EPA Webinar Series:
The Application of the Ionising Radiation Regulations (IRR19) in Veterinary Medicine

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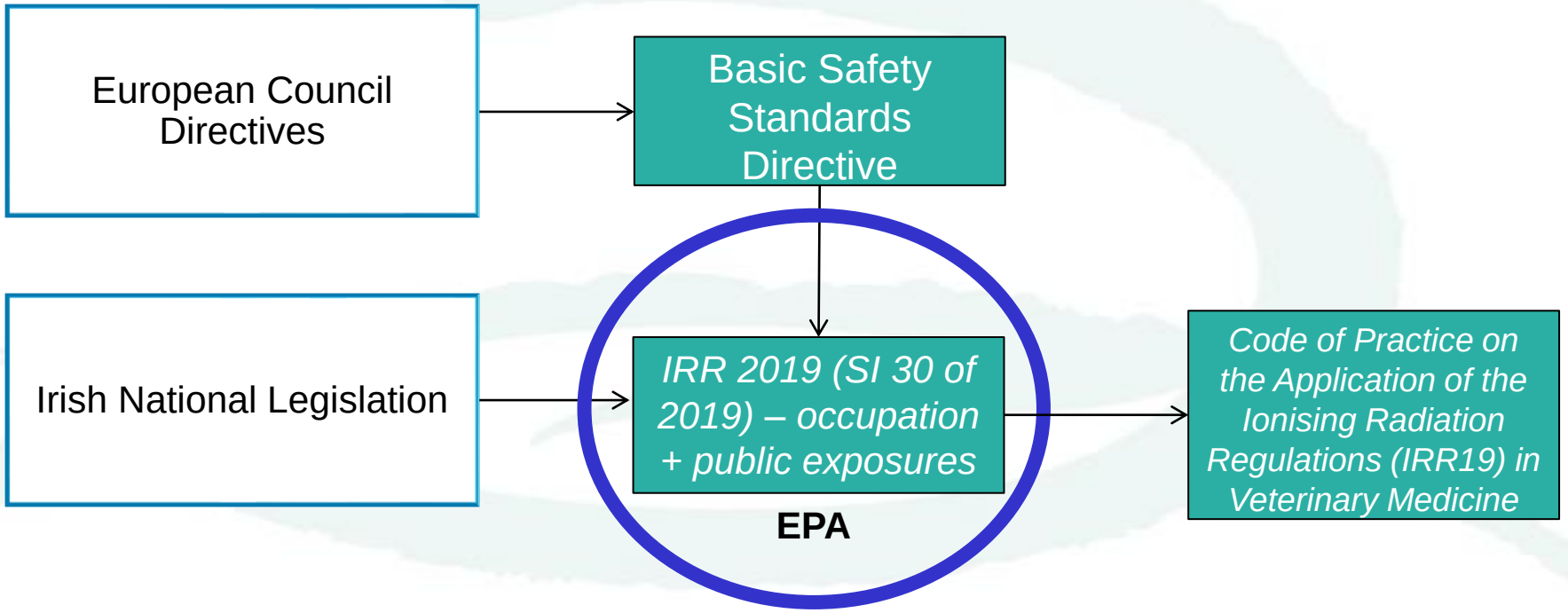
19/07/2023

Overview

- Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019
- Registration vs Licence
- Roles & Responsibilities
  - Undertaking
  - Radiation Protection Adviser
  - Radiation Protection Officer
- The Risk Assessment
- Radiation Safety Procedures
- Radiation Protection Training
- Maintenance of Equipment
- Reporting Incidents

Ionising Radiation Regulations (IRR19)



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EPA Radiation Protection Regulation Unit

Risk-based regulatory approach

Vet Code of Practice

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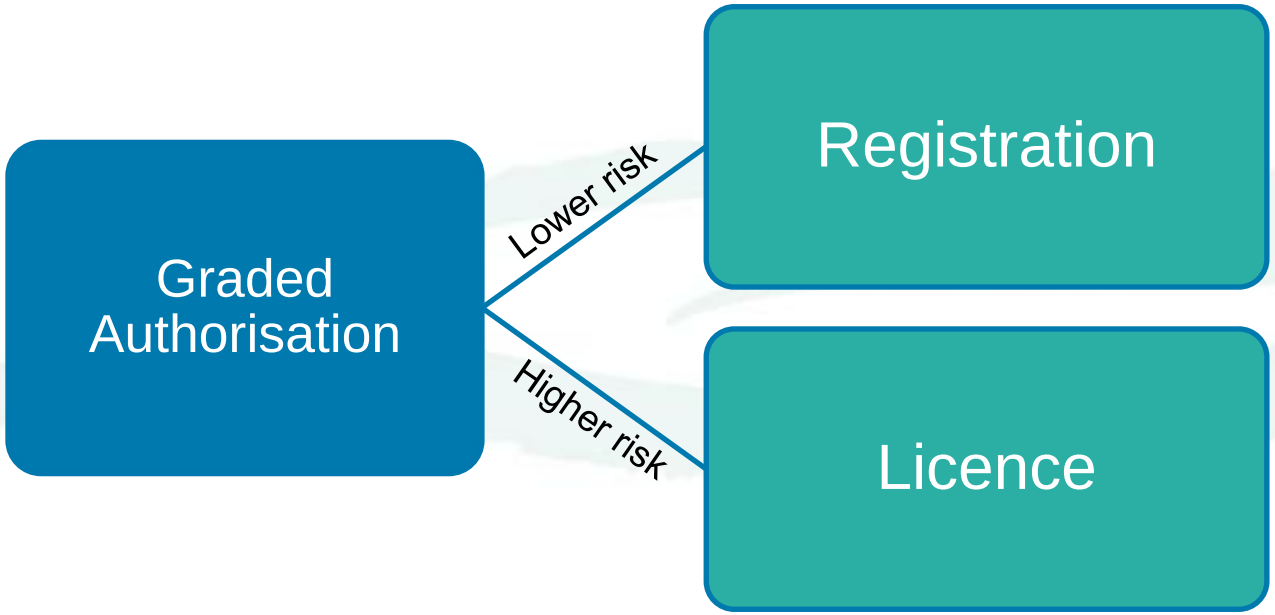
Authorisation

- Authorisation = consent to carry out a radiological practice.

- IRR19 provides for **Graded Authorisation** (two forms of authorisation commensurate with risk: registration and licensing).



Apply for an Authorisation

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Practices subject to Registration versus Licence

Registered practices

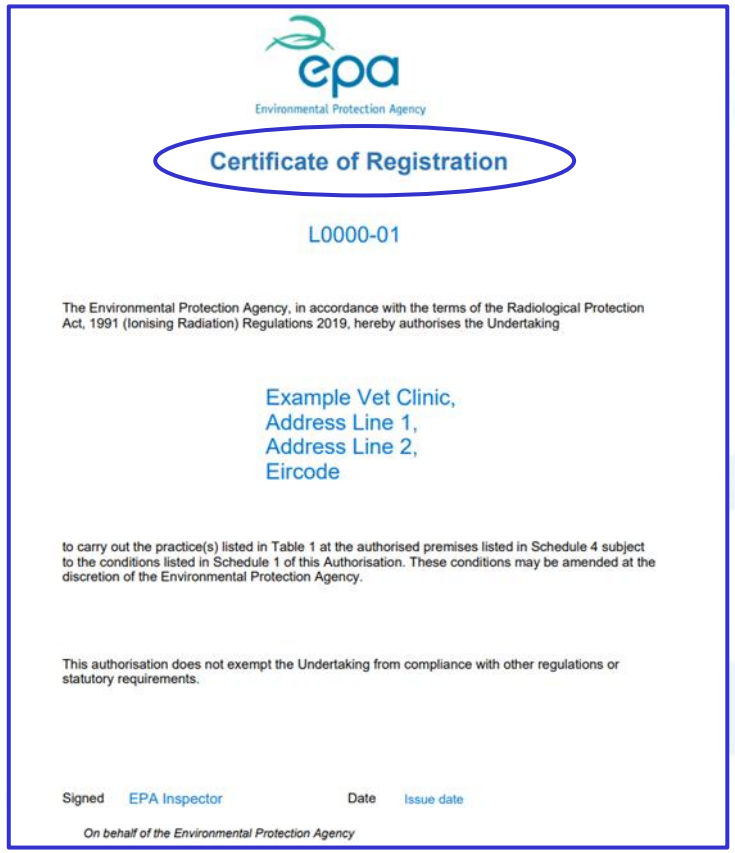
General veterinary radiography carried out in a risk-assessed veterinary clinic.

List of practices

Licensed practices

- General veterinary radiography performed in the field.
- Veterinary nuclear medicine.
- Veterinary fluoroscopy.
- Veterinary radiography using CT.
- Veterinary dental radiography using a handheld intra-oral unit in a risk assessed veterinary clinic.

Registration / Licence



Environmental Protection Agency

Certificate of Registration

L0000-01

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2019, hereby authorises the Undertaking

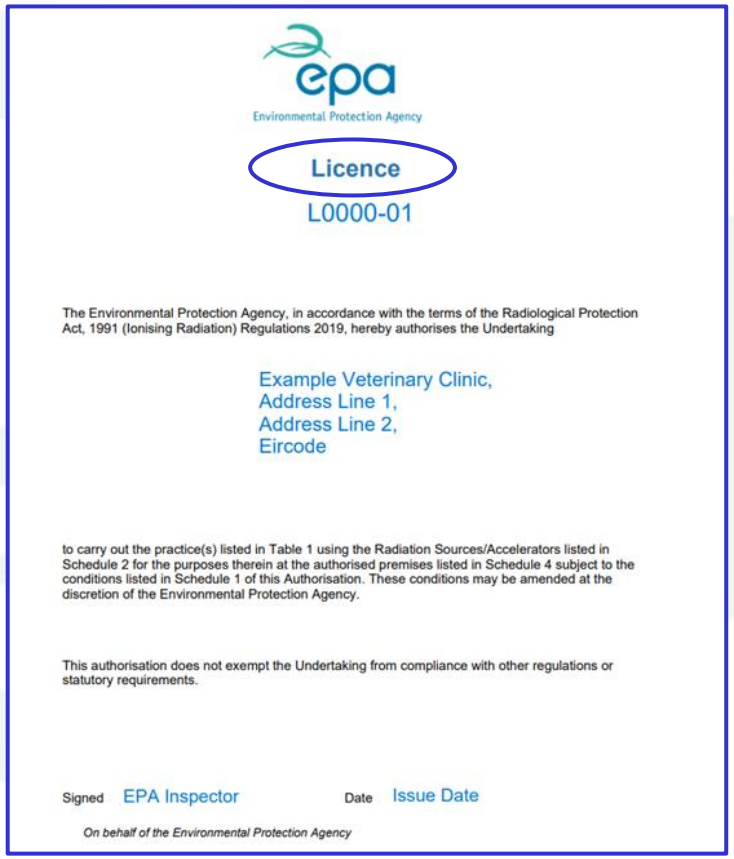
Example Vet Clinic,
Address Line 1,
Address Line 2,
Eircode

to carry out the practice(s) listed in Table 1 at the authorised premises listed in Schedule 4 subject to the conditions listed in Schedule 1 of this Authorisation. These conditions may be amended at the discretion of the Environmental Protection Agency.

This authorisation does not exempt the Undertaking from compliance with other regulations or statutory requirements.

Signed EPA Inspector Date Issue date

On behalf of the Environmental Protection Agency



Environmental Protection Agency

Licence

L0000-01

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2019, hereby authorises the Undertaking

Example Veterinary Clinic,
Address Line 1,
Address Line 2,
Eircode

to carry out the practice(s) listed in Table 1 using the Radiation Sources/Accelerators listed in Schedule 2 for the purposes therein at the authorised premises listed in Schedule 4 subject to the conditions listed in Schedule 1 of this Authorisation. These conditions may be amended at the discretion of the Environmental Protection Agency.

This authorisation does not exempt the Undertaking from compliance with other regulations or statutory requirements.

Signed EPA Inspector Date Issue Date

On behalf of the Environmental Protection Agency

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Registration / Licence

	Registration	Licence
Table 1 List of your authorised practices	✓	✓
Schedule 1 List of Authorisation Conditions you must adhere to	✓	✓
Schedule 2 Inventory list of authorised items	✗	✓
Schedule 3 Radiation Protection Officer and Radiation Protection Adviser	✗	✓
Schedule 4 List of premises authorised for the use of X-rays	✓	✓

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Registration / Licence - Table 1

Table 1

Practice	Grade	Authorised From	Authorised To
General veterinary radiography carried out in a risk assessed veterinary clinic	Registered	Indefinite	
General veterinary radiography performed in the field	Licensed	10 Years	

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Registration / Licence - Schedule 1

Environmental Protection Agency **Schedule 1**

Conditions

A. GENERAL

1. The Licensee or Registered Person shall note that compliance with this Authorisation and its Conditions does not exempt the Licensee or Registered Person from compliance with Statutory Instrument No. 30 of 2019 and the Radiological Protection (Amendment) Act, 2002.

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Licence - Schedule 2

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Licence Only **Schedule 2**

Inventory of X-ray Equipment

Authorisation No: **Expiry Date:** **Authorised:**

Premises:

Location	**Manufacturer**	**Model**	**Purpose**
			Veterinary Radiography
Practice	**Type**	**Licensing Restriction**	
General veterinary radiography performed in the field	Mobile		
Activities			
Use			

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Licence - Schedule 3

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Licence Only

Schedule 3

Radiation Protection Officers / Radiation Protection Advisers

Authorisation No: **Expiry Date:** **Authorised:**

Name	Title	Department / Location / Address
	Radiation Protection Officer	

Name	Title	Department / Location / Address
	Radiation Protection Advisor	

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Registration - the Self-Declaration Form

Please complete all sections below

I confirm that, prior to the commencement of any registered practice, I have, in accordance with the provisions of Ionising Radiation Regulations 2019 (IRR19):

Completed a risk assessment to assess the nature and magnitude of the risks of exposure to ionising radiation arising from the practice or from potential exposures resulting from the practice for workers and members of the public who may be affected, and to identify the protective measures needed to restrict exposures to ionising radiation (regulation 31 and associated EPA guidance).	☐
Have implemented the protective measures identified in the radiation risk assessment that will restrict my employees' and other persons' exposure to ionising radiation (regulation 32 and associated EPA guidance)	☐
Will consult with a suitable Radiation Protection Adviser (RPA) as appropriate (regulation 33 and associated EPA guidance)	☐
Have designated a Radiation Protection Officer (RPO) to supervise or perform radiation protection tasks (regulations 34 and 80 and associated EPA guidance)	☐
Will provide appropriate training, information and instruction to any of my employees engaged in work with ionising radiation, and those likely to be affected by that work, and such training will be repeated at appropriate intervals (regulation 35 and associated EPA guidance)	☐
Have, where required, correctly classified and demarcated any controlled and/or supervised areas (regulations 36 and 37 and associated EPA guidance)	☐
Have drawn up procedures to be followed in the event of a reasonably foreseeable incident liable to have radiation safety implications as identified in the risk assessment (regulation 32 and associated EPA guidance)	☐

I declare that to the best of my knowledge the particulars given in this application for Registration are true, and that I am duly authorised to submit this application for Registration on behalf of the Undertaking.

Signature: _____ Print Name: _____

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Registration / Licence - Schedule 4

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Authorised premises

Authorisation No: **Expiry Date:** **Authorised:**

Name	Address
Veterinary Clinic	Address 1
Name	**Address**
Equine Clinic	Address 2

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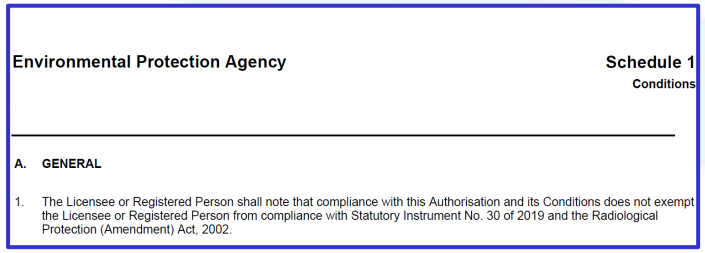
Registration / Licence

	Registration	Licensing
Radiological practices	X-ray examination of small animals in a defined X-ray area	▶ Off-site/large animal X-ray examinations ▶ Computerised tomography (CT) ▶ Fluoroscopy ▶ Nuclear medicine (diagnosis or treatment) ▶ Use of handheld intra-oral X-ray unit
Duration of authorisation	Indefinite (unless surrendered or revoked)	10 years (renewable)
Schedule of equipment	An up-to-date schedule of equipment should be retained on file by the undertaking	An up-to-date schedule of equipment should be retained on EDEN
RPO/RPA	Up-to-date evidence should be retained on file by the undertaking.	An up-to-date record should be retained on EDEN.

Regulatory Requirements & Guidance

- Authorisation Conditions
- Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019
- Code of Practice on the Application of the Ionising Radiation Regulations (IRR19) in Veterinary Medicine



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Schedule 1
Conditions

A. GENERAL

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Ionising Radiation Regulations 2019

The Vet Code of Practice

- IRR19 Guidance all radiological practices & sectors

Guidance for Undertakings on the application of the Ionising Radiation Regulations (IRR19)

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Roles & Responsibilities – the Undertaking

- Who is the undertaking?

The undertaking e.g., Veterinary practitioners/practice owner has **primary legal responsibility** for compliance with the Regulations (IRR19) and the conditions of their Authorisation.

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Keep a record

Roles & Responsibilities – the Undertaking

Responsible for:

- Ensuring that **risks** to staff and members of the public from their activities are **adequately assessed.**
- Implementing arrangements for the **radiation protection** of all staff and members of the public.
- Designating an **RPO** and providing them with appropriate resources and training.
- Seeking advice from an **RPA** to ensure compliance with IRR19 and providing the RPA with access, adequate information and facilities.
- Ensuring that X-ray **equipment** is **operated** only by **appropriately trained staff** under the responsibility of a veterinary practitioner.
- Ensuring that X-ray **equipment** is **appropriately installed**, **tested** and **subject to QA** .
- Ensuring **records and documentation** are **maintained** and **accessible**.

The Undertaking - Maintenance of Records

Parameter	Recommended retention period
Risk assessments	2 years after a risk assessment has been superseded
Local radiation safety procedures	2 years after procedures have been superseded
Details of X-ray equipment including date of acquisition, make/model, serial number and/or other unique identifiers.	2 years after disposal of the equipment
Installation report and user manuals	
Servicing reports	5 years
Quality assurance/quality control reports	
Staff training records	
Incident/accident procedures and reports	
Monthly visual checks as applicable	
Disposal of X-ray equipment	
Dosimetry reports where relevant	Indefinitely

Roles & Responsibilities – Radiation Protection Adviser (RPA)

- Who is the RPA?

The RPA is a qualified expert (external consultant) approved by the EPA to give radiation protection advice pursuant to IRR19

Named on Schedule 3 of **Licence** (EDEN)
Covered under the Self-Declaration form for **Registrants**

Contact details for approved RPAs

Philip Loan*
John Upton**
Daniel Cannon
Brendan Tuohy
Eoin O'Scannail
Ruairi O'Donnell

*has a narrow availability
** service available for the southern part of the country

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Roles & Responsibilities – Radiation Protection Adviser (RPA)

- Veterinary practitioners should consult an RPA:

At Design/ Planning Stage

- Acquisition of new equipment
- Prepare/Update Risk Assessments
- Prepare/Update local Radiation Safety Procedures
- Design and shielding of new buildings/facilities
- Acceptance testing of new equipment
- Development of Quality Assurance programme

As required

- Dose monitoring
- Review and update of Risk Assessment
- Quality Assurance testing
- Radiation Protection and RPO training
- Incident investigations/reports
- Changes to equipment/facilities

Roles & Responsibilities – Radiation Protection Officer (RPO)

- Who is the RPO?

The RPO is e.g. a veterinary practitioner/nurse, who is designated by the undertaking to supervise/ implement radiation protection arrangements.

RPO must report directly to the undertaking.

RPO must have sufficient knowledge, authority, time & resources to carry out the function.

Named on Schedule 3 of **Licence** (EDEN)
Covered under the Self-Declaration form for **Registrants**

Roles & Responsibilities – Radiation Protection Officer (RPO)

Responsibilities & Typical Tasks

- Liaise with RPA & EPA
- Supervise and monitor compliance (audit) with radiation safety procedures and implementation of the Vet Code of Practice
- Monitor compliance with Regulations, Code of Practice & Authorisation conditions
- Oversee safe operation of x-ray equipment
- Provide/facilitate radiation safety training (additional training required for RPO role)
- Maintain X-ray equipment records and relevant documentation

Roles & Responsibilities – Veterinary Staff

Veterinary Practitioner must:

- Ensure procedure chosen has the lowest risk consistent with clinical indications
- Ensure person(s) carrying out procedure are appropriately trained
- Ensure protective measures for staff and public are in place and adhered to

All staff must:

- Comply with the Vet Code of Practice
- Utilise PPE provided (e.g. lead apron)

Risk Assessment (RA)

- **Prior to using** the X-Ray equipment, the Undertaking/Vet Practitioner, in consultation with an RPA, must make an assessment of the **nature and magnitude of the risks of exposure** to ionising radiation for workers and members of the public.
- The Risk Assessment should take account of:
  - Fixed use of x-ray equipment **and** off-site/mobile use.
  - Type of x-ray equipment
  - Design and structure of the building
  - Occupancy and clinical layout
  - Routine and reasonably foreseeable workloads
  - Reasonably foreseeable incidents and accidents

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Risk Assessment (RA)

Scope

- Risk Assessment is fundamental to ensuring exposures are kept as low as reasonably achievable
- Carried out in consultation with an RPA
- Carried out for each practice/location and for transportation/storage off-site

Purpose

- Identify the severity and likelihood of risks associated with normal operational use
- Identify the severity and likelihood of risks associated with reasonably foreseeable incidents
- Identify the operational control measures to reduce the risk

Risk Assessment Framework outlined in new IRR19 Guidance

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Risk Assessment (RA)

- The purpose of the risk assessment outcome is to **identify control measures** which minimise exposure of workers and public including:
  - design measures (e.g., shielding, or physical security) and operational safety measures necessary to optimise radiation protection
  - Personal Protective Equipment to be used;
  - The signage requirements;
  - Radiation safety measures to be taken in the event of an incident;
  - categorisation of exposed workers;
  - where appropriate, the arrangements for personal dosimetry

Risk Assessment Framework outlined in new IRR19 Guidance

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Risk Assessment

- The risk assessment must be reviewed periodically to be maintained up to date.
- The risk assessment must be updated whenever there is a change to facilities, equipment or work practices liable to impact on radiological safety, for example:
  - Change in operational procedures
  - Change in the layout of premises or occupancy/ function of an adjoining room
  - Increase in workload
  - Modification of equipment
  - Relocation of x-ray unit
  - Acquisition of new x-ray equipment

Risk Assessment Framework outlined in new IRR19 Guidance

Personal Protective Equipment

- The requirements for protective equipment will be determined by the risk assessment.
- Lead aprons, gloves and shields must be hung without folds.
- Radiographical examination of personal protective devices should be carried out:
  - at regular intervals of no more than 12 months; or
  - more frequently if damage is suspected.

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Classification of Areas

"controlled area" an area subject to special rules, to which access is controlled;

"supervised area" an area subject to supervision;

- For small animal radiography applications, classification of areas is not normally required.

- When there are exposed workers (e.g., for large animal radiography and nuclear medicine applications) a risk assessment will determine the classification of areas.

Categorisation of Workers

"exposed worker" a person who is liable to receive doses exceeding the dose limits for public exposure;

Indicates a legislative requirement to wear a **personal dosimeter**

Category A worker

- liable to receive > 6 mSv in a year

Category B worker

- liable to receive > 1 mSv but < 6 mSv in a year

- For small animal radiography applications, staff are unlikely to be categorised as exposed workers
- The risk assessment carried out in consultation with RPA will determine if there are any exposed workers

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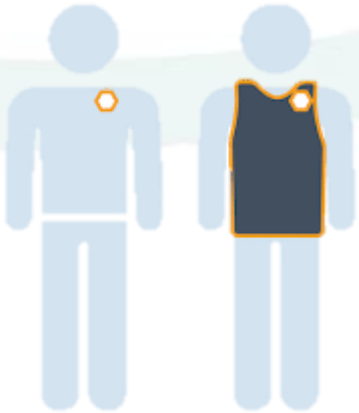
Personal Dosimetry

- Responsibility of the undertaking to provide dosimetry monitoring and provide individual badges to exposed workers (when indicated by RA)
- In general, dosimeters will likely be required for people involved in:
  - large animal X-ray examinations,
  - fluoroscopy or
  - nuclear medicine.
- The RPA will advise the type of dosimeter and instructions for use.
- Dosimetry records must be kept for no less than 30 years after the termination of work.

EPA approved dosimetry services



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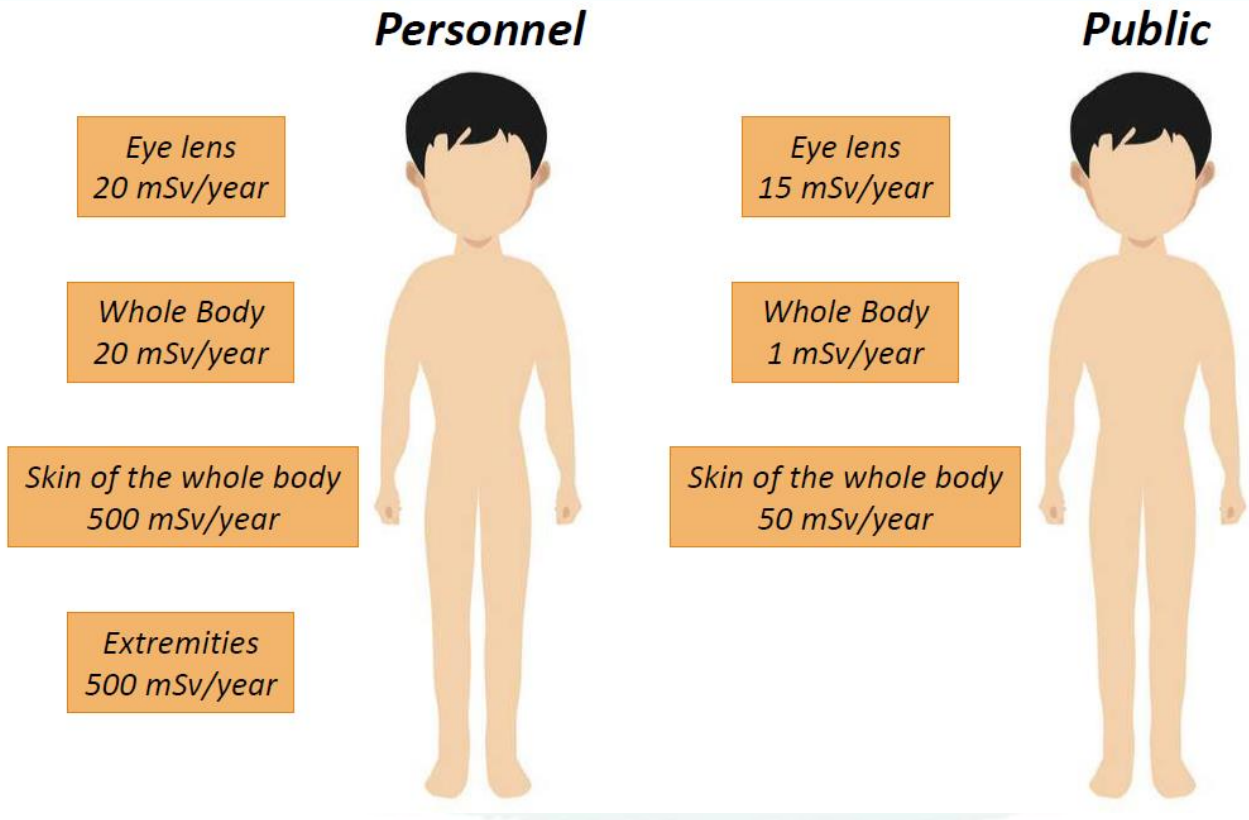
Dose limitations: workers and the public

Dose limits apply to the sum of the doses received in **all** workplaces



Specified in Part 3 Section 2 of IRR19 & Authorisation Conditions

- Exposed workers over 18 years of age (Regulation 23) → 20 mSv/y
- Pregnant workers (Regulation 24) → 1 mSv/y Dose limit to foetus following declaration
- Students/apprentices between 16 and 18 years of age (Regulation 26) → 6 mSv/y
- All other persons, including members of the public (Regulation 27) → 1 mSv/y

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Radiation Safety Procedures (RSPs)

What?

- RSPs must take account of the outcome of the Risk Assessment (RA)
- RSPs set out the necessary operational measures to protect people from the hazards associated with ionising radiation
- The Code of Practice on the Application of the Ionising Radiation Regulations (IRR19) in Veterinary Medicine can act as RSPs for small animal X-rays in a clinic unless the RA indicates otherwise.

Who?

- Must be made available to all relevant staff (including Code of Practice)
  - a signed and dated log of receipt must be available for inspection
- The RSPs must be followed by those carrying out and assisting with X-ray examinations
  - Before the exposure the risks and precautions to be observed must be explained to participants/ animal owners

Code of Practice on the Application of IRR19 in Veterinary Medicine

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RSPs as per the Vet Code of Practice 5.3

- The *general safety procedures for diagnostic X-ray examinations* are set out in Section 5.3.

1. Deciding when to take the X-ray
2. Preparing to take the X-ray
3. Taking the X-ray
4. Holding the animal
5. Holding the image receptor

Local Radiation Safety Procedures

- Large animal and off-site examinations (and where indicated in the RA) using ionising radiation require local radiation safety procedures to be prepared.

The local RSPs must take account of:

- What is the position/ restraint of the animal?
- What is the position of staff/public – How to suitably restrict the area?
- What PPE (e.g. lead apron) is needed?
- Has the X-ray beam been collimated – What is the exposure factor?
- What are the reasonably foreseeable incidents?

Large animal/off-site examinations

1. Site selection:
   - Use stables rather than open field (Utilise shielding from architectural features)
   - Avoid areas with regular through traffic
   - Ensure you can see entirety of examination area during the procedure
   - Select a site where access of unauthorised persons can be physically restricted
2. Warning signs, bollards, cones, or other means must be used to prevent access
3. Adequate means needed to ensure the security of the X-ray unit during transportation to and from site

Keep a record

Registration / Licence

	Registration	Licensing
Risk Assessment	A risk assessment should be completed before bringing any new equipment into service. This should be retained on file by the undertaking.	A risk assessment should be completed before bringing any new equipment into service and must be reviewed and updated periodically. It should be submitted with the licence application through EDEN.
Local radiation safety procedures	Not required – compliance with this Code of Practice is sufficient.	Required and should be submitted with the licence application through EDEN.

Radiation Protection Training for Staff

- It is the responsibility of the undertaking to provide training
- Training policy should include:

- Who is to be trained.
- What the training will cover i.e., training content
- Details of role specific training for staff groups (next slide)
- When the training will occur i.e., new staff training and refresher training
- Details of the training provider e.g., RPA

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Radiation Protection Training for Staff

RP Training for **all staff**

- Operational protection measures set out in the EPA Code of Practice and those identified in the Risk Assessment(s)
- Safety features of the x-ray equipment in use
- Procedures to be followed in the event of an equipment malfunction liable to have radiation safety implications
- Where appropriate, possible risks to foetus and additional protective measures during pregnancy

Additional RP training for staff categorised as **exposed workers**

- General principles of radiation protection related to their working environment
- Health risks created by exposure to ionising radiation
- The importance of the risk assessment and of staff inputting to its development/ maintenance

Additional training for **RPO**

- Legal responsibilities and duties of the RPO
- An understanding of relevant legislation and the Vet Code of Practice
- An understanding of the conditions attached to the EPA's authorisation

Refresher training every 3-5 years or if anything changes

Training records must be signed by staff and maintained by Undertaking/RPO

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Keep a record

Installation, Maintenance and Disposal of Equipment

Purchasing a new X-ray

- Acceptance tests, by a suitable competent person, are required before use*
- Equipment must be CE marked

*consult your RPA

Maintenance

- Equipment performance kept under routine surveillance
- Identify any defects/faults and correct as soon as possible
- Service engineer must follow local RSPs and those outlined in Code of Practice
- Maintenance report required

Disposal

- Appropriate measures so equipment cannot be switched on inadvertently when not in use.
- The EPA guidance note must be followed to ensure compliance with WEEE regulation and EPA requirements.

*Installation and servicing to be done by person who holds **EPA authorisation for installation/servicing of radiological equipment**.
Clear written arrangements for radiation safety responsibility are required before handover
Keep up-to-date inventory of equipment, including location of use on-site (documented on schedule 2 for licensees)

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Keep a record

Maintenance of Equipment – Records

Quality control	Control interval not more than
Verify correct voltage	36 months
Verify correct radiation output	36 months
Verify exposure time	36 months
Check radiation field aligns with edge of the light field using a metal marker such as a coin	12 months
Check for any deterioration in image quality since the previous quality control	12 months
Visual check of mechanical functions, emergency switches, warning lights, etc.	12 months
Visual check of radiation shielding	12 months

Service engineer

Internal checks

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Reporting of Incidents

What should be reported?

- Exposure of a person due to a design flaw or incorrect operation of equipment
- Theft/loss of x-ray equipment
- A (suspected) dose exceeding dose limits *
- Inappropriate/unauthorised use of x-ray equipment

How should it be reported?

- Reported by the Undertaking
- By email (recommended) - radiationincidents@epa.ie
- By telephone (053) 916 0600 + transfer to Radiation Protection Regulation Team
- EPA will advise if incident investigation is needed

What to include in the incident investigation?

- Sequence of events leading to incident
- Causes of incident
- Necessary remedial action
- Estimated doses received by all persons

What to include inn the incident report?

- Key facts around the incident
- Consequences for exposed persons
- Recommendations to avoid incident reoccurrence
- Details of follow-up actions

*Licence Condition B2 & Registration Condition C4 states if a Category A worker receives a dose of 6 mSv or a Category B worker receives a dose of 2 mSv within a continuous 16-week period this must be reported to the EPA.

- This is in addition to annual dose limits described on previous slide
- The dosimetry provider will need to be told what limits you wish to be alerted of if they operate outside of Ireland

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Keep a record

Maintenance of Records

Parameter	Recommended retention period
Risk assessments	2 years after a risk assessment has been superseded
Local radiation safety procedures	2 years after procedures have been superseded
Details of X-ray equipment including date of acquisition, make/model, serial number and/or other unique identifiers.	2 years after disposal of the equipment
Installation report and user manuals	
Servicing reports	5 years
Quality assurance/quality control reports	
Staff training records	
Incident/accident procedures and reports	
Monthly visual checks as applicable	
Disposal of X-ray equipment	
Dosimetry reports where relevant	Indefinitely

Q&A Session

Useful Links (QR codes throughout presentation)	
Register for Webinar 2: Inspection programme, licence amendments and EDEN	https://tinyurl.com/EPAweb2
Code of Practice on the Application of the Ionising Radiation Regulations (IRR19) in Veterinary Medicine	https://www.epa.ie/publications/compliance--enforcement/radiation/EPA-2020-Veterinary-Code-of-Practice.pdf
Practices subject to Registration/Licence	https://www.epa.ie/our-services/licensing/radiation/graded-authorisation/list-of-practices/
Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019	https://www.irishstatutebook.ie/eli/2019/si/30/made/en/pdf
Guidance for undertakings on the application of the Ionising Radiation Regulations (IRR19)	https://www.epa.ie/publications/licensing--permitting/radiation/EPA_IRR19_Guidance_2022.pdf
EDEN Ireland (apply for/ amend authorisation)	https://www.edenireland.ie/
Radiation Protection Adviser (RPA) Register and contact details	https://www.epa.ie/our-services/licensing/radiation/rpa/rpa-register/
List of EPA approved dosimetry providers	https://www.epa.ie/our-services/licensing/radiation/approved-dosimetry-services/
Guidance on the Management of X-ray units at end-of-life	https://www.epa.ie/publications/compliance--enforcement/waste/Guidance-for-management-of---X-ray-units-at-end-of-life.pdf

ORPedensupport@epa.ie