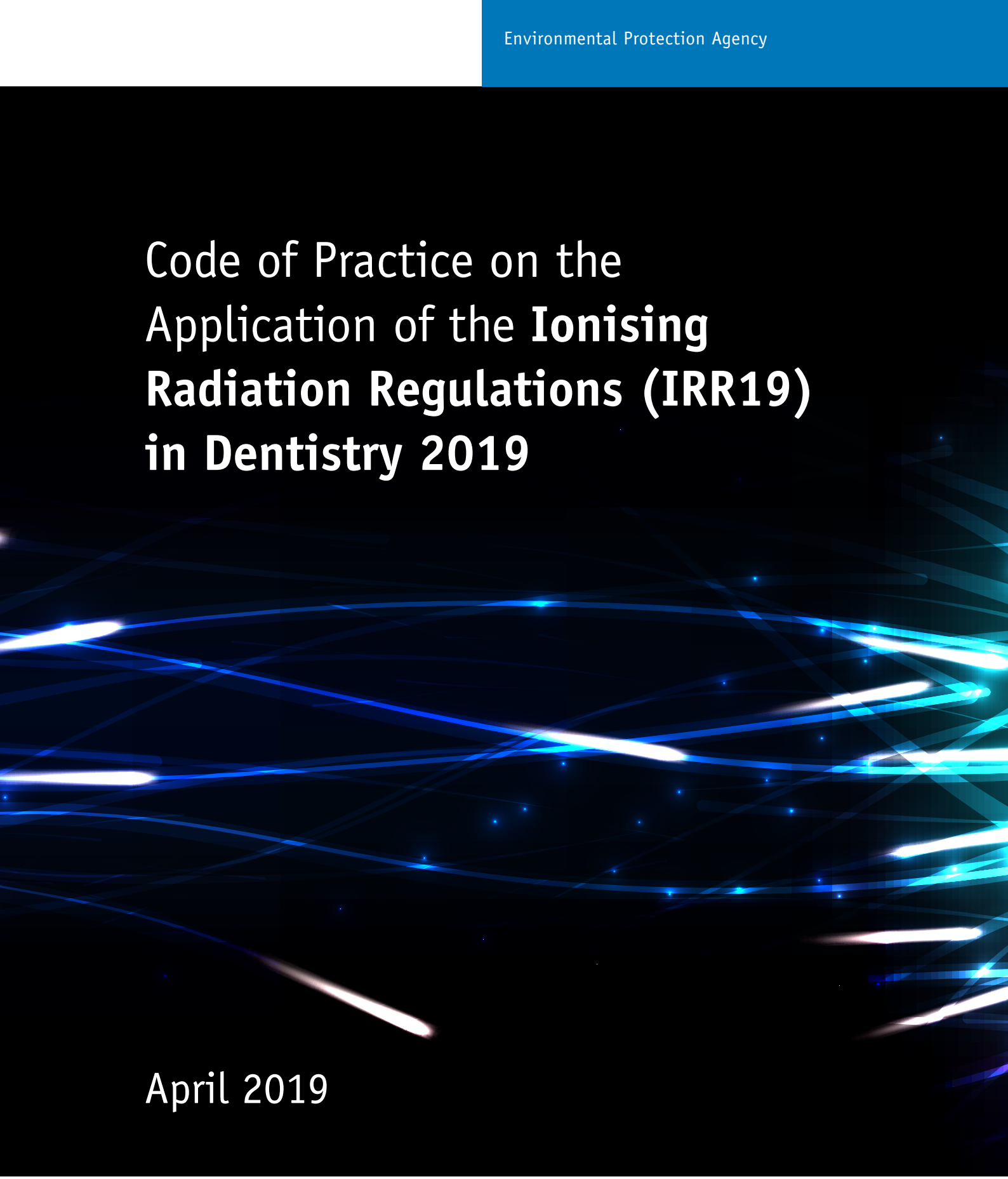
Environmental Protection Agency

Code of Practice on the Application of the **Ionising Radiation Regulations (IRR19) in Dentistry 2019**



April 2019

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Environmental Protection Agency

The Environmental Protection Agency (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: *We implement effective regulation and environmental compliance systems to deliver good environmental outcomes and target those who don't comply.*

Knowledge: *We provide high quality, targeted and timely environmental data, information and assessment to inform decision making at all levels.*

Advocacy: *We work with others to advocate for a clean, productive and well protected environment and for sustainable environmental behaviour.*

Our Responsibilities

LICENSING

We regulate the following activities so that they do not endanger human health or harm the environment:

- waste facilities *(e.g. landfills, incinerators, waste transfer stations);*
- large scale industrial activities *(e.g. pharmaceutical, cement manufacturing, power plants);*
- intensive agriculture *(e.g. pigs, poultry);*
- the contained use and controlled release of Genetically Modified Organisms *(GMOs);*
- sources of ionising radiation *(e.g. x-ray and radiotherapy equipment, industrial sources);*
- large petrol storage facilities;
- waste water discharges;
- dumping at sea activities.

NATIONAL ENVIRONMENTAL ENFORCEMENT

- Conducting an annual programme of audits and inspections of EPA licensed facilities.
- Overseeing local authorities' environmental protection responsibilities.
- Supervising the supply of drinking water by public water suppliers.
- Working with local authorities and other agencies to tackle environmental crime by co-ordinating a national enforcement network, targeting offenders and overseeing remediation.
- Enforcing Regulations such as Waste Electrical and Electronic Equipment (WEEE), Restriction of Hazardous Substances (RoHS) and substances that deplete the ozone layer.
- Prosecuting those who flout environmental law and damage the environment.

WATER MANAGEMENT

- Monitoring and reporting on the quality of rivers, lakes, transitional and coastal waters of Ireland and groundwaters; measuring water levels and river flows.
- National coordination and oversight of the Water Framework Directive.
- Monitoring and reporting on Bathing Water Quality.

MONITORING, ANALYSING AND REPORTING ON THE ENVIRONMENT

- Monitoring air quality and implementing the EU Clean Air for Europe (CAFÉ) Directive.
- Independent reporting to inform decision making by national and local government *(e.g. periodic reporting on the State of Ireland's Environment and Indicator Reports)*.

REGULATING IRELAND'S GREENHOUSE GAS EMISSIONS

- Preparing Ireland's greenhouse gas inventories and projections.
- Implementing the Emissions Trading Directive, for over 100 of the largest producers of carbon dioxide in Ireland.

ENVIRONMENTAL RESEARCH AND DEVELOPMENT

- Funding environmental research to identify pressures, inform policy and provide solutions in the areas of climate, water and sustainability.

STRATEGIC ENVIRONMENTAL ASSESSMENT

- Assessing the impact of proposed plans and programmes on the Irish environment *(e.g. major development plans)*.

RADIOLOGICAL PROTECTION

- Monitoring radiation levels, assessing exposure of people in Ireland to ionising radiation.
- Assisting in developing national plans for emergencies arising from nuclear accidents.
- Monitoring developments abroad relating to nuclear installations and radiological safety.
- Providing, or overseeing the provision of, specialist radiation protection services.

GUIDANCE, ACCESSIBLE INFORMATION AND EDUCATION

- Providing advice and guidance to industry and the public on environmental and radiological protection topics.
- Providing timely and easily accessible environmental information to encourage public participation in environmental decision-making *(e.g. My Local Environment, Radon Maps)*.
- Advising Government on matters relating to radiological safety and emergency response.
- Developing a National Hazardous Waste Management Plan to prevent and manage hazardous waste.

AWARENESS RAISING AND BEHAVIOURAL CHANGE

- Generating greater environmental awareness and influencing positive behavioural change by supporting businesses, communities and householders to become more resource efficient.
- Promoting radon testing in homes and workplaces and encouraging remediation where necessary.

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 an Advisory Committee of twelve members who meet regularly to discuss issues of concern and provide advice to the Board.

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April 2019

ENVIRONMENTAL PROTECTION AGENCY

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- Dublin Dental University Hospital
- Heath Information and Quality Authority (HIQA)
- Henry Schein Ireland
- Irish Association of Physicists in Medicine (IAPM) Radiation Protection Special Interest Group (RP SIG)
- Irish Dental Association (IDA)
- Medical Physics & Bioengineering Department, St. James's Hospital
- National Radiation Safety Committee and the National Dental Subcommittee
- Public Health England (PHE)

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Section 1 Introduction

Oral radiology is an essential part of modern dentistry and brings very significant benefits for patients. Any use of ionising radiation carries intrinsic risks and hence the use of radiology in dentistry is regulated to ensure the safety of patients, staff and members of the public.

Irish 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 Ionising Radiation Regulations, 2019 (S.I. No. 30 of 2019), hereafter called IRR19, which covers the protection of workers and members of the public [Ref. 1].
- 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 [Ref. 2].

The Environmental Protection Agency (EPA) is the Competent Authority for IRR19 and the Health Information and Quality Authority (HIQA) is the Competent Authority for S.I. 256 of 2018.

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

Throughout this code the term 'undertaking/dentist' is used to refer to the person with primary responsibility for compliance with the Regulations.

This code of practice[1] is intended to support undertakings/dentists in complying with IRR19.

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

[1]This code of practice supersedes the EPA's earlier Code of Practice for Radiological Protection in Dentistry (1996) and incorporates the EPA's position statements on the use of lead aprons (2011) and on personal dosimetry (2011).

Section 2 Statutory Controls

2.1 Introduction

IRR19 provides for the establishment of a comprehensive system of regulation covering the use of ionising radiation in Ireland and sets out the role of the EPA as the national regulator. This system of regulation comprises four elements as illustrated in Figure 1.

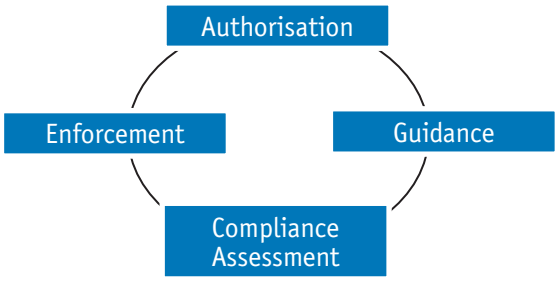

Figure 1 The regulatory system

Regulation is risk-based, with the greatest regulatory effort being directed towards higher risk activities. This risk-based 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 rigorous form of authorisation and will be subject to greater enforcement focus.

2.2 Authorisation

The use of oral radiology in Ireland must be authorised in advance by the EPA through either a registration or a licence.

Registration is appropriate when using fixed X-ray equipment including intraoral, panoramic, cephalometry and cone beam CT.

Licensing is appropriate where oral radiology procedures are undertaken using hand-held equipment (Section 4.4.5).

Irrespective of the form of authorisation, all undertakings/dentists carrying out oral radiology must fully comply with the relevant provisions of the IRR19 and are subject to compliance assessment including inspection by the EPA.

There are significant differences between the two forms of authorisation, which are set out in Table 2.

Table 2 Forms of Authorisation (oral radiology)

	Registration	Licensing
Duration of authorisation	Indefinite (unless surrendered or revoked)	10 years (renewable)
Documentation to be submitted with applications	• self-declaration confirming compliance with the requirements for registration	• risk assessment • additional safety procedures • other information as specified by the EPA

2.2.1 Application for authorisation

All applications for an authorisation must be made through the online EDEN system. The information to be provided in an application includes:

- The nature of the radiology activities for which authorisation is sought (these are referred to as practices in EDEN);
- The legal details of the undertaking/dentist;
- The name of the Radiation Protection Adviser (RPA) consulted;
- The address of the undertaking/dentist and of the premises at which oral radiology is to be carried out.

Depending on the nature of the activities for which an authorisation is sought, the EDEN system will guide the user through the registration or licensing process as appropriate.

For registration, an undertaking/dentist must self-declare that they have:

- Completed a risk assessment in consultation with an RPA to identify any necessary protective measures (Section 4);
- Implemented this Code and any additional measures identified in the risk assessment (Section 4);
- Designated a Radiation Protection Officer (RPO) (Section 3);
- Provided staff with the appropriate training (Section 5);
- Developed procedures to be followed in the event of an incident liable to have radiation safety implications for workers and members of the public (Section 6.4).

Undertakings/dentists holding an EPA registration must retain on file documentary evidence supporting the self-declaration. In addition, an inventory must be maintained of X-ray 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.

For licensing an undertaking/dentist must upload copies of their risk assessment and the additional safety procedures (as appropriate) through EDEN at the time of application.

Where an undertaking/dentist operates clinics across multiple premises, the requirements in relation to the risk assessment and additional safety procedures apply to each clinic. Each individual premises must be listed in the registration or licence as appropriate.

When a certificate of registration or licence is granted this must be displayed publicly within each premises.

2.2.2 Amendments to an authorisation

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

- Add or remove a dental premises under an existing registration or licence;
- Carry out an additional oral radiology practice not covered by an existing licence or registration. An amendment would be necessary, for example, before introducing cone beam CT in a clinic already registered for the use of intraoral or panoramic;
- Removal of an oral radiology practice under an existing registration or licence;
- Make any changes to the schedule of X-ray equipment used for licensed practices.

Applications to amend an authorisation must be made through EDEN.

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

2.2.3 Selling or transferring a dental practice

If a dental practice is sold or transferred, the new undertaking/dentist must apply for a registration or licence as appropriate in his or her own name, as authorisations are non-transferable.

2.3 Guidance

The EPA, as part of its regulatory function, sets out practical guidance for the purpose of supporting undertakings in complying with their legal requirements. This Code of Practice is the primary source of guidance for the protection of staff and public in oral radiology.

2.4 Compliance assessment

Compliance assessment by the EPA is a key element of the system of regulation. In accordance with IRR19 the EPA will routinely assess whether those authorised to use ionising radiation are compliant with the Regulations and any conditions associated with their authorisation. The assessment processes include:

- self-assessment;
- review of safety documentation;
- on-site inspections.

2.4.1 Self-assessment

To verify continued compliance, the EPA may issue self-assessment questionnaires to dentists for completion and return within a specified period. An inspector may follow up with an on-site inspection.

2.4.2 Review of safety documentation

The EPA may at any time request copies of the current risk assessment, commissioning report or other relevant documentation for the purpose of reviewing their adequacy.

2.4.3 On-site inspections

An inspector from the EPA may visit the premises to verify compliance with the legislation and this Code. The inspection may be announced or unannounced.

The inspector may examine documents including:

- Commissioning/quality assurance (QA) reports;
- Risk assessments;
- RPO designation;
- RPA consultation;
- Relevant training records;
- Inventory of equipment.

The EPA will issue an inspection report online through EDEN.

2.5 Legal enforcement

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. Such enforcement action may include:

- Placing of conditions on the licence or registration to limit or restrict the use of X-ray equipment;
- Issue of a legal direction to address an immediate risk or danger;
- Serving of an enforcement notice requiring specific corrective action to be taken;
- Prosecution in the district or circuit court;
- Revocation of a licence or registration.

In taking any enforcement action the EPA aims to be:

- Proportionate in its approach. The EPA will ensure that any enforcement action taken by it is balanced with the risk posed to staff and/or the public;
- Consistent in its decisions. In responding to any breach of the Regulations, the EPA will take account of factors such as the scale and nature of the breach, management response to the incident or breach and the history of previous incidents or breaches;
- Transparent in its actions. The EPA aims to make it clear to those regulated what is expected of them. It will also aim to be clear as to why it intends to take, or has taken, any enforcement action.

Section 3 Governance and Responsibilities

Knowing who is accountable, and where the distinct governance roles and responsibilities sit in a dental setting, is essential to ensuring safety for all staff.

There must be evidence that governance arrangements associated with radiation protection are clearly defined and have been notified to staff, as appropriate. In the case of large institutions these arrangements may include a radiation safety committee.

All staff have an obligation to comply with the requirements outlined in this Code and any additional safety procedures.

3.1 The undertaking

The undertaking is the entity with primary legal responsibility for compliance with the Regulations. In dentistry, this is usually, but not always, the principal dentist or practice owner.

The undertaking/dentist's responsibilities shall include but not be exclusive to the following:

- Ensuring that risks to staff and members of the public from all activities involving the use of ionising radiation are adequately assessed;
- Implementation of arrangements for the radiation protection of all staff and members of the public;
- Designation of an RPO, who shall report directly to the undertaking/dentist;
- Provision of appropriate resources and training to the RPO (as outlined in Section 5 of this Code) to effectively carry out the responsibilities listed in Section 3.3 of this Code;
- Seeking advice from an RPA to ensure compliance with IRR19;
- Providing the RPA with access, adequate information and facilities for the discharge of his/her functions;
- Ensuring that X-ray equipment is operated only by appropriately trained staff (Section 5) and under the responsibility of a dental practitioner;
- Ensuring that X-ray equipment is appropriately installed, commissioned and subject to quality assurance;
- Ensuring, where the authorisation covers multiple premises, that local governance arrangements are in place;
- Ensuring that documentation relevant to compliance with IRR19 is maintained and accessible as required by the EPA.

3.2 The RPA

An RPA is a qualified expert approved by the EPA to provide radiological protection advice pursuant to IRR19. The EPA publishes a list of approved RPAs on its website.

In accordance with the Regulations, the undertaking/dentist shall seek advice from an RPA on a range of matters including but not limited to:

- Preparation or update of risk assessments and additional safety procedures where relevant;
- Estimation of doses to workers and members of the public;
- Classification of areas and categorisation of workers;
- Quality assurance measures;
- Radiation protection training of relevant staff;
- Dose monitoring where appropriate;
- Safety aspects associated with the acquisition of any new X-ray equipment;
- Commissioning and acceptance into service of new X-ray equipment;
- Preparation and submission of incident reports;
- Design (including shielding specifications) of any new buildings or facilities;
- Modifications to any existing X-ray equipment or facilities;
- Changes to the use of any buildings or adjoining buildings where X-rays are in use.

3.3 The RPO

The RPO shall be designated by the undertaking/dentist to supervise or implement the radiation protection arrangements. The RPO shall report directly to the undertaking/dentist.

The RPO's responsibilities shall include but not be exclusive to the following:

- Liaise with the RPA, as required, to comply with IRR19;
- Ensure that adequate records are maintained to provide assurance that the dental facility complies with the requirements outlined in this Code;
- Oversee the ongoing safe operation of X-ray equipment;
- Monitor implementation of this Code and additional safety procedures where applicable;
- Facilitate and/or provide training, as appropriate;
- Maintain an adequate records of all X-ray equipment associated with the undertaking/dentist's authorisation;
- Maintain relevant documentation in a manner that is accessible by the EPA;
- Consult and liaise with the EPA as the regulatory authority;
- Supervise radiation protection arrangements in order to minimise personal radiation doses.

Where an authorisation covers multiple premises, the governance arrangements must ensure that the RPO functions are appropriately carried out at each location. This may necessitate the nomination of additional RPOs and/or named member(s) of staff with relevant experience to support the RPO(s).

Section 4 Measures for the Protection of Staff and Members of the Public

4.1 Risk assessment

Undertakings/dentists must ensure that all exposures from radiological procedures under its control are kept as low as reasonably achievable for staff and members of the public. The purpose of the risk assessment is to identify the protective measures needed to restrict exposures to radiation. The risk assessment should be carried out by the undertaking/dentist in consultation with their RPA. The risk assessment must be:

- carried out prior to acquiring X-ray equipment (Section 4.1.1) and
- reviewed and maintained (Section 4.1.2).

4.1.1 Carrying out the risk assessment

Prior to acquiring X-ray equipment, the undertaking/dentist must make an assessment acceptable to the EPA of the nature and magnitude of the risks of exposure to ionising radiation for workers and members of the public.

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 operation as well as from reasonably foreseeable incidents (such as equipment failure or operator errors). Specifically, the risk assessments should take account of:

- The type of X-ray equipment;
- The design and structure of the building;
- Occupancy of adjoining areas;
- The clinical layout;
- Routine and reasonably foreseeable workloads;
- Other factors relevant to public/occupational exposure.

The purpose of this assessment is to determine:

- Whether any additional shielding is required so that the dose to members of the public does not exceed 0.3 mSv per year;
- If additional safety procedures are required (Section 4.5);
- If specific measures are necessary to prevent exposure in the event of reasonably foreseeable incidents during routine work;
- If staff are liable to receive an annual radiation dose that is above the statutory limit for a member of the public. In such situations, staff will be categorised as exposed workers and classification of areas will be required in accordance with IRR19.[2]

4.1.2 Review and maintenance of the risk assessment

The risk assessment must be reviewed and revised if necessary, under the following circumstances:

- Where an increase to the workload is anticipated, or has taken place;
- Where X-ray equipment has been modified, for example where a panoramic unit has been upgraded to cone beam CT;
- In cases where the layout of the premises has changed and this may affect its shielding properties;
- The relocation of dental X-ray equipment within the premises;
- A change in occupancy or function of an adjoining room;
- The acquisition of new X-ray equipment;
- Other circumstances where it is reasonable to believe that the risk assessment is no longer appropriate.

[2]In most dental situations staff are unlikely to be categorised as exposed workers and therefore classification of areas is not normally required. Where there are exposed workers a risk assessment shall determine the classification of areas.

4.2 Site requirements

4.2.1 Room design

Room design and positioning of X-ray equipment are critical to the protection of staff and public from any hazards associated with the use of ionising radiation. The planning of the room layout should take place at an early stage and involve all key stakeholders such as the undertaking/dentist, supplier/installer, RPA and architect if relevant. This is normally done in conjunction with the risk assessment (see 4.1.1). No structural shielding is required if the workload is fewer than 20 intraoral exposures per week and the distance between the patient and the wall or other boundary is at least 2 metres. For all other circumstances the requirement for shielding should be determined from the risk assessment. Detailed guidance on room design is provided in the EPA's design code for diagnostic facilities [Ref. 3].

General considerations relevant to the design of dental surgeries are set out below. In addition, considerations relevant to specific types of equipment are set out in Table 3 below.

General design considerations

- The room accommodating the equipment must be designed in consultation with the RPA, who will determine the shielding requirements considering: equipment type, reasonably foreseeable workloads, room layout and occupancy of adjacent areas.
- The equipment should be installed and used so that the primary beam is not directed towards unshielded floors, ceilings, doors or windows if the space beyond them is occupied.
- The operator must be able to observe the patient and the X-ray tube exposure indicator during radiography procedures. If the X-ray equipment is controlled from outside the room, a shielded viewing panel or other appropriate means must be provided.
- The room layout must be such that the dentist can control access while an X-ray is being taken. In designing the layout, particular care should be taken in situations where there are multiple points of access.
- The exposure and isolation switches must be located at a point more than 2 metres from the patient's head during exposure. They should be clearly labelled and positioned to be easily accessible to the operator.
- There should be measures in place to prevent unauthorised exposures while the X-ray equipment is switched on or in an exposure-ready state. This may be necessary where the operator exposure controls are located outside the room in a public area.
- If more than one X-ray unit is located in a room, it must not be possible for the operator to inadvertently energise the wrong X-ray unit or to accidentally irradiate persons working independently in another part of the room.

Table 3 Specific design considerations

Equipment type	Specific considerations
Intraoral	▶ In rooms with more than one treatment bay, there must be adequate shielding or distance between the dental chairs.
Extraoral	▶ Room design, shielding and equipment siting for extraoral equipment should take account of the higher radiation outputs when compared to intraoral equipment. In particular, the risk assessment must consider: ▶ the shielding requirements; ▶ whether the equipment should be sited in a dedicated radiology room; ▶ whether there is a need for a protective operators' screen; ▶ appropriate signage and/or warning lights.
Cone beam CT	▶ The shielding requirements for a cone beam CT are likely to be greater than for other dental X-ray equipment due to its higher radiation output. ▶ Cone beam CT must be installed in a dedicated X-ray room. ▶ Where a cone beam CT is installed into a room previously designed for intraoral or extraoral, it is necessary to revise the risk assessment and to determine if additional shielding and/or access controls are required. This includes situations where an existing extraoral is upgraded to function as a cone beam CT. ▶ A radiation warning sign shall be posted on the entrance door. ▶ Warning lights shall be used. Standard two-stage warning lights are recommended. ▶ The risk assessment should consider the requirements for: ▶ the protective operator's screen; ▶ positioning and security of isolation and exposure switches.

4.3 Equipment requirements

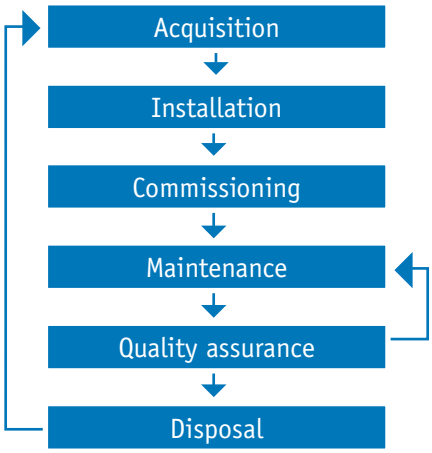

Figure 2 Equipment Life cycle

4.3.1 Acquisition of new equipment

In specifying and acquiring new dental X-ray equipment, the undertaking/dentist must have regard to the following:

- All equipment must be CE marked and be approved for use under the medical devices regulations [Ref. 5];
- Account must be taken of any relevant advice or guidance issued by HIQA, the Health Products Regulatory Authority (HPRA), the Dental Council, the European Commission or other relevant authorities.

4.3.2 Installation

X-ray equipment must be installed by suitably competent and qualified installers. The installer shall provide a written installation report, which should include details of the safety checks carried out. This report should be retained in accordance with Section 7 of this Code and be available to your RPA and to an EPA inspector on request.

These provisions also apply to X-ray equipment which is being relocated.

4.3.3 Commissioning

Equipment shall not be used on patients until it has been successfully commissioned. Commissioning is a set of acceptance tests carried out, independent of the installer, by a suitably qualified person on behalf of the undertaking/dentist in consultation with an RPA. These tests are designed to ensure that the equipment is safe to use and to establish baseline values against which the results of routine quality assurance tests can be compared. Commissioning reports must be retained in accordance with Section 7 of this Code and must include:

- The results of performance tests against the parameters listed in Appendix 1;
- A statement as to whether each test result falls within the acceptable criteria;
- The Standards (EU, international, etc.) against which these results have been assessed.

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

4.3.4 Maintenance and servicing of equipment

All X-ray equipment shall be maintained in good working condition and serviced as per manufacturer's instructions and any defects in their performance or safety shall be corrected as soon as possible by a suitably qualified and competent person. Equipment deemed to have a fault that may impact on radiation protection and safety must be taken out of service until the fault is rectified. Maintenance reports must be retained in accordance with Section 7 of this code.

The advice of an RPA shall be sought on an appropriate preventive maintenance schedule taking account of the manufacturer's recommendations, workload, age of the equipment and other relevant factors.

4.3.5 Quality assurance (QA)

All X-ray equipment must be subject to quality assurance assessment every two years (24 months). The parameters to be assessed and the acceptable tolerances should be determined by the RPA considering international guidance, the manufacturer's recommendations and any relevant factors arising from the risk assessment. In general, the parameters assessed as part of the quality assurance testing will be similar to those assessed during commissioning (see Appendix 1). Quality assurance reports must be retained in accordance with Section 7 of this Code.

4.3.6 Disposal

Prior to disposal, X-ray equipment 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. A record shall be maintained of all X-ray equipment disposed of in accordance with Section 7 of this Code.

4.3.7 Safety and security

Undertakings/dentists must put suitable security arrangements in place to prevent, in so far as is possible, the loss of, theft of, unauthorised access to or unintended use of X-ray equipment. X-ray units held in storage should be clearly labelled and their presence confirmed on a monthly basis. Particular care should be taken in relation to the security of portable or hand-held X-ray equipment.

4.4 Operating procedures

4.4.1 General operating procedures

- The operator and other staff should stand at least 2 metres from the tube and the patient's head during exposure. During the exposure, the operator must control access to this area.
- Where the room is too small to allow a 2 metre distance, the risk assessment should determine the need for any protective measures such as use of a protective screen or positioning of the operator outside the room.
- The operator and other staff must not be exposed to the primary beam during either a radiography examination or equipment testing.
- The primary beam shall not be directed through unshielded doors, floors, windows or ceilings behind which persons may be situated.
- During the exposure, the operator must position themselves so that they can simultaneously observe both the patient and the X-ray exposure indicator.
- Hand-held equipment shall only be used with the X-ray beam in the horizontal plane and with the backscatter shield in place.

4.4.2 Holding or supporting of patients during procedures

In certain situations, it will be necessary to hold a patient during a radiology examination. In general, members of staff should not be assigned to perform such duties in order that one person does not regularly receive such exposures. Where a patient is held by a carer such as a family member, the provisions of S.I. 256 of 2018 covering the protection of 'carers and comforters' will apply.

Recognising that in practice the distinction between 'carers and comforters' and staff may not always be clear, the EPA recommends that the following general rules should always be applied where a patient is held during a radiology examination:

- Persons assigned to hold patients during an examination should be over 18 years of age, must not be pregnant, must be provided with protective aprons and must be positioned so as to avoid being exposed to the primary beam;
- Appropriate records of such exposures should be maintained.

Undertakings/dentists should be aware that they may need to meet any additional requirements in relation to 'carers and comforters' as specified by HIQA.

4.4.3 Personnel dosimetry

IRR19 requires that staff liable to receive an annual dose of more than 1.0 mSv be categorised as exposed workers and be subject to personnel monitoring.

Where staff remain at a distance greater than 2 metres from the patient's head during exposure and the workload is fewer than 100 intraoral or 50 extraoral per week (or some pro-rata combination), personnel dosimetry is not normally required as such staff are unlikely to exceed the 1.0 mSv dose limit. In all other circumstances a risk assessment shall be undertaken to determine if staff should be categorised as exposed workers and be subject to personnel monitoring.

Exposed workers must be monitored using personal dosimeters provided by an approved dosimetry service. A list of approved dosimetry services is available on the EPA website.

In the case of exposed workers who are pregnant, the undertaking/dentist must ensure that the work practices are reviewed in consultation with an RPA to determine whether specific safety procedures or additional dosimetry is required to ensure that adequate protection is afforded to the foetus.

Where hand-held equipment is used, the risk assessment shall consider whether monitoring of the equivalent dose to the hands of the operator is required.

4.4.4 Lead aprons and thyroid collars

The Radiological Protection Institute of Ireland (RPII) and the Health Service Executive (HSE) published a joint position statement of the use of lead aprons and collars in oral radiology [Ref. 4], which concluded that:

- There is no justification for the routine use of lead aprons for patients in dental radiography;
- There is no requirement to provide a lead apron to a pregnant patient;
- Where comforters, carers or staff are involved in assisting or holding patients during radiographic procedures, a lead apron shall be provided for their protection;
- Where the thyroid will be exposed, special consideration should be given to the shielding of the thyroid. A thyroid collar may be required where intraoral radiographs with circular collimation are taken on persons under the age of 30 years.

Where lead aprons and/or thyroid collars are required, they must be:

- CE marked and of appropriate lead equivalent thickness;
- Examined visually once a year for tears or cracks and records kept of these checks;
- Stored appropriately to avoid damaging the integrity of the apron.

4.4.5 Use of hand-held X-ray equipment

Handheld intraoral X-ray equipment has the potential to result in higher doses to the operator and members of the public than conventional dental systems mounted on a wall or stand. The use of handheld intraoral X-ray equipment will, therefore, remain subject to licensing.

It should be noted that European guidance [Ref. 6] recommends that as a general rule the use of handheld equipment should be limited to situations where the use of a fixed or semi-mobile units is impractical and should not be considered as a replacement for fixed or semi-mobile units.

4.5 Additional safety procedures

For most oral radiology practices, compliance with the operational measures set out in this section will ensure adequate protection of staff and members of the public. Where the risk assessment indicates the need for specific additional safety procedures, these must be documented and available to all relevant staff.

Section 5 Training

Regular and appropriate radiation safety training is essential for effectively managing and minimising the risks associated with the use of ionising radiation in dentistry. IRR19 sets out the responsibilities of undertakings/dentists with regard to the provision of such training.

5.1 Radiation protection training for operators

The undertaking/dentist must provide radiation protection training for all staff involved in the use of dental X-ray equipment on the following:

- The operational protection measures set out in this guide;
- The safety features of any X-ray equipment they may use during their work, including any specific procedures or precautions pertinent to their own protection;
- Procedures to be followed following any equipment malfunction liable to have radiation safety implications;
- Where appropriate, the possible risks to the foetus and any additional relevant protective measures during pregnancy.

Where the risk assessment indicates that staff should be classified as exposed workers, the following additional topics should be included:

- General principles of radiation protection related to their working environment;
- Health risks created by exposure to ionising radiation;
- The importance of the risk assessment of the working environment and of operators' input to the developing and maintaining of this assessment.

The training should be updated whenever there is a change to equipment or working conditions relevant to radiation safety. In any event, training should be repeated at least every five years.

A record of this training, to include date of training, names of persons who have attended, who provided the training and topics covered by the training shall be maintained by the undertaking/dentist and accessible as required by the EPA.

5.2 Additional training for RPOs

RPOs should receive appropriate training to carry out their task adequately. The training will need to reflect the complexity of the work being done. This should include periodic refresher training, additional to operator training, ensuring the RPO is fully competent and aware of the role they are expected to fulfil.

In addition to the topics covered in Section 5.1, the RPOs should be provided with training on the following topics:

- Legal responsibilities and duties of the Radiation Protection Officer as outlined in Section 3.3 of this code;
- An understanding of relevant legislation and this Code;
- An understanding of the conditions attached to the undertaking/dentist's authorisation.

A record of RPO training shall be maintained by the undertaking/dentist and accessible as required by the EPA.

5.3 Other persons

The undertaking/dentist must also provide sufficient information to other persons who are working in the environment of ionising radiation to ensure their safety, and records of this information provision should be maintained.

Section 6 Incidents

6.1 What incidents must be reported

The following incidents must be reported to the EPA:

- Any incident involving the exposure of any person arising from a design flaw malfunction or incorrect operation of X-ray equipment;
- The theft or loss of X-ray equipment;
- Any incident involving a dose, or suspected dose, in excess of any dose limits for staff and members of the public specified in IRR19;
- Any inappropriate or unauthorised use of X-ray equipment.

6.2 How they should be reported

Incidents must be reported by the undertaking/dentist to the EPA as soon as possible after they occur. Incidents should be reported by phone or email (RadiationIncidents@epa.ie) to the EPA, who will advise as to whether formal reporting and incident investigation are required.

HIQA has produced separate guidelines on reporting of patient exposure incidents in accordance with S.I. 256 of 2019. The two agencies have put in place arrangements to exchange information on incident notifications as appropriate.

6.3 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/dentist, 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 QA on the X-ray unit.

The incident report must include the following:

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

This report must be signed and dated by the person who prepared it and forwarded to the EPA. A copy must be kept.

6.4 Procedures in the event of an incident

The undertaking/dentist 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. Such incidents could include: failure of the X-ray equipment to terminate at the end of exposure or damage to the equipment affecting the shielding of the X-ray tube head.

Procedures encompassing switching off the X-ray equipment at the isolation switch without approaching the tube head, informing the RPO and prohibiting the use of the X-ray equipment pending further investigation will normally suffice.

Section 7 Maintenance of Radiation Safety Records

The undertaking/dentist shall make and fully maintain relevant records to demonstrate compliance with IRR19 and shall have these records accessible when required by the EPA. Where appropriate, suggested retention periods have been aligned with Dental Council guidelines for similar record types.

The records shall include, but not be limited to:

Parameter	Recommended retention period
Risk assessments	Superseded risk assessments should be retained for 8 years.
Additional safety procedures	Superseded additional safety procedures should be retained for 8 years.
Details of X-ray equipment including: date of acquisition, make/model, serial numbers and/or other unique identifiers for X-ray equipment items. A suggested template for this information is include in Appendix 4. Installation report & user manuals Commissioning reports	Until 2 years after disposal of the equipment
Servicing reports QA reports Staff training records Dates on which this Code and additional safety procedures were made available to the operators and any other relevant persons Incident/accident procedures and reports Monthly visual checks as applicable Disposals of X-ray equipment	8 years
Dosimetry reports where relevant	Indefinitely

Appendix 1 Parameters to be considered in the commissioning of a dental X-ray unit

Parameters	Comments
Adequacy of the information provided by supplier/ installer	Is this clear and is it sufficient to allow for the safe operation of the unit?
Installation report	Has an adequate installation report been provided?
Tube voltage Filtration Focal spot size Beam size/collimation Exposure mechanism Radiation leakage from tube housing Skin-focus distance	Is this within the range set out in relevant international standards and the manufacturer's specifications?
Radiation output	Is this within the range set out in relevant international standards and the manufacturer's specifications, and is it appropriate for the intended use?
Positioning of controls/isolation switch	Can the equipment be properly operated remotely?
Warning signals/warning lights	Are they clear, and do they comply with the requirements set out in this guide?

Appendix 2 **Bibliography**

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2. European Union (Basic Safety Standards for protection against dangers arising from medica exposure to ionising radiation) Regulations 2018. S.I. No. 256 of 2018.
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4. The Use of Lead Aprons in Dental Radiology – Joint Position Statement published by the Radiological Protection Institute of Ireland and the Health Service Executive, 2011.
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6. HERCA Position Statement on use of handheld portable dental x-ray equipment.
http://www.herca.org/uploaditems/documents/HERCA%20position%20statement%20on%20use%20of%20handheld%20portable%20dental%20x-ray%20equipment.pdf

The above list in not intended to be exhaustive and is included for guidance only. Account should be taken of the relevant internal standards for the particular equipment.

Appendix 3 **Template for equipment records**

X-ray Equipment Type	Manufacturer	Make/Model	X-Ray Tube Serial Number	Kilovoltage Range	Date of Acquisition

Interpretation

Additional safety procedures means operational measures necessary to protect staff and members of the public, which are specific to the undertaking and/or practice and additional to the operational measures set out in Section 4 of this code. The need for such measures is identified in the risk assessment.

Carers and comforters means individuals knowingly and willingly incurring an exposure to ionising radiation other than as part of their occupation when supporting or comforting individuals undergoing or having undergone medical exposure.

Dental practitioner means a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985).

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

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

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.

Oral radiology means the speciality of dentistry concerned with performance and interpretation of diagnostic imaging used for examining the craniofacial, dental and adjacent structures. It includes cone beam computed tomography (CT) and intra-oral, panoramic and cephalometric imaging.

RPA means a Radiation Protection Adviser and is an individual or a body who meets the competence requirements set 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 and is an individual or unit designated by the undertaking/dentist to supervise or implement the radiation protection arrangements.

Radiological practice means a human activity which can increase the exposure of individuals to ionising radiation from the use of X-ray equipment or any other radiation source.

Undertaking means a natural or legal person with legal responsibility for carrying out the practice of oral radiology.

An Ghníomhaireacht um Chaomhnú Comhshaoil

Tá an Ghníomhaireacht um Chaomhnú Comhshaoil (GCC) freagrach as an gcomhshaol a chaomhnú agus a fheabhsú mar shócmhainn luachmhar do mhuintir na hÉireann. Táimid tiomanta do dhaoine agus don chomhshaol a chosaint ó éifeachtaí díobhálacha na radaíochta agus an truaillithe.

Is féidir obair na Gníomhaireachta a roinnt ina trí phríomhréimse:

Rialú: *Déanaimid córais éifeachtacha rialaithe agus comhlíonta comhshaoil a chur i bhfeidhm chun torthaí maithe comhshaoil a sholáthar agus chun díriú orthu siúd nach gcloíonn leis na córais sin.*

Eolas: *Soláthraímid sonraí, faisnéis agus measúnú comhshaoil atá ar ardchaighdeán, spriocdhírithe agus tráthúil chun bonn eolais a chur faoin gcinnteoireacht ar gach leibhéal.*

Tacaíocht: *Bímid ag saothrú i gcomhar le grúpaí eile chun tacú le comhshaol atá glan, táirgiúil agus cosanta go maith, agus le hiompar a chuirfidh le comhshaol inbhuanaithe.*

Ár bhFreagrachtaí

CEADÚNÚ

Déanaimid na gníomhaíochtaí seo a leanas a rialú ionas nach ndéanann siad dochar do shláinte an phobail ná don chomhshaol:

- saoráidí dramhaíola *(m.sh. láithreáin líonta talún, loisceoirí, stáisiúin aistrithe dramhaíola)*;
- gníomhaíochtaí tionsclaíocha ar scála mór *(m.sh. déantúsaíocht cógaisíochta, déantúsaíocht stroighne, stáisiúin chumhachta)*;
- an diantalmhaíocht (m.sh. muca, éanlaith);
- úsáid shrianta agus scaoileadh rialaithe Orgánach Géinmhodhnaithe *(OGM)*;
- foinsí radaíochta ianúcháin *(m.sh. trealamh x-gha agus radaiteiripe, foinsí tionsclaíocha)*;
- áiseanna móra stórála peitril;
- scardadh dramhuisce;
- gníomhaíochtaí dumpála ar farraige.

FORFHEIDHMIÚ NÁISIÚNTA I LEITH CÚRSAÍ COMHSHAOIL

- Clár náisiúnta iniúchtaí agus cigireachtaí a dhéanamh gach bliain ar shaoráidí a bhfuil ceadúnas ón nGníomhaireacht acu.
- Maoirseacht a dhéanamh ar fhreagrachtaí cosanta comhshaoil na n-údarás áitiúil.
- Caighdeán an uisce óil, arna sholáthar ag soláthraithe uisce phoiblí, a mhaoirsiú.
- Obair le húdaráis áitiúla agus le gníomhaireachtaí eile chun dul i ngleic le coireanna comhshaoil trí chomhordú a dhéanamh ar líonra forfheidhmiúcháin náisiúnta, trí dhíriú ar chiontóirí, agus trí mhaoirsiú a dhéanamh ar leasúchán.
- Cur i bhfeidhm rialachán ar nós na Rialachán um Dhramhthrealamh Leictreach agus Leictreonach (DTLL), um Shrian ar Shubstaintí Guaiseacha agus na Rialachán um rialú ar shubstaintí a ídíonn an ciseal ózóin.
- An dlí a chur orthu siúd a bhriseann dlí an chomhshaoil agus a dhéanann dochar don chomhshaol.

BAINISTÍOCHT UISCE

- Monatóireacht agus tuairisciú a dhéanamh ar cháilíocht aibhneacha, lochanna, uiscí idirchriosacha agus cósta na hÉireann, agus screamhuiscí; leibhéil uisce agus sruthanna aibhneacha a thomhas.
- Comhordú náisiúnta agus maoirsiú a dhéanamh ar an gCreat-Treoir Uisce.
- Monatóireacht agus tuairisciú a dhéanamh ar Cháilíocht an Uisce Snámha.

MONATÓIREACHT, ANAILÍS AGUS TUAIRISCIÚ AR AN GCOMHSHAOL

- Monatóireacht a dhéanamh ar cháilíocht an aeir agus Treoir an AE maidir le hAer Glan don Eoraip (CAFÉ) a chur chun feidhme.
- Tuairisciú neamhspleách le cabhrú le cinnteoireacht an rialtais náisiúnta agus na n-údarás áitiúil *(m.sh. tuairisciú tréimhsiúil ar staid Chomhshaol na hÉireann agus Tuarascálacha ar Thascairí)*.

RIALÚ ASTAÍOCHTAÍ NA NGÁS CEAPTHA TEASA IN ÉIRINN

- Fardail agus réamh-mheastacháin na hÉireann maidir le gáis cheaptha teasa a ullmhú.
- An Treoir maidir le Trádáil Astaíochtaí a chur chun feidhme i gcomhair breis agus 100 de na táirgeoirí dé-ocsaíde carbóin is mó in Éirinn.

TAIGHDE AGUS FORBAIRT COMHSHAOIL

- Taighde comhshaoil a chistiú chun brúnna a shainaithint, bonn eolais a chur faoi bheartais, agus réitigh a sholáthar i réimsí na haeráide, an uisce agus na hinbhuanaitheachta.

MEASÚNACHT STRAITÉISEACH TIMPEALLACHTA

- Measúnacht a dhéanamh ar thionchar pleananna agus clár beartaithe ar an gcomhshaol in Éirinn (m.sh. mórphleananna forbartha).

COSAINT RAIDEOLAÍOCH

- Monatóireacht a dhéanamh ar leibhéil radaíochta, measúnacht a dhéanamh ar nochtadh mhuintir na hÉireann don radaíocht ianúcháin.
- 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 cosanta ar an radaíocht a sholáthar, nó maoirsiú a dhéanamh ar sholáthar na seirbhísí sin.

TREOIR, FAISNÉIS INROCHTANA AGUS OIDEACHAS

- Comhairle agus treoir a chur ar fáil d'earnáil na tionsclaíochta agus don phobal maidir le hábhair a bhaineann le caomhnú an chomhshaoil agus leis an gcosaint raideolaíoch.
- Faisnéis thráthúil ar an gcomhshaol ar a bhfuil fáil éasca a chur ar fáil chun rannpháirtíocht an phobail a spreagadh sa chinnteoireacht i ndáil leis an gcomhshaol *(m.sh. Timpeall an Tí, léarscáileanna radóin)*.
- Comhairle a chur ar fáil don Rialtas maidir le hábhair a bhaineann leis an tsábháilteacht raideolaíoch agus le cúrsaí práinnfhreagartha.
- Plean Náisiúnta Bainistíochta Dramhaíola Guaisí a fhorbairt chun dramhaíl ghuaiseach a chosc agus a bhainistiú.

MÚSCAILT FEASACHTA AGUS ATHRÚ IOMPRAÍOCHTA

- Feasacht chomhshaoil níos fearr a ghiniúint agus dul i bhfeidhm ar athrú iompraíochta dearfach trí thacú le gnóthais, le pobail agus le teaghlaigh a bheith níos éifeachtúla ar acmhainní.
- Tástáil le haghaidh radóin a chur chun cinn i dtithe agus in ionaid oibre, agus gníomhartha leasúcháin a spreagadh nuair is gá.

BAINISTÍOCHT AGUS STRUCHTÚR NA GNÍOMHAIREACHTA UM CHAOMHNÚ COMHSHAOIL

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

- An Oifig um Inmharthanacht Comhshaoil
- An Oifig Forfheidhmithe i leith cúrsaí Comhshaoil
- An Oifig um Fianaise is Measúnú
- Oifig um Chosaint Radaíochta agus Monatóireachta Comhshaoil
- An Oifig Cumarsáide agus Seirbhísí Corparáideacha

Tá Coiste Comhairleach ag an nGníomhaireacht le cabhrú léi. Tá dáréag comhaltaí air agus tagann siad le chéile go rialta le plé a dhéanamh ar ábhair imní agus le comhairle a chur ar an mBord.

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