

IMPLEMENTING DECREE

No. 162

of 25th May 2017

On The Requirements for Safety Assessment According to the Atomic Act

The State Office for Nuclear Safety pursuant to the article 236 of the Act No. 263/2016 Coll., the Atomic Act, to implement the article 48 paragraph 6 sets:

Article 1

Adjustment subject

This Decree incorporates the relevant Euratom legislation¹⁾ and stipulates

- a) regulation of safety assessment performance and individual types of assessment and time limits in which they are conducted,
- b) method of documenting the safety assessment and individual types of assessment and content of the documentation of safety assessment and individual types of assessment, and
- c) method of assessment utilization.

Article 2

Definitions

For the purposes of this Decree, the following definitions apply:

- a) uncertainty means an assessment of the impact of uncertainties associated with individual elements of the logical model of the current state of the nuclear installation created within the probabilistic safety assessment (hereinafter referred to as the “probabilistic safety assessment model”) on the overall results of the probabilistic safety assessment,
- b) sensitivity analysis means an analysis of the degree of impact of the used assumptions and specified input data of the assessment of a certain fact on the results of this assessment,
- c) generic operational data means a numerical data on the reliability of systems, structures and components not based on information on the past state of the nuclear installation to be assessed and applicable to the determination of the reliability of systems, structures and components of this nuclear installation,
- d) initiating event means an event requiring the response of the nuclear installation or its operator to transfer the nuclear installation into a safe state, which in the event of failure of the response could lead to damage to nuclear fuel or leakage of radioactive substance from the nuclear installation,
- e) scenario means a sequence of events including, in particular, the accidental occurrence of an initiating event, the response of individual systems, structures and components ensuring safety functions and the transfer of the nuclear installation into a safe or other state,

¹⁾ Council Directive 2009/71/Euratom of 25 June 2009, establishing a Community framework for the nuclear safety of nuclear installations.

Council Directive 2011/70/Euratom of 19 July 2011, establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

Council Directive 2014/87/Euratom of 8 July 2014, amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations.

- f) specific operational data means a numerical data on the reliability of systems, structures and components based on information on the past state of the nuclear installation to be assessed, and
- g) large early release means a leakage of more than 1% of the initial amount of ^{137}Cs in the nuclear installation within 10 hours from the announcement of a radiation accident.

Article 3

General requirements for safety assessment

(1) The safety assessment shall be performed according to up-to-date and practical by application of proven methodologies in accordance with the current level of science and technology and good practice.

(2) The safety assessment shall consider any modifications capable to affect nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security that occur in the course of the life cycle of the nuclear installation.

(3) The safety assessment shall consider new knowledge from operating experience and information on the risks and consequences of the use of nuclear energy relevant in aspect of nuclear safety, which could significantly affect the safety assessment.

(4) In the process pursuant to paragraphs 2 and 3, a graded approach shall be applied according to the impact of considered facts on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security.

Article 4

Deterministic safety assessment

(1) The deterministic safety assessment shall prove the acceptability of the consequences of the response of the nuclear installation and its systems, structures and components and personnel to initiating events in terms of nuclear safety, radiation protection, technical safety and radiation emergency management.

(2) The deterministic safety assessment shall assess

- a) the capability of the nuclear installation to ensure performance with the principles of safe use of nuclear energy,
- b) the resistance, reliability and efficiency of safety systems and other systems, structures and components with impact on nuclear safety within the conditions they are assigned for, and
- c) the competence of personnel to assure the performance of the basic safety functions of the nuclear installation.

(3) The deterministic safety assessment shall assess compliance with the requirements of the Decree on the Requirements for Nuclear Installation Design.

(4) The results of the deterministic safety assessment shall be cited in the initial safety analysis report, preliminary safety analysis report, operational safety analysis report for the first physical commissioning of the nuclear installation with a nuclear reactor, operational safety analysis report and safety analysis report for decommissioning of the nuclear installation.

Probabilistic safety assessment

Article 5

(1) The probabilistic safety assessment shall include

a) level 1 of the probabilistic safety assessment, in which an analysis of the design of the nuclear installation and its operation, including previous life cycle stages, shall be performed to identify a sequence of events that may lead to damage to the nuclear fuel or system, structure or component containing other radioactive substances present in the installation and determine the frequency of occurrence per year with which such damage may occur as a result of the sequence of such events, and

b) level 2 of the probabilistic safety assessment, in which an analysis of the chronological evolution of the consequences of damage to the nuclear fuel and other systems, structures or components containing radioactive substances present in the nuclear installation identified in level 1 of the probabilistic safety assessment shall be performed, including quantitative assessment of the resulting phenomena; the means by which leaked radioactive material may be released into the environment shall be identified in level 2 of the probabilistic safety assessment.

(2) The probabilistic safety assessment shall take account of

- a) radioactive substances present in the nuclear installation,
- b) operating modes of the nuclear installation, including outages, and
- c) internal and external initiating events, including internal and external hazards.

(3) A probabilistic safety assessment model shall be created as part of the probabilistic safety assessment, which shall be based on realistic modelling of the course of development of internal and external initiating events.

Article 6

(1) The creation of the probabilistic safety assessment model shall be based on

- a) the utilisation of the nuclear installation design data on facts affecting nuclear safety, radiation protection and radiation emergency management,
- b) the justification of the determination of the time for which the response of the nuclear installation to internal and external initiating events is modelled,
- c) the division of operating modes of the nuclear installation into operating states according to the facts related to the state of the nuclear installation, which may lead to the same response of the nuclear installation to the initiating events,
- d) for plant operating states, the determination of initiating events, which are not practically eliminated,
- e) the creation of groups of initiating events according to letter d) and the determination of their frequency of occurrence per year,
- f) the definition of acceptance criteria for preventing the melting of nuclear fuel or the release of radioactive substances,
- g) the use of a causal analytical method to evaluate the course of the process and its events leading to a potential radiation emergency, using the acceptance criteria referred to in letter f),
- h) the construction of event trees for individual groups of initiating events in the form of a graphical logical model based on the results of the use of the causal analytical method,
- i) the identification and elimination of looping in the probabilistic safety assessment model,
- j) the use of a deductive method based on the probabilistic approach, which retrospectively analyses the development of an adverse event or system failure, to find all chains of causes that may lead to that event, using the acceptance criteria referred to in letter f),
- k) the construction of faults trees for each equipment used in response to the initiating event in the form of a graphical logical model based on the results of the use of the deductive method,
- l) the performance of a comprehensive human factor analysis to include possible errors by personnel performing activities related to the use of nuclear energy, activities in exposure situations and

activities in the management of radiation emergency; this analysis shall take into account factors capable of influencing the activities of personnel in all operating states of the nuclear installation, including dependencies between human errors,

- m) the performance of a comprehensive common cause failure analysis, and
- n) the performance of an analysis of radiation emergencies leading to the release of radioactive substances from the nuclear installation.

(2) Furthermore, the probabilistic safety assessment model shall take into account

- a) all functional dependencies between systems, structures or components and dependencies resulting from their location,
- b) the interdependencies of events affecting nuclear safety that may result from the failure of the nuclear installation, and
- c) the interdependencies between different nuclear installations located in the same site of the nuclear installation.

Article 7

Based on the probabilistic safety assessment model, the following shall be performed

- a) a calculation of the frequency of damage to nuclear fuel in the core of a nuclear reactor (hereinafter referred to as the “core”) per year comprising
 - 1. overall frequency of occurrence,
 - 2. frequency of occurrence for individual plant operating states, and
 - 3. frequency of occurrence for individual groups of initiating events,
- b) a calculation of the frequency of damage to nuclear fuel inside and outside the core per year comprising
 - 1. overall frequency of occurrence,
 - 2. frequency of occurrence for individual plant operating states, and
 - 3. frequency of occurrence for individual groups of initiating events,
- c) a calculation of the frequency of large early release of radioactive substances per year comprising
 - 1. overall frequency of occurrence,
 - 2. frequency of occurrence for individual plant operating states, and
 - 3. frequency of occurrence for individual groups of initiating events,
- d) determination of the accuracy of the calculation of the probabilistic safety assessment model in order to achieve realistic results,
- e) identification of the main scenarios leading to damage to nuclear fuel or leakage of radioactive substance from the nuclear installation for the level 1 and 2 of probabilistic safety assessment,
- f) for level 1 and 2 of the probabilistic safety assessment, identification of the smallest groups of events,
 - 1. the co-occurrence of which in the scenario results in damage to nuclear fuel or leakage of radioactive substances from the nuclear installation, and
 - 2. which contribute most significantly to the overall risk posed by the nuclear installation,
- g) the importance analysis for the overall results of the probabilistic safety assessment, for each individual
 - 1. systems, structures and components,

2. human errors, and
 3. common cause failures, and
- h) the monitoring of the level of risk posed by the nuclear installation during operation of the nuclear installation.

Article 8

(1) The following shall be performed in the probabilistic safety assessment model

- a) an analysis of the statistical uncertainties associated with the data used in the probabilistic safety assessment model and needed to determine the reliability of systems, structures and components and the probabilities or annual frequencies of human errors, and
- b) a sensitivity analysis of quantities that show a high degree of uncertainty, may have a significant effect on the results of the probabilistic safety assessment and are associated with
 1. the initial assumptions used to create the probabilistic safety assessment model,
 2. the data used in the probabilistic safety assessment model needed to determine the reliability of systems, structures and components to perform their specified functions, and
 3. the data used in the probabilistic safety assessment model needed to determine the probabilities or annual frequencies of human errors.

(2) The results of the probabilistic safety assessment shall be compared with the probabilistic acceptance criteria to verify compliance of nuclear safety with the probabilistic acceptance criteria. The results of the sensitivity and uncertainty analyses performed shall be taken into account in comparing the results of the probabilistic safety assessment with the probabilistic acceptance criteria.

(3) The probabilistic safety assessment shall be subjected to an independent peer review after its implementation in order to identify potential deficiencies.

(4) All elements that affect the probabilistic safety assessment to be performed shall be taken into account in this probabilistic safety assessment, if it is used for the assessment of

- a) the frequency of testing of systems, structures and components,
- b) the allowed outage times periods for systems, structures and components, or
- c) changes in the quantities referred to in letter a) or b).

Article 9

Time limits for the performance of probabilistic safety assessment

(1) The probabilistic safety assessment shall be performed within 12 months from the implementation of the modification in the use of nuclear energy, in the parts that could be affected by this modification, if it is a modification affecting

- a) the characteristics of the site of the nuclear installation,
- b) the actual state and operation of the nuclear installation after modification in the design of the nuclear installation or modification in the method of testing and maintenance of the nuclear installation,
- c) the current status of internal regulations,
- d) the data needed to determine the reliability of systems, structures and components and the probabilities of occurrence of individual human errors, based in particular on the acquisition of specific operational data from the nuclear installation or the nuclear installation of a similar type,
- e) up-to-date technical information on the state of the nuclear installation, or

f) up-to-date information on the characteristics and behaviour of the nuclear installation in the event of an operational event, including radiation emergency.

(2) The probabilistic safety assessment shall be performed in summary at least once every five years of operation of the nuclear installation.

(3) The probabilistic safety assessment pursuant to the paragraph 2 shall

a) take into account updated data needed to determine the reliability of systems, structures and components and the probabilities of occurrence of individual human errors based on

1. specific operational data from the nuclear installation or the nuclear installation of a similar type, if available, or

2. generic operational data from the nuclear installation or the nuclear installation of a similar type, and

b) use currently available analytical methods and tools relevant to good practice.

Use of the probabilistic safety assessment

Article 10

(1) The probabilistic safety assessment shall be used during the life cycle of the nuclear installation to assess important information on the risk and consequences of the use of nuclear energy, to reassess the current level of nuclear safety, radiation protection and radiation emergency management, and to take measures to prevent reduction of their levels and improve them.

(2) The probabilistic safety assessment shall be continually used to reduce the risk posed by the nuclear installation in order to determine the need for modifications in the design of the nuclear installation resulting from deficiencies of

a) the design of the nuclear installation, or

b) internal regulations.

(3) The probabilistic safety assessment shall be used to determine priorities in the planning of measures to increase the level of nuclear safety, radiation protection and radiation emergency management. In this planning, emphasis shall be placed on measures with a significant impact on nuclear safety, radiation protection, radiation emergency management, and security.

(4) The probabilistic safety assessment shall be used to assess the overall risk posed by the nuclear installation.

(5) The probabilistic safety assessment shall be used to verify

a) the balance of the nuclear installation design,

b) the absence of small deviations of the characteristics of the nuclear installation from their usual values set by legislation, which are capable of causing a significant reduction in the level of nuclear safety of the nuclear installation,

c) the absence of elements of the nuclear installation design or group of initiating events representing a disproportionately large contribution to the overall risk posed by the nuclear installation, and

d) the contribution of factors that are determined with significant uncertainty to the achievement of an overall low level of risk posed by the nuclear installation.

(6) The probabilistic safety assessment shall be used to assess

a) the need and acceptability of modifications in the nuclear installation,

b) the need and acceptability of modifications in limits and conditions,

c) the need and acceptability of modifications in internal regulations, and

d) the severity of events at the nuclear installation.

(7) The method of using the probabilistic safety assessment pursuant to paragraphs 1 in the conditions of the permit holder shall be determined by the internal regulation of the permit holder.

Article 11

(1) The probabilistic safety assessment shall be used in the elaboration of emergency procedures and in the verification of their correctness.

(2) The results of the probabilistic safety assessment shall be used to verify whether the in-service inspection program includes all systems, structures and components with an impact on nuclear safety.

(3) The results of the probabilistic safety assessment shall be used to verify whether all systems, structures and components with an impact on nuclear safety are subject to the ageing management process.

(4) The probabilistic safety assessment shall be used to identify systems, structures and components with an impact on nuclear safety, the operability of which shall be ensured permanently. The results of the probabilistic safety assessment identifying such systems, structures and components shall be included in the preliminary safety analysis report, in the operational safety analysis report for the first physical start-up of the nuclear installation with a nuclear reactor, in the operational safety analysis report, and in the safety analysis report for decommissioning of the nuclear installation.

(5) The results of the probabilistic safety assessment shall be used as input information in the preparation and verification of safety-relevant training programs for personnel, including simulator training for main control room operators.

(6) Whenever the probabilistic safety assessment is used, the limitations for that use shall be identified and taken into account. The appropriateness of using the probabilistic safety assessment shall be verified with the respect to these limitations.

Article 12

Probabilistic safety assessment documentation

The probabilistic safety assessment documentation shall include:

- a) a description of the scope of the probabilistic safety assessment,
- b) a description of the methodology and documentation of the quality assurance of the probabilistic safety assessment,
- c) an information on the nuclear installation to be assessed necessary for performing the probabilistic safety assessment,
- d) a list of operating states of the nuclear installation into which all operating modes of the nuclear installation have been divided for the purposes of the probabilistic safety assessment, and a description of the process of their determination,
- e) a description of the process of selecting and grouping initiating events, their list and a description of individual groups of initiating events with annual frequencies of their occurrence, including analysis of these frequencies, as well as assignment of individual groups of initiating events to individual operating states of the nuclear installation, into which the operation of the installation was divided for the purpose of the probabilistic safety assessment,
- f) a description of the compiled event trees, including the assumptions and criteria used, according to the article 6 paragraph 1 letter h),
- g) a list of human errors included in the probabilistic safety assessment and a description of their analysis,

- h) a list of the data needed to determine the reliability of the systems, structures and components that have been used to model equipment failures and repairs, maintenance and testing, and a description of their analysis,
- i) a list of common cause failures and a description of their analysis,
- j) a description of the solution to looping in the probabilistic safety assessment model,
- k) a list of the main assumptions used in performing the probabilistic safety assessment and the limitations of the probabilistic safety assessment model,
- l) a description of the analysis of systems and compiled fault trees, including the assumptions used,
- m) a description of the relationships between levels 1 and 2 of the probabilistic safety assessment,
- n) a description of the analysis of the radiation emergency leading to the release of radioactive substance from the nuclear installation, which brings the most significant contribution to the risk posed by the nuclear installation,
- o) a definition of the categories of releases of radioactive material released into the vicinity of the nuclear installation by their magnitude and time level,
- p) a description and characteristic of the amount of radioactive material released into the vicinity of the nuclear installation depending on the category of release referred to in letter o),
- q) a description of the main results of level 1 and 2 of the probabilistic safety assessment according to the article 7,
- r) results of sensitivity analyses,
- s) results of uncertainty analyses,
- t) conclusions and recommendations for possible increase in the level of nuclear safety, including assessment of the effectiveness of severe accident management strategy, and
- u) a description of the level 1 and 2 of the probabilistic safety assessment including for each level
 1. probabilistic safety assessment for power conditions,
 2. probabilistic safety assessment for low power and shutdown conditions, and
 3. probabilistic safety assessment for individual internal and external initiating events.

General requirements for the performance of periodic safety review

Article 13

(1) The periodic safety review shall compare the state of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management, and security achieved at the nuclear installation with the requirements of legislation and the requirements arising from the current level of science and technology and good practice (hereinafter referred to as the “safety requirements”) existing at the time of its implementation.

(2) The periodic safety review shall systematically and comprehensively examine the following areas in regular intervals:

- a) nuclear installation design,
- b) actual state of systems, structures and components,
- c) qualification of systems, structures and components to perform the functions required by the design of the nuclear installation (hereinafter referred to as “equipment qualification”),
- d) ageing management of systems, structures and components,
- e) deterministic safety analyses,

- f) probabilistic safety assessment,
- g) risk analysis,
- h) operational safety,
- i) use of operating experience from other nuclear installations and findings of science and research,
- j) organisation and management,
- k) procedures and regulations,
- l) human factor,
- m) management of radiation emergency
- n) radiological impact of the nuclear installation operation on its surroundings.

(3) The periodic safety review of a nuclear research facility shall systematically and comprehensively further examine at regular intervals the area of special nature of the use of nuclear reactor for research, education, radionuclide production, neutron radiography, materials testing or medical services (hereinafter referred to as the “use of nuclear reactor”).

(4) The periodic safety review for a radioactive waste repository shall systematically and comprehensively further examine at regular intervals the area of special nature of the use of radioactive waste repository.

(5) The periodic safety review shall verify the state referred to in paragraph 1 during the operation and decommissioning of the nuclear installation and for the period of validity of the permit for the closure of a radioactive waste repository.

(6) For each area referred to in paragraph 2 to 4, a set of requirements and criteria shall be defined, the fulfilment of which can be considered as compliance with the safety requirements.

(7) For each area referred to in paragraphs 2 to 4, a partial evaluation of all safety requirements for the relevant area shall be performed. The results of partial evaluations of the areas referred to in paragraphs 2 to 4 shall be used to carry out a comprehensive evaluation of all areas.

Article 14

(1) Within the bounds of the periodic safety review, the safety significance of any identified deviations from the safety requirements shall be evaluated.

(2) Based on the evaluation of the safety significance of all identified deviations from the safety requirements, a proposal of a set of corrective actions to achieve and ensure the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security of nuclear installation required by safety requirements until next periodic safety review (hereinafter referred to as “the set of measures”) and a schedule for their implementation shall be created.

(3) The periodic safety review shall further assess whether all deviations from the safety requirements identified during operation or decommissioning of the nuclear installation or identified by previous periodic safety review have been resolved.

(4) The periodic safety review shall be performed in accordance with the strategy for approach to periodic safety review (hereinafter referred to as the “strategy”). The strategy shall be developed before performing the periodic safety review.

Article 15

Time limits for the performance of periodic safety review

(1) The first periodic safety review shall be performed within six years from the start of operation of the nuclear installation.

(2) The periodic safety review, with the exception of the first periodic safety review, shall be performed within ten years from the previous periodic safety review.

(3) The periodic safety review during decommissioning of the nuclear installation shall be performed at the end of each stage of decommissioning of the nuclear installation, and also in the case of modification in the originally planned method of decommissioning of the nuclear installation.

Article 16

Scope of the periodic safety review

(1) Depending on the type of nuclear installation, all areas affecting nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management, and security in individual operating units of the nuclear installation and at the nuclear installation as a whole according to the article 13 paragraphs 2 to 4 shall be included in the periodic safety review.

(2) For nuclear installations without a nuclear reactor or with a nuclear reactor with power output less than 50 MW, the scope of the periodic safety review shall be adapted to the design characteristics of the nuclear installation and the method of operation of the nuclear installation.

Subject of the periodic safety review

Article 17

The periodic safety review shall assess

- a) in the area of nuclear installation design, the actual design of systems, structures and components and their operation against applicable safety requirements, including the method of documenting the modifications made to the nuclear installation and the capability of the nuclear installation to meet the principles of safe use of nuclear energy,
- b) in the area of actual state of systems, structures and components, whether the systems, structures and components with an impact on nuclear safety meet the technical requirements prescribed by technical specification, meet the design requirements, continue to perform the functions anticipated by the nuclear installation design and whether their state is properly documented,
- c) in the area of equipment qualification, the state and capacity of systems, structures and components capability to meet the design requirements under the conditions to which they are exposed throughout their lifetime, taking into account the impact of the working environment, including accident conditions; equipment qualification shall be assessed in terms of whether
 1. it is properly performed and documented, and
 2. it is regularly verified and evaluated in the process of planned maintenance, inspections and functional tests of systems, structures and components,
- d) in the area of ageing of systems, structures and components,
 1. the performance of systematic monitoring and effective management of the ageing process of systems, structures and components with an impact on nuclear safety in a manner that allows the safety function to be maintained throughout the life cycle of the nuclear installation,
 2. the extent of wear and degradation of materials, including the impact of wear and degradation on the ability of systems, structures and components to perform their function and on the prediction of future development, and
 3. documentation of the ageing management process,
- e) in the area of deterministic safety analyses, the scope, completeness, applicability and up-to-date of the deterministic safety analysis, including consistency of the deterministic assessment methods

used, computer codes, safety criteria and standards used with the current level of science and technology and good practice, taking into account

1. all modifications in the design of the nuclear installation which have been made at the nuclear installation,

2. the current state of systems, structures and components, and

3. the expected state of systems, structures and components at the end of the period before the next periodic safety review, and

f) in the area of probabilistic safety assessment,

1. the accident management system and its consistency with the results of the probabilistic safety assessment so as to determine the appropriateness of this system for preventing severe damage to the core or mitigating its consequences,

2. the scope and completeness of the probabilistic safety assessment in terms of whether the impact of the radioactive substance present in the nuclear installation, the operating states of the nuclear installation and the considered initiating events for the nuclear installation are taken into account,

3. regular updates of the probabilistic safety assessment in order to assess the current state of the nuclear installation, including the current status of internal regulations,

4. compliance of the methodologies, computer codes and success criteria used with the current level of science and technology and good practice,

5. compliance of the use of probabilistic safety assessment with the requirements of the current level of science and technology and good practice, and

6. compliance of the probabilistic safety assessment with the requirements of this Decree to probabilistic safety assessment.

Article 18

Furthermore, the periodic safety review shall assess

a) in the area of risk analysis,

1. the adequacy of the nuclear installation protection against internal and external events in relation to the current state of all systems, structures and components with an impact on nuclear safety and actual values of potential risk obtained from the current assessment of the site of the nuclear installation in which the nuclear installation is located, regarding to the potential occurrence of climate changes and transport and other industrial activities, and

2. precaution of the prevention of occurrence of accident conditions and to mitigate their consequences by defence in depth application,

b) in the area of operational safety,

1. the long-term level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security during operation of the nuclear installation and trend analysis of its development based on the continual assessment of nuclear safety, radiation protection and technical safety and operating experience,

2. a system for detection, classification, recording and reporting of operational events,

3. the method of elaboration and keeping the documentation of the feedback system, and

4. the effectiveness of the feedback system,

c) in the area of the use of operating experience from other nuclear installations and science and research findings,

1. the existence and application of a system for obtaining, sorting, evaluating and recording information from the operation of other nuclear installations of a similar type, and

2. the extent to which new scientific and research findings are reflected in improvements of nuclear safety, radiation protection, technical safety, radiation situation monitoring and radiation emergency management of the nuclear installation,

d) in the area of organisation and management,

1. the method of implementation of the management system and the overall level of safety culture,

2. the adequacy of the number of personnel with qualifications required to perform activities especially important for nuclear safety and radiation protection and activities important for nuclear safety,

3. personnel training system,

4. requirements for personnel qualification, and

5. the adequacy of personnel qualifications for the performance of given activity, and

e) in the area of procedures and regulations, procedures and internal regulations for the operation and decommissioning of the nuclear installation in terms of

1. their compliance with the current state of the nuclear installation and its operation or decommissioning,

2. their complexity, verification, approval,

3. implementation of management system of changes for their modifications, and

4. the degree of their observance.

Article 19

Furthermore, the periodic safety review shall assess

a) in the area of human factor, whether the human factor does not increase the risk of the initiating event occurrence, including assessment of whether

1. the prescribed activities and interventions of the personnel, which are referred to as actions in support of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security, are feasible and have the necessary technical and organisational support,

2. the number of personnel performing activities important for nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security is sufficient,

3. the process of selection and training of personnel affecting nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security is effective,

4. the overall personnel policy and its management by leaders are in accordance with the requirements for safety culture,

5. the working environment has appropriate layout and technical equipment in accordance with the ergonomic requirements according to the current state of science and technology and good practice, and

6. the operating experience feedback programs for human failure activities that have contributed or may have contributed to operational events are capable of identifying the causes of such failures and their corrective actions, and

b) in the area of radiation emergency management,

1. the requirement of the nuclear installation design for the equipment of shelters and their ability to perform their function with regard to equipment obsolescence,

2. the requirement of the nuclear installation design for the permanent operability and habitability of shelters designated as emergency control centre and technical support centre,

3. whether the process of planned maintenance of shelters is regularly checked and evaluated,
4. whether a system for acquiring, sorting, analysing, evaluating and recording information on the occurrence of radiation emergencies and the progress of response to them at another nuclear facilities of a similar type exists and is used,
5. the sufficiency of the number of personnel with the required qualifications for supervision of the management and response to the radiation emergency according to the individual intervention instructions,
6. whether the system of education of natural persons designated to perform activities according to the intervention instruction, on-site emergency plan or emergency regulations in the matter of radiation emergency management is in accordance with the current state of science and technology and good practice,
7. whether the working environment in the shelters designated as emergency control centre and technical support centre has the configuration and technical equipment in accordance with the ergonomic requirements according to the current state of science and technology and good practice,
8. the corrective measures for the deficiencies identified during the verification of the functionality of technical means according to the on-site emergency plan taken since the previous periodic safety review,
9. the corrective measures for the deficiencies identified during emergency exercises, including on-site emergency plan and intervention instructions, during which the scenario involving radiation accident has been practised, taken since the previous periodic safety review,
10. a system for providing basic information for the case of radiation accident to the population in the emergency planning zone,
11. a system for information of the population in the emergency planning zone in the event of radiation accident, and
12. significant modifications in the area of the nuclear installation and in the emergency planning zone, which may have an impact on ensuring the radiation emergency management for the period since the previous periodic safety review.

Article 20

Furthermore, the periodic safety review shall assess

- a) in the area of radiological impact of the nuclear installation operation on its surroundings,
 1. the up-to-date and complexity of the monitoring program of discharges and the monitoring program of surroundings with regard to modifications made to the nuclear installation and modifications in the infrastructure in the vicinity of the nuclear installation,
 2. the up-to-date of the methods and technical means used for the monitoring of discharges and surroundings and for the evaluation of doses for a representative person in the aspect of the current state of science and technology and good practice,
 3. the development of long-term trends of the variables values monitored according to the monitoring program of discharges and the monitoring program of surroundings in comparison with the results of radiation situation monitoring before the nuclear installation commissioning, and
 4. the development of long-term trends in the values of the committed effective dose for a representative person in comparison with the authorised limits set by the Office,
- b) in the area of special nature of the use of nuclear research facility
 1. the current use of the nuclear reactor and anticipated changes in its use,
 2. the appropriateness of existing internal regulations for the use of the nuclear reactor,

3. the effectiveness of the management system of the processes and activities associated with the use of the nuclear reactor,

4. changes in the documentation related to the nuclear research facility regarding the use of the nuclear reactor,

5. the impact of using method of the nuclear reactor on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security,

6. the appropriateness of the limits and conditions set specific for the use of the nuclear reactor,

7. the ageing management process for equipment used for the use of the nuclear reactor, and

8. qualification of personnel performing processes and activities in the use of the nuclear reactor, and

c) in the area of special nature of the use of radioactive waste repository

1. procedures verifying whether the attributes of radioactive waste comply with the conditions of acceptability for disposal in a radioactive waste repository, and

2. facts affecting nuclear safety, radiation protection, radiation situation monitoring, radiation emergency management and security of a radioactive waste repository after its closure, including analysis of its operation and potential development of barriers, the site of this repository, and the biosphere.

Article 21

Periodic safety review documentation

(1) The strategy shall contain

a) a description of the scope of the periodic safety review,

b) a description of the periodic safety review performance, including timetable for the realization of the various stages and the requirements for

1. the outputs of the periodic safety review, and

2. the validation of the outputs of the periodic safety review according to the Decree on the Requirements for Management System,

c) procedures to identify and resolve deviations between existing and required functional and power characteristics of the nuclear installation,

d) evaluating method of the safety significance of deviations from safety requirements,

e) a list of periodic safety review documentation, and

f) a description of the periodic safety review management system, including communication method in performing the periodic safety review.

(2) Methodologies under the article 3 paragraph 1 for the periodic safety review shall be prepared separately for each area to be assessed pursuant to the article 13 paragraphs 2 to 4 and shall contain

a) a description of the requirements of legislation and the requirements of technical standards or technical regulations to be used in the assessment,

b) a description of the methods of assessment, and

c) a description of the criteria used to assess the safety requirements fulfilment.

(3) The results of the assessment of individual safety requirements shall be recorded in review sheets of the performed assessment. The review sheet of the performed assessment shall contain

a) a description of the documents used for the assessment,

- b) a description of the way of fulfilling the criterion pursuant to the article 13 paragraphs 6 and 7,
- c) deviations from the fulfilment of the criterion pursuant to the article 13 paragraphs 6 and 7 identified,
- d) an evaluation of the safety significance of deviations from the safety requirements, and
- e) the corrective actions recommendations to resolve deviations from the safety requirements.

(4) The results of the assessment of individual areas of the periodic safety review shall be recorded in partial reports on the assessment of the areas of the periodic safety review. These partial reports shall contain

- a) a description of the assessment objective,
- b) a list of safety requirements,
- c) the assessment result of each safety requirement, indicating
 - 1. safety requirements,
 - 2. the criteria used for assessing the fulfilment of safety requirements and methodologies pursuant to the article 3 paragraph 1,
 - 3. a description of the assessment process, and
 - 4. a proposal for addressing deviations from safety requirements, and
- d) in the case of partial report on the assessment of the actual state of systems, structures and components also
 - 1. a list of systems, structures and components for which it is impossible to verify the actual state by technical methods,
 - 2. a description of the indirect methods of assessing the state of systems, structures and components referred to in point 1, and
 - 3. evaluation of the impossibility of verifying the actual state by technical methods in terms of importance for nuclear safety, radiation protection, technical safety, radiation situation monitoring and radiation emergency management.

(5) The results of the periodic safety review with the draft set of measures shall be processed in the final summary report on the periodic safety review (hereinafter referred to as the “summary report”). The summary report shall be submitted to the Office within three months from the time limit expiration for the performance of the periodic safety review pursuant to the article 15.

(6) The summary report shall contain

- a) a brief description of the periodic safety review performed, indicating its objectives, scope, procedure, sources used and references to the most important documentation used and prepared,
- b) in the case of another than the first periodic safety review, a comparison of the assessed areas with the state in the previous periodic safety review,
- c) an overview of the results and findings enabling the assessment of the achieved level of nuclear safety, indicating the identified deviations from the safety requirements and the measures to resolve them,
- d) a conclusion on the overall level of nuclear safety, radiation protection, technical safety, radiation situation monitoring and radiation emergency management achieved during the period under assessment,
- e) the final set of measures, and
- f) a comprehensive plan for the implementation of the set of measures, including timetable for their realization.

Article 22

Continual safety assessment

(1) Throughout the life cycle of the nuclear installation, the permit holder shall perform a continual safety assessment by assessing the current state of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security and the method of fulfilment of the principles of peaceful use of nuclear energy and ionising radiation.

(2) The continual safety assessment shall include

a) monitoring, evaluation and recording of

1. quantities and facts important from the point of view of nuclear safety,

2. the results of radiation situation monitoring according to the monitoring programs, and

3. data on the reliability and operability of systems, structures and components with an impact on nuclear safety,

b) assessment of the system of planning and implementation of changes in the use of nuclear energy,

c) assessment of the management system effectiveness,

d) monitoring of compliance with the conditions set out in the permit issued by the Office,

e) assessment of the results of the regular verification of the conformity of operated selected equipment with the technical requirements, including assessment of the results of the supervision performed by the permit holder over its suppliers, and

f) assessment of processes and activities to prevent the course of accident conditions at the nuclear installation and to mitigate their consequences pursuant to the article 49 paragraph 1 letter u) of the Atomic Act.

(3) The assessment of quantities and facts important from the point of view of nuclear safety and radiation protection shall be performed by comparison of their current state with the values set by the nuclear installation design and internal regulations.

(4) For the assessment pursuant to the article 3, a set of safety and reliability indicators shall be established and used for these quantities and facts, which will enable monitoring of the development of the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security by comparing the same data for previous periods.

(5) The continual safety assessment shall assess the effectiveness of internal regulations.

(6) Records of the outputs of the continual safety assessment shall describe the implementation of the continual safety assessment and its result achieved.

(7) The result of the continual safety assessment shall be taken into account in the internal regulations, the operational safety analysis report, the safety analysis report for decommissioning of the nuclear installation and the probabilistic safety assessment.

Special safety assessment

Article 23

(1) The special safety assessment before implementation of change in the use of nuclear energy related to selected equipment shall assess

a) the impact of change realization on the ability of the nuclear installation to meet the principles of safe use of nuclear energy,

b) the completeness and accuracy of the proposed change in terms of current requirements for nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security, and

c) compliance of the change with the requirements of the documentation for the permitted activity and internal regulations.

(2) The special safety assessment before implementation of change in the use of nuclear energy related to organisation and management shall assess

- a) fulfilment of the requirements for the management system after the implementation of the change,
- b) the impact of the change on activities especially important from the point of view of nuclear safety and activities important from the point of view of nuclear safety, and
- c) compliance of the state after the change realization with the requirement to ensure and maintain the human resources needed to fulfil the obligations related to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security.

(3) The special safety assessment before implementation of another change in the use of nuclear energy, which is the operation of the nuclear installation beyond its designed lifetime at the first physical commissioning of the nuclear installation, shall assess for the entire period of its further operation

- a) the degree of ageing of systems, structures and components with an impact on nuclear safety, the damage of which may limit the scope of performance of the safety function,
- b) the reliability of systems, structures and components with an impact on nuclear safety recorded within the continual safety assessment,
- c) fulfilment of the acceptance criteria and maintenance of the safety margins for systems, structures and components with an impact on nuclear safety with regard to the effects of ageing,
- d) the ability of systems, structures and components with an impact on nuclear safety to perform the safety functions specified by the nuclear installation design,
- e) the validity of ageing analyses containing time-limited assumptions, and
- f) the effectiveness of keeping of knowledge and experience of personnel about the nuclear installation from all previous stages of its life cycle.

(4) The special safety assessment pursuant to the paragraph 3 shall be performed no later than 24 months before reaching design lifetime of the nuclear installation estimated by the nuclear installation design at the first physical commissioning of the nuclear installation.

(5) If the date of the special safety assessment pursuant to the paragraph 3 is the same as the planned date of the periodic safety review pursuant to the article 15, this special safety assessment shall be performed within the assessment of the appropriate areas pursuant to the article 13 paragraphs 2 to 4.

Article 24

(1) The special safety assessment in the event of radiation emergency at the nuclear installation or at another nuclear installation of a similar type shall assess

- a) the significance of radiation emergency at the nuclear installation or another nuclear installation of a similar type in terms of nuclear safety, radiation protection, technical safety, radiation monitoring, radiation emergency management and security using feedback system procedures under the Decree on Assuring Nuclear Safety of the nuclear installation ,
- b) the suitability of measures proposed to prevent or reduce the possibility of recurrence of the radiation emergency, and
- c) in the event of radiation emergency originated at another nuclear installation of a similar type, the suitability of applying the corrective actions proposed by the operator of that installation for the nuclear installation own.

(2) The special safety assessment in case of suspect of reduction in the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security shall assess

- a) the ability of the nuclear installation to meet the principles of safe use of nuclear energy,
- b) the validity of deterministic safety analyses,
- c) compliance of the operation of the nuclear installation with the requirements of the documentation for the performed activity and internal regulations,
- d) the possibility of increasing the frequency of the initiating event or the development of accident conditions,
- e) the impact of human factor,
- f) the state of physical safety barriers against release of radioactive substances or ionising radiation,
- g) the outputs of radiation situation monitoring by comparison with the authorised limits set by the Office,
- h) the exposure of a representative person in case of release of radionuclide into the environment,
- i) the correctness of determining the cause of the reduction of the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management or security,
- j) the real state of systems, structures and components with an impact on nuclear safety, the failure of which has led to suspect of the reduction of the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management or security,
- k) the adequacy of measures to restore the required level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management or security, if proposed, and
- l) the effectiveness of the measures referred to in letter k), if adopted.

Article 25

Special safety assessment documentation

(1) The results of the special safety assessment before implementation of change in the use of nuclear energy shall be summarised in a report which shall contain

- a) identification of the change,
- b) the expected date of implementation of the change,
- c) a description of the reasons for implementation of the change,
- d) a description of the difference between the current state and the proposed state,
- e) a description of the impact of the change on
 - 1. management system documentation,
 - 2. documentation for the performed activity, and
 - 3. the ability of the nuclear installation to meet the principles of safe use of nuclear energy,
- f) type of the change,
- g) assessment of the effect of the change on the human factor, and
- h) the results of the safety assessment.

(2) In the case of assessment pursuant to the article 23 paragraph 3, the report shall also contain

- a) a list of systems, structures and components with an impact on nuclear safety,
- b) the results of the ageing management process,
- c) the results of the assessment of the reliability of systems, structures and components with an impact on nuclear safety,
- d) the results of the assessment of the validity of ageing analyses containing time-limited assumptions,
- e) a list of changes implemented since the start of operation of the nuclear installation, and
- f) the program for continued operation of the nuclear installation.

(3) The special safety assessment documentation pursuant to the article 24 paragraph 1 shall contain

- a) the results of the assessment of the significance of radiation emergency for the nuclear installation,
- b) the results of the assessment of the conclusions of the report on the occurrence and course of radiation emergency, and
- c) a list of corrective measures to prevent the occurrence of radiation emergency of the same category and the expected date of their implementation.

(4) The special safety assessment documentation pursuant to the article 24 paragraph 2 shall contain

- a) a report on the results of the special safety assessment containing the results of the assessment pursuant to the article 24 paragraph 2,
- b) a list and description of measures according to the article 24 paragraph 2 letter k), and
- c) the results of the probabilistic safety assessment in the event that the measures pursuant to the article 24 paragraph 2 letter k) lead to change in the mode of the use of nuclear energy.

Article 26

Transitional provisions

The periodic safety review of the nuclear installation being operated prior the date of coming into force of this Decree shall be performed within ten years after the force of this Decree.

Article 27

Entry into force

This Decree shall come into force on 15th June 2017.

Chairperson:

Ing. Drábová, Ph.D., m. p.