**Translation from Finnish**

**Legally binding only in Finnish and Swedish**
**Ministry of Social Affairs and Health, Finland**

# Radiation Act
# (859/2018)

By decision of Parliament, the following is enacted:

## Chapter 1
## General provisions

### Section 1
### Purpose of the Act

The purpose of this Act is to protect human health against detriments caused by exposure to radiation. The Act also aims to prevent and reduce environmental and other detriments of radiation.

### Section 2
### Scope of the Act and limitations thereof

This Act applies to radiation practices, existing exposure situations and emergency exposure situations.

This Act applies to medical and occupational exposure to non-ionizing radiation only if so provided in this Act.

This Act does not apply to:

1) the use of electrical appliance emitting ionizing radiation and operating at a potential difference of less than five kilovolt;
2) background radiation caused by cosmic radiation at ground level;
3) background radiation arising from radioactive substances occurring naturally in the human body;
4) the exposure of persons other than the air crew of an aircraft to cosmic radiation in aviation;
5) public exposure to cosmic radiation during space flights.

**Section 3**
**Relation to other legislation**

The Nuclear Energy Act (990/1987) contains provisions on the application of this Act to the use of nuclear energy as referred to in the Nuclear Energy Act.

This Act applies to the assessment of exposure to natural radiation in mines and to establishing the requirements for radiation safety of mining. In other respects, the safety of mines and the regulatory control thereof are provided for in the Mining Act (621/2011).

The Occupational Health and Safety Act (738/2002) contains further provisions on the occupational health and safety and protection of workers.

The medical surveillance of radiation workers is also subject to the provisions of the Occupational Health Care Act (1383/2001).

In addition, the Health Protection Act (763/1994) contains provisions on exposure to radiation in dwellings and other premises used by people as well as on the radioactivity of household water.

Accounting for exposure to radiation in new construction and renovations is also provided for in the Land Use and Building Act (132/1999).

Provisions on environmental protection are also laid down in the Environmental Protection Act (527/2014). The waste management of waste other than radioactive waste is subject to what is provided in the Waste Act (646/2011).

The transport of radioactive substances is also subject to what is provided elsewhere in the law on the transport of dangerous materials.

**Section 4**
**Definitions**

For the purposes of this Act, the following terms have the following meanings:

1) **dose measurement service** means an operational unit or service provider carrying out individual monitoring of workers;
2) **dose limit** means the radiation dose arising from ionizing radiation which may not be exceeded during a specific period of time;

3) **dose constraint** means a constraint on the individual radiation dose of a person other than a patient arising from ionizing radiation during a specific period of time, used to optimize radiation protection in radiation practices;
4) **unsealed source** means a radiation source containing a radioactive substance the structure or properties of which do not prevent the radioactive substance from spreading into the environment;
5) **individual monitoring** means the measurement and determination of an individual dose arising form external and internal radiation;
6) **non-ionizing radiation** means ultraviolet radiation, visible light, infrared radiation, radio frequency radiation, low-frequency and static electric and magnetic fields, and ultrasound;
7) **ionizing radiation** means radiation that produces ions in a medium;
8) **high-activity sealed sourc***e* means a sealed source in which the activity of the contained radioactive substance is greater than the activity value laid down pursuant to section 75, subsection 5;
9) **natural radiation** means ionizing radiation originating from space or natural radioactive substances when they are not being used as radiation sources;
10) **medical exposure** means:
    a) the exposure of patients or asymptomatic individuals as part of their own examination, procedure or treatment intended to benefit their health as well as the exposure of their carers and comforters;
    b) the exposure of a research subject taking part in medical research as referred to in the Medical Research Act (488/1999);
11) **orphan source** means a radioactive source subject to a safety licence which is not in the possession of the undertaking entitled to its use or possession;
12) **potential exposure** means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;
13) **radon** means radon-222 isotope;
14) **radioactive substance** means a substance which decays by itself and emits ionizing radiation;
15) **radioactive waste** means radioactive substances or devices, goods and materials contaminated by radioactive substances for which there is no use or for which an owner cannot be found, and which shall be rendered harmless due to radioactivity;
16) **rendering radioactive waste harmless** means all the measures necessary to treat, isolate, emplace or restrict the use of waste in such a way that it will not result in detriments to human health or the environment;

17) **transfer** means importation or exportation from one Member State of the European Union to another;
18) **protective action** means an action taken to reduce people's exposure to radiation or the possibility thereof in an emergency exposure situation or existing exposure situation;
19) **high-powered laser equipment** means a laser product belonging to Class 3B or 4 as specified in the EN 60825-1 standard;
20) **radiation appliance** means a device which produces radiation electrically or in which a radioactive substance is used due to its radioactivity;
21) **radiation** means ionizing and non-ionizing radiation;
22) **radiation source** means a radiation appliance and a radioactive substance used because of its radioactivity;
23) **use of radiation** means:
    a) the use and manufacture of, trade in, installation, maintenance and remediation of radiation sources;
    b) the possession, safekeeping, import, export, transfer and storage of radiation sources and radioactive waste;
    c) the transport of radioactive substances and radioactive waste;
    d) rendering radioactive waste harmless;
24) **medical use of radiation** means the use of radiation giving rise to medical exposure;
25) **radiation practices** mean:
    a) the use of radiation;
    b) practices or circumstances in which exposure to natural radiation exceeds the reference level despite remedial measures;
    c) protective actions carried out in an existing exposure situation in which the occupational exposure exceeds the reference level;
26) **radiation work** means work carried out in radiation practices in which the radiation exposure to a worker can exceed a dose limit of the members of the public;
27) **radiation worker** means a worker engaged in radiation work;
28) **radiation safety deviation** means an event or situation that compromises or may compromise radiation safety and unplanned medical exposure;
29) **occupational physician familiar with radiation** means an occupational physician familiar with radiation as referred to in section 1 of the Act on the Recognition of Physicians as Physicians Undertaking Medical Surveillance of Workers belonging to Category A (170/2017);
30) **emergency helper** means a person other than an emergency worker who provides assistance in protective actions or participates in other work necessary for society in an emergency exposure situation;

31) **emergency exposure situation** means a situation in which the consequences of a radiation safety deviation require or may require special measures to limit or reduce the radiation exposure of persons participating in the emergency work or protective actions or the exposure of members of the public.
32) **reference level of exposure for an emergency exposure situation** means the level of radiation dose above which exposures are planned to be prevented for all persons in an emergency exposure situation;
33) **emergency worker** means a person with a pre-determined task in an emergency exposure situation who may be exposed to ionizing radiation in the course of the emergency work or protective actions in an emergency exposure situation;
34) **undertaking** means the holder of a safety licence as referred to in section 48, the holder of a licence as referred to in section 165, enterprise, corporation, foundation or institution as well as any employer or private entrepreneur conducting a radiation practice;
35) **import** means importation to Finland from outside of the European Union;
36) **occupational exposure** means exposure of workers incurred in the course of their work;
37) **outside worker** means a worker, apprentice or student who is not employed by an undertaking, but takes part in the undertaking's radiation practice;
38) **sealed source** means a radiation source containing a radioactive substance the structure or properties of which prevent the radioactive substance from spreading into the environment under planned conditions of use;
39) **existing exposure situation** means an exposure situation attributable to ionizing radiation which does not constitute an emergency exposure situation or radiation practices;
40) **export** means exportation from Finland to outside of the European Union;
41) **reference level means** the value of the radiation dose, exposure or activity concentration which would not be appropriate to be allowed to exceed in an existing exposure situation;
42) **members of the public** means any persons other than workers, outside workers, emergency workers, emergency helpers or persons subject to medical exposure;
43) **public exposure** means exposure of a person other than medical or occupational exposure.

## Chapter 2
## General principles of radiation protection

### Section 5
### Principle of justification

Radiation practices and protective actions are justified if the overall benefits achieved exceed the detriment caused (**principle of justification**).

**Section 6**
**Principle of optimization**

To optimize radiation protection, occupational exposure and public exposure to ionizing radiation shall be kept as low as is reasonably achievable, and medical exposure shall be limited to what is necessary to achieve the intended examination or treatment result and performance of the procedure (**principle of optimization**).

**Section 7**
**Principle of limitation**

In radiation practices the radiation dose of workers and members of the public may not exceed the dose limit (**principle of limitation**).

Section 161 contains provisions on the limitation of exposure to non-ionizing radiation.

**Section 8**
**Exemption for a worker's radiation dose exceeding the dose limit**

The Radiation and Nuclear Safety Authority (hereinafter referred to STUK) may grant an exemption to a radiation dose exceeding the dose limit for a designated worker in exceptional circumstances pursuant to the conditions and in compliance with the procedures provided in Article 52 of Council Directive 2013/59/Euratom, laying down the basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

**Section 9**
**Dose constraints and constraints for potential exposure**

Dose constraints and constraints for potential exposure are set, taking into account the characteristic features of the practice, in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection.

The dose constraints concerning occupational and public exposure are furthermore set in such a way that the combined amount of radiation doses arising from all practices subject to a safety licence is anticipated to remain below the dose limit.

**Section 10**
**Further provisions**

Further provisions on the assessment of the radiation practices' and protective actions' compliance with the principle of justification, and on the optimization of radiation protection and on the calculation and determination basis for radiation exposure are given by government decree for the purposes of implementing European Union legislation.

The dose limits of workers and members of the public are given by government decree for the purposes of implementing European Union legislation.

STUK issues more detailed regulations on the general dose constraints applicable to specific radiation practices and radiation sources and on constraints for potential exposure and their use as well as on demonstrating the implementation of the justification and the optimization of radiation protection.

**Section 11**
**Accounting for risks in regulatory control**

When supervising compliance with obligations pursuant to this Act, the regulatory authority considers:
1) the nature and extent of the exposure situation;
2) the risks associated with radiation exposure and radiation sources;
3) the impact that the regulatory control may have in the reduction of risks and the improvement of radiation safety.

The objective of regulatory measures is to keep radiation sources subject to a safety licence under regulatory control throughout the source's entire life cycle.

**Section 12**
**Safety culture and safety management**

The management of an organization responsible for compliance with the obligations laid down in this Act shall ensure that the organization's activities maintain and develop a good safety culture, and that persons working at all levels of the organization, in accordance with their tasks:
1) are aware of the radiation risks involved in the practice and the protective actions and understand their relevance for safety;
2) follow safe operating methods;

3) participate in the continuous development of safety.

In addition, the organization's management shall ensure that the safety management combines procedures, operating methods and leadership for the management of safety.

STUK issues more detailed regulations on the maintenance and promotion of a good safety culture and safety management based on international recommendations.

## Chapter 3
## Regulatory authorities and other regulatory duties

### Section 13
### Ministries

The Ministry of Social Affairs and Health has supreme authority and highest directing power in supervising compliance with this Act.

The Ministry of Economic Affairs and Employment has supreme authority and highest directing power in supervising compliance with this Act in matters concerning the use of nuclear energy as referred to in the Nuclear Energy Act.

### Section 14
### Radiation and Nuclear Safety Authority

STUK supervises compliance with this Act, unless otherwise provided elsewhere.

STUK acts as the supervisory facility referred to in Article 35 of the treaty establishing the European Atomic Energy Community and carries out the regulatory duties, liaising duties and reporting duties falling under the scope of the radiation safety supervision to be implemented pursuant to the treaty, unless otherwise provided elsewhere.

STUK acts as the competent authority referred to in Council Directive 2006/117/Euratom, on the supervision and control of shipments of radioactive waste and spent fuel, hereinafter referred to as the Waste Shipment Directive.

STUK prepares and implements an environmental radiation monitoring programme representing all members of the public to monitor the amounts of radioactive substances in the environment and the magnitude of the public exposure resulting from them.

STUK compiles and publishes nationwide assessments on exposures arising from medical use of radiation and their development.

STUK maintains the national metrological standards necessary to ensure the reliability of radiation measurements.

STUK acts as the competent authority referred to in the Act on the Recognition of Professional Qualifications (1384/2015) for the purposes of deciding on the qualifications of a radiation safety expert and a radiation safety officer. The Act on Health Care Professionals (559/1994) contains provisions on the recognition of the professional qualifications of health care professionals.

**Section 15**
**Municipality's health protection authority**

A municipality's health protection authority supervises compliance with the reference levels of the radioactivity in household water referred to in section 154 and the radon concentration in dwellings and other premises used by people referred to in section 158, as well as the investigation obligation referred to in section 146, subsection 1, with regard to household water, dwellings and other spaces with public access.

The supervision carried out by a municipality's health protection authority referred to in subsection 1 is subject to the Health Protection Act.

A municipality's health protection authority furthermore carries out the surveys of sunbeds in accordance with section 173 and 174.

**Section 16**
**Customs**

Finnish Customs supervises, for its part, the import and export of radiation sources and radioactive waste and the consumer goods referred to in section 69 as well as the transit of radioactive waste through Finland's territory. In addition, Customs supervises, for its part, international shipments of radiation sources and radioactive waste and international traffic.

Customs supervises, for its part, compliance with the import and export prohibition of products falling under the scope of the prohibition to use radioactive substances referred to in section 68.

The supervision carried out by Customs is subject to the Customs Act (304/2016).

**Section 17**
**Other authorities**

Compliance with the action level applicable to foodstuffs and animal feed and the prohibition to use radioactive substances referred to in section 68 is supervised by the authorities referred to in chapter 4 of the Food Act (23/2006) and the authorities referred to in chapter 4 of the Feed Act (86/2008) in terms of their respective branches of activity.

The Finnish Safety and Chemicals Agency (Tukes) supervises the prohibition referred to in section 68 in terms of cosmetics and toys.

The authorities referred to in this section comply with the relevant laws applicable to their respective branches of activity in their supervision.

**Section 18**
**Advisory Committee on Radiation Safety**

Appointed by the Government, the Advisory Committee on Radiation Safety operates in connection with STUK, participating in the preparation of matters related to radiation safety.

The Committee's composition, quorum, term and tasks are laid down by government decree.

**Chapter 4**
**Radiation and Nuclear Safety Authority's registers**

**Section 19**
**Registers**

For the purposes of carrying out the tasks specified in this Act, STUK maintains:

1) a workers' dose register, including information on occupational exposure as referred to in section 20, subsection 2;
2) a register of training organizations providing approved radiation safety officer training;
3) a register on radiation safety experts approved pursuant to section 39, subsections 1, 4 and 5, and on radiation safety officers approved pursuant to section 42, subsections 3 and 4;
4) a safety licence register containing information on radiation practices and the related undertakings, radiation safety officers, radiation sources and the facilities and places in which radiation practices are carried out;

5) a register on the radon concentrations in dwellings, other premises used by people and workplaces;
6) a register on the licences for the use of high-powered laser equipment referred to in section 165, including information on the operations, the undertaking, the person in charge and the equipment.

In addition, STUK's registers may contain data on the supervision targets falling under the scope of this Act necessary for the regulatory control and its development.

The processing of personal data furthermore complies with what is provided elsewhere in the law.

**Section 20**
**Workers' dose register**

STUK maintains a workers' dose register to ensure the health of radiation workers, emergency workers, emergency helpers and radiation safety.

In terms of individual monitoring, the register contains the identifying information of each worker and information on:
1) their tasks;
2) undertakings and the employers of outside workers;
3) the methods employed for determining individual radiation doses;
4) factors impacting radiation exposure;
5) the results of individual monitoring.

In addition, the register contains information on the methods and results of radiological surveilance insofar as they are employed in the determination of a worker's individual radiation dose.

Further provisions on the information to be stored in the dose register are given by government decree.

**Section 21**
**Disclosure and storage of information included in the workers' dose register**

The personal data included in the workers' dose register is subject to non-disclosure.

In addition to the provisions of the Act on the Publicity of the Activities of Public Authorities (621/1999), information on occupational exposure may be disclosed from the register notwithstanding the non-disclosure provisions to an occupational physician familiar with radiation, an undertaking and the employer of an outside worker, provided that access to said information is indispensable for the purposes of medical surveillance, the classification of radiation workers or the subsequent monitoring of a worker's exposure laid down in this Act.

The information in the dose register is stored for as long as the worker is engaged in radiation work and, subsequently, until the person in question attains or would have attained the age 75 years, although until 30 years have elapsed from the termination of the radiation work. STUK may store the aforementioned information for longer than this for research purposes related to ensuring radiation safety.

Further provisions on the information to be disclosed from the dose register are given by government decree.

## Chapter 5
## Undertaking's obligations

### Section 22
### Responsibility for radiation safety

The undertaking is responsible for the radiation safety of the practice. This responsibility cannot be transferred to another.

The obligations imposed on undertakings are not diminished by the appointment of a radiation safety officer or some other person in charge or by the use of experts in the operations.

### Section 23
### Criteria for organizing practices

The undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in this Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible. The undertaking shall implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.

The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice.

Further provisions on the requirements concerning the financial and human resources referred to in subsection 2 may be given by government decree.

STUK issues further technical regulations for the prevention of radiation safety incidents and the limitation of their consequences.

**Section 24**
**Justification assessment concerning new types of or existing practices**

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained.

STUK confirms the practice as justified either as part of granting the safety licence or separately.

Further provisions on the procedures to be followed in the justification assessment and the necessary explanations are given by government decree.

**Section 25**
**Establishing dose constraints and constraints for potential exposure**

The undertaking shall establish the dose constraints and constraints for potential exposure to be used in the radiation practice in advance, unless STUK has established the constraints to be used in the practice in general by virtue of section 10. Constraints on the occupational exposure of an outside worker shall be established in co-operation with the employer of the outside worker.

The constraints for potential exposure of workers and members of the public must be established beforehand for such radiation safety deviations referred to in section 26, subsection 1, paragraph 1, which may result in significant radiation exposure.

The information concerning the constraints referred to above in subsection 1 must be delivered to STUK either as part of the granting of the safety licence or separately.

**Section 26**

**Safety assessment concerning radiation practices**

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;
2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;
3) presents measures to ensure radiation safety and the optimization of radiation protection;
4) presents measures to prevent and prepare for identified radiation safety deviations;
5) presents the categorization of the radiation practice.

The safety assessment shall be prepared in writing and kept up to date.

STUK confirms the safety assessment either as part of granting the safety licence or separately.

STUK issues more detailed regulations on the content and preparation of the safety assessment.

**Section 27**

**Categorization of radiation practices**

In practices subject to a safety licence, the undertaking shall categorize the radiation practices based on the radiation exposure caused by the practices and the radiation sources used in the practices. The categorizations shall be presented in the safety assessment.

STUK confirms the categorizations concerning the radiation practice as part of granting the safety licence.

Further provisions on the categorizations concerning radiation practices are given by government decree.

**Section 28**

**Appointment and tasks of a radiation safety officer**

In practices subject to a safety licence, the undertaking shall appoint a radiation safety officer and, if necessary, deputy. The task of the radiation safety officer is to take care of the implementation of radiation protection as assistance to the operator.

The undertaking shall ensure that the radiation safety officer has sufficient authority to carry out the appointed tasks.

STUK issues more detailed regulations on the deputizing arrangements concerning radiation safety officers.

**Section 29**
**Management system of radiation practices**

In practices subject to a safety licence, the undertaking must have a written management system for the radiation practice.

The management system must include the name, birthdate and contact details of the radiation safety officer and, taking into account the nature and extent of the radiation practice and the conditions at the facility or place where the practice is carried out, sufficient information on:

1) the qualifications, training and induction of persons to verify compliance with the requirements provided in sections 33, 37 and 38;
2) tasks which are significant in terms of radiation safety and security arrangements, the division of responsibilities and flow of information;
3) measures to maintain and develop a good safety culture as referred to in section 12;
4) arrangements for the use of a radiation safety expert and a medical physics expert;
5) other administrative and organizational arrangements aiming to ensure radiation safety and to implement the security arrangements.

STUK issues more detailed regulations on the information to be presented in the management system.

**Section 30**
**Quality assurance**

The undertaking shall establish quality objectives for practices subject to a safety licence and define and implement systematic measures with which to ensure the realization of the quality objectives (**quality assurance**) and the fulfilment of the requirements laid down in the law.

The undertaking shall draw up a quality assurance programme for the implementation of quality assurance. The programme must detail the quality assurance measures, their performance, performance intervals, action limits, measures for when the action limits are exceeded, and responsibilities for taking measures pursuant to the programme. In addition, the progamme must

include instructions on performing the technical testing and checking of radiation sources and radiation appliances and other equipment as well as software and auxiliary devices with an impact on safety.

The results of the quality assurance must be documented. The quality assurance programme shall be reviewed on a regular basis and updated when necessary.

STUK issues more detailed regulations on quality assurance measures and their performance intervals and instructions as well as the documentation of results.

**Section 31**
**Duty to provide information and storage of information**

The undertaking shall ensure that the radiation safety instructions concerning workers' tasks and other documents pertaining to workers' radiation safety are available to them.

Documents pertaining to the safety of radiation practices and information equivalent to them must be stored for as long as it is necessary to ensure the radiation safety of the practices, unless otherwise provided in this Act.

Further provisions on the availability and storage of information pertaining to the safety of radiation practices are given by government decree.

**Section 32**
**Use of experts**

In practices subject to a safety licence, the undertaking shall use a radiation safety expert in the planning, implementation and monitoring of the radiation protection of workers and members of the public, excluding such radiation practices which do not cause occupational exposure, public exposure or potential exposure.

A medical physics expert shall furthermore be used in the planning, implementation and monitoring of the radiation protection of the person subject to exposure when the case concerns medical exposure or imaging as referred to in chapter 14, involving the use of medical equipment referred to in the Act on Medical Equipment and Supplies (629/2010).

The experts mentioned in subsections 1 and 2 shall be used in the appropriate manner, in proportion to the radiation exposure and potential exposure resulting from the practice.

Further provisions on the use of experts are given by government decree.

**Section 33**
**Training and induction of workers**

The undertaking shall ensure that all workers engaged in radiation practices or whose tasks otherwise require special expertise in radiation protection are in possession of the qualifications, radiation protection education and training and induction to their duties required by the practices and the tasks.

The undertaking shall keep a worker-specific record on the radiation protection training and induction for which it is responsible.

STUK issues more detailed regulations on the provision and content of the radiation protection training and induction referred to in subsection 1 when the training or induction is provided in the form of continuing training and supplementary training.

**Section 34**
**Supplementary training maintaining professional skills**

The undertaking shall ensure that workers engaged in radiation practices are provided with sufficient and regular supplementary training on radiation protection.

The undertaking shall keep a worker-specific record on the supplementary radiation protection training for which it is responsible.

Further provisions on regular supplementary radiation protection training and the content thereof are given by a decree of the Ministry of Social Affairs and Health.

**Section 35**
**Responsibility of a private entrepreneur and an undertaking's representative for their own radiation protection and education and training**

A private entrepreneur and the representative of an undertaking in a position other than a worker shall ensure, when engaging in radiation practices, their own radiation protection by complying with the provisions applicable to the protection, radiation protection education and training and induction as well as supplementary training of workers.

## Chapter 6
## Qualification requirements and radiation protection competence

### Section 36
### A radiation safety expert's fields of expertise

A radiation safety expert's fields of expertise are:

1) radiation practices in health care and veterinary medicine;
2) radiation practices in industry and research;
3) the use of nuclear energy.

### Section 37
### Qualifications of a radiation safety expert

A radiation safety expert shall have a master's degree as referred to in the Universities Act (558/2009) from a suitable field of mathematical-natural science or engineering. Radiation safety experts shall furthermore possess the radiation protection training required by the field of expertise and sufficient work experience in the field of expertise applicable to the task.

In health care and veterinary medicine radiation practices, the radiation safety expert shall also have the right to use the occupational title of a medical physicist by virtue of the Health Care Professionals Act.

In the road and rail transport of radioactive substances, the radiation safety expert shall furthermore have the safety adviser's certificate referred to in section 10 c, subsection 2 of the Act on the Transport of Dangerous Goods (719/1994) proving expertise in the mode of transport in question for the transport of radioactive materials.

Further provisions on the knowledge requirements and sufficient work experience required in terms of a radiation safety expert's field of expertise are given by a decree of the Ministry of Social Affairs and Health.

### Section 38
### Qualifications of a medical physics expert

A medical physics expert shall have the right to use the occupational title of a medical physicist pursuant to the Health Care Professionals Act.

**Section 39**

**Approval of radiation safety expert and recognition of qualifications**

STUK grants persons who meet the qualification criteria specified in section 37 a right, specific to a field of expertise, to act as a radiation safety expert upon application.

A medical physicist who meets the qualification criteria for a radiation safety expert in the field of health care and veterinary medicine radiation practices may act as a radiation safety expert in said field of expertise without the approval referred to in subsection 1.

If radiation protection training for radiation safety experts in some particular field of expertise is not available in Finland, STUK determines the criteria required by the tasks in terms of the radiation safety expert's education and training and work experience and recognizes the qualifications on a case-by-case basis.

In a case falling under the scope of the Act on the Recognition of Professional Qualifications, STUK decides on the right conferred by radiation safety expert qualifications obtained abroad to act as a radiation safety expert in Finland in the fields of radiation practices in industry and research and the use of nuclear energy pursuant to the Act in question.

What is provided in subsection 4 also applies to the temporary and occasional provision of services.

In cases other than those falling under the scope of the Act on the Recognition of Professional Qualifications, STUK may, for a special reason and on conditions determined by STUK, issue a person trained abroad a right to act as a radiation safety expert in Finland in the fields of radiation practices in industry and research and the use of nuclear energy.

**Section 40**

**Withdrawing the approval of a radiation safety expert and prohibition of practice**

STUK may withdraw a radiation safety expert's approval or prohibit them from acting as a radiation safety expert if the radiation safety expert fails to meet the qualification criteria specified in section 37 or if the advice provided to the undertaking by the radiation safety expert has been essentailly incorrect and the expert has failed to remedy the deficiencies within a reasonable period of time despite a request to do so.

**Section 41**

**Qualifications of a radiation safety officer**

In health care and veterinary medicine radiation practices, a radiation safety officer shall have a master's degree as referred to in the Universities Act from a suitable field of mathematical-natural science, engineering, medicine, dentistry or veterinary medicine, in accordance with the nature of the practices and the risks involved.

In addition to what is provided in subsection 1:

1) a person with a right to practice the profession of a radiographer in the capacity of a licenced professional as referred to in the Act on Health Care Professionals may act as a radiation safety officer in other native x-ray practices than computed tomography practices of a primary health care service provider as referred to in the Health Care Act (1326/2010) or a service provider referred to in Act on Private Health Care 152/1990). A radiographer may also act as a radiation safety officer in veterinary radiography practices;
2) a person with a suitable university degree may act as a radiation safety officer in the installation, maintenance and repair of radiation equipment and sources in health care.

A radiation safety officer shall have a master's degree as referred to in the Universities Act from a suitable field of mathematical-natural science or engineering:

1) on the use of an accelerator in research and isotope production;
2) on the use of unsealed sources, excluding low-risk practices;
3) on the use of nuclear energy.

In practices other than those referred to in subsection 1 and 2, the radiation safety officer shall possess training suitable for the practice.

A radiation safety officer shall furthermore possess the radiation protection training required by the practice type-specific field of expertise and sufficient work experience in a field suitable for the task.

However, a radiation safety expert may act as a radiation safety officer within their field of expertise without separate radiation protection training of a radiation safety officer.

In the road and rail transport of radioactive substances, however, a person who holds a safety adviser's certificate referred to in section 10 c, subsection 2 of the Act on the Transport of

Dangerous Goods proving expertise in the mode of transport in question for the transport of radioactive materials can act as a radiation safety officer.

Further provisions on the practice type-specific fields of expertise and the knowledge requirements and sufficient work experience required from a radiation safety officer are given by a decree of the Ministry of Social Affairs and Health.

**Section 42**
**Approval of radiation safety officer and recognition of qualifications**

The undertaking shall ensure a radiation safety officer's qualifications before they start working in the position with certificates that prove their qualifications.

If the radiation protection training required by a radiation safety officer's practice type-specific field of expertise is not available in Finland, STUK determines the criteria required by the tasks in terms of the education and training and work experience.

In a case falling under the scope of the Act on the Recognition of Professional Qualifications, STUK decides on the right conferred by radiation safety officer qualifications obtained abroad to act as a radiation safety officer in Finland pursuant to the Act in question.

What is provided in subsection 3 also applies to the temporary and occasional provision of services.

In cases other than those falling under the scope of the Act on the Recognition of Professional Qualifications, STUK may, for a special reason and on conditions determined by STUK, issue a person trained abroad a right to act as a radiation safety officer in Finland.

**Section 43**
**Certificate provided for radiation protection training**

The training organization shall provide the person who has passed the training for a radiation safety expert or radiation safety officer with a certificate.

Further provisions on the content of the certificate provided by training organizations are given by a decree of the Ministry of Social Affairs and Health.

**Section 44**

**Language proficiency and other practical requirements for experts and radiation safety officers**

The undertaking shall ensure that radiation safety experts, medical physics experts and radiation safety officers possess the language skills required by their tasks. However, in health care radiation practices, the language skills requirement concerning a health care professional and the employer's responsibility for ensuring adequate language skills is subject to section 18a of the Health Care Professionals Act.

In addition, experts and radiation safety officers shall be in possession of any other practical prequisites required for carrying out their tasks.

Further provisions on the practical prequisites concerning the carrying out the tasks referred to in subsection 2 are given by a decree of the Ministry of Social Affairs and Health.

**Section 45**

**Statement on radiation protection training provided by an university**

At the request of a university organizing training, STUK issues a statement on the radiation protection training of a radiation safety expert and radiation safety officer or any material changes thereto to ensure that the training provides the necessary knowledge and the radiation protection skills required for the task.

**Section 46**

**Approval of other radiation protection training**

STUK approves, on the basis of an application, the radiation protection training for a radiation safety officer organized by a training organization other than a university.

The approval of such radiation protection training requires

1) the training to fulfil the requirements laid down pursuant to section 41, subsection 7;
2) the training organization to possess sufficient human resources with adequate expertise to provide such training;
3) the training organization to have other practical prerequisites for the provision of the training.

The approval for the training is given for a fixed period, a maximum of five years at a time, and it may be withdrawn if the prerequisites for the approval cease to exist or if material deficiencies are

observed in the provision of the training, and such deficiencies are not remedied within a prescribed period of time despite a request to do so.

**Section 47**
**Radiation protection skills in medical use of radiation**

The undertaking is responsible for ensuring that workers engaged in medical use of radiation are in possession of the applicable qualifications, including radiation protection skills.

Further provisions on the applicable qualifications and competence criteria for radiation protection are given by a decree of the Ministry of Social Affairs and Health.

## Chapter 7
## Licensing system

**Section 48**
**Safety licence and its granting**

The use of radiation requires a licence (**safety licence**), unless otherwise provided in this Act. Other radiation practices require a safety licence if separately laid down in the law.

STUK grants a safety licence upon application until further notice or, for a special reason, for a fixed period of time. The licence may also be granted separately for different stages of the practice. The licence may include conditions necessary for ensuring safety.

A safety licence is granted provided that:
1) the radiation practice complies with the principles of justification, optimization and limitation;
2) a safety assessment pursuant to section 26 has been drawn up for the radiation practice;
3) the practice can be carried out safely;
4) the undertaking has the right to engage in a trade in Finland.

**Section 49**
**Practices exempt from a safety licence**

A safety licence is not required for:
1) the use of non-ionizing radiation;

2) in practices other than those referred to in chapters 13 and 14, the use of such a radiation source compliant with the justification principle in which the exposure is insignificant due to the amount of the radioactive substance or the safety features of the radiation appliance;
3) a practice in which the radioactive substance derives from a permitted discharge of a radioactive substance and from radioactive waste or a radioactive material which has been reused, recycled, utilized or disposed of in a manner specified under section 84;
4) the transfer of a radiation source;
5) the export of a radiation source which does not contain a radioactive substance;
6) the transport of radioactive substances, excluding the road or rail transport of high-activity sealed sources;
7) the holding of health care or veterinary medicine X-ray equipment, provided that the holder has a safety licence for the use of equivalent appliance in the field of health care or veterinary medicine or for the installation, maintenance or remediation of such appliance;
8) such remediation or maintenance work of a radiation appliance which does not concern the appliance's parts producing radiation or shielding from radiation or any equivalent parts in a way that impacts safety;
9) other practices which meet the criteria for an exemption from a safety licence pursuant to section 50, subsection 1.

Further provisions on practices exempt from a safety licence as referred to in subsection 1, paragraph 9 are given by government decree.

STUK issues more detailed regulations for the implementation of European Union legislation in terms of the insignificant amount of radioactivity (exemption level) and an appliance's safety features as referred to in subsection 1, paragraph 2.

**Section 50**
**Exemption from safety licence under a decision by the Radiation and Nuclear Safety Authority**

STUK may exempt radiation practices other than those referred to chapter 13 or 14 from a safety licence, if exemption is the most appropriate alternative and:
1) the radiation exposure and potential exposure caused the practice is insignificant enough not cause a health detriment;
2) the practice has been demonstrated to be justified;
3) the practice is inherently safe.

The decision may include conditions necessary for ensuring safety.

The decision may be withdrawn if the prerequisites for exemption are not met or if the conditions for exemption have not been complied with and the deficiencies are not remedied within a prescribed period of time despite a request to do so.

Further provisions on the prerequisites for exemption from a safety licence are given by government decree for the purpose of implementing European Union legislation.

**Section 51**
**Application for safety licence**

A safety licence application shall include:

1) information of the applicant;
2) the purpose of the practice and information on the facility or place where the practice is carried out;
3) the management system for the radiation practice;
4) the certificates verifying the qualifications of the radiation safety expert and radiation safety officer;
5) the safety assessment concerning the radiation practice;
6) a plan on the security arrangements;
7) information on the radiation sources, the related appliances and shieldings and on the maintenance arrangements concerning the sources and appliances;
8) the arrangements for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice;
9) the quality assurance procedures complied with in the practice;
10) information other than what is specified in paragraphs 1 through 9 relevant to the safety of the practice.

Further provisions on the information to be provided in an application for a safety licence are given by government decree.

**Section 52**
**Amending a safety licence**

STUK amends the conditions for a safety licence subsequent to its granting if material changes in the circumstances and special reasons due to them require the conditions to be changed for the sake of ensuring safety.

A substantial change to a practice requires prior amendment of the safety licence. In addition, STUK must be notified of any other changes to a practice subject to a safety licence.

Further provisions on changes to practices subject to an amendment of the safety licence or a notification are given by government decree.

**Section 53**
**Validity of a safety licence**

STUK withdraws a safety licence when the radiation practice specified in the licence has been discontinued and the licensee has demonstrated in an acceptable manner that it has relinquished or rendered harmless the radiation sources specified in the licence and the radioactive waste generated in the practice and the waste referred to in section 78, subsection 3.

STUK may withdraw the safety licence if the prerequisites for granting it are not met or if the licensee repeatedly or essentially breaches the conditions for the licence or the provisions and regulations provided in this Act or pursuant to it, and fails to remedy the deficiencies or its conduct despite a request to do so.

A safety licence expires when the licensee dies or loses its legal capacity or if the licensee loses its right to practice its profession. The radiation safety officer must immediately inform STUK of the matter.

**Section 54**
**Furnishing security**

The undertaking shall furnish a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures if the licence is granted for:

1) the use, manufacture, trade, possession, safekeeping, import, export, transfer or storage of a high-activity sealed source;
2) the use, manufacture, trade, possession, safekeeping, import, export, transfer or storage of a radioactive substance or a radiation source containing such a substance, provided that the

combined nuclide-specific activity of the radioactive substance being held at any one time is greater than the activity of an equivalent high-activity sealed source;

3) the maintenance, remediation or rendering harmless of radiation appliances containing sealed sources, provided that sealed sources are being removed from their fixed container and the combined nuclide-specific activity of the sealed sources to be removed annually is greater than the activity of an equivalent high-activity sealed source;
4) a practice which generates or may generate radioactive waste, or the waste specified in section 78, subsection 3, provided that the costs arising from rendering it harmless are substantial.

However, a security need not be furnished if the practice referred to in sub-section 1 concerns a radioactive substance with a shorter half-life than 150 days.

The practice may not be commenced before the security has been furnished.

The State, a municipality or a joint municipal authority is not required to furnish a security.

**Section 55**
**Basis for imposing a security**

STUK decides on the furnishing of a security. The security is furnished separately for each high-activity sealed source in a practice specified in section 54, subsection 1, paragraph 1, and separately for each radionuclide in a practice specified in paragraph 2 or 3. The security decision may be amended if the circumstances change.

The security consists of, for a practice referred to in section 54, paragraph 1–3, a fixed basic charge and a surcharge determined on the basis of a radionuclide and activity, and for a practice referred to in paragraph 4, the case-specifically estimated overall costs.

The security may be furnished in the form of a surety, insurance or a pledged deposit. The party providing the security must be a credit, insurance or other professional financial institution with a registered office in a state located within the European Economic Area.

Further provisions on the amount of the security and its verification are given by government decree.

**Chapter 8**
**A product's radiation safety**

**Section 56**
**Demonstrating a product's radiation safety**

The undertaking which manufactures, imports, brings to the market, offers, keeps for sale, sells or otherwise hands over radiation sources or accessories and other products related to the safety of a radiation practice (**product**) shall be able to demonstrate that the product is safe.

**Section 57**
**The product's market surveillance**

Regarding public exposure, the market surveillance of products generating ionizing or non-ionizing radiation or containing radioactive substances is subject, unless otherwise provided elsewhere, to the Act on the Market Surveillance of Certain Products (1137/2016). The economic operator specified in the Act in question is the party subject to the demonstrating obligation referred to in section 56 of this Act.

If a product referred to in section 56 may cause a significant detriment to health, the regulatory authority may also prohibit a legal or natural person other than the undertaking referred to in section 56 from manufacturing, importing, exporting, transferring, placing on the market, offering, keeping for sale, selling or otherwise handing over the product.

Compliance with requirements in terms of health care equipment is provided for separately. Health care equipment generating non-ionizing radiation is furthermore subject to the requirements specified in chapter 8 and section 161 of this Act insofar as they cause public exposure.

The compliance of technical equipment used at work and construction products and the surveillance thereof is laid down separately.

**Section 58**
**Assessment of a product's radiation safety**

The regulatory authority assesses the radiation safety of a product referred to in section 56 pursuant to the applicable product safety legislation or according to standards referred to in the Official Journal of the European Union.

In addition, the assessment of a product's radiation safety must pay attention to the following:

1) international or national standards pertaining to product safety other than those mentioned in subsection 1;

2) any recommendations of the European Commission which contain instructions concerning the assessment of radiation safety;
3) the guidance and recommendations issued by regulatory authorities;
4) the codes of conduct concerning radiation safety;
5) current information and technology.

If a product cannot be assessed in the manner referred to in subsection 1, the regulatory authority may assess the product's radiation safety according to what is provided in subsection 2. Furthermore, even if a product accords with the bases used for the assessment of a product's safety specified in subsection 1 and 2, the regulatory authority may pursue an action pursuant to chapter 3 of the Act on the Market Surveillance of Certain Products if the product nevertheless poses a risk to health.

## Chapter 9
## Radiation measurements

### Section 59
### The reliability of radiation measurements

The measurements carried out for assessing the radiation exposure and ensuring safety referred to in this Act shall be performed with a method suitable for the purpose and proved reliable. The results of the measurements must be metrologically traceable to the International System of Units. The radiation meter or measuring instruments shall be appropriately calibrated.

STUK issues more detailed regulations on verifying the reliability of measurements and on the radiation meters' and measuring equipments' calibration, accuracy, use and suitability for a particular purpose.

### Section 60
### Approval of a dose measurement service

STUK approves a dose measurement service until further notice or, for a special reason, for a fixed period of time.

The approval requires:
1) the use of a documented dose measurement system compliant with the requirements laid down in section 59;
2) the sufficient competence of the personnel;

3) an accredited quality system applicable to steering the practice, including the operation of the dose measurement service and the methods employed by it;
4) the necessary technical means for delivering the dose data to the workers' dose register.

In lieu of accreditation, STUK may accept a quality system pursuant to the standard concerning the competence of European testing and calibration laboratories, provided that there is an adequate, justified reason for the lack of accreditation related to the operation of the dose measurement service.

Further provisions on the dose measurement system and the information to be provided in an application are given by government decree.

**Section 61**
**Competence of the dose measurement service's personnel and maintenance of professional skills**

The personnel of the dose measurement service participating in the determination of the radiation dose shall possess education and training applicable to their duties. The dose measurement service must induct its personnel for such tasks.

The dose measurement service shall keep a worker-specific record of the training and induction of the personnel referred to in subsection 1.

**Section 62**
**Quality assurance of dose measurement service**

The dose measurement service's quality assurance, quality assurance programme and documentation and storage of the results of quality assurance is subject to what is provided in section 30 and 31 in terms of practices subject to a safety licence.

**Section 63**
**Regulatory control of dose measurement service**

The regulatory control and charges of a dose measurement service is subject to what is provided in chapter 20 in terms of undertakings.

A dose measurement service shall participate in performance testing concerning the dose measurement system upon the request of STUK.

STUK issues more detailed regulations on the performance testing of a dose measurement system.

**Section 64**
**Approval of other radiation measurements**

Measurements of ionizing radiation carried out to determine occupational, public or medical exposure and ensure safety in radiation practices or an existing exposure situation shall have the approval of STUK. However, radiation measurements which STUK supervises as part of a dose measurement service's practice or a practice pursuant to a safety licence do not require separate approval.

The prerequisite for approval is the fulfilment of the requirements laid down in section 59, subsection 1.

The approval is given for a fixed period of time, for a maximum of five years at a time.

Further provisions on the information to be provided in an application are given by government decree.

**Section 65**
**Amending and withdrawing the approval**

STUK amends the conditions for the approval of a dose measurement service and the radiation measurements referred to in section 64 subsequent to the approval if reasons necessary in terms of the reliability of radiation measurements so require.

STUK withdraws the approval if the practice specified in the approval has been discontinued.

STUK may withdraw the approval if the conditions for the approval are not met, if there are material deficiencies in the measurements or if the practice otherwise fails to meet the requirements laid down in this Act and the deficiencies are not remedied within a prescribed period of time despite a request to do so.

**Chapter 10**
**Radiation sources**

**Section 66**
**In-service radiation safety**

The undertaking shall ensure that a radiation source, the facility and place where it is used and stored, and the equipment and devices related to it are such that the radiation source can be used safely.

The undertaking shall ensure that the use and storage facility or place of a radiation source subject to a safety licence is marked with a sign indicating radiation hazard. The radiation source shall be marked with a sign warning of a radiation hazard if this is technically possible. In addition, the source shield or source container or storage shield of a radiation source containing a radioactive substance must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard.

What is provided in subsection 2 also applies to other radiation sources the safe use of which requires this.

STUK issues more detailed regulations of a technical nature on the radiation safety during use referred to in subsection 1, the markings referred to in subsection 2 and 3, appliances' in-service acceptability requirements and other requirements pertaining to the use of the appliances.

**Section 67**
**Security arrangements**

The undertaking shall protect radiation sources subject to a safety licence against illegal operation or loss or otherwise falling into the hands of third parties at their use and storage facilities. These security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety.

The security arrangements include, depending on the risks involved in the radiation sources:
1) drawing up a plan on the security arrangements and keeping the plan up to date;
2) protecting the radiation sources with structural barriers and the presence of personnel;
3) the regular verification of the location of the radiation source;
4) the use of access control and other technical surveillance measures;
5) restricting access to materials concerning radiation sources and security arrangements.

STUK issues more detailed regulations on the security arrangements and their determination in accordance with the radiation sources.

**Section 68**
**Prohibitions of use**

A radioactive substance may not be used deliberately in:

1) foodstuffs as referred to in the Food Act;
2) animal feed as referred to in the Feed Act;
3) cosmetic products as referred to in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products;
4) jewellery and other equivalent personal accessories;
5) toys as referred to in the Toy Safety Act (1154/2011);
6) in the tracer tests carried out in water supply systems the water of which is used as household water.

Products falling under the scope of the aforementioned prohibition specified in subsection 1 may not be imported, exported or transferred.

What is provided with regard to radioactive substances in subsection 1 and 2 also applies to practices in which the increase of radioactivity derives from the activation of consumer goods or the material used in manufacture of the consumer goods.

**Section 69**
**Manufacture, import, export and transfer of consumer goods**

The deliberate mixing or adding of a radioactive substance to consumer goods other than those specified in section 68 and the import, export and transfer of such consumer goods to Finland is subject to a safety licence.

STUK notifies the competent authorities of other Member States of the European Union of the reception of an application pursuant to subsection 1. Said authorities will also be informed of the decision made and the basis for the decision, should the Member State in question make a request to this end.

What is provided with regard to radioactive substances in subsection 1 also applies to practices in which the increase of radioactivity derives from the activation of consumer goods or the material used in the manufacture of the consumer goods.

**Section 70**
**Identification of a sealed source**

The manufacturer shall identify a sealed source the use of which is subject to a safety licence. The unique identifier must be marked with as permanent a method as possible on the shield of the sealed source. The unique identifier must furthermore be marked on the sealed source, if this is technically possible. If the marking of a sealed source is not technically possible, the identifying details must be indicated in the documents accompanying the sealed source.

The importer of the sealed source or the party responsible for its transfer to Finland must ensure that the source has been identified as required in subsection 1.

An unidentified sealed source may not be used in, imported or transferred to Finland.

STUK issues more detailed regulations on the information pertaining to the identification of a source to be delivered with the sealed source.

**Section 71**
**Record-keeping and notification obligation**

In practices subject to a safety licence, the undertaking shall keep a record on the radiation sources related to the safety licence. The records must indicate the radiation sources held by the undertaking as well as the reception and handing over of the sources and their removal from the licence. A radiation source may be removed from the records five years after its handing over or removal from the licence. The records shall be kept up to date.

The holder of a safety licence conferring the right to manufacture, safekeep, trade, export or import radiation sources shall deliver data on the radiation sources received, handed over and in its possession to STUK once every calendar year.

In addition, the holder of a safety licence conferring the right to use or hold high-activity sealed sources shall deliver data on the high-activity sealed sources in its possession to STUK once every calendar year.

STUK issues more detailed regulations on the record keeping referred to in subsection 1 and on the information to be provided, referred to in subsection 2.

**Section 72**
**Obligations of the transferor, recipient and transporter**

A radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence.

The recipient shall provide the transferor with a certificate on the reception of the radiation source referred to in subsection 1.

The party which transports the radiation source shall notify STUK of the transportation subject to a safety licence prior to the start of the transport or the radiation source's arrival to Finland.

STUK issues more detailed regulations on the content of the notification referred to in subsection 3.

**Section 73**
**Obligation to provide information**

When handing over a radiation source generating ionizing radiation, the manufacturer or importer shall provide the recipient with detailed information on the structure of the source and its properties having an impact on safety together with the source. A sealed source is also subject to a certificate demonstrating compliance with regulations.

The undertaking handing over a radiation source generating ionizing radiation to another is obligated to provide the recipient, in connection to the handing over, with any information and certificate and other information relevant to radiation safety in its possession, received from the manufacturer or importer as referred to in subsection 1.

STUK issues more detailed regulations on the content of the information referred to in subsection 1 and 2 and their provision.

**Section 74**
**Installation, maintenance and remediation**

The undertaking shall ensure that the party installing, maintaining and remediating a radiation source subject to a safety licence possesses the safety licence required by the work.

For its part, the party performing the work must take care on the working environment's radiation safety during the work and, once the work is completed, ensure that the appliance functions properly.

STUK issues more detailed regulations on ensuring radiation safety during and at the end of installation, maintenance and remediation work.

**Section 75**
**Sealed sources**

The radioactive substance used in a sealed source shall be selected in such a way that the substance's half-life is no greater than is necessary in terms of the practice and the source's purpose of use.

When assessing whether the use of a high-activity sealed source is justified, the possibility of using an appliance generating radiation electrically instead of a high-activity sealed source or some other alternative technology shall be considered.

The undertaking shall ensure that the sealed source remains tight. The test necessary to ensure this must be presented in the quality assurance programme referred to in section 30, subsection 2.

The sealed source must be removed from use in the manner specified in section 83, subsection 2 no later than 40 years after demonstrating its conformity with the requirements.

STUK issues more detailed regulations for the implementation of European Union legislation in terms of the activity values of a high-activity sealed source and the tests to be carried out as specified in subsection 3.

**Section 76**
**Import and export of sealed sources**

Only a sealed source whose manufacturer has undertaken in writing to receive the source once its use has discontinued and containing a radioactive substance whose half-life is such that the appliance can be safely aged may be imported or transferred to Finland.

A high-activity sealed source may only be exported to a state with adequate technical, legislative and administrative capabilities to manage the safety of the source and its use.

The undertaking shall ensure that the required departure and arrival notifications are prepared of sealed sources for the competent authorities of the country of origin and country of destination.

Further provisions on the procedures related to the import and export of sealed sources are given by government decree.

**Section 77**
**Customs declaration**

When importing and exporting radiation sources or the consumer goods referred to in section 69, their quality and quantity as well as whether they are a subject to a safety licence must be clearly stated in the customs declaration or an appended statement. In addition, the customs declaration must include the number of the safety licence authorizing the import or export.

## Chapter 11
## Radioactive waste

**Section 78**
**General principles**

Radiation practices shall be organized in such a way that they generate as little radioactive waste as practically possible without compromising the practice's accordance with the principle of justification, optimization and limitation.

Radioactive waste generated in radiation practices may not be deliberately diluted for the purpose of releasing it from regulatory control.

What is laid down in terms of radioactive waste also applies, in parts regarding the radiation protection of members of the public and workers, to waste which is not radioactive waste as referred to in this Act, but in whose waste management radiation safety must be considered.

Further provisions on the basis for establishing whether a waste is radioactive waste or the kind of waste referred to in subsection 3 are given by government degree.

STUK issues more detailed regulations of a technical nature on limiting occupational and public exposure in the waste management of the waste referred to in subsection 3.

**Section 79**
**Undertaking's duty of care**

The undertaking shall, during the radiation practice and when discontinuing it, ensure that the radioactive waste will not be detrimental to health or the environment.

The undertaking shall ensure that the radioactive waste generated in its practice is rendered harmless.

**Section 80**
**Subsidiary duty of care**

To the extent that an undertaking does not within a reasonable period of time meet or cannot be expected to meet its duty of care specified in section 79, the State ensures that the radioactive waste is rendered harmless.

The State also carries out the measures referred to in subsection 1 if the origin of the waste is unknown or if the undertaking responsible for the duty of care is not found.

In the event that there is no undertaking whose line of business includes rendering radioactive waste harmless or if an undertaking cannot return a disused radiation source to the manufacturer or supplier or transfer it to another undertaking, the State ensures that the radioactive waste is rendered harmless.

The undertaking or another party involved in the production or management of the radioactive substance or waste must compensate the State for the costs incurred from rendering the waste harmless as referred to in subsection 1 and 3.

Section 193 contains provisions on the charging of such costs. In a situation referred to above in subsection 1, the costs are compensated for primarily with the security referred to in section 54, subsection 1.

Further provisions on the State's duty of care referred to in subsection 1–3 are given by government decree.

**Section 81**
**Certain provisions' application on radioactive waste**

Any radioactive waste the holding of which requires a safety licence is subject to what is provided:
1) in section 66 on the in- in-service safety of radiation sources;
2) in section 67 on security arrangements;

3) in section 71 on the record-keeping and notification obligations regarding radiation sources;
4) in section 72 on the obligations of the transferor, recipient and transporter;
5) in section 77 on customs declarations.

**Section 82**
**Import, export, transfer and transit**

Radioactive waste may only be exported to a state with adequate technical, legislative and administrative capabilities to manage radioactive waste.

A radiation source manufactured outside Finland may not be imported or transferred to Finland as radioactive waste.

The import, export, transfer and transit of radioactive waste through Finland must be executed according to the procedures laid down in the Waste Shipment Directive.

In addition to what is provided in Article 17 of the Waste Shipment Directive, STUK publishes the standard document referred to in the article in question in its collection of regulations.

**Section 83**
**Decommissioning of radiation sources and facilities**

The undertaking must be prepared to manage used radiation sources and radioactive waste generated by the practice as well as to clean the facilities used in the practice from radioactive substances.

The undertaking shall remove any radiation sources containing radioactive substance subject to a safety licence which have become obsolete by returning them to the manufacturer or supplier or by transferring them to another undertaking with the appropriate safety licence. A source may nevertheless be stored without returning or transferring it, provided that the source's half-life and activity is such that it can be aged safely.

The undertaking must clean any areas, facilities and their structures contaminated by radioactive substances in such a way that the remaining amount of radioactive substances does not exceed the clearance level referred to in section 85, subsection 2.

The cleaning requires a safety licence if the amount of radioactive substances prior to the cleaning is greater than the clearance level.

If the amount of radioactive substances cannot be made lower than the clearance level with reasonable measures, the undertaking must present a plan on the measures concerning the area, facilities or structures to STUK.

The undertaking may not delay the performance of the measures referred to in subsection 2 and 3 without justification.

STUK issues more detailed regulations on decommissioning of radiation sources and facilities and on their cleaning.

**Section 84**
**Prequisites for reuse, recycling, utilization and disposal**

Notwithstanding its radioactivity, waste and other material deriving from radiation practices may be reused, recycled, utilized and disposed of in accordance with the Waste Act, provided that the amount of radioactive substance it contains does not exceed the clearance level referred to in section 85, subsection 2.

If the amount of the radioactive substance is greater than the clearance level, the practice referred to in subsection 1 requires the approval of STUK.

The prequisites for the approval and its withdrawal are subject to what is provided in section 50 regarding the prequisites for an exemption from a safety licence and the withdrawal of such an exemption.

**Section 85**
**Clearance levels**

Clearance levels are set in a way that keeps occupational and public exposure low. Clearance levels may pertain to a particular type of or individual area, facility or structure referred to in section 83 or a practice referred to in section 84.

STUK issues more detailed regulations on clearance levels for the implementation of European Union legislation.

**Section 86**
**Orphan sources**

Practices which repeatedly handle, or store orphan sources are subject to a safety licence.

The undertaking shall immediately notify STUK if it suspects or knows of the finding or melting of an orphan source or any significant contamination caused by such an orphan source.

As a consequence of an event referred to in subsection 2, the contaminated products, waste and other materials are subject to section 84.

**Section 87**
**National waste management policy and programme**

The Ministry of Social Affairs and Health draws up, in cooperation with STUK, a national programme for the waste management of radioactive waste outlining the general goals and principles of the waste management of radioactive waste as well as the amounts and locations of the waste, and an estimate of the costs and schedules of the waste management.

When the programme is being drawn up, the public must be reserved a chance to express their opinion. The Ministry of Social Affairs and Health announces the commencement of the programme's preparation. The programme must be kept up to date.

Further provisions on the programme are given by government decree.

**Chapter 12**
**Occupational exposure**

**Section 88**
**Organizing workers' radiation protection**

The radiation protection of radiation workers must be organized as provided in this chapter. The protection of other workers is subject to what is laid down in this Act regarding the radiation protection of members of the public, unless otherwise provided elsewhere.

The undertaking and the employer of an outside worker are responsible for the radiation protection of their workers engaged in radiation practices in accordance with the division of responsibilities provided in sections 102–104. Outside workers must enjoy a level of protection equal to the undertaking's own workers.

STUK issues more detailed technical regulations on the protection of a worker in radiation practices.

**Section 89**
**Investigation obligation**

In practices requiring a safety licence, the radiation exposure of workers and means to reduce it must be assessed before starting the work. The assessment must be adjusted if change affecting occupational exposure takes place in the practice.

The worker's previous occupational exposure must also be investigated prior to the commencement of radiation work.

STUK issues more detailed regulations on the investigation and assessment of radiation exposure.

**Section 90**
**Classification of radiation workers**

Radiation workers shall be classified into category A or B. The basis for this classification is an estimate on the exposure and potential exposure caused by the work.

A worker may only be classified in category A if an occupational physician familiar with radiation has deemed the worker to be fit for this category based on the state of the worker's health.

The classification must be carried out prior to the commencement of the radiation work and reviewed regularly based on radiological and medical surveillance.

Further provisions on the classification of radiation workers are given by government decree.

**Section 91**
**Controlled areas and supervised areas**

The controlled areas and supervised areas of working areas must be identified and differentiated. The basis for the differentiation is an assessment on the radiation exposure and potential exposure in the area.

A controlled area must be delineated. Access to the area must be restricted to the individuals who have been appropriately instructed. Access to as well as working in and visits to the controlled

area must be controlled in accordance with the written instructions. Special arrangements shall furthermore be put in place for the purpose of protecting individuals from ionizing radiation and preventing the spread of radioactive contamination.

Further provisions on the need and grounds for identifying and differentiating between areas and on the requirements concerning controlled and supervised areas are given by government decree for the purpose of implementing European Union legislation.

**Section 92**
**Radiological surveillance and individual monitoring**

Radiological surveillance of controlled areas and supervised areas must be conducted on a regular basis.

The surveillance must allow for:
1) establishing that workers have been correctly classified;
2) determining the radiation exposure to the workers;
3) an immediate observation of unforeseen deviations in factors with an impact on occupational exposure.

Individual monitoring shall furthermore be arranged for radiation workers belonging in category A. The individual monitoring shall be based on individual measurements performed by a dose measurement service. The measurements must be performed in one-month periods or for a working period, if the duration of the work is shorter than the one-month measurement period.

The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure.

Further provisions on the recording of the results of radiological surveillance and individual monitoring are given by government decree.

STUK issues more detailed regulations of a technical nature on the organization of the radiological surveillance and individual monitoring at the workplace and on the determination of an individual radiation dose on the basis of the radiological surveillance.

**Section 93**
**Reporting the monitoring results**

Workers shall be provided with the results of the individual monitoring concerning them without delay.

Upon request, workers shall also be provided with the results of the radiological surveillance used to determine their individual radiation doses.

**Section 94**
**Reporting abnormal radiation exposure**

An established or suspected radiation dose exceeding the dose limit must immediately be reported to:

1) the worker in question;
2) the occupational physician familiar with radiation who performs the medical surveillance of a category A radiation worker;
3) STUK.

The worker in question must also be immediately informed of any exposure exceeding the dose constraint.

**Section 95**
**Medical surveillance**

A category A radiation worker must be provided with medical surveillance, which includes a pre-employment examination by an occupational physician familiar with radiation and a follow-up examination at least every three years.

In the interim years of the period of time referred to in subsection 1, it shall be ensured that the worker informs the occupational physician familiar with radiation whether there have been any such material changes in the worker's state of health subsequent to the most recent medical examination which may have an effect on their capability to carry out radiation work.

In the event that there is a material change in the worker's state of health, the worker must undergo an extra medical examination performed by the occupation physician familiar with radiation.

The occupational physician familiar with radiation must be provided with information on the workplace conditions relevant for the medical surveillance, the results of the worker's individual monitoring and any other information relevant for the medical surveillance.

**Section 96**
**Prohibition on assigning radiation work**

If a worker, according to the assessment of an occupational physician familiar with radiation, is unfit for a task in which the worker is classified in category A, they may not be classified in this category or assigned to an equivalent task.

If the worker has received a radiation dose exceeding the dose limit, they may not be assigned to radiation work before they have been deemed fit for radiation work in the manner specified in section 106.

The worker has the right to submit the matter concerning them, referred to in subsection 1 and 2, to STUK for consideration. The employer must inform the worker of the said right.

**Section 97**
**Special medical surveillance**

If the worker has received a radiation dose exceeding the dose limit of workers, the measures deemed necessary by the exposed worker's occupational physician familiar with radiation must be carried out in addition to the medical surveillance laid down in section 95.

**Section 98**
**Prohibition on dismissal**

An employment relationship or a permanent public post may not be terminated based on the worker receiving a radiation dose exceeding the dose limit of workers.

**Section 99**
**Age limits and exposure conditions concerning apprentices and students**

A radiation worker must be at least 18 years of age.

The radiation protection of an apprentice or student must be organized in the same manner as the radiation protection of a worker engaged in the radiation practices.

A minor apprentice or student, who must be under the age of 18 but at least 16 years of age, may only engage in the use of radiation sources to the extent that it is necessary for their education

and training and the related work exercise. They may not, however, be classified in category A or assigned to an equivalent task.

Further provisions on the dose limits of apprentices and students are given by government decree for the purpose of implementing European Union legislation.

**Section 100**
**Protection during pregnancy and breastfeeding**

Once a worker has notified the undertaking or, in the case of an outside worker, their employer of their pregnancy or of breastfeeding a child, the foetus and breastfed child must be protected in a manner equivalent to the protection of a member of the public.

Radiation workers must be reminded of the importance of the notification referred to in subsection 1.

Further provisions on the measures to protect a foetus or a breastfed child are given by government decree.

**Section 101**
**Delivering data to the workers' dose register**

The information from the individual monitoring of category A radiation workers referred to in section 20, subsection 2 shall be delivered to the workers' dose register on a regular basis.

If the radiological surveillance has been carried out as the individual monitoring of category B radiation workers performed by a dose measurement service, the information specified in subsection 1 shall be delivered to the dose register regularly also for category B workers.

STUK issues more detailed regulations on delivering the information to the dose register.

**Section 102**
**Undertaking's obligations in the protection of its own workers**

In its capacity as an employer, the undertaking is obligated to carry out the measures laid down in section 88–101 to protect its own workers.

**Section 103**

**Obligations of the employer of an outside worker**

In addition to what is laid down in section 96 and section 98–100, the employer of an outside worker shall carry out the following measures to protect the worker:

1) investigate the worker's previous occupational exposure in advance pursuant to section 89, subsection 2, and assess the total radiation exposure to which the worker is exposed in the work of all undertakings in advance;
2) classify radiation workers in accordance with section 90;
3) organize medical surveillance and special medical surveillance pursuant to section 95 and 97 for category A radiation workers;
4) for its part, ensure that a worker's education and training and induction to their tasks as well as any supplementary training is implemented in accordance with section 33 and 34;
5) consult an occupational physician familiar with radiation in accordance with section 97 in the event that a worker's radiation dose exceeds the dose limit.
6) for its part, ensure that the information to be registered and the results of individual monitoring are delivered to the workers' dose register in accordance with section 101;
7) for its part, ensure that an occupational physician familiar with radiation is provided with the reports and information specified in section 94 and section 95, subsection 2, and in section 95, subsection 4 for the purposes of performing medical surveillance of a worker.

**Section 104**

**Undertaking's obligations in the protection of an outside worker**

In addition to what is laid down in section 99 and 100, the undertaking shall carry out the following measures to protect an outside worker:

1) investigate an outside worker's previous occupational exposure and assess, in advance, the radiation exposure to which the outside worker is exposed due to work for which the undertaking is responsible and the means to reduce it pursuant to section 89;
2) ensure that classification of an outside worker carried out by the employer in accordance with section 90 is appropriate with regard to the practice for which the undertaking is responsible;
3) in the practice for which it is responsible, organize the radiological surveillance and individual monitoring for an outside worker belonging in category A pursuant to section 92 and make sure that the information specified in section 20, subsection 2 is delivered to the dose register;
4) ensure that an outside worker belonging in category A has been organized the medical surveillance referred to in section 95 and the special medical surveillance referred to in section

97, and that the outside worker is medically fit for the assigned task in the practice for which the undertaking is responsible;

5) for its part, ensure that the information referred to in section 95, subsection 4 is delivered to an occupational physician familiar with radiation.

The undertaking and the employer may agree in writing that the employer takes care of the individual monitoring and the delivery of information to the dose register referred to in subsection 1, paragraph 3.

In the work for which the undertaking is responsible, the protection of an outside worker is subject to what is provided in terms of a radiation safety deviation and the exposure caused by it in section 94, 130 and 131.

The undertaking must also ensure the protection of a private entrepreneur participating in the undertaking's radiation practices in accordance with what is laid down with regard to the protection of an outside worker in this section.

**Section 105**
**Worker's duty to participate in the investigation of radiation exposure**

Where there is reasonable basis to suspect that the worker has received a radiation dose exceeding the dose limit of workers, the worker is obligated to take part in the investigation of the exposure to which they have been subject.

A worker's duty to participate in a medical examination is laid down in section 13 of the Occupational Health Care Act.

**Section 106**
**Physician's statement on a worker's fitness for radiation work**

The fitness of a category A radiation worker for radiation work must be established prior to the commencement of working and at least once a year during the work. The capability to perform radiation work must also be established if the worker is found or suspected of receiving a radiation dose exceeding the dose limit of workers.

The fitness for radiation work is determined by an occupational physician familiar with radiation on the basis of the worker's state of health, using the following categorization:

1) fit;

2) fit, subject to certain conditions;
3) unfit.

The occupational physician familiar with radiation must provide the worker with a certificate on their fitness for radiation work and on the conditions for continuing radiation work in connection with the medical examination.

The physician's certificate concerning the medical surveillance must indicate:
1) the category referred to in subsection 2;
2) details on any possible restrictions in radiation work;
3) the date of the most recent review of health examination performed by an occupational physician familiar with radiation;
4) the validity of the physician's certificate.

**Section 107**
**Physician's duty to contact**

The occupational physician familiar with radiation must contact STUK if an observation made in the context of medical surveillance gives reason to believe the serious compromise of radiation safety.

The physician may, non-disclosure provisions notwithstanding, provide STUK with the information needed to investigate the matter. In respect of personal data, the right to provide information is nevertheless limited solely to the data indispensable for the matter in question.

**Section 108**
**Reporting and retention of medical data**

The health records of a category A radiation worker maintained by occupational health care must include information on the worker's tasks and posts relevant for the medical surveillance. In addition, the documents must include the results of the medical surveillance conducted for the purpose of assessing the worker's fitness to be classified as a category A radiation worker prior to their current post. The information must be kept up to date for as long as the worker belongs in the category in question.

Non-disclosure provisions notwithstanding, the information referred to in subsection 1 may be provided to STUK solely for the purpose of considering the matter referred to in section 96, subsection 3, or if such provision is necessary in terms of regulatory control.

The occupational physician familiar with radiation must provide the undertaking or the employer of an outside worker with the information on the medical surveillance of a worker necessary to fulfil the obligations laid down in this Act.

## Chapter 13
## Medical exposure

### Section 109
### Justification assessment concerning medical exposure

When considering the justification for medical exposure, the assessment covers the benefit to be expected of the examination, procedure or treatment which exposes an individual to radiation, including the direct medical benefit to the patient or asymptomatic individual and the benefits to society and, on the other hand, any possible detriment caused to the aforementioned due to the exposure.

STUK issues more detailed technical regulations on the practical measures involved in a justification assessment.

### Section 110
### Justification of medical exposure in special circumstances

Individual examination, procedure or treatment resulting in medical exposure which is not generally justified may be considered justified with respect to a single individual due to a special need related to them.

The basis must be drawn up on a case-by-case basis and recorded in the health records.

### Section 111
### Justification of the medical exposure of an asymptomatic individual

If the medical exposure required for the early detection of a disease in an asymptomatic individual is not part of a screening programme, the justification of the exposure pursuant to section 109 and 110 is subject to the preparation of special written grounds concerning the individual in question.

The author of the grounds shall be the physician or dentist responsible for the medical exposure, and they must hear the referrer. The preparation of the grounds must comply with the criteria for access to examination drawn up by the Council for Choices in Health Care in Finland, working in

conjunction with the Ministry of Social Affairs and Health, a requirement which also applies to health care services referred to in Act on Private Health Care.

The physician or dentist responsible for the medical exposure shall ensure that the asymptomatic individual exposed to radiation has been provided with the information referred to in section 113, subsection 1, paragraph 3.

**Section 112**
**Optimization of radiation protection in medical exposure**

The undertaking is responsible for the implementation of the requirements concerning the optimization of radiation protection in medical exposure. In addition, the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant. The optimization of the radiation protection of a pregnant individual being examined, receiving treatment or subject to a procedure must account for the exposure of the foetus.

The undertaking shall specify the responsibilities in terms of the optimization of radiation protection in medical exposure.

The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

STUK issues more detailed regulations of a technical nature on the practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

**Section 113**
**Oblications of referring physicians and dentists**

The physician or dentist giving the referral must ensure the following prior to the performance of the examination, procedure or treatment:

1) any material information on previous examinations, procedures and treatments is acquired;
2) the referral includes the information needed for the optimization of the radiation protection, including the indication of the examination or treatment;

3) the individual exposed to radiation or any other individual concerned is provided with information on the benefits of the examination, procedure or treatment and any possible health detriment caused by the exposure.

The physician or dentist giving the referral must, for their part, assess the justification of the medical exposure caused by the examination, procedure or treatment.

The physician or dentist giving the referral must have at their disposal referral guidelines concerning normal examinations, procedures and treatment causing exposure to radiation and information on the radiation doses caused by the examinations, procedures and treatments. If necessary, the referrer must consult experts before giving the referral.

**Section 114**
**Responsibility for medical exposure**

The physician or dentist responsible for the medical exposure is responsible for the justification of the medical exposure caused by the examination, procedure or treatment and for the optimization of radiation protection and, for their part, the medical assessment of the results of the examination, procedure or treatment. The responsibility requires qualifications pursuant to the quality of the examination, procedure or treatment. The undertaking must ascertain the fulfilment of the required qualifications.

The undertaking is responsible for that procedures pertaining to assigning and transferring responsibility are clear arranged.

A radiographer may participate in the practical procedures under the authorization of the physician referred to in subsection 1 for the purpose of ascertaining the justification for the medical exposure.

Further provisions on the qualification requirements of a physician or dentist responsible for medical exposure are given by a decree of the Ministry of Social Affairs and Health.

**Section 115**
**Performer of the examination, procedure or treatment**

A radiographer may perform the examination exposing a patient to radiation pursuant to the referral and administer the planned treatment independently. Other health care professionals may,

under the supervision of the physician responsible for the medical exposure, assist in the use of X-ray equipment they have been educated and trained to operate.

The undertaking and the physician responsible for medical exposure may authorize a health care professional other than a radiographer who has received the appropriate supplementary training and is familiar with nuclear imaging to perform a pre-determined native computed tomography examination pursuant to a standard programme on a nuclear medicine hybrid device, if the examination is a fixed part of nuclear imaging.

A health care professional who has received professional education and training for dental X-ray examinations may perform dental X-ray examinations according to the instructions of a physician or dentist.

Other individuals engaged in the performance of examinations, procedures or treatment causing exposure to radiation must have the education and training and experience required by their tasks.

The undertaking is responsible for the clear organization of the responsibilities and procedures concerning the performance of examinations, procedures and treatment.

**Section 116**
**Responsibilities of the performer of the examination, procedure or treatment**

The performer of an examination, procedure or treatment must, for their part, ensure that the examination, procedure or treatment is performed safely before targeting radiation at a human being. In particular, it must be ensured that:

1) the safety and shielding arrangements of the radiation source are in order and the appliances in use function properly;
2) the patient is appropriately protected, and the radiation exposure has been limited to the parts of the body intended to be irradiated;
3) any radioactive substance administered to the patient has been appropriately checked.

**Section 117**
**Applicability of appliances**

The undertaking must carry out examinations, procedures and treatment causing exposure to radiation with appliances applicable to the purpose in question.

**Section 118**
**Self-assessment and clinical audit**

The undertaking shall have individuals engaged in medical radiological procedures to carry out self-assessments to develop the practices.

The undertaking shall organize a systematic evaluation of procedures resulting in medical exposure (**clinical audit**) which, at regular intervals,

1) reviews the examination and treatment practices employed, exposures as well as the examination and treatment results;
2) compares the aforementioned to good practices;
3) presents measures deemed necessary to the develop the practices and prevent unjustified exposure.

Self-assessments and clinical audits are subject to the preparation of a report.

Further provisions on the performance and reporting of self-assessments and clinical audits are given by a decree of the Ministry of Social Affairs and Health.

**Section 119**
**Assessment of a radiation dose**

The undertaking must record such information on examinations, procedures and treatment resulting in exposure to radiation based on which the radiation dose caused by the examination, procedure or treatment to the individual being examined or treated can be determined, when necessary. The estimated radiation dose of a foetus, and information about the examination, procedure or treatment relevant in terms of the radiation exposure must be recorded in the health records.

Upon the request of STUK, an undertaking must provide information on the number of examinations, procedures and treatments resulting in exposure to radiation and on the radiation doses.

STUK issues more detailed regulations on the recording of the information.

**Chapter 14**
**Non-medical imaging exposure**

**Section 120**
**Scope of application**

This chapter contains provisions on non-medical imaging exposure to ionizing radiation.

**Section 121**
**Justification assessment**

The undertaking shall assess whether the practice referred to in this chapter is justified at least every five years.

**Section 122**
**Imaging with a health care appliance**

Any imaging carried out with a health care appliance is subject to section 30 with regard to quality assurance, section 66 with regard to the device's in-service radiation safety, and chapter 13 with regard to medical exposure. The recording and storage of the information concerning the imaging is subject to what is provided in the Act on the Status and Rights of Patients (785/1992) on the drawing up and keeping of health records.

The imaged individual is not subject to the dose limits concerning members of the public in practices referred to in subsection 1.

**Section 123**
**Dose constraint for other than health care appliance**

The undertaking must set the dose constraint for the imaged person if the imaging is carried out by other than health care appliance.

The value of the dose constraint must remain significantly below the dose limit for the members of the public.

**Section 124**
**Provision of information and requesting consent**

The party requiring imaging must ensure that the individual to be exposed or their legal representative is provided with the appropriate information on the radiation exposure and possible health detriments caused by the imaging. The information must be given in the native language of

the individual to be exposed or their legal representative or in a language they can justifiably be expected to understand.

The individual to be exposed or their legal representative is requested for a consent to the imaging, unless otherwise provided elsewhere. The opinion of an incompetent person to be exposed shall be determined whenever possible in relation to their age and level of development. If an incompetent person, based on their age and level of development, is able to give their consent to imaging, the consent of their legal representative is not required. If the incompetent person is unable to give consent for the imaging, his or her legal representative will decide on the consent. The consent may be given and withdrawn in free-form. The imaging may not be performed if the existence of the consent required by law or its voluntary nature is unclear.

In imaging carried out by other than health care appliance, the provision of the information and the request for consent referred to in subsection 1 is ensured by the undertaking.

Further provisions on the provision of information concerning the radiation exposure and possible health detriments as well as the request for consent are given by government decree.

**Section 125**
**Person inspection with a method causing radiation exposure**

The competent authority gives a written order for a person inspection as referred to in the Coercive Measures Act (806/2011) or the Customs Act to be performed with a method that exposes the inspected person to radiation.

The consent referred to in above in section 124 is not requested in a person inspection performed based on the Coercive Measures Act or the Customs Act.

**Chapter 15**
**Public exposure**

**Section 126**
**Limiting radiation exposure**

The undertaking must limit public exposure by:

1) taking care of in-service radiation safety of radiation sources and the facilities and places where they are used as provided in section 66, subsection 1;

2) preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency;
3) restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary.

The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking.

**Section 127**
**Discharges and their limit values**

The undertaking must limit the discharges of radioactive substances to the environment and the sewerage system to the absolute minimum. In any event, the amount of the discharge may not exceed the limit value for a minor discharge. A record must be kept of the discharges.

STUK may nevertheless authorize a discharge exceeding the limit value for a minor discharge if there is an absolute need for the discharge despite limiting measures and the undertaking has drawn up a plan for the discharges and assessed the exposure caused by the discharges.

STUK sets limit values for the discharge referred to in subsection 2 in such a way that the public exposure is as low as possible, accounting for the nature and extent of the practice and the means available for limiting discharges, and that the anticipated amount of exposure caused by the discharges is lower than dose constraint.

The undertaking must regularly provide STUK with information on the discharges referred to in the authorization granted by virtue of subsection 2 and on their monitoring.

The secretions of patients who have received a radioactive substance in medical use of radiation are not subject to subsection 1 and 2.

STUK issues more detailed regulations on the general limit values of minor discharges and more detailed technical regulations on the plan concerning discharges and their monitoring, discharge monitoring and record keeping and the delivery of the information for the purpose of implementing European Union legislation.

**Section 128**
**Monitoring public exposure**

In practices subject to a safety licence, the undertaking shall monitor public exposure based on regular assessments and, if necessary, measurements in the event that the public exposure is greater than one-third of the dose constraint applicable to the practice in question despite the measures limiting radiation exposure.

If public exposure must be monitored due to discharges, the undertaking shall, prior to the commencement of the activity, carry out a baseline environmental radioactivity study, in which radiation measurements and determinations of radioactive substances determine the pre-operational environmental radioactivity status.

STUK issues more detailed regulations of a technical nature on the arrangement of the monitoring referred to in subsection 1 and the performance of the baseline environmental radioactivity study.

**Chapter 16**
**Radiation safety deviations and emergency exposure situations**

**Section 129**
**Preparedness for radiation safety deviations**

In practices subject to a safety licence, the undertaking must prepare for radiation safety deviations. The undertaking shall have an up-to-date plan of action for the deviations.

STUK issues more detailed regulations on the plan for radiation safety deviations referred to in subsection 1.

**Section 130**
**Immediate measures in a radiation safety deviation**

In the event of a radiation safety deviation, the undertaking in a practice subject to a safety licence shall assess the situation and take the measures necessary to ensure radiation safety.

The undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of:

1) the radiation safety deviation due to which the radiation safety of the workers or members of the public at the facility and place where the radiation is used or its surroundings may be compromised;
2) any significant unplanned medical exposure;
3) the loss, unauthorized use or holding of a radiation source subject to a safety licence;
4) any significant spreading of a radioactive substance indoors or in the environment;
5) any other abnormal observations and information which may be of material significance in terms of radiation safety.

The undertaking shall immediately notify any significant exposure arising from a radiation safety deviation and the reasons for it to:
1) the exposed worker;
2) the referrer and the physician responsible for medical exposure as well as the exposed individual or their legal representative, in terms of medical exposure;
3) any other individuals exposed, insofar as possible.

If the radiation safety deviation requires rescue operations or protective actions from an authority, the undertaking shall take part in them.

Further provisions on reporting an observed or suspected defect or deficiency in a medical radiation appliance are laid down in the Act on Medical Equipment and Supplies.

STUK issues more detailed regulations on the content and preparation of the notifications referred to in subsection 2 and 3 and on any significant unplanned medical exposure as referred to in subsection 2, paragraph 2.

**Section 131**
**Measures after a radiation safety deviation**

The undertaking shall ensure that a radiation safety deviation and the reasons for it and the exposures arising from it are investigated. A record shall be kept of radiation safety deviations and their investigations and the results of said investigations.

The undertaking shall implement the remedial measures required due to a radiation safety deviation, which prevent similar deviations.

The undertaking shall notify STUK of the results of the investigation concerning the radiation safety deviation and of the remedial measures.

The undertaking shall notify STUK of the summarized information on any radiation safety deviations related to radiation practices other than those referred to in section 130, subsection 2.

STUK issues more detailed regulations on the investigations concerning radiation safety deviations, on the content of the information to be recorded, and on the content and preparation of the notifications.

**Section 132**
**Limiting exposure arising from an emergency exposure situation**

In emergency exposure situations, protective actions shall aim to ensure that the exposure of members of the public, emergency workers, and emergency helpers is lower than the reference level of exposure for an emergency exposure situation.

When setting the reference levels, the principles of radiation protection and acceptability in terms of society must be considered. STUK sets the reference levels of exposure for an emergency exposure situation for members of the public. Other reference levels will be laid down pursuant to subsection 3.

Further provisions on the use of reference levels in preparedness planning and emergency exposure situations, the basis for the selection of reference levels of exposure for an emergency exposure situation concerning members of the public, and the reference levels applicable to the exposure of emergency workers and helpers are given by government decree.

**Section 133**
**Information to public for an emergency exposure situation**

Members of the public must be provided with advance information on protection in an emergency exposure situation. Members of the public exposed to radiation in an emergency exposure situation must be informed of the situation and the protective actions required.

Further provisions on the obligation to provide information referred to in subsection 1 are given by a decree of the Ministry of the Interior.

**Section 134**

**Radiation protection of persons involved in protective actions in an emergency exposure situation**

An employer shall designate emergency workers in advance and determine their tasks in an emergency exposure situation in advance. An emergency helper's participation in protective actions shall be voluntary. An emergency worker's participation in protective actions shall be voluntary when it is possible that the exposure exceeds the reference level referred to in section 132, subsection 1. Implementation of protective actions that may result in exposure to radiation may not be assigned to pregnant or breastfeeding individuals or individuals younger than 18 years of age.

The occupational exposure of emergency workers and emergency helpers must be kept lower than the dose limits of workers to the extent possible. If this requirement cannot be met, the limitation of radiation exposure is subject to the reference levels referred to in section 132.

The radiological surveillance referred to in section 92 shall be arranged to emergency workers and emergency helpers in an emergency exposure situation. The employer is responsible for the radiological surveillance concerning emergency workers. The party having the work done is responsible for the radiological surveillance concerning emergency helpers., unless otherwise agreed between the employer and the party having the work done. Emergency workers and emergency helpers shall immediately be notified of any radiation dose higher than the reference level to which they have been exposed.

**Section 135**

**Special medical surveillance of persons involved in protective actions**

Emergency workers and emergency helpers exposed in an emergency exposure situation shall be arranged special medical surveillance in accordance with section 97. Special medical surveillance shall furthermore be arranged for those emergency workers and emergency helpers in an emergency exposure situation who separately request it.

The employer is responsible for the special medical surveillance of an emergency worker. The municipality is responsible for the special medical surveillance of an emergency helper.

**Section 136**

**Training for emergency exposure situations**

The employer shall ensure that emergency workers are provided with adequate training at regular intervals on the health risks related to tasks in an emergency exposure situation and on protection against such risks.

The training must be supplemented in an emergency exposure situation with guidance relevant to and required by the situation.

The party having the work done shall provide an emergency helper in an emergency exposure situation with the necessary guidance on the radiation-related health risks involved in their tasks and on protection against such risks.

STUK issues more detailed regulations on the content of the training and the practical implementation of the guidance.

**Section 137**
**Transition from an emergency exposure situation to an existing exposure situation**

The government decides on a transition from an emergency exposure situation to an existing exposure situation, once the measures necessary to limit the radiation hazard and bring the radiation sources under control have been carried out.

## Chapter 17
## Existing exposure situations

**Section 138**
**Undertaking's and area holder's duty of care**

The undertaking from whose practice an existing exposure situation arises is responsible for investigating the radiation exposure arising from it and for carrying out the protective actions and for cleaning the areas, facilities and structures used in the practice, and the environment, of radioactive substances.

Provisions on the cleaning of areas, facilities and structures used in the practice are laid down in section 83. The cleaning of the environment is subject to the reference levels referred to in section 140.

If the undertaking is not identified or fails to fulfil its duty laid down in subsection 1, and if the existing exposure situation has arisen with the consent of the holder of the area or the holder has

been aware or should have been aware of the state of the area when acquiring it, the holder of the area must take care of the duty laid down in subsection 1 insofar as it is not clearly unreasonable.

STUK issues more detailed regulations on the performance of the investigation referred to in subsection 1.

**Section 139**
**State's duty of care**

The State takes care of the cleaning the areas, facilities, structures and the environment of radioactive substances to the extent that:

1) the undertaking or holder of the area does not within a reasonable period of time meet or cannot be expected to meet its duty of care specified in section 138; or
2) the undertaking responsible cannot be identified.

STUK assesses the radiation exposure arising from the existing exposure situation referred to in subsection 1 and determines the required measures, should there be a reason to suspect exposure higher than the reference level.

The National Supervisory Authority for Welfare and Health draws up a plan on the measures and the provision of guidance for individuals living or working in the area. Unless otherwise determined by the principle of justification, the National Supervisory Authority for Welfare and Health may decide that the existing exposure situation does not require measures. Further provisions on the supervision of the measures pursuant to the plan are laid down separately.

The undertaking is obligated to compensate for any necessary costs incurred by the State due to the measures referred to in subsection 1–3. Section 190 contains provisions on the charging of such costs. The costs are compensated for primarily with the security referred to in section 54, subsection 1.

Further provisions on the performance of the assessment referred to in subsection 2 and on drawing up the plan referred to in subsection 3 and on the responsibilities related to the implementation of the plan are given by government decree.

**Section 140**
**Reference levels in existing exposure situations**

The aim in existing exposure situations is to carry out the protective actions in such a way that occupational and public exposure remain below the set reference level.

The party having the work carried out shall immediately inform the workers involved of any exposure greater than the reference level.

The setting of the reference levels must account for the principles of radiation protection and acceptability in terms of society. STUK confirms the reference levels for members of the public in an existing exposure situation.

Further provisions on the reference levels for occupational exposure in protective actions and on the basis for the reference levels for public exposure in an existing exposure situation are given by a decree of the Ministry of Social Affairs and Health.

**Section 141**
**Safety licence in existing exposure situations**

The prerequisite for protective actions in an existing exposure situation is a safety licence, if the radiation dose arising from occupational exposure is higher than the reference level referred to in section 140.

**Section 142**
**National action plan for identifying existing exposure situations**

The Ministry of Social Affairs and Health draws up a national action plan for identifying existing exposure situations and for the implementation of the measured referred to in the plan.

Further provisions on the drawing up and implementation of the action plan are given by government decree.

**Chapter 18**
**Natural radiation**

**Section 143**
**Limitation of Chapter's scope of application**

A practice carried out by a natural person for some other than a commercial purpose is only subject to section 157 and 158 of the provisions in this chapter concerning the obligations of someone undertaking a construction project and the owner and holder of a building.

This chapter does not apply to a practice carried out by a private entrepreneur in such a way that they themselves are the only person exposed to radiation.

**Section 144**
**General criteria for setting reference levels for natural radiation**

The setting of the reference levels for natural radiation for the purposes of the situations referred to in section 151–158 must account for the principles of radiation protection and acceptability in terms of society.

The reference level for radon concentration in workplace and any occupational exposure to radon is set in such a way that the radiation dose to workers due to radon is, at maximum, three-tenth of the workers' dose limit.

Workplaces in which work is carried out regularly apply the reference level for the radon concentration in workplace. Work of a short duration is subject to the reference level for occupational exposure to radon.

The reference level for public exposure for other exposure than that arising from radon may not exceed the dose limit for members of the public.

**Section 145**
**Special notification requirement**

Prior to the commencement of the practice, the party responsible for it shall notify STUK of:
1) any mining as referred to in the Mining Act;
2) any extraction work or other work carried out in an underground passageway or tunnel, in which a single worker's combined working hours per year is more than 100 hours;
3) the management, use, storage and utilization of materials and waste containing natural radioactive substances in which the activity concentration of uranium-238, thorium-232 or their progeny is greater than one becquerel in a gram;
4) the practice of aviation as referred to in section 152.

Information that is central to radiation safety shall be notified for the practice and its organization.

**Section 146**
**Investigating radiation exposure**

Radiation exposure arising from natural radiation shall be investigated in the situations referred to in section 145 and section 151–156.

STUK may also obligate the party responsible for a practice to carry out investigations in other situations, if the occupational or public exposure arising from the practice or the radon concentration in workplace can exceed the reference level.

The investigation referred to above in subsection 1 and 2 shall be repeated to the extent that the practice or conditions change in such a way that the occupational or public exposure or the radon concentration in workplace can exceed the reference level.

The party responsible for carrying out the investigation must immediately notify STUK of the investigation's results.

The results of an investigation concerning occupational exposure shall be processed in the workplace in accordance with what is provided in section 27 of the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces (44/2006).

**Section 147**
**Limiting radiation exposure**

The party obligated to carry out the investigation referred to above in section 146 shall implement the measures to limit exposure to natural radiation, if the occupational or public exposure arising from the practice or the radon concentration in workplace or household water exceeds the reference level.

**Section 148**
**Safety licence in a practice with exposure to natural radiation**

Practices that cause exposure to natural radiation are subject to a safety licence if the occupational or public exposure arising from the practice or the radon concentration in workplace or household water exceeds the reference level despite the measures referred to in section 147.

The practice of aviation is not subject to section 28 concerning radiation safety officers.

**Section 149**
**Exposure to natural radiation in the workplace**

Occupational exposure arising from natural radiation is subject to chapter 12, if the occupational exposure arising from the practice or the radon concentration in the workplace exceeds the reference level despite the measures referred to in section 147.

Section 35 and 90; section 92, subsection 2, paragraph 1 and 3 and subsection 3; and section 95 of the Act shall not apply if solely the radon concentration in the workplace or the exposure arising from radon or cosmic radiation exceeds the reference level. Section 91 shall furthermore not apply if the occupational exposure arising from cosmic radiation alone exceeds the reference level.

The undertaking shall determine the radiation dose caused to a worker regularly if the radon concentration in workplace or the occupational exposure to radon or cosmic radiation exceeds the reference level. The results of the determination are subject to what is provided on the recording and follow-up of the results of radiological surveillance in section 92, subsection 4, and what is provided on delivering information concerning individual monitoring to the workers' dose register in section 101.

**Section 150**
**Public exposure in practices causing exposure to natural radiation**

The radiation protection of members of the public is subject to chapter 15 if the public exposure arising from the practice can exceed the reference level despite the measures referred to in section 147.

Radon as well as radiation exposure arising from radioactive substances in construction products and household water are not subject to subsection 1.

**Section 151**
**Investigating radiation exposure arising from the processing of soil material**

Anyone utilizing soil, rock or other materials occurring in nature or materials resulting from the use of these materials is obligated to investigate the radiation exposure arising from their practices, if the exposure arising from natural radiation can exceed the reference level.

**Section 152**
**Investigating and limiting radiation exposure of an aircraft crew**

An employer engaged in aviation by virtue of a licence issued by the Finnish Transport Agency is obligated to investigate the radiation exposure arising from its practice, if the principal flight altitude is more than 8,000 meters.

The duty to investigate referred to in subsection 1 also applies to anyone engaged in military aviation and State aviation as referred to in the Aviation Act (864/2014).

If the occupational exposure arising from cosmic radiation can exceed the reference level referred to in section 144, the undertaking shall plan the work shifts of the aircraft's crew in such a way that exposure to the most exposed individuals is limited.

**Section 153**
**Investigating radiation exposure arising from construction products**

Anyone who manufactures, imports or transfers a construction product as referred to in Regulation (EU) No. 305/2011 of the European Parliament and of the Council, laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, hereinafter the **Construction Product Regulation**, shall investigate the radiation exposure arising from the product, if the combined exposure resulting from the radioactivity of the construction products in the product's intended purpose of use can exceed the reference level.

If the investigation referred to in subsection 1 indicates that the radiation exposure is greater than the reference level, the party obliged to investigate shall:

1) state in the information concerning the product the radioactive substances contained by the construction product and the exposure arising from them in the construction product's intended purpose of use;
2) give instructions in the information concerning the product on how to limit the exposure arising from the use of the construction product in such a way that it remains below the reference level.

The provision of the information and instructions referred to above in subsection 2 is subject to Article 11, paragraph 6 of the Construction Product Regulation.

**Section 154**
**Radioactivity in household water**

If the activity concentration in household water or the radiation exposure arising from radioactive substances in the water exceeds the reference level, the installation distributing the household

water shall carry out measures to limit the exposure arising from the water and to meet the quality requirements for household water referred to in section 17 of the Health Protection Act.

**Section 155**
**Investigating radon concentration in workplace**

An employer shall investigate the radon concentration in a workspace or other place of work if the facilities are located:

1) in areas defined by STUK in which more than a tenth of representative results of radon measurements exceed the reference level for radon concentrations in workplaces on the basis of the radon concentration data in the register referred to in section 19, subsection 1, paragraph 5;
2) on an esker or other gravel or sandy soil with good air permeability;
3) wholly or partly underground;
4) an installation which distributes water or in a food establishment the water of which does not derive solely from a body of surface water and has contact with indoor air.

However, the investigation need not be carried out if none of the workers work in the workspace for more than 20 hours in a year or if the facility referred to in subsection 1, paragraph 1 or 2 is located on the second or upper floor of the building seen from the ground level, or if the floor and walls of the building are not in contact with the ground and the good ventilation of the space in between is apparent.

The radon concentration in workplace shall be measured on a regular basis if the workspace or other workplace is in an underground quarry or an underground mining site as referred to in the Mining Act.

Should the investigation indicate that the worker can receive a radiation dose exceeding the dose limit of a worker without remedial measures, the employer shall immediately arrange individual monitoring for the workers.

**Section 156**
**Investigating the radon concentration in other premises used by people**

The indoor radon concentration shall be investigated in any other premises used by people as referred to in chapter 7 of the Health Protection Act, insofar as the spaces are located in a place referred to in section 155, subsection 1, paragraph 1–3 of this Act. The division of responsibility

regarding the duty to investigate is subject to what is provided in section 27, subsection 2 of the Health Protection Act regarding identifying, removing and limiting a health detriment.

The investigation need not be carried out if the facility is located on the second or upper floor of the building seen from the ground level, or if the floor and walls of the building are not in contact with the ground and the good ventilation of the space in between is apparent.

**Section 157**
**Limiting the indoor radon concentration in a construction project**

The party undertaking a construction project shall ensure that the building is designed and constructed in such a way that the indoor radon concentration is as low as possible.

The fulfilment of the obligation provided above in subsection 1 is assessed by comparing the indoor radon concentration to the relevant reference level.

**Section 158**
**Limiting the indoor radon concentration in a dwelling or other space with public access**

The owner and holder of a building shall each respectively ensure that the indoor radon concentration is as low as possible considering the circumstances.

The fulfilment of the obligation provided above in subsection 1 is assessed by comparing the indoor radon concentration to the relevant reference level.

Further provisions on identifying, removing and limiting a health detriment caused by radiation and their regulatory control in a dwelling or other premise used by people are laid down in the Health Protection Act.

**Section 159**
**National action plan for preventing radon risks**

The Ministry of Social Affairs and Health prepares a national action plan for the prevention of long-term risks arising from radon.

**Section 160**
**Further provisions on natural radiation**

Further provisions on the following are given by government decree:

1) the practices pertaining to the utilization of soil materials referred to in section 151;
2) the constructions products referred to in section 153, subsection 1;
3) the preparation and updating of a national action plan as referred to in section 159 and the matters discussed in the plan.

Further provisions on the following are given by a decree of the Ministry of Social Affairs and Health:

1) the reference levels referred to in section 144, set for the situations referred to in section 151–158;
2) the performance of radon concentration measurements in dwellings and other premises used by people referred to in section 158.

STUK issues more detailed regulations on the following:

1) the content of the notification referred to in section 145;
2) the radiation protection of workers and members of the public in practices causing exposure to natural radiation;
3) investigating radiation exposure and the performance of the related measurements and the notifications of the results in the situations referred to in section 145 and section 151–155;
4) measures to limit exposure to radiation in the situations referred to in section 145 and section 151–155;
5) the determination of a radiation dose caused to a worker as referred to in section 149, subsection 3.

## Chapter 19
## Non-ionizing radiation

### Section 161
### Limiting exposure caused by non-ionizing radiation

In practices which cause exposure to non-ionizing radiation:

1) exposure to an electromagnetic field or ultrasound may not cause harmful tissue damage or changes to vital functions;
2) short-term exposure to optical radiation may not cause harmful tissue damage and any long-term health detriments must be as minor as possible;
3) public exposure may not exceed the limit value for exposure.

Further provisions on the limit values for exposure and limiting the public exposure caused by non-ionizing radiation are given by a decree of the Ministry of Social Affairs and Health.

**Section 162**
**Exposure exceeding limit value in a cosmetic procedure**

In a cosmetic or other comparable procedure performed someplace other than a health care unit as referred to in the Act on the Status and Rights of Patients, the exposure may exceed the limit value if the fulfilment of other requirements provided in section 161 can be otherwise ensured.

The undertaking shall ensure that the customer is provided with the necessary information on the risks involved in the procedure prior to the performance of the procedure referred to in subsection 1.

STUK issues technical regulations on the fulfilment of the requirements referred to in subsection 1 and the information to be provided to customers.

**Section 163**
**Limitation of regulatory control**

The regulatory control referred to in this Act is not applicable to such radiation appliance generating non-ionizing radiation which cannot cause radiation exposure higher than a tenth of the limit values for exposure caused by non-ionizing radiation, or the use of such appliances.

**Section 164**
**Public exposure arising from the medical use of non-ionizing radiation**

The medical use of non-ionizing radiation may not result in a health detriment to members of the public.

If the exposure caused to members of the public by the medical use of non-ionizing radiation is higher than a tenth of the limit value for the exposure referred to in section 161 or otherwise poses a risk of a health detriment to members of the public, STUK is to be notified of the practice no later than 30 days before its commencement. Any material changes are also subject to a notification.

**Section 165**
**Licence for the use of high-powered laser equipment**

The use of high-powered laser equipment as a lighting effect, in an advertisement, work of art or some other equivalent presentation or game is subject to a licence issued by STUK if the public has access to the place where the equipment is used or a space in which the laser beams travel.

The application for the licence must include:
1) information of the applicant;
2) a description of the laser equipment and their intended purpose of use;
3) a risk assessment concerning the practice;
4) information on the person in charge referred to in section 168.

The licence is granted if the practice uses equipment compliant with the requirements and the practice can be conducted safely. STUK may include conditions in the licence which are necessary for ensuring safety and supervision.

STUK issues more detailed regulations on the information to be provided in the application concerning the licence.

**Section 166**
**Notifications concerning the use of high-powered laser equipment and changes in practice**

The undertaking must inform STUK of a high-powered laser equipment's each instance of use in advance in a practice referred to in section 165.

STUK must also be notified of any changes to the information referred in section 165, subsection 2.

STUK issues more detailed regulations on the content of the notifications and the deadlines for their submission.

**Section 167**
**Use of high-powered laser equipment**

The undertaking shall organize the practice referred to in section 165 in such a way that members of the public are not accidentally or easily exposed to laser radiation exceeding limit values.

STUK issues more detailed regulations on the fulfilment of the requirements provided in subsection 1 and section 161, subsection 1, paragraph 2.

**Section 168**
**Appointment and tasks of person in charge**

The undertaking shall name a person in charge for the practice referred to in section 165, tasked with organizing the installation and use of the laser equipment as well as the in-service monitoring.

**Section 169**
**Own-checking the use of high-powered laser equipment**

The undertaking must ensure that the own-checking of the use of high-powered laser equipment is organized adequately in respect of the nature and extent of the practice. The use must be checked continuously if the beams travel at a height of less than six meters in a space open to members of the public.

STUK issues more detailed regulations on the own-checking of the use of high-powered laser equipment.

**Section 170**
**Amending and withdrawing the licence**

STUK amends the conditions of the licence referred to in section 165 if reasons necessary in terms of ensuring safety so require.

STUK withdraws the licence if the undertaking has discontinued its practice.

STUK may withdraw the licence if the conditions for granting it are not met or if the licensee repeatedly or essentially breaches the conditions for the licence or the provisions and regulations provided in this Act or pursuant to it, and fails to remedy the deficiencies or its conduct within the prescribed period of time despite a request to do so.

**Section 171**
**Preventing a health detriment caused by sunbed services**

Sunbed services on offer may not cause a health detriment to members of the public.

The undertaking shall ensure that an individual less than 18 years of age is not exposed or given the chance to expose themselves to the ultraviolet radiation of a solarium.

What is provided in subsection 2 does not apply to exposure taking place at a physician's orders for the purposes of the treatment of a disease, diagnosis or medical research conducted with ultraviolet radiation.

**Section 172**
**Requirements for offering sunbed services**

The undertaking must appoint a person in charge who is at least 18 years of age and has been appropriately inducted to the facility where a sunbed device is offered to the public. The undertaking must ensure that the person in charge is present at the place of use when offering sunbed services. When necessary, the person in charge guides the customer to protect their eyes and the device's safe use in other respects) and controls that a person less than 18 years of age is not given a chance to use the sunbed device. When necessary, the person in charge shall check the age of the person using the sunbed device.

The undertaking must furthermore ensure that information about the hazard caused by ultraviolet radiation generated by the device and on limiting exposure are visibly displayed in the place where the device is used.

**Section 173**
**Surveying of sunbeds**

A municipality's health protection authority checks the following aspects in the context of its regulatory control pursuant to the Health Protection Act:

1) the placement of the sunbed device and the prevention of its use in such a way that a person less than 18 years of age cannot use the device without the personnel noticing it;
2) the presence of the person in charge referred to in section 172, subsection 1;
3) the provision of usage instructions to customers;
4) the visible display of information pertaining to the risks caused by the exposure to ultraviolet radiation generated by the solarium device and the limiting of exposure in the immediate vicinity of the device;
5) protecting customers' eyes;
6) the adjustment of the timer in the sunbed device;
7) the title and type of the sunbed device;
8) the titles and types of the sunbed lamps.

**Section 174**
**Survey report and remedying deficiencies or negligence**

The municipality's health protection authority delivers a copy of the survey report or equivalent information to STUK.

STUK may undertake the measures referred to in this Act to remedy a deficiency or negligence observed by a health protection authority.

**Section 175**
**Use of non-ionizing radiation in the Finnish Defence Forces and the Finnish Border Guard**

The Finnish Defence Forces and the Finnish Border Guard monitor the safety of the equipment in their possession generating non-ionizing radiation and their use, unless otherwise provided elsewhere.

The use of non-ionizing radiation in the Defence Forces and the Border Guard shall be carried out safely and in accordance with the requirements of section 161, subsection 1, paragraph 1 and 2, without prejudice to the use of non-ionizing radiation as a means of the use of force by the Defence Forces and the Border Guard. These requirements also apply to occupational exposure to non-ionizing radiation.

The Finnish Defence Forces and Finnish Border Guard request a statement from STUK on the instructions concerning the safe use of non-ionizing radiation they have drawn up. Any material changes to the instructions are also subject to a request for statement.

The Defence Command issues more detailed regulations on the monitoring and on the safety of the use in the Finnish Defence Forces referred to in subsection 1 and 2.

The Headquarters of the Finnish Border Guard issues more detailed regulations on the monitoring and on the safety of the use in the Finnish Border Guard referred to in subsection 1 and 2.

**Chapter 20**
**Regulatory control, charges and appeal**

**Section 176**
**Right to inspection, information and investigation**

For the purpose of supervision compliance with this Act, STUK shall have the right to:

1) inspect and observe a practice referred to in this Act and circumstances that may result in harmful exposure to radiation and to access the facility in which the practice is engaged or in which the circumstances are manifested;
2) inspect the fulfilment of the in-service requirements of the radiation sources used in the practice as well as the instruments, equipment and supplies with an impact on radiation safety;
3) perform, free of charge, the tests and measurements required by the supervision take and obtain the necessary samples, photographs and other possible recordings, and to install the devices required by the supervision in the facility in which the practice is engaged in or in its vicinity;
4) to obtain from the party engaged in the practice, non-disclosure provisions notwithstanding, information necessary for supervision and, in terms of personal data, the absolutely necessary information;
5) investigate a radiation safety deviation or procedure observed in radiation practices which has or may have material relevance for the safety of the radiation practice; the investigator may also hear persons other than those employed by the undertaking, party to the matter being investigated or otherwise aware of it.

The supervision measures referred to above in subsection 1 may only be extended to facilities used for housing of a permanent nature if the inspection is necessary for clarifying matters under investigation and there is reason to suspect that an offence referred to in chapter 34, section 4; chapter 44, section 1, 12 or 12 a or; chapter 48, section 1, subsection 1, paragraph 1 of the Criminal Code of Finland (39/1889) has been committed. An outside expert referred to in section 181 of this Act cannot be given a right to inspect facilities used for housing of a permanent nature. The inspection is subject to section 39 of the Administrative Procedure Act (434/2003).

Once a mining authority has granted an exploration permit referred to in section 9 of the Mining Act for the location and exploration of a deposit containing uranium or thorium, STUK shall have the right to monitor and supervise the exploration area and its environment to the extent necessary so as to ensure radiation safety. STUK is furthermore entitled to necessary observing and supervision when some other mining mineral is being excavated and processed pursuant to the mining permit referred to in section 16 of the Mining Act, and the practice has or may have an effect on the environment's radiation safety.

**Section 177**

**Remedying deficiencies detected in a practice**

STUK or an individual inspector thereof may obligate an undertaking to remedy their practice to such a state that it meets the requirements laid down in this Act. The undertaking may furthermore be obligated to implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.

The implementation of the measures shall be set a time limit. The decision may obligate the undertaking to notify the remediation of the deficiencies and the measures undertaken due to the decision.

**Section 178**
**Discontinuation or restriction of practice**

STUK may decide on the discontinuation or restriction of a practice if the practice fails to accord with this Act or may cause an obvious health detriment.

In cases that are urgent in terms of safety an inspector may decide on the discontinuation or restriction of a practice.

The inspector shall submit the matter without delay to STUK for decision. The inspector's decision is valid until STUK gives its decision in the matter, but in no case for more than 14 days.

**Section 179**
**Authorities' right to obtain and disclose information**

Notwithstanding non-disclosure provisions, the regulatory authorities referred to in this Act shall have the right to obtain information necessary for carrying out its duties laid down in this Act from another regulatory authority and to use samples acquired by another regulatory authority for the purposes of regulatory control. In respect of personal data, the right to obtain information is limited solely to the information absolutely necessary for regulatory control.

Notwithstanding non-disclosure provisions, the regulatory authority may disclose information received in the course of regulatory control on the financial status, trade secret, and exposure to radiation of a private individual or a corporation and of the state of a private individual's health to the other regulatory authorities referred to in this Act when they are performing the regulatory control laid down in this Act, another authority which needs the information to perform an regulatory function in the field of radiation protection, and to the regulatory authorities of other Member States of the European Union for the purposes of supervision on implementation of the European Union's radiation legislation.

The regulatory authority may furthermore, non-disclosure provisions notwithstanding and for the purposes of statutory duties, disclose information on the holders of safety licences and radiation sources and their locations to the Police and emergency authorities as well as to the authorities referred to in section 6 of the Act on the Transport of Dangerous Goods and ministries.

**Section 180**
**Official assistance**

Regarding the import, export and transit of radiation sources and radioactive waste, the Customs provides official assistance for supervising compliance with and for the enforcement of this Act.

In addition to what is provided with regard to the provision of official assistance in the Police Act (872/2011), the Police is obligated, upon request, to provide a regulatory authority with official assistance in a matter pertaining the discontinuation and restriction as well as prohibition of a practice referred to in this Act.

**Section 181**
**Outside experts**

STUK may in its regulatory control duties rely on the assistance of an outside expert for the performance of inspections, investigations studies and measurements to clarify a matter relevant to the regulatory control.

The outside expert shall have the qualifications required by the tasks they perform. When performing duties referred to in this Act, the outside expert is subject to provisions concerning penal liability as a public official. Provisions on any liability for damages are laid down in the Tort Liability Act (412/1974).

**Section 182**
**Inspection programme**

STUK draws up an inspection programme concerning the inspections of practices subject to a safety licence.

Further provisions on the content of the inspection programme are given by government decree.

**Section 183**
**Use of regulatory control observations**

STUK uses the inspection findings and other observations pertaining to radiation safety to develop regulatory control and reports on them to undertakings, authorities and any other parties concerned in the extent as is necessary to promote safety.

**Section 184**
**Notices of conditional fine, enforced compliance and suspension**

STUK may enforce a decision it has made or a prohibition it has given pursuant to this Act with a notice of conditional fine or at the threat of having a neglected measure taken at the defaulter's expense, or suspending the practice or prohibiting the use of the radiation source.

STUK may impose a conditional fine to enforce a duty to provide information and obligation to present documents referred to in section 176, subsection 1, paragraph 4.

The Act on Conditional Fines (1113/1990) lays down provisions on notices of conditional fine, enforced compliance and suspension.

**Section 185**
**Radiation violation**

A party who intentionally or through negligence

1) engages in a practice subject to a safety licence without a safety licence referred to in section 48, subsection 1 or violates the conditions of a safety licence,
2) violates a prohibition issued under section 57, subsection 2 to manufacture, import, export, transfer, place on the market, offer, keep for sale, sell or otherwise hand over of a product referred to in section 56,
3) violates the prohibition laid down in section 70, subsection 3 to use, import or transfer an unidentified sealed source to Finland,
4) neglects the record-keeping or notification obligation concerning radiation sources provided in section 71, subsections 1 - 3,
5) hands over contrary to section 72, subsection 1 a radiation source to a party who does not hold the necessary safety licence referred to in section 48, subsection 1,
6) neglects the duty to provide information related to the transfer of a radiation source laid down in section 73, subsection 1 or 2,
7) violates the prohibition laid down in section 82, subsection 2 to import or transfer a radiation source manufactured somewhere else than in Finland to Finland as radioactive waste,

8) reuses, recycles, utilizes or disposes of waste or some other material contrary to section 84, subsection 1 without the approval referred to in section 84, subsection 2,
9) neglects the obligation laid down in section 94, subsection 1 to report an established or suspected radiation dose exceeding the dose limit,
10) neglects the record-keeping duty concerning discharges referred to in section 127, subsection 1 or the duty to provide information referred to in subsection 4,
11) uses an appliance generating non-ionizing radiation in its practice contrary to section 164, subsection 2 without notifying STUK of the practice,
12) uses high-powered laser equipment without a licence from STUK contrary to section 165, subsection 1, or breaches the licence conditions,
13) neglects the obligation of a solarium service provider laid down in section 171, subsection 2 to ensure that an individual less than 18 years of age is not exposed or given the chance to expose themselves to the ultraviolet radiation
14) neglects the duty laid down in section 172 to designate an on-site radiation safety person for a solarium device or the obligation concerning the presence of such a person or to keep information visible,
15) violates a decision concerning obtaining information made pursuant to section 176, subsection 1, paragraph 4,
16) violates a decision concerning the discontinuation or restriction of a practice referred to in section 178, subsection 1 or 2,

shall be sentenced to a fine for a **radiation violation**, unless the act is insignificant in consideration of the circumstances or unless a more severe punishment is laid down elsewhere in the law.

The prosecution for a radiation violation can be waived or the punishment for it not imposed if the financial consequences of another official decision given due to the act can be considered sufficient to the offender regarding the seriousness of the act or if the offender violates a prohibition or decision pursuant to this Act, and enforced with a conditional fine.

**Section 186**
**Reference provisions concerning punishments**

The punishment for the endangerment of health is laid down in chapter 34, section 4 and 5 and for negligent endangerment in section 7 and 8 of the Criminal Code of Finland.

The punishment for a health offence is laid down in chapter 44, section 1, and for careless handling in section 12, and for the possession of radioactive material offence in section 12a of the Criminal Code of Finland.

The punishment for a work safety offence is laid down in chapter 47, section 1 of the Criminal Code of Finland.

The punishment for an impairment of the environment is laid down in chapter 48, section 1, 2 and 4 and for an environmental infraction in section 3 of the Criminal Code of Finland.

**Section 187**
**Statement on the bringing of charges**

The prosecutor shall request a statement from STUK prior to bringing charges for a radiation violation referred to in section 185.

**Section 188**
**Enforcement of decision despite appeal**

A decision made pursuant to section 40, 177 or 178 may stipulate that the decision is to be complied with despite an appeal.

If the stipulation referred to in subsection 1 has been given, the appeal official shall process the appeal as urgent.

**Section 189**
**Regulatory charge and the basis thereof**

STUK collects an annual regulatory charge from an undertaking engaged in a practice subject to a safety licence and a licence referred to in section 165 to cover the costs arising from supervision compliance with this Act.

The regulatory charge comprises a practice-specific basic charge and a radiation source-specific surcharge.

The regulatory charges are collected in accordance with the Annex.

The decision may be served as an ordinary service referred to in section 59 of the Administrative Procedure Act.

In the case of a radiation practice or a radiation source for which a regulatory charge cannot be determined in accordance with the Annex, the Radiation and Nuclear Safety Authority shall charge a basic charge and a source-specific surcharge for radiation sources in accordance with charge category A provided in the Annex.

**Section 190**
**Validity of payment obligation and due date of payment**

The payment obligation commences at the beginning of the year following the issuance of the safety licence or the licence referred to in section 165. In terms of a change affecting the payment, the payment obligation commences at the beginning of the year following the amendment to the licence. The payment obligation concludes at the end of the year during which the undertaking has notified STUK of the discontinuance of the practice or during which STUK has otherwise established the practice to have discontinued.

The regulatory charge is imposed for each calendar year and will fall due annually on the date determined by STUK, although on the last of April, at the earliest. STUK sends the payment decision concerning the regulatory charge to the parties liable for payment no later than 30 days prior to the due date.

**Section 191**
**Increases to and subsequent collection of regulatory charges**

If a practice subject to a safety licence or the licence referred to in section 165 has been engaged in without a licence referred to in this Act, the regulatory charge or the proportion of it which has not been collected will be charged from the undertaking with an increase of 50 per cent.

The subsequent collection of an increased regulatory charge can be effected within three years as of the beginning of the year following the calendar year during which the payment obligation would have commenced.

**Section 192**
**Other charges**

Provisions concerning the charges collected for the performances of State authorities are laid down in the Act on Criteria for Charges Payable to the State (150/1992).

If the practice in the use of non-ionizing radiation fails to meet the requirements of this Act, STUK may obligate the undertaking to compensate for the costs arising from the inspection.

**Section 193**
**Collection of and interest on payments**

Payments and compensations payable to the State are directly distrainable. Provisions on their collection are laid down in the Act on the Enforcement of Taxes and Public Payments (706/2007).

If a payment is delayed, it shall be subject to an interest for late payment as provided in section 4 of the Interest Act (633/1982). In lieu of an interest for late payment STUK may charge a five-euro charge for delay, provided that the amount of the interest for late payment would remain smaller than this.

If regulatory charges are returned due to an adjustment or an appeal, the payment to be returned is subject to an interest on return laid down in section 32 of the Tax Collection Act (769/2016) as of the date of payment to the date of return.

**Section 194**
**Adjustment of regulatory charge for the benefit of the liable party**

If a party liable for payment has been imposed too much of the regulatory charge due to an error, the payment decision shall be adjusted, unless the matter has been resolved with a decision given to an appeal. An adjustment for the benefit of the party liable for payment can be made within three years as of the beginning of the year following the imposition of the payment.

**Section 195**
**Adjustment of regulatory charge for the benefit of the payee**

If the regulatory charge or a part thereof has not been imposed on a party liable for payment due to an error in calculation or because the matter has not been investigated in respect of some aspect without undue influence from the party liable for payment, the payment decision shall be adjusted, unless the matter has been decided with a decision given to an appeal. The adjustment for the benefit of the payee can be made within a year as of the beginning of the calendar year during which the payment was imposed or should have been imposed.

**Section 196**
**Appeal**

A decision made by an inspector pursuant to section 177 as well as a decision concerning a regulatory charge referred to in section 189 and some other charge referred to in section 192, subsection 1 may be subject to rectification from the regulatory authority as provided in the Administrative Procedure Act. The time limit for rectification in a matter concerning the imposition of a regulatory charge referred to in section 189 shall nevertheless be 60 days from the notification of the decision.

Any other decision made pursuant to this Act and a decision made to a claim for rectification may be appealed as provided in the Administrative Judicial Procedure Act (586/1996). The decision of an Administrative Court may be appealed only if the Supreme Administrative Court grants the leave to appeal.

A decision by STUK in a matter referred to in section 96, subsection 3 may not be appealed. Nor may a decision by an inspector in a matter referred to in section 178, subsection 2 be appealed.

Any regulatory charge shall be paid within the prescribed period of time despite an appeal.

Any other charge imposed by a State authority may be appealed as provided in the Act on Criteria for Charges Payable to the State.

**Chapter 21**
**Miscellaneous provisions**

**Section 197**
**Safety licences in official activities**

STUK does not require a safety licence for a radiation practice necessary for carrying out its statutory duty or the provision of executive assistance related to a radiation source.

Other authorities do not require a safety licence for the temporary holding of a radiation source which has come into their possession in official functions.

In situations referred to in this section, the authority shall ensure that the practice is safe in the sense provided in this Act.

**Section 198**
**Further information on standards**

STUK provides further information on the standards referred to this Act which are not available in Finnish or Swedish.

**Section 199**
**Hearings on regulations issued by STUK**

Prior to issuing regulations under this Act, STUK provides the Ministry of Social Affairs and Health, the Ministry of Economic Affairs and Employment, the Advisory Committee on Radiation Safety and, to the extent necessary, undertakings and other authorities a chance to be heard.

**Chapter 22**
**Entry into force and transitional provisions**

**Section 200**
**Entry into force**

This Act enters into force on 15 December 2018. However, section 189 of the Act concerning regulatory charges will only be applicable as of 1 January 2019.

This Act repeals Radiation Act (592/1991), hereinafter referred to as the **Radiation Act of 1991**.

If the Radiation Act of 1991 is referred to elsewhere in the law, the reference shall be considered to refer to this Act.

**Section 201**
**Decrees given pursuant to the Radiation Act of 1991**

The following decrees given pursuant to the Radiation Act of 1991 shall remain in force:

1) the decree by the Ministry of Social Affairs and Health on the quality requirements for household water and on regulatory inspections (1352/2015);
2) the decision of the Ministry of Social Affairs and Health regarding STUK's charges and grounds for payment (580/1993);
3) the decree by the Ministry of the Interior on communication in emergency situations (774/2011).

**Section 202**
**Transitional provisions**

The safety licences issued and the decisions made prior to this Act's entry into force pursuant to the Radiation Act of 1991 shall remain in force on the conditions mentioned in the licences and decisions, unless otherwise provided below.

An undertaking shall draw up and deliver the safety assessment referred to in section 26 to STUK within 18 months of this Act's entry into force.

An undertaking which has, at the time this Act enters into force, a safety licence for a practice referred to in section 54, subsection 1, and a security for it, shall comply with this Act's provisions concerning a security within six months of this Act's entry into force.

A safety licence shall be applied within three months of this Act's entry into force for a practice commenced prior to this Act's entry into force and referred to in section 86, subsection 1, in which orphan sources are repeatedly handled or stored , a practice which involves exposure to natural radiation as referred to in section 148 and the road and rail transport of high-activity sealed sources. The same applies to the holding of health care or veterinary medicine X-ray equipment, provided that the undertaking does not have a safety licence for the use of equivalent equipment in the field of health care or veterinary medicine or for the installation, maintenance or remediation of such equipment.

The person named as the radiation safety officer for the safe use of radiation in a safety licence valid at the time this Act enters into force is entitled to continue as the radiation safety officer referred to in this Act in the applicable practice type-specific field of expertise.

A certificate proving the qualifications of a radiation safety officer for the safe use of radiation, issued no later than on 31 December 2019, can be accepted as the certificate proving the qualifications of a radiation safety officer in their applicable practice type-specific field of expertise in the context of the application process concerning the safety licence.

Decisions concerning the approval of training for radiation safety officer valid at the time this Act enters into force shall remain in force for the period of time prescribed in the decision, but in no case further than 31 December 2019.

A training organization other than a university may apply for changing a training programme for radiation safety officers into a training for the radiation safety officers referred to in this Act for a period of six months as of this Act's entry into force.

The undertaking shall comply with the obligation set down in this Act on using a radiation safety expert in their radiation practice no later than within 12 months of this Act's entry into force.

Whoever is entitled to use the occupational title of a medical physicist pursuant to the Health Care Professionals Act and has the qualifications for a radiation safety officer in the field of the general use of radiation in a medical field at the time this Act enters into force has the right to act as the radiation safety expert in the radiation practice of health care and veterinary medicine.

The person who, prior to this Act's entry into force, has completed a master's degree referred to in section 37, subsection 1 and worked in the position of a radiation safety officer or in some other position related to radiation protection in the field of radiation physics, radiochemistry or nuclear engineering for the use of radiation in industry or research or the use of nuclear energy for at least 24 months may apply for a certificate showing the qualifications of a radiation safety expert for radiation practices in industry and research and the use of nuclear energy fields of expertise from the Advisory Board for Radiation Safety within six months of this Act's entry into force. The Advisory Board for Radiation Safety issues a certificate proving the qualifications of a radiation safety expert to the applicant, if the qualification criteria laid down in section 37 are met. The certificate is free of charge.

An inspection concerning high-powered laser equipment based on provisions pursuant to section 44 of the Radiation Act of 1991, such as it is in Act 592/1991, prior to this Act's entry into force, shall be valid as the licence referred to in section 165 of this Act in accordance with the conditions set in the inspection, although for no later than until 31 December 2020.

An undertaking engaged in imaging with the health care equipment referred to in chapter 14 at the time this Act enters into force shall apply for an amendment to their safety licence within six months of this Act's entry into force to be able to continue the practice. STUK processes the application concerning the amendment free of charge.

An undertaking using non-ionizing radiation in the manner referred to in section 164 at the time this Act enters into force shall notify STUK of its practice within three months of this Act's entry into force. STUK processes the notification free of charge.

An undertaking shall comply with the prohibition to use an unidentified sealed source laid down in section 70, subsection 3 and the prohibition to use a more than 40-year-old sealed source laid down in section 75, subsection 4 no later than within five years as of this Act's entry into force.

A workplace referred to in section 155, subsection 1, paragraph 1 and 2, the radon concentration of which has been established, by measurements, as being higher than the reference level laid down in the provisions issued pursuant to section 160, subsection 2, paragraph 1, but no more than 400 becquerels in a cubic meter, applies the reference level given on the basis of the latter provision for a period of ten years as of this Act's entry into force.

A dwelling or other premises used by people built prior to this Act's entry into force which is not a workplace and the radon concentration of which has been found, by measurements and prior to this Act's entry into force, to be higher than the provided reference level, but no more than 400 becquerels in a cubic meter, shall ensure compliance with the provided reference level no later than in the context of the next repair measure in which a reduction of the radon concentration is practical.

A person trained to use X-ray equipment used to measure bone mineral content prior to 1 January 2000 and a health care professional who has subsequently used the equipment on a regular basis can, notwithstanding what is provided in section 115, continue to use the equipment in question in the radiation practice of the same holder of a safety licence.

The Advisory Board for Radiation Safety established prior to this Act's entry into force continues until the end of its term, after which the Ministry of Social Affairs and Health sets the Advisory Board for a fixed period of time, extending no further than 31 December 2019, to manage the task referred to in subsection 11. During the terms mentioned, the Advisory Board for Radiation Safety is subject to section 7 of the Radiation Act of 1991 and any provisions issued pursuant to it.

This Act also applies to any matters pending at STUK at the time the Act enters into force.

**Annex**

**Regulatory charges**

## 1. Charge categories and corresponding charges

The charge categories are the practice-specific charge category and the radiation source -specific charge category.

The practice-specific basic charges are:

| **Practice-specific charge category** | **Practice-specific basic charge** |
|---|---|
| A | 160 € |
| B | 400 € |
| C | 1000 € |
| D | 1500 € |
| E | 3700 € |
| F | 9500 € |
| G | 20000 € |

The radiation source -spesific sur-charges are:

| **Radiation source -specific charge category** | **Radiation source -specific sur-charge** |
|---|---|
| A | 35 € |
| B | 70 € |
| C | 120 € |
| D | 370 € |
| E | 500 € |
| F | 750 € |
| G | 1000 € |
| H | 3000 € |
| I | 5400 € |

## 2. Regulatory charge for the use of ionizing radiation

The regulatory charge for the use of ionizing radiation that requires a safety licence consists of a practice-specific basic charge and a source-specific sur-charge. If a safety licence covers more than one practice or radiation source, the regulatory charge shall be determined by adding together all the practice-specific basic charges and the radiation source-specific surcharges related to the licence.

The practice-specific charge category is determined based on the practice as follows:

| **Practice-specific charge category** | **Practice** |
|---|---|
| A | Use of sealed sources |
| | Use of X-ray appliance (does not cover radiotherapy, nuclear medicine or dental X-ray practices using a panoramic tomography or dental X-ray device to image an in-mouth image detector, nor imaging a person with other than healthcare appliance) |
| B | Trade in radiation sources |
| | Installation, maintenance and repair of radiation sources and manufacture of radiation appliances |
| | Transport of radioactive substances |
| | Practices in which orphan sources are repeatedly handled or stored |
| | Imaging a person with other than healthcare appliance |
| | Use of unsealed sources (does not apply to healthcare and veterinary medicine) |
| | Use of particle accelerators in industry and transillumination (excluding radionuclide production) |
| C | Use of particle accelerators in research and radionuclide production |
| | Receipt, treatment and storage of radioactive waste when not part of another practice |
| D | Use of unsealed sources in veterinary medicine |
| | Radiotherapy in veterinary medicine |
| E | Nuclear medicine |

The radiation source-specific sur-charge is determined based on the radiation source and its use as follows:

| **Radiation source-specific charge category** | **Radiation sources** |
|---|---|
| A | Dental X-ray appliance for imaging an in-mouth image detector |
| | Dental X-ray imaging appliance used in veterinary medicine |
| B | Seal source (other than a high activity sealed source). The charge is collected from a maximum of 100 sources. |
| | X-ray appliance (does not apply to X-ray appliance for healthcare, veterinary and industrial radiography or to X-ray appliances with separately built protection structures) |
| | Panoramic tomography device used in a dental X - ray practice |
| C | X-ray appliance for industrial radiography or with X-ray appliances with separately built protection structures (does not apply to healthcare or veterinary X-ray appliance) |
| | X-ray appliance in veterinary medicine (other than a dental X-ray appliance) |
| | X-ray appliance in healthcare (other than a panoramic tomography device for dental X - ray practice or dental X-ray device to image an in-mouth image detector) the use of which causes an effective dose of 0,1 mSv or less to the patient and no deterministic harm [1)] |
| | Particle accelerator (does not apply to particle accelerators in healthcare or veterinary medicine) |
| | Unsealed sources in a laboratory when the amount of radioactive substance to be handled at one time is less than k · 10 · exemption value [2)] |
| D | X-ray appliance in healthcare (other than a panoramic tomography device for dental X - ray practice or dental X-ray device to image an in-mouth image detector) the use of which causes an effective dose of more than 0,1 mSv but 100 mSv at the most to the patient and no deterministic harm [1)] |
| | Unsealed sources in a laboratory when the amount of radioactive substance to be handled at one time is more than k · 10 · exemption value but k · 10000 · exemption value at the most [2)] |
| | Unsealed sources in tracer tests elsewhere than in a laboratory |

| | |
|---|---|
| E | High-activity sealed source |
| | Radiotherapy appliance in veterinary medicine |
| F | X-ray appliance in healthcare (other than a panoramic tomography device for dental X - ray practice or dental X-ray device to image an in-mouth image detector) the use of which causes an effective dose of more than 100 mSv or the local or organ absorbed dose is greater than 10 Gy [1)] |
| | Unsealed sources in a laboratory when the amount of radioactive substance to be handled at one time is k · 10000 · exemption value or greater [2)] |
| | X-ray superficial radiotherapy appliance |
| G | Radiotherapy single-energy accelerator, X-ray deep radiotherapy appliance or brachytherapy appliance |
| | Radiotherapy multienergy accelerator |

1) The effective dose to a patient from a single examination or procedure, including radiation exposure due to a radiation safety deviation.
2) The factor k is determined by the method of handling the radioactive material as follows: particularly high-risk work k = 0.1, treatment using conventional chemical methods k = 1, simple treatment k = 10 and storage k = 100. If different processing methods are used in the laboratory, then the fee category of the activity is determined on the basis of the processing method leading to the highest fee.

**3. Regulatory charge for a practice causing exposure to natural radiation**

The regulatory charge for a practice causing exposure to natural radiation is collected only if the practice requires a safety licence in accordance with section 148.

The regulatory charge consists of a practice-specific basic charge. If a safety licence covers more than one practice, the regulatory charge shall be determined by adding together all the practice-specific basic charges.

The practice-specific charge category is determined based on the practice as follows:

| **Practice-specific charge** | **Practice** |
|---|---|
| B | Practice of aviation |
| C | Practice in which workers are exposed to radon |
| | Practice in which workers or the members of the public are exposed to other natural radiation than radon or cosmic radiation |
| G | Practice which causes releases of radioactive substances to the environment |

## 4. Regulatory charge for the use of non-ionizing radiation

The regulatory charge for the use of non-ionizing radiation is collected for the use of a high-power laser equipment in the practices referred to in section 167 of the Radiation Act.

The regulatory charge consists of a practice-specific basic charge and a source specific sur-charge.

The practice-specific charge is determined as follows:

| **Practice-specific charge category** | **Practice** |
|---|---|
| A | Use of high-power laser equipment (includes use of one high-power laser equipment permanently installed in one place) |

The radiation source-specific sur-charge is determined based on the radiation source and its use as follows:

| **Radiation source-specific charge category** | **Practice** |
|---|---|
| E | Movable high-power laser equipment |