



STATUTORY INSTRUMENTS.

S.I. No. 34 of 2019



RADIOLOGICAL PROTECTION ACT 1991 (AUTHORISATION
APPLICATION AND FEES) REGULATIONS 2019

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I, RICHARD BRUTON, Minister for Communications, Climate Action and Environment in exercise of the powers conferred on me by subsection (7) of section 30 of the Radiological Protection Act 1991 (No. 9 of 1991) and with the consent of the Minister for Public Expenditure and Reform, hereby make the following Regulations: —

Citation and Commencement

1. (1) These Regulations may be cited as the Radiological Protection Act 1991 (Authorisation Application and Fees) Regulations 2019.

(2) These Regulations shall come into operation on the 8th day of February 2019.

Interpretation

2. (1) “Agency” means the Environmental Protection Agency established under Section 19 of the Environmental Protection Agency Act 1992 (No. 7 of 1992);

“an inspector” means a person appointed under section 28 of the Principal Act to be an inspector for the purposes of the Principal Act and any orders or Regulations made under the Principal Act;

“application portal” means the online Environmental Data Exchange Network maintained by the Environmental Protection Agency at www.epa.ie

“authorisation” means a registration or a licence;

“exposure” means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);

“Ionising Radiation Regulations” means the Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019 (S.I. No. 30 of 2019);

“licence” means a licence granted by the Agency to permit a person to carry, subject to conditions (if any) specified in the licence, the relevant activity in respect of which the licence is granted, pursuant to the Ionising Radiation Regulations;

“licensee” means a person to whom a licence is for the time being granted;

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“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;

“non-medical imaging exposure” means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;

“practice” means a relevant activity that is managed as a planned exposure situation;

“Principal Act” means the Radiological Protection Act 1991 (No. 9 of 1991);

“quality assurance” means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;

“quality control” means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

“radiation source” means an entity that may cause exposure such as by emitting ionising radiation or by releasing radioactive material and encompasses a radiation generator, radioactive material, radioactive source and radioactive substance;

“radioactive source” means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;

“radioactive waste management” means all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal of radioactive waste, excluding off-site transportation;

“registered person” means a person to whom a registration is for the time being granted;

“registration” means a registration granted by the Agency to permit a person to carry out, subject to the conditions (if any) attached to the registration, the activity pursuant to the Ionising Radiation Regulations;

“relevant activity” means a human activity which can increase the exposure of individuals to radiation from a radiation source and includes the custody, production, processing, handling, holding, storage, use, recycling, manufacture, import, distribution, transport, export or other disposal of the radiation source;

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

“workplace” includes any place, land or other location at, in, upon or near which, work is carried out whether occasionally or otherwise and, in particular, includes: –

- (a) a premises, including a cave or mine;
- (b) an installation on land and any offshore installation;
- (c) a tent, a temporary structure or movable structure; and
- (d) a vehicle, vessel, aircraft or spacecraft.

(2) A word or expression that is used in these Regulations and is also used in the Principal Act shall, unless the contrary intention appears, have the same meaning that it has in the Principal Act.

(3) In these Regulations: —

- (a) a reference to a Regulation or schedule is a reference to a Regulation of or schedule to these Regulations unless it is indicated that a reference to some other enactment is intended;
- (b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs unless it is indicated that reference to some other provision is intended.

Authorisation procedure

3. (1) An application for the grant or the amendment of an authorisation or renewal of a licence, shall be made by electronic means through the application portal.

(2) An application for an authorisation shall be made to the Agency not later than one month before the proposed commencement of the practice.

(3) (a) An application for the renewal of a licence shall be made to the Agency not later than one month before the expiration of the licence;

(b) A practice shall not be continued by the applicant beyond the expiration of the licence previously in force in respect of the practice concerned unless and until the licence has been renewed or a registration in respect of the practice has been granted.

(4) An application for an amendment of a registration or a licence shall be made to the Agency before the proposed implementation of the change in respect of the practice concerned. The change in practice shall not be implemented by the applicant until such time as the registration or licence has

been amended by the Agency in accordance with Regulation 12(2) of the Ionising Radiation Regulations.

Information to be provided

4. (1) The application for the grant or the amendment of an authorisation or renewal of a licence shall include the particulars specified in Schedule 1, Part 1, and may include at the discretion of the Agency: —

- (a) the particulars specified in Schedule 1, Part 2;
- (b) radiation safety procedures referred to in Regulation 32 (1) of the Ionising Radiation Regulations; and
- (c) the risk assessment for the proposed practice referred to in Regulation 31 (2) of the Ionising Radiation Regulations;
- (d) for relevant workplaces, the information referred to in Regulation 51(3) of the Ionising Radiation Regulations;
- (e) for practices involving non-medical imaging exposure using medical radiological equipment, the plan referred to under Regulation 16(4)(b) of the Ionising Radiation Regulations;
- (f) for practices involving radioactive waste management, a safety assessment referred to under Regulation 17(3) of the Ionising Radiation Regulations;
- (g) in the case of an application for an amendment of a licence or registration, the grounds for the amendment and a revised risk assessment for the proposed practice referred to in Regulation 31(2) of the Ionising Radiation Regulations;
- (h) the agreed arrangements under Regulation 33(3) of the Ionising Radiation Regulations with the named radiation protection adviser or advisers that are in place to meet the requirements of those Regulations;
- (i) such other particulars as the Agency may specify.

(2) Where in the opinion of the Agency the information supplied by an applicant in an application for the grant or the amendment of an authorisation or renewal of a licence is insufficient or inadequate for the purpose of enabling the Agency to decide whether or not to grant, renew or amend a licence or to grant or amend a registration, it may by electronic means (sent to the applicant at the electronic mail address specified in the application submitted in accordance with Regulation 3(1)) require the applicant to furnish the Agency with such additional information as it specifies in the notice.

- (3) (a) The Agency may, in the case of an application for the grant or the amendment of an authorisation or renewal of a licence to carry out a practice of a class or type carried out immediately before the commencement of the Ionising Radiation Regulations in

accordance with Regulation 5(1)(a) of the Ionising Radiation Regulations, require the applicant to submit with the application, in accordance with Regulation (3)(1), the grounds on which it believes the practice continues to be justified and provide such supporting information, as the Agency deems to be necessary, in regards to any economic, social, health, environmental or other benefits arising from the proposed practice in relation to the detriment it may cause.

- (b) The Agency shall, on receipt of the grounds and any supporting information submitted under subparagraph (a) decide whether the practice is justified in accordance with Regulation 5(1)(b) of the Ionising Radiation Regulations.

(4) The Agency may, in the case of an application for the grant or the amendment of an authorisation or renewal of a licence to carry out a practice, require the applicant to submit with the application, in accordance with paragraph (1), the grounds on which it believes the proposed practice is justified and provide such supporting information, as the Agency deems to be necessary, so as to allow the implementation of the justification requirement in Regulation 5(1)(b) of the Ionising Radiation Regulations.

(5) The Agency may, in relation to an application for the grant or the amendment of an authorisation or renewal of a licence to carry out a practice of a class or type involving medical exposure, require the applicant to submit with the application, documentary evidence that the practice has been justified by the Health Information and Quality Authority in accordance with Regulation 7 of 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).

Issue of Licence or Certificate of Registration

5. The Agency shall, where it has granted an authorisation, issue, by electronic means, a certificate in respect of a registration to the registered person or licence to the licensee (sent to the applicant at the electronic mail address specified in the application submitted in accordance with Regulation 3(1)). The licence or certificate, as the case may be, shall include the following particulars:

- (i) name and address of the licensee or registered person;
- (ii) address(es) of site(s) where practices are to authorised be carried-out;
- (iii) list of authorised practices;
- (iv) date from which authorisation is effective;
- (v) the expiry date in the case of licences;

- (vi) the signature of an inspector.

Expiry of an authorisation

6. (1) Unless revoked by the Agency pursuant to its powers under section 30(5) of the Principal Act, a licence shall, subject to any condition relating to expiry specified in the licence, expire on the date specified in that behalf in the licence, normally 10 years after the date granted.

(2) Unless revoked by the Agency pursuant to its powers under section 30(5) of the Principal Act a registration shall not require to be renewed.

Authorisation fee charging

7. (1) A fee shall be paid to the Agency by an applicant in respect of an application for the grant of an authorisation or renewal of a licence.

(2) The fee payable by an applicant in respect of an application for the grant of an authorisation or renewal of a licence shall be the amounts indicated in columns 2 and 3 of Schedule 2 opposite the relevant fee category specified in column 1 of Schedule 2.

(3) The Agency shall determine the appropriate fee category for each application, having regard to:-

- (a) the number of radiation sources to which the application relates;
- (b) the purpose of the practice to which the application relates;
- (c) the quantity of the radioactive substance to which the application relates;
- (d) the profession or work activity to which the practice relates.

(4) The Agency may specify the method of payment, which may include payment by electronic means or direct debit.

(5) A fee paid under this Regulation shall not be refundable by the Agency to the applicant in whole or in part if the licence or registration is not granted, or is revoked by the Agency pursuant to its powers under section 30(5) of the Principal Act or the practice concerned is amended or terminated by the licensee prior to the expiry of the licence or at any time by the registered person.

Transitional Provisions

8. The provisions of these Regulations shall not apply to a licence granted and which is in force immediately before the commencement of these Regulations until application is made for its renewal.

Revocations

9. The Radiological Protection Act 1991 (Licensing Application and Fees) Regulations 2007 (S.I. No. 654 of 2007) are hereby revoked.

SCHEDULE 1

**INFORMATION TO BE PROVIDED IN AN AUTHORISATION
APPLICATION FOR A PRACTICE**

PART 1.

(1) The name and address of the applicant and a telephone number, fax number or electronic mail address at which it can be contacted at that address.

(2) The address of the premises where or from where the practice is to be carried out and a telephone number, fax number or electronic mail address at which the applicant can be contacted at that address.

(3) The nature and business of the applicant.

(4) The addresses of any premises, other than the address stated under paragraph (2), at which the practice is to be carried out.

(5) The proposed date of commencement of the practice.

(6) A description of the work and the purpose of the practice for which authorisation is being sought.

(7) The following additional information if the Agency requires it:

- (a) particulars of the sources of ionising radiation,
- (b) the quantities of any radioactive substances involved,
- (c) the identity of any person engaged in the practice, and
- (e) the name of the radiation protection adviser consulted.

PART 2.

- (a) Responsibilities and organisational arrangements for protection and safety.
- (b) Staff competences, including information and training.
- (c) Design features of the facility and of radiation sources.

- (d) Anticipated occupational and public exposures in normal operation.
- (e) Safety assessment of the activities and the facility in order to:
 - (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
 - (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
 - (iii) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;
 - (iv) define the operational limits and conditions of operation.
- (f) Emergency procedures.
- (g) Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.
- (h) Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.
- (i) Management of disused sources.
- (j) Quality assurance.

SCHEDULE 2

Fee Category	Authorisation charge €	Licence Renewal Charge €
Applications subject to registration	300	NA
Dental applications subject to licensing	1,000	250
Dental radiography carried out at an additional risk assessed clinic under an existing registration.	75	NA
Applications of ionising radiation for teaching or research in a third level college	2,000	500
Industrial imaging practices using X-ray subject to licensing	1,000	250
Industrial/ laboratory applications using unsealed sources subject to licensing	1,000	250
Standard industrial applications using sealed (non HAS) sources subject to licensing	1,000	250
Complex industrial applications using sealed (non HAS) sources	2,000	500
Transport of HASS	2,000	500
Assembly or manufacture of devices incorporating sealed sources	2,000	500
Industrial applications using HASS	4,000	1,000
Radionuclide production in an accelerator	4,000	1,000
Medical diagnostic imaging application subject to licensing	1,000	250
Applications of X-ray for medical intervention or treatment	2,000	500
Diagnostic nuclear medicine applications	2,000	500
Application of sources other than x-ray for medical treatment	4,000	1,000
Veterinary diagnostic applications subject to licensing	1,000	250
Veterinary nuclear medicine applications	2,000	500
Veterinary radiotherapy applications	4,000	1,000



GIVEN under my Official Seal,
8 February 2019

RICHARD BRUTON,
Minister for Communications, Climate
Action and Environment.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These Regulations set out the application process for the authorisation to carry out a practice involving the use of radiological sources and sets out the relevant schedule of applicable fees.

These Regulations revoke the Radiological Protection Act 1991 (Licensing Application and Fees) Regulations 2007 (S.I. No. 654 of 2007).

These Regulations may be cited as the Radiological Protection Act 1991 (Authorisation Application and Fees) Regulations 2019.

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