STUK

GUIDE **ST 1.1** / 23 MAY 2013

SAFETY IN RADIATION PRACTICES

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APPENDIX DEFINITIONS

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Authorization

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

Under section 70, paragraph 2, of the Radiation Act (592/1991), STUK – Radiation and Nuclear Safety Authority (Finland) issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

Translation. In the event of any differences in interpretation of this guide, the Finnish and Swedish versions shall take precedence over this translation.

1 General

This Guide sets out the general safety fundamentals concerning the use of ionizing radiation and practices involving exposure to natural radiation, in accordance with which radiation practices must be conducted. Detailed guidelines are provided in other ST Guides.

This Guide does not discuss non-ionizing radiation and natural background radiation. Neither does this Guide discuss matters that fall within the scope of the Nuclear Energy Act except where they relate to borderline issues in the scopes of the Radiation Act and the Nuclear Energy Act.

The definitions of the terms used in the Guide are presented in the Appendix.

The foundations for the safety and acceptability of radiation practices are set forth in the Radiation Act (592/1991). The use of nuclear energy is governed by the Nuclear Energy Act (990/1987).

2 General principles

The purpose of radiation protection is to protect human beings, society, the environment and future generations from the harmful effects of radiation without unnecessarily restricting acceptable uses of radiation or practices causing exposure to radiation.

The use of radiation and other radiation practices are acceptable when they meet the following criteria:

- The benefits derived from the practice exceed the detriments that it causes (principle of justification)
- The practice is organized to keep any radiation exposure hazardous to health as low as reasonably achievable (principle of optimization, the ALARA principle: As Low As Reasonably Achievable)
- The radiation exposure of an individual does not exceed the dose limits (principle of limitation).

The principles of justification, optimization and limitation are prescribed in section 2 of the Radiation Act.

2.1 Justification

Before beginning any new type of practice, the responsible party must investigate and evaluate the justification for the practice. The benefits of the practice to the persons exposed to radiation or to society must outweigh the overall detriment that the practice causes. The responsible party shall provide an account of the purpose of the practice, explain the justification for the practice and submit to STUK all information that is required for assessing the realization of the principle of justification.

The responsible party must reassess the justification for practices that have already begun whenever new information becomes available that could affect the justification. The justification must also be reassessed whenever suitable new alternative methods for achieving the same objective become available. If a practice ceases to yield adequate benefits in relation to its drawbacks, its continuation is no longer justified.

In the medical use of radiation, the justification for a procedure involving exposure to radiation must be assessed by the referring physician. The physician responsible for the procedure is responsible for the verification of the justification of the procedure.

The research plan for a scientific study relating to the medical use of radiation must include the assessment of the radiation exposure caused to the subjects and present the justification for the exposure. It is a condition for beginning a study that a competent ethical committee first hears experts in the medical use of radiation and issues a statement in favour of the research plan. The opinion of the Advisory Board for Radiation Safety must be obtained when necessary.

Exposure of human beings to radiation otherwise than for medical purposes is not permitted unless there are special grounds that justify the practice and the matter has been carefully assessed. For the purpose of assessing justification, an applicant for a safety licence or STUK may procure a statement from the Advisory Board for Radiation Safety, and from other experts when necessary.

Provisions concerning the medical uses of radiation are laid down in chapter 10 of the Radiation Act and in the Decree of the Ministry of Social Affairs and Health (423/2000), hereinafter referred to as the MSAH Decree. Provisions concerning medical research are laid down in the act (488/1999), and provisions concerning the Advisory Board for Radiation Safety are laid down in the Radiation Act, section 7, and in the Radiation Decree (1512/1991), section 30.

2.2 Optimization

The responsible party shall be liable for the implementation of such measures to improve radiation safety that can be considered reasonable with respect to their costs and their impacts upon radiation safety. The planning of measures to improve radiation safety must allow for radiation exposure both during regular activities and in the event of any abnormal events. The objective is to minimize the number of people who are exposed to radiation and that individual doses and the likelihood of exposure are kept as low as reasonably achievable.

Where necessary, STUK will impose dose constraints, i.e. limiting values for radiation exposure which are lower than the maximum values for radiation exposure, when these are warranted in order to implement the principle of optimization and to allow for exposure arising from various radiation sources. For example, dose constraints have been set for the designing of radiation shielding for rooms of use of radiation sources as well as for family members of patients who have received radionuclide therapy.

The provisions concerning STUK's authorization to set dose constraints are laid down in section 7 of the Radiation Decree. The design of rooms for radiation sources is discussed in Guide ST 1.10, and radiation safety in nuclear medicine is discussed in Guide ST 6.3.

2.3 Limitation

The principle of limitation is implemented through the use of dose limits, i.e. maximum values for radiation exposure, set for workers engaged in radiation work as well as the general public. The purpose of dose limits is to ensure that the total exposure arising from various practices does not cause an unacceptable detriment. Even in cases in which the radiation exposure remains below the prescribed maximum values, the exposure must be reduced in accordance with the principle of optimization. In the Member States of the European Union, dose limits are based on the Directive of the Council of the European Union.

Provisions concerning dose limits are laid down in sections 3–6 of the Radiation Decree. Dose limits are based on Council Directive 96/29/Euratom. Provisions concerning the application of dose limits in the medical use of radiation are laid down in section 7 a of the Radiation Decree.

2.4 Prohibitions concerning the use of radiation

The use of radioactive materials in foodstuffs, cosmetics, toys and corresponding consumer products is prohibited. It is also prohibited to import or export such consumer products if they contain radioactive materials.

Mixing or combining radioactive materials with consumer products of kinds other than those mentioned above that are not used as radiation sources is permissible only on special, justifiable grounds. This requires a licence granted by STUK. Importing and exporting of such consumer products also requires a licence granted by STUK.

Decommissioned radiation sources not manufactured in Finland must not be imported to Finland as radioactive waste.

It is also prohibited to import high-activity sealed sources that are not identified in accordance with all relevant regulations.

It is prohibited to transport high-activity sealed sources into countries that lack the technical, legislative and administrative means to ensure the safety of such sources and their use.

Ionizing radiation is allowed only in the irradiation of dried aromatic herbs, spices and vegetable seasonings. The irradiation of other foodstuffs is prohibited.

Provisions are laid down in section 27 of the Radiation Act concerning STUK's authority to grant licences for mixing or combining radioactive substances in consumer products and for the import and export of

such materials. The same section also prohibits the use of radioactive substances in foodstuffs, cosmetics, toys and corresponding consumer products, and the import and export of such consumer products if they contain radioactive substances. Imports of radioactive waste to Finland are governed by section 52 a of the Radiation Act. Sections 31 d and e of the Radiation Act lay down provisions concerning the identification, import and export of high-activity sealed sources. The irradiation of food is governed by the Decree of the Ministry of Trade and Industry (852/2000) concerning the treatment of foodstuffs with ionizing radiation.

3 Statutes guide the safety of radiation practices

3.1 Finnish legislation

The use of ionizing radiation and practices involving exposure to natural radiation are governed by the Radiation Act. The Radiation Decree, the MSAH Decree on the medical use of radiation, and the MSAH Decision (944/1992) on the maximum concentration of residential indoor radon have been issued pursuant to the Radiation Act.

The Nuclear Energy Act applies to the use of nuclear energy, nuclear materials and nuclear waste as well as mining and enrichment activities aimed at producing uranium or thorium. These activities and materials are also governed by the general principles in section 2 of the Radiation Act, and the provisions in chapter 9 concerning radiation work. Nuclear materials and nuclear waste that due to their minimal amounts do not fall within the scope of the Nuclear Energy Act are subject to regulatory control under the Radiation Act if such materials might cause exposure to radiation detrimental to human health. Practices other than the mining and enrichment operations mentioned above, falling within the scope of the Nuclear Energy Act, in which naturally occurring radioactive materials (e.g. uranium and thorium and their progeny occurring naturally in minerals) cause substantial exposure to radiation, are subject to regulatory control under the Radiation Act.

Certain radioactive materials (e.g. ^{3}H and ^{226}Ra), and certain X-ray appliances and particle accelerators are also governed by the Act on the Control of Exports of Dual-Use Goods (562/1996).

The use of radiation and other radiation practices are also governed by the ionizing radiation requirements of the Occupational Safety and Health Act (738/2002), the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces (44/2006) and the Occupational Health Care Act (1383/2001), and by the provisions and regulations issued pursuant thereto. The Medical Devices Act (629/2010) and the provisions and regulations issued pursuant thereto contain provisions on radiation appliances used in health care and the placing on the market of such appliances.

Transportation of radioactive materials is governed by the provisions of chapter 8 of the Radiation Act and by legislation on transportation of hazardous goods.

3.2 European Union legal acts

Radiation practices, appliances that produce radiation, radioactive substances and the radiation exposure that they cause are governed by the Treaty establishing the European Atomic Energy Community (Euratom) and by the legislation issued pursuant thereto. All Regulations and Decisions by the Council of the European Union and the European Commission are applicable as such in all Member States. On the other hand, Council Directives are implemented through national legislation.

Radiation appliances and radioactive substances are governed by the Treaty establishing the European Economic Community (the EEC Treaty) regulating the free movement of goods, and the Product Directives issued pursuant thereto.

3.3 International conventions and regulations

The Radiation Protection Convention of the International Labour Organization (ILO, No. 115, 1960) shall be applied in matters relating to workers engaged in radiation work. In addition, the radiation safety standards and guides of the International Atomic Energy Agency (IAEA) shall be followed.

Importing high-activity sealed sources from outside the European Union and exporting them to destinations outside the European Union shall

comply with the authorization and notification procedures set out in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and in the IAEA Guidance on the Import and Export of Radioactive Sources.

Shipments of radioactive materials shall comply with all relevant international transportation regulations and international treaties on transportation. The most important of these include the ADR agreement (road transport), the RID regulations (rail transport), the IMDG code (sea transport) and the ICAO-TI technical instructions (air transport).

3.4 STUK's decisions and guides

Applying its statutory rights, STUK issues decisions on radiation practices. These decisions are binding for parties responsible for radiation practices. Decisions have been issued on e.g. the acceptability criteria during the use of radiation appliances in health care and on reference levels for radiation exposures due to medical examinations.

Pursuant to paragraph 2 of section 70 of the Radiation Act, STUK issues general guidelines, known as Radiation Safety Guides (ST Guides), concerning the safety of the use of radiation and other radiation practices. The responsible party may design safety solutions other than those presented in these Guides. In such cases, the responsible party shall be able to prove that the solution leads to a level of safety defined in the Radiation Act and set forth in more detail in the ST Guides. Any procedure that differs from the procedures set out in the ST Guides must be submitted to STUK for approval.

4 The use of radiation requires a licence or notification

4.1 Practices requiring a safety licence

The use of ionizing radiation in Finland requires a safety licence (see item 4.3 Exemption from safety licensing and notification procedure). Safety licence applications are submitted to STUK in writing.

A safety licence can be granted when the use of radiation meets the general principles set forth in chapter 2, and it has been reliably demonstrated that the purpose of the use of radiation, the methods employed, the radiation sources and equipment, the rooms of use and radiation shieldings, the security arrangements, the user's organization and the safety guidance all comply with the statutory safety level, as further described in the ST Guides. A further condition of licensing is that an appropriate plan has been prepared for handling any radioactive waste that may be produced in the course of the practice. The terms and conditions that are necessary from the point of view of ensuring safety are specified in the safety licence.

Should any practice undergo changes, STUK shall be notified within two weeks. If the change is so fundamental that it would require a change of the safety licence, the application for the change shall be submitted well in advance before a changed practice is commenced.

Provisions are laid down in section 16 of the Radiation Act concerning safety licences and STUK's authority to grant safety licences. Provisions concerning changes to practices are laid down in section 16 of the Radiation Decree. Changes are also discussed in Guide ST 1.6.

4.2 Furnishing security

Holders of safety licences are required to furnish securities in certain cases. The purpose of the security is to ensure that the costs of rendering radioactive waste harmless and of any necessary environmental decontamination measures are met. A security must be furnished in the following cases:

- The licence is granted for extensive manufacture of, use of, or trade in radioactive substances or radiation sources containing such substances.
- The practice produces, or may produce, radioactive waste that cannot be rendered harmless without considerable expense.
- The activity of a high-activity sealed source exceeds by 100 times or more the activity level specified in Annex 1 of the Sealed Sources

Directive*). (However, no security is required for a source with a half-life of less than 150 days.)

However, the duty to furnish a security does not apply to the State, municipalities, federations of municipalities or comparable bodies governed by public law or independent institutions governed by public law. The need to furnish a security and the size of the security are decided by STUK when the safety licence is granted.

The general provisions concerning the furnishing of a security are laid down in section 19 of the Radiation Act. The provisions concerning securities for high-activity sealed sources are laid down in section 31 f of the Radiation Act.

4.3 Exemption from safety licensing and notification procedure

The Radiation Act sets forth the practices that are exempted from safety licensing.

STUK may exempt even other uses of radiation from safety licensing if it can be ascertained with sufficient reliability that such uses of radiation will not cause any detriment to health or any danger.

Licence-exempt uses of radiation may be specified as notifiable to STUK and licence-exempt radiation appliances may be specified as notifiable for entry in the register maintained by STUK. The notification obligation and all other terms and conditions of exemption are specified in the decision of exemption issued by STUK.

Section 17 of the Radiation Act lays down provisions concerning practices exempted from safety licensing, STUK's authority to grant exemptions from safety licensing for uses of radiation, and STUK's authority to specify licence-exempt uses of radiation as notifiable. The registration of licence-exempt radiation appliances is governed by section 20 of the Radiation Decree. The terms and conditions for exemption from safety licensing are presented in Guide ST 1.5.

5 The party running a radiation practice shall be responsible for safety

The party running a radiation practice, the responsible party, shall be responsible for the safety of the radiation practice and obligated to take all actions to maintain and promote radiation safety. The responsible party shall be responsible for ensuring that the radiation practice fulfils all requirements and regulations under the Radiation Act and any statutes issued pursuant thereto. The responsibilities and duties of responsible parties are discussed in other ST Guides.

The responsible party also remains responsible for the duties prescribed in radiation legislation when the organization uses external specialists. The responsible party is likewise responsible for arranging the radiation protection, monitoring of radiation exposure and medical surveillance for workers subcontracted for radiation work.

The responsible party must maintain records of the radioactive substances and radiation appliances for which the said party is responsible – including details of their location, procurement and release to other parties. This bookkeeping must be kept up to date at all times. STUK must also be notified of the commissioning and decommissioning of radiation sources and radiation appliances in accordance with instructions separately issued by it.

Provisions are laid down in section 14 of the Radiation Act concerning the responsible party's general duty of care. The obligation of the responsible party to arrange for the protection of workers of outside undertakings is set forth in section 37 a of the Radiation Act. Notifications regarding commissioning and decommissioning of radiation appliances are governed by section 16 of the Radiation Decree.

*) "Sealed Sources Directive" refers to Council Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources.

6 Good safety culture and quality assurance promote safety

6.1 Safety culture

The creation and maintenance of a good safety culture require the participation of all workers, the commitment of the highest management, and visible leadership. A safety culture can be promoted through efficient communication and through the improvement of the staff's competences so that all staff members are capable of assuming responsibility and giving their carefully considered input to the maintenance and further development of safety. The purpose of this is not only the prevention of accidents but also the creation of conditions that lead to safety at work, encouraging workers to work safely at all times. The management shall provide the opportunity for workers to give feedback on matters relating to radiation safety and likewise ensure that workers actively participate in the development of practices that ensure as low radiation exposures as are reasonably achievable.

A good safety culture is created and maintained by:

- promoting the commitment of all workers to radiation safety at all levels of the organization
- ensuring consensus in all matters relating to the radiation safety of the radiation user's organization
- providing the workers with tools and methods that allow them to carry out their duties safely
- encouraging all workers to develop and apply working methods and guidelines that improve radiation safety
- ensuring that all workers in the organization are aware of radiation safety and will carry their personal responsibility for it
- encouraging open communication about radiation safety within the organization and among all relevant parties
- encouraging workers to question and learn instead of accepting too easily the current practices
- offering means for the organization to continuously develop, improving its safety culture.

6.2 Planning and maintaining safety

All rooms of use of radiation and their structural shieldings must be designed so that radiation appliances can be used safely in them. All radiation appliances shall be in proper working order and suited to their intended uses. The ways of working and the applied methods shall be safe and consistent with good practice. Planning of practices must allow for alternative methods that do not require the use of ionizing radiation.

The planning phase includes the creation of an appropriate radiation user's organization with clearly defined responsibilities and guidelines. This organization must also be capable of functioning in the case that an abnormal event takes place. The responsible party must identify the risks involved in the practice in advance and manage these risks in a systematic manner. Radiation exposure caused to workers and other individuals must be assessed in advance and continually monitored during activities. Investigation levels for radiation exposure, specific to each activity, or some other corresponding procedure must be used to ensure that all radiation exposure that deviates from forecasts is detected and investigated. Remedial measures must be taken without delay when necessary.

The responsible party shall chart the possible abnormal events in advance and make the respective preparations. The preparatory measures must be planned in appropriate extents according to the risks involved. The potential exposures due to certain events must be allowed for when e.g. classifying workers and working areas and issuing guidelines. STUK shall be notified promptly of all abnormal events.

The safe use of radiation sources must be ensured throughout the entire life cycle of the sources. The responsible party shall present a plan in the safety licence application showing how care shall be taken of the radioactive waste and decommissioned radiation sources previously contained by radiation appliances.

Safety includes radiation protection measures

and also security arrangements seeking to prevent radiation sources from falling into the hands of outsiders as well as seeking to prevent other types of abuse.

The Radiation Act, sections 24 and 26, issue provisions concerning the design of rooms in which radiation appliances and radioactive materials are used and stored. Further instructions on the use of investigation levels are provided in Guides ST 1.6 and ST 7.1. Matters relating to radiation users' organizations and the establishment of such are discussed in Guide ST 1.4. Provisions concerning the classification of workers and working areas are laid down in section 32 of the Radiation Act and in section 10 of the Radiation Decree. Abnormal events and notifications of such to STUK are discussed in section 17 of the Radiation Decree and in Guide ST 1.6. Provisions concerning releases of radioactive substances are laid down in section 23 of the Radiation Decree, and the duty of the responsible party to manage radioactive waste is prescribed in section 50 of the Radiation Act. More detailed instructions on waste management are available in Guide ST 6.2, and instructions on the decommissioning of sealed sources are available in Guide ST 5.1. Security arrangements are discussed in Guide ST 1.11.

6.3 Quality assurance

The statutory requirements of the responsible party can be best met through the use of a management system (a quality system) that is designed for use in the radiation practice. The management system shall be described in guidelines and other documents, and all respective documents shall be arranged to form a unified, continuously updated totality (the procedures manual or similar).

The purpose of quality assurance is to ensure that the use of radiation fulfils all relevant requirements. The quality assurance programme includes written definitions of the functions that are used for assuring quality. It also describes the methods used for monitoring the condition and properties of radiation appliances. Responsibilities and operating guidelines shall be specified for each individual appliance. Sufficient service shall be available for all appliances, and also regular service shall be arranged for all of them.

Regular evaluations may be used to chart the effectiveness of the management system and the need to improve safety, and to anticipate any imminent safety defects. All significant deficiencies observed in radiation practices shall be rectified without delay.

Quality assurance for the medical uses of radiation is prescribed in section 40 of the Radiation Act.

7 Radiation sources' compliance with requirements shall be demonstrated

Radiation sources and appliances that are marketed or in use must meet the product-specific requirements prescribed for them.

If a product has been found to comply with requirements in one European Union Member State, then it may be marketed throughout the internal market. One condition of this is that the product complies with the harmonized regulations of the European Union. When demonstrating compliance with requirements, a manufacturer may use the harmonized European standards pertaining to each Product Directive (see item 3.2), the names of which standards are published in the Official Journal of the European Union. If the Product Directive does not require the use of harmonized standards, then the product may be declared compliant with the essential requirements of the Directive without standards.

If there is no Directive for the product, or any other applicable general European regulation, then the national legislations of Member States are applied.

7.1 Duties of parties placing radiation sources on the market

The manufacturer and the party that places a product on the market are liable for the safety of the product and for demonstrating its compliance with requirements. The party (the importer, seller or other transferor) that places on the market any radiation appliance, radioactive substance or material

containing radioactive substance, or an item of equipment or some other product associated with safety in radiation practices has a duty to demonstrate that the product meets the safety requirements that pertain thereto. Compliance with requirements is demonstrated, depending on the product, either through an evaluation and/or inspection performed by a notified body, or by a document that explains the measures taken to verify compliance (manufacturer's declaration and technical documents). When the product meets the requirements pertaining thereto and there is a Product Directive for it in accordance with the New Approach, the manufacturer or the manufacturer's authorized representative within the European Economic Area prepares a declaration of conformity and attaches a CE marking to the relevant product items.

Section 21 of the Radiation Act lays down the provisions concerning the duty of the party placing a product on the market to demonstrate the product's conformity to requirements.

7.2 On-site surveillance

Radiation appliances and radioactive substances as well as equipment relating to radiation safety are also controlled through on-site surveillance. On-site surveillance concerns the use and maintenance of products, the safety of appliances and facilities, the working conditions and the environmental conditions. STUK oversees the use of radiation and practices involving exposure to natural radiation by e.g. performing inspections in places of use of radiation.

STUK's authority to exert regulatory control over radiation practices is set forth in chapter 14 of the Radiation Act.

7.3 Product restrictions

If a radiation appliance or source fails to meet the relevant safety requirements, STUK is authorized to prohibit its sale or other transfer.

If any faults or deficiencies are detected in radiation appliances already on the market that would require the appliances to be withdrawn from the market or to undergo corrective measures, these measures shall be performed by the party who placed the appliances on the market, i.e. usually the importer or manufacturer of the appliances. Regarding medical devices, the party that oversees the performance of such measures is the National Supervisory Authority for Welfare and Health (Valvira).

STUK's authority to prohibit the sales or other transfers of products that fail to meet the relevant safety requirements is set forth in section 56 of the Radiation Act.

8 Safety shall be ensured also in practices involving exposure to natural radiation

The responsible party is obligated to investigate the radiation exposure arising from natural radiation in a manner acceptable to STUK if it is found, or if there are justified grounds to suspect, that the practice is to be considered a radiation practice. The following investigations are among those that must be performed:

- The radon concentration in working premises must be measured if work is conducted in the premises on a permanent basis (more than 600 hours per year) and if there are justified grounds to suspect that the action level of 400 Bq/m^3 for radon concentration in inhaled air during working hours may be exceeded. STUK's website (www.stuk.fi) lists the municipalities in which radon concentration must be measured in all workplaces. The radon concentration must be measured in all public premises regardless of times of occupancy and work, if there are justified grounds to suspect that the action level of 400 Bq/m^3 for radon concentration in inhaled air may be exceeded in these premises.
- The exposure of workers to cosmic radiation in aviation must be investigated if aviation is conducted at altitudes of more than 8000 metres.
- The radiation exposure of workers must be investigated if there are justified grounds to suspect that exposure arising from natural

sources of radiation other than radon or cosmic radiation may exceed the value 1 mSv per year.
- Regarding the utilization of natural resources, the radiation exposure of the population must be investigated if there are justified grounds to suspect that exposure arising from natural sources of radiation other than radon may exceed the value 0.1 mSv per year.
- The activity concentration of construction materials and household water must be measured and the radiation exposure arising from these sources must be investigated if there are justified grounds to suspect that any of the action levels given for them may be exceeded.

The results of these investigations shall be reported to STUK without delay. The responsible party is required to limit exposure to natural radiation by taking the measures that are warranted in view of the investigation and the circumstances. Workers' radiation exposure must be monitored and medical surveillance must be arranged for them if the radiation exposure cannot be reduced below the action level even after carrying out all reasonable measures to reduce the exposure.

STUK must be notified before any activities begin in mining operations, in underground excavation work lasting for longer than two months, and in any extensive utilization of natural resources containing uranium or thorium (special duty of notification). In addition, STUK shall be notified of all post-quarry equipping and building work.

When utilizing natural resources, the responsible party shall ensure that radioactive waste and releases pose no hazard to health or to the environment.

Provisions concerning the investigation of radiation exposure in practices liable to cause exposure to natural radiation are laid down in section 45 of the Radiation Act, and provisions concerning the limiting of exposures, protection of workers, and the special duty of notification are laid down in chapter 7 of the Radiation Decree. Guides ST 12.1–12.4 provide instructions for investigating, limiting and monitoring the exposure to natural radiation. Guides ST 12.2 and ST 12.3 present the action levels for activity concentrations of building materials and household water. Provisions are laid down in section 50 of the Radiation Act concerning the responsible party's duty of care regarding radioactive waste.

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Appendix

Definitions

Notified body
An impartial institution or body that has been accredited by a competent authority in a European Union Member State to assess compliance with requirements under the Directives in accordance with the New Approach, and whom this authority notifies to the European Commission and other Member States.

Dual-use item
Product, technology, service or other commodity which, in addition to its usual civil purposes or applications, can be used for the development or manufacture of weapons of mass destruction, or for that of missile systems intended for guiding such weapons to their intended targets, or a product, technology, service or other commodity which can generally promote military operative capability.

On-site surveillance
Regulatory control of a product during its use.

Quality assurance
All the planned, systematic measures taken in order to ensure that all methods, appliances and their use fulfil the specified quality requirements.

Natural background radiation
Cosmic radiation on the surface of the earth, radiation arising from natural radioactive substances occurring within the undisturbed earth's crust and from radionuclides naturally contained within the human body (e.g. ^{40}K).

Additional information: Natural background radiation does not fall within the scope of the Radiation Act.

Natural radiation
Ionizing radiation originating in outer space or in naturally occurring radioactive substances when they are not used as radiation sources.

Use of radiation
Use of radiation sources in medicine, industry, research and education, manufacture of and trade in radiation sources, and related activities such as possession, safekeeping, servicing, repair, installation, import, export, storage and transport of such sources, and rendering radioactive waste harmless.

Medical use of radiation
Activities in which radiation is applied to a human body or part of a body deliberately in order to examine or treat an illness or for the sake of medical examinations or other medical procedures.

Radiation practices
The use of radiation, operations or circumstances in which human exposoure to natural radiation causes or may cause a health hazard.

Additional information: If necessary, STUK shall decide in individual cases whether an operation is to be considered a radiation practice.

Party running a radiation practice (the responsible party)
The holder of a safety licence, or any business or sole trader, enterprise, corporation, foundation or institution which uses radiation sources in its operations or any employer or self-employed person engaged in radiation practices.

Additional information: When the responsible party not a physical person (such as a limited liability company, foundation or municipality), the party responsible for the operation as a whole is the party with the highest authority in the organization.

Management system
The system comprising the organizational structures, procedures, processes and resources required for managing and developing the practice.

Additional information: A management system can also be called a quality system.

Safety culture

The way in which individuals and the organization work to ensure safety.

Additional information: Safety culture includes a systematic way of working that promotes safety as well as leadership and management, values and attitudes that support such a culture.

Nuclear material

Special fissionable materials and source materials, such as uranium, thorium and plutonium, suited for obtaining nuclear energy.

Nuclear waste

a) Radioactive waste in the form of spent nuclear fuel or in some other form, generated in connection with or as result of the use of nuclear energy.
b) Materials, objects and structures which, having become radioactive in connection with or as a result of the use of nuclear energy and having been removed from use, require special measures because of the danger arising from their radioactivity..