Guidance for undertakings

on the application of the Ionising Radiation Regulations **(IRR19)**

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

The EPA is responsible for protecting and improving the environment as a valuable asset for the people of Ireland. We are committed to protecting people and the environment from the harmful effects of radiation and pollution.

The work of the EPA can be divided into three main areas:

Regulation: *Implementing regulation and environmental compliance systems to deliver good environmental outcomes and target those who don't comply.*

Knowledge: *Providing high quality, targeted and timely environmental data, information and assessment to inform decision making.*

Advocacy: *Working with others to advocate for a clean, productive and well protected environment and for sustainable environmental practices.*

Our responsibilities include:

Licensing

- Large-scale industrial, waste and petrol storage activities;
- Urban waste water discharges;
- The contained use and controlled release of Genetically Modified Organisms;
- Sources of ionising radiation;
- Greenhouse gas emissions from industry and aviation through the EU Emissions Trading Scheme.

National Environmental Enforcement

- Audit and inspection of EPA licensed facilities;
- Drive the implementation of best practice in regulated activities and facilities;
- Oversee local authority responsibilities for environmental protection;
- Regulate the quality of public drinking water and enforce urban waste water discharge authorisations;
- Assess and report on public and private drinking water quality;
- Coordinate a network of public service organisations to support action against environmental crime;
- Prosecute those who flout environmental law and damage the environment.

Waste Management and Chemicals in the Environment

- Implement and enforce waste regulations including national enforcement issues;
- Prepare and publish national waste statistics and the National Hazardous Waste Management Plan;
- Develop and implement the National Waste Prevention Programme;
- Implement and report on legislation on the control of chemicals in the environment.

Water Management

- Engage with national and regional governance and operational structures to implement the Water Framework Directive;
- Monitor, assess and report on the quality of rivers, lakes, transitional and coastal waters, bathing waters and groundwaters, and measurement of water levels and river flows.

Climate Science & Climate Change

- Publish Ireland's greenhouse gas emission inventories and projections;
- Provide the Secretariat to the Climate Change Advisory Council and support to the National Dialogue on Climate Action;
- Support National, EU and UN Climate Science and Policy development activities.

Environmental Monitoring & Assessment

- Design and implement national environmental monitoring systems: technology, data management, analysis and forecasting;
- Produce the State of Ireland's Environment and Indicator Reports;
- Monitor air quality and implement the EU Clean Air for Europe Directive, the Convention on Long Range Transboundary Air Pollution, and the National Emissions Ceiling Directive;
- Oversee the implementation of the Environmental Noise Directive;
- Assess the impact of proposed plans and programmes on the Irish environment.
- Environmental Research and Development
- Coordinate and fund national environmental research activity to identify pressures, inform policy and provide solutions;
- Collaborate with national and EU environmental research activity.

Radiological Protection

- Monitoring radiation levels and assess public exposure to ionising radiation and electromagnetic fields;
- Assist in developing national plans for emergencies arising from nuclear accidents;
- Monitor developments abroad relating to nuclear installations and radiological safety;
- Provide, or oversee the provision of, specialist radiation protection services.

Guidance, Awareness Raising, and Accessible Information

- Provide independent evidence-based reporting, advice and guidance to Government, industry and the public on environmental and radiological protection topics;
- Promote the link between health and wellbeing, the economy and a clean environment;
- Promote environmental awareness including supporting behaviours for resource efficiency and climate transition;
- Promote radon testing in homes and workplaces and encourage remediation where necessary.

Partnership and networking

- Work with international and national agencies, regional and local authorities, non-governmental organisations, representative bodies and government departments to deliver environmental and radiological protection, research coordination and science-based decision making.

Management and structure of the EPA

The EPA is managed by a full time Board, consisting of a Director General and five Directors. The work is carried out across five Offices:

- Office of Environmental Sustainability
- Office of Environmental Enforcement
- Office of Evidence and Assessment
- Office of Radiation Protection and Environmental Monitoring
- Office of Communications and Corporate Services

The EPA is assisted by advisory committees who meet regularly to discuss issues of concern and provide advice to the Board.

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on the application of the Ionising Radiation Regulations (IRR19)

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GLOSSARY

Authorisation means the registration or licensing of a radiological practice. The EPA website lists the practices subject to registration and licensing.

BSS means the European Union Basic Safety Standards (BSS) Directive (Council Directive 2013/59/EURATOM).

Design control means radiation protection measures that are incorporated into a building or work area during construction and fit-out. In general, design control measures should not be dependent on human behaviour and include, for example, room layout; shielding of walls; doors and windows; permanent barriers to restrict access; and other engineered control measures.

Disused source means a sealed source that is no longer used or intended to be used for the practice for which authorisation was granted but continues to require safe management.

Dose constraint means an upper bound of individual dose that may be used in the risk assessment for the purpose of optimising radiation protection controls. Dose constraints should be established by the undertaking in consultation with an RPA for the purpose of prospective optimisation of protection. Dose constraints are intended for planning purposes only and should not be confused with dose limits.

Employer means for the purpose of the Regulations a person or organisation that employs exposed workers but does not have operational responsibility for the controlled or supervised areas.

EDEN (Environmental Data Exchange Network) means the EPA's online portal for licensees and regulatory customers.

EPA means the Environmental Protection Agency.

Exposed worker means a person who is liable to receive a dose in excess of a public dose limit during the course of their work.

High-activity sealed source (HASS) means a sealed source containing a radionuclide whose activity is equal to or above the relevant HASS threshold activity level set out in IRR19 Schedule 3.

HIQA means the Health Information and Quality Authority.

IAEA means the International Atomic Energy Agency.

Ionising radiation means energy transferred in the form of particles or electromagnetic waves with sufficient energy to produce ions directly or indirectly.

IRR19 means the Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019 (S.I. No. 30 of 2019). A reference in the guidance document to a "Regulation" should, unless stated otherwise in the text, be interpreted as a reference to IRR19.

Medical exposure means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research.

Medical physics expert has the meaning given to it in Regulation 2(1) of S.I. No. 256 of 2018: an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the Minister for Health.

Medical radiological equipment means radiological equipment used for radio diagnostic procedures, radiotherapy, interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes.

Medical radiological installation means a facility where medical radiological procedures are performed.

Medical radiological procedure means a medical diagnostic or therapeutic procedure involving medical exposures.

Non-medical human imaging means any use of ionising radiation for human imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed.

Notification means the submission of information to the EPA to notify the intention to carry out a practice within the scope of IRR19. An application made to an RPA for an authorisation is considered to constitute a notification within the meaning of IRR19.

Operational controls means radiation protection measures that depend on radiation safety procedures, training, emergency procedures or the use of PPE. In general, operational controls will depend to some degree on human behaviour and so the implementation will involve appropriate training and management oversight.

Outside worker means an exposed worker who is not directly employed by the undertaking that is legally responsible for the practice and has operational control over the relevant supervised or controlled areas.

Planned exposure situation means a situation in which exposure arises from the planned operation of a source or from a planned activity that results in an exposure due to a source. Since provision for protection and safety can be made before embarking on the activity concerned, the associated exposures and their likelihood of occurrence can be restricted from the outset. Planned exposure situations include both situations where exposure is expected to occur with certainty and situations where exposure may occur (potential exposures).

PPE means personal protective equipment.

Practice means radiological practice. It should not be confused with the business or premises of a dentist, doctor or veterinary surgeon.

Primary Act means the Radiological Protection Act 1991, as amended.

Radiation safety procedures means the procedures specific to an individual facility setting out practical measures to be followed to optimise the protection and safety of people both during their planned work and in the event of an incident or unforeseen event. Radiation safety procedures should be developed in consultation with a RPA.

Radiation source means an entity that may cause exposure by emitting ionising radiation or by releasing radioactive material. This includes radiation generators and radioactive material/sources/substances as defined in IRR19.

Radiological emergency means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences.

Radiological equipment means equipment incorporating a radiation generator or radioactive source(s).

Radiological practice means a human activity that can increase the exposure of individuals to ionising radiation from the use of a radiation source, which can be managed as a planned exposure situation.

Radionuclide means a form of a chemical element that undergoes radioactive decay, resulting in the emission of ionising radiation.

RPA means a radiation protection adviser: an individual or a body that meets the competence requirements set out by the EPA to provide radiation protection advice and whose name appears on the RPA register maintained by the EPA.

RPO means a radiation protection officer: an individual or a unit designated by the undertaking to implement the radiation protection arrangements.

RSC means a radiation safety committee.

Undertaking has the meaning given to it in IRR19: a natural or legal person with legal responsibility for carrying out the radiological practice. The undertaking is the person with primary responsibility for compliance with the regulations.

1. INTRODUCTION

Ionising radiation is widely used in the medical, dental, veterinary, industrial and education/research sectors. Its applications include the diagnosis and treatment of cancer, security scanning at our airports and ports and ensuring that our bridges and other infrastructure are free from critical defects. While such applications deliver enormous benefits to society, it is vital that the use of ionising radiation is strictly regulated to ensure it is used safely and the potential radiation risk is assessed and controlled.

Irish radiation protection legislation is based on the European Union Basic Safety Standards (BSS) Directive (Council Directive 2013/59/EURATOM) and this Directive has been transposed into Irish law through:

- the Radiological Protection Act 1991, as amended, hereafter referred to as the Primary Act;
- the Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019 (S.I. No. 30 of 2019), which covers the protection of workers and members of the public. These Regulations are hereafter referred to as IRR19. *A reference in the guidance document to a "Regulation" should, unless stated otherwise in the text, be interpreted as a reference to IRR19*;
- 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), which covers the protection of patients during medical exposures.

The EPA is the competent authority for IRR19 and HIQA is the competent authority for S.I. No. 256 of 2018.

Table 1: Summary of regulatory responsibilities

Protection remit	Regulations	Competent authority/Regulator
Workers and members of the public	IRR19 (S.I. No. 30 of 2019)	EPA
Patients	S.I. No. 256 of 2018	HIQA

To legally carry out medical radiological procedures in Ireland, it is necessary to comply with both IRR19 and S.I. 256 of 2018.

It should be noted that in addition to any responsibilities under radiological legislation, undertakings (especially those that are in the position of an employer) may have duties under the Safety, Health, and Welfare at Work Act (and associated regulations), the General Data Protection Regulation (GDPR) (and associated legislation) and other legislation that requires separate consideration and is outside the scope of this guide.

The words "shall", "must" and "should" in this code have been chosen with purpose. The words "shall" or "must" indicate a mandatory requirement, whereas "should" indicates an advisory recommendation.

1.1 PURPOSE AND SCOPE OF THIS GUIDE

This guide is issued in accordance with the EPA's powers to issue guidelines and recommendations for persons dealing with radiation sources pursuant to Section 8(g) of the Primary Act and in accordance with the various provisions of IRR19 in respect of issuing guidelines.

This guide sets out the EPA's view of what in typical circumstances constitutes compliance with IRR19. *This guide is intended to assist authorised users of radiation sources in fulfilling their obligations but is not intended to offer a legal interpretation of IRR19.* It should therefore be read in conjunction with the relevant Regulations.

The EPA have published separate Codes of Practice for the dental and veterinary sectors. While the Codes of Practice cover the main regulatory requirements for those sectors, this guide provides supplementary information and additional detail. Dental and veterinary undertakings should, therefore, be familiar with both the relevant Code of Practice and this guide.

This document does not attempt to comprehensively cover every regulation in IRR19 but instead focuses primarily on regulations for which the EPA believes that guidance is likely to be helpful. Furthermore, this guide is intended to cover only the responsibilities of undertakings in planned exposure situations. It does not for example cover responsibilities of Government such as the National Plan for Nuclear and Radiological Emergency Exposures or the national action plan for radon in homes.

Appendix 1 lists the regulations covered by this guidance and cross-references the Regulations with the relevant sections.

Appendix 2 sets out a list of supplementary material intended to assist undertakings in understanding their obligations under the relevant Regulations.

2. THE SYSTEM OF RADIATION PROTECTION

As already noted, the Primary Act and associated Regulations establish national arrangements for regulatory control of radiological practices in order to protect people from the harmful effects of ionising radiation. In line with European and international standards, these arrangements are based on the principles of:

- **Justification:** Any practice involving the use of ionising radiation is not justified unless the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause, as set out in Section 2.1. The use of ionising radiation would be unlikely to be justified, for example, where a similarly effective non-radiological technique was available.
- **Optimisation:** Arrangements to protect people from the harmful effects of radiation must be optimised with the aim of keeping doses as low as reasonably achievable, taking into account the current state of technical knowledge and economic and societal factors.
- **Dose limitation:** Doses to people must be kept below the statutory dose limits as set out in Section 2.3.
- **Regulatory control:** As set out in Section 2.2, the radiological practices are subject to regulatory control for the purpose of ensuring the optimisation of protection and compliance with dose limitation.

2.1 JUSTIFICATION OF A RADIOLOGICAL PRACTICE

The EPA may not authorise a radiological practice unless it meets the requirements for justification, which have been set out in Regulation 5. The EPA in accordance with Regulation 5(6) has published on its website the list of practices currently deemed to be justified.

Any radiological practice not carried out within the Irish jurisdiction before the commencement of IRR19 (4 February 2019) is considered to be a new practice and so, in accordance with Regulation 5(1), must be justified before it can be authorised by the EPA.

IRR19 established separate arrangements covering the justification of medical exposures and all other types of exposure, as follows:

- In the case of medical exposures, the practice must be justified by HIQA in accordance with Regulation 7 of S.I. No. 256 of 2018.
- In the case of all other exposure types, the practice must be justified by the EPA with regard to its economic, social, health, environmental or other benefits in relation to the detriment it may cause, in accordance with Regulation 5(1)(b).

To demonstrate that a radiological practice is justified, it is necessary to demonstrate that the practice yields an overall net benefit taking account of the risks and benefits to individuals, the risks and benefits to society and the availability of alternative non-radiological technologies. Recognising that justification is broader, therefore, than radiation protection, Regulation 5(2) requires the EPA to consult with the Minister before justifying a class or type of practice. Furthermore, Regulation 5(3) provides that the EPA may consult others, as it considers appropriate, including relevant Ministers, professional bodies and other state agencies.

The EPA may review the justification of existing practices if new information about their efficacy or potential consequences or alternative techniques become available. If following such a review a practice is deemed to be no longer justified, the EPA must withdraw or revoke such registrations or licences, as appropriate, in accordance with Regulation 5(5).

When an application is made for authorisation of a new radiological practice, the applicant must submit evidence to support justification of the practice. The EPA may publish separate guidance on the format and scope of the evidence required.

2.2 REGULATORY CONTROL

In accordance with Regulation 12(5), all practices involving the use of ionising radiation must be authorised in advance by the EPA unless the practice has been exempted from the requirement for notification in accordance with Regulation 9 (see Section 2.2.1). Regulatory control is intended to ensure that the risks associated with a radiological practice are effectively managed on an ongoing basis and exposures are optimised. It comprises four elements, as illustrated in Figure 1.

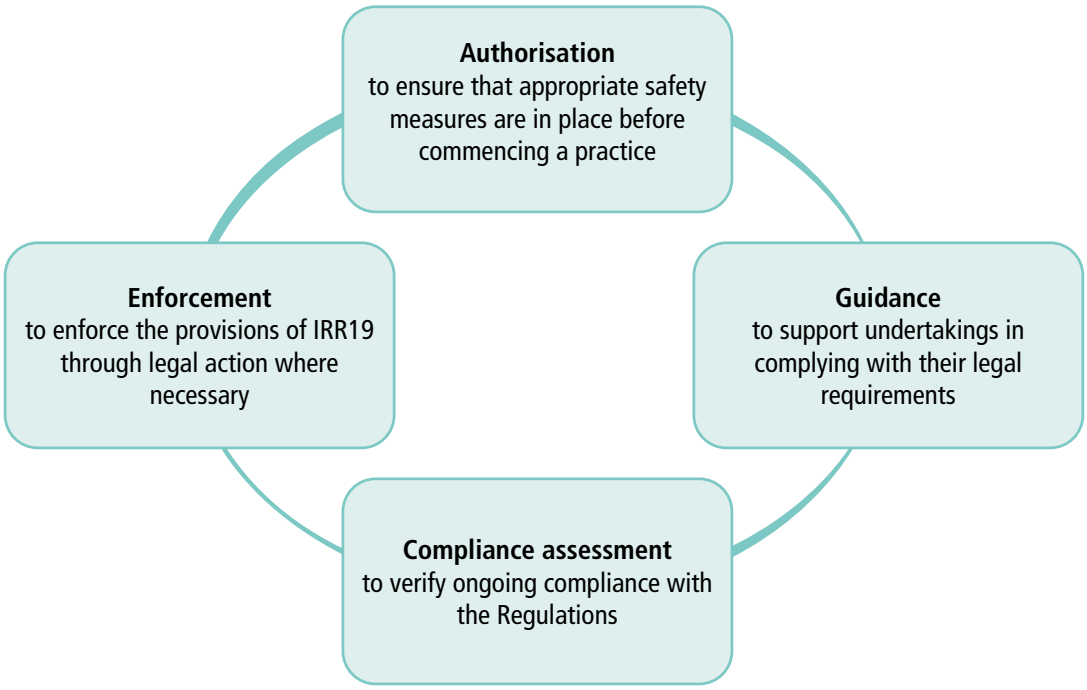

Figure 1: The system of regulatory control

Regulation is risk-based, with the greatest regulatory effort being directed towards higher risk activities. This approach informs each of the four elements of the regulatory system. This means that higher risk activities will be inspected more frequently, will be subject to a more onerous form of authorisation and will be subject to greater enforcement focus.

2.2.1 EXEMPTION FROM REGULATORY CONTROL

Regulations 8 and 9 provide that certain practices may be exempted by the EPA from the requirements for notification and authorisation. The EPA considers that practices involving the following are exempted from the requirements for authorisation in accordance with Regulation 9(1):

- the holding, handling or use of any amount of solid materials with activity concentration values less than the relevant thresholds set out in IRR19 Schedule 7 Table A;

- the holding, handling or use of moderate amounts of materials with activity or activity concentration values less than the relevant thresholds set out in IRR19 Schedule 7 Table B. In accordance with IRR19 Schedule 7 (3) (d), the EPA has specified "moderate amounts" to mean amounts less than 1000 kg (based on IAEA Technical Guidance RS-G 1.7);
- the use of an electrical apparatus such as an X-ray generator that operates at a potential difference ≤ 30 kV and does not cause in normal operating conditions a dose rate exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface.

Additionally, the EPA may, following due consideration, exempt from the requirements for notification and authorisation:

- practices involving the holding, handling or use of certain types of apparatus containing a sealed source that have been approved by the EPA in accordance with Regulation 9(1)(c);
- specific types of practice based on the general exemption criteria established in Part 3 of IRR19 Schedule 7 in accordance with Regulation 9(2).

The EPA will maintain on its website a list of apparatus types or practices exempt from authorisation in accordance with Regulation 9(1)(c) or Regulation 9(2) respectively.

2.2.2 AUTHORISATION OF RADIOLOGICAL PRACTICES

IRR19 provides for two forms of authorisation commensurate with risk: registration and licensing. Registration is appropriate to lower risk practices, whereas licensing is necessary for higher risk or more complex practices. The key differences between the two forms of authorisation are summarised in Table 2.

Irrespective of the form of authorisation, all undertakings carrying out a radiological practice must fully comply with the relevant provisions of the IRR19 and any conditions attached to a licence or registration and are subject to compliance assessment including inspection by the EPA. Regulations 14 and 15 provide that the EPA may attach conditions to a licence or registration respectively.

Undertakings must, where it is specified in the authorisation conditions, ensure that a copy of the front cover of the licence or registration, as appropriate, is displayed in a place, where it is clearly visible to staff and visitors.

An application for registration or licensing, submitted to the EPA by an undertaking, is considered to fully satisfy the requirements for notification (Regulation 8). A separate notification is required only in relation to Regulation 66(6) (radon in workplaces) and practices involving naturally occurring radioactive material identified by EPA (in accordance with Regulation 68) as being liable to be a concern from a radiation protection point of view.

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

Applying for an authorisation (registration or licence)

All applications for an authorisation must be made through the EPA's online Environmental Data Exchange Network (EDEN) at *www.edenireland.ie*. In accordance with Regulation 12(5) and Section 29A of the Primary Act, applications must be submitted and approved by the EPA before commencing any radiological practice or acquiring a radioactive source.

Depending on the radiological practices for which an authorisation is sought, the EDEN system will guide the user through the registration or licensing process as appropriate. It should be noted that where an applicant selects both registerable and licensable practices, the higher form of authorisation of licensing applies.

Applications for authorisation of a new practice should be made as soon as practicable to avoid any delays in commencing the practice. In general, applications covering relatively simple licensable practices should be made not later than one month before the date on which it is proposed to commence the practice. For large or complex facilities, such as a new nuclear medicine department in a hospital, the authorisation process may take several months, and this should be factored into the project planning.

The undertaking must consult with an approved RPA at the outset that will advise on all aspects of radiation protection. For large projects undertakings should also engage with the EPA at an early stage and before making a formal application so that the necessary regulatory requirements can be discussed and to mitigate any problems or delays in the licensing process.

Practices subject to registration

For registration, an undertaking must complete a self-declaration form through EDEN confirming that he or she has:

- consulted with a suitable RPA as appropriate;
- completed a risk assessment (including room design and shielding) in consultation with an RPA to identify any necessary protective measures;
- implemented the protective measures identified in the risk assessment;
- designated an RPO;
- provided staff with the appropriate training;
- correctly classified and demarcated any controlled and/or supervised areas;
- developed procedures to be followed in the event of an incident liable to have radiation safety implications for workers and members of the public.

Undertakings holding an EPA registration must retain on file documentary evidence supporting the self-declaration. In addition, an inventory must be maintained of equipment used for authorised practices. The EPA may at any stage following registration request copies of supporting documents for the purpose of verifying the self-declaration.

Practices subject to licensing

For practices subject to licensing, the undertaking must, at the time of application, provide the following at a minimum:

- the practice(s) for which authorisation is sought;
- the purpose of the practice including description of planned activities;
- details of the legal entity including the Companies Registration Office (CRO) registered name where appropriate;
- the address of the undertaking and of the premises at which the practice(s) will be carried out;
- the name of the RPA consulted;
- the designated RPO;
- the schedule of equipment including as appropriate details of make, model, serial number, activity, location, purpose (what practice it is used for);
- a copy of the risk assessment(s) for each radiological practice;
- a copy of the radiation safety procedures;
- a copy of agreed arrangements with the RPA;
- in the case of large building projects, a copy of the draft plans (layout and shielding), as agreed between the RPA and the undertaking;
- for radioactive sources, details of the takeback agreement in place with supplier or manufacturer for when the source becomes disused.

The inspector may specify additional information to be uploaded to EDEN depending on the type of installation. For certain types of installation (such as radiotherapy facilities), the EPA may publish more detailed guidance on its website covering the specific information required in a licence application.

Licensing of practices involving a high-activity sealed source (HASS)

Licensing is applicable to all practices involving the use of HASS. Such practices are subject to a number of additional requirements as set out in Regulations 70 to 74 of IRR19. Further guidance on these requirements is covered in Section 6.2.3.

Applications for licensing of any practice involving the use of HASS must, in addition to the information referred to in Section 2.3.2, include:

- details of the arrangements that have been made for the safe and secure management and control of these sources, including when they become disused sources;
- details of the financial security or other equivalent means in place to ensure that adequate resources are available for the safe and secure management of sources when they become disused. Such arrangements must be designed to provide for management and disposal even where the undertaking becomes insolvent or ceases activities;
- site security plan;
- transport security plan (relevant to licensees transporting HASS only).

It should be noted that a site and transport security survey will need to be conducted with An Garda Síochána's National Crime Prevention Unit before authorisation is granted. This security survey will be arranged through the EPA.

Authorisation of non-medical human imaging (NMHI) practices

The justification and authorisation process for NMHI practices is outlined in Appendix 7.

Selling or transferring a business

It is not permitted to transfer an authorisation (licence or registration) from one person/company to another. If there is a change in the authorised legal entity, the original authorisation must be revoked and a new authorisation application submitted in the name of the new legal entity. This would apply, for example, in the case of a dentist selling their practice to another dentist or one company being taken over by another.

Amendments to an authorisation

It is necessary to apply through EDEN for an amendment to an authorisation when it is intended to:

- carry out an additional practice not covered by an existing licence or registration;
- remove a practice under an existing registration or licence;
- make any changes of X-ray equipment or radioactive sources used for licensed practices (including relocation or replacement of licensed items);
- add or remove a premise under an existing registration or licence;
- add, remove or amend the name of an RPA or RPO.

Applications to amend an existing licence must be made before any changes are brought into effect.

2.2.3 COMPLIANCE ASSESSMENT

Compliance assessment by the EPA is a key element of the system of regulation. In accordance with IRR19 and the Primary Act, the EPA routinely assesses whether those authorised to use ionising radiation are compliant with the Regulations, any conditions associated with their authorisation and this Guidance Document. The assessment processes include the following:

Self-assessment

The EPA may issue questionnaires to undertakings for completion and return within a specified period. An inspector may follow up with an on-site inspection.

Review of safety documentation

The EPA may at any time request copies of the current risk assessment, evidence of appropriate installation, acceptance testing or other relevant documentation for the purpose of reviewing their adequacy.

Site inspections

An EPA inspector may carry out site inspections to verify compliance with radiation protection regulations, transport regulations and EPA authorisation conditions. The EPA will issue an inspection report to the undertaking through EDEN within 28 working days.

The inspection may be announced or unannounced and will include interviews/discussions with management and staff, observation of radiation protection in practice, and examination of records and documents including but not limited to:

- risk assessments;
- radiation safety procedures;
- RPA agreed arrangements (where relevant);
- installation/acceptance/quality assurance reports;
- radiation protection training records;
- inventory of equipment.

Remote compliance assessments

The EPA may perform remote compliance assessments. These will generally involve the uploading of documentation in advance via EDEN followed by a compliance meeting using video conference. This may be followed up by a site inspection where particular issues or concerns are identified. Following the assessment, the EPA will issue an inspection report in the normal way through EDEN.

Powers of inspectors

Section 29 of the Primary Act sets out the powers of EPA inspectors. These cover the measures that an inspector may take either for the purpose of assessing compliance with the Act or any Regulation made under the Act or for the purpose of preventing or alleviating the escalation of danger.

For the purpose of assessing compliance with IRR19 and the Primary Act, inspectors have the power to:

- enter a premises (Section 29(3)(a));
- inspect radiation sources (Section 29(1));
- require the production of documentation (Section 29(1));
- take copies or extracts of documents (Section 29(1));
- require a person to give reasonable information for the purpose of assessing compliance (Section 29 (1));
- take with them a member of An Garda Síochána (Section 29(3)(b)).

For the purpose of preventing or alleviating the escalation of danger, inspectors have the power to:

- by direction, order persons to evacuate any land, building or other premises (Section 29 (3)(c));
- by direction, order persons to perform or refrain from performing any act (Section 29 (3)(d)).

2.2.4 ENFORCEMENT

The EPA general approach to enforcement is set out in its Compliance and Enforcement Policy 2019, which is available on *www.epa.ie*. This policy aims to promote a shared understanding of the enforcement principles and criteria underpinning enforcement decisions and to demonstrate that, in taking such decisions, there is proportionality of action, consistency of approach and transparency of process.

In deciding on enforcement action in a given set of circumstances the EPA will, subject to the provisions of the relevant legislation, take into consideration the guiding principles illustrated in Figure 2.

Figure 2: **EPA compliance and enforcement principles**

The EPA aims to work collaboratively with users of ionising radiation to promote a culture of compliance with the Regulations. However, on occasion it will be necessary for the EPA to take legal action to enforce the provisions of IRR19. The enforcement tools available to ionising radiation inspectors include:

- reports of inspection findings;
- warning letters;
- amendment of an authorisation to limit or restrict the use of source of ionising radiation in accordance with Section 30(5) of the Primary Act (commonly referred to as a licence restriction);
- serving of an enforcement notice requiring specific corrective action to be taken in accordance with Regulation 82 of IRR19;
- summary prosecutions and prosecutions on indictment.

In exceptional circumstances the EPA may, in accordance with Regulation 14(5) revoke a licence or registration.

The hierarchy of enforcement tools is illustrated in Figure 3. Where appropriate, the EPA will in the first instance seek to bring about a return to compliance through inspection findings or warning letters. In more serious cases or in situations of protracted noncompliance, inspectors will typically use enforcement notices, authorisation restrictions and or prosecutions.

Figure 3: **General hierarchy of enforcement tools available under IRR19**

2.2.5 GUIDANCE

The EPA, as part of its regulatory function, sets out practical guidance to support undertakings in complying with their legal requirements. The full list of current guidance documents is available on the EPA website (*www.epa.ie*).

2.3 DOSE LIMITATION

Regulations 23, 26 and 27 set out legally binding dose limits for exposed workers, apprentices and students and members of the public as summarised in Table 3. It should be noted that these limits apply to the sum of all exposures received by an individual. A breach of a dose limit is an offence under IRR19.

Table 3: 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

Notes:

1. Regulation 22 provides that persons under 18 years of age may not be assigned to any work that would result in them meeting the definition of an exposed worker.
2. In special circumstances the EPA may in accordance with Regulation 23(2) authorise a higher limit of up to 50 mSv in a single year subject to a maximum of 100 mSv in any five consecutive years. Before authorising the higher limit, the EPA must be satisfied that the higher dose is appropriate.
3. The dose must be averaged over any area of 1 cm^2, regardless of the area exposed.
4. Guidance on assessing dose to the lens of the eye is given in Appendix 3.

3. GOVERNANCE AND RESPONSIBILITIES

The undertaking has primary legal responsibility for compliance with the Regulations and must ensure that adequate governance arrangements are in place for the management and oversight of radiation protection. The undertaking will seek advice from a radiation protection adviser (RPA) and may delegate operational responsibility for the implementation of radiation protection arrangements to a radiation protection officer(RPO)/radiation protection unit(RPU); however, legal responsibility always remains with the undertaking and cannot be delegated to the RPA or RPO.

Knowing who is accountable and where the distinct governance roles and responsibilities sit is essential to ensuring safety for all staff. There must be evidence that governance arrangements for radiation protection are clearly defined. In the case of large institutions or undertakings with multiple sites, these arrangements may include a committee or working group to coordinate radiation safety. It is important that the governance arrangements provide for clear lines of reporting back to the undertaking so that it is aware of radiation protection issues and can act in a timely manner to address them.

The undertaking must demonstrate an understanding of and commitment to radiation protection and should work with its staff to create and maintain a good radiation safety culture within the organisation.

3.1 RESPONSIBILITIES OF THE UNDERTAKING

As outlined above, the undertaking has primary legal responsibility for compliance with the Regulations and the conditions of their authorisation. These responsibilities include, but are not limited to:

- 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;
- 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.

3.2 RESPONSIBILITIES OF STAFF

All staff must:

- comply with the relevant provisions of IRR19 and any radiation safety procedures;
- utilise any PPE and personal dosimetry where required;
- where relevant, notify the undertaking of any other workplaces where they are liable to be exposed to ionising radiation (this applies only to staff working in multiple workplaces).

3.3 KEY RADIATION PROTECTION ROLES

The RPO and RPA roles are defined in IRR19 and are critical elements of the overall system of radiation protection. The key differences between the two roles are summarised in Table 4.

Table 4: The RPO and the 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.

The BSS provides that Member States must ensure that arrangements are in place for the recognition of RPAs while they may, if appropriate, establish the arrangements for the recognition of RPOs. Under Irish law, arrangements have been provided only for the recognition of RPAs.

Regulation 79 provides that the EPA must establish criteria for the approval of RPAs, implement arrangements for approval of RPAs and maintain a register of approved RPAs. The criteria established by the EPA provide for two categories of RPA, referred to as Level 1 and Level 2. Undertakings may seek advice from a Level 1 RPA in relation to certain lower risk or lower complexity practices, while a Level 2 RPA may advise in relation to all practices. The EPA has published details of the RPA approval arrangements separately and maintains a list of approved RPAs on its website (www.epa.ie).

Regulation 80 requires the EPA to establish minimum training requirements for RPOs. These requirements are set out in Section 7.2 of this guide.

The advice set out in this guidance document is intended to give flexibility to the undertaking as to how it provides for the implementation of the RPO and RPA functions.

3.3.1 THE RPO

As noted in Section 3.1, the undertaking must put in place systems and processes to ensure that people are properly protected from ionising radiation. Specifically, Regulation 34 requires the undertaking to delegate operational responsibility either to an individual (referred to as an RPO) or to a team (referred to as a radiation protection (RP) unit) for the implementation of occupational and public radiation

protection arrangements. The EPA recognises that such arrangements will vary depending on the nature of the practices being carried out.

Where the RPO function is carried out by a unit rather than an individual, the organisational structure of the unit and the responsibilities of its individual members should be clearly documented. The head of the unit should be designated and notified to the EPA through EDEN.

The RPO or staff of the RP unit must be technically competent in radiation protection relevant to the practice(s) being carried out. In addition, the RPO should have the appropriate level of standing and authority within the organisation. Responsibility for ensuring that the person or unit appointed to carry out the functions of RPO is appropriately qualified rests with the undertaking.

The RPO/RP unit must be within the direct line management structure of the organisation. The RPO or head of the RP unit must report directly to the undertaking in matters relating to radiation protection and have a direct communication channel with senior management in the organisation. This is to ensure that an independent route is in place for the reporting of radiation safety issues to the appropriate managers and to facilitate the implementation of corrective measures. The undertaking must ensure that the RPO/RP unit has sufficient authority, time and resources to carry out the function.

The RPO/RP unit should provide links between the workplace, the undertaking, the RPA and the regulator and should be the central point of reference within an organisation for radiation protection matters.

The tasks to be undertaken by the RPO/RP unit, as set out in Regulation 34(3), may include:

- 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;
- supervising the implementation of the health surveillance programme;
- 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;

In organisations where the EPA licence conditions require a radiation safety committee (RSC), the RPO or head of the RP unit, as appropriate, should sit on the RSC.

Regulation 34(4) provides that the role of RPO or head of the RP unit may be carried out by the RPA. Where this happens, the undertaking must ensure that the requirements of both roles are fulfilled. An RPA fulfilling such a role, for example, must report directly to the undertaking on issues relating to radiation protection and have the necessary time and resources available.

Where the licence or registration covers multiple locations or premises or where the organisation is divided organisationally according to speciality, the undertaking must ensure that RPO tasks are appropriately resourced for location and speciality. Where RPO tasks are carried out by an RP unit, the undertaking must have written arrangements setting which staff are responsible for carrying out each task at each location and for each speciality. The arrangements must explicitly provide for the escalation of radiation protection issues to senior management regardless of where in the organisation they arise.

As noted above, the nature of the RPO role can vary depending on the type and scale of the organisation. The level of knowledge, experience and authority required by the RPO will consequently also vary. The EPA considers that it is a matter for each undertaking to establish the most appropriate arrangements to implement the RPO function in its individual organisation, provided that the requirements of IRR19 are satisfied. Table 5 lists some typical considerations on the establishment of appropriate RPO arrangements in sample workplace types.

Table 5: Issues to be considered when implementing RPO arrangements in some sample workplace types

Type of workplace	Considerations on the establishment of RPO arrangements
Individual dental or veterinary practices	Depending on the size of the practice the RPO function might be carried out by the dentist/veterinary surgeon themselves or delegated to a senior member of staff. An employee involved in compliance assurance or liaison with regulators may be suitable to act as an RPO. The RPO arrangements in place must be proportionate considering both the range of radiographic practices being carried out and the complexity of those practices. Where, for example, only low-risk radiological practices are involved, the RPO functions may be only a minor part of an individual's work.
Dental undertaking with multiple clinics	Considerations are generally similar to individual dental practices. For a multi-clinic undertaking, this could be a significant role and may be integrated into a broader compliance role. The arrangement should ensure that there is a consistent approach to radiation protection across all sites.
Industrial radiography	The RPO should be a person trained and experienced in industrial radiography techniques and should have an appropriate level of authority within the organisation.
Primary care centre or small satellite hospital	It is vital to ensure that radiation protection is adequately covered at each location with clear reporting lines to the undertaking in place. In most cases radiographers are likely to be central to arrangements.

Type of workplace	Considerations on the establishment of RPO arrangements
Large hospital	The RPO function is more likely to be delivered by an RP unit than an individual RPO. Factors to be considered include: ▶ Does the head of the RP unit have sufficient authority within the hospital system? In general, the role should be headed by someone in a management position. In many hospitals the head of the RP unit role rests with someone in a senior physics role or a dedicated clinical specialist RP role. ▶ Where RP staff are also responsible for clinical delivery, they should have adequate protected time to perform RP duties. The management arrangements should aim to minimise the potential for a conflict between clinical delivery and radiation protection. ▶ Where an authorisation covers multiple premises, the arrangements must ensure that the RPO functions are appropriately carried out in all departments at each location including diagnostic radiology, radiotherapy and nuclear medicine. ▶ The EPA recognises that in large hospitals the head of the RP unit is often someone who is also an approved RPA (as provided for in Regulation 34(4)). The EPA's regulatory experience suggests that this arrangement can work well, provided the RPA is an employee of the hospital.
Universities/Colleges	It is vital to ensure that the RPO arrangements cover all departments and premises where ionising radiation is used. In universities the RPO function is generally delivered either by someone from science (typically physics) who has a knowledge of ionising radiation or by someone with a broader health and safety remit. In all cases the RPO must be someone with appropriate authority and support to allow them to control the use of radiation across the institution. It may be useful to form a committee to support the RPO with membership drawn from the main departments using ionising radiation.

3.3.2 THE RPA

The role of the RPA is to give advice to undertakings or employers of outside workers on legal and operational matters relating to compliance with IRR19 concerning public and occupational exposure to ionising radiation. Regulation 2 defines an RPA as 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".

Regulation 33(1) specifies that undertakings must seek advice from an RPA or RPAs for the purposes of meeting their responsibilities for the protection of workers and the public and must provide the RPA with access, adequate information and facilities for the discharge of their functions. Regulation 33(2) specifies the range of matters on which advice should be sought from an RPA. This advice is critical to both the establishment of radiation protection arrangements and the ongoing maintenance of those arrangements.

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;

- 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;
- environmental monitoring programme;
- arrangements for radioactive waste management;
- arrangements for the prevention of accidents and incidents;
- preparedness and response in emergency exposure situations;
- training and retraining programmes for exposed workers;
- investigation and analysis of accidents and incidents and appropriate remedial actions;
- employment conditions for pregnant and breastfeeding workers.

In addition to providing advice on the range of matters listed above, the RPA(s) should act as an advocate for radiation protection within the undertaking and should proactively engage with the RPO and others with responsibility for radiation protection. In accordance with Regulation 33(4), the RPA must in the case of medical radiological practices liaise with the medical physics expert (MPE). This liaison should aim to promote coherence and consistency of approach to the implementation of S.I. No. 256 of 2018 and IRR19. Furthermore, it should be noted that EPA registration and licence conditions may set out additional requirements covering the tasks to be performed by an RPA.

In order to give advice pursuant to the Regulations, the RPA must appear on the register of RPAs published on the EPA's website. The RPA should only provide advice within their areas of competence and has a responsibility to advise the undertaking of any limitations in that regard. The responsibility lies with the undertaking in accordance with Regulation 33(1) for ensuring that the RPA they consult with has appropriate knowledge and experience relevant to the practice being carried out.

The level of involvement of the RPA should be commensurate with the scale of the organisation and the complexity of the practices being undertaken. For an organisation carrying out only registered practices such as the use of an X-ray fluorescence (XRF) analyser, dental radiography using orthopantomography (OPG), RPA involvement would typically include detailed advice at the early stages of setting up, updates to the risk assessment as necessary and the provision of periodic training and QA testing. A RPA should also be consulted following modifications/ upgrades of registered equipment e.g. OPG upgrade to cone beam CT (CBCT).

RPA involvement in larger organisations carrying out licensed practices (e.g. a hospital carrying out multiple radiological procedures) would generally be extensive, requiring regular on-site presence of the RPA.

The type of service provided by an RPA will ordinarily depend on the nature of the practice and facilities in question and on the agreed arrangements in place with the undertaking or employer. An RPA may provide advice on the full range of radiation protection issues or may provide specialized advice on certain topics. Furthermore, an RPA may operate as an independent professional adviser, a corporate body providing RPA services or a member of staff of the undertaking or employer.

Licensees are required under Regulation 33(3) to devise agreed arrangements with their RPA(s) detailing the nature of the service provided. These arrangements must specify the areas of RPA competencies, the radiological practices, the scope of advice provided and the sites covered. For external RPAs the arrangements should also include the allocated time both on site and off site for RPA duties. EPA standard licence conditions require that the identity of the RPA or RPAs be notified through EDEN.

3.3.3 THE RADIATION SAFETY COMMITTEE (RSC)

Undertakings must have in place appropriate arrangements to facilitate coordination and cooperation between senior management, staff and contractors with responsibilities for radiation protection. For certain types of workplace, the EPA authorisation conditions include a requirement to establish a RSC for this purpose. This typically arises in large hospitals or universities where responsibility for radiation protection may span multiple departments, buildings or sites.

The RSC should provide high-level oversight of the implementation of radiation protection requirements and should promote safety culture across the workplace. The RSC must meet at least twice per year. The membership should cover all relevant departments or units using radiation and should include the RPO, the RPA and senior managers with delegated responsibility for radiation protection. The RSC must have written terms of reference, which should include, as a minimum, the purpose of the committee, membership, responsibilities, arrangements for setting and distributing meeting agendas, meeting frequency, quorum, arrangements for chairing meetings and arrangements for administrative support. The terms of reference may be incorporated into the radiation safety procedures.

EPA inspectors may seek evidence of arrangements for the coordination of radiation protection. Where the authorisation conditions require a RSC, such evidence may include the terms of reference, minutes of recent RSC meetings and action lists generated from RSC meetings.

3.4 DIVISION OF RESPONSIBILITIES BETWEEN UNDERTAKINGS AND EMPLOYERS

Responsibilities for the protection of workers may fall to the undertaking, the employer of outside workers or both, depending on specific circumstances. The essential distinction between the responsibilities of the undertaking and the employer of an outside worker is set out in Regulation 29:

- The undertaking is responsible for *assessing and implementing radiation protection* arrangements (for all workers including outside workers) – Regulation 29(1).
- The employer of an outside worker is responsible for the radiation protection of its workers in accordance with IRR19 (either directly or through contractual agreements with the undertaking) – Regulation 29(3).

Regulation 29(2) specifies that undertakings may exercise their responsibility for operational radiation protection of outside workers either directly or through contractual agreements with the employer of outside workers, including the sharing of information directly related to the nature of their work.

Further clarity on the responsibilities of employers of outside workers is provided in Regulation 37(8), which provides that "the employers of outside workers must ensure either directly or through contractual arrangements with the undertaking that the radiation protection of their workers is equivalent to the protection afforded to exposed workers employed on a permanent basis by the undertaking".

In order to ascertain the division of responsibilities between the undertaking and the employer of an outside worker in a specific exposure situation, it is necessary firstly to be clear in relation to:

- Who is the undertaking?
- Are the exposed workers involved outside workers or employees of the undertaking?

Who is the undertaking?

Regulation 2 defines the undertaking as the entity with "legal responsibility under these Regulations for the carrying out of a practice". **The EPA interprets this to mean that the undertaking is the legal entity holding the authorisation (registration or licence) under which the practice is being carried out**. In effect this means that the identity of the undertaking is more likely to be determined by who is authorised for the practice rather than by the institution in which the exposure occurs.

Which exposed workers are outside workers?

Regulation 2 defines an outside worker as "any exposed worker who is not employed by the undertaking responsible for the supervised and controlled areas but performs activities in these areas". **The EPA interprets this to mean that any exposed worker not directly employed by the undertaking legally responsible for the practice is an outside worker.**

In certain exposure situations the contractual agreements between the parties will be critical to determining the identity of the undertaking and whether the exposed workers involved are outside workers.

Some sample scenarios where exposed workers may be outside workers are set out in Table 6.

Table 6: Example scenarios: classification of workers

Type of worker	Classified as outside worker?
Technical service provider (such as industrial radiographer)	In most circumstances the technical services provider will be the undertaking as it holds the authorisation and controls the controlled/supervised area during the authorised practice. Consequently, its workers should not be classified as outside workers.
Self-employed medical practitioner carrying out medical radiological procedures in a hospital under the hospital's authorisation	The hospital is the undertaking as the practice is being carried out under its authorisation, therefore exposed workers will be outside workers. However, both will have responsibilities respectively under Regulations 29(1) and 29(3). The hospital will be responsible for assessing and implementing radiation protection arrangements while the self-employed worker (as an employer) will be responsible for ensuring that those arrangements are in place.
Medical practitioner carrying out medical radiological procedures in a hospital that is not their direct employer on behalf of their employer	Exposed workers are likely to be outside workers subject to the contractual agreements. In such situations the employer must ensure, either directly or through contractual agreements with the undertaking, that the radiation protection of its outside workers is in accordance with the relevant provisions of IRR19 (Regulation 29(3)).

Type of worker	Classified as outside worker?
Provider of outsourced radiology services within a hospital, i.e. the hospital's radiology services are run by a contractor	The service provider (contractor) is likely to be the undertaking where: (1) the service provider holds the authorisation and (2) contractual agreements are in place that assign responsibility for controlled/supervised area to the service provider during the authorised practice. In such circumstances the service provider's employees should not be classified as outside workers.
Agency staff working in a radiology department	Where it is determined that the agency staff are outside workers, the hospital will be responsible for assessing and implementing radiation protection arrangements while the agency will normally be responsible for ensuring that those arrangements are in place. In many situations it is likely that the hospital with take direct responsibility for their radiation protection and so for practical purposes they can be treated as if they were directly employed. The division of responsibility should be clearly set out in the contractual arrangements.

3.5 TRANSFER OF RESPONSIBILITY FOR RADIATION PROTECTION DURING INSTALLATION AND SERVICING OF RADIOLOGICAL EQUIPMENT

Where a service company installs or services radiological equipment at the premises of a customer such as a hospital, the division of responsibility for radiation protection between the service company and the customer must be clear at all times. This division of responsibility must be documented through contractual agreements before any work commences.

The Regulations provide for two possible governance arrangements covering installation/servicing work, as follows:

1. The service company is authorised by the EPA for the practice of installation and servicing of radiological equipment and formally takes responsibility for operational radiation protection during the installation/service through contractual agreements with the customer. In this case, the service company acts as the undertaking during the specified work.

2. The customer retains responsibility for radiation protection and so the employees of the service company (if exposed workers) are deemed to be outside workers. In this case the customer remains the undertaking at all times.

In the absence of appropriate contractual agreements and an EPA authorisation for the service company, the customer (i.e. the institution in which the work takes place) is considered to be the undertaking.

If a service company that is based outside the state wishes to act as an undertaking, it must obtain an authorisation from the EPA. Such companies must ensure that they comply fully with Irish Regulations and should for this purpose consult with an RPA on the EPA's register of approved RPAs.

Where the staff of a service company have been categorised as exposed workers, they must be subject to individual monitoring and medical surveillance in accordance with Irish Regulations. This means, for example, that individual monitoring must be carried out for all exposed workers (regardless of whether they are category A or B as described in Section 4.5). Furthermore, the relevant dosimetry and medical surveillance records must be available to an EPA inspector irrespective of who the undertaking is or where the service company is based. Where the service company is based in an EU Member State (MS) other than Ireland, the dosimetry data provided by a dosimetry service approved in that MS may, subject to the approval of the EPA, meet the requirements of Regulation 41.

3.6 CONTRACTUAL AGREEMENTS BETWEEN UNDERTAKINGS AND EMPLOYERS

It is vital that the contractual agreements between undertakings and employers specify unambiguously the responsibilities for radiation protection at each step of a planned exposure. Such agreements must clearly specify responsibility for controlled and supervised areas when any practices regulated under IRR19 are being carried out and should include, *inter alia*:

- detail of assigned responsibilities for the controlled/supervised area during the authorised practice;
- details of who is responsible for radiological protection of workers – employer or undertaking;
- specific operational arrangements, e.g. designated contact persons, exchange of information in relation to risk assessments and radiation safety procedures, controlled area handover procedures/ forms, record keeping;
- compliance with optimisation principles and dose limits;
- responsibility for dosimetry and records management (e.g. who is providing the dosimeter and monitoring the results – the undertaking or the employer?);
- provision of appropriate PPE (who is responsible for providing it, etc.);
- provision of appropriate radiation protection training (who provides which training, etc.).

For outside workers the employer must take direct responsibility for organisation of medical surveillance. The undertaking must ensure that such workers have been classified as medically fit before commencing work.

Where a third party takes over responsibility for radiation protection during installation or service of equipment, the contractual arrangements must provide a clear line of sight of responsibility for radiation protection at each stage in the process as discussed in Section 6.1.2.

3.7 COMPLIANCE WITH DOSE LIMITS WHERE EXPOSURE OCCURS IN MULTIPLE WORKPLACES

Workers may be exposed to radiation in multiple workplaces under the control of different undertakings. It is important to note that the dose limits set out in Regulation 23 apply to the sum of the exposures received across all workplaces. The relevant undertakings/employers, therefore, should cooperate to ensure that the total exposure is kept below the relevant dose limit(s). This may involve the sharing of information relating to radiation exposure of workers including:

- estimates of potential exposures for the purpose of completing the risk assessment (Section 4);
- dose monitoring records and estimates doses received, where these are not included in the dose record, for the purpose of managing compliance with the dose limits and assessing whether protection has been optimal.

IRR19 provides two mechanisms for the sharing dosimetry information between undertakings or employers for the purposes of carrying out a risk assessment (Regulation 31(6)) and the categorisation of workers (Regulation 39(2)).

These are:

1. In accordance with Regulation 37(7), undertakings must ensure that for each *outside worker* working in their controlled area, an estimate of the dose received is entered into the radiation passbook as soon as is reasonably practicable after work has been carried out.

2. In accordance with Regulation 50(1)(e), *exposed workers* must disclose to the undertaking details of other undertakings under whose control the worker is liable to be exposed. Where an exposed worker discloses such, the undertakings must share information in accordance with the mechanism summarised in Figure 4.

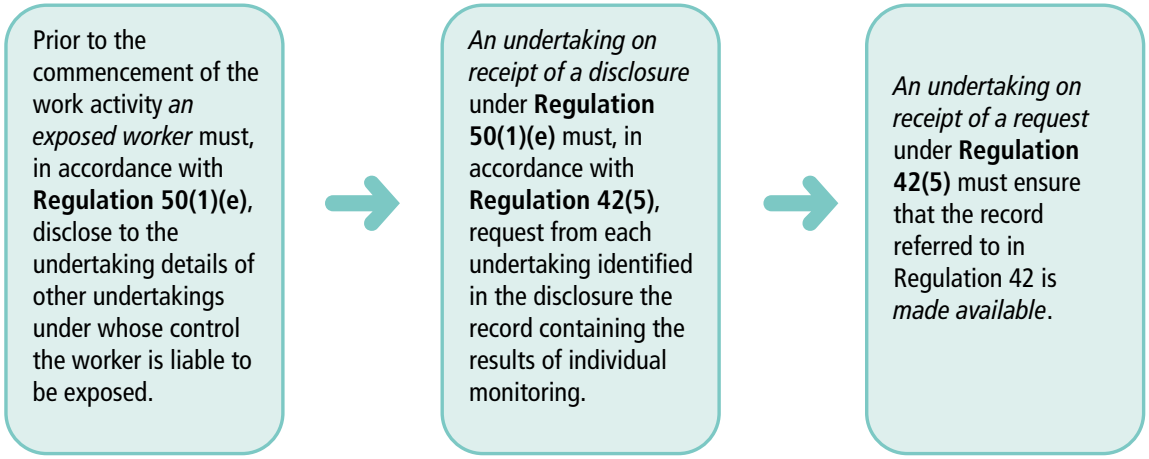

Figure 4: Exchange of information between undertakings on receipt of a declaration

It is noted that where exposed workers regularly move between institutions, the information provided on a radiation passbook may not be sufficiently "real time" to allow for effective management of doses. It is also recognised that in such situations it will not always be clear whether the exposed worker is in fact an outside worker. Therefore, the EPA recommends that regardless of whether passbooks are used, undertakings should take all reasonable steps to encourage and facilitate disclosure by exposed workers in line with Regulation 50(1)(e).

In situations where staff routinely work in multiple workplaces, the relevant undertakings and employers should put in place documented arrangements for the proactive management of exposures so as to ensure the optimisation of protection and compliance with dose limits. These documented arrangements may form part of the contractual agreements between undertakings and employers as set out in Section 3.6 above.

Such agreements should cover, *inter alia*:

- the sharing of dosimetry data using the mechanism described in Section 3.6, a radiation passbook or a combination of the two;
- the sharing of relevant information from the risk assessment;
- measures to educate workers on the importance of sharing information on exposure in accordance with Regulation 50;
- proactive management of exposure where the cumulative dose reported by the dosimetry service is approaching a dose limit. Such arrangements should take into account actual doses reported on the dosimeter, estimated exposure since the last dosimetry report and potential exposure from incidents.

Notwithstanding the above, it should be noted that in situations where a dose limit is exceeded, the undertaking responsible for the exposure at the point at which the limit was exceeded will in accordance with the law be deemed to have been responsible for the exceedance.

4. THE RISK ASSESSMENT

The risk assessment is fundamental to ensuring that radiation protection in the workplace is optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable.

The purpose of the risk assessment is to identify control measures which minimise exposure of workers and members of the public to ionising radiation and ensure that doses are kept below the limits set out in Regulation 23. A comprehensive and well executed risk assessment is essential to ensuring that all individuals either directly involved in or potentially impacted by the practice are afforded the required protection from exposure to ionising radiation.

The risk assessment must take account of the nature and magnitude of the risks of exposure to radiation for staff and members of the public from normal operations (expected exposures) as well as from reasonably foreseeable incidents and accidents (potential exposures).

The undertaking must carry out the risk assessment in consultation with an EPA-approved RPA who has appropriate radiation protection experience relevant to the practice being assessed. It is important that a multidisciplinary approach is taken to ensure that all staff who have knowledge of the operational and working conditions associated with the practice are consulted and have an input into the risk assessment process. The risk assessment should be signed by the person(s) who completed it and the RPA involved. Other people who were consulted during the assessment process should also be recorded.

Regulation 31(2) requires that a risk assessment is completed before commencing a practice and that it must be in a form acceptable to the EPA. This document sets out a recommended framework for risk assessments that aims to assist undertakings in meeting this requirement. All risk assessments must be documented and readily available for inspection by EPA inspectors.

The risk assessment must be reviewed periodically, and immediately if circumstances arise whereby it is no longer adequate and appropriate, for example changes to working conditions or workloads. The frequency of periodic review will depend on the nature of the practice and must be determined by the undertaking in consultation with their RPA.

If the risk assessment provided by the undertaking is deemed insufficient or inadequate by the EPA, a notice in writing may be issued requiring the undertaking to furnish the EPA with the relevant additional information required after consultation with an RPA as set out in Regulation 31(4).

4.1 RISK ASSESSMENT FRAMEWORK

The EPA has developed a risk assessment framework that comprises two distinct stages:

1. **The design stage:** The purpose of this stage is to identify the design control measures that must be incorporated into the building or work area during construction and fit-out to allow the practices to be carried out safely. These measures may include room layout; shielding of walls, doors and windows; permanent barriers to restrict access; and other engineered control measures. In general, design control measures should not be dependent on human behaviour for their effective operation.

2. **The operational stage:** The purpose of this stage is to determine the operational control measures required to safely carry out the practice. These measures may include radiation safety procedures, radiation safety training, emergency procedures and the use of PPE. In

general, operational controls will depend to some degree on human behaviour and so the implementation will involve appropriate training and management oversight.

The relative importance of the design and operational control measures to the overall optimisation of protection will vary depending on the nature of the practice being assessed. For example, for practices not carried out at fixed locations (such as site non-destructive testing (NDT) radiography or site veterinary radiography), there may be limited opportunity to control exposures through design measures (such as building shielding or engineered access controls). In such situations the optimisation of protection will require a greater reliance on operational control measures identified through Stage 2. Conversely, for practices such as external beam radiotherapy the design control measures such as shielding (Stage 1) will be critical to the optimisation of protection.

As a general rule, people should be protected from radiation to the greatest extent practicable through design control measures that are independent of human behavioural factors. The design measures should be supplemented as necessary with operational control measures to fully optimise radiation protection. Operational control measures should normally be considered in the optimisation process in the following order: procedures & training, education and the use of personal protective equipment.

This risk assessment should start with the identification of appropriate dose constraints on which the controls measures should be based. Dose constraints are based on optimised protection and should not be confused with dose limits.[1] In general, the use of a dose constraint is appropriate for members of the public who may be exposed as a result of a practice.

It is noted also that there are some inherently low-risk radiological practices, where the radiation protection issues are not likely to be complex. Typical practices falling into this category include the use of a cabinet X-ray unit or an X-ray unit for scanning mail. In such cases, completing the risk assessment may be a relatively simple process. The assessment will typically involve a critical review of the inbuilt safety measures and advice provided by the manufacturer or supplier of the device intended for use.

4.2 DESIGN STAGE

The design stage of the risk assessment must be completed prior to the installation and commissioning of all sources of ionising radiation.

Each installation must be assessed separately taking account of the specific characteristics of the location and specification of the equipment to be used. Factors to be considered at the design stage include, at a minimum:

- nature of the radiation source;
- output of the radiation source;
- position of the radiation source in the room;
- orientation(s) of the radiation beam;
- typical annual workload of the system;
- occupancy of areas adjacent to the room.

The design controls must be such that doses remain below the relevant dose constraints without operational controls in place. In accordance with Regulation 20, dose constraints shall be established in

1 It should be noted that optimisation and dose limitation are separate elements of the system of protection and so it is important not to confuse dose constraints and dose limits.

accordance with guidelines issued by the EPA. Current EPA guidance is summarised in Table 7. The EPA may from time to time publish additional guidance on its website.

Table 7: EPA guidelines on design dose constraints

Exposure situation	Design dose constraint
Exposure to members of the public or workers outside of a controlled or supervised area.	Not greater than 0.3 mSv in a year to the most exposed individual
Instantaneous dose rate (IDR) used in the design of shielding and building layout in a radiotherapy facility.	30 µSv/h

In assessing compliance with the dose constraints for medical applications, account should be taken of the principles and approach set out in the EPA's guidance document *"The Design of Diagnostic Medical Facilities Where Ionising Radiation Is Used"* (2009). Design control measures should be future-proofed by taking into account any likely or reasonably foreseeable changes in workload, occupancy of surrounding areas or other factors likely to impact on exposures. Planning of a new build must take place in consultation with an RPA and all relevant stakeholders should be involved, including, as appropriate, the supplier/builder and the architect.

Outputs from the design stage of the risk assessment must include, at a minimum:

- the building layout and shielding requirements for the installation;
- the required engineered control measures including access controls and safety/warning devices such as emergency stops & interlocks;
- the classification of areas as controlled or supervised as appropriate (see Section 4.4);
- a map of the dose rates at various strategic locations within the room, such as wall boundaries, doors and potential operator positions. Typical and maximum dose rates should be determined. These dose rates will be used at the operational stage of the risk assessment to estimate expected and potential doses to staff.

4.3 OPERATIONAL STAGE

The operational stage of the risk assessment should identify the control measures necessary to ensure that the doses received by workers and members of the public during the conduct of the practice remain below the relevant dose limit (see Section 2.5) and their protection is optimised. Both the expected exposures arising from the practice during normal operations and the potential exposures from reasonably foreseeable incidents must be considered.

The operational stage of the risk assessment should take account of the following, at a minimum:

- dose rates at strategic locations identified as part of the design stage of the risk assessment, which, where appropriate, have been verified through measurement;
- design control measures in place;
- type(s) of procedure and the environment in which they will be carried out;
- individuals or groups at risk including workers and members of the public and, where applicable,

their typical workloads, level of involvement in the procedures and positions with respect to the radiation source;

- results of any previous personnel dosimetry or area monitoring relevant to the proposed work;
- where appropriate, dose constraints as recommended by the RPA;
- advice from the manufacturer or supplier of equipment about its safe use and maintenance;
- potential exposures to staff and members of the public from reasonably foreseeable incidents.

Exposure to all persons in the vicinity of the radiation source must be considered, including, where applicable, operators, support staff, maintenance personnel, contractors, cleaners and members of the public. In most cases the assessment of radiation exposure can be done by staff group, where the nature of the work and the level of involvement in the procedure is relatively uniform across the group. In some cases, however, it will be necessary to assess staff on an individual basis. This might arise, for example, in the case of cardiologists who perform specific types of procedures or use different techniques. The risk assessment must identify the operational control measures required to ensure that radiation exposure of each staff group/individual during normal operations is as low as reasonably achievable.

The following types of measures should be considered:

- operational measures to restrict access;
- radiation safety procedures;
- radiation safety training for staff;
- general information for staff and members of the public in the vicinity (including signage);
- emergency procedures/contingency plans to deal with reasonably foreseeable incidents and accidents;
- use of appropriate PPE (lead aprons, masks, gloves, lead glasses, screens, personal dosimeters, etc.).

In identifying reasonably foreseeable incidents or accidents, the following types of incident/accident should be considered at a minimum:

- failure of engineered control measures such as interlocks/safety and warning systems;
- failure of operational controls such as operator not using PPE/using damaged PPE, or a person enters the controlled area during a procedure;
- failure of exposure to terminate;
- loss or theft of radiation source;
- physical damage to source/X-ray unit;
- malfunction of radiological equipment.

For each reasonably foreseeable incident identified, the risk assessment should identify the additional operational controls required to reduce the likelihood of such an incident and to mitigate the effects of the incident should it occur.

Once the required operational controls have been identified, the risk assessment should evaluate the expected and potential doses to staff. These estimates will form the basis for the categorisation of workers (see section 2.5).

4.3.1 PRACTICES LIABLE TO LEAD TO EXPOSURE TO THE LENS OF THE EYE

Where the RPA considers that a practice has the potential to result in significant exposure to the eyes of the workers involved, the operational risk assessment should include an estimate of the expected and potential eye dose in accordance with Appendix 3. Practices liable to result in significant exposure to the lens of the eye include:

- interventional radiology;
- interventional cardiology;
- nuclear medicine & PET-CT;
- manual brachytherapy;
- industrial radiography.

4.3.2 INFREQUENT HIGH-DOSE EVENTS

It is noted that it will not be practicable in all circumstances to make a realistic quantitative estimate of annual potential doses. There are some practices for which the likelihood of an incident occurring is low; however, the severity of such an incident is high in terms of the potential dose a worker could receive. Such practices include site industrial radiography or high dose rate brachytherapy. An industrial radiographer/radiation therapist using a HASS source could be expected to receive relatively low doses under normal circumstances due to strict engineering and operational control measures. The probability of an incident occurring is also low, due to advances in technology and reliability of the equipment.

However, the possibility of an incident, such as an equipment malfunction leading to the source getting stuck or falling out, remains, and so workers could potentially be exposed to very high dose rates and exceed dose limits in a matter of seconds should such an incident occur. In such cases a precautionary approach should be taken and the need for control measures should be identified on the basis that any such reasonably foreseeable incidents do occur. Typically, such a precautional measure would include the use of personal dosimetry.

4.3.3 ESTIMATING DOSES WHERE WORKERS MAY BE EXPOSED IN MULTIPLE UNDERTAKINGS

Dose limits apply to *the sum* of all occupational exposures received by an individual across all planned exposure situations. Noting that workers may be exposed to radiation in multiple workplaces under the control of different undertakings, the risk assessment, therefore, must take account of all work performed by the individual, including that performed in other workplaces. As discussed in Section 3.6, workers are required under the Regulations to disclose to the undertaking details of other undertakings under whose control they are liable to be exposed. Undertakings should make arrangements to share information relating to radiation exposure of their workers for the purposes of:

- completing the risk assessment in accordance with Regulation 31(6);
- categorisation of workers in accordance with Regulation 39(2).

4.3.4 OUTPUTS FROM THE OPERATIONAL STAGE OF THE RISK ASSESSMENT

Outputs from the operational stage of the risk assessment must include, at a minimum:

- operational control measures required, such as:
  - radiation safety procedures
  - planned systems of work
  - radiation safety training
  - PPE
- expected doses to staff and members of the public with operational control measures;
- potential doses to staff and members of the public from reasonably foreseeable incidents and accidents;
- the categorisation of workers as Category A, Category B or non-exposed as appropriate (see Section 4.5);
- programme of individual dose monitoring for staff where necessary;
- programme of radiological surveillance of the workplace where necessary;
- emergency procedures/contingency plans to deal with reasonably foreseeable incidents.

4.4 CLASSIFICATION OF WORKPLACES

Regulation 2 defines:

- a "controlled area" as an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled. **The EPA interprets "special rules" to mean "operational control measures";**
- a "supervised area" as an area subject to supervision for the purpose of protection against ionising radiation.

Regulation 36 specifies that the undertaking must, on the basis of the risk assessment, classify areas within the workplace as controlled or supervised areas according to the expected annual doses and the probability and magnitude of potential exposures. Regulation 37 sets out the requirements for both controlled and supervised areas that are summarised in this section.

The EPA interprets Regulation 36 to mean that an area must be classified as a controlled area where the risk assessment determines that operational control measures are required to ensure the optimisation of protection. In other words, a controlled area is an area where radiation protection cannot be optimised solely through design control measures.

In line with Regulation 36(2), other areas within the workplace subject to supervision for the purpose of radiation protection must be classified as supervised areas.

Classification of workplaces should be based on the assessment of risk and not solely on historic dosimetry results. Many workers in controlled areas will receive no occupational doses because of the control measures in place; however, the area will still be subject to special rules or operational control measures and so remains a controlled area.

It should be noted that categorisation of workers and classification of areas are independent outputs from the risk assessment. It is not the case that a person working in a controlled area is necessarily an exposed worker. Similarly, an area does not necessarily become a controlled area because an exposed worker works there.

4.5 CATEGORISATION OF WORKERS

In accordance with Regulation 39, the undertaking or employer, as appropriate, must determine whether or not workers are categorised as exposed workers (Category A or B) prior to the commencement of any work activity that may give rise to an exposure. The categorisation must be based on the risk assessment and must be done in consultation with the RPA.

The categorisation of workers should be based on the doses that workers are "liable to receive" rather than on actual measured exposures. The dose that a worker is liable to receive is the sum of **expected doses from routine operations** and **potential doses from reasonably foreseeable incidents**, taking into account all practices in which the worker is involved. This means that while historic dosimetry records may form part of the risk assessment, they should not be the sole basis on which categorisation decisions are made. Both expected and potential doses should be estimated on an annual equivalent basis from the risk assessment. The categorisation should also take into account low-probability high-consequence events, for which it is not meaningful to determine annual equivalents.

The **expected dose from routine operations** is the estimated dose to personnel working in controlled or supervised areas with all operational control measures in place.

For each reasonably foreseeable incident identified in the risk assessment, the dose per incident and the likely annual frequency of occurrence should be estimated. These are then multiplied together to determine the **potential dose from reasonably foreseeable incidents**. If, for example, the risk assessment identifies failure to wear a lead apron in an interventional suite as a foreseeable incident, the risk assessment should estimate the dose from carrying out a procedure without the apron together with the number of times in a year this is likely to occur.

The EPA interprets the "liable to receive" provision in Regulation 39 to mean that the workers should be categorised as exposed workers where:

- It is 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 in Table 8; **OR**
- The nature of the practice is such that the potential exists for low-probability high-consequence incidents, protection is dependent primarily on operational controls and the risk assessment cannot demonstrate conclusively that in all reasonably foreseeable circumstances that dose will be below public dose limits. Practices that typically fall into this category include field use of radiographic techniques or applications using HASS.

Regulation 39 requires that workers are categorised as exposed workers if they are **liable to receive** an effective dose greater that 1 mSv in a year or an equivalent dose greater than 50 mSv in a year for extremities or skin or 15 mSv in a year for the lens of the eye.

Exposed workers are designated as Category A or Category B depending on the effective or equivalent doses that they are deemed liable to receive on the basis of the risk assessment (see Table 8). It should be noted that the public dose limit is applicable to any worker whom the undertaking has not categorised as an exposed worker. For convenience, the public dose limit is also shown in Table 8.

Table 8: Dose thresholds for categorisation of exposed workers

	Category A	Category B	Public dose limit
Effective dose	>6 mSv/y	1–6 mSv/y	1 mSv/y
Equivalent dose to lens of eye	>15 mSv/y	NA*	15 mSv/y
Equivalent dose to skin and extremities	>150 mSv/y	50–150 mSv/y	50 mSv/y

* Category B is not applicable to workers categorised on the basis of eye dose.

In all cases the EPA will seek to confirm that the decision to categorise workers is based on a robust and detailed risk assessment and that the information, calculations and assumptions underpinning it are accurate, site-specific and evidence-based.

Worked Example of Categorisation

A nurse working in Cardiology has an estimated dose of 0.6 mSv per year working with all operational controls in place. The RPA identifies failure to wear PPE as a reasonably foreseeable incidents and estimates that the nurse could receive approximately 1 mSv additional dose should that incident occur. The RPA estimated that this incident could potentially happen twice per year. The nurse would be deemed liable to receive approximately 2.6 mSv and should therefore be categorised as a Category B worker

4.5.1 CATEGORISATION OF WORKERS WITH MORE THAN ONE UNDERTAKING

The categorisation of workers must also consider, where relevant, exposures received while under the control of any other undertakings. As set out in Section 3.6, Regulation 50 requires that workers disclose to the undertaking details of other undertakings under whose control they are liable to be exposed. Undertakings should make arrangements to share information relating to radiation exposure of their workers and this information should be considered as part of the risk assessment. It should be noted that for the purpose of assessing compliance with annual dose limits, the sum of the dose received in all workplaces should be taken into account. If a worker exceeds a dose limit, the undertaking under whose control they are working at the point when the dose limit is exceeded is deemed to be responsible.

4.5.2 RESPONSIBILITY FOR OTHER PERSONS WORKING IN A CONTROLLED OR SUPERVISED AREA

Undertakings are responsible for the protection of all those working in controlled or supervised areas regardless of whether they have been categorised as exposed workers. As noted above, the public dose limits are applicable to anyone not categorised as an exposed worker.

A decision not to categorise a person working in a controlled area, made on the basis that they are not liable to receive a dose in excess of 1 mSv/year due to the control measures in place, only remains valid if those control measures, such as training, procedures and PPE requirements, are implemented in practice. Take, for example, a healthcare assistant accompanying a patient to and from the nuclear medicine department in a hospital. While it may be valid not to categorise the healthcare assistant as an exposed worker, the undertaking is still responsible for ensuring that appropriate radiation safety measures are in place and that adequate training is provided.

Undertakings must ensure that all required control measures are fully implemented and should verify this through regular audits. EPA inspectors may require the undertaking to provide evidence that persons working in a controlled or supervised area have been appropriately categorised.

4.6 REVIEW AND MAINTENANCE OF THE RISK ASSESSMENT

The risk assessment must be reviewed if there is any change to the conduct of the practice such that the assumptions underpinning the original assessment are no longer valid. For example, the introduction of a new piece of equipment with a higher radiation output, an increase in workload, the introduction of a new type of procedure, and change in occupancy of adjacent rooms should all trigger a review of the risk assessment.

Even where there are no obvious changes, the risk assessment should be reviewed at least annually for licensed practices and every two to four years for registered practices. These periodic reviews may consist of simply confirming that previous assumptions are valid, the required protective measures are in place and radiation dose to staff is optimised from the conduct of the practice. At a minimum, periodic reviews should seek to verify that:

- All assumptions underpinning the risk assessment remain valid.
- There have been no changes to radiological practices being carried out.
- There has been no change to radiological equipment relevant to radiation safety.
- There have been no changes to building structure or layout material to radiation safety.
- There have been no changes to the existing risk assessment.

5. OPERATIONAL RADIATION PROTECTION

5.1 RADIATION SAFETY PROCEDURES

The undertaking must ensure that radiation safety procedures are in place and available to all staff. The procedures must be developed in consultation with an RPA, taking into account the outcome of the risk assessment. They should set out the operational measures necessary for optimising the protection and safety of people during normal working conditions and in the event of incidents or accidents. The undertaking must take all reasonable steps to ensure that the provisions of the documented radiation safety procedures are complied with.

The undertaking must provide staff with adequate training and periodic refresher training to enable them to comply with the radiation safety procedures. These procedures must be brought to the attention of and made available to the exposed workers including outside workers, apprentices and students concerned, and other persons who may be affected by them.

The radiation safety procedures must be reviewed periodically and updated whenever there is any change to facilities, equipment or procedures liable to impact on the protection of people. The procedures may be reviewed by the EPA when reviewing a licence application or amendment and during inspections.

When the EPA is satisfied that any radiation safety procedures are inadequate, it may give a direction to the undertaking concerned under Regulation 32(4) to amend the procedures after consultation with an RPA. The undertaking is legally obliged to comply with the direction within 30 days from the date of the direction given by the EPA.

The radiation safety procedures must cover as appropriate in line with the risk assessment:

- measures to control access to controlled and supervised areas including the use of interlocks, warning signs, lights and audible alarms;
- operational control measures to protect those working in a controlled or supervised area;
- measures to protect the general public or those outside of the controlled or supervised area;
- the use of radiological surveillance, PPE or dosimetry (including instructions on their wear and storage);
- safety of radiological equipment;
- safety of radioactive sources;
- measures to be taken in the event of a radiological incident or accident.

5.2 CONTROLLED & SUPERVISED AREAS

Undertakings must put arrangements in place to ensure that their controlled and supervised areas, as determined by the risk assessment, meet the requirements of Regulation 37.

For controlled areas, these arrangements must include:

- physical demarcation or delineation of the area;

- signage indicating that the area is controlled and displaying the nature and risks of the radiation source(s);
- where appropriate, measures to prevent and monitor radioactive contamination within and around the controlled area; for example, washing and changing facilities, protective clothing/ overshoes, contamination monitors/survey meters;
- where appropriate, radiological surveillance of the workplace (Section 5.3).

Access must be restricted to individuals who have received appropriate instructions and training relevant to the specific workplace and the activities being carried out in the controlled area. These individuals must follow the radiation safety procedures or other written work instructions. Each person working in the controlled area must be provided with the appropriate PPE and trained in its correct usage.

Persons who are not categorised as exposed workers may only enter or remain in the controlled area provided they are following suitable written arrangements for the purpose of ensuring their annual dose does not exceed 1 mSv and the undertaking can demonstrate by personal dose monitoring or other appropriate measurements that this dose limit is not exceeded.

In relation to outside workers, undertakings must confirm that:

- Category A workers have been passed as medically fit;
- the categorisation for Category B workers is appropriate taking into account the doses liable to be received within the undertaking.

Requirements for supervised areas include radiological surveillance and signage as appropriate. Again, persons working in supervised areas must be given appropriate instructions and training relevant to the specific workplace and the activities being carried out in the area.

5.3 RADIOLOGICAL SURVEILLANCE OF THE WORKPLACE

Depending on the nature and extent of the radiological risks in a controlled or supervised area, it may be necessary to carry out radiological surveillance in accordance with Regulation 38. Such surveillance may include measurements, for example, of external doses rates, activity concentration in air or surface density of contamination. The need for radiological surveillance and the nature of the measurements to be included must be identified as part of the risk assessment. The radiological surveillance programme must be designed in consultation with the RPA and documented in the radiation safety procedures. The procedures must specify:

- nature of the radiological surveillance to be carried out;
- measuring instruments to be used;
- monitoring frequencies;
- monitoring locations;
- training in the use of monitoring equipment;
- list of personnel responsible for performing the measurements;
- calibration required for the measuring instruments and frequency at which this must be conducted.

The undertaking must ensure that the results of all radiological surveillance measurements are recorded and maintained. These results can be used, if necessary, for estimating individual doses where a dosimeter is unavailable, in accordance with Regulations 41(2) and 41(3). In addition, records must be maintained of maintenance and calibrations carried out on measuring instruments used for radiological surveillance measurements.

The calibration records maintained for measuring instruments used in QA programmes must be retained in accordance with Appendix 4 and the undertaking must ensure that these records are made available to the RPA or an EPA inspector when requested.

5.4 PROTECTION OF INDIVIDUALS

5.4.1 INDIVIDUAL MONITORING

The undertaking must arrange for individual monitoring of exposed workers so as to ensure that radiation protection is optimised, and that no occupationally exposed worker receives a dose in excess of the relevant dose limit.

Personal dosimeters must be provided by an approved dosimetry service where the risk assessment indicates that a worker is **liable to receive** doses in excess of one of the thresholds set out in Table 9. The type of dosimeter and the instructions for use must be determined in consultation with the RPA as part of the risk assessment. Dosimeters must be of a type approved under the EPA Approval of Dosimetry Services scheme. A list of approved dosimetry services is available on the EPA website.

While it is reasonable to expect that approved dosimeters would be accurate under the conditions within which they have been calibrated, the accuracy of individual dose assessments based solely on dosimetry may be limited by factors such as user compliance with wearing instructions or differences in the radiation characteristics. It is recommended, therefore, that where measured doses approach a dose limit or are high relative to what would ordinarily be expected for a particular practice or work activity, the practical dosimetry arrangements should be kept under review by an RPA, a physicist or another appropriate expert. Such a review should consider whether the dosimetry represents a true reflection of the dose received taking into account factors such as the nature of the radiation, the characteristics of the dosimeter, beam energy, beam angle and real-life use of dosimeters.

Table 9: Dose thresholds for individual monitoring

Type of exposure	Dose threshold	Dosimetry requirements
Effective dose	1 mSv/y	$H_p(10)$ worn under lead apron or other PPE
Equivalent dose to skin or extremities	50 mSv/y	$H_p(0.07)$ extremity dosimeter worn unshielded in accordance with the risk assessment
Equivalent dose to lens of the eye in an inhomogeneous field (e.g. radiation fields associated with interventional radiology)	15 mSv/y	$H_p(3)$ eye dosimeter worn unshielded close to the most exposed eye in accordance with the risk assessment. The EPA recommends that a collar dosimeter also be worn as a check.[2]
Equivalent dose to lens of the eye in a situation where all parts of the body are evenly exposed (typically where the worker is remote from the source)	15 mSv/y	$H_p(3)$ or $H_p(10)$ if worn outside of any PPE. Where no lead apron or other PPE is used, a single $H_p(10)$ dosimeter worn on the trunk may give an acceptable estimate of both whole-body and eye dose.

Where the risk assessment demonstrates the need for an Hp(3) dosimeter (equivalent dose to the eye) or Hp(0.07) (equivalent dose to an extremity), these should ordinarily be worn in addition to an Hp(10) dosimeter worn under the lead apron to estimate whole-body effective dose.

The undertaking must ensure that arrangements are in place to review all dosimetry results in order to ensure that worker doses are adequately managed, and that action is taken promptly in the event of high or anomalous dosimetry data. Where the approved dosimetry service reports a dose in excess of one of the reporting thresholds set out in the licence or registration conditions, the undertaking must notify the EPA within two weeks.

Furthermore, the undertaking should ensure that a dose investigation is undertaken in consultation with an RPA where the dosimetry data indicates that:

- There is a significant anomaly in the dose record (such as a dose is indicated for an individual not expected to receive a dose, the recorded dose significantly varies from normal exposure patterns for a worker or no dose is recorded where a dose is expected).
- The measured dose exceeds a reporting threshold set out in the licence or registration conditions. In such cases the investigation should firstly assess whether the dose measured on the dosimeter was actually received by a person. Where the dose is considered to be a genuine dose to a person, the investigation should assess if the person is liable to exceed the relevant dose limit over 12 months. The results of a high-dose investigation should be submitted to the EPA within two weeks of the completion of the investigation.

In all cases the dose investigation should consider if there is a need to revisit the risk assessment.

For each person classified as an exposed worker, the undertaking must, in accordance with Regulation 42(6), make arrangements to maintain radiation dose records during the period of the person's working life involving exposure to ionising radiation and afterwards until he or she has or would have attained the age of 75 years, but, in any case, not less than 30 years after termination of the work involving

2 It is recognised that in many work situations the continuous wearing of a dosimeter close to the eye may be difficult and that lead glasses may be removed periodically. The use of a dosimeter positioned on the lead collar may therefore provide useful confirmatory data.

exposure to ionising radiation. The undertaking/employer must ensure that, in accordance with Regulation 43, the records are available to the EPA, the worker concerned, the occupational health service and an undertaking pursuant to a request under Regulation 42(5).

5.4.2 ESTIMATION OF INDIVIDUAL DOSES

In accordance with Regulation 41(2) & 41(3), the undertaking must estimate the dose to the exposed worker:

- where an individual dose measurement is not possible or inadequate because of loss or damage to a dosimeter, or
- where there is reason to believe that the dose received by the exposed worker is much greater or less than that recorded on the dosimeter.

The dose estimation can be done from individual measurements made on other exposed workers, from results of radiological surveillance of the workplace or on the basis of calculation methods approved by the EPA. Regulation 41(2) also applies to undertakings with apprentices and students and any employers of outside workers.

Where the EPA considers any dose estimation to be inadequate, it may direct in writing the undertaking (or employer in the case of an outside worker) to carry out whatever additional investigations it considers necessary in order to establish the estimated dose (Regulation 41(4)).

5.4.3 MEDICAL SURVEILLANCE OF EXPOSED WORKERS

In the case of Category A workers, the undertaking or employer as appropriate must:

- appoint an occupational health service to carry out medical surveillance in accordance with Regulation 45 for each Category A worker employed or retained by it;
- provide the occupational health service with access to any relevant information and records that it may require including information and records with regard to the environmental conditions existing in the working premises;
- ensure in accordance with Regulation 46 that any conditions or limitations identified by the occupational health service are complied with;
- make arrangements for continued medical surveillance where the occupational health service indicates the need for medical surveillance to be continued for a specified time after the worker concerned has ceased to be employed;
- ensure that records of medical surveillance are retained in accordance with Regulation 47.

When an exposed worker, outside worker, apprentice or student receives an exposure in excess of the dose limits, the undertaking or employer, in the case of the outside worker, must comply with the requirements for special medical surveillance as specified in Regulation 48.

Regulation 49 sets out the appeals process for any person aggrieved in relation to medical surveillance.

5.5 PREGNANT AND BREASTFEEDING WORKERS

In accordance with Regulation 24, once a worker informs the undertaking that they are pregnant, the undertaking must ensure that the worker's employment conditions are such that the dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv. In practice, this means that the undertaking must review the relevant risk assessments including the expected and potential doses for the worker and determine whether any additional protective measures or changes to work practices are required.

Similarly, once a worker informs the undertaking that they are breastfeeding an infant, the relevant risk assessment(s) must be reviewed to determine whether their work involves a significant risk of intake of radionuclides or bodily contamination. IRR19 clearly states that workers who are breastfeeding must not be employed in such work and therefore their work practices should be adjusted as necessary.

It is important that undertakings clearly communicate to all workers the importance of making an early declaration of pregnancy/intention to breastfeed to allow for this process.

5.6 PERSONAL PROTECTIVE EQUIPMENT - (PPE)

The undertaking must provide personal protective equipment (PPE) in accordance with the operational risk assessment. PPE may include lead aprons, thyroid collars, glasses/face shields, ceiling-suspended shields, table-mounted and mobile shields or personal dosimeters (passive or active). Regulation 50 requires that exposed workers make full and proper use of PPE provided, including personal dosimeters. Training on the correct use of PPE is essential and must form part of the radiation protection programme. PPE should be maintained in good condition and tested in accordance with the QA programme.

6. SAFETY OF RADIOLOGICAL EQUIPMENT AND RADIOACTIVE SOURCES

6.1 RADIOLOGICAL EQUIPMENT

6.1.1 ACQUISITION

When acquiring equipment that incorporates a radiation generator or a radioactive source, the undertaking must ensure that it is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance. The undertaking must also ensure that the design permits the restriction of exposures to a level that is as low as reasonably achievable.

In specifying and acquiring such equipment, the undertaking must ensure that:

- The equipment is appropriate to the nature of the radiological practice.
- The equipment is CE marked and approved for use under relevant regulations (e.g. medical devices regulations).
- The equipment meets, as appropriate, the guidelines and/or certification of the International Electrotechnical Commission and the International Organization for Standardization.
- The equipment complies with relevant advice or guidance issued by, as appropriate, HIQA, the Health Products Regulatory Authority (HPRA), the Dental & Veterinary Councils, the European Commission or other relevant authorities.

The undertaking must maintain an up-to-date inventory of its equipment, including the locations in which it is used on site. Records must be maintained of all acquisitions, transfers and disposals of equipment. The undertaking must ensure that the inventories and relevant records are readily available for inspection at all times by inspectors of the EPA and these must be maintained for a period of two years from date of disposal of any item of equipment.

Procedures for the acquisition, installation, acceptance, maintenance and quality control of all radiological equipment (hardware and software) must be developed in consultation with an RPA, the MPE and other relevant professionals.

6.1.2 INSTALLATION AND SERVICING

All equipment must be installed and serviced in accordance with manufacturers' specifications and maintained in good working condition. Installation and servicing must be performed by a competent person. Installation/servicing personnel must follow the appropriate safety procedures as set out by their employer and/or the undertaking in which they are working.

When installation or servicing is carried out by a person holding an EPA authorisation, the installer/service company may take responsibility for radiation protection during the installation or servicing as long as clear contractual arrangements are in place detailing the handover of responsibility and designation of controlled areas (see Section 3.5). These arrangements should provide a clear line of sight of responsibility for radiation protection at all stages.

The undertaking must arrange for routine surveillance of all equipment in order to monitor its functioning, minimise breakdowns and ensure operation within manufacturers' specifications. The nature of such surveillance should be commensurate with the type of radiological equipment and the

conditions of its use. The advice of an RPA must be sought on an appropriate surveillance/preventive maintenance schedule taking account of the manufacturer's recommendations, workload, age of the equipment and other relevant factors. Equipment deemed to have a fault impacting on radiation safety must be taken out of service until the fault is rectified.

Servicing of equipment must include not just the equipment and its hardware but also, as relevant, software, viewing equipment and other supporting systems. In addition to radiological safety, the servicing should also address electrical and mechanical safety aspects of the equipment.

The undertaking must ensure that written reports are provided following all installation and servicing work. Such reports should be signed off by an authorised representative on behalf of the installation/service company and by a representative of the undertaking or customer. Installation reports must include details of the equipment set-up and safety checks carried out. Service reports must include details of checks carried out, faults identified and corrective actions taken. Records of servicing must be retained for each piece of equipment. Such records should also include details of the handover arrangements implemented.

6.1.3 ACCEPTANCE OF NEW EQUIPMENT AND FACILITIES INTO SERVICE

Acceptance tests on all equipment must be undertaken before it is brought into use. Acceptance testing must be performed by a suitably competent person in consultation with an RPA. The purpose of these tests is to:

- verify that any safety requirements specified in the risk assessment (e.g. shielding, beam orientation) have been implemented;
- verify that the equipment functions appropriately, safely and in accordance with the manufacturer's specifications;
- verify that the results of equipment performance tests fall within acceptable criteria. The performance tests and the acceptance criteria must be based on relevant international standards (EC, IAEA, IPEM, etc.) and be determined in consultation with the RPA;
- verify that any authorisation conditions relevant to safety or installation have been implemented;
- establish baseline values against which the results of routine quality control tests can be compared.

These provisions also apply to equipment that is being relocated, has undergone major modifications affecting radiation output, such as the fitting of a new X-ray tube, or has been sold on.

Acceptance testing reports, signed by a suitably qualified person, must be retained in accordance with the guidance set out in Appendix 4 and be readily available for inspection by the EPA.

Prior to acceptance testing of new equipment, the undertaking must, in accordance with the risk assessment, ensure that a radiation survey is undertaken to confirm that the shielding requirements are met for exposed workers and members of the public.

For medical equipment, the undertaking must ensure that the RPA liaises with the MPE, in accordance with Regulation 33(4), regarding the criteria for acceptance into service. Equipment must not be released for clinical use until it is operating safely and within those acceptance criteria. Equipment must only be used clinically within the parameters for which it has been tested and accepted for use. The undertaking must ensure that all acceptance testing data is readily available for inspection by the EPA.

6.1.4 QUALITY ASSURANCE

The undertaking must establish an appropriate QA programme, in consultation with an RPA and in accordance with the conditions of their authorisation, which should be available to the EPA for review. For medical equipment the RPA should liaise with the MPE in developing the QA programme. The QA programme must be implemented by a suitably competent person. The extent of the QA programme will depend on the complexity of the practice and must be commensurate with the level of risk.

The QA programme must establish the parameters to be assessed, the testing frequency and the acceptable tolerances, based on relevant international guidance, manufacturer's recommendations and any relevant factors arising from the risk assessment. The testing frequency may also take into account the likelihood of a measured parameter falling outside the acceptable tolerance range and the consequences of such an occurrence.

The QA programme must also include, where appropriate, radiation measuring instruments such as well counters, dose calibrators, radiation survey meters and contamination monitors. For these instruments, the frequency of calibration must be included in addition to any QA tests required.

Quality assurance reports must be retained in accordance with the guidance set out in Appendix 4. The undertaking must put in place arrangements for implementation and oversight of the QA programme including:

- persons responsible for carrying out the tests;
- procedures for performing the tests required;
- actions to be taken when tests are out of tolerance;
- arrangements for follow-up of issues identified during testing;
- identification of trends.

6.1.5 STORAGE AND DISPOSAL

Suitable security arrangements must be in place to prevent theft, loss, unauthorised access to and unauthorised removal of all equipment incorporating radiation generators or radioactive sources. Appropriate measures must be put in place to ensure that such equipment cannot be switched on inadvertently when not in use. A suitable warning notice must be affixed to all authorised items when taken out of use and put into storage, stating clearly that the items must not be used or moved from their storage location without the prior authorisation of the RPO.

Prior to disposal, radiation generators must be rendered permanently incapable of producing ionising radiation. X-ray equipment falls within the scope of the WEEE regulations and must be disposed of accordingly. The EPA guidance note on "Management of X-Ray Units at End-of-Life", 2015 must be followed to ensure compliance with WEEE regulation and EPA requirements. A record must be maintained of all X-ray equipment disposed of in accordance with Appendix 4.

6.2 RADIOACTIVE SOURCES

6.2.1 GENERAL REQUIREMENTS

Procedures must be established covering the procurement, receipt, storage and handling of both sealed and unsealed radioactive sources, ensuring the control of and accountability for each source at all times. These procedures must set out who is authorised/responsible for carrying out the duties specified. The companies involved in the delivery and collection of these sources should be made aware of these procedures.

Detailed records of all radioactive sources must be maintained and include the following details: a unique identifier (e.g. serial number for sealed sources or batch number for unsealed sources), the activity, the date of receipt of delivery, the locations where the sources are used and stored on site and the dates and methods of disposal.

Suitable security arrangements must be in place to prevent theft, loss, fire damage, unauthorised access to and unauthorised removal of all radioactive sources. These arrangements must be documented in written protocols/procedures. When not in use, sealed and unsealed radioactive sources must be segregated from non-radioactive materials and kept in secure and safe storage. Such sources must be adequately shielded and clearly labelled at all times, with appropriate warning notices used to indicate the ionising radiation hazard associated with them.

Undertakings may request removal of authorised sealed and unsealed sources from the EDEN source inventory, where such sources have decayed to below the exemption thresholds specified in IRR19 Schedule 7 Tables A and B. The undertaking must maintain evidence to support such removals for audit by an EPA inspector. Where removal has been approved, the relevant sources may be disposed of through non-radioactive waste streams provided that all radiation warning markings are first removed, and the disposal complies with the relevant legal requirement for non-radioactive waste.

The undertaking must notify the relevant local authority chief fire officer on an annual basis of the location, nature and amount of all radioactive sources held. This notification must include a map highlighting the location and nature of the sources. If a change of location occurs of any fixed radioactive source, a revised plan must be submitted to the chief fire officer.

6.2.2 SEALED SOURCES

Adequate arrangements must be in place for safe and secure management and control of sealed sources. Prior to acquiring sealed radioactive sources, the undertaking must obtain written agreement from the manufacturer/supplier that each radioactive source will be accepted back when no longer required. The EPA recommends that the undertaking should request confirmation from the manufacturer/supplier that the take-back agreement is still valid every three to four years.

When sealed sources reach end of life/become disused, the sources must be returned to the manufacturer/supplier as soon as possible. If sources are used beyond the manufacturer's recommended working life, a risk assessment must be carried out in consultation with an RPA to verify that it is safe to continue to use them.

It should be noted that when sources are purchased from a supplier outside the jurisdiction, the undertaking is also responsible for compliance with the relevant regulations covering transport and importation. Further information on transportation, importation and security of sources can be found in Appendix 5.

In cases where a sealed radioactive source is being acquired to replace an existing source, the undertaking must arrange to return the sealed source being replaced to the manufacturer or supplier at the earliest possible opportunity.

The undertaking is required to prevent leakage of any radioactive substance or material from its container. It must ensure that:

- Suitable tests are carried out to detect leakage of any radioactive substance or material from its container at least once every two years or more frequently if recommended by the manufacturer or supplier or if the EPA gives direction to do so.
- Where damage to any container or other protection is suspected, a leak test is undertaken immediately.
- The leak test record includes the date of the leak test, unique identification of the source/serial number, method of test indicating the pass/fail criteria, the result of the test together with pass/fail conclusion, and any remedial action if failure occurred.
- If leakage tests results are in excess of 200 Bq, use of the radioactive source is discontinued immediately and advice and guidance is sought from an RPA.
- Records of every leakage test performed are retained until the radioactive source involved has been returned in the appropriate manner, and these records are available for inspection by the EPA.

6.2.3 ADDITIONAL REQUIREMENTS FOR HIGH-ACTIVITY SEALED SOURCES

A sealed source containing a radionuclide whose activity is equal to or above the relevant HASS threshold activity level set out in IRR19 Schedule 3 is classified as a high-activity sealed source (HASS).

It should be noted that if a HASS falls below the activity thresholds in IRR19 Schedule 3, it remains under regulatory control as long as the activity exceeds the exemption value set out in IRR19 Schedule 7.

In addition to the measures set out in Sections 6.2.1 and 6.2.2 above, IRR19 sets out a number of specific requirements for practices involving the use of HASS as set out below.

- Undertakings must implement arrangements to comply with the requirements set out in IRR19 Schedule 12, including:
  - verifying at specific intervals that each source is still present and in good condition at its place of use or storage;
  - checking the integrity of the source after any event, including fire, that may have damaged the source and, where appropriate, informing the EPA of the outcome and measures taken;
  - ascertaining, before transferring the source to another undertaking, that the recipient has the appropriate licence.
- Undertakings must ensure that there is adequate provision in place, by way of a financial security or equivalent means, for the safe and secure management of sources when they become disused sources. Such provision must remain valid throughout the time that they hold the HASS and should also cover situations where the undertaking becomes insolvent or ceases its activities. A documented financial costing for the safe management of HASS, along with a written guarantee from the undertaking to cover the cost of management/disposal, must be submitted with all licence applications/amendments for HASS. The financial arrangements must be confirmed in writing to the EPA on an annual basis.

- Undertakings must check annually that any manufacturer/supplier with which it has an agreement for dealing with HASS when they become disused sources is still in a position to honour that agreement; if it is not, the licensees will be required to make new arrangements.
- Undertakings must ensure that adequate measures are in place concerning site security as are appropriate to the source(s) and premises in question. All HASS must be classified in accordance with the IAEA categorisation of radioactive sources and the relevant security requirements implemented as set out in Appendix 6.
- Undertakings must maintain accurate and up-to-date individual records for each HASS, which include the information set out in Schedule 11 of IRR19. An EPA Record Sheet for HASS template for this purpose can be found on the EPA website (*www.epa.ie*).

A completed HASS Record Sheet must be provided to the EPA:

- when the source is acquired;
- at intervals, determined by the EPA, of not more than 12 months;
- if the information on the Record Sheet changes;
- in advance of any HASS licence amendments to transfer the source to another undertaking or return it to the manufacturer/supplier. In these instances, the name of the undertaking or manufacturer/supplier to which the source is transferred must be included on the Record Sheet;
- within four weeks of the closure of the record for a specified source;
- whenever requested by the EPA.

All information prepared by the licensee or provided by the manufacturer/supplier must be retained for the period that the HASS are held. Where a HASS is sold or transferred to a different licensee, all records must be transferred to the new undertaking and provided to any third parties to whom the HASS are transferred.

Requirements for identification and marking of HASS are outlined in IRR19 Schedule 13 and include the following.

- Each HASS must be identified by a unique number. This number must be engraved or stamped on the source, where practicable. The number must also be engraved or stamped on the source container.[3]
- The source container and, where practicable, the source must be marked and labelled with an appropriate sign to warn people of the radiation hazard.
- A photograph of each manufactured source design type and a photograph of the typical source container must be provided by the manufacturer/supplier.
- Each HASS must be accompanied by written information indicating that the source is sufficiently identified and marked. The information must include photographs of the source, source container, transport packaging, device and equipment as appropriate.

3 If it is not possible to engrave/stamp the unique ID number on the container (for example, in the case of reusable transport containers), the container must, at least, bear information on the nature of the source.

6.2.4 UNSEALED SOURCES

Design and layout considerations for areas where unsealed sources are used are included in detail in "The Design of Diagnostic Medical Facilities Where Ionising Radiation Is Used", June 2009. This publication can also be utilised for industrial and education facilities using unsealed sources.

Contamination monitoring

Contamination monitoring must be undertaken when unsealed sources are used. The workplace monitoring programme should cover both the areas where the work is carried out and the persons carrying out the work. The programme must be developed and implemented by the undertaking in conjunction with its RPA, and should specify:

- areas/items to be monitored, e.g. work surfaces, equipment, toilets/drains, clothing, hands;
- frequency of monitoring, e.g. periodic, continuous;
- methods of monitoring, e.g. survey meter, contamination monitor, wipe testing;
- action/investigation levels.

Results of contamination monitoring must be documented and records maintained.

Decontamination

Procedures must be established for decontamination of work areas and workers due to spillages or other incidents with unsealed sources.

Adequate materials should be available to prevent/remediate contamination, such as disposable gloves, towels, overshoes and gowns. A "spill-kit" containing suitable material to facilitate a clean-up should be maintained and clearly labelled in an easily accessible area along with appropriate instructions. Staff working with unsealed sources must be trained in decontamination procedures. If radioactive contamination of the skin is deemed to have occurred, decontamination must be carried out immediately.

When accounting for potential contamination scenarios during the design stage, consideration should be given to whether specific design measures (such as negative pressurisation) are necessary to prevent the spread of contamination through the ventilation system. A dedicated shower facility for decontamination purposes where unsealed sources are used/administered should also be considered.

Disposal

Unsealed substances with short-lived radionuclides can be stored securely until they decay to below exemption values (as specified in IRR19 Schedule 7) and then disposed of as conventional (non-radioactive) waste. Radiation surveys must be carried out prior to putting these sources into storage and before disposal to confirm that background radiation levels have been reached. In accordance with Regulation 19(4), *it is prohibited to dilute unsealed sources for the purpose of releasing from regulatory control.*

Associated short-lived radioactive waste such as vials containing residual radionuclides; biological waste; infectious waste requiring sterilisation; broken glassware; syringes; needles; contaminated gloves or clothing; and liquid scintillation solutions must also be stored until they have reached background levels. A secure lockable space with restricted access should be provided for the storage of such waste. This space must be properly marked and ventilated where appropriate.

Records must be kept that identify the nature, volume and origin of the radioactive waste.

When storing short-lived radioactive waste, the following should be noted: Undertakings must ensure that appropriate security arrangements are in place during the decay storage.

- Waste must be grouped (segregated) in accordance with the expected period of time necessary for the decay of the radionuclides (depending on the initial activity and the physical half-life) and the physical form of the waste.
- All waste must be monitored before it is disposed of as conventional waste and records of this monitoring must be maintained.

Unsealed disused substances with long-lived radionuclides may only be stored as an interim measure to facilitate their shipment abroad for recycling/reuse purposes.

6.2.5 TRANSPORT OF RADIOACTIVE SOURCES

The EPA is the competent authority for the transportation of Class 7 dangerous goods (radioactive material) within, to or from Ireland. Carriers routinely engaged in radioactive transportations have either an EPA licence or registration to undertake such activity, depending on the practice(s) relevant to them. Such authorised users include distributors, industrial radiographers and users of nuclear moisture density gauges. Undertakings must ensure that the carrier or distributor they use hold an appropriate authorisation.

Companies transporting high-activity sealed sources require a licence. For all other sources a once-off registration is sufficient. A list of carriers that are authorised to transport radioactive sources is available on the EPA website. Further details on the requirements covering the transportation of radioactive sources can be found in Appendix 5.

6.3 RELEASE OF RADIOACTIVE MATERIAL FROM REGULATORY CONTROL (CLEARANCE)

In general, the disposal, recycling or reuse of radioactive materials arising from a regulated practice is itself subject to authorisation by the EPA. Depending on the specific circumstances of the exposure situation, the EPA may treat the disposal, recycling or reuse as a separate practice subject to authorisation in its own right or as an activity under the original authorisation subject to specific licence or registration conditions.

IRR19 provides for the first time in Irish legislation specific provision for the release from regulatory control of radioactive materials arising for an authorised practice. The process of release of material from regulatory control is referred to as clearance. Regulation 19(2) provides that radioactive materials may be released from regulatory control for the purpose of disposal, recycling or reuse under one of two conditions:

1. Solid radioactive material may be released from regulatory control where the activity concentration values of the material are less than the relevant thresholds set out in IRR19 Schedule 7 Table A.
2. Radioactive material may be released from regulatory control if it complies with specific clearance levels and associated requirements established by the EPA in accordance with the criteria set down in IRR19 Schedule 7(3)(c).

It should be noted that where radioactive material is released from regulatory control, the practice giving rise to the material remains under regulatory control. In such circumstances the EPA may attach specific conditions to the authorisation for the practice setting out the conditions under which materials are cleared. These may include, *inter alia*, limits on activity concentration, limits on activity released in a year, monitoring or testing of materials, radiation safety procedures, record keeping and reporting.

As noted in Section 6.2.4, Regulation 19(4) prohibits the deliberate dilution of radioactive materials specifically for the purpose of releasing them from regulatory control. The mixing of materials as part of the normal operation of an authorised practice is not, however, subject to this prohibition. Furthermore, it should be noted that the EPA may under certain circumstances authorise the mixing of radioactive and non-radioactive materials for the purposes of reuse or recycling.

7. TRAINING & EDUCATION

Regular and appropriate radiation safety training is essential to effectively manage and minimise the risks associated with the use of ionising radiation. Regulation 35 sets out the responsibilities of undertakings for the provision of radiation protection education, training and information. Training should be sufficient to ensure that all those involved in work or affected by work with ionising radiation, including apprentices, students and outside workers, are informed as to how to work safely and to reduce the risk to their health.

Undertakings must set out a training policy in consultation with the RPA, setting out the content and frequency of training for each category of worker. The policy should address both initial and refresher training. As well as ensuring that the training provided meets the requirements of Regulation 35, undertakings must ensure that any additional training needs identified in risk assessments are included.

Training should be updated whenever there is a change to equipment, use of different radionuclides or change to working conditions or procedures relevant to radiation safety.

The policy should as appropriate cover the requirements for the following types of worker:

- exposed workers;
- other staff working in the vicinity of radiation sources;
- staff working with HASS;
- the RPO and staff assigned to the RP unit.

7.1 RADIATION PROTECTION TRAINING FOR EXPOSED WORKERS

All exposed workers, apprentices and students including outside workers must be provided with appropriate education and training in radiation protection in accordance with Regulation 35(1), including information on health risks, general safety principles such as time, distance & shielding and the specific operational procedures and precautions required within their own workplace. The information and instruction received should be suitable and sufficient for the recipient to know:

- 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;
- 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.

7.2 TRAINING FOR RPOs

RPOs must receive the training necessary to allow them to effectively carry out the tasks set out in Section 3.3.1. The training should be designed in consultation with the RPA and be appropriate to the nature of the radiological practices and complexity of the work. In general, the training should cover, *inter alia*:

- 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.

Where the RPO function is carried out by an RP unit rather than an individual RPO, the training requirements may be split among the members of the team so long as each member of the team is appropriately trained for the tasks he/she is expected to perform. The training requirements for each member of the RP unit should be documented and accessible to an EPA inspector. The head of the RP unit would be expected to have a detailed knowledge of the overall RPO function including both the legal responsibilities of the RPO and the specific organisational arrangements within the undertaking for the delivery of those responsibilities.

7.3 OTHER STAFF WORKING IN THE VICINITY OF RADIATION SOURCES

The undertaking must provide adequate and proportionate radiation protection training for all staff working in the vicinity of a radiation source. The training programme is an output from the risk assessment and should be designed in consultation with an RPA. Such training should cover, *inter alia*:

- the relevant control measures identified in the operational risk assessment;
- the responsibility of the individual in maintaining a safe workplace;
- when appropriate, the correct operation of equipment and materials, as well as safety features of any equipment that they may use during their work, including any specific procedures or precautions pertinent to their own protection;
- procedures to be followed in the event of an equipment malfunction liable to have radiation safety implications;
- when appropriate, the importance of making an early declaration of pregnancy and the intention to breastfeed.

The nature of the training and the level of detail required will vary in accordance with both the risk assessment and the nature of the role. For example, a cleaner who has very limited interaction with the work with ionising radiation is likely to need only minimal training, while non-categorised staff working in controlled/supervised areas would generally need more comprehensive training. It should be noted

that under Regulation 37(1), undertakings must ensure that any person working in a controlled area (including outside workers) must receive specific training in connection with the characteristics of the workplace and the activities.

7.4 ADDITIONAL TRAINING FOR STAFF WORKING WITH HASS

Undertakings engaged in work with ionising radiation involving HASS must ensure that the information and training given to exposed workers includes:

- specific requirements for the safe management and security and control of HASS for the purpose of preparing such employees for any event that may affect their radiation protection;
- specific information on the possible consequences of the loss of adequate control of HASS sealed sources.

This training must be repeated at least annually and documented, and must include practising the response to potential incidents, e.g. failure of HASS to retract, with a view to preparing the relevant workers adequately for such events.

7.5 REFRESHER TRAINING, RECORDS AND AUDITING

The undertaking should provide refresher education and training at appropriate intervals in accordance with the training policy.

The undertaking must maintain a record of all training, education or information provided in accordance with the policy. This record must be accessible to an EPA inspector and be sufficient to demonstrate that all staff who require radiation protection training have received it. Training records should include the names of individual staff who require training, the type of training required, the date on which they attended training, the person who provided the training and the topics covered.

The adequacy of training should be audited from time to time, taking into account:

1. feedback from staff;
2. compliance with documented work practices;
3. learnings from near misses or accidents;
4. review of the effectiveness of the training.

8. REPORTING OF INCIDENTS TO THE EPA

8.1 WHAT INCIDENTS MUST BE REPORTED

Table 10 sets out the types of incident that should be reported to the EPA and how they should be reported.

Table 10: Details of reportable incidents

Category	Nature of incident	How and when to report
Incidents involving loss or damage of radioactive sources/ radiation generators	Loss of radioactive source as a result of theft or fire	▶ During office hours phone EPA on (053) 916 0600 and ask to be transferred to the Radiation Protection Regulation Team ▶ Out of hours contact An Garda Síochána Communications on (01) 666 3108/3109, who will in turn contact the EPA Duty Officer ▶ In all cases follow up by email to *RadiationIncidents@epa.ie* within 24 hours ▶ Incident report within two weeks
	Any incident involving the loss or damage of a HASS	
	Any other incident involving loss of, damage to or radiation leakage from, or otherwise involving, a radiation generator or radioactive source	▶ During office hours phone EPA on (053) 916 0600 and ask to be transferred to the Radiation Protection Regulation Team ▶ In all cases follow up by email to *RadiationIncidents@epa.ie* within three working days ▶ Incident report within two weeks
Incidents involving exposure to staff or member of the public	Any incident involving a dose, or suspected dose, in excess of any dose limits for staff and members of the public (see Section 4.1)	▶ During office hours phone EPA on (053) 916 0600 and ask to be transferred to the Radiation Protection Regulation Team ▶ In all cases follow up by email to *RadiationIncidents@epa.ie* within three working days ▶ Incident report within two weeks
	Any incident involving the unintended exposure of a person arising from a design flaw, malfunction or incorrect operation of a licensed item.	
Emergency response	Activation of an emergency response plan prepared in accordance with Regulation 58.[4] (Emergency response plans are only required where this has been specified in licence conditions.)	▶ During office hours phone EPA (053) 916 0600 and ask to be transferred to the Radiation Protection Regulation Team ▶ Out of hours contact the EPA Duty Officer ▶ In all cases follow up by email to *RadiationIncidents@epa.ie* within 24 hours

4 Where a site requires an emergency response plan under Regulation 58, this is specified in licence conditions.

Category	Nature of incident	How and when to report
Transport of radioactive material	Any incident occurring during the transport of radioactive materials. For example, there is damage or suspected damage to the packages being carried, or an incident that could give rise to public concern	▶ During office hours phone EPA on (053) 916 0600 and ask to be transferred to the Radiation Protection Regulation Team ▶ Out of hours contact An Garda Síochána Communications on (01) 666 3108/3109, who will in turn contact the EPA Duty Officer ▶ In all cases follow up by email to *RadiationIncidents@epa.ie* within 24 hours ▶ Incident report within two weeks
Incidents involving patients in a medical facility	Any incident involving malfunction of equipment	▶ During office hours phone EPA on (053) 916 0600 and ask to be transferred to the Radiation Protection Regulation Team ▶ Follow up by email to *RadiationIncidents@epa.ie* within three working days ▶ Incident report within two weeks

8.2 MEDICAL INCIDENTS

HIQA has produced separate guidelines on reporting of patient exposure incidents in accordance with S.I. 256 of 2018. EPA and HIQA have put in place arrangements to exchange information on incident notifications where appropriate.

8.3 WHAT MUST BE INCLUDED IN AN INCIDENT INVESTIGATION

The purpose of an incident investigation is to establish:

- the sequence of events leading to the incident;
- the cause(s) of the incident;
- what remedial action is necessary to prevent a recurrence;
- the estimated dose(s) received by all persons involved in the incident.

Incident investigations must always involve the undertaking, the exposed person, the operator, the RPO and the RPA. Other persons who may be involved in the investigation include the service engineer and the person who carried out the quality assurance of the X-ray unit.

The incident report must include:

- the key facts concerning the incident;
- the consequences (if any) for the individual(s) exposed;
- recommendations to avoid a recurrence of the incident;
- details of the follow-up action with the exposed person(s).

This report must be signed and dated by the undertaking and the person who prepared it and forwarded to the EPA. A copy must be maintained in accordance with Appendix 4.

8.4 PROCEDURES IN THE EVENT OF AN INCIDENT

The undertaking must have procedures to be followed in the event of an incident liable to have radiation safety implications for workers and members of the public.

For licensable practices the undertaking must evaluate in consultation with an RPA the potential for an incident or event to occur that would necessitate prompt action to mitigate serious adverse consequences for human health, safety, quality of life, property or the environment. Where this evaluation determines that such an incident or event is liable to occur or where required in the EPA licence conditions, the undertaking must develop and maintain an **emergency response plan** in accordance with Regulations 58, 59 and 60. Such a plan must be developed in consultation with the RPA and have regard to any guidance published by the EPA.

A copy of this plan should be submitted to EPA and, where appropriate, the relevant Local Authority as soon as practicable after it is prepared. Submission to the Local Authority would be appropriate in situations where the response could potentially involve the local fire services, require assistance from An Garda Síochána, require activation of a major emergency plan or in some other way require the involvement or resources of the Local Authority.

APPENDIX 1 SCOPE OF THIS GUIDE

Regulation	Topic	Guidance
Regulation 5	Justification of practices	2.1 – The EPA may provide separate sector-specific guidance on the format and scope of the evidence required to support an application for justification
Regulation 6	Practices involving consumer products	Not included in this guide – It is considered that Regulation 6 is clear and that guidance on this topic is unnecessary
Regulation 7	Prohibition of practices	Not included in this guide – Regulation 7 clearly sets out the list of prohibited practices. It is considered that guidance on this topic is unnecessary
Regulation 8	Notification	2.2.2 – As noted in this section, an undertaking is considered to have satisfied the requirements for notification by making an application for registration or licensing
Regulation 9	Exemption from notification	2.2 & 2.2.1
Regulation 10	Registration or licensing	2.2.2
Regulation 11	Licensing	2.2.2
Regulation 12	Authorisation	2.2.2
Regulation 13	Authorisation procedure	2.2.2
Regulation 14	Conditions specified in a licence	2.2.2
Regulation 15	Conditions attached to a registration	2.2.2
Regulation 16	Non-medical imaging practices	Appendix 7
Regulation 17	Radioactive waste licences	Not included in this guide – separate guidance will be provided on this topic
Regulation 18	Licensing of importation and exportation of radioactive waste	2.2.2
Regulation 19	Release from regulatory control	6.3
Regulation 20	Dose constraints for occupational and public exposure	4.2
Regulation 21	Reference levels	Not included, as emergency exposure situations are outside the scope of this guide

Regulation	Topic	Guidance
Regulation 22	Age limit for exposed workers	2.4
Regulation 23	Dose limits for occupational exposure	2.4
Regulation 24	Protection of pregnant and breastfeeding workers	5.5
Regulation 25	Specially authorised exposures	Not included in this guide, as the EPA will apply Regulation 25 on a case-by-case basis – to date no specially authorised exposures have been approved
Regulation 26	Dose limits for apprentices and students	2.4
Regulation 27	Dose limits for public exposure	2.4
Regulation 28	Estimation of the effective and equivalent dose	5.4.2
Regulation 29	Responsibilities of the undertaking and employers	3.4
Regulation 30	Arrangements in workplaces	Section 5 – Separate guidance will be provided covering radon in workplaces and exposure of air crews to cosmic radiation
Regulation 31	Prior risk assessment	4
Regulation 32	Radiation safety procedures	5.1
Regulation 33	Consultations with a radiation protection adviser	3.3.2
Regulation 34	Role of radiation protection officer	3.3 & 3.3.1
Regulation 35	Radiation protection education, training and information	7
Regulation 36	Classification of workplaces	4.4
Regulation 37	Requirements for controlled and supervised areas	5.2
Regulation 38	Radiological surveillance of the workplace	5.3
Regulation 39	Categorisation of exposed workers	4.5
Regulation 40	Operational protection of apprentices and students	2.3
Regulation 41	Individual monitoring	5.4.1 & 5.4.2

Regulation	Topic	Guidance
Regulation 42	Recording and reporting of results	3.7 (sharing of records with other undertakings or employers), 5.4.1 (making and retaining of records). Further guidance will be provided when the arrangements for a National Dose Register have been finalised
Regulation 43	Access to the results of individual monitoring	5.4.1
Regulation 44	National Dose Register	Separate guidance will be issued covering the National Dose Register and radiation passbooks
Regulation 45	Medical surveillance of exposed workers	5.4.3
Regulation 46	Medical classification	Not included in this guide – it is considered that Regulation 46 is clear and that guidance on this topic is unnecessary
Regulation 47	Medical records	5.4.2
Regulation 48	Special medical surveillance	Not included in this guide – it is considered that Regulation 48 is clear and that guidance on this topic is unnecessary
Regulation 49	Appeals in relation to medical surveillance	Not included in this guide – it is considered that Regulation 49 is clear and that guidance on this topic is unnecessary
Regulation 50	Duties of exposed workers, apprentices, students and employers	3.2
Regulation 51	Operational protection of members of the public	Covered implicitly by Sections 4 & 5. Further guidance specifically on the Regulation is considered unnecessary
Regulation 52	Tasks for the undertaking	Covered implicitly by Sections 4 & 5. Further guidance specifically on the Regulation is considered unnecessary
Regulation 53	Monitoring of radioactive discharges	Not included in the guide at this time. The EPA will consider the need for separate guidance to be provided on this topic
Regulation 54	Estimation of doses to members of the public	Not included in the guide at this time. Currently there are no authorised undertakings to which this regulation applies
Regulation 55	National Plan for Nuclear and Radiological Emergency Exposures	Not included as emergency exposure situations are outside the scope of this guide
Regulation 56	Contaminated areas and existing exposure situations	Not included as emergency exposure situations are outside the scope of this guide
Regulation 57	Major emergency plans	Not included as emergency exposure situations are outside the scope of this guide
Regulation 58	Emergency preparedness for licensed undertakings	Section 8 – The EPA may provide more detailed sector-specific guidance on emergency preparedness arrangements

Regulation	Topic	Guidance
Regulation 59	Duty of undertakings to inform members of the public likely to be affected in the event of a radiological exposure situation	Not included in this guide – the EPA will develop separate guidance on emergency preparedness for undertakings
Regulation 60	Emergency response for undertakings	Not included in this guide – the EPA will develop separate guidance on emergency preparedness for undertakings
Regulation 61	Communication and recording of significant events	Section 8
Regulation 62	Emergency occupational exposure	Not included as emergency exposure situations are outside the scope of this guide
Regulation 63	Prior information and training for emergency workers	Not included as emergency exposure situations are outside the scope of this guide
Regulation 64	National Radon Control Strategy	Not included as existing exposure situations are outside the scope of this guide
Regulation 65	Indoor exposure to radon in domestic dwellings	Not included as existing exposure situations are outside the scope of this guide
Regulation 66	Radon in workplaces	Not included in the guide at this time. Separate guidance will be provided on this topic
Regulation 67	Gamma radiation from building materials	Not included in the guide as the requirement does not apply to undertakings
Regulation 68	Identification of practices involving naturally-occurring radioactive material	Not included in the guide at this time. The EPA will consider the need for guidance for undertakings on the identification of such practices
Regulation 69	Control of radioactive sources and radiation generators	Section 6
Regulation 70	Requirements for control of high-activity sealed sources	Section 6
Regulation 71	Specific requirements for licensing of high-activity sealed sources	Sections 3 & 6
Regulation 72	Record keeping by the undertaking	Section 6
Regulation 73	Record keeping by the competent authority	Not included in the guide as the requirement does not apply to undertakings
Regulation 74	Control of high-activity sealed sources	Section 6
Regulation 75	Metal contamination in recycling installations	Not included in the guide at this time. Separate guidance will be provided on this topic

Regulation	Topic	Guidance
Regulation 76	Detection of orphan sources	Not included in the guide as the requirement does not apply to undertakings
Regulation 77	Recovery and disposal of orphan sources	Not included in the guide as the requirement does not apply to undertakings
Regulation 78	Recognition of dosimetry services	Not included in this guide – separate guidance is provided on the requirements for approval of dosimetry services
Regulation 79	Radiation protection advisers	3.3.2 (role of RPA). Separate guidance will be provided on recognition of RPAs
Regulation 80	Radiation protection officers	3.3.1
Regulation 81	Inspections	2.2.4
Regulation 82	Enforcement notices	2.2.4

APPENDIX 2 SUPPLEMENTARY INFORMATION

Topic	Guidance/material	Comments
Legislation	Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019. S.I. No. 30 of 2019 (IRR19). *http://www.irishstatutebook.ie/eli/2019/si/30/made/en/pdf*	National Regulation covering the protection of workers and members of the public from the harmful effects of ionising radiation
	European Union (Basic safety standards for protection against dangers arising from medical exposure to ionising radiation) Regulations 2018. S.I. 256 of 2018. *http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf*	National Regulation covering the protection of patients from the harmful effects of ionising radiation
	COUNCIL DIRECTIVE laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. COUNCIL DIRECTIVE 2013/59/ EURATOM. *https://eur-lex.europa.eu/eli/dir/2013/59/oj*	European Basic Safety Standards Directive
	IAEA General Safety Requirements Part 3. Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. IAEA, Vienna, 2014. *https://www-pub.iaea.org/MTCD/publications/PDF/Pub1578_web-57265295.pdf*	International Basic Safety Standards (IAEA). The European and international safety standards were developed collaboratively and so are closed aligned. However, reading the two sets of standards together can sometimes give additional clarity
	IAEA General Safety Requirements Part 7. Preparedness and Response for a Nuclear or Radiological Emergency. IAEA, Vienna. *https://www-pub.iaea.org/MTCD/Publications/PDF/P_1708_web.pdf*	International Basic Safety Standards (IAEA) covering radiological emergency preparedness
EPA guidance	Code of Practice on the Application of the Ionising Radiation Regulations (IRR19) in Dentistry, 2019 *https://www.epa.ie/publications/compliance--enforcement/radiation/EPA-Ionising-Radiation-Dentistry.pdf*	Guidance for dental undertakings on compliance with IRR 19
	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*	Guidance for veterinary undertakings on compliance with IRR 19
	The Design of Diagnostic Medical Facilities where Ionising Radiation is used, 2009. *https://www.epa.ie/publications/compliance--enforcement/radiation/RPII_Code_Design_Medical_Facilities_09.pdf*	Guidance on the design of diagnostic medical facilities
	Guidance for RPA Applications	
	Management of X-ray Units at End-of-Life *https://www.epa.ie/publications/compliance--enforcement/waste/Guidance_Note_on_x-ray_units.pdf*	

APPENDIX 3 MEASURES FOR THE PROTECTION OF THE LENS OF THE EYE

The risk assessment

For any practice that the RPA believes has the potential to result in significant exposure to the eyes of the workers involved, the operational risk assessment should include an estimate of the expected and potential doses to the lens of the eye.

Practices that may result in significant exposure to the lens of the eye include:

- interventional radiology;
- interventional cardiology;
- nuclear medicine & PET-CT;
- manual brachytherapy;
- industrial radiography.

The operational risk assessment should consider all workers identified to be at risk of significant exposure to the lens of the eye. The dose estimation should be made for individual workers where it is considered that the exposure is likely to vary significantly between workers or it can be made for groups of workers where it is considered that exposure is likely to be homogeneous across the group.

The dose estimation must be based on a realistic evaluation of the specific operational conditions likely to influence eye dose. The factors to be considered in estimating the eye doses include:

- the nature of the practice or procedures being carried out and the techniques employed;
- the role or profession of the individuals taking part in the practice or procedure, and their workload, positioning and level of involvement in the procedure;
- manufacturers' information or guidance on the sources or equipment used;
- the characteristics of the radiation source(s) and imaging equipment used;
- the source geometry (e.g. under- or over-couch setting in interventional radiology);
- the availability and use of operational control measures such as ceiling-mounted shields and protective eyewear.

Other information such as workplace monitoring data, literature data, whole-body dosimetry results, confirmatory eye dose measurements, simulations and the results of pilot studies may also be considered as part of the risk assessment. In particular, noting that:

1. the dose threshold for categorisation and dose monitoring of 15 mSv is relatively close to the annual dose limit of 20 mSv;
2. there are many variables to be taken into account in estimating the expected and potential doses to the eye,

it is advisable to carry out confirmatory measurements to support the output of the risk assessment.

Eye dosimetry

Where the risk assessment indicates that a worker is liable to receive an equivalent dose to the lens of the eye of greater than 15 mSv/year, the undertaking (or employer as appropriate) must in accordance with Regulation 41 ensure that the eye dose is monitored based on individual measurements carried out by an approved dosimetry service (see Section 6.2). In designing an eye dose monitoring programme, account should be taken of the following.

- For inhomogeneous fields, dose measurements should, where practicable, be made using an $H_p(3)$ dosimeter placed close to the most exposed eye.
- Noting the practical difficulties associated with placement of a dosimeter close to the eye, the EPA recommends the use of a dosimeter on the lead collar in addition to the $H_p(3)$ dosimeter close to the eye. The additional collar dosimeter may be used to assess exposure where there is uncertainty regarding the actual wearing of the primary eye dosimeter during a procedure. It is noted that, for example, where a dosimeter is attached to protective glasses, the glasses may be removed during the procedure, resulting in under-measurement of the exposure.
- Where protective glasses are used and the dosimeter is positioned above the glasses, a correction factor may be used in accordance with the advice of an RPA to assess the dose to the lens of the eye. In general, the EPA recommends that a correction factor of no greater that 0.5 be used, unless the undertaking can provide appropriate evidence of a specific exposure situation to support the use of a higher factor.
- In homogeneous fields such as where the worker is at a distance from the source, it may be possible, subject to the advice of an RPA, to assess eye dose using an $H_p(10)$ dosimeter placed on the body outside of any protective wear.
- The undertaking must in all cases consult with an RPA on the type(s) of dosimeter to be used, the positioning of dosimeters and the optimal wear period.

Assessing compliance with the dose limit for the lens of the eye

A number of practical issues may need to be taken into account in assessing the dose to the lens of the eye based on individual dosimetry measurements. These include in particular:

- difficulties associated with placement of dosimeters close to the lens of the eye;
- the type of dosimeter used;
- the protection afforded by PPE;
- the level of consistency in the use of protective eyewear.

The advice of an RPA should be sought on the interpretation of the results of individual measurements for the purpose of assessing compliance with the dose limit for the lens of the eye. Such advice should take into account the specific circumstances in the individual workplace. Table 11 sets out some of the issues to be considered when assessing the dose to the lens of the eye for a range of exposure scenarios.

Where it is determined that the actual dose to the lens of the eye is different to that recorded on the dosimeter, a record must be retained of any corrections applied. Such a record should be sufficient to allow the recorded dose to be recalculated from the dose on the dosimeter.

Table 11: Assessment of dose to the lens of the eye under different exposure scenarios[5]

Exposure scenario	Considerations in assessing dose to the lens of the eye
Practice involving non-homogeneous exposure fields such as interventional radiology/cardiology where workers are positioned close to the radiation source and wear protective clothing on their trunks but not their heads	**If Hp(3) dosimeter is positioned close to the eye under protective eyewear**, the dose to the lens of the eye may be assessed directly from the dosimetry measurement. However, assurance should be obtained that the eyewear is worn consistently during procedures. Such assurance should normally be based on audits during procedures.
	If Hp(3) dosimeter is positioned close to the eye but outside of protective eyewear, it may be appropriate to apply a correction factor to the dosimetry measurement to calculate the dose to the lens of the eye. In the absence of a work-activity specific assessment of the protection afforded by protective eyewear, a default correction factor of 0.5 may be used provided that: ▶ The protective eyewear meets minimum standards such as IEC 61331 Part 3, and ▶ There is assurance based on audits that protective eyewear is worn consistently during procedures. Work-activity specific correction factors may be used where the undertaking has made a realistic assessment of the protection afforded by eyewear. Such assessments must: ▶ Be based on actual measurements made under simulated working conditions. ▶ Be based on the actual circumstances under which the work activity/procedure is carried out, including: the specific type of eyewear, the actual radiological equipment used, the operating procedures, etc. ▶ Demonstrate that the conditions on which its correction factors are based are realistic and reflect operational practice. For example, audits that workers are consistently and correctly wearing their dosimeters and protective eyewear must be regularly conducted and the results recorded. ▶ Be conducted in accordance with advice from the RPA. ▶ Be acceptable to the EPA.
	Dosimeter (Hp(3) or Hp(.07)) worn on the lead collar. It is recognised that there are practical difficulties associated with wearing a dosimeter close to the eye, particularly during complex and/or lengthy procedures. This can lead to the eye dosimeters being worn inconsistently and therefore inaccurate dosimetry results. For this reason, the EPA recommends that, in addition to the Hp(3) dosimeter close to the eye, a collar dosimeter is worn. The same considerations regarding correction factors as outlined above apply for the collar dosimeter, and it is further recommended to perform a pilot study to determine the conversion factor between the collar dose measurement and the Hp(3) dose measured close to the eye.
Practices such as industrial radiography where the radiographer works at a significant distance from the source.	Where no lead apron or PPE is used, a single Hp(10) dosimeter worn on the trunk may give an acceptable estimate of both whole-body and eye dose.

5 Table included for illustrative purposes. The assessment of the dose to the lens of the eye should be based on the advice of the RPA specific to the circumstances of each individual workplace.

Use of personal protective equipment specific to eye dose

The following is advised.

- Ceiling-mounted shields – these should be located close to the patient and source of radiation.
- Protective eyewear – the design of protective eyewear is particularly important. Wrap-around glasses and those with side shields, which fit closely to the face of the wearer, are desirable to reduce exposure to radiation incident from the side or below the glasses. Face masks may provide enhanced protection.
- The position of viewing monitors should be at eye level, again to minimise radiation incident from below the glasses.

Education and training required for eye dose

Such education and training should include the potential effects of radiation on the lens of the eye, correct use of equipment and exposure settings to optimise doses and correct use of PPE. Staff should also be educated on the importance of, and involved in, the development of the risk assessment and radiation safety procedures for the work in which they are involved.

APPENDIX 4 RETENTION OF RADIATION SAFETY RECORDS

Indicative guidance on retention periods for key radiation safety records is set out below. The guidance is not intended to be definitive but merely to set out what would constitute acceptable retention periods from a regulatory perspective. It is recognised that undertakings will need to take into account broader legislative and governance requirements in determining actual retention periods.

Topic	Parameter	Recommended retention period
Governance	Agreed arrangements (contractual agreements) between undertakings and employers	Five years after the agreement has been terminated or superseded
	Agreed arrangements between undertakings and RPAs	Two years after the agreement has been terminated or superseded
	Agreed arrangements between undertakings for the purpose of managing radiation of workers liable to be exposed at sites controlled by multiple undertakings	Two years after the agreement has been terminated or superseded
	Governance arrangements within the undertaking (including appointment of RPO and RSC)	Two years after the arrangement has been terminated or superseded
	Exchange of information between undertakings or employers pursuant to a declaration under Regulation 50	Two years
Risk assessment	Risk assessments (including supporting studies or assessments)	Two years after a risk assessment has been superseded
	Radiation safety procedures	Two years after procedures have been superseded
	Categorisation of workers	Five years
	Classification of workplaces	Two years
	Periodic review and update of risk assessment	Two years
	Review of risk assessment following declaration of pregnancy	Five years
	Review of risk assessment following incident	Five years

Topic	Parameter	Recommended retention period
Protection of individuals	Agreed/contractual arrangements with approved dosimetry service	Five years
	Dosimetry reports for exposed workers (Regulation 42)	Until the individual has or would have attained 75 years of age, but in any case no less than 30 years after termination of the work involving exposure to ionising radiation
	Results of dose investigations carried out (ref. Section 5.4.1)	Where it had been demonstrated that a dose limit *has not been exceeded*: five years or Where a dose limit *has been exceeded*: until the individual has or would have attained 75 years of age, but in any case no less than 30 years after termination of the work involving exposure to ionising radiation
	Estimation of dose (ref. Section 5.4.2)	Five years
	Medical records for Category A workers (Regulation 47)	Until the individual has or would have attained 75 years of age, but in any case no less than 30 years after termination of the work involving exposure to ionising radiation
Equipment	Details of acquisition/ transfer/ disposal of radiological equipment	Two years after disposal of the equipment
	Installation report and user manuals	Two years after disposal of the equipment
	Servicing reports	Five years
	Quality assurance/quality control reports	
	Staff training records	
	Incident/accident procedures and reports	
	Monthly visual checks as applicable	
Sources/ radioactive material	Acquisition of sealed sources	Five years after disposal of the source in question
	Acquisition and inventory of unsealed sources	Two years after disposal/decay to exemption value of the material in question
	HASS records pursuant to Regulation 72	Five years after disposal of the source in question
	Records associated with the export of radioactive material for reuse or disposal	10 years after disposal of the source in question

Topic	Parameter	Recommended retention period
Training	Training policy	Two years after the policy has been superseded
	Training records (including what training has been provided, whom it has been provided to and when it was provided)	Five years
	Specific training in relation to HASS (what, who and when)	Ten years
	Details of refresher training provided	Five years
Incidents	Reports of incident investigations	Five years

APPENDIX 5 TRANSPORT OF RADIOACTIVE MATERIAL

The undertaking must ensure that all activities associated with the transport of radioactive material are in accordance with the relevant national and international legal requirements, having regard to:

- The IAEA Regulations for the Safe Transport of Radioactive Material;
- The "European Agreement Concerning the International Carriage of Dangerous Goods by Road" (known as the ADR);
- International Maritime Dangerous Goods Code (transport by sea);
- International Civil Aviation Organisation Technical Instructions (transport by air);
- National transport regulations regarding the Carriage of Dangerous Goods.

The European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 (as amended), apply to the transport of dangerous goods by road in tanks, in bulk and in packages. This includes the packing, loading, filling and unloading of the dangerous goods in relation to their carriage. They apply the provisions contained in the technical annexes to the ADR.

Specific advisory material on the requirements of the IAEA Regulations has been published by the IAEA and is available on its website: www.iaea.org.

The Regulations and the ADR place duties on the various participants associated with the transport by road of dangerous goods. They contain requirements for the vehicles, tanks, tank containers, receptacles and packages containing the dangerous goods during their transport. They require that the drivers and others involved in the transport by road of the dangerous goods (including their packing/loading/filling/transport/unloading) be adequately trained and, in the case of drivers, hold a certificate of such training. The Regulations also contain provisions on an EU harmonised approach to the road checks aspect of their enforcement.

Consignor obligations and responsibilities

"Consignor" means any person, organisation or government that prepares a consignment for transport.

No person may offer radioactive material for transport unless it is properly marked, labelled, placarded, described and certified on a transport document, and otherwise in a condition for transport as required by the IAEA Regulations for Transport.

The consignor must include in the transport documents with each consignment the identification of the consignor and consignee (entity taking delivery), including their names, addresses, the UN number, proper shipping name, DG's Class 7, radionuclide(s), physical/chemical form, maximum activity, category of the package, transport index (as appropriate), special form source certificate (as appropriate) and certificate of declaration.

The consignor must also:

- provide the correct package type and contents for transport;
- provide the contact details of the consignee;

- provide the carrier with the relevant transport documents;
- provide information for carriers on the requirements for loading, stowage, carriage, handling and unloading of the package, mode of transport and emergency arrangements;
- have a radiation protection programme* in place for its staff;
- ensure that staff involved receive appropriate training commensurate with their duties;
- have a documented system in place for consigning Class 7 packages;
- notify the EPA and provide package approval as appropriate (only for IAEA Category 1 and 2 sources);
- keep evidence that the package complies with the IAEA Regulations;
- have details of the shipment in the event of an accident during carriage to assist the emergency services/EPA.

Carrier obligations and responsibilities

"Carrier" means any person, organisation or government undertaking the carriage of radioactive material by any means of transport. The carrier must ensure that:

- The conveyance radiation and contamination levels are within limits.
- The package is properly stowed and segregated.
- Emergency response instructions (in writing) are made available to the driver and can be implemented, including those by the consignor as appropriate.
- The radiation protection programme* for staff/drivers is implemented and a documented management system has been established.
- Drivers and carrier's staff receive appropriate training (ADR awareness, security, ADR Class 7 specialisation) with respect to their duties.
- The package is accepted only if it is not damaged and transport documents are provided.
- The vehicle is properly placarded (if required) and relevant ADR-specified equipment is on board.
- They have the appropriate authorisation/registration and emergency procedures in place to transport radioactive material in Ireland and abroad (if required).
- The package is handed over and signed for by the consignee.

Consignee obligations and responsibilities

"Consignee" means any person, organisation or government that is entitled to take delivery of a consignment. The information applicable to the consignment must accompany the consignment to its final destination. The consignee must ensure that:

- They are pre-authorised to receive the radioactive sources.
- A radiation protection programme* and a documented management system are established and implemented in practice (radiation safety procedures, ordering/receipt protocols).
- Appropriate training is provided to staff regarding their duties.
- Appropriate actions are taken in the event of a non-compliance (such as mis-delivery, damaged/incorrect package or higher dose rate than expected). The communication of a non-compliance to the consignor and the relevant competent authority, respectively, must be made as soon as practicable and shall be immediate whenever an emergency exposure situation has developed or is developing.

**A Radiation Protection Programme is intended to establish and document in a systematic and structured way, the framework of controls applied by a transport organisation, to satisfy the radiation protection requirements and provisions established in the IAEA Transport Regulations, to limit both normal and potential exposures of workers and members of the public*

APPENDIX 6 IAEA CATEGORISATION SYSTEM FOR SECURITY OF SEALED SOURCES

The international (IAEA) basic safety standards set out a five-level categorisation system for sealed sources based on the level of danger that a source represents. Sources in Category 1 are considered the most dangerous. An exposure of only a few minutes to an unshielded Category 1 source may be fatal. At the lower end of the categorisation system are sources in Category 5. However, even these sources could give rise to doses in excess of regulatory dose limits if not properly controlled, and therefore should be kept under appropriate regulatory control.

To provide adequate security without imposing overly restrictive measures, the concept of security groups is used. Four security groups (A, B, C and D) have been developed. Security Group A requires the highest degree of security while the requirements of the other groups are progressively lower. Each security group has a corresponding goal defined as the overall result that the security system should be capable of providing.

The International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, include general requirements for the security of radioactive sources, but only for sources in Security Group D. While those control measures provide a sufficient level of security for radioactive sources in Category 5, additional measures specified in this guidance should be applied to radioactive sources in Categories 1 to 4. This approach is summarised in Tables 6.1 and 6.2.

Table 12: Categories and security groups for commonly used sources

IAEA source category	Typical practices and radionuclides	A/D	Security group
1	Irradiators (sterilisation) – industrial Irradiators self-shielded – education and research and blood irradiators (Co-60 and Cs-137) Teletherapy sources (Co-60, Cs-137) Fixed multibeam teletherapy (Co-60)	A/D ≥ 1000	A
2	Industrial gamma radiography (Ir-192, Se-75) High/medium dose rate brachytherapy (Co-60, Cs-137, Ir-192)	1000 > A/D ≥ 10	B
3	Fixed industrial gauges and conveyer gauges (Cs-137, Co-60, Cf-252) Well logging gauges (Am-241/Be, Cs-137, Cf-252), onshore and offshore	10 > A/D ≥ 1	C
4	Low dose rate brachytherapy (Cs-137, Ir-192) Gauges – density, thickness, moisture (Co-60, Kr-85, Sr-90, Am-241, Am-241/Be, Pm-147, Cs-137) other than high-activity sources Bone densitometers (Cd-109, Gd-153) Static eliminators (Po-210, Am-241)	1 > A/D ≥ 0.01	C
5	Low dose rate brachytherapy eye plaques and implants (Sr-90, Ru/Rh-106) X-ray fluorescence devices (Fe-55, Cd-109, Co-57) Electron capture devices (Ni-63) Lightning preventors (Am-241, Ra-226) Positron emission tomography check sources (Ge-68) Mossbauer spectrometry sources (Co-57)	0.01 > A/D > exemption levels	D

Table 13. Recommended security requirements for different security groups

<table>
<tr><th>Security
Group A
(IAEA Cat 1)</th><th>Security
Group B
(IAEA Cat 2)</th><th>Security
Group C
(IAEA Cat 3) & (IAEA Cat 4)</th><th>Security
Group D
(IAEA Cat 5)</th></tr>
<tr><td colspan="4">Compliance with relevant legislation and regulations</td></tr>
<tr><td colspan="4">Appropriate secure premises & source holding devices</td></tr>
<tr><td colspan="4">Key control measures</td></tr>
<tr><td colspan="3">Access control measures</td><td rowspan="5"></td></tr>
<tr><td colspan="3">Vetting of personnel – background, references, etc.</td></tr>
<tr><td colspan="3">Ability to upgrade security for increased risk/threat</td></tr>
<tr><td colspan="3">Site security plan</td></tr>
<tr><td colspan="3">Information security plan</td></tr>
<tr><td colspan="2">Protection by at least three appropriate physical security layers</td><td>Protection by at least two appropriate physical security layers (Appendix 3)</td><td>Protection by at least one appropriate physical security layer</td></tr>
<tr><td colspan="3">Protection by a monitored intruder alarm system</td><td rowspan="4"></td></tr>
<tr><td colspan="3">An Garda Síochána response to verified alarm activation</td></tr>
<tr><td>Surveillance by a CCTV system with recording facilities
and/or
On-site 24-hour security to a level required by and approved by An Garda Síochána</td><td>Surveillance by a CCTV system with recording facilities</td><td>CCTV recording system
(depending on the site (permanent/temporary), crime profile, location, etc.)</td></tr>
<tr><td colspan="3"></td></tr>
</table>

APPENDIX 7 NON-MEDICAL HUMAN IMAGING

The use of X-ray, CT or other ionising radiation techniques for human imaging, where the primary intention of the exposure is not to bring a health benefit to the individual being exposed, is classified as non-medical human imaging. Typical examples of non-medical human imaging include use of dual-energy D-ray absorptiometry (DEXA) or CT for sports performance, and use of X-rays as part of visa applications, for security purposes or for age determination. In accordance with Regulation 16(1), the EPA is responsible for identifying practices involving non-medical imaging.

Where a practice is deemed by the EPA to fall into the category of non-medical human imaging, the EPA is the competent authority for both justification in accordance with Regulation 5 and regulatory control including authorisation, compliance assessment and enforcement. This is the case regardless of whether medical radiological equipment is used or whether the exposure occurs in a medical radiological installation or elsewhere. Under such circumstances, the EPA is responsible for enforcement of the relevant provisions of both IRR19 and S.I. 256 of 2018.

Specific regulatory requirements relating to non-medical human imaging

The Regulations impose a number of specific requirements in relation to non-medical human imaging practice, which include:

- Practices must be carried out in accordance with the criteria for individual implementation established by the EPA in accordance with Regulation 16(3).
- Individual exposures must be justified in accordance with Regulation 5(6), taking into account the specific objectives of the procedure and the characteristics of the individual involved.
- Prior to any exposure, information on the exposure must be provided to the individual to be exposed (Regulation 16(2)(i)).
- Consent must be obtained from the individual to be exposed, unless otherwise provided in legislation (Regulation 16(2)(ii)).

Regulation 16(3)(a) provides that the EPA *"shall establish, as appropriate, requirements for practices involving non-medical imaging exposure, including criteria for individual implementation".* For the purposes of establishing such requirements the EPA may consult with such other persons or bodies as it sees fit (Regulation (3)(b)). Such requirements will be specific to a practice and may include, *inter alia*:

- age restrictions;
- dose reference levels/specific dose constraints;
- quality control criteria;
- specific protocols, consistent with the objective of the exposure and required image quality;
- conditions for oversight or approval of programmes involving the use of non-medical imaging;
- conditions for individual justification;
- other restrictions on the application of the practice.

Justification

Where a non-medical human imaging practice is deemed to be justified, the justification shall be limited by the requirements established under Regulation 16. In other words, where the application of a justified practice fails to meet the Regulation 16 requirements, it shall no longer be considered justified. The EPA shall include justified non-medical human imaging practices in the list of justified practices published in its website in accordance with Regulation 5(6). Additionally, for each justified non-medical human imaging practice, the EPA will publish the practice-specific Regulation 16(3) requirements.

Authorisation

In accordance with Regulation 16(4)(b), applications for authorisation *(registration or licence)* of any practice involving non-medical human imaging must include a detailed plan demonstrating how the undertaking will meet the relevant requirements of S.I. 256 of 2018. The plan should cover, *inter alia*, the requirements relating to equipment, optimisation, responsibilities, training, special protection during pregnancy and the appropriate involvement of the MPE. Such plans will be subject to examination and approval by the EPA before the grant of an authorisation.

Where the EPA amends a non-medical human imaging practice stated to be authorised by attaching or specifying new conditions, by amending the definitions of the authorised practice or by amending Regulation 16(3) requirements, the EPA may require an undertaking to submit to it an updated plan demonstrating how it will continue to meet the relevant requirements.

AN GHNÍOMHAIREACHT UM CHAOMHNÚ COMHSHAOIL

Tá an GCC freagrach as an gcomhshaol a chosaint agus a fheabhsú, mar shócmhainn luachmhar do mhuintir na hÉireann. Táimid tiomanta do dhaoine agus don chomhshaol a chosaint ar thionchar díobhálach na radaíochta agus an truaillithe.

Is féidir obair na Gníomhaireachta a roinnt ina trí phríomhréimse:

Rialáil: *Rialáil agus córais chomhlíonta comhshaoil éifeachtacha a chur i bhfeidhm, chun dea-thorthaí comhshaoil a bhaint amach agus díriú orthu siúd nach mbíonn ag cloí leo.*

Eolas: *Sonraí, eolas agus measúnú ardchaighdeáin, spriocdhírithe agus tráthúil a chur ar fáil i leith an chomhshaoil chun bonn eolais a chur faoin gcinnteoireacht.*

Abhcóideacht: *Ag obair le daoine eile ar son timpeallachta glaine, táirgiúla agus dea-chosanta agus ar son cleachtas inbhuanaithe i dtaobh an chomhshaoil.*

I measc ár gcuid freagrachtaí tá:

Ceadúnú

- Gníomhaíochtaí tionscail, dramhaíola agus stórála peitril ar scála mór;
- Sceitheadh fuíolluisce uirbigh;
- Úsáid shrianta agus scaoileadh rialaithe Orgánach Géinmhodhnaithe;
- Foinsí radaíochta ianúcháin;
- Astaíochtaí gás ceaptha teasa ó thionscal agus ón eitlíocht trí Scéim an AE um Thrádáil Astaíochtaí.

Forfheidhmiú Náisiúnta i leith Cúrsaí Comhshaoil

- Iniúchadh agus cigireacht ar shaoráidí a bhfuil ceadúnas acu ón GCC;
- Cur i bhfeidhm an dea-chleachtais a stiúradh i ngníomhaíochtaí agus i saoráidí rialáilte;
- Maoirseacht a dhéanamh ar fhreagrachtaí an údaráis áitiúil as cosaint an chomhshaoil;
- Caighdeán an uisce óil phoiblí a rialáil agus údaruithe um sceitheadh fuíolluisce uirbigh a fhorfheidhmiú
- Caighdeán an uisce óil phoiblí agus phríobháidigh a mheasúnú agus tuairisciú air;
- Comhordú a dhéanamh ar líonra d'eagraíochtaí seirbhíse poiblí chun tacú le gníomhú i gcoinne coireachta comhshaoil;
- An dlí a chur orthu siúd a bhriseann dlí an chomhshaoil agus a dhéanann dochar don chomhshaol.

Bainistíocht Dramhaíola agus Ceimiceáin sa Chomhshaol

- Rialacháin dramhaíola a chur i bhfeidhm agus a fhorfheidhmiú lena n-áirítear saincheisteanna forfheidhmithe náisiúnta;
- Staitisticí dramhaíola náisiúnta a ullmhú agus a fhoilsiú chomh maith leis an bPlean Náisiúnta um Bainistíocht Dramhaíola Guaisí;
- An Clár Náisiúnta um Chosc Dramhaíola a fhorbairt agus a chur i bhfeidhm;
- Reachtaíocht ar rialú ceimiceán sa timpeallacht a chur i bhfeidhm agus tuairisciú ar an reachtaíocht sin.

Bainistíocht Uisce

- Plé le struchtúir náisiúnta agus réigiúnacha rialachais agus oibriúcháin chun an Chreat-treoir Uisce a chur i bhfeidhm;
- Monatóireacht, measúnú agus tuairisciú a dhéanamh ar chaighdeán aibhneacha, lochanna, uiscí idirchreasa agus cósta, uiscí snámha agus screamhuisce chomh maith le tomhas ar leibhéil uisce agus sreabhadh abhann.

Eolaíocht Aeráide & Athrú Aeráide

- Fardail agus réamh-mheastacháin a fhoilsiú um astaíochtaí gás ceaptha teasa na hÉireann;
- Rúnaíocht a chur ar fáil don Chomhairle Chomhairleach ar Athrú Aeráide agus tacaíocht a thabhairt don Idirphlé Náisiúnta ar Ghníomhú ar son na hAeráide;
- Tacú le gníomhaíochtaí forbartha Náisiúnta, AE agus NA um Eolaíocht agus Beartas Aeráide.

Monatóireacht & Measúnú ar an gComhshaol

- Córais náisiúnta um monatóireacht an chomhshaoil a cheapadh agus a chur i bhfeidhm: teicneolaíocht, bainistíocht sonraí, anailís agus réamhaisnéisiú;
- Tuairiscí ar Staid Thimpeallacht na hÉireann agus ar Tháscairí a chur ar fáil;
- Monatóireacht a dhéanamh ar chaighdeán an aeir agus Treoir an AE i leith Aeir Ghlain don Eoraip a chur i bhfeidhm chomh maith leis an gCoinbhinsiún ar Aerthruailliú Fadraoin Trasteorann, agus an Treoir i leith na Teorann Náisiúnta Astaíochtaí;
- Maoirseacht a dhéanamh ar chur i bhfeidhm na Treorach i leith Torainn Timpeallachta;
- Measúnú a dhéanamh ar thionchar pleananna agus clár beartaithe ar chomhshaol na hÉireann.
- Taighde agus Forbairt Comhshaoil
- Comhordú a dhéanamh ar ghníomhaíochtaí taighde comhshaoil agus iad a mhaoiniú chun brú a aithint, bonn eolais a chur faoin mbeartas agus réitigh a chur ar fáil;
- Comhoibriú le gníomhaíocht náisiúnta agus AE um thaighde comhshaoil.

Cosaint Raideolaíoch

- Monatóireacht a dhéanamh ar leibhéil radaíochta agus nochtadh an phobail do radaíocht ianúcháin agus do réimsí leictreamaighnéadacha a mheas;
- Cabhrú le pleananna náisiúnta a fhorbairt le haghaidh éigeandálaí ag eascairt as taismí núicléacha;
- Monatóireacht a dhéanamh ar fhorbairtí thar lear a bhaineann le saoráidí núicléacha agus leis an tsábháilteacht raideolaíochta;
- Sainseirbhísí um chosaint ar an radaíocht a sholáthar, nó maoirsiú a dhéanamh ar sholáthar na seirbhísí sin.

Treoir, Ardú Feasachta agus Faisnéis Inrochtana

- Tuairiscú, comhairle agus treoir neamhspleách, fianaise-bhunaithe a chur ar fáil don Rialtas, don tionscal agus don phobal ar ábhair maidir le cosaint comhshaoil agus raideolaíoch;
- An nasc idir sláinte agus folláine, an geilleagar agus timpeallacht ghlan a chur chun cinn;
- Feasacht comhshaoil a chur chun cinn lena n-áirítear tacú le hiompraíocht um éifeachtúlacht acmhainní agus aistriú aeráide;
- Tástáil radóin a chur chun cinn i dtithe agus in ionaid oibre agus feabhsúchán a mholadh áit is gá.

Comhpháirtíocht agus líonrú

- Oibriú le gníomhaireachtaí idirnáisiúnta agus náisiúnta, údaráis réigiúnacha agus áitiúla, eagraíochtaí neamhrialtais, comhlachtaí ionadaíocha agus ranna rialtais chun cosaint chomhshaoil agus raideolaíoch a chur ar fáil, chomh maith le taighde, comhordú agus cinnteoireacht bunaithe ar an eolaíocht.

Bainistíocht agus struchtúr na Gníomhaireachta um Chaomhnú Comhshaoil

Tá an GCC á bhainistiú ag Bord lánaimseartha, ar a bhfuil Ard-Stiúrthóir agus cúigear Stiúrthóir. Déantar an obair ar fud cúig cinn d'Oifigí:

- An Oifig um Inbhuanaitheacht i leith Cúrsaí Comhshaoil
- An Oifig Forfheidhmithe i leith Cúrsaí Comhshaoil
- An Oifig um Fhianaise agus Measúnú
- An Oifig um Chosaint ar Radaíocht agus Monatóireacht Comhshaoil
- An Oifig Cumarsáide agus Seirbhísí Corparáideacha

Tugann coistí comhairleacha cabhair don Ghníomhaireacht agus tagann siad le chéile go rialta le plé a dhéanamh ar ábhair imní agus le comhairle a chur ar an mBord.

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

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