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Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste, explanatory memorandum**MAIN CONTENT**

The Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste is laid down by virtue of Section 7 q of the Nuclear Energy Act (990/1987), as it is in Act 676/2015. It repeals the Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste (Y/4/2016) that entered into force on 1 January 2016.

The regulation gives the provisions concerning the safety of disposal of nuclear waste that specify the provisions of the Nuclear Energy Act. The content of the new regulation largely corresponds to the regulation repealed. Its essential aim is to make the regulation reflect the changes made to the Nuclear Energy Act and the Radiation Act. These also result in some changes to references.

In conjunction with the clarification of the Nuclear Energy Act, the authorisation to give orders on the structural radiation safety of a nuclear facility and the managing of the releases of radioactive substances has been added to the Act. Therefore, a requirement proposal on the means of limiting radiation exposure and releases has been added to the regulation. The reform of the Radiation Act (859/2018) results in the need to define the requirements specifying the assessment and monitoring of the exposure of the workers and the members of the public (Section 9, Section 28).

Provisions concerning the decommissioning license of nuclear facilities have also been added to the Nuclear Energy Act, so the implementation of decommissioning is discussed in the Act as a stage separate from operation. This results in the need to set separate requirements in the regulation for the safety of the decommissioning of a nuclear facility.

Other needs for changes relate to the clarification need of individual requirements.

The regulation is intended to enter into force on 15 December 2018.

General rationale**1 Introduction**

Within the European Atomic Energy Community (Euratom), Council Directive 2009/71/Euratom was issued on establishing a framework for the nuclear safety of nuclear facilities. After the Fukushima nuclear power plant accident, the Directive was changed in 2014 through Directive 2014/87/Euratom on the changing of Directive 2009/71/Euratom on establishing a framework for the nuclear safety of nuclear facilities (hereafter referred to as the supplement to the Nuclear Safety Directive [NSD]).

On 5 December 2013, the new Council Directive 2013/59 was issued in the EU, laying down basic safety standards for the protection against the dangers arising from ionising

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radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/42/Euratom and 2003/122/Euratom, also called the BSS Directive (Basic Safety Standards).

The new Radiation Act (859/2018), which was issued on 9 November 2018 and entered into force on 15 December 2018, and lower-grade regulations issued under it were used to implement the EU's new BSS Directive. Requirements prescribed in the Radiation Act, also concerning the use of nuclear energy, entered into force as an annexed act to the Radiation Act, and they are also applied to operations governed by the Nuclear Energy Act. The requirements of the BSS Directive, which had to be separately implemented for the use of nuclear energy and which required changes to the Nuclear Energy Act, were included in the presentation package of the Radiation Act for reasons related to technical legislative procedure, and they entered into force as an annexed act to the Radiation Act on xx December 2018.

The supplement to the Nuclear Safety Directive (NSD) was enforced through the amendment (14.12.2017/905) to the Nuclear Energy Act (990/1987) that entered into force on 1 January 2018. At the same time, updates were made to the Act's provisions on pressure equipment due to the new Pressure Equipment Act (1144/2016) that entered into force on 1 January 2017. In addition to these changes, the Act was clarified and supplemented, for example as concerns the decommissioning of nuclear facilities. Specification needs have also been observed in the assessment of the requirements of the Euratom Nuclear Waste Directive, which was issued in 2011 and enforced in Finland through the amendment to the Nuclear Energy Act in 2013. These specifications are now added to the Nuclear Energy Act.

Few new requirements at the regulatory level resulted from the Nuclear Safety Directive, because the issues had been taken into account in advance in the preparation of the requirements of the directives and the IAEA and WENRA's reference levels during the update of Government Decrees on Nuclear Power Plant Safety (733/2008) and the Emergency Response Arrangements at Nuclear Power Plants (735/2008) in 2013. In the phase of issuing the regulations, significant changes were made to the Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste (Y/4/2016) compared to the previous Government Decree (736/2008), and the requirements were harmonised with the Regulation on the Safety of a Nuclear Power Plant (Y/1/2016).

2 Current status

The principles and requirements concerning the safety of a nuclear facility are laid down in Chapter 2 a of the Nuclear Energy Act. Chapter 6 of the Act contains provisions on the principles of nuclear waste management as well as disposal and decommissioning. Until 31 December 2015, provisions specifying these requirements were included in the Government Decree on the Safety of Disposal of Nuclear Waste (736/2008).

The amendment (676/2015) of the Nuclear Energy Act transferred the authority for issuing general safety provisions to the Radiation and Nuclear Safety Authority (STUK). In connection with the amendment of the Nuclear Energy Act, previous general safety provisions issued as Government Decrees were repealed. The general safety provisions of the Radiation and Nuclear Safety Authority were issued on 22 December 2015, and

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they entered into force on 1 January 2016. The Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste was issued as part of this reform by virtue of Section 7 q of the Nuclear Energy Act.

This regulation is based on the authority for issuing regulations of a technical nature that is regulated by Section 7 q of the Nuclear Energy Act and that entered into force on 1 January 2016. Currently, the scope of STUK's authority for issuing regulations is based on the earlier Government Decrees that are subordinate to the Nuclear Energy Act.

The Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste, which entered into force on 1 January 2016, does not include legal norms on the structural radiation safety of nuclear waste facilities, radiation measurements, the managing and monitoring of the releases of radioactive substances or the assessment of the public's radiation doses.

3 Key objectives and proposals

The regulation lays down the provisions specifying the Nuclear Energy Act as regards the nuclear safety and radiation safety requirements concerning the safety of disposal of nuclear waste. The regulation shall apply to the disposal of spent nuclear fuel originating from a nuclear facility and other nuclear waste into facilities constructed into bedrock and the ground, and to radioactive waste referred to in Section 4 of the Radiation Act (859/2018) when it is disposed of in an emplacement room for nuclear waste. The proposed safety requirements concern the design of nuclear waste facilities, their operational safety, and the long-term safety of disposal of nuclear waste. Regulation Y/4/2016 noted deficiencies in the processing of nuclear waste storage facilities that are not part of a nuclear power plant. With the further specifications of the scope of the application, the regulation largely abandoned the term '*nuclear waste facility*', since it does not cover waste storage facilities. The key principle is that disposal shall be implemented so that radiation exposure which would exceed the level considered acceptable at the time of disposal cannot occur in the future, either.

The regulation replaces and updates the Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste (Y/4/2016). The update is part of the update project of the nuclear energy industry and radiation legislation.

Its essential aim is to make the Regulation on the Safety of Disposal of Nuclear Waste reflect the proposed changes to the Nuclear Energy Act. The need to change the Nuclear Energy Act is based on the national enforcement of the NSD and BSS directives and the clarification of the Act implemented at the same time. This regulation is not used to implement the NSD directive or the supplementary requirements of the Nuclear Waste Directive, because they are implemented on the Act level.

The authorisation to give orders on the structural radiation safety of the nuclear facility, radiation measurements, the managing and monitoring of the releases of radioactive substances and the estimation of the public's radiation doses has been added to Section 7 q of the Nuclear Energy Act in connection with the clarification of the Act (Section 9, Section 28). A requirement proposal on the means of limiting radiation exposure and releases has been added to the regulation.

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Provisions concerning the decommissioning license of nuclear facilities were added to the Nuclear Energy Act, so the implementation of decommissioning is discussed in the Act as a stage separate from operation. This shall be taken into account in the paragraphs on the decommissioning license of a nuclear facility and the safety of decommissioning.

4 Impacts of the proposal

The regulation presents certain requirements that are new in terms of their content, the impact of which is estimated to be minor in view of the current situation.

5 Drafting of the regulation

The regulation on the safety of disposal of nuclear waste has been drafted at the Radiation and Nuclear Safety Authority (STUK) as standard clerical work within the framework of the project (RYSÄ) that STUK established in order to guide the drafting of the regulations, to ensure coherence between the different regulations and to manage conformity to law and the layout of STUK's regulations.

Statements concerning the regulation proposal were requested with a letter dated 3 November 2017 from the Ministry of Employment and the Economy, the Ministry of Social Affairs and Health, the Ministry of the Environment, the Ministry of the Interior, the Ministry for Foreign Affairs, Fortum Power and Heat Oy, Teollisuuden Voima Oy, Fennovoima Oy, VTT Technical Research Centre of Finland Ltd, the Finnish Safety and Chemicals Agency, the Geological Survey of Finland, Talvivaara Sotkamo Oy, the Rescue Services of Satakunta and Eastern Uusimaa and the Police Departments of Southwest Finland and Eastern Uusimaa.

Statements were received from Fortum Power and Heat Oy, Teollisuuden Voima Oyj, Posiva Oy, Fennovoima Oy, VTT Technical Research Centre of Finland Ltd, the Geological Survey of Finland, the Ministry of Employment and the Economy, the Rescue Services of Satakunta and the Police Department of Southwest Finland.

The following parties reported that they had no statements or comments on the draft: the Ministry of the Environment, the Ministry of the Interior and the Finnish Safety and Chemicals Agency.

Many of the same comments were received on the Radiation and Nuclear Safety Authority regulations on the Safety of a Nuclear Power Plant (Y/1/2018) and the Safety of Disposal of Nuclear Waste (Y/4/2018), and they have been processed together. The statements demanded a clear line between the application of the waste regulation (Y/4/2018) and the Regulation on the Safety of a Nuclear Power Plant (Y/1/2018). Furthermore, it was not always clear which requirements concerned nuclear waste facilities, which concerned disposal facilities and which concerned both. The requirements concerning the processing of spent fuel were also commented on. As in the case of the safety regulation, the statements commented on the consistency between the Act's new requirements on the licensee's responsibility for subcontractors and equivalent requirements already existing in the regulation. The introduction of the decommissioning licence into the law results in gimmickry in the regulation in regard to

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the disposal facility: the decommissioning of a disposal facility is impossible because of the relating definition, and only a closure license is granted to it.

On the basis of the statements, the scopes of application of regulations Y/1/2018 and Y/4/2018 were clarified in the regulations and in the explanatory memorandums. The contents of the requirements of the regulation on the licensee's responsibility for subcontractors were reviewed, and the requirements overlapping with the Act were removed. Terminology was reviewed regarding the use of the terms *nuclear facility* and *nuclear waste facility*. The term '*nuclear waste facility*' was abandoned, since nuclear waste storage facilities are not covered by the definition. *Nuclear waste processing facility* refers to above-ground facilities. *Disposal facility* refers to facilities intended exclusively for final disposal, primarily underground. In addition, the different variations of the terms *nuclear safety* and *radiation safety* were replaced by the term *safety* whenever possible. The issue is clarified in section "*Overall safety of a nuclear facility*" of the explanatory memorandum.

Statements regarding draft 4 of the regulation proposal were requested from the Advisory Committee on Nuclear Safety and the Advisory Committee on Radiation Safety with letters dated 28 February 2018. In its statement issued on 6 April 2018, the Advisory Committee on Nuclear Safety states that the draft prepared by STUK for the safety regulation regarding the disposal of nuclear waste presents a clear summary of the essential requirements concerning the safety of disposal of nuclear waste and the related procedures to be followed. In addition, the appendices to the statement of the Advisory Committee on Nuclear Safety included detailed comments aimed at specifying the requirements of the regulation. In its statement issued on 9 May 2018, the Advisory Committee on Radiation Safety states that the regulation takes into account the amendment to the Nuclear Energy Act (905/2017) that entered into force on 1 January 2018 and the proposed amendments to the Radiation Act in a sufficient manner. The Advisory Committee on Radiation Safety considers it worthwhile that the regulation takes into account the possible future development of nuclear waste management by including the disposal facilities of very low-level waste in the scope of the regulation. The Advisory Committee on Radiation Safety also appreciates that the nuclear waste management collaboration pursued in the field is evident in the regulation.

In spring 2018, the Steering Committee of the RYSÄ-project decided that the final draft of the regulation would be published on the STUK website for public comments during the summer. No comments were offered by the public, but some further comments concerning clarification of some of the requirements were received from licensees Teollisuuden Voima Oyj and Posiva Oyj.

6 Regulation's entry into force

The regulation shall enter into force at the same time as the amendment to the Nuclear Energy Act (859/2018) that enters into force as an annexed act to the Radiation Act (862/2018) on 15 December 2018.

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Detailed rationale**Overall safety of a nuclear facility**

The most important objective of the safety design of nuclear facilities is to prevent large releases of radioactive substances into the environment. This requires ensuring the functions at a nuclear facility, the failure of which could result in a significant release of radioactive substances or radiation exposure of personnel at the facility. An operational occurrence or accident shall be detected quickly, and the aggravation of any event shall be prevented. The criticality safety and residual heat removal of spent fuel shall be ensured during storage, and damages to the fuel rod cladding shall be prevented during processing and storage. Effective emergency response arrangements are used to control accident situations at the nuclear facility and to further minimise their consequences for the environment and people. The most important objective of the disposal of nuclear waste is to isolate nuclear waste from the living environment for a sufficiently long time regarding the amounts and half-lives of the radioactive substances contained by it in order to keep the radiation doses to people and animals low.

Other safety objectives relating to the use of nuclear energy include keeping nuclear facilities safe as radiation workplaces and controlling other nuclear commodities safely and appropriately in accordance with the obligations of international agreements.

The safety of nuclear facilities is affected by technology and also by the activities of people and organisations.

With security arrangements, licensees secure nuclear facilities and nuclear commodities against illegal activities, so the implementation of the security arrangements ensures for its part the attainment of the above-mentioned objectives.

Section 1 Scope

The regulation shall apply to the disposal of spent nuclear fuel and other nuclear waste, originating in a nuclear facility, into facilities to be constructed in bedrock and into the ground. The regulation shall also apply to processing and storage facilities for nuclear waste that are not part of a nuclear power plant and to which, therefore, the Radiation and Nuclear Safety Authority's Regulation on the Safety of a Nuclear Power Plant (Y/1/2018) shall not apply. Out of the existing nuclear facilities, the regulation shall apply to the licensees' disposal facilities, the research reactor as concerns nuclear waste management, the future encapsulation plant and disposal facility for spent nuclear fuel, and any possible storages for low and intermediate level waste that are not a part of a nuclear power plant. The regulation is not intended to apply to the interim storage of spent nuclear fuel at nuclear power plants, or to cases where a licence applicant or licensee proposes the construction of an interim storage for spent nuclear fuel outside of the nuclear power plant area.

The regulation shall also apply to radioactive waste referred to in the Radiation Act (859/2018) if it is handled at a nuclear facility or disposed of in a disposal facility for nuclear waste referred to in Paragraph 1.

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In the scope, the interfaces of this regulation and regulation Y/1/2018 have been elaborated. If the amount of spent nuclear fuel stored at the nuclear waste processing facility is greater than 100 tonnes of uranium, regulation Y/1/2018 shall be applied to it in the same manner as to interim storage facilities for spent nuclear fuel. If the amount of spent nuclear fuel is less than 100 tonnes of uranium, this regulation shall be applied. This regulation shall also be applied to storage and handling facilities of low and intermediate level nuclear waste, if they are not part of the nuclear power plant.

Section 2 Definitions

The key terms and definitions used in the regulation are presented in Section 2 of the regulation.

The definitions take into account the changes made to the Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant Y/1/2018 (the so-called safety regulation).

Section 3 Demonstration of a nuclear waste facility's compliance with safety requirements

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

1) demonstration of compliance with the safety requirements of a nuclear facility.

Pursuant to the Nuclear Energy Act, compliance with requirements concerning the safety of a nuclear facility shall be proven reliably and the overall safety of the facility shall be assessed at regular intervals. A licence for the construction or operation of a nuclear facility may be granted if the plans concerning the facility meet the safety requirements in accordance with the Act.

Pursuant to the Nuclear Energy Act, for the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology.

The IAEA general safety requirements [1] require that all methods and computer software used for safety assessment must be qualified for their purpose.

Paragraph 5 on the assessment of the safety of decommissioning has been added to the section. The safety of decommissioning is assessed already during the operating stage of a nuclear facility in decommissioning plans made every six years, the accuracy of which develops as the facility approaches the end of its service life. Safety shall be assessed in detail when applying for a decommissioning license based on the final decommissioning plan of the nuclear facility. According to Section 7 e of the Nuclear Energy Act, the overall safety of a nuclear facility shall be assessed at least once every 10 years. However, the overall safety of a facility for the large-scale disposal of nuclear waste shall be assessed at least once every 15 years.

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Section 4 Long-term safety of the disposal of nuclear waste

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 1) demonstration of compliance with the safety requirements of a nuclear facility, and
- 2) long-term safety of the disposal of nuclear waste.

The IAEA requirements [2] and WENRA reference levels [3] provide instructions for the assessment of the long-term safety of disposal facilities.

Pursuant to the Nuclear Energy Act, compliance with requirements concerning the safety of a nuclear facility shall be proven reliably and the overall safety of the facility shall be assessed at regular intervals. A licence for the construction or operation of a nuclear facility may be granted if the plans concerning the facility meet the safety requirements in accordance with the Act.

Pursuant to the Nuclear Energy Act, for the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology.

Long-term safety should be assessed upon selecting the disposal site, since the characteristics of the disposal site are very significant in terms of the long-term safety of the disposal of nuclear waste. The detail level of this safety assessment shall take into account the status of the facility's design. A concept-level safety assessment is performed during site selection, and it is then developed and specified as the licensing and design proceed. Long-term safety is assessed for the last time when the licensee has performed the disposal of nuclear waste in accordance with Section 33 of the Nuclear Energy Act and prepares for the final closure of the disposal facility.

The time period discussed in the safety assessment shall extend as far into the future as the disposed waste can be seen to constitute a risk to the safety of people and the living environment. This time period may be different for different disposal facilities, depending on the volume and characteristics of the nuclear waste disposed of in them.

The change to the section specifies the nuclear facility licensing stages in which the long-term safety of final disposal shall be assessed.

Section 5 Safety classification

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 2) safety classification of a nuclear facility.

The proposed safety classification is similar to the safety classification for nuclear power plants, a requirement similar to which is included in the IAEA safety requirements [4]

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and [5] and in the reference levels [7] that WENRA updated and published due to the Fukushima accident.

During operation, the dispersion of radioactive substances from the facility into the environment is prevented by means of barriers based on the defence-in-depth principle and safety functions mitigating the consequences of an accident that are designed to keep the barriers intact. The safety classification is divided into a structural safety classification that is based on the barriers for radioactive substances, and a functional safety classification that is based on the safety functions that work to ensure the integrity of the barriers.

The purpose of the functional safety classification is to define the safety functions of the nuclear facility. The systems, structures and components related to the safety functions shall be divided into safety classes in a manner where their safety class corresponds to the safety significance of the function whose implementation they participate in. A safety function may be a combination of several different systems and their related auxiliary systems.

The safety class is used to define the quality requirements for the design, manufacturing and installation of each item and the assessments, inspections and tests related to the verification of quality, including environmental qualification of equipment. Furthermore, the scope of regulatory control is based on the safety classification.

Safety functions related to long-term safety refer to the functions brought about by the physical and chemical characteristics and processes of engineered and natural release barriers, which are intended for isolating the nuclear waste from the bedrock or the living environment. The components of the final disposal system shall be classified on the basis of their safety significance while considering the significance of each component for long-term safety.

Section 6 Ageing management

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

3) ageing management of a nuclear facility

Ageing management covers the systems, structures and components of both the nuclear waste processing facilities and disposal facilities during their operating stage. During operation, the systems, structures and components are subjected to stresses and environmental effects that may reduce their operability. Preparations for this are made already at the design stage by defining the best structural decisions for the operating conditions and high quality requirements. Maintaining operability with the defined safety margins even during operational occurrences and accidents shall be ensured by means of tests and analyses before the commissioning.

During operation, the operability of systems, structures and components must be ensured by means of periodic inspections, tests and service. Most equipment is designed to be replaced during the service life of the facility before any changes affecting

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operability can occur. Ageing management in terms of the overall service life of the facility is important for systems, structures and components that are designed to last until the decommissioning of the facility, and the ageing of these systems shall be monitored with particular care and any problems shall be anticipated well in advance before they can jeopardise the safety of the facility. Ageing management also includes the research of ageing phenomena and the utilisation of operating experience received from similar equipment at other nuclear facilities.

The requirements related to systems, structures and components may also change during the service life of the nuclear facility, and the available technology may develop. This may lead to the systems, structures and components no longer meeting the level of requirements. Manufacturers or other actors may also discontinue their operations. This type of obsolescence shall be managed by taking the necessary actions if any systems, structures or components are in danger of becoming obsolete.

The replacement of systems, structures and components by new or similar technology, as well as repairs and modifications, shall be carried out in a systematic manner. The design basis shall be followed and the effects on the other systems, structures and components of the nuclear facility shall be analysed.

The requirements related to the prevention and control of ageing have been inserted into a separate Paragraph 2.

Section 7 Management of human factors relating to safety

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

4) management of human factors relating to safety at a nuclear facility

People, technology and the organisation form a socio-technical system whose operation affects the safety of the nuclear facility throughout its life cycle. The operation of the socio-technical system naturally includes variation that can be manifested in different ways, for example, in failures and errors, in milder defects and cutting corners or in unplanned activity. Through their activities, people may also compensate for the defects of other system parts or optimise parts of the operation. Good design of technical solutions and the organisation's practices takes into account the characteristics of human activity and uses management procedures for human factors to make solutions that are tolerant of error and guide people towards good operations. The management procedures for human factors aim to enable the success of human activity and avoid the impacts of the deficiencies of human activity on the safety of the nuclear facility. As concerns safety, particularly dangerous situations are those where the same errors are made in parallel subsystems of safety systems or in redundant systems. The management of human factors includes systematic procedures observed in system design, placement, use and maintenance in order to prevent common cause failures due to human action. The management of human factors is based on multidisciplinary knowledge of the operation of the socio-technical system. In addition to technical expertise, it utilises information on the actions of people and the organisation and the interaction between people and technology.

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In the proposed change, the concept 'human error' has been replaced by the concept 'human factor'. The impact of human action on safety can be either direct or transferred, and the concept of error gives too simple a picture of the effect mechanism. Human factors can be identified on individual and group levels and from the point of view of the organisation and culture. The operating environment, the norms of society and values also affect human factors.

The requirements of the section have been specified to concern nuclear facilities, which means all facilities within the scope of the regulation. Decommissioning has been added to the section. Human factors must also be taken into account during the planning of decommission and during decommission.

Section 8 General design bases for the safety of a nuclear facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 10) safety of handling and storage of radioactive waste at a nuclear facility;
- 25) design requirements for the safety of a nuclear facility; and
- 26) long-term safety of the disposal of nuclear waste.

General requirements concerning disposal are provided, among other places, in the IAEA requirements [2] and WENRA reference levels [3]. Disposal shall be implemented in stages, with particular attention paid to aspects affecting long-term safety. The planning of the construction, operation and closure of a disposal facility shall account for the reduction of the activity of nuclear waste through interim storage, the utilisation of high-quality technology and scientific research data, and the need to improve the understanding of the performance and long-term safety of the barriers via investigations and monitoring.

The optimisation of the disposal solution is required in particular as regards the safety aspects and timing. The different stages of implementation for the disposal are (1) site studies (which may require the construction of an underground research facility) and the other necessary research, development and design work for the disposal system and the nuclear facility, (2) the construction of the disposal facility, (3) the final processing of the waste (including, for example, the encapsulation of spent fuel assemblies) and the transfer of the waste packages into the emplacement rooms, (4) closing the emplacement rooms and other underground facilities, and (5) possible supervisory activities after the operation of the disposal facility has ended.

The design and implementation of the processing and storage of nuclear waste processed by and accumulated at the nuclear facility shall apply a holistic approach that takes into account any dependencies between the different stages of nuclear waste management. The requirement refers to the timely execution of the different stages of disposal while taking into account the reduction in activity and heat generation in the waste, the technological maturity of the methods, the adequacy of available research data, the need to ensure the operational safety of the nuclear facility by means of

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supervision activities, and other relevant factors. Avoiding unnecessary delays in the disposal activities is an important related principle, which is included in the general convention on spent nuclear fuel and radioactive waste management (2011/70/Euratom).

Section 9 Safety of workers and the members of the public during the operation of the facility

Paragraph 1 of the section does not use the term *maximum value* because the Radiation Act uses terms *dose limit* and *dose constraint* instead of this term.

The limitation of public and worker radiation exposure is governed by the Nuclear Energy Act, the Radiation Act and the related Nuclear Energy Decree and Government Decree on ionising radiation. Paragraph 1 of the section originally presented references to these. The reference to Section 7 c of the Nuclear Energy Act has been retained, and a reference to Subsection 1(1) of the new Section 2 a, from which the dose limits are taken, has been added. The references to the paragraphs concerning dose limits (maximum values) in the Nuclear Energy Decree and the Radiation Decree have been removed because they are also included in the Nuclear Energy Act.

The authorisation to give orders on the structural radiation safety of the nuclear facility, radiation measurements, the managing and monitoring of the releases of radioactive substances and the assessment of the public's radiation doses has been added to Section 7 q of the Nuclear Energy Act in connection with the clarification of the Act. Paragraph 2 added to Section 9 of the regulation provides more detailed regulations on the limiting of radiation exposure pursuant to Section 7 q of the Nuclear Energy Act, particularly on the structural radiation safety of the nuclear facility and the managing of the releases of radioactive substances in accordance with Section 7(20) of the Nuclear Energy Act. The paragraph lists the main means that can and must be used to limit public and worker radiation exposure and emissions of radioactive substances. STUK's YVL Guides present detailed requirements relating to these.

Section 10 Radiation exposure caused by the disposal after closure

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 1) demonstration of compliance with the safety requirements of a nuclear facility, and
- 2) long-term safety of the disposal of nuclear waste.

The long-term radiation impacts of disposal are discussed in the IAEA' safety requirements concerning disposal [2] and in the ICRP guidelines [8]. The dose limits and constraints are moved from Government Decree 736/2008 to the Nuclear Energy Decree (161/1988).

The section does not use the term *maximum value* because the Radiation Act uses terms *dose limit* and *dose constraint* instead of this term.

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Section 11 Taking account of rare events during the assessment of the long-term safety of disposal

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 1) demonstration of compliance with the safety requirements of a nuclear facility, and
- 26) long-term safety of the disposal of nuclear waste.

The long-term radiation impacts of disposal are discussed in the IAEA safety requirements concerning disposal [2] and in the ICRP guidelines [8]. The proposed section sets targets for the safety assessment regarding the evaluation of the radiation safety of rare events impacting long-term safety that increase radiation exposure due to the waste placed in disposal. These events may include, for example, bedrock sample drilling that hits a waste package, the boring of a deep well near the emplacement rooms or the creation of a bedrock displacement that intersects the emplacement room. Radiation exposure caused by rare events shall be assessed whenever possible. If the quantitative analysis of the probabilities and consequences of such events is not possible, the text of the section allows for using qualitative methods to assess the significance of the events.

Section 12 Siting of nuclear facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 5) safety of the site of a nuclear facility

The site of a nuclear facility is discussed in the IAEA safety requirements [5] and [2], for example. In the siting of a nuclear facility, the aim is to protect the facility against external threats as well as to minimise any environmental detriments and threats that might arise from it. Section 31 of this regulation presents the principles that guide the siting of a disposal facility.

The normal operation of the nuclear facility or anticipated operational occurrences do not limit land use outside of the facility area. In the environment surrounding the nuclear facility, however, precautions in the form of land use and public protection plans shall be taken with a view to the possibility of a postulated accident and a design extension condition. This means, among other things, that facilities or population centres where the necessary protective measures, such as sheltering indoors or evacuation, would be difficult to implement, shall not be placed in the vicinity of the nuclear facility. In the facility's vicinity, no activities may be carried out that could pose an external threat to the facility. No activities that might adversely affect the geological environment of the disposal facilities are allowed in their vicinity.

Prior to the licensing procedure proper, the environmental effects of the nuclear facility project are studied and evaluated by environmental impact assessment (EIA). The EIA

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procedure is governed by the Act on Environmental Impact Assessment Procedure (252/2017) and the Government Decree on Environmental Impact Assessment Procedure (713/2006), and it also involves an appropriate international hearing of countries near Finland in accordance with the convention on the assessment of cross-border environmental impacts (Espoo convention, Finland's Statute Book No. 67/1997). The Land Use and Building Act (132/1999) and Decree (895/1999) also contain provisions regarding zoning that guides the use of land areas and construction.

Section 13 Defence-in-depth

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

6) defence-in-depth of a nuclear facility

The requirement for defence-in-depth is included in the safety regulations for nuclear power plants, and it is applied to nuclear facilities while taking into account the lesser hazard caused by the facilities. The three first levels of defence defined in the regulation on the safety of nuclear power plants, along with the final level, are applied to nuclear facilities. Accidents similar to severe reactor accidents are not possible at nuclear facilities within the scope of this regulation, since the amount of spent nuclear fuel handled and stored at a nuclear waste facility at any given time is limited and the activity volumes of other radioactive substances are smaller than at nuclear power plants. The IAEA safety requirements for nuclear facilities [5] also include requirements concerning this matter. This section concerns the operation stage of a nuclear waste facility, but not the time period following the closure of a disposal facility.

The section requires that the safety of the nuclear facility be ensured by applying the functional defence-in-depth. The functional defence-in-depth safety principle refers to ensuring the safety of nuclear facilities by using consecutive, redundant functional levels that ensure the integrity of the technical release barriers for the dispersion of radioactive substances. The functional levels involve safety functions and systems and equipment implementing them.

The primary goal for the design of nuclear facilities is to prevent operational occurrences during normal operation. To this end, high quality requirements are applied to the design, manufacturing, installation and service of equipment and the operation of the facility. Equipment are designed with high safety margins, their condition is monitored during operation and appropriate instructions are followed during their service. The personnel responsible for the safe operation of the nuclear facility shall be trained for their duties and the organisation shall have a high level of safety culture.

Notwithstanding the careful design and operation of the nuclear facility, preparations for operational occurrences and accidents are made by means of safety functions that are designed to detect disturbances and accidents and mitigate their consequences. This includes ensuring the integrity of the release barriers for radioactive substances, limiting the dispersion of radioactive substances and constraining their releases and limiting the radiation exposure of the members of the public and personnel. The appropriate design of the safety functions (defence-in-depth, redundancy, diversity and separation) aims to

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ensure that the probability of accidents leading to large releases of radioactive substances is very small.

As the final level of the defence-in-depth safety approach, preparations are made for the mitigation of the consequences of an accident by applying different accident management methods and emergency and rescue arrangements during situations where substantial amounts of radioactive substances have been released into the environment.

The most significant change in the requirement is the consideration of design extension conditions at nuclear facilities handling spent nuclear fuel. At nuclear waste facilities, these events are mostly possible as a result of rare common cause failures. The inclusion of design extension conditions in the regulation also requires that a corresponding dose limit be defined in the Nuclear Energy Decree.

Paragraph 2 has been specified for the scope, and the word 'also' has been removed from level 3 requirement text so that, in justified situations, the management of accident situations does not require both automatic and manually actuated functions. Paragraph 3 has been divided into separate requirements, as in the safety regulation.

Section 14 Technical barriers for preventing the dispersion of radioactive substances

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

7) engineered barriers for preventing the dispersion of radioactive substances from a nuclear facility

Technical barriers for preventing the dispersion of radioactive substances are discussed in the IAEA safety requirements [5], for example. The section requires ensuring safety by applying the principle of structural defence-in-depth, i.e. structural levels that aim to prevent the dispersion of radioactive substances. The levels based on barriers for radioactive substances are related to the reliability and leak tightness of mechanical structures and equipment. At a nuclear facility, the dispersion of radioactive substances can mostly be prevented by means of careful handling, maintaining the integrity of the spent nuclear fuel and waste packages during handling, and ventilation solutions.

Section 15 Safety functions and provisions for ensuring them

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

8) safety functions of a nuclear facility and ensuring them

Notwithstanding the careful design and operation of the nuclear facility, preparations for operational occurrences and accidents are made by means of safety functions designed to detect disturbances and accidents and mitigate their consequences, i.e. ensure the integrity of the release barriers for radioactive substances.

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The handling of spent nuclear fuel at nuclear facilities shall be planned in a manner where a loss of power supply will not jeopardise safety.

Paragraph 4 has been harmonised with the safety regulation by separating mechanical damage caused as a result of processing from criticality and the loss of cooling, which shall in practice be eliminated.

In the 2018 update, Paragraph 4 was divided into three independent requirements to facilitate the management of requirements. At the same time, the protection requirements for spent nuclear fuel were more specifically targeted to the fuel cladding. If the cladding remains unbroken during the processing of spent fuel, no releases occur.

Paragraph 5 was removed during the 2018 update because the same safety level is already reached based on Section 15(1).

Section 16 Safety of nuclear waste processing and storage

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 9) safety of fuel handling and storage at a nuclear facility, and
- 10) safety of handling and storage of radioactive waste at a nuclear facility

Section 3 of the Nuclear Energy Act defines nuclear waste as materials, objects and structures that have become radioactive in connection with or as a result of the use of nuclear energy, have been removed from use, and require special measures because of the hazard arising from their radioactivity. The regulation further defines nuclear waste as waste generated during the operation and decommissioning of a nuclear facility whose activity concentration exceeds the limiting values that the Radiation and Nuclear Safety Authority has defined in its Guide.

Waste that exceeds the limiting values shall be managed as nuclear waste. The dependencies between the different stages of the generation and management of nuclear waste shall be considered. Waste shall be sorted and classified in a manner that allows their further processing in a safe and appropriate manner. Generally, the goal of further processing is to minimise the volume of waste and to bring the waste to a state that is stable in terms of storage and disposal. The most common processing methods include cutting and compressing the waste, solidification of liquid waste and packaging waste inside containers. Waste classification and limit values set for waste classes are used, for example, in the assessment of whether the waste batch in question is suitable for the packing and disposal solutions in use or whether exceptional solutions are needed, as in the case of damaged nuclear fuel assemblies, for example.

When the immediate disposal of the waste is not possible, it shall be stored inside a storage facility located at the nuclear facility whose conditions are appropriate in terms of safety and the preservability of the waste packages. A licensee under a waste management obligation who intends to deliver nuclear waste to a handling, storage or disposal facility of another licensee shall agree with that licensee on the acceptable

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handling and packing of the waste in order to ensure that the waste is handled and packed in a manner that meets the acceptability criteria for waste and waste packages at the receiving nuclear facility. The extension of the requirement is due to the new WENRA reference levels of nuclear waste processing from 2018.

Paragraph 2 was repealed because the change to the scope of the regulation implements the content of the requirement.

Section 17 Protection against external hazards affecting safety

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

11) protection against external hazards affecting the safety of a nuclear facility

External hazards are discussed in the IAEA' requirements [5] and WENRA reference levels [11], for example. External events at a nuclear facility may compromise the safety of the nuclear facility. They may compromise the integrity of the systems, structures and components related to safety functions, cause an operational occurrence or an accident or prevent safety functions from being executed. Such hazards include various weather phenomena (such as high or low temperatures, high winds, blizzards, lightning), earthquakes, high sea level (flooding) and unlawful and other unauthorised activities compromising nuclear safety, including an aircraft crash. These phenomena and hazards shall be taken into account during the design of the facility. This can be achieved by taking into account the loads and interactions caused by different events in the design of the systems, structures and components related to safety functions and by utilising the different means of safety design (defence-in-depth, redundancy, diversity and separation). In Paragraph 1, 'safety functions' has been changed to 'safety'.

Section 18 Protection against internal hazards affecting safety

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

12) protection against internal hazards affecting the safety of a nuclear facility

Internal hazards are discussed in the IAEA requirements [5] and WENRA reference levels [11], for example. The systems related to safety functions shall be protected against internal hazards by following the same principles as were presented in Section 17 regarding external hazards. Internal hazards may include, for example, fire, flood, explosion, electromagnetic radiation, drop of heavy objects, rock slides and other possible internal hazards. The safety functions shall be appropriately protected against the hazards listed above, at a minimum, by utilising the methods of safety design (defence-in-depth, redundancy, diversity and separation). In Paragraph 1, 'safety functions' has been changed to 'safety'.

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Taking into account unlawful and other unauthorised activities compromising nuclear safety has been added to the internal events observed in the design has been added to the internal events observed in the design.

Section 19 Safety of monitoring and control of the nuclear waste facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

13) safety of monitoring and control of a nuclear facility

The monitoring and control of a nuclear facility is discussed in the IAEA safety requirements [5], for example. The persons operating the nuclear facility shall have access to equipment that provides information regarding the state of components and systems that are important in terms of the safety of the nuclear facility.

During the early stages of disturbances and accident situations, the nuclear facility shall be equipped with automatic systems that trigger the safety functions when necessary and control and monitor their operation during operational occurrences in order to prevent accidents.

Section 20 Taking the safety of the decommissioning of a nuclear facility into consideration in design, and the safety of the decommissioning of a nuclear facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

24) taking the safety of the decommissioning of a nuclear facility into consideration in design, and the safety of the decommissioning of a nuclear facility

The decommissioning of a nuclear facility is discussed in the IAEA safety requirements [9], for example. The design of a nuclear facility shall take account of the radiation protection requirements of the decommissioning of the facility. Numerous arrangements that are useful for the decommissioning are equally important for radiation protection and waste management during the operation of the facility. These include selecting structural materials in a manner that makes surfaces easy to decontaminate, for example.

The activity concentrations that will be accumulated by the structures and components of a nuclear facility shall be assessed during the design stage of the nuclear power plant. This allows for simplifying the design of the plant unit's decommissioning.

The nuclear facility's room arrangements are also important in terms of the facility's decommissioning and major repair projects. They should be designed in a manner that simplifies the repair and removal of large components, the appropriate handling of components and structures that may become contaminated by radioactive substances, and the decontamination of systems.

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As a general term, decommissioning also covers the management of the waste created during it to the extent intended, so 'waste management' has been removed as unnecessary.

Section 21 Safety of the closure of the disposal facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

26) long-term safety of the disposal of nuclear waste.

The closure of a disposal facility is discussed in the IAEA safety requirements [2] and WENRA reference levels [3] and [10], for example. The design of the disposal facility shall take into account the safe closure of the facility after its operation has ended. The disposal facility shall be designed, constructed and operated in a manner that allows it to be permanently closed without jeopardising long-term safety. For example, the methods for excavating the rooms inside bedrock shall be selected in a manner where the damage caused by the excavation does not significantly impair long-term safety.

Section 22 Safety of the construction of a nuclear facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

14) safety of the construction of a nuclear facility

The construction of a nuclear facility is discussed in the IAEA requirements [2] and [5] and WENRA reference levels [3] and [11], for example. The basis for the safety of a nuclear facility is laid down during the construction stage, and any errors made at this time may jeopardise the safe operation of the facility and cause unnecessary problems during operational occurrences and accident situations. To this end, the key task of the holder of a construction licence for a nuclear facility shall be to ensure that safety has been appropriately considered during the construction of the nuclear facility.

The holder of the construction licence shall ensure that the nuclear facility is constructed and implemented in conformity with the safety requirements and using approved plans and procedures. The construction licence holder's personnel, at different levels of the organisation, shall be aware of the requirements related to the facility's nuclear safety and acknowledge the safety significance of their tasks. The licensee shall also ensure that the other organisations participating in the construction of the nuclear facility follow the safety requirements related to nuclear safety and understand their significance. The responsibilities at the different levels of the licensee's organisation shall be clearly defined and work shall be performed according to written instructions where safety has been appropriately considered. Furthermore, work shall be documented. Paragraph 3 has been removed, because the requirement was included in the Nuclear Energy Act in connection with the amendment (905/2017).

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Section 23 Safety of the commissioning of a nuclear facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

15) safety of the commissioning of a nuclear facility;

The commissioning of a nuclear facility is discussed in the IAEA requirements [2] and [5] and WENRA's reference levels [3] and [11], for example. The purpose of commissioning is to demonstrate that the facility is operating according to plan and that the operating instructions are appropriate. During the commissioning of a nuclear facility, a detailed plan is drawn up on how to demonstrate the compliance of the operation of the facility's systems, structures and components. The licensee uses these tests to demonstrate that the entire facility and, in particular, the systems important in terms of safety are compliant with the design bases.

Before transferring to the commissioning stage, the nuclear facility shall have an appropriate operating organisation, a sufficient number of professional operating personnel and operating instructions that are suited for their purpose. The requirements concerning the organisation and personnel have been removed from Paragraph 2, because the requirements are presented in more detail in Section 38 and, according to Section 36 of the Nuclear Energy Decree, the description concerning the organisation and personnel shall be presented as part of the operating licence application. The requirement that the commissioning procedures shall be planned and instructions shall be provided has been added to Paragraph 1.

Section 24 Safety of operation

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

16) safety of the operation of a nuclear facility

The operation of a nuclear facility is discussed in the IAEA requirements [2] and [5] and WENRA reference levels [3] and [11], for example. The basis for the original first paragraph of this section is Section 7 f of the Nuclear Energy Act, according to which safety shall take priority during the operation of a nuclear facility and the licensee shall be responsible for the operation of the nuclear facility in compliance with the safety requirements. Paragraph 1 has been removed because the operating organisation is not the same as the licensee responsible for safety.

The operators of the nuclear facility shall be assisted by equipment that provide sufficient information concerning the normal operational state of the nuclear facility and any deviations thereof as well as updated written procedures that allow the facility to be safely controlled and monitored. The operators shall also have access to equipment that can be used to monitor the implementation of safety functions and the progress of an accident during operational occurrences and accident situations. Furthermore, procedures for the identification and control of incidents shall be available to assist the

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operators during operational occurrences and accident situations (Paragraph 3). The documentation requirement concerning significant events was put into a separate paragraph (Paragraph 4).

Repair and maintenance will need to be carried out during facility operation in order to ensure the operating condition of the facility. For the avoidance of human errors, any service and repair work shall be based on written orders and instructions.

Operational activities take place at the nuclear facility during operation and different events affecting safety also occur. In order to analyse these situations after they have occurred, the facility shall have in place procedures for recording the evolution of these scenarios.

A new Paragraph 5 concerning plant modifications was added. Modifications to a nuclear facility can be designed for different reasons during operation. The holder of the operating license shall ensure that these modifications are designed and implemented in conformity with the safety requirements and using approved procedures.

Section 24 a Safety of decommissioning

Because of the addition of the provisions concerning the decommissioning license of nuclear facilities in the Nuclear Energy Act, it is necessary to set separate requirements in this regulation for the decommissioning license phase of nuclear facilities and the safety of decommissioning.

There shall be plans and procedures for decommissioning that ensure the maintaining of safety at the facility in different phases of decommissioning. During decommissioning, there shall be enough operators and other personnel at the facility in accordance with Section 25.

Section 25 Taking operating experience and safety research into consideration in order to improve safety

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

17) taking operating experience and safety research into consideration in order to improve the safety of a nuclear facility

Operating experience activities are discussed in the IAEA requirements [2] and [5] and WENRA reference levels [3] and [11], for example. All safety-significant operational events shall be investigated for the purpose of identifying the root causes as well as defining and implementing the corrective measures. The safety of the nuclear facility is ensured by systematically monitoring the condition of the facility and the operating experience received from it, in order to repair any defects and correct design errors by means of maintenance and/or modifications.

For the enhancement of safety, the licensee shall systematically monitor and assess operating experience from its own nuclear facility and from other facilities, the results of

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safety research and technical developments. The components and structures of a nuclear facility will age during operation, regardless of careful maintenance. Safety research also continuously provides new information. The starting point for the operational supervision of the nuclear facility is to ensure that the condition of the facility remains compliant with the design bases and that operating experience and advances in the fields of science and technology are taken into account during the further improvement of the facility's safety.

Monitoring operating experience and the results of safety research will also offer valuable information concerning events that may not have been considered during the basic design of the facility. Considering these events will lead to safety improvements and they shall be taken into account insofar as this is possible in view of the technological aspects.

To facilitate the management of requirements, Section 25 was divided into three paragraphs in the 2018 update.

Section 26 Operational Limits and Conditions

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

18) Operational Limits and Conditions of a nuclear facility

Operational Limits and Conditions are discussed in the IAEA requirements [5] and WENRA reference levels [3] and [11], for example. The Operational Limits and Conditions are a key document in terms of the operation and supervision of the nuclear facility. The licensee shall operate the facility in compliance with the regulations set in the Operational Limits and Conditions, and compliance with them shall be monitored and any deviations reported.

The Operational Limits and Conditions set out the specific requirements concerning different systems and equipment that are used to ensure the operation of the facility in compliance with the design bases and safety analyses. These requirements include, for example, the requirements concerning the operability of systems and maximum allowable times for equipment repair during the operation of the facility. Requirements and limiting values are also laid down for the system process variables.

Functional tests repeated at regular intervals are used to ensure the functionality of the systems and equipment of the nuclear facility. The tests important for safety and their performance intervals have also been defined in the Operational Limits and Conditions.

The Operational Limits and Conditions are also needed in the decommissioning phase, for which a new requirement has been added (Paragraph 3). The phased abandonment of requirements shall be planned.

Paragraph 1 has been divided into two paragraphs so that the requirements concerning the adherence to, monitoring of and deviating from the Operating Limits and Conditions form their own Paragraph 2, as in the safety regulation.

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Section 27 Condition monitoring and maintenance to ensure the safety of the facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

19) condition monitoring and maintenance of a nuclear facility to ensure the safety of the facility.

Condition monitoring and maintenance are discussed in the IAEA requirements [2] and [5] and WENRA reference levels [3] and [11], for example. The operational reliability of the systems, structures and components is a prerequisite for the safe operation of a nuclear facility. The facility shall be designed in a manner that allows for inspecting, testing, maintaining and overhauling all the systems, structures and components that are important in terms of safety. The nuclear facility shall have in place condition monitoring and maintenance programmes and instructions that contain detailed procedures for ensuring the integrity and operability of systems, structures and components important for safety. These procedures are based on applicable standards, manufacturer recommendations and the licensee's own operating experience or experience from other nuclear facilities.

The requirements concerning condition monitoring and maintenance have been put into a separate Paragraph 2.

Section 28 Radiation measurements, monitoring of releases of radioactive substances and estimation of radiation doses to public and workers

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

20) structural radiation safety at a nuclear facility, radiation measurements and control and monitoring of releases of radioactive substances at a nuclear facility and estimation of radiation doses to the public.

Based on the BSS directive, Paragraphs 2–4 have been added to the Section. Paragraph 1 has been divided to separately address the measurements of radiation levels and activity levels performed inside the nuclear facility (Paragraph 1) and the requirements concerning environmental monitoring (Paragraph 1a). The radiation levels of nuclear facility rooms and the activity concentrations of indoor air shall be measured to a sufficient extent in order to define the habitability of the rooms, the need to use protective equipment and similar changes in time for workers' radiation protection. In addition, these room measurements and measurements of the activity concentrations of gases and liquids in the systems provide information on the amounts of radioactive substances in the nuclear facility, the operation of processes and systems and their changes (for example, accumulation of activity, leaks or any activity released into the environment) for measures during the normal operation of the facility and during disturbances and accidents. The releases of radioactive substances shall be monitored and their concentrations in the environment shall be observed in order to know whether

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the releases are sufficiently low to be acceptable or whether measures reducing the releases or other measures are needed.

The radiation doses to the workers and the public in the surroundings shall be measured or otherwise assessed in order to know whether they are sufficiently low to be acceptable. The radiation doses to the public cannot normally be measured, primarily because of their small size, so they shall be estimated in some other way. Radiation doses are caused by external and internal radiation exposure, so they must be taken into account in the measurements and estimations.

According to the BSS directive and the international radiation protection recommendations, for the radiation doses to the public, it is necessary and sufficient to define the radiation dose for an individual who, based on his/her age, place of residence and lifestyle, represents the most exposed group but is not necessarily the most exposed individual. In the definition of radiation exposure, the significant migration routes of radioactive substances, for example, to the environment and ingestion of the representative person in terms of exposure shall naturally be taken into account.

The radiation doses and the releases and concentrations of radioactive substances in the environment shall be reported to the Radiation and Nuclear Safety Authority for control and related communication.

Section 29 Disposal functions

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 16) safety of the operation of a nuclear facility, and
- 26) long-term safety of the disposal of nuclear waste.

Disposal is discussed in the IAEA requirements [2] and WENRA reference levels [3], for example. Paragraphs 1 and 2 of section 29 of the regulation concern the transfer of waste packages into the emplacement room. Transfers shall be planned in a manner that prevents accidents scenarios that could result in the release of radioactive substances. Care shall be taken during the handling of waste packages to be placed in disposal in order to prevent the packaging from becoming damaged in a manner that could significantly shorten its service life. Attention shall be paid to reducing the radiation exposure of workers.

Paragraph 3 discusses separating the disposal functions and construction functions. New emplacement rooms, tunnels and holes may be excavated while the ones completed previously are being filled or once they have already been filled with waste packages. Safety aspects and nuclear safeguards require that interference between these functions shall be limited. Therefore, the disposal activities and the expansion of the emplacement rooms shall be performed in phases or, alternatively, sufficient physical distance shall be maintained between these activities by the use of separate transfer routes, for example. Furthermore, excavation work shall not take place too close to the waste packages that have already been placed in disposal.

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Paragraph 4 of the section concerns the storage of records concerning the waste placed in disposal. Pursuant to Section 116(2) of the Nuclear Energy Decree, the licensee under a waste management obligation shall maintain records of the waste in a manner confirmed by the Radiation and Nuclear Safety Authority. The records concerning the waste placed in disposal are transferred at periodic intervals to the Radiation and Nuclear Safety Authority, which in turn is responsible for their long-term storage. The file concerning the waste placed in disposal and the information concerning the disposal facility are used to compile a collection of documentation, which is archived for future generations.

Section 30 Long-term safety of the disposal of nuclear waste

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

26) long-term safety of the disposal of nuclear waste.

The principle of defence-in-depth contained in Section 7 b of the Nuclear Energy Act is followed as regards the long-term safety of disposal. It means that the release of radioactive substances into the environment is prevented by means of consecutive, mutually complementing barriers and the safety functions implemented by them. The matter is also discussed in the IAEA safety requirements [2], for example. In the context of disposal, the principle of defence-in-depth described in Section 7 b of the Nuclear Energy Act is also referred to as the multiple barrier principle.

The long time span related to disposal means that the application of defence-in-depth has certain specific features. The release barriers shall be passive, since no automatic or human-regulated actuator can be considered reliable over the time span of the disposal. Additionally, the performance of engineered barriers, in particular, will usually degrade over very long periods of time. This does not necessarily result in a degradation of the safety level, however, since the amount of radioactive substances will also reduce quickly over time. After very long periods of time, the safety of the disposal can mainly be based on release barriers with a sufficiently long stability and their characteristics, such as the bedrock and its favourable conditions and materials that are naturally stable in the disposal environment. The degradation of the safety functions refers to justified degradation that can be assumed to occur based on knowledge and research concerning the release barriers.

The proposed requirement aims to ensure that the disposal solution has been sufficiently ensured in terms of safety as regards, for example, quality deviations in the release barriers and any anticipated changes (geological, hydrogeological, geochemical, rock mechanical etc.) in the climate and bedrock.

The bedrock at the site as well as engineered structures and materials can be used as release barriers. The safety functions included in the release barriers are isolation functions and physical-chemical interactions that prevent and limit the release and transport of the radioactive substances placed in disposal. Functions that prevent intrusion into the emplacement rooms can also be interpreted as release barriers.

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Section 31 Disposal site

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

- 5) safety of the site of a nuclear facility, and
- 26) long-term safety of the disposal of nuclear waste.

In this regulation, disposal site shall refer to the location of the disposal facility and, after disposal has been completed, the area entered in the real estate register in accordance with Section 85 of the Nuclear Energy Decree ([161/1988](#)), and the ground and bedrock under it. The requirements concerning the disposal site apply to the bedrock to a depth after which the properties of the bedrock no longer substantially affect the safety of the disposal. However, determining a specific depth limit is not reasonable. The selection of a disposal site is discussed in the IAEA requirements [2] and WENRA reference levels [3], for example. Section 31(1) of the regulation concerns the geological characteristics of the disposal site that are important in terms of the safety of disposal. Firstly, they need to offer favourable and stable conditions in order for the engineered release barriers to operate effectively and remain functional for as long as possible. The bedrock itself will also act as a release barrier, since it prevents and delays the release of radioactive substances released from the emplacement room into the living environment. The dilution of radioactive substances into large volumes of water in either the groundwater or surface water systems will reduce the possibility of high individual exposure. In addition to the favourable characteristics described above, there is also a set of factors that suggests the unsuitability of the site, such as the proximity of exploitable natural resources, exceptionally high tension inside the rock, seismic or tectonic anomalies and exceptional groundwater characteristics that reduce the performance of the release barriers. Even a single unfavourable characteristic such as these may indicate that the area is unsuitable for use as a disposal site.

Paragraph 2 requires that the suitability of the bedrock be confirmed by means of studies performed at the planned disposal depth even before the actual emplacement rooms are constructed. This is important in terms of both the constructability of the rooms and the achievement of good long-term isolation. The amount of the nuclear waste to be placed in disposal and its radioactivity are taken into account when determining the extent of the studies. The emplacement rooms for spent nuclear fuel will need to be divided into several blocks of bedrock that are separated by discontinuity zones that are geotechnically or hydrogeologically unsuitable for use as a disposal environment. The disposal tunnels and holes shall be placed at a suitable respect distance from these discontinuity zones. The tension of the bedrock shall also be taken into account when selecting the site for the emplacement rooms and while positioning them.

Paragraph 3 requires that no significant or exceptional deposits of exploitable natural resources shall be present at the disposal site or its vicinity. The bedrock at the site should be as uninteresting as possible and as average as possible in terms of Finnish bedrock in general and its characteristics. The aim shall be to select the disposal site

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from an area whose bedrock will not attract interest due to its exceptional mineral composition, or otherwise, in the future. It is very challenging, or even impossible, to anticipate changes in the demand for minerals and elements as technology advances.

Paragraph 4 requires emphasising factors that influence long-term safety during the different stages of the implementation of underground rooms at the disposal facility. This applies to the positioning of the rooms, the excavation, strengthening and sealing methods used, the backfill materials and the timing and technology used in the closing of the emplacement rooms.

Pursuant to Paragraph 5, the emplacement rooms shall be placed sufficiently deep in order to prevent above-ground natural phenomena and the effects of human activity from jeopardising safety. The most significant natural phenomena are the effects of an ice age which may reach to a depth of several hundred metres. Notable human activity includes rock blasting, constructing facilities inside bedrock, drilling wells and polluting groundwater. Their impacts will typically reach to a maximum depth of a few hundred metres. When optimising the disposal depth, attention shall also be paid to the geological structures of the bedrock and the correlation between the condition parameters (tension, temperature, flow and characteristics of groundwater) and depth. The activity level of the waste and its other properties will also affect the optimal disposal depth. Spent nuclear fuel and other high level waste shall be placed at a depth of several hundred metres, whereas a disposal depth of a few tens of metres is usually sufficient for intermediate and low level waste. Disposal in the ground is also possible for very low level waste.

If nuclear waste is disposed of in a facility constructed into the ground, the disposal requirements set forth in this regulation shall be considered while taking into account the danger that the waste constitutes. Only very low-level waste, the average activity concentration of which does not exceed the value of 100 kBq per kilogram, and the total activity of which does not exceed the limits laid down in section 6(1) of the Nuclear Energy Decree, can be placed in a facility constructed in the ground.

Section 32 Engineered barriers

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

26) long-term safety of the disposal of nuclear waste.

This section lays down the requirements for the performance of engineered release barriers. They shall ensure the isolation of disposed radioactive substances from the bedrock for a certain period of time, the length of which depends on the duration of the radioactivity in waste. For short-lived waste, this period shall be at least several hundreds of years, and for long-lived waste, at least several thousands of years. Short-lived and long-lived waste are defined in Section 2 of this regulation. In short-lived waste, the activity concentration after 500 years will be below the level of 100 megabecquerels (MBq) per kilogram in each disposed waste package, and below an average value of 10 MBq per kilogram of waste in one emplacement room. Waste is classified as long-lived if its activity concentration after 500 years is above the level of

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100 megabecquerels (MBq) per kilogram in a disposed waste package, or above an average value of 10 MBq per kilogram of waste in one emplacement room. In practice, all low and intermediate level waste generated during the operation of a nuclear power plant and most of the decommissioning waste from a nuclear power plant are regarded as short-lived waste. In addition to spent nuclear fuel, long-lived waste includes the heavily activated metal decommissioning waste, such as the reactor pressure vessel and most of its internal structural parts and components.

The design of the waste packages containing spent nuclear fuel shall give due consideration to the fact that the tendency for the creation of an uncontrolled fission reaction chain may change over time. Radioactive decay will change the amounts of fissile materials and neutron absorbing materials inside the waste package. If the integrity of the waste package is lost, it may be filled with groundwater, which will increase the reactivity of the waste and the probability of an uncontrolled chain reaction. Deformations that occur inside the waste package may also affect reactivity. The goal for the design of the waste package shall be to make criticality accidents impossible even in the long term. If criticality cannot be completely ruled out in the analyses, the effects of potential criticality shall be assessed.

Paragraph 1 of the Section was unnecessarily difficult to understand. It had combined underground disposal and disposal in the ground, so the significance of technical barriers has been clarified in this respect. The paragraph has also been divided into several paragraphs: Paragraph 1 is concerned with the prevention of releases, Paragraph 1a with the slowing of their passage in the environment and Paragraph 1b with the characteristics of the materials of technical barriers.

Section 33 Research and monitoring programme

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

17) taking operating experience and safety research into consideration in order to improve the safety of a nuclear facility, and

26) long-term safety of the disposal of nuclear waste.

In order to ensure the performance of the barriers, a research and monitoring programme shall be established and implemented for the operation of the disposal facility. It will be used to monitor the development of the performance of the release barriers and to gather information for updating the safety cases. The information gathered in the programme can be used to further improve the design of the disposal system. If necessary, and if technology allows it, the research and monitoring programme can be resumed even after the closure of the facility. The programme may include, for example, the follow-up of tensions and deformations in the bedrock by means of precision measurements, the monitoring of the flow and characteristics of groundwater and specific tests related to the development of the performance of the engineered barriers, such as monitoring the saturation of the buffer material and the effects of heat generation of the waste.

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It is also possible that the emplacement room has some engineered barriers or waste packages equipped with monitoring instruments, or that some waste packages are removed from an emplacement room for the purposes of detailed investigation towards the end of the operating period. When planning long-term tests related to the release barriers or waste packages, attention shall be paid to surveying the initial status of the system being examined in order to ensure that the necessary prerequisites are in place for interpreting the results.

Section 34 Protection zone

A protection zone shall be reserved for the disposal site, for which prohibitions on measures pursuant to Section 63(1)(6) of Nuclear Energy Act may be placed in order to ensure the safety of the disposal. Pursuant to Section 85 of the Nuclear Energy Decree, the prohibitions on measures will be entered in the property register, land register or list of titles in order to ensure that, if the ownership of the area is transferred, the new owner will be made aware of the land use limitations. The licensee should be in possession of a land area corresponding to the protection zone during the implementation of the disposal.

Section 35 Long-term safety

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

26) long-term safety of the disposal of nuclear waste.

A collection of documentation referred to as a safety case shall be compiled in order to demonstrate the long-term safety of disposal. It is based on the utilisation of experimental research, computational methods and expert judgement. The safety case is used to demonstrate the fulfilment of the radiation safety targets and to justify the suitability of the disposal solution and disposal site. The structure and presentation (as regards transparency and traceability, for example) shall support the demonstration of compliance with safety targets and the verification of its justifications.

The consequences and probabilities of rare events that significantly increase radiation exposure shall be assessed whenever possible; in other cases, their significance shall be assessed by means of qualitative analyses. These events include, for example, rock displacements that reduce the isolation of the disposal, boring deep wells into the groundwater discharge zones that pass through the emplacement rooms, and searching for natural resources in the disposal area.

The demonstration of compliance with the safety goals also requires complementary analyses that may include, for example, calculations made with simplified methods, comparisons with natural analogues, observations concerning the geological history of the site, what-if type analyses that test the robustness of barrier performance, and probabilistic analyses. The significance of such considerations grows as the assessment period of interest increases; the judgement of safety beyond one million years can only be based on such complementary considerations. Complementary considerations shall

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also be applied parallel to the actual safety analysis in order to enhance the confidence in results of the whole analysis or a part of it.

The assessment of radiation doses for the most exposed individuals shall be based on the assumption of a family or village community that derives nourishment from the immediate surroundings of the disposal site and is most exposed to radiation. Typical radiation doses caused through wider water areas shall also be analysed. Human habits and nutritional needs can be assumed to be similar to the current ones. Effects on non-human biota shall also be analysed in order to demonstrate compliance with the requirement concerning environmental protection. These analyses can largely be based on the publications concerning the subject from the ICRP and the IAEA. Based on the general information concerning radiation effects, it appears obvious that the proposed radiation safety constraints offer sufficient protection for the flora and fauna of the disposal area.

The proposed regulation also sets forth, as a new requirement, that dose estimates based on simplified reference biospheres shall also be prepared for those time periods where radionuclide specific limiting values for activity discharges apply. This aims to improve the transparency of the assessment of long-term safety and the intelligibility of the results.

Section 36 Reliability of the safety case

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

26) long-term safety of the disposal of nuclear waste.

When studying the input data, assumptions and models used in the safety analyses, it should be considered that the radiation safety goal is twofold depending on the period of assessment. The radiation safety goal for a time period that extends to approximately 10,000 years in the future is based on the assessment of individual doses or risks. At this time, the geological conditions at the disposal site can be assumed to be largely similar to the current ones; however, different anticipated changes due to land uplift, the construction of the emplacement rooms and the waste placed in disposal shall be taken into account.

Over a very long period of time, future climate change may cause substantial changes even deep within the bedrock. These may concern, for example, groundwater flow and hydrostatic pressure, groundwater chemistry and rock shifts. Changes in the bedrock shall be taken into account in the long-term safety assessment by providing sufficiently large ranges of variation for the condition parameters that are applicable to the evolution in question within the safety assessments.

The modelling and determination of input data shall be based on the best available experimental knowledge and expert judgement obtained through empirical experiments, geological investigations and evidence from natural analogues. The models and input data shall be appropriate to the evolution, assessment period and disposal

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system of interest. The various models and input data shall be mutually consistent, apart from cases where the conflicts are due to the simplifications made.

Safety analyses involve substantial uncertainties that are due to shortcomings and uncertainties in research data related to the properties of bedrock, for example, and the challenges in anticipating the long-term behaviour of the disposal system. The goal is to take these uncertainties into account in safety assessments based on scenario analysis. In deterministic analyses, the aim is to select the conceptual models, initial data and assumptions in a manner that will cause the analysis results to overestimate the actual radiation effects with a high level of certainty. In probabilistic analyses, on the other hand, the uncertainties are considered as probability distributions of the input parameters.

Some of the uncertainties related to safety analyses are such that they cannot be substantially reduced by means of further research and their magnitude cannot be quantitatively assessed. However, the significance of the uncertainties included in the safety analysis may be assessed by means of sensitivity analyses, for example, and by performing parallel and complementary assessments to the safety analysis, which may provide magnitude estimates of the consequences of the disposal or the significance of phenomena related to disposal.

Section 37 Presentation of, and updates to, the safety case

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

26) long-term safety of the disposal of nuclear waste.

The safety case drawn up during the construction licence phase shall be based on a detailed technical plan and site-specific bedrock studies. The safety case for the operating licence stage shall, in particular, utilise the additional information regarding the bedrock received during the construction of the disposal facility. The safety case is presented as an appendix or background report to the safety analysis report

Due to the long life cycle of the facilities intended for the disposal of nuclear waste, the safety case shall be updated regularly. A relatively short update interval is preferable from the viewpoint of ensuring competence; unless otherwise provided in the licence terms, the update should take place every 15 years or at the end of the different stages of the disposal programme. The update shall take into account the results from safety research, and the experimental information concerning the operation of the disposal system that has been received from the investigation and monitoring programme of the disposal facility during operation.

The safety case shall be updated before and after the permanent closure of the disposal facility. An approved safety case is a prerequisite for determining that the nuclear waste has been appropriately disposed of and that the waste management obligation can be determined as completed in accordance with Sections 32–34 of the Nuclear Energy Act.

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The performance of a periodic safety assessment was previously required at regular intervals. In the proposed amendment to Section 7 e of the Nuclear Energy Act, this interval is defined as fifteen years.

Section 38 Ensuring safety by management, organisation and personnel of a nuclear facility

Pursuant to Section 7 q of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority issues more specific provisions on the technical details of the principles and requirements stipulated in this chapter, with regard to the following aspects:

21) nuclear facility management, organisation and personnel to the extent that provisions are required to ensure the safety of the use of nuclear energy

Safety culture

Safety culture is discussed in the IAEA requirements [5] and WENRA reference levels [3] and [11], for example. A good safety culture shall be maintained during the design, construction and operation of a nuclear facility. The licensee and the senior management of the nuclear facility shall visibly and systematically commit to solutions promoting safety and act in a manner that ensures the safety of the facility at every level and during each procedure. Security arrangements and safeguards of nuclear materials are also essential parts of the safety culture.

The manner in which an organisation is led is one of the key factors in terms of its functioning. The activities of the personnel are guided by the focus areas defined by the management and the values and expectations manifested in the operations of the management. The structure of the organisation, the sufficiency of personnel resources and well planned work distribution form the basis for meaningful and motivating work tasks. The example set by the management plays a key role in maintaining a high level of safety culture. Those working at a nuclear facility shall have good prerequisites for the continuous development of safety.

The careful performance of tasks is absolutely necessary during the operation of the nuclear facility and the service and repair tasks. The goal is to protect the equipment against disturbances and radiation. All work shall be planned in advance and performed carefully. Design and manufacture that impacts long-term safety shall be performed carefully and while understanding the safety significance of the work. The personnel shall act responsibly and acknowledge the safety significance of their tasks. Training in particular shall emphasise that any discovered deficiencies or defects must be immediately rectified. The risk of financial losses shall never prevent the performance of procedures that are necessary in terms of safety.

The safety culture of nuclear facilities cannot be constructed solely on following rules. Training and practical work shall emphasise that everyone must have the necessary competence for their work and acknowledge the importance of their task in terms of the safety of the nuclear facility.

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Updated, clear procedures form an important basis for safety. The personnel whose activities are regulated by the procedures shall be aware of their contents, understand them and be committed to following them. In order to meet these objectives, the users themselves shall ensure that the procedures are maintained and updated.

Safety and quality management

Safety and quality management is discussed in the IAEA requirements [13] and WENRA reference levels [3] and [11], for example. The management system of a nuclear facility refers to the processes and methods by means of which the organisation defines its safety and quality policies, the goals for its operation and the methods by means of which these goals are achieved. One of the goals for the management system is to develop and maintain a high level of safety culture that also includes the prerequisites for advanced quality management. The organisations participating in the design, construction, commissioning, operation, decommissioning and closure of a nuclear facility shall have in place a management system and it shall be regularly assessed and continuously improved. The management system shall compile all the management requirements within the organisation and describe the planned and systematic procedures that ensure the meeting of the requirements. It shall be compatible with the goals of the organisation and promote achieving them.

The key goal for the management system is to ensure radiation safety and nuclear safety. The management system shall cover the entire life cycle of the facility, from the site selection to the decommissioning and closure of the disposal facility. It shall oblige the entire personnel as well as the contractors, suppliers and partners in co-operation who work at the nuclear facility.

One of the important tasks of the management system is to create the prerequisites for a high level of quality management. For this part, during the entire life of the facility from its design to the construction, operation, decommissioning and closure, the licensee is responsible for developing and maintaining a documented management system that defines the quality requirements and safety goals for the equipment, tasks and work related to the nuclear facility that is important in terms of safety.

The quality requirements set by the management system shall cover all organisations that participate in the design, construction, operation and decommissioning of the nuclear facility.

Lines of management, responsibilities and expertise

Organisational requirements are discussed in the IAEA requirements [13] and WENRA reference levels [3] and [11], for example. The manner in which an organisation is led is one of the key factors in terms of its functioning. The activities of the personnel are guided by the focus areas defined by the management and the values and expectations manifested in the operations of the management. The structure and management relationships of the organisation, the tasks and related responsibilities of the personnel, the sufficiency of personnel resources and well planned work distribution form the basis for meaningful and motivating work tasks. It is essential in terms of the functioning of the organisation that its operation and the related risks are assessed and developed in

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order to discover any deficiencies in a timely manner. When developing the organisation's structure or operating methods, it shall be ensured that the modifications implemented support the achievement of safety goals and that the process of change implementation is controlled.

Tasks that are significant in terms of the safe operation of the nuclear facility shall be named. Training programmes shall be prepared for developing and maintaining the professional qualifications of these persons, and an adequate command of the skills required for the duties shall be verified. It is a prerequisite for the safety of the nuclear facility that the holder of the licence for the use of nuclear energy employs sufficient personnel with the training and professional skill required for the tasks as well as sufficient information concerning the requirements related to the safety of the facility.

The personnel shall acknowledge the safety significance of their tasks. Nuclear facilities have specific tasks whose importance in terms of safety is considered so high that they require the appointment of responsible persons whom the Radiation and Nuclear Safety Authority will approve for their tasks. These tasks include the facility's responsible manager and the persons responsible for emergency response arrangements, security, nuclear safeguards and radiation safety. The persons occupying these positions shall possess sufficient authority and genuine prerequisites for bearing the responsibility vested in them.

The licensee shall directly employ adequate and competent personnel for ensuring the safety of the nuclear facility. To accomplish this, the personnel shall, among other things, be familiar with the design bases and safety requirements of the facility and be able to ensure the conformance of the nuclear facility concerned. Furthermore, the organisation shall have access to professional expertise required for the safe operation of the facility, the maintenance of all equipment important to safety and the management of accidents. The careful performance of tasks is absolutely necessary during the operation of the nuclear facility, the service and repair tasks and the management of accident situations. All work shall be planned in advance and performed carefully. The personnel employed in these tasks shall act responsibly and acknowledge the safety significance of their work. The thorough and diverse processing of matters related to safety requires that the licensee has a group of experts that is independent of the other parts of the organisation, supports the responsible manager and convenes on a regular basis to handle safety-related issues and issue recommendations thereon if necessary. Herein, an expert independent of the other parts of the organisation refers to a person who is not participating in the decision-making concerning safety matters within the organisation.

Section 39 Entry into force

The section contains provisions on the entry into force of the regulation. It repeals the Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste Y/4/2016 issued on 22 December 2015.

The regulation is intended to enter into force on 15 December 2018

Upon the entry into force, this regulation shall be applied to any pending matters.

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Availability of the regulation, guidance and advice:

This regulation has been published as part of the regulations issued by the Radiation and Nuclear Safety Authority that can be found on Finlex at: <http://www.finlex.fi/en/viranomaiset/normi/555001/>. The regulation is also available from the Radiation and Nuclear Safety Authority.

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