



VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

Act on Radiation Protection, No. 44/2002, as amended by Act No. 28/2008, Act No. 88/2008, Act No. 82/2010, Act No. 162/2010, Act No. 126/2011 and Act No. 121/2013.

SECTION I

Objectives and scope.

Article 1

This Act is to secure that necessary safety measures are taken against radiation from radioactive materials and radiological equipment for the purpose of limiting the detrimental effects of such radiation. [When a decision to use radiation is taken, care shall be taken to ensure that the advantage entailed for the individual or for the community is greater than the possible damage resulting from its use, and that the level of exposure of persons to radiation is as low as possible, taking reasonable account of the purpose of the radiation in each instance and the economic and social factors involved.]¹⁾

The objectives of the Act shall be realized through detailed measures, *inter alia*, the inspection of any handling of radioactive materials and radiological equipment, studies and research, monitoring of radioactive substances in the environment, measures against radiological emergencies, and through education and guidelines on radiation protection.

¹⁾ Act No. 121/2013, Article 1.

Article 2

The Act applies to:

1. Safety measures against radiation [in all circumstances and all activities]¹⁾ that could cause a risk of radiation exposure to persons, for example, upon the production, import, export, delivery, possession, installation, use, handling and disposal of radioactive substances and radiological equipment (*cf.* the fourth paragraph of Article 13).
2. Safety measures [in activities or circumstances which result]¹⁾ in increased levels of natural radiation from the environment.
3. Safety measures against ionizing radiation from radioactive substances and radiological equipment insofar this does not fall under the auspices of other parties according to international conventions.
4. Monitoring and research in respect of radioactive substances in the environment and foodstuffs.
5. [The radiological aspect of measures [to combat radiation hazards of all types].¹⁾]²⁾

¹⁾ Act No. 121/2013, Article 2. ²⁾ Act No. 28/2008, Article 1.

Article 3

In this Act the definitions of the following terms are as follows:

1. *Radiation*: Ionizing and non-ionizing radiation.
2. *Ionizing radiation*: Radiation from radioactive substances, X-rays, or other radiation with similar biological effects.

3. *Non-ionizing radiation*: Ultraviolet radiation and all other electromagnetic radiation with longer wave length, for example, microwaves or other electromagnetic waves that have similar biological effects, as well as electromagnetic fields.
 - [4. *Radiological equipment*: Equipment which is powered by electricity and which produces radiation, e.g. linear accelerators, X-ray machines, solar lamps and laser light pointers.]¹⁾
 - [5. *Medical radiation*: The following types of radiation are considered to be medical radiation:
 - a. radiation of individuals for the diagnosis or treatment of disease,
 - b. radiation of the families or companions of patients and other persons (excluding, however, the employees of healthcare institutions), during diagnosis or treatment,
 - c. radiation of participants in scientific research in the health sector.]¹⁾
 6. *Activity*: Work activity that may cause ionizing radiation exposure to individuals.
 7. *Effective dose*: A measure of the quantity of ionizing radiation where the health risk of an individual constitutes the basis.
 - [8. *Holder*: A person or entity who has received a license from the Icelandic Radiation Safety Authority for use of radioactive materials or radiological equipment emitting ionizing radiation.]¹⁾
 - [9.]¹⁾ *Designated supervisor*: An employee who has the appropriate education and experience, appointed by [a holder]¹⁾ to act on his behalf as being responsible for an activity in respect of radiation protection.
 - [10.]¹⁾ *Quality assurance*: Any organized or planned measure deemed as necessary to create sufficient trust in that facilities, system, system parts, or measures work in a satisfactory manner and in accordance with accepted standards.
 - [11.]¹⁾ *Quality control*: The part of the quality assurance that applies to measures (planning, coordination, implementation) that are intended to maintain quality or improve it. Quality control entails controlling, assessing and keeping inside the set limits any characteristic factors regarding the effectiveness of equipment that may be defined, measured and monitored.
 - [12. *Forensic radiation*: Radiation of individuals for purposes other than medical, e.g. for the investigation of criminal cases or for safety purposes.]¹⁾
- ¹⁾ Act No. 121/2013, Article 3. ²⁾ Act No. 28/2008, Article 2.

SECTION II

The Icelandic Radiation Safety Authority.

Article 4

The Icelandic Radiation Safety Authority is an institute under the auspices of [the Minister].¹⁾ The institute's role is to undertake safety measures against radiation from radioactive substances and radiological equipment.

The Minister appoints the director of the Icelandic Radiation Safety Authority for a term of five years at a time. The director shall have a university degree in the institute's sphere of activity. The director is in charge of the management of the institute. He shall see to it being operated in accordance with existing laws and regulations at all times, and is responsible for its daily operation.

¹⁾ Act No. 126/2011, Article 342.

Article 5

The Icelandic Radiation Safety Authority undertakes:

1. Monitoring and supervising the implementation of this Act, and the regulations ...¹⁾ set on grounds of the Act.
2. Any inspections and research deemed as necessary according to this Act and the regulations ...¹⁾ set on grounds of the Act.
3. Monitoring workers' exposure to ionizing radiation, and maintaining a dose register of the results of the dose estimates for every worker.

4. Regular assessment of the total ionizing radiation exposure of the general public from activities [and circumstances]¹⁾ covered by this Act.
5. Regular assessment of patients' exposure to ionizing radiation from medical radiation under this Act.
6. Monitoring and researching radioactive substances in foodstuffs and the environment.
7. Instruction regarding radiation protection for workers who work with radiation, as well as disseminating information to the general public and the mass media.
8. Research in the field of radiation protection.
9. [The radiological aspect of measures [to combat radiation hazards of all types],¹⁾ including the analysis of threat, coordination of precautionary measures with international standards, the operation of precautionary and monitoring systems and other related matters.]²⁾
- [10. Necessary dosimetry and maintenance of national standards for use of ionizing radiation Iceland.]²⁾
- [11.]²⁾ Collaborating with foreign authorities in the field of radiation protection and nuclear issues.
- [12.]²⁾ Other factors pertaining to the implementation of this Act, and other projects in the field of radiation protection in accordance with further decisions thereon by the Minister.

The Minister may request the institute to address certain matters or projects relating to the duties under this Act.

The institute shall prepare, apply for and maintain accreditation regarding certain factors of research and inspections carried out by the institute.

The institute is authorised to enter into agreements on certain factors of the implementation with parties who meet the professional criteria of the institute.

Parties operating activities covered by this Act shall [assist the institute gathering the necessary information]²⁾ to facilitate that the assessment under items 4 and 5 is as realistic as possible.

¹⁾ Act No. 121/2013, Article 4. ²⁾ Act No. 28/2008, Article 3.

Article 6

...¹⁾

¹⁾ Act No. 121/2013, Article 5.

SECTION III

[Permit insurance and reporting for import etc.]¹⁾

¹⁾ Act No. 28/2008, Article 5.

Article 7

The production, import, [export],¹⁾ ownership, storing, delivery, [use, recycling, re-use]²⁾ and disposal of radioactive substances, be they pure, mixed with other substances or installed in equipment, are subject to licenses by the Icelandic Radiation Safety Authority. The granting of licenses is subject to conditions set by the institute, including on the handling of radioactive substances upon the end of their use. Applications for such licenses shall be made on the institute's forms or in another format acceptable by the institute.

A license is not required in respect of radioactive substances if their total content or their concentration per mass unit is under the exemption limits as determined by the Icelandic Radiation Safety Authority. Additionally, such licenses are not required for phosphorescence watches, pocket compasses, meters, and other such equipment containing very small quantities of radioactive substances, under further decisions by the Icelandic Radiation Safety Authority.

The import of radiological equipment capable of producing ionizing radiation is subject to reporting [unless radiation from them is under the limits determined by the Icelandic Radiation Safety Authority].²⁾ [Importers shall dispatch a notification to the Icelandic Radiation Safety Authority no later than 1 February each year on any such equipment imported in the previous year. Domestic producers shall also dispatch such notifications on domestic buyers of equipment subject to reporting.]¹⁾

[Use of radiation equipment that is subject to reporting requirements and that emits ionizing radiation is subject to licensing by the Icelandic Radiation Safety Authority. Changes in activities that have an impact on radiation safety measures are also subject to licensing by the Icelandic Radiation Safety Authority. The granting of licences is subject to conditions set by the authority. Applications for such licences shall be submitted on forms produced by the authority, or in another form approved by the authority. In the case of new types of activity, an assessment of the risks involved shall be stated specially (*cf.* Article 8).

Only persons who meet the requirements of the Icelandic Radiation Safety Authority regarding qualifications and experience may undertake the installation and repair of radiation equipment that is subject to reporting requirements and that emits ionizing radiation. Those who undertake the installation of such radiation equipment shall notify the Icelandic Radiation Safety Authority of such installation within four weeks of its completion.]²⁾

The Minister may decide by means of a regulation³⁾ that the import of certain categories of radiation equipment capable of producing non-ionizing radiation, be subject to reporting.

¹⁾ Act No. 28/2008, Article 4. ²⁾ Act No. 121/2013, Article 6. ³⁾ Regulation No. 954/2011.

SECTION IV

Assessment of the benefits and risks of using radiation.

Article 8

Any new types or categories of activities [or equipment]¹⁾ that may cause ionizing radiation exposure to people shall be assessed in advance with respect to the economic, social or other benefits in comparison with the risk of detrimental health impact such radiation may have. [Parties intending to begin such activities or to manufacture or import such equipment shall send the Icelandic Radiation Safety Authority a report on such an assessment of the intended activity or use.]¹⁾ Commencement of the activities prior to receiving the consent of the Icelandic Radiation Safety Authority, and of an evaluation by the Director of Health in the case of medical activities, is prohibited. A review shall be made of activities already taking place with respect to an assessment under the first sentence, when new essential information is available on its benefits or consequences.

[The Minister shall issue regulations containing more detailed provisions on the assessment of the benefits and risks of the use of ionizing radiation, and also on forensic radiation.]¹⁾

¹⁾ Act No. 121/2013, Article 7.

SECTION V

Use of radioactive substances and radiological equipment.

Article 9

...¹⁾

[Individuals younger than 18 years old are unauthorized to use tanning lamps, for other purpose than medical, in places that have licence according to the Health and Safety and Pollution Control Act. The Minister may specify on implementation of this provision in a regulation. Monitoring, coercive measures and penalties are subject to the provisions of the Health and Safety and Pollution Control Act.]²⁾

By means of a regulation³⁾, the Minister may decide that the use of certain categories of radiological equipment emitting non-ionizing radiation be subject to authorization [and other limitations].²⁾

¹⁾ Act No. 121/2013, Article 8. ²⁾ Act No. 82/2010, Article 1. ³⁾ Regulation No. 810/2003. Regulation No. 954/2011.

Article 10

[The holder]¹⁾ is responsible for ensuring that the use of radioactive substances and radiological equipment, and also all instruments, equipment and activities pertaining to radiation protection are in accordance with this Act, and the regulations and rules set hereunder.

Where activities employ ionizing radiation, [the licensee]¹⁾ shall appoint a responsible person who possesses the appropriate qualifications and experience. The Icelandic Radiation Safety Authority shall be informed of his or her name, qualifications and experience. The appointment of the responsible person

shall be subject to the approval of the Icelandic Radiation Safety Authority. The responsible person, who acts on grounds of a mandate from [the licensee]¹⁾, shall be responsible for the activities being in accordance with this Act, and the regulations and rules set hereunder.

In instances of activities employing ionizing radiation, an appropriate [quality control]¹⁾ scheme shall be implemented for radiation protection.

The Minister shall issue a regulation²⁾ setting out further provisions regarding the qualifications, experience and duties of responsible persons, and on the arrangement and execution of [the quality control].¹⁾

¹⁾ Act No. 28/2008, Article 7. ²⁾ Regulation No. 626/2003. Regulation No. 640/2003. Regulation No. 809/2003, cf. No. 920/2003. Regulation No. 811/2003.

Article 11

Parties working under this Act shall organize the appropriate response to radiological accidents, and shall provide information on special risk factors according to further rules thereon set by the Icelandic Radiation Safety Authority. They shall notify the Icelandic Radiation Safety Authority if a radiological accident occurs. They shall conduct an initial assessment of the possible consequences, and shall take all the appropriate measures to limit such consequences.

[The Minister shall issue regulations containing more detailed provisions on precautionary measures against, and responses to, radiation accidents, including as regards the provision of information to the public and the reference levels for the concentration of radioactive substances in foods.]¹⁾

¹⁾ Act No. 121/2013, Article 9.

Article 12

[The storage, handling and disposal of radioactive substances and radioactive wastes shall be the responsibility of the licensee.]¹⁾ The same applies to other waste, equipment or packaging containing radioactive substances, or contaminated by them.

The Icelandic Radiation Safety Authority shall be notified when [equipment subject to licensing]¹⁾ or equipment capable of emitting ionizing radiation is finally taken out of use. For as long as equipment contains radioactive substances or is capable of emitting ionizing radiation, it shall be kept in safe storage, and shall be safeguarded [by the Icelandic Radiation Safety Authority according to Article 17.]¹⁾ The Icelandic Radiation Safety Authority is authorised to demand the disposal or removal of radioactive substances and radiological equipment no longer in use [or in what the authority regards as safe storage].¹⁾ If the institute's demands on the disposal or removal are not met within a specified deadline, the institute may carry this out at [the holder's]²⁾ expense.

[Use of radioactive substances shall be such as to minimise the resultant amount of radioactive waste. Each year, licensees shall give the Icelandic Radiation Safety Authority a report on the amount of radioactive waste their activities generate.

The Minister shall issue regulations containing more detailed provisions on the sorting, storage, handling and disposal of radioactive substances and radioactive waste.]¹⁾

¹⁾ Act No. 121/2013, Article 10. ²⁾ Act No. 28/2008, Article 8.

[Article 12 a

The introduction of radioactive substances in the manufacture of foods, animal feeds, toys, jewellery and cosmetics is forbidden. The importation of products of this type into which radioactive substances have been introduced is also prohibited.]¹⁾

¹⁾ Act No. 121/2013, Article 11.

SECTION VI

Radiation protection at workplaces.

Article 13

Any radiation exposure of workers and members of the public resulting from [circumstances and]¹⁾ activities covered by this Act shall be as low as reasonably achievable, economic and social factors being taken into account.

In instances of activities where work takes place using radiation, ionizing, as well as non-ionizing radiation, measures shall be taken to protect the workers and others against radiation. Such measures shall be in accordance with the scope of the risk in question. In instances of activities using ionizing radiation, appropriate monitoring shall be carried out of the workers' exposure and that of other persons relating to the practice. The workers shall have adequate education and shall be given training and instruction ensuring their sufficient competence and knowledge of radiation protection, as well as on the safe use of radiation. Visitors and others who have access to the workplace shall be provided with information on the rules that need to be abided by for radiation protection purposes.

[In activities or circumstances that entail increased natural ionizing radiation, the appropriate measures shall be taken to protect people against such radiation.]¹⁾

The Minister sets further provisions in a regulation²⁾ on radiation protection at workplaces, including the arrangement of radiation protection and safety measures for reducing radiation, the age limits of those working with ionizing radiation, the effective dose to workers, apprentices and members of the public, [maximum levels of natural radioactive substances and demands regarding remedial measures if concentrations exceed the permitted levels],¹⁾ as well as on monitoring effective doses, and the medical monitoring of persons working with ionizing radiation, the classification of work areas and warning signs, shielding and installations of premises, education, professional training, and instructions to persons using radiation, or who work at areas where radiation is used.

Measures for protecting workers at workplaces against the detrimental effects of non-ionizing radiation are subject to the Act on Working Environment, and Health and Safety in the Workplace, and the rules set according to the said act.

¹⁾ Act No. 121/2013, Article 12. ²⁾ Regulation No. 626/2003. Regulation No. 627/2003. Regulation No. 640/2003. Regulation No. 809/2003, cf. 920/2003. Regulation No. 811/2003.

Article 14

The dose register, which the Icelandic Radiation Safety Authority shall maintain on the results of individual radiation monitoring (*cf.* the third indent of the first paragraph of Article 5) is subject to the Act on the Protection and Processing of Personal Data. The results shall be stored for the entire period the worker is subjected to ionizing radiation in his work, and until such time he reaches the age of 75, or would have become 75 years of age, however, under no circumstances for less than 30 years after the relevant person stops working in the position causing him to be exposed to ionizing radiation. Special notes shall be made of results that are not based on individual monitoring. The effective dose of a radiation accident shall be especially recorded, as well as the circumstances of the radiation, and the measures taken.

The results of individual monitoring shall be accessible by the worker, his employer, and the workplace physician, as well as by the health authorities according to further rules set by the Minister.

SECTION VII

Medical radiation.

Article 15

The responsible person under Article 10 is responsible for the use of medical radiation. He or she shall see to it that only competent persons with recognized specialist qualifications education carry out medical radiation.

Upon the use of medical radiation, the responsible person, or the person he or she has commissioned to carry out such radiation, shall consider whether the use of radiation is justifiable with respect to the

objective of the exposure, the patient's symptoms and condition. [The benefits and risks entailed in the use of other equipment that is to hand which employs less, or no, ionizing radiation shall also be taken into account.]¹⁾

[In diagnosis and tests, the person responsible, or the person he or she has commissioned to carry out the work,]¹⁾ shall ensure that the radiation exposure is as low as reasonably achievable for the intended purpose of the exposure, the instruments and the equipment available, as well as other factors of impact.

Appropriate plans for quality assurance and quality control of the practice, shall be set at any such place where medical radiation is used; [this shall include the assessment of the radiation of patients in accordance with guidelines issued by the Icelandic Radiation Safety Authority].¹⁾

[In the treatment of disease, the person responsible, or the person he or she has commissioned to carry out the work, shall ensure that the radiation of tissue outside the treatment area is a little as is compatible with the aim of the treatment. Care shall be taken to ensure that persons are not exposed to radiation by accident or as the result of mistakes. The person responsible shall notify the Icelandic Radiation Safety Authority of such radiation and give his or her assessment of the possible consequences.]¹⁾

The Minister shall issue a regulation²⁾ setting further provisions on radiation safety measures in connection with medical radiation, including references levels, arrangement and the application of schedules for quality assurance.

[The provisions of this Article shall also apply, as appropriate, to forensic radiation.]¹⁾

¹⁾ Act No. 121/2013, Article 13. ²⁾ Regulation No. 626/2003. Regulation No. 640/2003. Regulation No. 809/2003, cf. No. 920/2003.

Article 16

Parties intending to examine a group of people, for example, for purposes of scientific research, and to employ ionizing radiation, shall obtain a licence from the Icelandic Radiation Safety Authority. Such an examination may not be launched until after the licence has been issued by the authority, and shall also subject to the opinion of the Director of Health.

[The Minister shall issue regulations containing more detailed provisions on radiation safety precautions to be taken in examinations of groups of people, including reference levels of radiation.]¹⁾

¹⁾ Act No. 121/2013, Article 14.

SECTION VIII

Inspection of radiological equipment and radioactive substances.

Article 17

According to Article 5, the Icelandic Radiation Safety Authority conducts regular inspections of the use of radioactive substances and radiological equipment for which licenses are required according to this Act. [Inspections shall take into account the risks involved in the use of the equipment.]¹⁾

The personnel of the Icelandic Radiation Safety Authority are authorised access to any such location where radioactive substances and radiological equipment capable of producing ionizing radiation are used and stored. An effort shall be made to ensure that such inspection causes as limited disturbance as possible of the daily operation of instruments and substances.

The Administration of Occupational Safety and Health conducts inspections and takes measures to prevent detrimental effects on employees of non-ionizing radiation in accordance with the provisions of the Act on Working Environment, Health and Safety in the Workplace, and the rules set on grounds of the said act.

The Minister sets in a regulation²⁾ further provisions on the arrangement and implementation of the inspections by the Icelandic Radiation Safety Authority.

¹⁾ Act No. 121/2013, Article 15. ²⁾ Regulation No. 626/2003. Regulation No. 640/2003. Regulation No. 809/2003, cf. No. 920/2003. Regulation No. 811/2003.

Article 18

[Persons licensed]¹⁾ to operate radiological equipment and handle radioactive substances shall implement the improvements, which the Icelandic Radiation Safety Authority deems as necessary, inside a specified deadline; otherwise, any further use of instruments and equipment may be suspended until improvements have been made.

In the event that of the safety precautions are seriously deficient, the Icelandic Radiation Safety Authority shall stop any further use of radioactive substances and radiological equipment until such time that improvements have been made.

¹⁾ *Act No. 28/2008, Article 9.*

Article 19

The registered [person licensed]¹⁾ to handle radioactive substances or operate radiological equipment capable of producing ionizing radiation shall pay a charge for regular inspections by the Icelandic Radiation Safety Authority (*cf.* Article 17) for evaluating applications for licenses (*[cf.* Articles 7 and 9]),¹⁾ as well as for monitoring the employees' radiation doses (*cf.* the third indent of the first paragraph of Article 5). The Minister shall set a tariff applying to of such controls after receiving the proposals of the Icelandic Radiation Safety Authority. The tariff shall be based on the costs of such control.

¹⁾ *Act No. 28/2008, Article 10.*

SECTION IX

...¹⁾

¹⁾ *Act No. 121/2013, Article 16.*

SECTION X

Various provisions.

Article 21

By means of a regulation,¹⁾ the Minister sets further provisions on the implementation of this Act and on the activities of the Icelandic Radiation Safety Authority, as well as setting a tariff for the service measurements made by the Icelandic Radiation Safety Authority, subject to the institute's recommendations.

¹⁾ *Regulation No. 626/2003. Regulation No. 627/2003. Regulation No. 640/2003. Regulation No. 809/2003, cf. No. 920/2003. Regulation No. 810/2003. Regulation No. 811/2003. Regulation No. 954/2011.*

Article 22

A breach of the provisions of this Act is subject to fine or imprisonment for up to two years, unless other law stipulates more severe penal action. ...¹⁾

¹⁾ *Act No. 88/2008, Article 233.*

Article 23

This Act shall take effect immediately, however, on 1 January 2003 in respect of the provisions on non-ionizing radiation, response (*cf.* the ninth indent of the first paragraph of Article 5) and accreditation under the third paragraph of Article 5. The Act's provisions on inspections shall be reviewed inside of five years from the Act's entry-into-force. ...

*[This translation is published for information only.
The original Icelandic text is published in the Law Gazette.
In case of a possible discrepancy, the original Icelandic text applies.]*