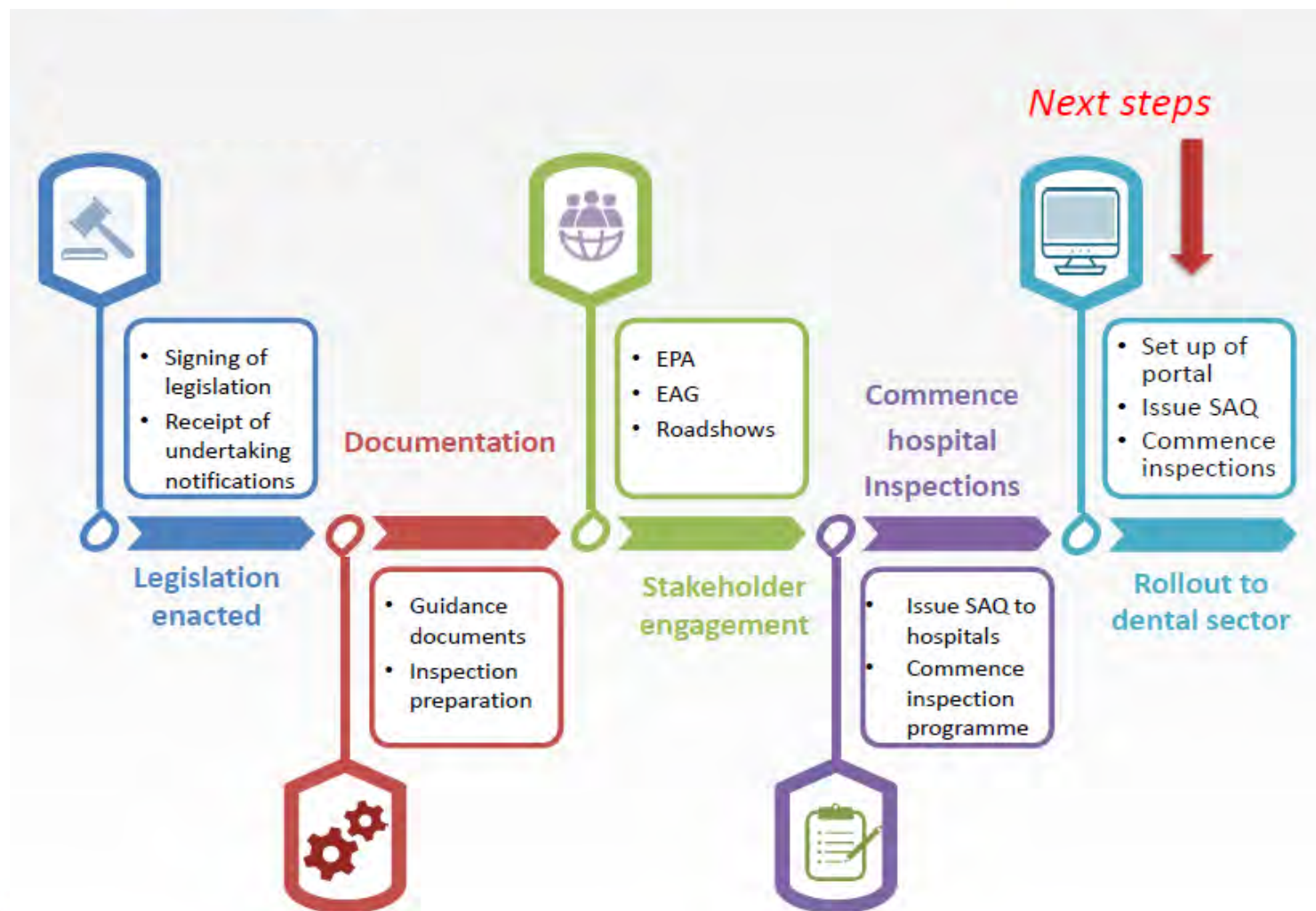
A person guilty of an offence under these Regulations is liable—  
(a) on summary conviction to a fine not exceeding class A or to imprisonment for a term not exceeding one year or both, or  
(b) on conviction on indictment to a fine not exceeding €225,000 or imprisonment for a term not exceeding 3 years or both.

# Final thoughts...

- There is an acknowledgment that dental exposures are generally seen as low risk compared to other imaging types, however with new advancements in technology, for example CBCT, there is a potential for increased radiation exposures to patients.
- Inspections will be more frequent in services with higher radiological risk, for example, hospitals.
- This will be a new process for both HIQA and the dental community
- Inspection reports published thus far demonstrates how we work together to achieve compliance



# Summary





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# Presentation 2: HIQA Portal

September 2020

Noelle Neville  
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

This system is more secure, more efficient and is a safer method of submitting notifications

Primary tool for information sharing between HIQA and undertakings

Allows undertakings review previous notifications that have been submitted to the portal

# Notifications

- Notifications are the most common forms of solicited information HIQA receive from undertakings
- Use the portal to inform HIQA of any changes since you submitted your declaration of undertaking, such as changes to your contact details, or the types of services you provide (undertaking/provider level)
- Submit notifications on significant radiation incidents at your facility (undertaking/facility level)



## Please select a Notification Type

Current Organisation: Mahon Dental Specialist Services (IR, ORG-0013458) (Provider)

Please select Notification Type \*

[NF201A] - Change of Undertaking Details  
[NF201B] - Change of Undertaking Representative Details  
[NF201C] - Change of Medical Radiological Installation Details or Service Type  
[NF201D] - New Medical Radiological Installation  
[NF201E] - Change of Designated Manager  
[NF201F] - Change of Partnership Details  
[NF201G] - Change of Unincorporated Body Details  
[NF202A] - Cessation of Undertaking practice  
[NF202B] - Cessation of medical radiological installation

*This screenshot shows what notifications are available when selecting ORG or provider (undertaking) level in the top right hand corner*

## Please select a Notification Type

Current Organisation: Mahon Dental Specialist (IR, OSV-0005844)

Please select Notification Type \*

[NF211A] - Incident notification Dental/Radiology/Nuclear Medicine  
[NF211B] - Incident notification Radiotherapy  
[NF211C] - Incident notification Other

**Select**

*This screenshot shows the notifications the undertaking and designated manager have access to when selecting the OSV level in the top right hand corner*

# 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

# Access to HIQA Portal for Undertakings

- Once you have been sent a link to activate your account you will have 72 hours to activate it with your password
- Should you not activate your account in this timeframe, the HIQA Team will contact you and arrange a suitable time to call back and assist you with this process
- It is important to note that your account will need to be activated before your self-assessment questionnaire is issued



# Super user portal access

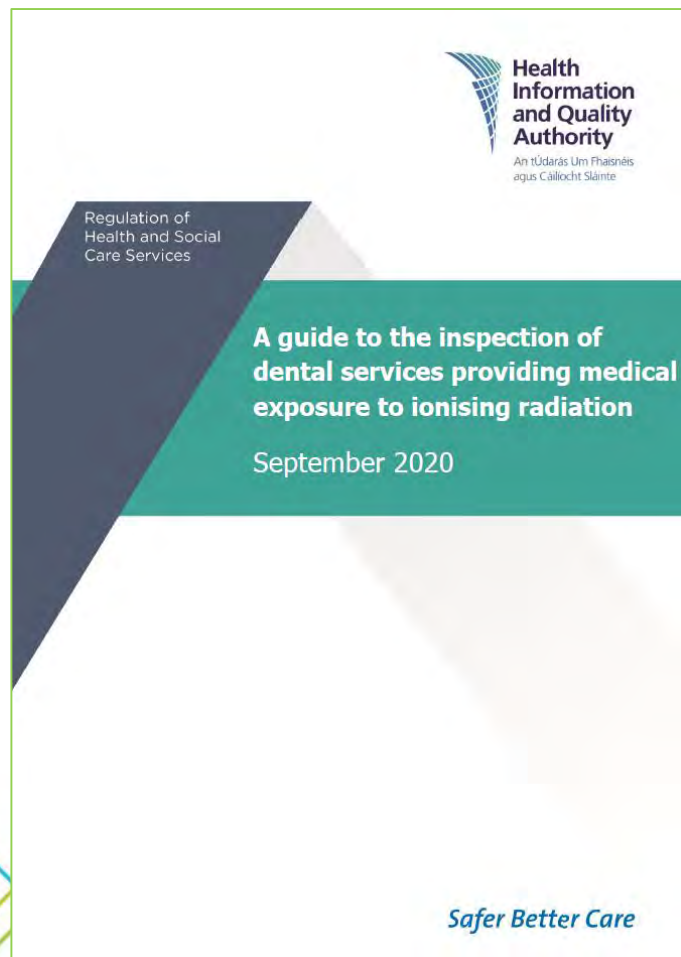
## The **Super-User**:

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

# Self-assessment questionnaire (SAQ) demonstration

**Top tip:** A sample SAQ is included in Appendix A of our guidance document, [\*A guide to the inspection of dental services providing medical exposure to ionising radiation\*](#), published on our website.

*Examples of the types of questions in the self-assessment questionnaire can be found in the appendix of the guide to inspection – see the example below, taken from the guide*



#### Dental self-assessment questionnaire sample

##### Regulation 5: Practitioners

Please tick yes or no	Yes	No
Is clinical responsibility for individual medical exposures only taken by a person who is a member of one or more of the following categories: <ul style="list-style-type: none"><li>dentist registered by the Dental Council in Ireland</li><li>medical practitioner registered by the Medical Council in Ireland or</li><li>radiographer or radiation therapist registered by the Radiographers Registration Board?</li></ul>		

**Self-assessment of compliance — tick the box which best reflects your performance under this regulation.**

Compliant	Not compliant
<input type="checkbox"/>	<input type="checkbox"/>

*This screenshot shows where you will find the SAQ on the portal.*

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Safer Better Care

Justin Timberlake

Home

My Account

Submit Notification

**Draft Notifications**

Notification History

Notifications awaiting Prescribed Docs

Change Password

Manage Sub Accounts

Help

HIQA (c) 2015

Logged In As: Justin Timberlake

Organisation: Mahon Dental Specialist (IR, OSV-0005844) [SIGN OUT](#)

### Draft Notifications

Current Organisation: Mahon Dental Specialist (IR, OSV-0005844)

10

Unique Id	Reference	Code	Submitted By	Date Submitted	Status
	NOT-0193401	SAQ_IR_D	Justin Timberlake	08/09/2020	Draft

Showing 1 to 1 of 1 entries

Previous 1 Next

www.hiqa.ie

*To access the SAQ, just double click on the notification shown above by the red arrow.*



*This screenshot gives examples of the type of question that you will be asked and how it will appear on the portal*

#### Regulation 5: Practitioners

Is clinical responsibility for individual medical exposures only taken by a person who is a member of one or more of the following categories:

- dentist registered by the Dental Council in Ireland
- medical practitioner registered by the Medical Council in Ireland
- radiographer or radiation therapist registered by the Radiographers Registration Board?

With respect to practitioners, please select yes or no: \*

Please select... | ▴ ▾

Self-assessment of compliance — Select which option best reflects your performance under Regulation 5. \*

Please select... | ▴ ▾

#### Regulation 6: Undertaking

Is responsibility for the protection of service users from medical exposure to ionising radiation clearly identified? \*

Please select... | ▴ ▾

Self-assessment of compliance — Select which option best reflects your performance under Regulation 6. \*

Please select... | ▴ ▾

*This slide shows that you will need to select your answers from the drop down lists in each box*

#### Regulation 6: Undertaking

Is responsibility for the protection of service users from medical exposure to ionising radiation clearly identified? \*

Please select...

No

Yes

Which option best reflects your performance under Regulation 6. \*

Please select...

Self-assessment of compliance — Select which option best reflects your performance under Regulation 6. \*

Please select...

1. Compliant
2. Substantially Compliant
3. Not Compliant

**Top tip:** For more information on the compliance descriptors above, please see the *Assessment-judgment framework* and HIQA's *Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation*.

*This screenshot shows that you can select **save draft** at any stage, for example, if you need to check some information or you want to take a break and come back to it at a later stage*

Regulation 22: Education, information and training in field of medical exposure

Do you ensure practitioners have adequate education, information, theoretical and practical training as well as relevant competence in radiation protection? \*

Please select... | ▾

Are the practical aspect of radiological procedures only delegated to individuals with adequate education, information, theoretical and practical training, and competence in radiation protection? \*

Please select... | ▾

Do you ensure that practitioners, and individuals to who the practical aspects of medical radiological procedures are delegated, have carried out continuing education and training after qualification? \*

Please select... | ▾

Self-assessment of compliance — Select which option best reflects your performance under Regulation 22. \*

Please select... | ▾

By submitting this Notification, I declare on behalf of the undertaking that the information I have provided is true to the best of my knowledge and belief.

Save Draft

Submit

[Go to Draft Notifications](#)

Message from webpage

!

Draft saved. Please check your Draft Notifications list.

OK

*This screenshot shows that when you select submit, you may get an error message popping up if one of the mandatory fields has not been completed*

Do you ensure practitioners have adequate education, information, theoretical and practical training as well as relevant competence in radiation protection? \*

Yes

Are the procedures with adequate theoretical and competence

Yes

Do you ensure that practitioners, and individuals to who the practical aspects of medical radiological procedures are delegated, have carried out continuing education and training after qualification? \*

Yes

Self-assessment of compliance — Select which option best reflects your performance under Regulation 22. \*

2. Substantially Compliant

By submitting this Notification, I declare on behalf of the undertaking that the information I have provided is true to the best of my knowledge and belief.

Save Draft Submit



*This screenshot shows that when you scroll back up through the form, you will see the issue highlighted*

(v) the Medical Council

With respect to the delegation of the practical aspects, please select yes or no: \*

No

Self-assessment of compliance — Select which option best reflects your performance under Regulation 10. \*

2. Substantially Compliant

#### Regulation 11: Diagnostic reference levels

Do you establish and review your diagnostic reference levels for the exposures you conduct? \*

Yes

Self-assessment of compliance — Select which option best reflects your performance under Regulation 11. \*

Please select...

This is a required field

#### Regulation 13: Procedures

Do you have written protocols for every type of standard medical radiological procedure; for each type of equipment; for relevant categories of patients? \*

Yes


Do you conduct clinical audits in relation to service users? \*

Yes

Self-assessment of compliance — Select which option best reflects your performance under Regulation 13. \*


2. Substantially Compliant










*This screenshot shows the message you get when you successfully submit the form.*



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 Justin Timberlake

-  Home
-  My Account
-  Submit Notification
-  **Draft Notifications**
-  Notification History
-  Notifications awaiting Prescribed Docs
-  Change Password
-  Manage Sub Accounts
-  Help

Logged In As: Justin Timberlake  
Organisation: Mahon Dental Specialist (IR, OSV-0005844) ▾ [SIGN OUT](#)

Thank you, you have successfully submitted your notification. Please note your reference number NOT-0193401, which will be e-mailed to you also.

[Go to Notification History](#) or [submit another Notification](#)

# Most frequent queries about Portal



I am locked out of my account



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



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



I missed the 72 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](mailto:portalsupport@hiqa.ie)**

# Presentation 3: HIQA's inspection process

September 2020

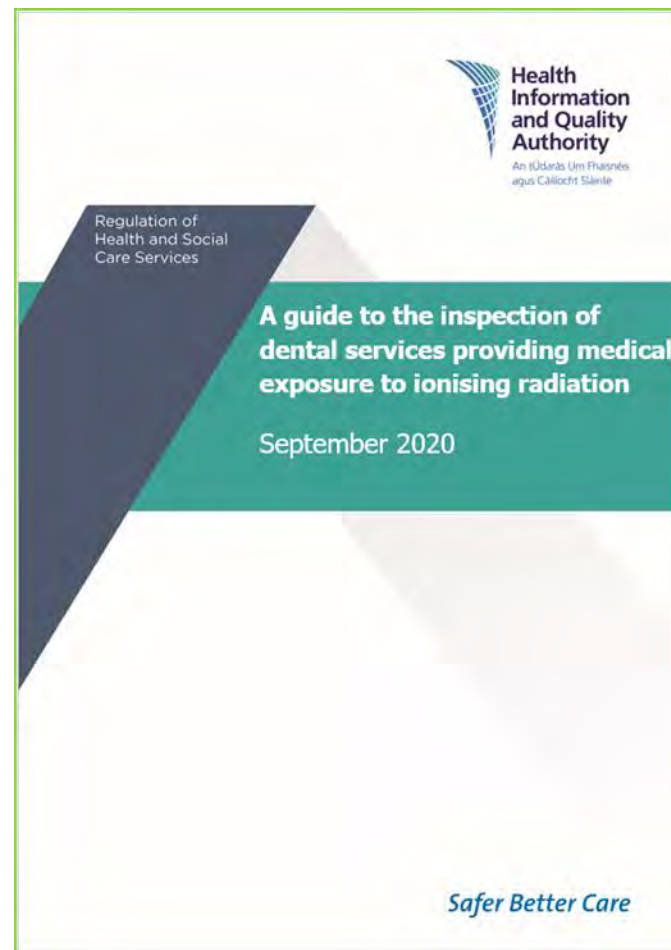
Lee O'Hora  
Inspector  
Ionising Radiation

*Safer Better Care*



# Inspections

HIQA will begin to inspect dental services providing medical exposure to ionising radiation in 4<sup>th</sup> Quarter 2020



# Inspections

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

# Inspections

On-site inspections may be:

- **announced inspections**
- a short notice announced inspection
- unannounced inspection

Duration:

- Dental practices, 3-4 hours
- Large dental hospital, one day



# Announced inspections

- When a standard announced inspection occurs, HIQA will issue the undertaking with a notification of inspection confirming the date of the announced inspection **10 working days** before the inspection.
- All communication from HIQA about the inspection will be communicated to the **designated manager** email address and copied to the Undertaking email address



# Announced inspections

- Communication will outline who HIQA will need to meet and will include a pre-inspection **information request**
- The requested information must be returned to HIQA in soft copy, by email, **within five working days**.
- Before the inspection, an inspector may contact the dental practice to speak with the undertaking or designated manager in preparation for the day of inspection. This will usually happen **one working day before inspection**.
- This is to minimize impact on the service for the morning or afternoon, as relevant, of the inspection day.

# Pre-inspection documentation

- **Radiation safety procedures** or equivalent document(s) which details:
  - the overarching management in this practice and chain of responsibilities for the radiation protection of people who use your service
  - how referrals for radiological exposures are received and justified (approved)
  - how radiological exposures are optimised
  - how events involving or potentially involving accidental and unintended exposures and significant events are managed
  - the policy on quality assurance and quality control of the radiological equipment

**Top tip:** Appendix B of HIQA's [guide to the inspection of dental services](#) provides an example of what documents will be requested pre-inspection.

# Pre-inspection documentation

- **Radiology Equipment records showing:**
  - acceptance testing of each item of radiological equipment installed after 8 January 2019
  - regular performance testing, from 8 January 2019, for all radiological equipment
  - a summary of the annual or periodic quality assurance or performance testing for all radiological equipment
  - a radiology equipment inventory (Format to complete is supplied in pre-inspection information request)



**Top tip:** Appendix B of HIQA's [guide to the inspection of dental services](#) provides an example of the information about your radiology equipment that will be requested.

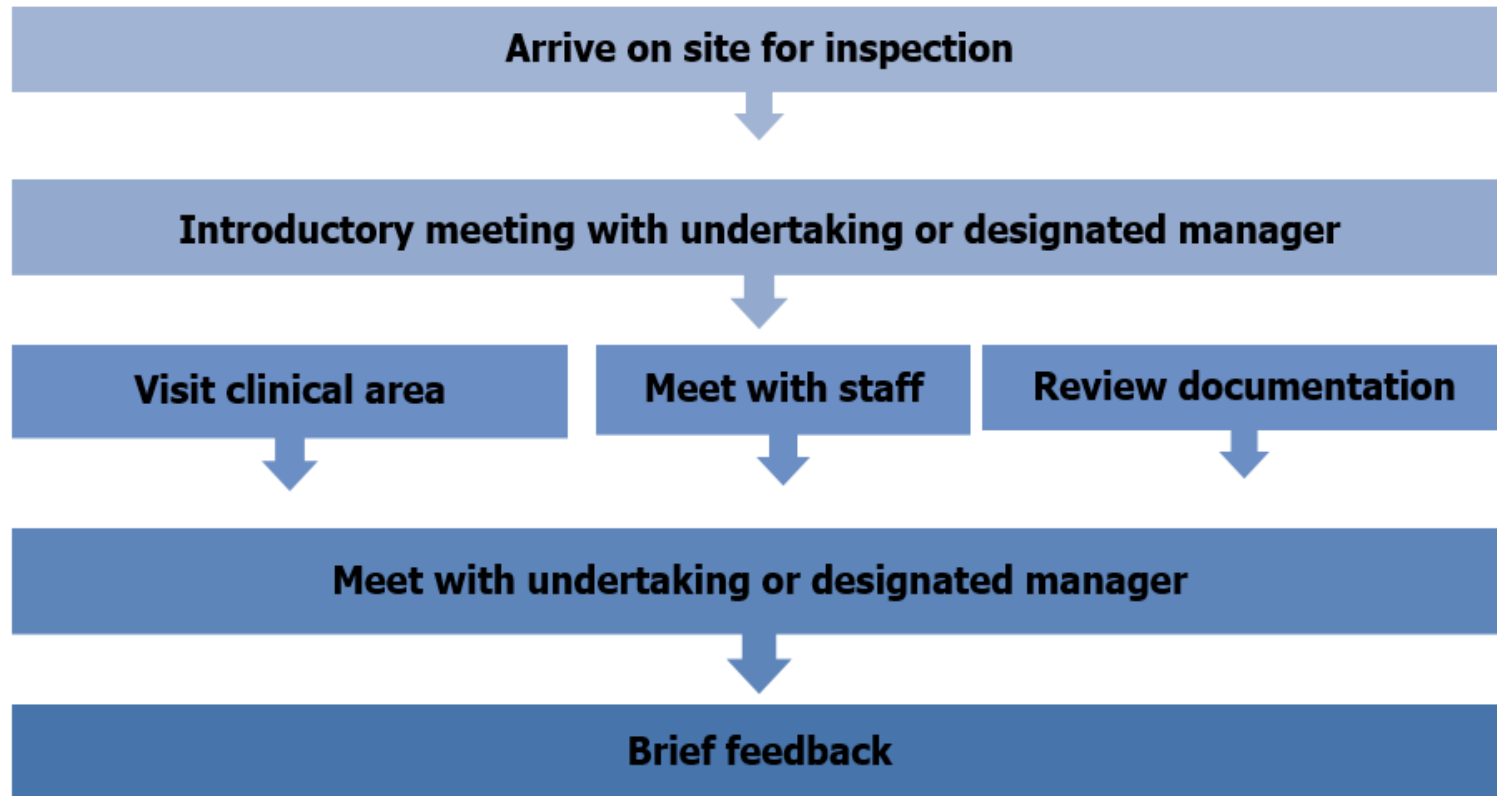
# Pre-inspection documentation

- Confirm if there are other Undertakings operating onsite
- Diagnostic reference levels for typical X-rays performed
- Radiation incidents and near misses
- Clinical audits undertaken
- Protocols for X-ray procedures



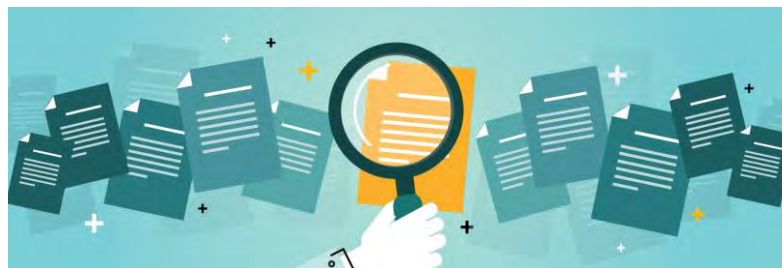


# Sample outline of the on-site inspection activities



# On-site documentation review

- List of the following professionals including associated professional recognition and training documentation for:
  - Practitioners for example, dentists
  - Medical Physics Expert(s) and
  - other individuals who conduct X-rays, for example dental nurses
- Facilitated access to patient records to view referrals for radiological procedures, imaging records and outcomes of the procedures

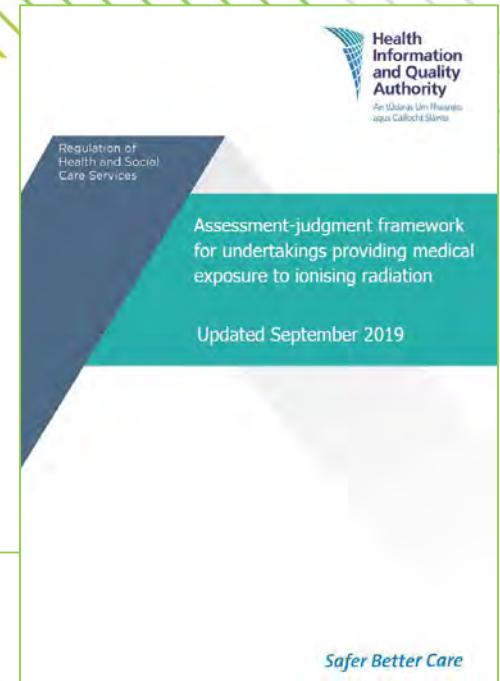


# On inspection



# Judgment

- A judgment about the level of compliance is made for each regulation using the documents shown here
- The *Assessment-judgement framework* sets out lines of enquiry for each regulation and supports inspectors in gathering evidence or making judgments on compliance
- The *Guide to the inspection of dental services providing medical exposure to ionising radiation* has SAQ example and a helpful 'things to consider' section





# Assessment-judgement framework

Regulation 5	Practitioners
Line of enquiry	<ol style="list-style-type: none"><li>1. Is the person who is taking clinical responsibility for an individual medical exposure one of the practitioners listed below:<ol style="list-style-type: none"><li>a. a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985)</li><li>b. a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or</li><li>c. 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)?</li></ol></li></ol>

**Top tip:** Appendix C of HIQA's the [guide to the inspection of dental services](#) gives some practical suggestions you may wish to consider when assessing your dental practice's level of compliance with the regulations.

# Example – Regulation 5, Practitioners



## Observe:

- process for ensuring that appropriate staff are involved in taking clinical responsibility for individual dental exposures
- the practical aspects of dental exposures

## Hear:

- from staff about how they ensure practitioner involvement at the relevant stages of individual dental exposures



## Read:

- referrals for dental exposures to assess if the practitioner is involved at the relevant stages
- Radiation safety procedures defining who is entitled to act as a practitioner and how this is achieved for each stage of clinical responsibility locally

# Compliance descriptors

## Compliant:

- the undertaking or other person is in **full compliance** with the relevant regulation

## Substantially compliant:

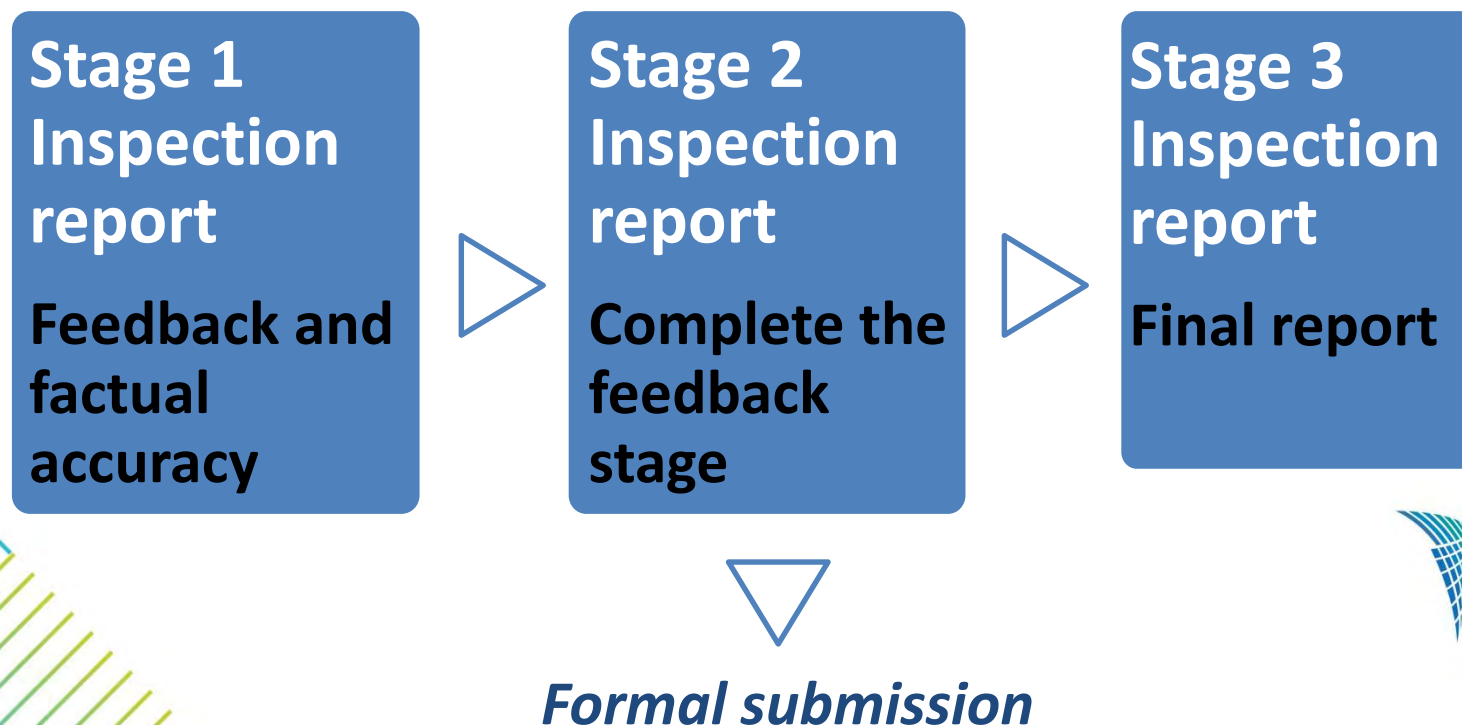
- the undertaking or other person has generally met the requirements of the regulation but **some action is required** to be fully compliant

## Not compliant:

- the undertaking or other person has not complied with a regulation and that **considerable action is required** to come into compliance

# Reporting process

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





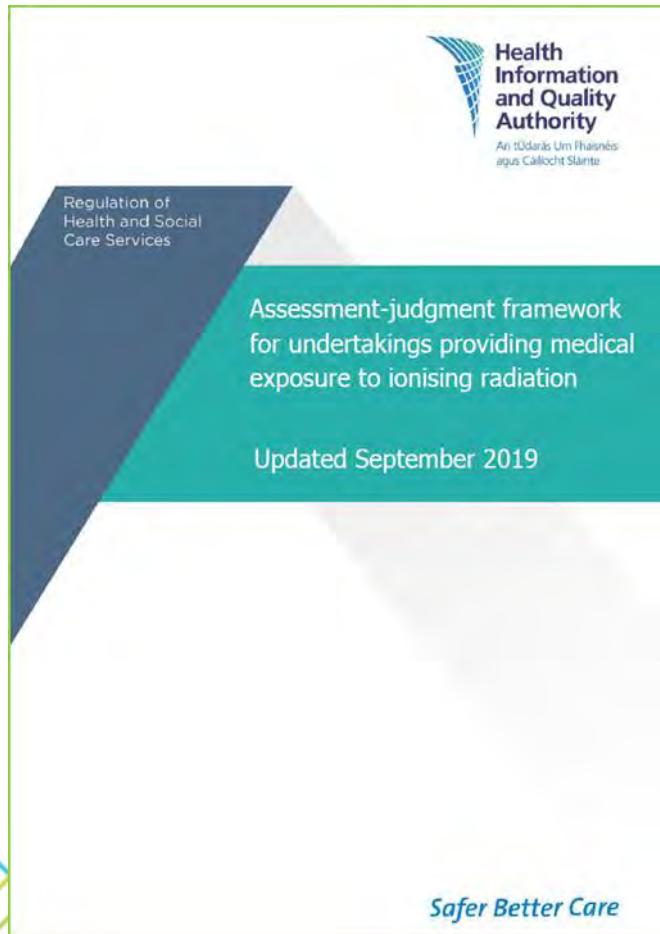
# Non-compliance

- 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 associated risk to service users
  - Undertaking:
    - set out what action(s) they will take to comply with the regulation
    - action(s) must be 'SMART'
      - » Specific
      - » Measurable
      - » Achievable
      - » Relevant
      - » Time bound

# Take home messages

- Inspection of dental practices will commence in the 4<sup>th</sup> quarter of 2020
- Initial inspections will be announced, communication with Designated Manager 10 days in advance of inspection
- Evidence gathered and compliance judgement made for each regulation reviewed on inspection day for each undertaking
- 3 Stage report process addressing non-compliance where relevant

# Next steps- What can you do to prepare?



<b>Line of enquiry</b>	<ol style="list-style-type: none"><li>1. Is the person who is taking clinical responsibility for an individual medical exposure one of the practitioners listed below:<ol style="list-style-type: none"><li>a. a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985)</li><li>b. a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or</li><li>c. 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)?</li></ol></li></ol>
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For the lines of enquiry, please see the [Assessment-judgment framework for undertakings providing medical exposure to ionising radiation](#)

# Next steps- What can you do to prepare?

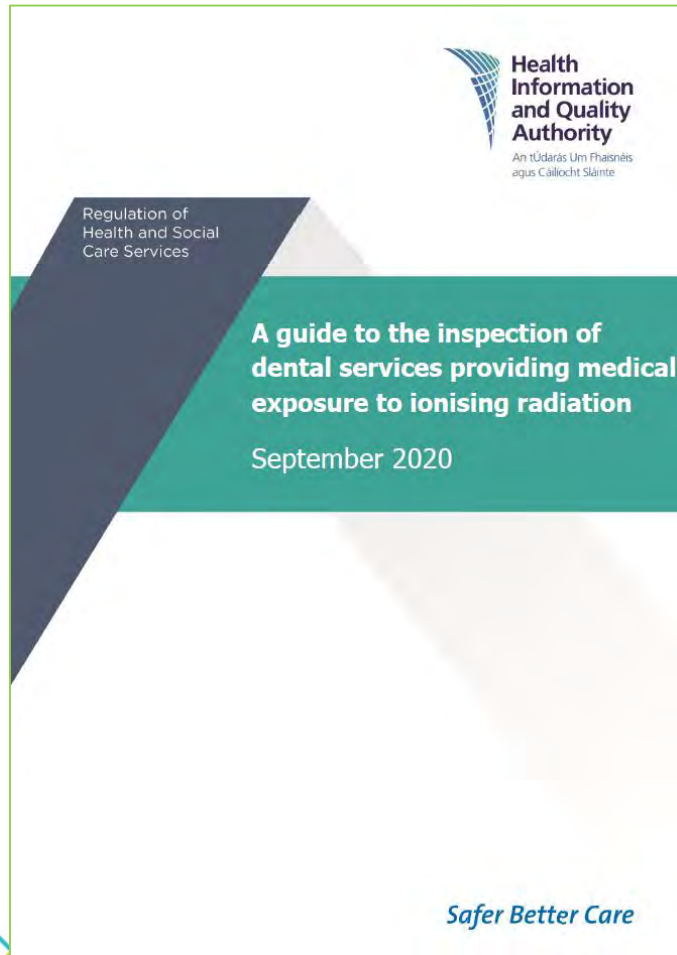


Regulation 5: Practitioners	
This regulation means that:	Examples of things to consider for this regulation
<ul style="list-style-type: none"><li>▪ Only a person as defined in Regulation 5, takes clinical responsibility for individual medical exposures.</li><li>▪ The practitioner acts in accordance with the scope of practice of their relevant professional bodies.</li></ul>	<ul style="list-style-type: none"><li>▪ Do you have documentation outlining the professionals and or professions who are considered practitioners in this practice?</li></ul>

For more examples of things to consider, check out Appendix C:  
[\*A guide to the inspection of dental services providing medical exposure to ionising radiation\*](#)



# Next steps- What can you do to prepare?



## Dental self-assessment questionnaire sample

Regulation 5: Practitioners		
<i>Please tick yes or no</i>	Yes	No
Is clinical responsibility for individual medical exposures only taken by a person who is a member of one or more of the following categories: <ul style="list-style-type: none"><li>▪ dentist registered by the Dental Council in Ireland</li><li>▪ medical practitioner registered by the Medical Council in Ireland or</li><li>▪ radiographer or radiation therapist registered by the Radiographers Registration Board?</li></ul>		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Not compliant
<input type="checkbox"/>	<input type="checkbox"/>

For an example of the SAQ please see Appendix A:  
[\*A guide to the inspection of dental services providing medical exposure to ionising radiation\*](#)



# Frequently Asked Questions

September 2020

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# List of available guidance

Question	Answer
What guidance documents are available to help dentists prepare for inspection?	<ul style="list-style-type: none"><li>• <a href="#"><u>Assessment-judgment framework for undertakings providing medical exposure to ionising radiation</u></a></li><li>• <a href="#"><u>A guide to the inspection of dental services providing medical exposure to ionising radiation</u></a></li><li>• <a href="#"><u>Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation</u></a></li><li>• <a href="#"><u>Guidance on Dose Constraints for Carers and Comforters and Individuals Participating in Medical and Biomedical Research Involving Medical Exposures to Ionising Radiation</u></a></li><li>• <a href="#"><u>Diagnostic Reference Levels Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation</u></a></li><li>• <a href="#"><u>Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy</u></a></li><li>• <a href="#"><u>Undertaking information handbook</u></a></li></ul>

# Undertaking related queries

Question	Answer
<b>I think I might be an undertaking but I'm not sure?</b>	<p>If you believe you may be an undertaking and have not previously declared to HIQA you should contact us at <a href="mailto:radiationprotection@hiqua.ie">radiationprotection@hiqua.ie</a> as soon as possible to discuss your individual circumstances.</p>
<b>Is a self-employed associate dentist an undertaking?</b>	<p>Whether an associate is an undertaking is dependent on their individual arrangement with the practice owner(s). It will depend on whether they are employed, or engaged by the owner(s), or are a separate legal entity operating at the same premises, and using the practice owners' equipment.</p> <p>If the associate decides he or she is not an undertaking and conducts medical exposures, then the practice owners as the undertaking, must satisfy themselves that, irrespective of the manner of engagement or employment with those that carry out medical radiological procedures, the practice owner(s) as the undertaking, must have oversight to ensure that those carrying out medical radiological procedures comply with the Regulations and in so doing, they, the practice owner(s), accept responsibility for the compliance of the associate with the Regulations.</p> <p>Please refer to the <a href="#">Undertaking Information Handbook</a> published on <a href="http://www.hiqua.ie">www.hiqua.ie</a> or email <a href="mailto:radiationprotection@hiqua.ie">radiationprotection@hiqua.ie</a> for additional information relative to your individual circumstances.</p>

# Designated manager related queries

Question	Answer
<b>What is the difference between the undertaking representative and the designated manager?</b>	<p>An <b>undertaking representative</b> is part of the legal entity that is the undertaking, for example, a partner in a partnership, a director of a company or the sole trader themselves.</p> <p>The <b>designated manager</b> can be this same person as the undertaking representative, and in many smaller dental practices, this may be the most appropriate person. However, in larger practices, a designated manager may be the person responsible for managing the day-to-day operational aspects of the practice.</p> <p>The designated manager is the link between the undertaking, in terms of governance and oversight arrangements, and HIQA for operational matters, such as organising an inspection or returning the self-assessment questionnaire.</p> <p>We provide more information about these two roles in the <a href="#"><u>Undertaking information handbook</u></a> which is published on our website.</p>

# Medical physics expert (MPE)

Question	Answer
<b>Where can undertakings get a list of MPEs?</b>	HIQA does not have a remit regarding the registration of Medical Physics Experts (MPEs). The Irish College of Physicists in Medicine is the current body responsible for this.
<b>Does every undertaking require access to a MPE?</b>	<p>Yes. These new regulations require each undertaking to have a MPE appropriately involved commensurate with the level of radiological risk. For standard dental radiological procedures this means having access to a MPE for consultation and advice, as appropriate.</p> <p>To comply with the regulations this person should be recognised as a MPE in Ireland by The Irish College of Physicists in Medicine.</p>



# The inspection

Question	Answer
<b>How much notice will I get before an inspection?</b>	The timeframe for an <b>announced</b> inspection is <b>10 working days</b> , but more information on this is provided in the third presentation in this slide deck.
<b>Is there flexibility regarding times and days for inspections?</b>	We will be reasonable in our approach in the scheduling of an inspection. Following announcement of an inspection, we will liaise with the practice regarding times and dates as much as is possible within the constraints of our inspection schedule.
<b>How much will my practice be impacted by the inspection?</b>	<p>HIQA has a regulatory requirement to carry out inspections to assess the compliance of undertakings against the regulations. We will minimise the time spent onsite and cognisant of reducing our impact on the practice we will request and review much of the required documents in advance of the inspection.</p> <p>While inspectors will aim to be onsite for less than 4 hours in most situations, inspectors will need to speak to specific and key individuals during the inspection, such as the dentist. Inspectors will also need to review records and see where dental exposures take place.</p> <p>For more detailed information about what the inspection will look like please see our guidance document; <a href="#"><u>A guide to the inspection of dental services providing medical exposure to ionising radiation</u></a>.</p>

# Self-assessment questionnaire (SAQ) and Portal

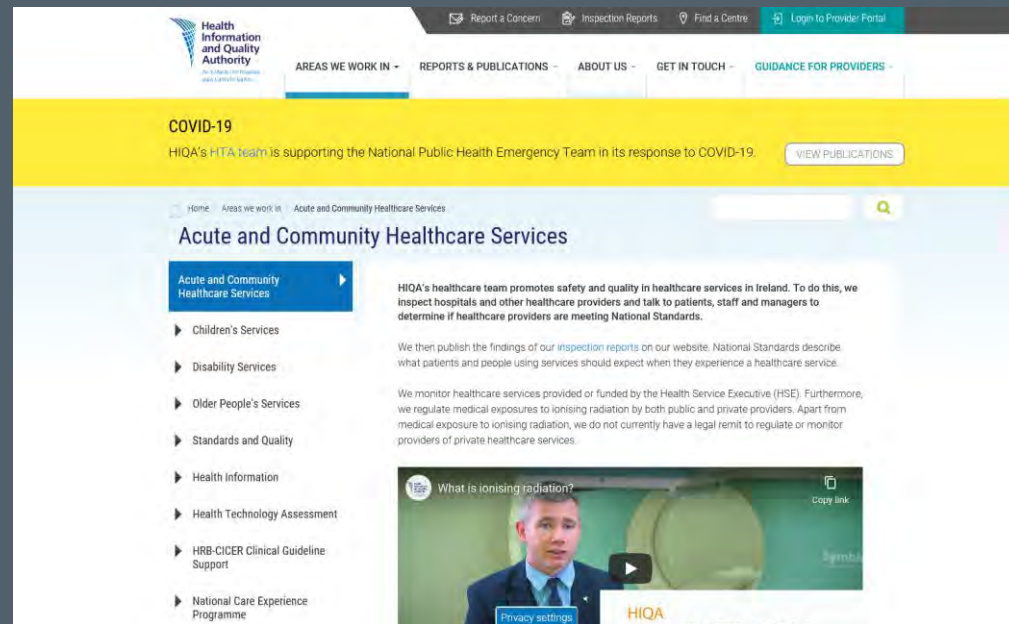
Question	Answer
<b>Will a SAQ be issued before every inspection?</b>	The SAQ will be rolled out in phases. You will be contacted initially to set up portal access for the designated manger. The SAQ will not be issued before each inspection, but periodically in a phased way.
<b>Once the SAQ has been issued how long do we have to complete it?</b>	<p>A period of 4 weeks will be allowed for the SAQ to be completed. A sample SAQ is included in Appendix A of our guidance document, <a href="#">A guide to the inspection of dental services providing medical exposure to ionising radiation</a>, published on our website.</p> <p>If you have any queries in relation to completing the SAQ you can contact us at <a href="mailto:radiationprotection@hiqa.ie">radiationprotection@hiqa.ie</a>.</p>
<b>Does each undertaking need to fill in SAQ even if they are working at the same practice?</b>	Yes. An SAQ will be issued for <u>every</u> undertaking for <u>each</u> dental practice that they work in.

# Diagnostic reference levels (DRLs)

Question	Answer
<b>What are DRLs?</b>	DRLs are dose levels set to aid optimisation of dental exposures. They provide a standard for comparison to help ensure the radiation protection of patients undergoing dental radiological procedures.
<b>What do I have to do?</b>	Undertakings must ensure that local facility DRLs are established, regularly reviewed and used, taking corrective action where necessary.
<b>What do I have to do once local DRLs are established?</b>	<p>The first step in using local facility DRLs is comparison with the national DRL value. If this does not exist for a particular procedure or clinical task, similar internationally established DRL values or peer reviewed literature can be consulted.</p> <p>HIQA has published national DRLs for intra oral, panoramic, and cone beam computed tomography dental procedures.</p>
<b>What if my DRLs exceed, or are substantially lower, than national DRLs?</b>	Where local facility DRLs are deemed too high or low when compared to national DRLs, an immediate investigation into the cause is required. Records of investigations and any corrective actions must be available for review by HIQA.
<b>What guidance is available about DRLs?</b>	Information on DRLs is available in guidance published on <a href="http://www.hiqa.ie">www.hiqa.ie</a> ; <a href="#"><i>Diagnostic Reference Levels Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation</i></a>

# Further Questions?

- For further information and all our guidance documents please visit:
  - [www.hiqa.ie](http://www.hiqa.ie)
  - Areas We Work
  - Acute and Community Healthcare Services
  - Ionising Radiation (Medical Exposures)



For queries relating to HIQA's portal please email [portalsupport@hiqa.ie](mailto:portalsupport@hiqa.ie)

For all other queries please email [radiationprotection@hiqa.ie](mailto:radiationprotection@hiqa.ie)