



# IONISING RADIATION (BASIC SAFETY STANDARDS AND JUSTIFICATION OF PRACTICES) REGULATIONS 2019

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Statutory Document No. 2019/0283



*Health and Safety at Work etc. Act 1974*

# IONISING RADIATION (BASIC SAFETY STANDARDS AND JUSTIFICATION OF PRACTICES) REGULATIONS 2019

*Approved by Tynwald:* 17<sup>th</sup> July 2019  
*Coming into Operation:* 1<sup>st</sup> August 2019

The Department of Environment, Food and Agriculture makes the following Regulations, after consulting such organisations as it considers represent interests affected by the regulations<sup>1</sup>, under section 15(1), (2) and (10) of, and paragraphs 1(1), 2(1), 3 to 5, 8, 13(2) and (3), 20 and 23 of Schedule 3 to, the Health and Safety at Work Etc. Act 1974<sup>2</sup> (an Act of Parliament), as it has effect in the Island<sup>3</sup>.

## PART 1 – GENERAL

### 1 Title

These Regulations are the Ionising Radiation (Basic Safety Standards and Justification of Practices) Regulations 2019.

### 2 Commencement

If approved by Tynwald these Regulations come into operation on 1 August 2019.

### 3 Interpretation

In these Regulations—

“**Basic Safety Standards Directive**” means Council Directive 2013/59/Euratom<sup>4</sup> laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives

<sup>1</sup> As required by section 82(4) of the Health and Safety at Work Etc. Act 1974 as it applies to the Island

<sup>2</sup> 1974 c.37

<sup>3</sup> SD 155/98 as amended by SD 984/07

<sup>4</sup> OJ L 013, 17.1.2014, p. 1.

89/618/Euratom<sup>5</sup>, 90/641/Euratom<sup>6</sup>, 96/29/Euratom<sup>7</sup>, 97/43/Euratom<sup>8</sup> and 2003/122/Euratom<sup>9</sup>;

“**building material**”, “**effective dose**”, “**emergency**”, “**equivalent dose**”, “**ionising radiation**”, “**orphan source**” and “**practice**” have the same meanings as in the Basic Safety Standards Directive;

“**imaging practice**” is a practice involving non-medical imaging exposure other than one that uses medical radiological equipment;

“**justification decision**” means a decision which is made by a Justifying Authority in the form specified in regulation 14 of the UK Justification Regulations that —

- (a) determines that a class or type of practice is justified, where it was not previously justified;
- (b) determines that a class or type of practice is no longer justified; or
- (c) introduces or changes conditions relating to the justification of a class or type of practice;

“**justified**” in relation a class or type of practice means that the individual or societal benefit resulting from the class or type of practice outweighs the health detriment that it may cause;

“**the Justifying Authority**” has the meaning given in regulation 6(1) of the UK Justification Regulations;

“**protective measures**” means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an exposure situation;

“**radiation source**” means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;

“**radioactive material**” means material incorporating any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;

“**remedial measures**” means the removal of a radiation source or the reduction of its magnitude (in terms of activity or amount) or the interruption of exposure pathways or the reduction of their impact for the purposes of avoiding or reducing doses that might otherwise be received in an exposure situation; and

“**UK Justification Regulations**” means the Justification of Practices Involving Ionising Radiation Regulations 2004<sup>10</sup> (as in operation from time to time).

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<sup>5</sup> OJ L 357, 7.12.1989, p. 31.

<sup>6</sup> OJ L 349, 13.12.1990, p. 21.

<sup>7</sup> OJ L 159, 29.6.1996, p. 1.

<sup>8</sup> OJ L 180, 9.7.1997, p. 22.

<sup>9</sup> OJ L 346, 31.12.2003, p. 57.

## PART 2 – LAND AND OTHER EXPOSURE SITUATIONS

### 4 Measures to be taken in relation to exposures from land

- (1) This regulation applies where –
  - (a) land is contaminated as a result of the after-effects of an emergency, past practice or past work activity; and
  - (b) the level of exposure of members of the public to ionising radiation cannot be disregarded from a radiation protection point of view.
- (2) The Department must –
  - (a) define the extent of the contaminated land; and
  - (b) set a reference level for the contaminated land, taking into account –
    - (i) principles of radiological protection and societal criteria; and
    - (ii) the range of reference levels set out in Annex I to the Basic Safety Standards Directive.
- (3) Before the resumption of habitation, or economic or social activities, on the land, the Department must ensure that appropriate arrangements are established for the on-going control of exposure of members of the public to ionising radiation, with the aim of establishing living conditions that can be considered as normal, including –
  - (a) the establishment of an infrastructure to support continuing self-help protective measures in the affected area, which may include the provision of information, advice and monitoring;
  - (b) remediation measures; and
  - (c) the delineation of the area.
- (4) In this regulation, “reference level” means the level of effective dose or equivalent dose above which optimisation of radiation protection for members of the public must be prioritised.

### 5 Provision of information concerning public exposures from radioactive contaminated land

- (1) The Department must ensure that information on the following matters is provided to members of the public exposed to ionising radiation from radioactive contaminated land –
  - (a) the potential health risks of their exposure; and

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<sup>10</sup> SI 2004 No. 1769

- (b) the available means for reducing their exposure.
- (2) The Department must for each area of contaminated land, as defined under regulation 4(2)(a), publish guidance concerning the management of exposure to ionising radiation from that area.
- (3) For the purposes of these regulations “contaminated land” includes, but is not limited to, land where radioactive substances are causing or could cause —
  - (a) harm to people;
  - (b) significant harm to property or protected species; or
  - (c) significant pollution of surface waters (for example lakes and rivers) or groundwater.

## **6 Measures to be taken in other exposure situations**

- (1) This regulation applies where the Department receives evidence about either of the following situations—
  - (a) the indoor exposure of members of the public to ionising radiation from building material incorporated into buildings or parts of buildings which cannot be disregarded from a radiation protection point of view; or
  - (b) the exposure of members of the public to ionising radiation from contaminated commodities which cannot be disregarded from a radiation protection point of view.
- (2) The Department must ensure that measures are taken to identify and evaluate the level of exposure of members of the public to ionising radiation.
- (3) The Department must ensure that a strategy is in put place to manage, as appropriate, any health risks identified as a result of the measures taken under paragraph (2).
- (4) The Department must ensure that the strategy—
  - (a) sets objectives;
  - (b) sets an appropriate reference level; and
  - (c) is developed and implemented taking into account the requirements of the requirements set out in Article 102 of the Basic Safety Standards Directive.
- (5) In this regulation —
  - (a) “contaminated commodities” means commodities which incorporate —

- (i) radionuclides from land contaminated as a result of the after-effects of an emergency, past practice or past work activity; or
  - (ii) naturally occurring radionuclides;
- but does not include food, drinking water and animal feeding stuffs; and
- (b) “reference level” means the level of effective dose, equivalent dose or activity concentration above which optimisation of radiation protection for members of the public must be prioritised.

### **PART 3 – BUILDING MATERIAL**

#### **7 Building material**

- (1) Where the Department is aware that relevant building material has been identified in the Island, the Department must ensure that before the relevant building material is placed on the market—
  - (a) the activity concentrations of any radionuclides specified in Annex VIII to the Basic Safety Standards Directive that are in the relevant building material are determined; and
  - (b) information is provided to the person nominated by the Department for this purpose, if requested by that person, on—
    - (i) the activity concentrations determined in accordance with sub-paragraph (a); and
    - (ii) the corresponding activity concentration index (calculated using the formula set out in Annex VIII to the Basic Safety Standards Directive and such other relevant factors as are specified in that Annex).
- (2) Where the relevant building material is liable to give gamma radiation doses exceeding 1 millisievert per year, the Department must exercise its functions to ensure that such measures are taken as it considers appropriate for the protection of members of the public, which may include imposing specific requirements in relevant building codes or restrictions on the use of such material.
- (3) In this regulation “relevant building material” means building material that—
  - (a) emits gamma radiation; and
  - (b) is of concern from a radiation protection point of view, taking into account the indicative list of types of building material in Annex XIII to the Basic Safety Standards Directive.

## PART 4 – RADON

### 8 Indoor exposure to radon

- (1) The Department must set a reference level for the exposure of members of the public to indoor radon concentrations. The reference level for the annual average radon activity concentration in air must not exceed 300 becquerels per cubic metre.
- (2) In this regulation, “reference level” means the level of activity concentration above which optimisation of radiation protection for members of the public must be prioritised.

### 9 Requirement to make available to the public information regarding radon

The Department must ensure that information on—

- (a) indoor radon exposure and associated health risks;
- (b) the importance of performing radon measurements; and
- (c) the technical means available for reducing existing radon concentrations,

is made available to the public.

### 10 Radon action plan

- (1) The Department must establish a national plan (“the action plan”) addressing long-term health risks from any source of radon ingress (whether from soil, building material or water) to—
  - (a) dwellings;
  - (b) buildings with public access; and
  - (c) workplaces.
- (2) The action plan must—
  - (a) take into account relevant issues identified in Annex XVIII to the Basic Safety Standards Directive; and
  - (b) be updated at intervals of no more than five years.

### 11 New buildings

The Department must exercise its functions to ensure that appropriate measures are in place to prevent radon ingress into new buildings.



## **12 Areas of high radon concentration**

The Department must identify areas where the radon concentration (expressed as an annual average) in a significant number of buildings is expected to exceed the relevant reference level set under regulation 8.

## **PART 5 – ORPHAN SOURCES**

### **13 Identification of orphan sources**

The Department must exercise its functions to ensure that arrangements are made for –

- (a) raising general awareness of the possible occurrence of orphan sources and potential hazards; and
- (b) issuing guidance for persons who suspect, or have knowledge, of the presence of an orphan source on informing the Department and on the actions to be taken.

### **14 Action to recover orphan sources left behind by past practices**

- (1) The Department must exercise its functions to ensure that an appropriate course of action is organised to recover orphan sources left behind from past practices.
- (2) The course of action may include the management, control and disposal of the orphan sources as well as the review of relevant documentation.

## **PART 6 – PERSONAL ORNAMENTS AND TOYS**

### **15 Addition of radioactive substances to personal ornaments or toys**

- (1) A person must not –
  - (a) knowingly or recklessly add any radioactive substance in the production of personal ornaments or toys; or
  - (b) knowingly or recklessly import or export any personal ornament or toy to which any radioactive substance has been added in its production.
- (2) A person must not –
  - (a) carry out a practice involving the activation of materials used in toys or personal ornaments;
  - (b) knowingly or recklessly import or export toys or personal ornaments in which materials have been activated;

- (c) knowingly or recklessly import or export materials that have been activated for use in toys or personal ornaments,

where that activation results, at the time of the placing on the market of the products or at the time of their manufacture, in an increase in activity which cannot be disregarded from a radiation protection point of view.

## PART 7 – JUSTIFICATION OF PRACTICES INVOLVING IONISING RADIATION

### 16 Justification of classes or types of practices

- (1) Subject to paragraph (2), no person shall carry out a practice resulting in exposure to ionising radiation unless –
- (a) the most recent justification decision applicable determined that class or type of practice to be justified; and
  - (b) the date (if any) specified by the Justifying Authority for ceasing to carry out the practice has not passed.
- (2) Despite paragraph (1) –
- (a) a person may carry out a practice, for a period of four months beginning on the date of the coming into operation of these Regulations, if he or she first carried out the practice in the Island or the United Kingdom before that date; and
  - (b) if that person has, within that period, applied for a justification decision, he or she may continue to carry out that practice after the expiry of that period until a justification decision has been made.
- (3) A copy of the justification decision must be provided to the Department within 10 working days of receipt by the applicant.
- (4) These Regulations do not affect any previous justification decision made before they come into operation<sup>11</sup>.
- (5) This regulation does not prevent anything permitted under regulation 12 of the Ionising Radiation (Medical Exposure) Regulations 2019.

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<sup>11</sup> A list of such decisions can be found on the United Kingdom Justification Register: <https://www.gov.uk/government/publications/justification-of-practices-involving-ionising-radiation-application-register>

## **PART 8 – JUSTIFICATION OF PRACTICES INVOLVING NON-MEDICAL IMAGING EXPOSURE**

### **17 Identification of imaging practices**

The Department must take reasonable steps to ensure the identification of imaging practices.

### **18 Approval of imaging practices**

- (1) Subject to paragraph (2), a person must not carry out a particular imaging practice unless the Department –
  - (a) has granted an approval to that person in respect of that particular imaging practice (an “Approval”); and
  - (b) has not withdrawn the Approval.
- (2) Despite paragraph (1) –
  - (a) a person may carry out a carry out a particular imaging practice, for a period of four months beginning on the date of the coming into operation of these Regulations, if he or she first carried out the practice in the Island or the United Kingdom before that date; and
  - (b) if that person has, within that period, applied for an Approval, he or she may continue to carry out that practice after the expiry of that period until the person is notified that Approval is not granted.
- (3) A person may apply to the Department for an Approval in respect of a particular imaging practice.
- (4) The Department must in any Approval it grants set out requirements, including criteria for implementation, with which the person must comply in carrying out the particular imaging practice.
- (5) In establishing the requirements to be contained in an Approval, the Department may consult such relevant person or body as it considers appropriate.
- (6) The Department may serve a notice on a person if the Department is of the opinion that the person is not complying with the requirements contained in that person’s Approval in carrying out the particular imaging practice to which the Approval relates (a “warning notice”).
- (7) The warning notice must specify –
  - (a) the matters constituting the failure to comply with the requirements in the Approval;
  - (b) the steps that must be taken to remedy the failure to comply; and

- (c) the period within which those steps must be taken, which must be no less than 28 days unless in the opinion of the Department it is necessary for those steps to be taken more quickly.
- (8) The Department may by notice withdraw an Approval from a person if—
- (a) the Department has served a warning notice on that person;
  - (b) the period specified in the warning notice for taking the steps to remedy the failure has passed; and
  - (c) the Department is of the opinion that the person has not taken the steps specified in the warning notice to remedy the failure to comply.
- (9) Where the Department has withdrawn an Approval from a person under paragraph (8), the Department may subsequently grant a new Approval to that person in respect of the same or any other particular imaging practice.
- (10) The Department may alter the requirements in an Approval if—
- (a) the Department has consulted the person who holds the Approval;
  - (b) the Department has served a notice on the person who holds the Approval (an “alteration notice”); and
  - (c) the alteration notice contains—
    - (i) the new requirements for the particular imaging practice; and
    - (ii) the date, which must be later than the date of the alteration notice, from which those new requirements are to apply.

## **19 Individual justification and regular review**

- (1) A person carrying out an imaging practice must—
- (a) ensure that each individual exposure is justified; and
  - (b) carry out regular reviews of the implementation of that imaging practice and after each review promptly provide to the Justifying Authority a written report summarising the results of that review.
- (2) For the purposes of this regulation an individual exposure is justified where the individual or societal benefit resulting from the exposure outweighs the health detriment that it may cause.
- (3) Reviews under paragraph (1)(b) must be carried out at a frequency which is appropriate having regard to the specific circumstances of the imaging practice including, but not limited to, how often the exposures take place.

## 20 Dose constraints

The dose constraints for imaging practices must be significantly below the dose limits set out in paragraphs 5 and 7 of Schedule 3 to the Ionising Radiations Regulations 2017, as they apply in the Island<sup>12</sup>.

## 21 Consent

- (1) A person proposing to subject an individual to an exposure as part of an imaging practice must first provide a reasonable level of information about the proposed exposure to, and obtain prior consent for the exposure from, the individual to be exposed.
- (2) The requirement in paragraph (1) to obtain prior consent does not apply to law enforcement authorities.
- (3) In this regulation, “law enforcement authority” means any authority responsible for preventing, detecting, investigating, combating and punishing criminal offences including, but not limited to –
  - (a) the police;
  - (b) any judicial authority;
  - (c) an officer in charge of an institution;
  - (d) an officer of an institution; or
  - (e) a person working at an institution who is authorised by the governor of the prison to exercise powers of search.
- (4) The expressions used in paragraphs (3)(c) to (e) have the meanings given in the Custody Act 1995.

**MADE 19 JUNE 2019**

**GEOFFREY BOOT**

*Minister for Environment, Food and Agriculture*

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<sup>12</sup> SD 2019/281



## *EXPLANATORY NOTE*

*(This note is not part of the Regulations)*

These Regulations implement some of the basic safety provisions of Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (“the Directive”). This Directive forms a part of the Island’s obligations under Protocol 3.

These Regulations are set out in 8 Parts.

### **Part 1**

Regulations 1 and 2 are the title and commencement provisions.

Regulation 3 is an interpretation provision.

### **Part 2 concerns contaminated land and other exposure situations (see Article 73 of the Directive).**

Regulation 4 imposes duties on the Department to ensure that certain functions are carried out in relation to exposures from contaminated land and exposures from buildings or contaminated commodities.

Regulation 4(2) requires the Department to define the extent of the contaminated land and ensure that reference levels are set for land which cannot be disregarded from a radiation protection point of view following radioactive contamination as a result of an emergency or past practice or past work activity.

Regulation 4(3) also requires the Department to put in place appropriate arrangements to ensure that exposure from ionising radiation is controlled on land which has been contaminated as a result of an emergency or past practice or past work activity.

The arrangements in regulations 4(2) and (3) are intended to establish normal living conditions and must be in place before habitation or economic or social activities can be resumed on the land.

Regulation 5 places a duty on the Department to ensure that specified information is provided to members of the public who have been exposed to ionising radiation from a designated site.

Regulation 6 places a duty on the Department to ensure certain steps are taken where evidence is received by the Department concerning indoor public exposure from building material which has been incorporated into buildings or concerning public exposure to contaminated commodities. The steps include measures to identify and evaluate the level of risk to the public, and the establishment of strategies to ensure that identified risks are managed. Any strategies which are established must set

objectives, set appropriate reference levels and be developed and implemented taking into account the requirements of Article 102 of the Basic Safety Standards Directive.

**Part 3 concerns building materials containing potentially concerning levels of radioactivity (see Article 75 of the Directive).**

Regulation 7 requires certain steps to be taken where building material containing potentially concerning levels of radioactivity is present in the Isle of Man. The Department must ensure that the activity concentrations of the building material are determined before it is placed on the market. Where the gamma radiation dose liable to be given by the building material is more than 1 millisievert per year, the Department must exercise its functions to take appropriate measures, for example by restricting the use to which the building material can be put.

**Part 4 concerns radon (see Article 74 of the Directive).**

Regulation 8 concerns indoor exposure to radon, and requires the Department to establish reference levels to inform decisions and actions relating to public radon exposure. The Department is also required by regulation 9 to publish information on radon, its health risks, its measurement, and how radon levels may be reduced.

Regulation 10 requires the Department to establish a national radon action plan that addresses the risks of buildings being penetrated by radon. The plan must be updated at least once every five years and must take into account various specific considerations listed in Annex XVIII to the Basic Safety Standards Directive.

Regulation 11 requires the Department to ensure that measures be put in place to prevent radon ingress into new buildings. Regulation 12 requires the Department to identify areas subject to high radon concentrations in buildings.

**Part 5 concerns orphan sources (see Articles 92 and 94 of the Directive).**

An orphan source is a particular source of radiation which should be but is not under regulatory control, for example because it has been lost or stolen.

Regulation 13 requires the Department to arrange for the raising of awareness about orphan sources, and issue guidance on what should be done about orphan sources.

Regulation 14 requires the Department to ensure that an appropriate course of action is organised to recover orphan sources.

**Part 6 concerns radioactive substances in personal ornaments and toys (see Article 21 of the Directive).**

Regulation 15 prohibits the addition of radioactive substances to personal ornaments or toys and the activation of materials used in toys or personal ornaments where that may increase their radioactivity. It also prohibits the import and export of such products and materials.



Parts 7 and 8 of these Regulations implement Article 6(1) and 6(2) of the Directive by introducing the international radiological protection principle of generic “justification” of classes of practices involving exposure to ionising radiation, that is weighing the health detriments of such practices against the individual or social benefits. Implementation of Article 6(1) and 6(2) of the Directive gives effect to the recommendations of the International Commission on Radiological Protection as set out in ICRP Publication No. 103<sup>13</sup>.

**Part 7 concerns the justification of classes or types of practice resulting in exposure to ionising radiation (see Articles 5 and 19 of the Directive).**

Regulation 16 prohibits practices unless the most recent justification decision applicable has found that class or type of practice to be justified and after any time allowed for ceasing the practice has expired. Regulation 16 also provides transitional arrangements for classes or types of practice already being carried out at the date these regulations come into operation.

Regulation 16 also creates a saving that permits, pursuant to regulation 12 of the Ionising Radiation (Medical Exposure) Regulations 2019, the exposure of individuals to radiation where it is medically justified for that individual even where the practice is not justified in general.

**Part 8 concerns practices involving non-medical imaging exposure (see Article 22 of the Directive).**

Regulation 17 provides that the Department must take reasonable steps to ensure the identification of non-medical imaging practices.

Regulation 18 prohibits non-medical imaging practices unless they have been approved or if the Approval has been withdrawn. It also provides transitional arrangements for non-medical imaging practices already being carried out at the date these regulations come into force.

Regulation 19 provides that any person carrying out a non-medical imaging practice must ensure that each individual exposure is justified and that regular reviews of non-medical imaging practices are undertaken.

Regulation 20 concerns dose constraints for non-medical imaging exposures.

Regulation 21 concerns requirements for consent to non-medical imaging exposures and specifies exemptions from those requirements.

**Offences**

Contravention of these Regulations amounts to an offence under section 33 of the Health and Safety at Work etc. Act 1974 as it applies to the Island, carrying an

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unlimited fine (on conviction on information) or a maximum fine of £20,000 (on summary conviction).