## Regulation of the Minister of Economic Affairs, the Minister of Social Affairs and Employment and the Minister of Health, Welfare and Sport of 18 October 2013, No. WJZ/12066857, laying down the Radiation Protection Implementing Regulation of the Minister of Economic Affairs (Radiation Protection Implementing Regulation (Economic Affairs))

The Minister of Economic Affairs, the Minister of Social Affairs and Employment and the Minister of Health, Welfare & Sport;

Having regard to Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJEU L 1996, L 159), Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJEU 1996, L 180), Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (OJEU 1990, L 349), and Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (OJEU 2003, L 346) and Articles 3 (1) and (2), 7b (2), 7e (2) and (3), 11 (4), 12 (1), 12a (2), 18, 19, 20d (3), 25 (5)-(8), 26 (2), 28 (e) and (f), 29 (3), 37 (8), 40 (2), 43 (1), 44 (2), 107 (4), 108 (4), 109, 110 (1) and (2), 120 (3), 120a (2), 121 (4), and 132 (1) of the Radiation Protection Decree;

Hereby order:

## Part 1: General Provisions

## **Article 1.1 Definitions**

In this Regulation the following terms are defined as follows:

- current individual dose: an effective dose resulting from the use of an area outside the location, taking the actual current use of the environment into account;
- Decree: the Radiation Protection Decree;
- Minister: the Minister of Economic Affairs;
- multifunctional individual dose: an effective dose resulting from the use of an area outside the location in such a way as to give rise to the highest possible dose;
- Act: the Nuclear Energy Act.

## Article 1.2 Values for activity concentrations and activity

- 1. Annex 1.1 sets out the radionuclide activities and activity concentrations to determine exemption limits and clearance limits for practices and work activities, and the clearance values for radionuclide discharges into water and the air due to work activities in GBq per calendar year.
- **2.** Annex 1.2 sets out the method for weighting and assessing activity concentrations and activities and designates the radionuclides that are exempt from aggregation.
- **3.** Annex 1.3 sets out the activity values against which a sealed source is to be assessed to ascertain whether it complies with the definition of high-activity source.

## Article 1.3 Determining doses

Effective doses shall be determined in the manner set out in Annex 1.4.

## Article 1.4 Algorithms for the analysis of effects of ionizing radiation on the environment

When determining the environmental dose equivalents and the equivalent and effective doses referred to in Article 3 (1) of the Decree, use shall be made of the algorithms set out in Chapters 2, 3 and 4 of Annex 1.5, and in cases as laid down in paragraph 5.1 of Annex 1.5, Chapters 5 and 6 of Annex 1.5.

## Article 1.5 Exception regarding the analysis of effects of ionizing radiation on the environment

Article 1.4 notwithstanding, if the Minister consents thereto, methods, parameters or parameter conditions other than those prescribed in Annex 1.5 may be used if a situation substantially differs from the assumptions upon which Annex 1.5 is based.

#### Article 1.6 Method for assessing environmental dose equivalents

The environmental dose equivalents and equivalent and effective doses referred to in Article 3 (1) of the Decree shall be assessed against the doses set out in Articles 6 (2) and 48 of the Decree, in line with the methods laid down in paragraphs 3.3, 4.3, 4.4 and Chapters 5, 6 and 7 of Annex 1.5.

#### Article 1.7 Radiation incident hotline

The hotline referred to in Article 12a of the Decree shall be the Human Environment and Transport Inspectorate.

#### Article 1.8 Mutatis mutandis clause: work activities

Articles 2.2-2.4, 2.9, 5.8 and 5.9 shall apply mutatis mutandis to work activities.

#### Part 2: Administrative and Organizational Measures (Radiation Protection)

#### **Article 2.1 Definitions**

In this Part the following terms are defined as follows:

- records: records as referred to in Article 120 of the Decree;
- radiation protection unit: a radiation protection unit as referred to in Article 12 of the Decree;
- *licence:* a licence for practices as referred to in §4.2 of the Decree and for the discarding of radioactive materials as referred to in §4.4 of the Decree.

## Article 2.2 Presence of radiation protection unit

- 1. A radiation protection unit shall be present in an undertaking and at locations if various practices involving a total of over 100 sources for which a licence is required are carried out by the undertaking in various parts of the organization or at various places.
- 2. A radiation protection unit shall be present at facilities as referred to in Section 15 (b) of the Act to which the Nuclear Facilities, Fissile Materials and Ores Decree applies.
- **3.** The licence for a type of undertaking other than one as referred to at (1) and (2) may include the condition that a radiation protection unit shall be present, if in that undertaking:
  - a. practices are carried out that are the same as those in the undertakings referred to at (1) and (2) or at the locations referred to at (1); and
  - b. in the Minister's opinion a management system is required similar to that in the undertakings referred to at (1) and (2).

## Article 2.3 Modus operandi of radiation protection unit

If a radiation protection unit is required, the undertaking shall have internal radiation protection regulations laying down at least:

- a. the aims of and criteria for the management system;
- b. the area of application;
- c. the radiation protection organization, with a description of the responsibilities, duties and powers of the parts of the organization and workers involved in carrying out the practices, and internal supervision and reporting on the subject;
- d. the staff complement, the experts required and the additional administrative or technical support required;
- e. a prohibition on carrying out practices without internal authorization;
- f. a management system for internal authorizations;
- g. methods and procedures for practices, including admission requirements for exposed workers, registration requirements and regular checks;
- h. a waste plan for the collection, storage and transfer of radioactive waste;
- i. a disaster plan for incidents or accidents involving sources.

## Article 2.4 Duties of the general coordinating expert in the radiation protection unit

The duties of the general coordinating expert in the radiation protection unit are:

- a. to prepare and draw up radiation protection policy and advise on this policy;
- b. to prepare, and if mandated to this effect, grant internal authorizations;
- c. to internally monitor compliance with the statutory provisions and the requirements in the internal regulations, in the radiation protection requirements and in the internal authorizations;
- d. to notify the Minister of new applications, insofar as a condition in the licence so requires;e. to manage and maintain proper records of relevant data relating to radiation protection,
- to manage and maintain proper records of relevant data relating to radiation protection, radiation applications and sources;
- f. to ensure that annual reports on radiation protection are made to the undertaking and the Minister.

## Article 2.5 Notifying practices involving sources

- 1. A notification as referred to in Article 21 of the Decree shall include at least:
  - a. the name and address of the person signing the notification;
  - b. the name and address of the undertaking;
  - c. the address of the source location;
  - d. a description of the sources being notified;
  - e. the maximum high tension expressed in kilovolts, if the source is apparatus;
  - f. the radionuclide and the maximum activity, if the source is a radioactive material;
  - g. a description of the application for which the source is to be used;
  - h. a declaration that the maximum effective dose per calendar year that a person could receive outside the location due to practices involving that source is less than 10 microsieverts.
- **2.** The declaration referred to at (1)(h) may be replaced by:
  - a. a statement of the actual maximum effective dose and
  - b. information on how Article 5 of the Decree is to be implemented in the case of persons outside the location.
- 3. A notification as referred to in Article 22 of the Decree shall include at least:
  - a. the name and address of the person signing the notification;
  - b. the name and address of the undertaking;
  - c. the address of the source location;
  - d. a description of the deregistered sources;
  - e. the maximum high tension expressed in kilovolts, if the source is apparatus;
  - f. the radionuclide and the maximum activity, if the source is a radioactive material;
  - g. if applicable, how the undertaking is to discard the source.

## Article 2.6 Licence applications for practices involving sources

- 1. An licence application for practices shall include at least:
  - a. the name and address of the person signing the application;
  - b. the name and address of the undertaking;
  - c. a description of the location and its address or land registry data; in the case of changing locations these shall be indicated as clearly as possible;
  - d. a description of the practice in respect of which the licence is being applied for and the purpose thereof;
  - e. the maximum total effective dose, both due to discharges and due to external radiation, based on environmental dose equivalents that a person could receive in a calendar year at any point outside the location due to all notifiable practices and practices for which a licence is required together at the location to which the licence application relates;
  - f. the maximum effective or equivalent dose that the workers involved in the practices could receive in a calendar year;
  - g. a description of the radiation protection organization and the expertise present concerning the practice;
  - h. a statement of the duration of the practice;
  - i. an overview of all notifiable practices and practices for which a licence is required at the location, specified in terms of nature and extent.
- **2.** If the application relates to a practice involving apparatus, it shall also include a description of the apparatus with data on the ionizing radiation that the apparatus is capable of emitting.
- 3. If the application relates to a practice involving radioactive materials, it shall also include:
  - a. a statement of the radionuclides in respect of which the licence is being applied for;
  - a statement of the maximum radiotoxicity equivalents to be discharged into the air, a public sewer, surface water or the ground due to all the practices for which a licence is required in the case of the location to which the application relates, expressed as radiotoxicity equivalents for inhalation/ingestion respectively and weighted for inhalation and ingestion;
  - c. the radiotoxicity equivalents in respect of which the licence to discharge is being applied for.
- 4. If the application relates to a practice involving a sealed source, it shall also include a statement of the chemical and physical state and form whereby these radioactive materials constitute a sealed source and an indication of the construction and quality of the source.
- 5. If the application relates to a practice involving radioactive materials, it shall also include a statement of the maximum activity at any time, weighted and aggregated in accordance with Annex 1.2, of the radionuclides in the radioactive materials that will be present at the location referred to at (1)(c).
- 6. If the application relates to a practice involving a high-activity source, it shall also include:
  - a. information on the volume of the source, the source container and the fixed shielding of that source;
  - b. written proof that the financial security required pursuant to Article 20 (1) of the Decree has been furnished.
- 7. If the environmental dose equivalent referred to at (1)(e) is higher than 10 microsieverts, or the radiotoxicity equivalents of the activities discharged represent a dose equal to or higher than 1 microsievert, in a calendar year at any point outside the location, the application shall also include a description of the measures to prevent and protect against damage at and outside the location.

## Article 2.7 Measures for high-activity sources

- 1. The undertaking shall furnish the Minister with the data referred to in Annex 2.1 within two weeks of acquiring a high-activity source, using the form included in that Annex.
- 2. Within two weeks of the start of each calendar year and after such time as it no longer has the high-activity source in its possession the undertaking shall furnish the Minister with:

- a. the identification number of the high-activity source;
- b. the name of the undertaking;
- c. the location of the high-activity source and its place at this location, stating whether it is a case of fixed use or storage for mobile use;
- d. the number of the licence;
- e. the type of radionuclide;
- f. the activity of the high-activity source on the production date or, if this activity is not known, the activity on the date when the source was first placed on the market;
- g. the production date referred to at (f) or the date on which the source was first placed on the market respectively.
- **3.** In the event of a change in the data furnished in accordance with (2) the undertaking shall furnish the Minister with the changed data within two weeks of that change.
- **4.** If a high-activity source is transferred to another person, together with the data furnished in this connection under (2) the undertaking shall furnish the name of the person to whom it has transferred the source.
- 5. If the undertaking no longer has any high-activity sources in its possession, it shall give notification of this when furnishing the data referred to at (2).
- 6. The undertaking shall furnish the Minister on request with the data referred to in Article 2.8 (3).

#### Article 2.8 Further content of records on sealed sources subject to a notification requirement

- 1. In addition to the data referred to in Article 120 (2), the records shall include at least:
  - a. data on the exposed workers referred to in Article 90 of the Decree;
  - b. the medical records referred to in Article 100 of the Decree.
- **2.** In the case of practices involving apparatus as referred to in Article 21 of the Decree, the records shall also include:
  - a. the brand, type and year of construction of the generator and the attached stand;
  - the maximum output that the system is capable of delivering, expressed as a function of the maximum high tension of the X-ray tube and the voltage that the generator is capable of delivering;
  - c. the place and nature of the application;
  - d. the name and expertise of the person who carried out a check;
  - e. the date and results of checks carried out.
- **3.** In the case of practices involving high-activity sources, the records for each high-activity source shall also include:
  - a. the data referred to in Annex 2.2 on the form included in that Annex, and
  - b. a colour photograph, supplied by the source manufacturer or supplier, of the design of the source and of the associated source container.

#### Article 2.9 Retention period for data in records

- 1. The data in records shall be retained for at least five years after the calendar year to which they relate.
- 2. The data referred to in Article 2.8 (1)(b) shall be retained for the period and in the manner laid down in Article 100 (2) of the Decree.

## Article 2.10 Industrial radiography records

1. The records referred to in Article 121 (1) of the Decree shall include:

- a. the name of the licensee and the number of the licence granted for the practices concerned;
- b. the date on which or period within a calendar year when the practices were carried out;
- c. the place, nature and extent of the practices;
- d. the maximum increase in the effective dose attributable to the practices that persons could receive at any point outside the location.
- 2. If the person taking images or using industrial radiography at the location does so in the context of non-destructive testing, the records referred to at (1) shall also include the total number of images and hours of industrial radiography at the same location. For the purposes of this clause the number of images shall be equated with the number of films used for that purpose.

## Part 3: Radiation Protection Expertise

#### Article 3.1 Definitions

In this Part the following terms are defined as follows:

- *diploma:* a diploma, certificate or other attestation document as referred to in the Radioactive Materials and Apparatus Experts (Recognition of Training) Temporary Regulation or the Radioactive Materials Experts (Recognition of Training) Regulation as this read until 20 July 2003;
- *register:* the register referred to in Article 7b (1) of the Decree.

#### Article 3.2 Registration

A person shall be registered, re-registered or exceptionally registered in the register by the Minister if the requirements laid down pursuant to this Part for registration, re-registration or exceptional registration have been met.

#### Article 3.3 Criterion for registration

- 1. A person being registered as a general coordinating expert shall be in possession of a Level 2 diploma.
- 2. A person being registered as a coordinating expert shall be in possession of at least a Level 3 diploma.
- 3. Registration in the register shall be once-off and for a maximum period of five years.

## Article 3.4 Criteria for re-registration (general coordinating expert)

- **1.** A person being re-registered as a general coordinating expert:
  - a. shall be in possession of a Level 2 diploma.
  - b. shall have a declaration by his employer certifying that in the five years prior to the date of the application he worked at least 500 hours per year within the area of application of ionizing radiation and
  - shall have earned 200 points for knowledge maintenance within the area of application of ionizing radiation in the five years prior to the application in accordance with Part A of Annex 3.1.
- 2. Re-registration in the register shall be for a maximum period of five years.

## Article 3.5 Criteria for re-registration (coordinating expert)

- 1. A person being re-registered as a coordinating expert:
  - a. shall be in possession of a Level 3 diploma.
  - b. shall have a declaration by his employer certifying that in the five years prior to the date of the application he worked at least 250 hours per year within the area of application of ionizing

radiation and

- c. shall have earned 120 points for knowledge maintenance within the area of application of ionizing radiation in the five years prior to the application in accordance with Part A of Annex 3.1.
- 2. Article 3.4 (2) shall apply mutatis mutandis.

#### Article 3.6 Criteria for exceptional registration of a general coordinating expert

- 1. A person being exceptionally registered as a general coordinating expert:
  - a. shall be recorded once-off in the register;
  - b. shall be in possession of a Level 3 diploma and
  - c. shall comply with the core competencies referred to in Part B of Annex 3.1.
- 2. Exceptional registration in the register shall be for a maximum period of five years.

#### Article 3.7 Criteria for exceptional registration of a coordinating expert

- 1. A person being exceptionally registered as a coordinating expert:
  - a. shall be recorded once-off in the register;
  - b. shall be in possession of a Level 3 diploma and
  - c. shall comply with the core competencies referred to in Part C of Annex 3.1.
- 2. Article 3.6 (2) shall apply mutatis mutandis.

## Article 3.8 Issue date of diploma, certificate or attestation document

A diploma as referred to in Articles 3.3 (1) and (2), 3.4 (1)(a), 3.5 (1)(a), 3.6 (1)(b) and 3.7 (1)(b) shall have been issued during a period when the institution that issued the diploma, certificate or other attestation document was recognized under Article 7f or 132 of the Decree.

#### Article 3.9 Application for provisional registration or re-registration

- 1. An application for registration or re-registration shall include at least:
  - a. the name and address of the applicant;
  - b. the level at which the applicant wishes to be registered;
  - c. a copy of the diploma issued by a recognized institution as referred to in Article 7f or 132 of the Decree indicating that radiation expertise at Level 2 or 3 or equivalent has been gained.
- 2. An application for re-registration shall also include:
  - a. proof that the work experience required has been acquired;
  - b. proof that the continuing education or training required has been taken.

#### Article 3.10 Discontinuation of transitional arrangements

The date referred to in Article 132 (1) of the Decree shall be 1 January 2014.

#### Part 4: Notifiable Sources

#### § 4.1. General requirements

## Article 4.1 Scope

This Part applies solely to notifiable sources as referred to in Article 21 of the Decree.

## Article 4.2 Definitions

In this Part the following terms are defined as follows:

- storage facility: room used solely for the storage of radioactive materials;
- contamination check: check of a surface or an object other than a sealed source for radioactive contamination, taking the following into consideration:
   1°. the surface area wiped shall be approx. 5 cm<sup>2</sup>;
  - 2°. the detection limit of the measurement shall be a maximum of 2 becquerels for all nuclides;
- source certificate: document from the manufacturer of the sealed source stating at least the activity, the nuclide, the data for the capsule, the classification under International Standard ISO 2919:1999 or later and the serial number;
- *diploma:* a diploma, certificate or other attestation document as referred to in the Radioactive Materials and Apparatus Experts (Recognition of Training) Temporary Regulation or the Radioactive Materials Experts (Recognition of Training) Regulation as this read until 20 July 2003;
- inherently safe apparatus: apparatus that is designed to prevent exposure to the primary beam as far as possible when using it and that is fitted with safety devices that switch off the apparatus immediately if these safety devices are breached;
- *internal transport:* the movement of radioactive materials, fuels or ores within a facility or location, or between two locations at a facility, if the transport is subject to regulations that apply to the facility and the transport does not take place on the public highway;
- *leak:* a source where a wiped activity of over 185 becquerels is detected;
- *leakage test:* a check of the casing of a radioactive material for radioactive contamination;
- radioactive contamination: alpha contamination of 0.4 becquerels or more per cm<sup>2</sup> or beta/gamma contamination of 4 becquerels or more per cm<sup>2</sup>;
- warning symbol: warning symbol as referred to in Article 20 (1) of the Decree.

## Article 4.3 Organization

- **1.** The undertaking shall ensure that:
  - a. practices are carried out by or under the supervision of a supervisory expert who has a Level 5a diploma;
  - b. the supervisory expert referred to at (a) has a written mandate for this responsibility and accounts to it by submitting a report as often as is necessary, at least once a calendar year;
  - c. the persons carrying out practices involving sources have at least a diploma at the following level of radiation expertise:
    - 1°. in the case of practices where the source comes into a freely radiating position: Level 5A;
    - 2°. in the case of removal from or placement of the sealed source in the source container or in the apparatus: Level 5A;
    - 3°. in the case of placement or removal of the sealed source from the source container or fixed instrumentation other than by a supplier: Level 4A;
    - 4°. responsibility for contamination checks: Level 3.
- 2. The report referred to at (1)(b) shall include an enumeration of the activities in that calendar year in the context of radiation protection and the results thereof.
- **3.** The report shall be stored in the management system and shall include:
  - a. an overview of the sources present at the undertaking and any changes therein, stating the place and nature of the application;
  - b. any changes in the organization of radiation protection;
  - c. any checking activities; and
  - d. any disasters and radiation incidents.

## Article 4.4 Environmental impact

The undertaking shall ensure that, if applicable, the contribution to the effective dose outside the location made by the notified and authorized practices is as low as is reasonably possible and that the multifunctional individual dose does not in any case exceed 10 microsieverts per calendar year.

## § 4.2. Sealed sources

## Article 4.5 Requirements for sealed sources

- **1.** The undertaking shall ensure that:
  - a. an incoming consignment containing a sealed source is unpacked and checked at a place designated by the supervisory expert;
  - b. if the packaging is damaged, or a radiation incident took place during transport, the supervisory expert is informed and a contamination check is carried out on the packaging prior to unpacking;
  - c. if a consignment containing a sealed source is delivered outside working hours, the supervisory expert is immediately informed and the source is immediately placed in a storage facility;
  - d. the return packaging of a consignment containing a sealed source is cleaned of radioactive contamination, both internally and externally, before it leaves the location, and any indications or warning symbols of radioactivity on it are removed or made illegible;
  - e. the construction of a sealed source complies with the requirements laid down on this subject in International Standard ISO 2919:1999 or later;
  - f. the sealed source is accompanied by the source certificate issued for this source;
  - g. the circumstances in which the sealed source is actually used are not more demanding than those for which it was designed;
  - h. the sealed source does not leak;
  - i. the data on the sealed source are known and the sealed source, where practicable, is provided with a serial number.
  - j. the sealed source or source container, where practicable, is provided with a warning symbol.

## Article 4.6 Safety requirements

- **1.** The undertaking shall ensure that:
  - a. measures are taken to prevent a sealed source being placed in the radiating position by an unauthorized person or unintentionally;
  - b. the sealed source only enters the radiating position if apparatus is being used where it is clearly perceptible at all times on the outside of the source container, if necessary with the aid of suitable monitoring equipment, whether the sealed source is in the radiating position;
  - c. the work location is not accessible, or at least not without warning, to persons not directly involved in the practices;
  - d. no combustible, fire-promoting or explosive substances are present in the vicinity of the sealed source unless their presence is necessary to operations;
  - e. a sealed source other than a sealed source being used in fixed instrumentation is stored after use in a storage facility;
  - f. a sealed source being used in fixed instrumentation is stored in a storage facility if:
    - 1°. the instrumentation is taken out of service permanently or
    - 2°. this is necessary from the point of view of radiation protection.
- **2.** Notwithstanding (1)(f), the source container with the sealed source need not be removed from the fixed instrumentation if:
  - a. the production process is temporary halted,
  - b. during the halt of the production process the source container containing the sealed source is locked and
  - c. the supervisory expert has authorized this.

## Article 4.7 Checks

- 1. The undertaking shall ensure that:
  - a. sealed sources are checked periodically, including visual inspection of the sealed source and, if used, the source container at least once a calendar year;
  - b. the sealed source, the source container or the instrumentation is checked for leaks, radioactive

contamination and the environmental dose equivalent rate on the outside of the source container at least once a calendar year in line with a written procedure, avoiding damage to the sealed source;

- c. the results of the checks referred to at (a) and (b) are recorded, stating:
  - 1°. the date of the check,
  - 2°. the serial number of the source that was checked,
  - 3°. how the check was carried out,
  - 4°. the name of the expert who carried out the check and
  - 5°. the results of the check.
- **2.** Notwithstanding (1), the leakage test or contamination check referred to at (1) need not be carried out on:
  - a. sealed sources with an activity of less than 1 MBq and less than 0.02 Re<sub>inh</sub> and
  - b. gaseous sealed sources.
- **3.** The undertaking shall ensure that if the sealed source referred to at (1) is to be taken out of service permanently, a leakage test is carried out in line with a written procedure before it is placed in the storage facility or transferred.

## Article 4.8 Storage facility

The undertaking shall ensure that:

- a. at no point at 0.1 metres from the surface of the storage facility a dose equivalent rate on the outside greater than 1 microsievert per hour is measured;
- b. the outside of the storage facility is provided with a clearly legible and indelible inscription 'RADIOACTIVE MATERIALS' and a clearly visible warning symbol;
- c. the storage facility is properly locked and can only be opened by the undertaking or persons authorized by the undertaking to open it;
- d. the construction of the storage facility, whether or not it forms part of a building, meets the requirement of no less than 60 minutes' fire resistance;
- e. the storage facility is demonstrably known to the fire brigade;
- f. the amount of radioactivity in the storage facility is recorded in a register designed specifically for this purpose, which is kept in or near the storage facility, these records being specified at least in terms of nuclide and activity. Any issue or receipt of a sealed source from/in the storage facility shall also be recorded immediately in this register, and in the case of issue the destination shall also be recorded;
- g. if the storage facility can easily be moved it is placed in a lockable room or cupboard that is properly locked and can only be opened by the undertaking or persons authorized by the undertaking to open it.

#### Article 4.9 Removal of sealed sources

The undertaking shall ensure that a sealed source for removal is identifiable as such and stored in a storage facility.

## § 4.3. Apparatus

#### Article 4.10 Requirements for apparatus

- 1. The undertaking shall ensure that, as regards inherently safe apparatus:
  - a. the apparatus is built into a device in such a way that it cannot be in or come into operation when the device is open. The casing of the apparatus is protected, if possible, with switches that automatically break mechanically;
  - b. the apparatus is used solely when the safety devices affixed to the device to limit radiation levels outside the device are functioning correctly;
  - c. at no point at 0.1 metres from an accessible surface of the device a dose equivalent rate greater than 1 microsievert per hour can be measured;

- d. operation of the apparatus is carried out in a place where the effective dose is less than 1 millisievert per year;
- e. the device is provided with a warning symbol.
- **2.** The undertaking shall ensure that, as regards apparatus other than referred to at (1):
  - a. shielding is provided such that the radiation emitted, except at the opening designed for the emission of the useful beam, can cause as little damage as is reasonably possible;
  - b. a tube or other means of determining the size of the useful beam guarantees the same degree of protection against radiation as the capsule of apparatus;
  - c. apparatus and the associated ancillary equipment and protective gear are set up and shielded in such a way that persons do not need to expose themselves to the primary beam unless they are undergoing a radiological procedure;
  - d. measures are taken in relation to the setup and modus operandi of apparatus to prevent damage being caused by scattered radiation;
  - e. apparatus cannot be operated by unauthorized persons;
  - f. measures are taken to prevent unauthorized persons entering the room or place when the apparatus is in operation;
  - g. the apparatus is provided with a warning symbol.
- 3. The shielding requirements referred to at (2)(a) do not apply:
  - a. to the testing of apparatus,
  - b. to X-ray tubes being used in a room or place equipped specifically for this purpose, or
  - c. during repairs or maintenance of or research using X-ray tubes in laboratories or testing rooms, provided measures have been taken to prevent damage due to external radiation as far as is reasonably possible.

## Article 4.11 Safety requirements

The undertaking shall ensure that:

- a. the room and the use of the apparatus are geared to each other in terms of radiation protection;
- b. the effective dose to persons at the place where the apparatus is operated and outside the room or place where the apparatus is used does not exceed 1 millisievert per year;
- c. facilities are present in the room to limit the exposure of workers;
- d. additional organizational measures are taken if the dose limitation required cannot be achieved by means of structural measures.

## Article 4.12 Checks

- **1.** The undertaking shall ensure that:
  - a. the proper operation of the apparatus and the safety devices is checked at least once a year by a supervisory expert;
  - b. the shielding and the leakage radiation level outside the apparatus or device that the apparatus is built into are checked at least once a year;
  - c. after any relevant dismantling or repair of apparatus its proper operation as referred to at (a) and (b) is checked.
- 2. The undertaking shall ensure as regards apparatus, that in the management system:
  - a. all apparatus present is recorded, specified in terms of:
    - 1°. brand, type and year of construction,
    - 2°. the maximum high tension of the generator, and
    - 3°. the place and nature of the application.
  - b. the results of the checks referred to at (1) are recorded, stating:
    - 1°. the date of the check,
    - 2°. the name of the expert who carried out the check,

- 3°. any defects and subsequent repairs, and
- 4°. the leakage radiation levels outside the apparatus.
- c. any dismantling or repair of the apparatus is recorded, stating:
  - 1°. the date and time of the commencement and termination of any relevant dismantling or repair of the apparatus,
  - 2°. the name of the expert who carried out the dismantling or repair,
  - 3°. any defects and the nature of the repairs, and
  - 4°. the results of the check on the proper operation of the apparatus, the safety devices and the shielding following the dismantling or repair.

## Part 5: Radiation Protection Instruments

#### § 5.1. Indicating instruments

## Article 5.1 Scope

This paragraph applies to indicating instruments to which radioactive materials have been added for illumination purposes.

#### Article 5.2 Warning symbol

The ionizing radiation warning symbol as referred to in Article 28 (e) of the Decree is shown in Annex 5.1.

#### Article 5.3 Checking constructional requirements

- 1. When checking whether indicating instruments after the addition of radioactive materials meet the requirements relating to construction laid down in or pursuant to Articles 28 (d) and 29 (3) of the Decree, at least the tests set out in Annex 5.2 shall be carried out.
- **2.** The results of the test referred to in Annex 5.2 at II and the check referred to in Annex 5.2 at III shall be recorded by the undertaking in records designed for this purpose.
- 3. The records referred to at (2) shall include at least the following data:
  - a. the brand, type and production date of the indicating instrument or, if this is not possible, a description of the indicating instrument;
  - b. the date and place when and where the test or check took place;
  - c. how the test and the check were carried out;
  - d. the results of the test and the check.

## Article 5.4 Indicating instruments for illumination purposes

- 1. After the addition of radioactive materials to indicating instruments for illumination purposes the undertaking shall check whether these indicating instruments meet the requirements laid down in or pursuant to Article 28 or 29 of the Decree and the constructional requirements laid down pursuant to Article 5.3.
- **2.** The undertaking shall record the implementation of the checks referred to at (1) and the results thereof in records designed for this purpose.
- **3.** The Minister may grant exemption from the obligations laid down at (1) and (2) if the undertaking can demonstrate to the Minister's satisfaction that the checks and records referred to at (1) and (2) are implemented by another party.
- **4.** An undertaking having an exemption as referred to at (3):
  - a. shall record in its records the name and address of the other undertaking referred to at (3) and
  - b. shall have a written agreement with this other undertaking concerning the implementation of the checks and the keeping of the records referred to at (1) and (2).

5. The records referred to at (2) shall be retained for at least five years.

## Article 5.5 Marks on indicating instruments

The undertaking shall ensure that an indicating instrument to which H-3 in lighting cells or Pm-147 in luminous paint has been added for illumination purposes displays in a place visible from the outside of the indicating instrument:

- a. the warning symbol referred to in Article 5.2;
- b. in the case of an indicating instrument as referred to in Article 5.4, the mark for T 1 GBq or Pm 10 MBq for H-3 in lighting cells and Pm-147 in luminous paint respectively.

## Article 5.6 Repair of or maintenance work on indicating instruments

The undertaking shall ensure that, following repair of or maintenance work on an indicating instrument to which radioactive materials have been added for illumination purposes:

- a. no non-compliance with the requirements laid down in and pursuant to Articles 27-29 of the Decree has developed as a result of that repair and maintenance work;
- b. the ionizing radiation warning symbol laid down pursuant to Article 5.2 is displayed in a place visible from the outside of the indicating instrument;
- c. the mark referred to in Article 5.5 (b) is displayed.

## § 5.2. Consumer products

## Article 5.7 Practices involving limited risk

Practices involving a limited risk of exposure of humans and to which the prohibitions referred to in Articles 23, 24 and 25 (1) of the Decree do not apply are listed in Annex 5.3.

## Article 5.8 Application of aggregation rules

Practices involving products as referred to in Article 24 (b) of the Decree where the radioactive materials added to these products shall not be included in aggregation as referred to in Article 25 (4) of the Decree are listed in Annex 5.4 to this Regulation.

## § 5.3. Ionization smoke detectors

## Article 5.9 Definitions

In this paragraph the following terms are defined as follows:

- a. detector: ionization smoke detector containing a radioactive material;
- b. *approved detector:* detector as referred to in Annex 5.5.

## Article 5.10 Exception for approved smoke detectors

The prohibition referred to in Section 29 of the Act in conjunction with Article 26 (1) of the Decree does not apply to:

- a. holding for storage, provided that the total number of detectors, whether or not combined with other brands and types than those designated in Annex 5.5, held in storage at the same place, does not exceed 500;
- b. holding and using an approved detector;
- c. holding and use in connection with the installation, removal and demonstration of an approved detector;
- d. discarding an approved detector by issuing it to another party in cases where it is held in accordance with this Regulation without a licence.

## Article 5.11 Requirements for approved detectors

- 1. Any person bringing or causing to be brought into Dutch territory an approved detector shall ensure that:
  - a. an approved detector is provided on the outside with an indication of the type listed in Annex 5.5;
  - b. an indication is displayed in the detector clearly indicating the presence of a radioactive material;
  - c. the detector is provided on the outside with the indication shown in Annex 5.6, remaining visible after installation, clearly indicating the presence of a radioactive material.
- **2.** Any person delivering or causing to be delivered an approved detector to users in the Netherlands shall ensure that upon each delivery to a user:
  - a. the detector is provided on the outside with the indication shown in Annex 5.6, remaining visible after installation, clearly indicating the presence of a radioactive material.
  - b. written information is enclosed stating the presence of a radioactive material in the detector and indicating the activities with the detector that could cause contamination and are therefore advised against.

#### Article 5.12 Mutatis mutandis clause

Paragraphs 2-4 of the Management of Electrical and Electronic Equipment Regulation shall apply mutatis mutandis to the removal of approved detectors.

#### Part 6: Security of radioactive materials

#### Article 6.1 Definitions

In this Part the following terms are defined as follows:

- a. *Category 1 material:* radioactive material designated as Category 1 in Annex 6.1 or that belongs in Category 1 on the basis of the conditions stated in that Annex;
- b. *Category 2 material:* radioactive material designated as Category 2 in Annex 6.1 or that belongs in Category 2 on the basis of the conditions stated in that Annex;
- c. *Category 3 material:* radioactive material designated as Category 3 in Annex 6.1 or that belongs in Category 3 on the basis of the conditions stated in that Annex;
- d. *licensee:* holder of a licence as referred to in Article 24 or 25 of the Decree for practices involving Category 1, 2 or 3 materials, with the exception of the holder of a licence solely for transport, holding in storage in connection with transport or bringing or causing to be brought into or out of Dutch territory.

#### Article 6.2 Protection against theft or misuse of radioactive materials

The licensee shall take such security measures as are necessary to reasonably protect Category 1, 2 or 3 materials against theft or misuse.

#### Article 6.3 Supervision of radioactive materials

- 1. The licensee shall exercise supervision of Category 1, 2 or 3 materials personally or electronically.
- 2. A person who exercises personal supervision shall be authorized for this purpose by the licensee.

#### Article 6.4 Delay in case of unlawful acquisition of radioactive materials

Where Category 1, 2 or 3 materials are not under personal supervision, the licensee's security measures shall be such that any attempt at theft or misuse is detected electronically and henceforth measures are in operation resulting in:

- a. at least a ten-minute delay in the time a person needs to gain unlawful access to a Category 1 material;
- b. at least a five-minute delay in the time a person needs to gain unlawful access to a Category 2 material;
- c. at least a three-minute delay in the time a person needs to gain unlawful access to a Category 3 material.

## Article 6.5 Gearing of security measures

The security measures referred to in Articles 6.2, 6.3 and 6.4 shall be geared to:

- a. the nature of the Category 1, 2 or 3 material;
- b. how the Category 1, 2 or 3 material is to be used or stored;
- c. the mobility of the Category 1, 2 or 3 material;
- d. the possible effects on humans, animals, plants and property due to exposure to ionizing radiation or the release of the Category 1, 2 or 3 material in the event of theft or misuse;
- e. the measures that have been or are to be taken to prevent or limit the harmful effects of ionizing radiation on humans, animals, plants and property.

#### Article 6.6 Security plan

- 1. A licensee shall have a security plan including a description of how Category 1, 2 or 3 material is to be protected.
- 2. The security plan shall include at least a description of:
  - a. the categorization of the radioactive materials to be protected in accordance with Annex 6.1;
  - b. how the Category 1, 2 or 3 material is to be used or stored;
  - c. where the Category 1, 2 or 3 material is to be used or stored;
  - d. the security measures already taken and to be taken;
  - e. what persons are authorized to exercise personal supervision as referred to in Article 6.3;
  - f. the duties and powers of the staff responsible for the security of the Category 1, 2 or 3 material;
  - g. the procedures that the staff responsible for the security of the Category 1, 2 or 3 material are required to adopt, setting out at least how they shall act in the event of theft or misuse of the Category 1, 2 or 3 material or an attempt thereto;
  - h. arrangements agreed with the police or a private-sector security service;
  - i. an evaluation programme to assess the security measures.
- 3. The licensee shall act in accordance with the security plan.

## Article 6.7 Access to the security plan

- 1. The licensee shall ensure that cognizance is taken of the security plan referred to in Article 6.6 solely by persons for whom this is necessary for the proper exercise of their duties.
- The licensee shall ensure that these persons, before taking cognizance of the security plan, submit a certificate of good conduct or a declaration as referred to in Section 1 (1)(b) of the Security Screening Act.

## Article 6.8 Implementation of evaluation programme

- 1. The licensee shall implement the evaluation programme referred to in Article 6.6 (2)(i) annually and after any breach of security. This shall include at least checking and testing the security measures and applying the security plan in a drill.
- **2.** The licensee shall amend the security plan insofar as the results of the evaluation programme so warrant.

## Part 7: Natural Sources of Ionizing Radiation

## **Article 7.1 Definitions**

In this Part the following terms are defined as follows:

- a. surface contamination: presence on the surface of an object consisting of non-radioactive solids of non-wipeable or wipeable natural sources with an average mass-to-area of less than 1 g/cm<sup>2</sup>;
   b.
  - 1°. the surface of an object that is accessible without further or destructive interference with that object, or
  - 2°. the surface of an object that is accessible if that object is opened or dismantled for use, maintenance or repair, for product or material use or for product or material re-use;
- c. *disposal:* destination where the Minister or the undertaking foresees that a natural source will remain for more than two years if no other destination is foreseen for that source.

#### Article 7.2 List of work activities requiring a notification or licence

The list of work activities where the values shown in Annex 1.1, Tables 1 and 2, could be exceeded is set out in Annex 7.1.

#### Article 7.3 Method for checking against notification/licensing requirements

- 1. The activities or activity concentrations of natural sources shall be weighted and aggregated for checking against the values shown in Annex 1.1, Table 1 or 2, using the method laid down in Annex 7.2 at 1A and 1B.
- **2.** The environmental dose equivalents and the equivalent and effective doses due to work activities shall be determined under Article 1.4 using the method laid down in Annex 7.2 at 2.
- **3.** The doses relating to work activities shall be assessed using the method laid down in Annex 7.2 at 3.

## Article 7.4 Requirements for notifiable work activities

Work activities which are notifiable under Article 103 (1) of the Decree shall be carried out with due observance of the requirements set out in Annex 7.3.

#### Article 7.5 Method for assessment by determining risks of damage

- 1. The damage due to work activities in cases where the activity concentration combined with the activity does not give a correct indication of the harmful effects due to radiation exposure as a result of the work activities shall be determined and assessed by:
  - a. determining/assessing the surface contamination of any accessible surface, or
  - b. determining/assessing the external radiation due to contamination of any non-accessible surface.
- 2. In cases as referred to in (1)(a), with a view to radiation protection, notwithstanding Article 107 (2) of the Decree, the prohibition on work activities involving natural sources laid down in the first paragraph of that Article shall apply if the surface contamination has a total beta activity equal to or higher than 4 Bq/cm<sup>2</sup>.
- **3.** The surface contamination of a material shall be measured using the method laid down in Annex 7.4.
- **4.** Paragraph 1 (a) shall not apply in cases where the measuring technique referred to at (2) cannot be used.
- **5.** In cases as referred to at (1)(b), with a view to radiation protection, if the external radiation under normal operating conditions at 0.1 metres from any accessible external surface of a source causes

an environmental dose equivalent rate higher than 10  $\mu$ Sv per hour, measures shall be taken such that a dose limitation of 1 mSv effective dose in a calendar year is achieved for those work activities.

## Article 7.6 Exemption to licensing requirement

In cases where the effective doses to members of the public due to discharges into water or the air could be higher than 10  $\mu$ Sv per calendar year, with a view to radiation protection, notwithstanding Article 108 (2) of the Decree, the prohibition laid down in paragraph 1 of that Article shall apply.

#### Article 7.7 Storage of radioactive waste from natural sources

- 1. It is prohibited to dispose of radioactive waste from natural sources in the cases referred to in Article 110 (2) of the Decree other than at an establishment designated for this purpose by the Ministers pursuant to Article 37 (8) of the Decree.
- 2. The storage of radioactive waste from natural sources as referred to at (1) that complies with the values referred to in Article 107 (2) of the Decree shall be carried out with due observance of the requirements set out in Annex 7.3.

#### Article 7.8 Mixing of natural sources

- 1. The mixing of natural sources other than waste with other natural sources or other materials shall be permitted, provided these sources are intended for a useful application.
- 2. In cases where, in the holding or use of natural sources or product or material re-use thereof in groundworks, road-building or hydraulic engineering, the activity concentration combined with the total activity of the natural sources concerned is higher than the values laid down in Annex 1.1, Table 1, the sources, if this is reasonably possible, shall be mixed with other materials in such a way that the activity concentration in the building material ultimately used is lower than the values laid down in Annex 1.1, Table 1.
- **3.** In cases referred to at (2) where the mixing of sources with other materials is not reasonably possible, the work activity shall not be permitted if the dose to members of the public is higher than 0.3 mSv effective dose in a year.

#### Article 7.9 Notification of work activities and supply chain notification

Work activities and their termination shall be notified on a form based on the model shown in Annex 7.5.

#### Article 7.10 Exemption from notification requirement and supply chain notification

- 1. The undertaking shall be exempt from notifying work activities if they are notified by another undertaking on a form based on the model shown in Annex 7.6.
- **2.** A groundworks, road-building or hydraulic engineering undertaking shall be exempt from notifying work activities if:
  - a. another undertaking gives notification that the natural source is an end-product in groundworks, road-building or hydraulic engineering and gives an estimate of the effective dose, expressed as the multifunctional individual dose and current individual dose to members of the public in a year due to disposal, and
  - b. the supply chain notifier provides a certificate with the sources stating that they are radioactive material that is permitted to be disposed of in this way.
- 3. The notification shall include the data set out on the form in Annex 7.6.
- **4.** In a case as referred to at (1) the undertaking shall inform the notifying undertaking of any change in the notified data in writing at least six weeks before the change takes effect.

## Article 7.11 Applying for a licence for work activities

An application for a licence for work activities shall be submitted on a form based on the model shown in Annex 7.7.

## Article 7.12 Exemptions in the case of groundworks, road-building and hydraulic engineering

- 1. The obligation laid down in Article 103 (1) of the Decree, the prohibition laid down in Article 107 (1) of the Decree and Article 7.8 (2) of this Regulation shall not apply to the presence of natural sources in ground, road-building or hydraulic engineering works outside a facility carried out or actually commenced before 26 September 2004.
- **2.** Paragraph 1 shall apply mutatis mutandis to radioactive waste tips set up before 26 September 2004.
- **3.** Paragraph 1 shall apply mutatis mutandis to ground, road-building or hydraulic engineering works within a facility if:
  - a. the effective dose to workers within the location does not exceed 1 mSv in a calendar year and
  - b. the current individual dose to members of the public outside the facility does not exceed 0.1 mSv in a calendar year.

# Article 7.13 Establishment for the receipt of radioactive waste from natural sources of ionizing radiation

The facilities for the tipping of hazardous waste shall be establishments for the receipt of radioactive waste from natural sources of ionizing radiation where:

- a. the activity of the natural sources concerned at any time is equal to or higher than the value shown in Annex 1.1, Table 1, and
- b. the activity concentration of the natural sources concerned is equal to or higher than the value shown in Annex 1.1, Table 1 and lower than ten times that value.

## Part 8: High-Activity Sources

## Article 8.1 Financial security

The minimum amount for which financial security is required to be furnished as referred to in Article 20d (3) of the Decree shall be  $\in$ 120 per dm<sup>3</sup>, or part thereof, of material to be removed.

## Part 9: Final Provisions

## Article 9.1

## 1.

The Consumer Products (Radiation Protection) Regulation is hereby repealed.

## 2.

The Radionuclide-containing Indicating instruments Regulation is hereby repealed.

## 3.

The Approved Ionization Smoke Detectors Regulation 2004 is hereby repealed.

4.

The Environmental Effects of Ionizing Radiation (Analysis) Regulation is hereby repealed.

5.

The Natural Sources of Ionizing Radiation Regulation 2008 is hereby repealed.

6.

The Administrative and Organizational Measures (Radiation Protection) Regulation is hereby repealed.

## 7.

The High-Activity Sources Regulation is hereby repealed.

## 8.

The Radioactive Materials (Security) Regulation is hereby repealed.

## 9.

The Regulation of the State Secretary for Housing, Spatial Planning and the Environment and the State Secretary for Social Affairs and Employment of 9 June 2005, No. SAS2005090776 concerning the designation of facilities for the tipping of hazardous waste as establishments for the receipt of radioactive waste (Government Gazette 2005, 111) is hereby repealed.

## Article 9.2

[Amends the Radioactive Materials and Apparatus Experts (Recognition of Training) Temporary Regulation.]

## Article 9.3

This Regulation shall enter into force on 1 January 2014.

## Article 9.4

This Regulation may be cited as the 'Radiation Protection Implementing Regulation (Economic Affairs)'.

This Regulation shall be published with its Explanatory Notes in the Government Gazette.

The Hague, 18 October 2013

The Minister of Economic Affairs, H.G.J. Kamp

The Minister of Social Affairs and Employment, L.F. Asscher

The Minister of Health, Welfare and Sport, E.I. Schippers

#### Annex 1.1 to Article 1.2 (1) Exemption and clearance limits

The following applies when using Table 1:

- Nuclides with the suffix «+» or «sec» in Table 1 represent parent nuclides that are in equilibrium with their progeny as stated in Appendix A to Table 1. In this case the values shown in Table 1 relate to the parent nuclide but take the ingrown progeny into account. In other words, in the case of equilibrium the assessment is made solely against the value for the parent nuclide.
- 2. Table 1 shows the values for activity concentrations and total activity for some 800 different radionuclides. Of these, some 400 were not included in Directive 96/29 or the Communications of the Commission but have been calculated by the National Radiological Protection Board (NRPB) of the United Kingdom (UK) (NRPB-R306) and have been added for the sake of completeness. Appendix A to Table 1 has been expanded for the same reason. The values for activity concentration and total activity apply equally to the application of Articles 25, 26, 37, 103 and 107 of the Radiation Protection Decree.
- 3. Annex 1.2 lists some natural radionuclides in this table that are exempt from aggregation when assessing natural sources in the Netherlands. They do not therefore need to be determined.
- 4. The notes on the Annexes include a note discussing the reason why the exemption values are the same as the clearance values.
- 5. For the sake of intelligibility the powers of the values in the table are shown using the 1E notation, i.e. 10<sup>-4</sup> and 10<sup>4</sup> are shown as 1E-4 and 1E+4 respectively.
- 6. If a radionuclide is not shown in Table 1, that radionuclide is exempt from the notification or licensing requirement and also from the weighted aggregation set out in Annex 1.2 of activities, activity concentrations or any other parameters as referred to in Article 25 (7) of the Radiation Protection Decree.

The following applies when using Table 2:

1. Table 2 shows the values for the total activity for discharges of radionuclides into water and the air due to work activities. These values apply solely to the application of Article 108 of the Radiation Protection Decree.

# Table 1: Exemption and clearance limits for artificial and natural sources for activity concentration and activity

Appendix A to Table 1: List of the nuclides referred to in point 1 of this Annex in secular equilibrium with their progeny

Appendix B to Table 1: Radionuclides where the activity/activity concentration of the shortlived progeny needs to be added to the parent's when calculating doses

Table 2: Clearance values for discharges of radionuclides into water and the air due to work activities, in GBq per calendar year.

Annex 1.2 to Article 1.2 (2)

Weighted aggregation of activities and activity concentrations

Annex 1.3 to Article 1.2 (3)

Activity values above which a sealed source complies with the definition of a high-activity source

Annex 1.4 to Article 1.3

Data for determining the committed effective dose

Table 2: Inhalation dose coefficients for members of the public

Table 3: Lung absorption type(s) used to calculate the inhalation dose coefficient for members of the public exposed to particle aerosols or gases and vapours

Table 4: Inhalation and ingestion dose coefficients for workers

Table 5: Effective committed dose e(g) per unit intake by inhalation (Sv Bq<sup>-1</sup>) for soluble or reactive gases and vapours, for both workers and members of the public aged over 17 years

Table 6: Effective dose per unit integrated air concentration (Sv d-<sup>1</sup>/Bq m<sup>-3</sup>) due to exposure of adults (workers or members of the public) to noble gases

Table 7: Compounds and f<sub>1</sub> values used to calculate ingestion dose coefficients

Table 8: Compounds, lung absorption types and  $f_{\rm 1}$  values used to calculate inhalation dose coefficients

Annex 1.5 to Articles 1.4–1.6

Algorithms for the Analysis of the Effects of Ionizing Radiation

Annex 2.1 to Article 2.7 (1)

## Standard form for furnishing data on high-activity sealed sources

## Annex 2.2 to Article 2.8 (3)

#### Standard form for high-activity sealed sources for the undertaking's records

#### Annex 3.1 to Articles 3.4-3.7

#### **Registration of expertise**

#### Part A: Points system for continuing education and training

Activity	Note	Value	Minimum points required per five years for re-registration
Continuing education and training	Proof of attendance at a course approved by the designated institution	10 points per day	Level 3: 60 points Level 2: 70 points
Continuing education and training with inal assessment	Proof of positive final assessment/examination result for a course approved by the designated institution	15 points per day	
Attending symposiums and conferences	Proof of attendance at a symposium, conference, etc. approved by the designated institution	5 points per day	Level 3: 20 points Level 2: 60 points
Presentation/poster presentation at a symposium, conference, visiting ectureship	Proof in symposium programme	10 points per lecture	
Publication in trade journal	Journal submitted	5 points per publication	
Publication in peer-reviewed journal	Journal submitted	10 points per publication	
Teaching at a recognized training nstitution or on a recognized refresher raining course	Course programme	2 points per teaching period	
Participating in national/international committees	List of participants	10 points per committee per year	
Membership of one or more trade associations	Proof of membership of one or more of the associations on a list compiled by the designated institution	2 points per year	

#### Part B: Core competencies of a general coordinating expert

In order to comply with the requirements for exceptional registration as a general coordinating expert the person must demonstrate that he has the following core competencies:

Core competency 1:

The general coordinating expert is able to convincingly provide substantive management of a number of local supervisory experts and of a radiation protection unit in order to lend form and content to the radiation protection system in complex organizations. This means being able to grant written prior internal authorizations based on risk surveys (RS&Es) carried out for all practices (and work activities) involving ionizing radiation in or by the organization (the undertaking). He is able to be the initial contact officer for compliance with all the relevant regulations (in particular on radiation), including the Nuclear Energy Act licence granted for the complex, for both the undertaking and the authorities (inspectorates) and is therefore able to organize internal supervision on a regular basis, e.g. by holding audits. Also in the case of non-compliance, incidents and other unexpected events concerning applications of radiation related to the organization (the undertaking) the radiation protection expert is able to take the initiative to manage the situation, solve problems and come up with measures to prevent repetition.

## In this context it is important for the general coordinating expert:

- 1. to be able to set up a radiation protection unit;
- 2. to be able to draw up a radiation protection policy plan in consultation with the undertaking;
- 3. to know the regulations currently in force and be able to apply them;
- 4. to be able to identify all radiation risks/potential radiation risks;
- 5. to be able to establish and maintain contacts with all the relevant stakeholders in the organization;
- 6. to be able to participate in relevant formal and informal discussions;
- 7. to be able to manage, motivate and coach staff of the radiation protection unit on substantive matters;
- 8. to be able to respond appropriately to radiation incidents;
- 9. to be able to keep an up-to-date Nuclear Energy Act dossier;
- 10. to be able to draw up and implement an audit plan;
- 11. to be able to write an annual radiation report;
- 12. to be able to put forward appropriate safety measures; and
- 13. to be able to communicate clearly with all the relevant stakeholders in the event of noncompliance.

#### To this end it is necessary for the general coordinating expert:

- 1. to be aware of his role in the organization;
- to be able to interpret and implement legislation and regulations, including regulations in related areas;
- 3. to be familiar with good practices in the discipline and be able to apply them;
- 4. to be able to organize effective discussions or participate in them effectively;
- 5. to have a general knowledge of the dispersion models of activity in water, the ground and the air and be able to apply them or cause them to be applied;
- 6. to be able to gauge and assess the ecological risks of intentional or unintentional discharges of activity by the organization;
- 7. to be able to apply radiation safety aspects to the design and use of particle accelerators;
- 8. to be familiar with the local, national and international emergency and disaster organizations;
- 9. to be able to draw up an incident/disaster response plan.

#### Core competency 2:

The general coordinating expert is able to communicate with, and pro-actively give advice to, all parts of the organization and outsiders concerning radiation matters. He is able to give advice in both depth and breadth on radiation protection matters and be regarded as a reliable partner. In the case of new developments he is able to familiarize himself with them substantively at an early stage so as to assess and optimize radiation protection aspects. He is able to draw up a goodquality application for a licence/licence amendment. In the foregoing the general coordinating expert is able to take account of all stakeholders and the basic principles of radiation protection (justification, the ALARA principle and dose limitation).

#### In this context it is important for the general coordinating expert:

- 1. to be able to assess shielding and dose calculations in complex situations or carry them out himself;
- 2. to be able to gear his communication to the target group;
- 3. to be able to give clear and well-founded professional advice; and
- 4. to be able to build authority based on his knowledge.

#### To this end it is necessary for the general coordinating expert:

- 1. to be familiar with the methodology and content of national and international organizations' publications; and
- 2. to have a good knowledge of the physical basis of the discipline and be able to apply it.

#### Core competency 3:

The general coordinating expert is able to work actively on the development of his own expertise and that of others, both inside and outside the organization (information and instruction, active participation in seminars and international and

other conferences). This means being able to translate scientific publications into information relevant to the practice of radiation protection and thus develop the discipline. Together with other general coordinating experts in the Netherlands he is able to actively promote radiation protection culture and is familiar with the ethical and communication aspects of the discipline.

## In this context it is important for the general coordinating expert:

- 1. to be able to reflect critically on scientific publications, mathematical models and regulations and express his opinion on them;
- 2. to be able to participate actively in conferences and symposiums;
- 3. to know his way around databases and literature search systems;
- 4. to have a command of the basic principles of radiation protection;
- 5. to be able to provide information and instruction, give talks, organize teaching, create posters and deal effectively with the press;
- 6. to be able to discuss the ethical aspects of radiation protection; and
- 7. to come across convincingly in a debate on arguments using debating techniques.

#### To this end it is necessary for the general coordinating expert:

- 1. to stand above the radiation protection expert training course material;
- 2. to be able to apply the basic principles of epidemiology;
- 3. to have a command of the normative and ethical basic principles related to radiation protection and its implementation in national and international codes;
- 4. to be familiar with the aspects of radiation protection culture;
- 5. to be able to name and explain the relationship between health effects and exposure;
- 6. to be able to make risk comparisons;
- 7. to have a command of risk communication methods;
- 8. to have a good command of the basic principles of radiobiology, from molecular effects to health damage, over the entire dose range from low to high;
- 9. to be familiar with the case history of radiation accidents; and
- 10. to be familiar with the scientific debate on the validity of e.g. the Linear No-Threshold hypothesis and the relationship between the effects of low versus high exposures.

## Part C: Core competencies of a coordinating expert

#### Core competency 1:

The coordinating expert is able to convincingly give appropriate substantive advice and instructions of a preventive nature to an organization, provide supervision and enforce relevant legislation and regulations (including the Nuclear Energy Act licence granted) in the area of ionizing radiation.

#### In this context it is important for the coordinating expert:

- to be able to carry out an appropriate risk survey and evaluation (RS&E) related to the undertaking's mission, taking workers' interests into account; to be aware of the tension between different interests and be able to deal with it smoothly and flexibly in practice without losing sight of the intended goal (a safe workplace);
- 2. to be able to draw up, evaluate and improve appropriate work plans and procedures;
- to be able to give advice (both solicited and unsolicited) on risk limitation policy and its practical implications for staff, visitors to the organization and the environment, and be able to champion and implement this policy in the organization appropriately and convincingly;
- 4. to be able to deal with the tension between the application of the ALARA principle and the associated costs;
- 5. to be able to gauge his position within the organization and in relation to the outside world correctly (organizational sensitivity) and thus act proportionately and in a management context;
- based on knowledge of various detection methods to be able to give appropriate advice on and assess the use/application of particular methods in the case of familiar – and in some cases unfamiliar – radiation sources;
- 7. in the case of new build and conversions to be able to give advice on the structural measures required for radiation safety;

- 8. to be able to measure radiation levels, surface contamination, activity (e.g. in excreta) and doses/dose rates reliably and reproducibly (measuring techniques, measurement statistics);
- 9. to be able to set up regular quality monitoring systems and hold audits;
- 10. to be able to recommend suitable personal protective equipment for the various work activities/practices (type of exposure) and situations (e.g. pregnant exposed workers);
- 11. to be able to assign the most suitable form of personal dosimetry to exposed workers;
- 12. to be able to interpret measurement data in the context of standards and limits;
- 13. to be able to calculate using radiometric parameters;
- 14. to be able to carry out shielding calculations, determine exposure paths and derived operational limits and calculate the effective dose/committed dose due to external radiation and internal contamination (using rules of thumb, ICRP models and measurements).

## To this end it is necessary for the coordinating expert:

- 1. to have a basic knowledge of mathematics, physics and chemistry at secondary school certificate level;
- to have a set of basic skills enabling him to read trade journals and apply the content (mathematics: integration/differentiation, statistics, arithmetic skills, use of spreadsheets etc.);
- 3. to have a knowledge of the three main principles of radiation protection (justification, ALARA, limits);
- 4. to have a knowledge of basic human anatomy and physiology;
- 5. to be able to carry out shielding calculations for all the types of radiation being used;
- 6. to be able to interpret the Nuclear Energy Act licence granted and to know when it needs to be amended;
- 7. to be able to calculate the site boundary dose using the models published for this purpose and others and also staff and visitor doses within the site boundary;
- 8. to have a knowledge of current and relevant legislation and regulations and keep proper records required in that connection;
- 9. to have a knowledge of security of radiation sources;
- 10. to be able to draw up a licence application or licence amendment or revision that complies with the requirements laid down;
- 11. to be familiar with all the dose and related concepts mentioned in the regulations and be able to apply them;
- 12. to be familiar with the requirements for a Nuclear Energy Act dossier and be able to apply them in the organization;
- 13. to be familiar with and apply the rules that apply to each part of the life cycle/logistics management chain of radioactive materials and sources/apparatus;
- 14. to be able to classify areas into special, supervised and controlled areas, including a description of the required structural measures and access procedures;
- 15. to be familiar with the transport regulations (ADR) concerning radioactive materials, be able to ascertain whether the ADR Class 7 requirements need to be complied with, be familiar with/able to recognize labels, be able to determine the Transport Index and fill in a transport document correctly;
- 16. to be familiar with and able to calculate using the current ICRP models for internal contamination calculations, including the concepts used in them such as U, SEE and SAF;
- 17. to be able to apply the ALARA principle to practices and work activities of varying complexity;
- 18. to be aware of the ecological aspects of ionizing radiation (health effects on plants, animals and ecosystems);
- 19. to be familiar with the nuclide map (or similar) and be able to use the data in it in calculations;
- 20. to have sufficient knowledge and understanding of radiobiology to be able to carry out risk estimates and give advice based on them to exposed persons (including pregnant women);
- to provide effective instruction/work instructions and information geared to the target group, to both individuals and groups;
- 22. to have a knowledge of the physical and radiobiological properties of alpha radiation, beta radiation, positrons, photons, neutrons, protons and apparatus that produces ionizing radiation (in particular X-ray equipment) and sources;
- 23. to be familiar with the secondary effects of high-energy radiation (Bremsstrahlung, (γ, n) reactions);
- 24. to have a broad general knowledge of background radiation (nature, type, origin, dose burden for each source term and exposure path).

Core competency 2:

The coordinating expert shall deal with an incident/imminent incident or undesirable event appropriately.

#### In this context it is important for the coordinating expert:

- 1. to be able to properly gauge the urgency/risk magnitude of an incident/imminent incident under pressure and on the spot;
- 2. to be able to prevent contamination/further contamination of the environment by applying the right measures;
- to be able to select the appropriate measures, detection and measuring techniques, initiate and/or apply them or cause them to be applied and interpret the resulting readings;
- 4. to be able to draw up and implement a decontamination plan;
- 5. to be able to actively take the responsibility that befits his role;
- 6. to be able to return an abnormal situation that has developed to a normal workable situation within one day if necessary (unless this is physically impossible);
- 7. to make an initial dose estimate within an hour based on readings and data as set out in the Radionuclides Handbook (or similar);
- 8. to be able to ensure that, in consultation with the management of the organization, appropriate management and collaboration with other experts and disciplines takes place (e.g. with the Communication/Information Department), including notification to the Inspectorate in line with a licence condition;
- 9. to be able to evaluate the incident and translate the findings into policy and internal procedures.

#### To this end it is necessary for the coordinating expert:

- 1. to be able to gain a rapid grasp of the situation by being familiar with the sources and the location, through regular contacts, past audits and familiarity with the work activities/practices;
- 2. to be familiar with practical rules of thumb and apply them promptly;
- 3. to have a knowledge of methods of decontamination/external decontamination for humans and rooms;
- 4. to gauge when a situation requires acute medical assistance as a result of radiation incidents;
- 5. to reassure persons who have been (or think they have been) exposed in a well-founded manner and restore a feeling of safety in the workplace.

#### Core competency 3:

The coordinating expert is able to work actively on the development of his own expertise and that of others, especially inside the organization.

#### In this context it is important for the coordinating expert:

- 1. to be able to communicate effectively with all those concerned (at all levels in the organization) on radiation risks and procedures;
- 2. to have a broad grasp of radiation protection and be able to gain a certain depth in that discipline;
- to be able to place radiation risks in the social context, both inside and outside the organization;
- to be able to compare the relationship between the risks of radiation and those of other agents and other risks in the workplace with risk policy (in particular health and safety), taking differences in risk perception into account;
- 5. to be able to draw up intelligible work protocols and assess them;
- 6. to be able to reflect on his own value system, integrity and ethics;
- 7. to be open to intervision and criticism;
- 8. to be able to reflect on his own risk perception in relation to radiation exposure;
- 9. to realize the limits of his expertise and continue to educate himself.

#### To this end it is necessary for the coordinating expert:

- 1. to be able to put the radiation protection system into practice;
- to sufficiently know his way around the internet and the literature so as to keep his own knowledge up to date, and to be familiar with the system of refresher training in the Netherlands;
- 3. to have a general knowledge of the properties and risks of non-ionizing radiation;
- 4. to have a general knowledge of source terms and practices or work activities in the national/international nuclear industry, medical applications (nuclear medicine incl. cyclotrons, radiotherapy, radiodiagnosis), the industrial world (oil and gas, dredging, non-destructive testing) and aviation.

#### Annex 5.1 to Article 5.2

The warning symbol displayed on indicating instruments to which radionuclides have been added for illumination purposes shall be a warning sign of sufficient dimensions to be visible to the naked eye. It is shown in the following figure:



*Fig. 1: Model of the warning symbol for the addition of radionuclides for illumination purposes* The background is yellow and the lines and the figure are black. This warning symbol shall also be positioned in such a way as to be visible from the outside of the indicating instrument without the indicating instrument first having to be opened or dismantled.

#### Annex 5.2 to Article 5.3

Check on construction following the manufacture of indicating instruments containing radioactive materials for illumination purposes.

Annex 5.3 to Article 5.8

Annex 5.4 to Article 5.9

Annex 5.5 to Articles 5.10–5.12

Annex 5.6 to Article 5.12

## Annex 6.1 to Article 6.1

## Annex 7.2 to Article 7.3

#### Method for aggregating and assessing doses due to work activities

#### Annex 7.3 to Articles 7.4 and 7.7

#### Requirements for notifiable work activities

- 1. Requirements concerning expertise
  - a. The undertaking shall ensure that the work activities are carried out by an expert as referred to in Article 9 (1) of the Radiation Protection Decree who has gained at least a Level 3 ionizing radiation diploma or an equivalent diploma.
  - Notwithstanding (a), the work activities may be carried out by other persons designated for this purpose, under the supervision of and following instruction by the expert referred to at (a), provided at least one expert is present who has gained a Level 5B ionizing radiation diploma or an equivalent diploma.
  - c. The presence of the expert referred to at (b) is not necessary if there is demonstrably adequate supervision and prior written instruction.
  - d. The experts referred to at (a) and (b) shall assess the situation on the spot prior to the work activities and subsequently at least once a year as well as in the event of important changes.
  - e. The expert referred to at (a) shall have been designated in writing by the undertaking as the responsible expert. He shall be available at all times.
  - f. Subparagraphs (a)-(e) shall apply only if at any time the mass of notifiable material present at the location exceeds 1 tonne.
- 2. Requirements concerning recording
  - a. The mass balance of the radioactive materials or waste involved in a work activity shall be recorded in a register.
  - b. The activities and activity concentrations of the radioactive materials or waste concerned shall be specified and recorded in a register.
  - c. Where those radioactive materials or wastes are located in the facility shall be specified and recorded in a register.
  - d. The registers referred to at (a), (b) and (c) shall be present at the location or near the place where the work activities take place or be otherwise immediately available.

## Annex 7.4 to Article 7.5

#### Measuring technique for and determination of surface contamination from natural sources

Annex 7.5 to Article 7.9

Annex 7.6 to Article 7.10

Supply chain notification form

Annex 7.7 to Article 7.11

Licence application for work activities form