SI 30 of 2019

Protection of staff, public and environment from radiation

Oifig an Stiúrthóra Seirbhísí Altranais & Cnáimhseachais | Office of the Nursing & Midwifery Services Director

CPD for Referrers of Medical Radiological Procedures

Study Day 1

June 8th 2023

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Saolta

Grúpa Ollscoile Cúram Sláinte

University Health Care Group

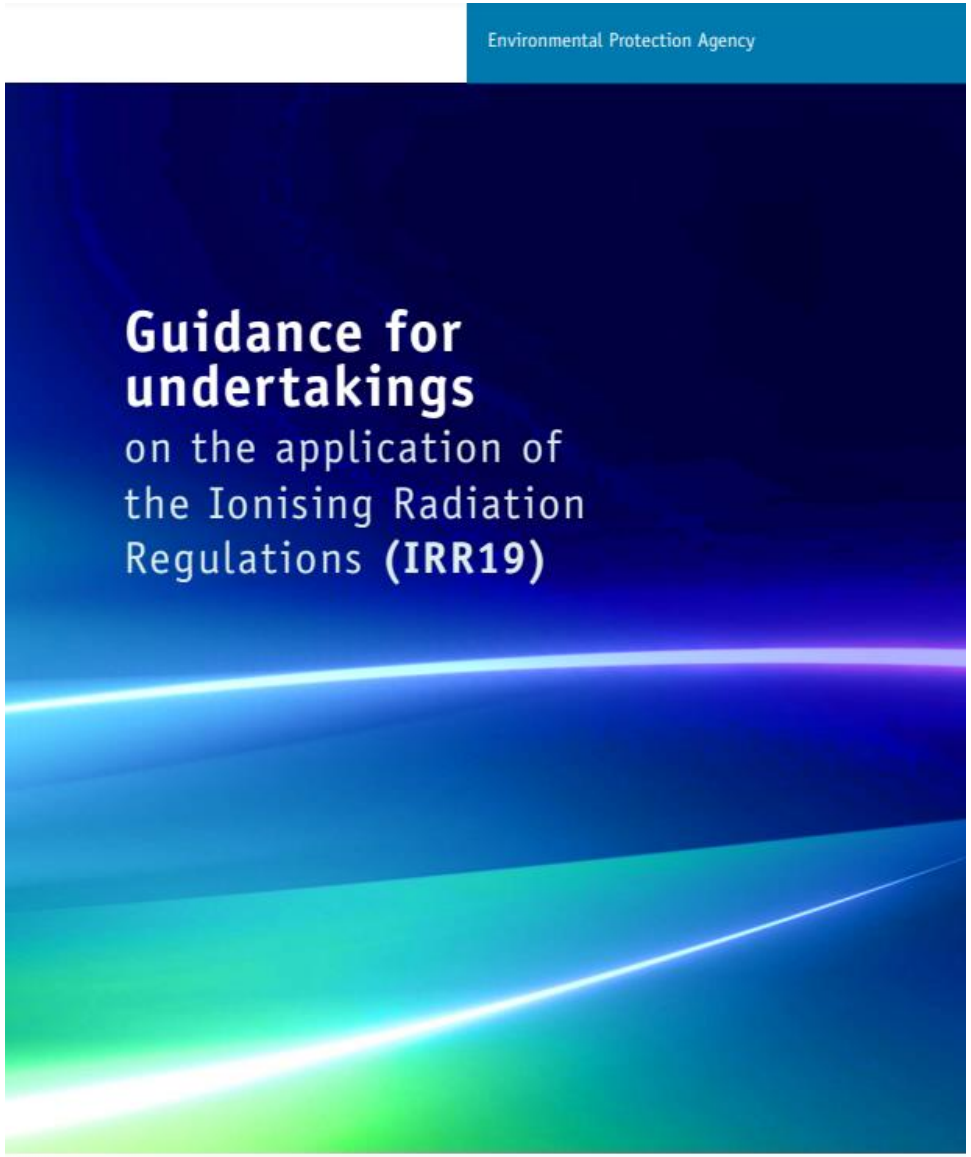
SI No. 30 of 2019

STATUTORY INSTRUMENTS.

S.I. No. 30 of 2019

RADIOLOGICAL PROTECTION ACT 1991 (IONISING RADIATION)
REGULATIONS 2019

https://www.irishstatutebook.ie/eli/2019/si/30/made/en/pdf



- June 2022
- https://www.epa.ie/our-services/licensing/radiation/
- Guidance document which will assist undertakings to comply with their legal requirements under the Ionising Radiation Regulations 2019.

Outline of guidance document

- System of radiation protection
  - Authorisation
- Governance & responsibilities
- Risk assessment
- Operational radiation protection
- Safety of radiological equipment
- Training & education
- Incidents

Governance & Responsibilities

- Undertaking

"undertaking" means a natural or legal person who has legal responsibility under these Regulations for the carrying out of a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities);

Regulation 2, Definitions, SI 30 2019

Responsibilities of Undertaking

- putting systems and processes in place to ensure adequate governance, management and oversight of radiation protection;
- consulting with an approved RPA (or RPAs) and (for licensed practices) ensuring that agreed arrangements with a named RPA are in place (Section 3.3.2);
- providing the RPA(s) with access, adequate information and facilities for the discharge of their functions;
- ensuring that risks from all activities involving the use of ionising radiation are adequately assessed and the required protective measures are implemented;
- ensuring that operational responsibility for radiation protection is appropriately assigned;
- designating an RPO, who may be an individual or a radiation protection unit, to supervise the implementation of radiation protection arrangements;

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Responsibilities of Undertaking

- providing appropriate resources and training to the RPO to effectively carry out the responsibilities listed in Section 3.4;
- ensuring that staff are adequately trained, adhere to the radiation safety procedures and, where appropriate, are provided with PPE including personal dosimetry;
- ensuring that equipment is appropriately set up/installed, calibrated, maintained and subject to appropriate quality assurance testing;
- ensuring that arrangements are in place for the safe and secure management and control of radioactive sources;
- ensuring that documentation relevant to compliance with IRR19 is maintained and available for inspection by the EPA.

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Radiation Protection Officer (RPO)

"..an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements;

Regulation 2, Definitions, SI 30 2019

Responsibilities of RPO

- acting as a first point of contact with the regulator;
- liaising closely with workers, supervisors and managers and the RPA(s) regarding the radiation protection arrangements in the workplace;
- liaising with the RPA(s) on all relevant matters concerning radiation safety;
- ensuring that work with radiation is carried out in accordance with the radiation safety procedures;
- supervising the implementation of the programme for workplace monitoring;
- maintaining adequate records of all radiation sources;
- carrying out periodic assessments of the condition of the relevant safety and warning systems;
- supervising the implementation of the personal monitoring programme;

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Responsibilities of RPO

- providing new workers with an appropriate introduction to the radiation safety procedures;
- inputting to the development and ongoing review of risk assessments;
- participating in the arrangements for prevention, preparedness and response for emergency exposure situations;
- supervising the implementation of the quality assurance (QA) programme;
- liaising with the RPA(s) on training requirements of exposed workers;

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Radiation Protection Adviser (RPA)

- "..an individual or a body, having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, which meets such criteria of competence as may from time to time be specified in writing by the Agency"[1]

- On register held by the EPA

- Concerned with radiation protection of staff, public and the environment

1. Regulation 2, Definitions, SI 30 2019

Consultations with RPA

The advice to be provided by an RPA must cover, where relevant, but not be limited to:

- optimisation and establishment of appropriate dose constraints;
- plans for new installations and acceptance into service of new or modified radiation sources from the point of view of radiation protection including any engineering controls, design features, safety features and warning devices relevant to radiation protection;

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Consultations with RPA

- preparation of risk assessments;
- preparation of radiation safety procedures;
- classification of controlled and supervised work areas;
- categorisation of workers;
- radiological surveillance of the workplace;
- individual monitoring/personal dosimetry;
- appropriate radiation monitoring instrumentation;
- quality assurance;

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RPO vs RPA

	RPA	RPO
Responsibilities of the RPO/ RPA	The RPA is responsible for the provision of professional advice on radiation protection covering both the setting up and the ongoing operation of radiological practices to comply with IRR19 and licence conditions.	The RPO is responsible for the implementation of the radiation protection arrangements in the workplace.
Responsibilities of the undertaking	The undertaking must consult with an RPA or RPAs as appropriate from the list of approved RPAs published by the EPA.	The undertaking must designate an individual or team (radiation protection unit) with appropriate expertise and resources to carry out the role of RPO.

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Radiation Safety Committee

- EPA licence conditions whether a RSC should be established:

10. The Licensee shall either establish, or be party to, a Radiation Safety Committee.

11. The Radiation Safety Committee shall be responsible for monitoring and overseeing radiation protection to ensure compliance with regulatory and licensing conditions and shall meet at least once every six months.

- Common in hospital setting
- Meets at least twice per year
- Discuss all maters relating to radiation safety in the workplace

Typical Radiation Safety Committee

- Undertaking / GM
- Consultant Radiologist
- RSM
- Nurse Referrer
- RPA
- MPE
- RPO
- RSO for different areas
- Risk Manager
- Other interested / relevant parties

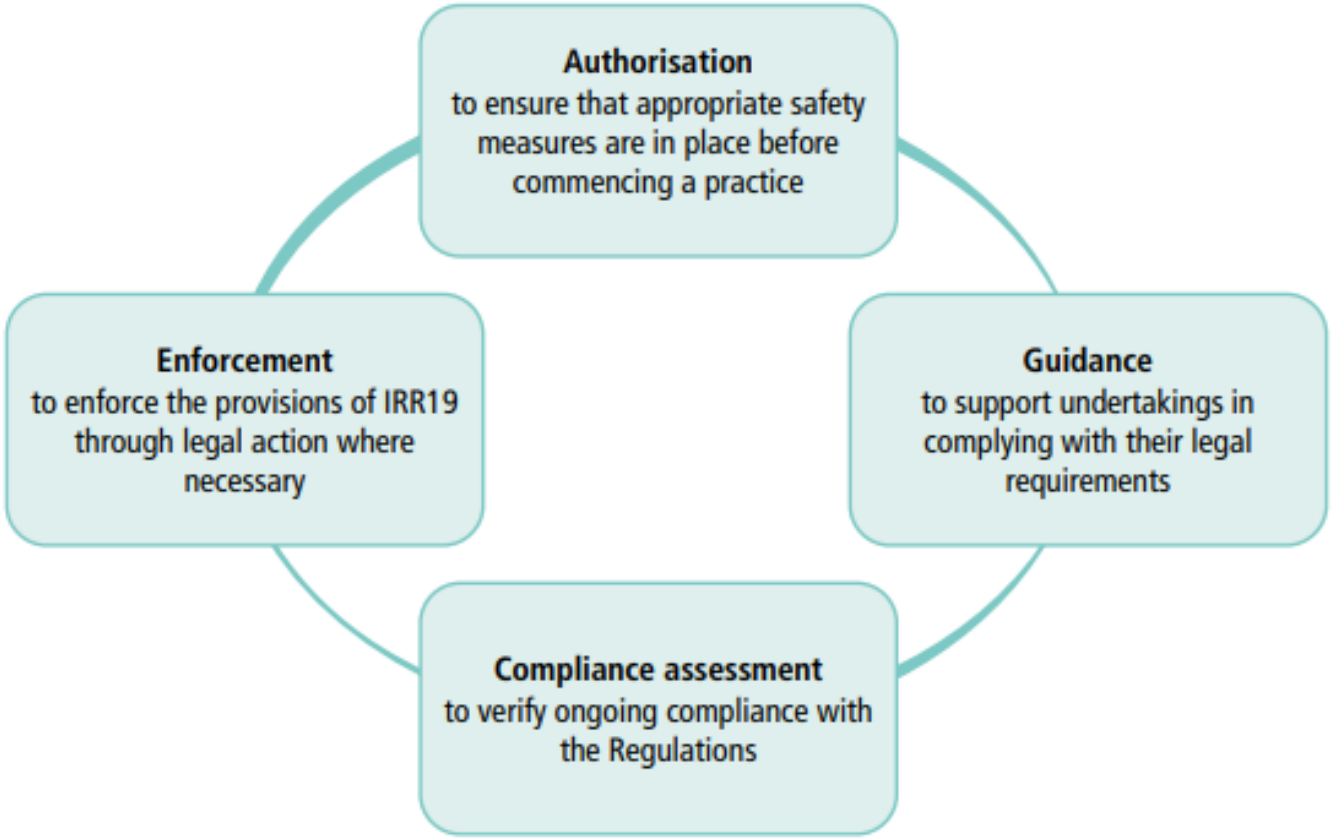
Responsibilities of Staff

- Comply with the legislation
- Utilise any PPE and dosimetry where required
- Ensure their own and others safety by following radiation protection principles
- Inform management of any defective or faulty equipment

System of Radiation Protection

- Justification
  - Risk / benefit
- Optimisation
  - ALARA
- Dose limitation
  - Below statutory limits
- Regulatory Control
  - Ensure effective risk management / controls in place

Regulatory Control – EPA



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Graded Authorisation

- Registration
  - Lower risk practices

- Licence
  - Higher risk / more complex practices

- Both to be applied for via EDEN website before commencing any practice / clinical service
- www.edenireland.ie

Practices subject to registration

Medical

Practice
General radiography giving rise to a medical exposure in a medical radiological installation
Bone densitometry giving rise to a medical exposure
Mammography giving rise to a medical exposure
Specimen radiography for medical purposes
Dental radiography using an intra/extra oral unit (except handheld)
Dental cone beam CT

Dental

Practice
Dental radiography using an intra/extra oral unit (except handheld)
Dental cone beam CT

https://www.epa.ie/our-services/licensing/radiation/graded-authorisation/list-of-practices/

Practices subject to Licensing

Medical

Practice
Radiotherapy using a LINAC in a medical radiological installation
Radiotherapy using brachytherapy in a medical radiological installation
Radiotherapy using X-ray in a medical radiological installation
Interventional radiology giving rise to a medical exposure in a medical radiological installation
CT giving rise to a medical exposure in a medical radiological installation
Mobile radiography/fluoro giving rise to a medical exposure in a medical radiological installation
Fluoroscopy giving rise to a medical exposure in a medical radiological installation
Nuclear medicine giving rise to a medical exposure in a medical radiological installation
PET/CT giving rise to a medical exposure in a medical radiological installation
Dental radiography using handheld intra- oral unit [5]
Product irradiation/sterilisation using HASS sources

https://www.epa.ie/our-services/licensing/radiation/graded-authorisation/list-of-practices/

Table 2: Summary of key differences between registration and licensing

	Registration	Licensing
Applicable to	Lower risk practices such as product inspection using cabinet X-ray or dental radiography (with the exception of hand-held units)	Higher risk or more complex practices such as brachytherapy or industrial radiography
Duration of authorisation	Indefinite (unless surrendered or revoked)	10 years (unless surrendered or revoked)
Risk assessment	The undertaking must confirm it has been completed through self-declaration form.	The risk assessment must be submitted with the licence application for review by the inspector
Management of key documents (including the risk assessment, radiation safety procedures and the inventory of equipment)	Documents must be maintained on file and be available to an EPA inspector	Documents must be submitted with the licence application through EDEN
When is it necessary to make an amendment?	▶ Change to a legal entity or address ▶ Change to the senior management contact or the contact for correspondence ▶ Before carrying out a new practice not covered by the existing registration	▶ Change to a legal entity or address ▶ Change to the senior management contact, the contact for correspondence, the RPO or the RPA ▶ Change to the schedule of equipment linked to any licensable radiological practice ▶ Before carrying out a practice not covered by the existing licence

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Environmental Protection Agency

Registration

L018

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

White Rock Centre, Galway

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 *A. Inspector* Date 28 March

On behalf of the Environmental Protection Agency

For Registration - Self declaration form submitted via EDEN to confirm:

- Consultation with a Radiation Protection Adviser (RPA)
- Risk assessment carried out in consultation with an RPA
  - Room design, shielding, protective measures
- Protective measures implemented
- Controlled & supervised areas designated if / as required

For Registration - Self declaration form submitted via EDEN to confirm:

- Radiation Protection Officer (RPO) in place
- Staff training completed
- Contingency plans in event of radiation incident

Undertaking (licence / registration holder)

- Maintain all evidence supporting self declaration on file (for registration)
- Ensure registration /licence cert is on display
- Inventory of all irradiating apparatus
- Documentation available to EPA
  - On request
  - On inspection => announced or surprise

EPA Compliance Assessment

- Questionnaires
  - Follow up inspection
- Document request at any point
- Site inspection
- Remote inspection

EPA Site inspections

- Risk assessments
- Radiation safety procedures (local rules)
- Installation reports
- Acceptance / Commissioning reports
- Quality assurance reports
  - Physics
  - In house QC
- Radiation protection training records
- X-ray equipment inventory

Powers of EPA

Figure 3: General hierarchy of enforcement tools available under IRR19

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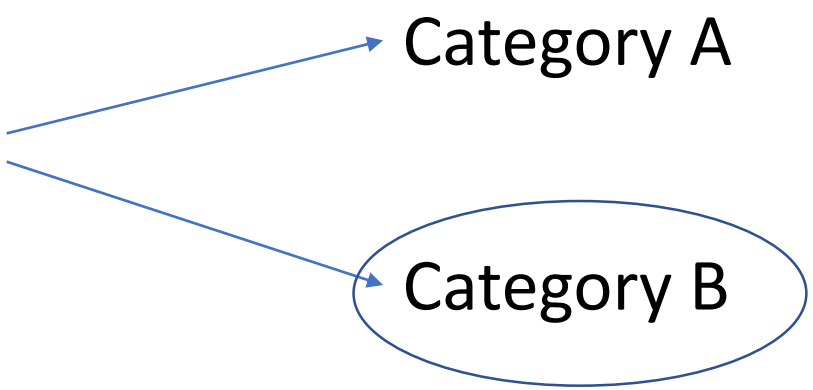
Dose Limits

- Exposed Workers



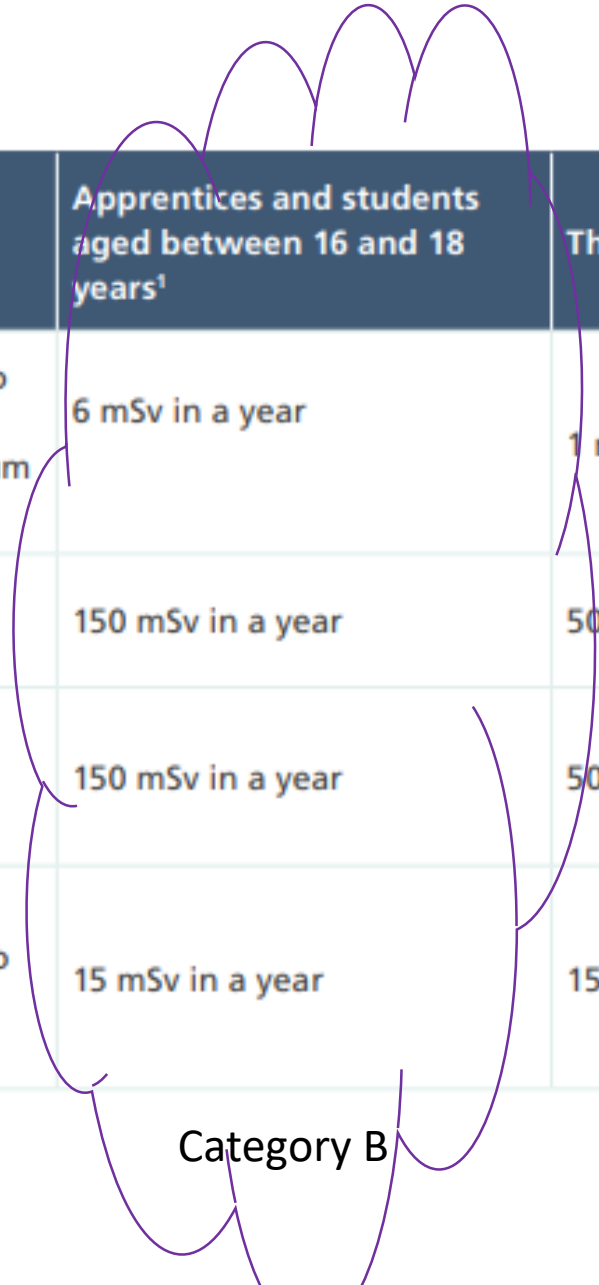
- Public

- “..an exposed worker who is liable to receive an effective dose greater than 1 mSv but less than 6 mSv in a year”

Regulation 39(1)(b) SI 30 2019

Dose Limits

Dose limit	Exposed workers	Apprentices and students aged between 16 and 18 years[1]	The public
Effective dose	20 mSv in any single year or, subject to Regulation 23(2), 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year[2]	6 mSv in a year	1 mSv in a year
Equivalent dose to the skin	500 mSv in a year[3]	150 mSv in a year	50 mSv in a year
Equivalent dose to the extremities	500 mSv in a year	150 mSv in a year	50 mSv in a year
Equivalent dose to lens of the eye[4]	20 mSv in any single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year	15 mSv in a year	15 mSv in a year



Category A

Category B

Unexposed

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Exposed worker?

- Consult with RPA
- Risk assessment
- Work practices
- Equipment
- “..determined based on the risk assessment that the sum of their expected doses from normal operation with operational control measures in place plus their potential doses from reasonably foreseeable incidents exceeds one of the dose thresholds”

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Operational Radiation Protection

- Radiation Safety Procedures / Local Rules
  - Covers all aspects required to ensure safety of people

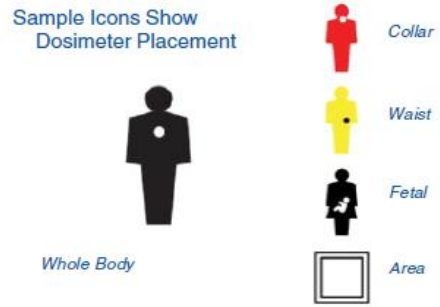
- Controlled & Supervised areas
- Individual monitoring / dosimetry of exposed workers
  - EPA approved service
- Estimation of individual doses
  - If monitoring not possible / available

Operational Radiation Protection

- Personal Protective Equipment
  - Must be provided if deemed necessary
- Staff required to wear PPE
- Trained on appropriate use / storage / maintenance

Personnel Dosimeter Badge

- <u>Legal requirement to wear badge once issued</u>
- It is worn at the position indicated on the badge unless instructed otherwise
- Wear when working in controlled areas
- Exchange at requested frequency
- If the badge is not used, this will be detected during readout and recorded on the staff member's dose record for that period



If Pregnant & an Exposed Worker?

- You are obliged to notify one of following:
  - Manager / Head of Department / Section
  - RPO
  - RPA
- Risk Assessment performed
- Dose limit to fetus of 1mSv (public limit) applied for remainder of pregnancy (from time of notification)
- Steps taken to ensure dose limit not exceeded

Training & Education for all exposed workers

- the risks to health from exposure to ionising radiation;
- general principles of radiation protection;
- the specific radiation protection procedures and precautions in connection with the work with ionising radiation to which they may be assigned;
- the responsibility of the individual in maintaining a safe workplace;
- the role of the risk assessment in identifying necessary safety measures;

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Training & Education for all exposed workers

- the relevant parts of the emergency response plans and/or procedures to be followed in the event of an incident;
- the importance of complying with medical, technical and administrative requirements;
- where relevant, the potential risks to the foetus, any additional relevant protective measures to take during pregnancy and to a nursing infant and the importance of making an early declaration of pregnancy or the intention to breastfeed.

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RPO training

- the tasks to be undertaken by the RPO as set out in Regulation 34(3) and Section 3.3 of this guide – where the RP function is being carried by an RP unit, each member of the RP unit must be adequately trained to perform their allocated tasks;
- the operational control measures identified in the risk assessment(s);
- an overview of relevant legislation, standards and this guide. The level of detail should be commensurate with the nature and complexity of the practices being carried out;
- the conditions attached to the registration or licence;
- in addition, the training for the RPO or head of the RP unit as appropriate should cover the information set out in Section 7.1.

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Safety of Radiological Equipment

- Acquired from reputable company
- Installed by competent engineers
- Commissioned by medical physics / RPA / MPE
- Training of users
- Serviced and maintained throughout life
- Regular QC/QA checks
- Disposed of / decommissioned as per EPA guidance at end of life

QUESTIONS?

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