

National legislative and regulatory activities

France

Liability and compensation

Decree No. 2018-1027 of 23 November 2018 publishing the decision on the exclusion of small quantities of nuclear substances outside a nuclear installation from application of the Convention on Third Party Liability in the Field of Nuclear Energy (text in Annex), adopted by the Steering Committee of the Nuclear Energy Agency in Paris on 3 November 2016¹

In accordance with Article 1(b) of the Paris Convention,² the Steering Committee for Nuclear Energy of the OECD Nuclear Energy Agency (NEA) may, if in its view the small extent of the risks involved so warrants, decide to exclude any nuclear installation, nuclear fuel or nuclear substances from the application of the Paris Convention.

This is notably the case, further to the decision of the NEA Steering Committee of 18 October 2007, for small quantities of nuclear substances outside a nuclear installation, which are excluded from the scope of application of the Paris Convention, provided that they fulfil certain conditions.³ In order to take into consideration the revision of certain international regulations on the safe transport of radioactive material, the NEA Steering Committee updated the criteria for exclusion by a decision dated 3-4 November 2016,⁴ which replaces the decision of 18 October 2007, henceforth abrogated.

Decree No. 2018-1027 of 23 November 2018 publishes this decision, thereby incorporating it into French domestic law and guaranteeing its enforceability.

Germany

Food irradiation

New version of the Food Irradiation Ordinance

A new consolidated version of the “Ordinance on the Treatment of Foodstuffs with Electronic-, Gamma-, and X-Rays, Neutron- or Ultraviolet-Radiation (Food Irradiation

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1. *Journal officiel “Lois et Décrets”* [Official Journal of Laws and Decrees] (J.O.L. et D.), 25 Nov. 2018, text no. 6.
 2. Convention on Third Party Liability in the Field of Nuclear Energy of 29th July 1960, as amended by the Additional Protocol of 28th January 1964 and by the Protocol of 15th November 1982 (1960), 1519 UNTS 329 (Paris Convention).
 3. Draft Decision on the Exclusion of Small Quantities of Nuclear Substances from the Application of the Paris Convention on Third Party Liability in the Field of Nuclear Energy, NEA/NE(2007)8, 21 Sept. 2007; Summary of Decisions Taken at the 115th Session of the Steering Committee for Nuclear Energy, NEA/SUM/DEC(2007)2, 25 Oct. 2007.
 4. Decision on the Exclusion of Small Quantities of Nuclear Substances outside a Nuclear Installation from the Application of the Convention on Third Party Liability in the Field of Nuclear Energy, NEA/NE(2016)8/FINAL, 16 Jan. 2017.

Ordinance)” was published on 15 February 2019 in the *Federal Gazette*.⁵ By the new version of the Food Irradiation Ordinance the following two Directives will be implemented into German law:

- Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation⁶ and
- Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation.⁷

The amendment retroactively entered into force on 13 July 2017.

Nuclear trade (including non-proliferation)

Amendments to the Foreign Trade Ordinance

The 13th Ordinance to amend the Foreign Trade Ordinance⁸ of 27 February 2019⁹ amends Articles 74, 76 and 77 of the Ordinance as last amended on 19 December 2018.¹⁰ The minor amendments entered into force on 7 March 2019.

Transport of radioactive materials

Amendments to the transport of dangerous goods ordinances

The following Ordinances on the transport of dangerous goods were amended:

- the Ordinance on the transport of dangerous goods by road, railways and internal waters of 30 March 2017¹¹ was amended by Article 1 of an Ordinance of 20 February 2019;¹²
- the Ordinance on the transport of dangerous goods by seagoing vessels of 7 December 2017¹³ as last amended 2018;¹⁴
- a new version of the Ordinance on the exception from regulations on the transport of dangerous goods (Dangerous Goods Exception Ordinance) of 11 March 2019.¹⁵

5. *Bundesgesetzblatt* [Federal Law Gazette] (BGBl.) 2019 I, p. 116. For more information on earlier versions of the Ordinance, please see NEA (1992), “Amendments to the Meat Hygiene Ordinance (1991)”, *Nuclear Law Bulletin* (NLB), No. 49, OECD, Paris, p. 53; NEA (1993), “Foodstuffs and Consumer Goods Act (1992)”, NLB 52, OECD, Paris, p. 54; NEA (2001), “Ordinance on the Treatment of Foodstuffs with Radiation (2000)”, NLB 67, OECD, Paris, pp. 35-36; NEA (2007) “Amendment to the Ordinance on the Treatment of Foodstuffs with Radiation (2006)”, NLB 79, OECD, Paris, pp. 62-63.

6. *Official Journal of the European Union* (OJ), L 66 (13 Mar. 1999), p. 16.

7. *Ibid.*, p. 24.

8. For more information on the Foreign Trade Ordinance, please see NEA (2016), “Amendments to the Foreign Trade Act and the Foreign Trade Ordinance (2015)”, NLB 98, OECD, Paris, pp. 69-70.

9. *Bundesanzeiger* [Federal Gazette] AT 6 March 2019 V1.

10. *Bundesanzeiger* AT 28 December 2018 V1.

11. BGBl. 2017 I, p. 711.

12. BGBl. 2019 I, p. 124.

13. BGBl. 2017 I, p. 3862.

14. BGBl. 2018 I, p. 131.

15. BGBl. 2019 I, p. 229.

The amendments, partly retroactively, came into force on 1 January, on 28 February and on 18 March 2019, respectively.

Greece

Nuclear safety and radiological protection (including nuclear emergency planning)

Transposition of the Euratom Basic Safety Standards

The Greek Radiation Protection Regulations have been amended in order to comply with the Euratom Basic Safety Standards Directive,¹⁶ as well as to take into account the findings of international peer reviews (for example the International Atomic Energy Agency's (IAEA) International Regulatory Review Service (IRRS) missions to Greece in 2012 and 2017) of the national regulatory framework and the regulatory experience gained in the last 20 years. The new Radiation Protection Regulations consist of:

- a presidential decree (PD), which is the main legislative document providing the regulatory framework for conducting activities related to ionising radiation;
- three ministerial decisions dealing with the notification and authorisation procedures, the assignment of responsibilities for the implementation of strategies for the management of existing exposure situations and the establishment of the national action plan addressing long-term risks from radon exposures;
- Greek Atomic Energy Commission (EEAE) decisions that are mostly technical rules to control or regulate specific tasks and activities; and
- regulatory guidance, which is a set of recommendations designed to assist persons and organisations in complying with the legal requirements.

The PD, entitled “Adaptation of the Greek legislation to Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/(EE L13/17.1.2014) – Establishment of radiation protection regulations” was published in the Official Government Gazette on 20 November 2018. The PD puts emphasis on the:

- graded approach of regulatory control based on risk assessment;
- regulatory control requirements, including the regulatory body, inspections and enforcement;
- clear allocation of responsibilities regarding radiation protection, including the prime responsibility of the undertaking for the practices applied;
- preparedness and response related to emergency exposure;
- protection from natural radiation sources and environmental issues in general;

16. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13 (17 Jan. 2014) (Euratom Basic Safety Standards Directive).

- importance of education, training and information for all the persons involved in the radiation protection system; and
- reduction of the eye lens dose limit for the exposed workers from 150 mSv to 20 mSv.

The provisions of the PD came into force on 6 February 2018, subject to transitional arrangements.

The ministerial decision entitled “Procedures for the regulatory control of practices of ionizing radiation – approval and recognition of services and experts” has been promulgated in the *Official Government Gazette* in April 2019. It is the main secondary legislation issued upon the publication of the previously mentioned PD on the adoption of the Euratom Basic Safety Standards Directive. The ministerial decision defines:

- the procedures and the necessary information and supporting documents for the notification and authorisation of practices subject to regulatory control for the purposes of radiation protection based on the graded approach;
- the practices for which registration or licensing is required;
- other types of practices for which registration or licensing is required (such as the employment of outside workers and the transport of radioactive material.);
- the arrangements for the a) approval of radiation protection experts, medical physics experts and occupational health services; b) authorisation of dosimetry services; and c) recognition of the radiation protection officers.

Lithuania

Nuclear safety and radiological protection (including nuclear emergency planning)

Transposition of the Euratom Basic Safety Standards¹⁷

Lithuania continued its efforts to transpose the Euratom Basic Safety Standards by adopting the following new Nuclear Safety Requirements and orders:

- New Nuclear Safety Requirements BSR-1.9.8-2018 “Rules of Procedure for Preparation of Radiation Protection Officer Job Description and Radiation Protection Office Statute”¹⁸ were adopted by the head of State Nuclear Power Safety Inspectorate (VATESI) in order to set clear requirements for the content of the Radiation Protection Officer Job Description and Radiation Protection Office Statute and set their basic functions.
- Order No. 22.3-263, 5 Nov. 2018, “List of Types of Justified Activities with the Sources of Ionising Radiation in the Nuclear Energy Area” was approved in 2018 by the head of VATESI in order to establish the list of types of justified activities in the nuclear energy area. New types of practices that are not listed but that will result in exposure to ionising radiation in the nuclear energy area shall be justified by an undertaking before approval by VATESI.

17. *Ibid.*

18. Order No. 22.3-309 (12 Dec. 2018) of the Head of State Nuclear Power Safety Inspectorate “On the approval of Nuclear Safety Requirements BSR-1.9.8-2018 ‘Rules of Procedure for Preparation of Radiation Protection Officer Job Description and Radiation Protection Office Statute’”, available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/f9db1f70fe0c11e8a969c20aa4d38bd4.

- Nuclear Safety Requirements BSR-1.9.5-2018 “Assessment of justification of activities with the sources of ionising radiation in the nuclear energy area” were adopted by the head of VATESI to set the requirements for information and documentation to be presented to VATESI in order to justify the practices not included in the “List of Types of Justified Activities with the Sources of Ionising Radiation in the Nuclear Energy Area” and establish the procedure of justification of this practice.
- Nuclear Safety Requirements BSR 1.9.6-2018 “Recognition of Radiation Protection Expert for Activities with Sources of Ionising Radiation in Nuclear Energy Area and Duties of Undertakings carrying out Aforementioned Activities to Consult with Radiation Protection Expert” were adopted by the head of VATESI in order to set the duty for undertakings to seek advice from a radiation protection expert as well as to set basic functions and responsibilities of the radiation protection expert to consult with undertakings. Additionally, the Requirements establish the procedure for VATESI to recognise the competence of a radiation protection expert.
- Nuclear Safety Requirements BSR-1.9.7-2018 “Rules of Procedure for Recognition of Dosimetry Services of Nuclear facilities” were adopted by the head of VATESI in order to establish the procedure for VATESI to recognise the competence of the dosimetry service, including the requirements for the information and documentation presented for the recognition of this service and requirements for the quality management system for the dosimetry service as well as requirements for assessing the accuracy of measurements to evaluate the occupational exposure.

Nuclear Safety Requirements for commissioning of nuclear facilities

New Nuclear Safety Requirements¹⁹ for commissioning of all types of nuclear facilities were adopted by the head of VATESI in order to streamline the regulation. The main goal of the Nuclear Safety Requirements was to streamline provisions on commissioning to gather them in one document. The Nuclear Safety Requirements include:

- content of the commissioning programme and requirements for its implementation;
- organisation and management of commissioning of nuclear facilities;
- requirements for commissioning tests;
- requirements for verification of operation procedures, including emergency preparedness, during implementation of commissioning programme;
- requirements for commissioning tests and commissioning programme reports.

The new Nuclear Safety Requirements come into force on 1 May 2019.

19. Order No. 22.3-295 (4 Dec. 2018) of the Head of State Nuclear Power Safety Inspectorate “On the approval of Nuclear Safety Requirements BSR-1.8.5-2018 ‘Commissioning of Nuclear Facility’”, available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/a78e2dd0f79911e880d0fe0db08fac89.

Revision of Nuclear Safety Requirements for decommissioning

VATESI reviewed and adopted a new version of Nuclear Safety Requirements BSR-1.5.1-2019 “Decommissioning of Nuclear Facilities”.²⁰ The goal of the amendment was to update national requirements for decommissioning based on international practice and national experience of the dismantling and decontaminations projects at the Ignalina nuclear power plant. The main updates include:

- an update of several definitions and the approval of two new definitions – “brown field” and “green field” – that are possible end states of the decommissioning process;
- more detailed requirements for assessing decommissioning safety;
- an update of the contents of the final decommissioning plan and safety analysis report;
- the establishment of new requirements for the demolition of buildings during decommissioning that are on the site of a nuclear facility and that are not used in operation and not needed anymore. Nuclear Safety Requirements BSR-1.8.2-2015 “Categories of Modifications of Nuclear Facility and Procedure of performing the Modifications” was amended²¹ to include procedures for the modification of the aforementioned buildings.

The aforementioned amendments come into force on 1 May 2019.

Slovak Republic

General legislation, regulations and instruments

Drafting of new Atomic Act

The drafting of the new Atomic Act (“new Act”) has continued after it was interrupted in 2016 by activities related to transposing the European Union *acquis communautaire* (the cumulative body of EU legislation and the case law of the European Court of Justice). The initial meeting of the working group was held on 18 June 2018. Since then, the Schedule and Basic Principles of the new Act were approved by the management of the National Regulatory Authority of the Slovak Republic (NRA SR). According to the Schedule, it is foreseen that the consultation process with respective subjects and institutions will start in May 2019 and will be finalised in May 2020 by submission of the new Act for the approval of the Government of the Slovak Republic. Upon its positive opinion, the new Act will be submitted to the National Council of the Slovak Republic (Slovak Parliament) for the final approval. The new Act should come into force on 1 January 2021.

20. Order No. 22.3-19 (24 Jan. 2019) of the Head of State Nuclear Power Safety Inspectorate on the amendment of Order No. 22.3-216, 30 Nov. 2015, of the Head of State Nuclear Power Safety Inspectorate “On the approval of Nuclear safety requirements BSR-1.5.1-2015 ‘Decommissioning of Nuclear Facilities’”, available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/1f7dcee01fae11e9875cdc20105dd260.

21. Order No. 22.3-17 (23 Jan. 2019) of the Head of State Nuclear Power Safety Inspectorate on the amendment of Order No. 22.3-99 (7 Oct. 2011) of the Head of State Nuclear Power Safety Inspectorate “On the Approval of Nuclear Safety Requirements BSR-1.8.2-2015 ‘Categories of Modifications of Nuclear Facility and Procedure of Performing the Modifications’”, available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/803f3fb01f0f11e9875cdc20105dd260.

The main principles of the prepared new Act are focused on:

- the follow-up in transposition works and implementation of obligations stemming from international agreements and developments in the field;
- ensuring the compatibility and linkage with other acts (e.g. Cyber-Security Act, e-Government Act, Act Against Bureaucracy, Act on Civil Service);
- the alignment with IAEA and Western European Nuclear Regulators Association (WENRA) standards and definitions and the outcomes from the IRRS mission held in 2015;
- the adjustment of NRA SR competencies and reflection on activities in relation to experiences gained from the practical application of the Atomic Act;
- the relationship with the environmental impact assessment (EIA) process governed by the separate act; and
- the review of definitions.

Bilateral meetings with Polish and Czech regulatory authorities

There are no major developments in the international contractual base of the NRA SR in the respective period. Two bilateral activities were undertaken by the NRA SR resulting from ongoing bilateral relations. The first was a bilateral meeting between the Slovak and the Polish regulatory authorities held in Mojmirovce, Slovak Republic from 24 to 25 October 2018. The meeting was organised by the NRA SR and led by its Chairwoman, Ms Marta Žiaková. The Polish delegation was led by the Vice-President of the Polish National Atomic Energy Agency, Ms Ewa Paluch. The participants exchanged information on the current development of activities undertaken by their institutions, about the state of play of the nuclear programmes and the developments in the legal regulation of nuclear energy in their countries, as well as on the international activities of partner organisations, with the focus on the EU and the Visegrad Group (V4) area (the Czech Republic, Hungary, Poland and the Slovak Republic). The next meeting will be held in Poland in 2019.

A bilateral meeting between the Slovak and the Czech regulatory authorities was held in Prague, Czech Republic from 4 to 5 March 2019. The Czech Delegation was led by the Chairwoman of the State Office for Nuclear Security, Ms Dana Drabova, and the Slovak Delegation was led by the Chairwoman of the NRA SR, Ms Marta Žiaková. Participants exchanged their information on current developments, activities undertaken by both authorities, emerging issues and legislation in the field of nuclear energy as well as on their international activities. The next meeting will be held in the Slovak Republic in 2020.

Nuclear safety and radiological protection (including nuclear emergency planning)

Decree on the regular, comprehensive and systematic evaluation of the nuclear safety of nuclear equipment

Decree 71/2019 Coll. amending and supplementing Decree No. 33/2012 Coll. on the regular, comprehensive and systematic evaluation of the nuclear safety of nuclear equipment was published in the Collection of Laws of the Slovak Republic and it entered into force on 15 March 2019. A draft of this Decree was the subject of an approval procedure on 12 November 2018 by the Standing Working Commission on technical legal provisions of the Legislative Council of the Government of the Slovak Republic. Subsequently, this draft was forwarded to a commenting phase according

to Directive 2015/1535²² and made available within the Technical Regulation Information System (TRIS) database until 15 February 2019. After the finalisation of the notification procedure the decree was submitted for publication.

Spain

Nuclear safety and radiological protection (including nuclear emergency planning)

*Royal Decree 1400/2018, of 23 November, approving the Regulation on Nuclear Safety in Nuclear Facilities*²³

Royal Decree 1400/2018, of 23 November, approving the Regulation on Nuclear Safety in Nuclear Facilities²⁴ has incorporated into Spanish legislation the provisions of the 2014 Amended Safety Directive.²⁵ According to Article 4.1.b of this directive, member states shall establish and maintain a national legislative, regulatory and organisational framework for the nuclear safety of nuclear facilities, contemplated in the national nuclear safety requirements that cover all the phases of the life cycle of nuclear installations.

In Spain, the Nuclear Energy Act or Law 25/1964, of 29 April, constitutes the legal framework establishing the basic principles and requirements for the nuclear safety of these facilities, while Law 15/1980, of 22 April, creating the Nuclear Safety Council (CSN), establishes this body as the only competent authority in this area in Spain. The CSN has been developing and regulating the nuclear safety of nuclear facilities through different binding Instructions. The existence of this legal framework, along with the regulatory framework constituted by the Regulation on Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3 December, ensured that, at the time, the transposition of 2009 Safety Directive,²⁶ which is now amended in significant aspects by the 2014 Amended Safety Directive, was not necessary.

Although the Spanish regulatory framework, to a large extent, already includes the different requirements of the 2014 Amended Safety Directive, there was no specific regulatory standard on nuclear safety. There has been, however, regulation in the form of Royal Decrees in other areas of the sector, such as:

- radiological protection (by means of the Regulation on the Protection of Health against Ionising Radiation, approved by Royal Decree 783/2001, of 6 July);
- management of radioactive waste (Royal Decree 102/2014, of 21 February, on the Safe Management of Spent Fuel and Radioactive Waste);
- physical protection (approved by Royal Decree 1308/2011, of 26 September, on the Physical Protection of Nuclear Facilities and Materials and Radioactive

22. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification), OJ L 241 (17 Sept. 2015).

23. An unofficial translation of the Royal Decree can be found online at: www.csn.es/documents/10182/1369702/Royal%20Decree%201400-2018,%20of%20the%2023rd%20of%20November,%20approving%20the%20Regulation%20on%20Nuclear%20safety%20in%20nuclear%20facilities.

24. *Official State Gazette* of 24 November 2018, No. 284, Sec. I, p. 114601.

25. 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, OJ L 219 (25 July 2014) (2014 Amended Safety Directive).

26. Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, OJ L 172 (2 July 2009) (2009 Safety Directive).

Sources) and the licensing processes of said facilities (the aforementioned Royal Decree 1836/1999, of 3 December).

Moreover, some aspects of the 2014 Amended Safety Directive not provided for in the Spanish regulatory framework have been identified. It was determined that these were necessary to transpose, incorporating these aspects as well as several other procedures other than the CSN Instructions, and thus obtaining a unified text with the range of a Royal Decree.

Royal Decree 1400/2018 establishes the basic requirements of nuclear safety applicable to nuclear facilities throughout their life cycle, in order to:

- prevent accidents and, should an accident occur, mitigate its consequences;
- avoid, either by physical impossibility or by being extremely unlikely with a high degree of confidence:
 - early radioactive releases requiring off-site emergency measures without sufficient time for their implementation; and
 - large radioactive releases requiring protective measures for the population that cannot be limited in time or area.

The Regulation is applicable to existing or planned nuclear installations in Spain within the scope of the Directive, which includes nuclear power plants and their individualised storage facilities (ISFs), the centralised storage facility (CSF) and the Juzbado Fuel Element Factory. The facilities for the disposal of spent fuel or radioactive waste are excluded from its scope of application.

Royal Decree 1400/2018 establishes in Article 5 the prime and non-delegable responsibility of the licence holder for the nuclear safety of its installation. It also includes in Article 6 a safety objective that states, *inter alia*, that the location, design, construction, commissioning, operation and dismantling of these facilities must aim to prevent accidents and, in the event that they occur, mitigate their consequences. In order to ensure the achievement of this safety objective, the licence holders are required to apply the so-called “defence-in-depth principle”, incorporating multiple levels of protection to face a possible failure (Articles 11 and 16). Likewise, the licence holder is obliged to perform an evaluation of the installation (location, design and operation) to determine that an adequate level of nuclear safety has been achieved and that the installation complies with the safety objective (Article 12).

Furthermore, the licence holder, under the supervision of the CSN, must carry out a periodic safety review (PSR) to re-evaluate, systematically and periodically, at least once every ten years, the nuclear safety of the facility, in order to obtain an overall assessment of its behaviour, through the systematic analysis of all aspects of nuclear safety and radiological protection (Article 13). As a result of the PSR, the licence holder must introduce nuclear safety improvements in the facility.

Other aspects addressed by the regulation are the establishment of a management system aimed at nuclear safety, reinforcement of safety culture, reinforcement of the necessary structures and means for on-site emergency management and co-ordination for external management, availability of adequate financial and human resources, qualification of staff and subcontracted personnel, training, and an emphasis on early notification of events and transparency (Article 7 et al.).

Switzerland

Nuclear safety and radiological protection (including nuclear emergency planning)

Several amendments to the Nuclear Energy Ordinance (NEO) and other ordinances entered into force on 1 February 2019. Since the regulations on accident analyses in these ordinances lacked precision, the Swiss Federal Council has set out the wording unambiguously. It is now in line with the intention of the Federal Council in the original legislation, the practice applied by the Swiss Federal Nuclear Safety Inspectorate (ENSI) for many years and international requirements. Only the wording has been specified; effectively, there are no changes to current practice with regard to accident analyses. In addition to these clarifications, the Federal Council also issued new regulations for the decay storage of low-level radioactive waste from the decommissioning of nuclear power plants. The various amendments are presented in detail below.

Nuclear Energy Ordinance

Article 2 of the NEO has been amended by adding a Section 1bis that states that facilities that are located outside of nuclear facilities, and which are used for decay storage (in French “*stockage pour décroissance*” and in German: “*Abklinglagerung*”) in the meaning of Article 117 of the Radiological Protection Ordinance, are not considered as nuclear facilities. Facilities for decay storage serve for the disposal of low-level radioactive waste, which gets radiological free release or can be recycled at the latest after 30 years.

The amendments to Articles 8 and 44 of the NEO note that accident analysis is regulated in both the legislation on Nuclear Energy as well as in the legislation on Radiological Protection, but that the two pieces of legislation are compatible. The aim of the amendments was to clarify whether for an incident such as an earthquake that takes place, statistically speaking, every 10 000 years (frequency of 10^{-4} per year), the dose limit for radioactive impact on humans of 1 or of 100 millisievert (msv) is applicable. The wording of NEO, Article 8 on deterministic accident analysis and of NEO, Article 44 about the provisional taking-out-of-service of nuclear power plants as well as the wording of two ordinances of the Département fédéral de l’environnement, des transports, de l’énergie et de la communication [Federal Department of the Environment, Transport, Energy and Communications] (DETEC) have been specified in the way to unmistakably reproduce the meaning that the Swiss Federal Council had intended from the beginning, on which ENSI based its practice and that is in line with international standards.

The new rules for proof that the plant design can overcome failures ask for a differentiation between incidents caused by natural events and other incidents. Following the new wording of Article 8, Section 4 on the design of a nuclear facility states that failures originating within the plant (Section 2) and failures not caused by natural events originating outside the plant (Section 3) have to be ordered by frequency according to Article 123(2) of the Radiological Protection Ordinance. It has to be proved that in the case of a failure, the dose limits of Article 123(2) of the Radiological Protection Ordinance are observed.

The new Section 4bis of Article 4 prescribes that for the design of a nuclear facility two kinds of failures caused by natural events have to be taken into account: a natural event with an expected frequency of 10^{-3} per year and a natural event with an expected frequency of 10^{-4} per year. The basis for the design are thus two separate, single frequencies that are prescribed exactly by the Ordinance. For failures with the expected frequency of 1 every 1 000 years (10^{-3} per year), the dose resulting from a single such event for members of the public must not be greater than 1 mSv and for failures with the expected frequency of 1 every 10 000 years (10^{-4} per year) not greater than 100 mSv.

Article 8(5) has new wording as well, which states that the licence holder must prove by probabilistic analysis that there is sufficient protection in the case of an incident beyond design basis. The additional technical, organisational and administrative measures in the sense of Article 7(d) can be taken into account.

Article 44 regulates the criteria for provisional taking out of service and the backfitting of nuclear reactors. In addition to some changes in the text without material importance, Article 44(1)(a) has been amended with the provision that the holder of the operating licence must provisionally take a nuclear reactor out of service and backfit it when accident analyses show that core cooling in the event of a failure within the design basis can no longer be ensured and as a consequence the resulting dose exceeds 100 mSv. Following the new wording of Section 2 for failures not caused by natural events, an expected frequency of more than 10^{-6} per year and for failures caused by natural events an expected frequency of 10^{-4} per year have to be applied.

Article 51a now expressly regulates what kind of radioactive waste is not subject to the disposal obligation in Article 31 of the Nuclear Energy Act but remains nevertheless subject to the scope of the Nuclear Energy Act. This is the case of nuclear waste that is discharged to the environment (Article 111 to 116 of the Radiological Protection Ordinance) or that is treated in decay storage (Article 117 of the Radiological Protection Ordinance).

Article 55 fixes the responsibility for authorisations and consents for the handling of radioactive waste, which in principle belongs to the Swiss Federal Office of Energy (SFOE). The new Section 2 reserves ENSI's responsibility of following the also new Article 11(2)(f) of the Radiological Protection Ordinance. ENSI thereby becomes the granting authority for all activities related to the decay storage (see *infra* the commentary on the amendments of the Radiological Protection Ordinance).

Ordinance of the DETEC on the Methodology and Boundary Conditions for the Evaluation of the Criteria for the Provisional Taking-out-of-Service of Nuclear Power Plants (TooSO)

In the context of the amendments to the NEO, the TooSO was revised and restructured. With regard to substantive changes, the applicability of the TooSO has been expanded under the revision of Article 1. Before the change, the TooSO was applicable only for taking out of service due to design errors or ageing-related deviations from the safety-related technical design.

Ordinance of the DETEC on Hazard Assumptions and Evaluation of Protection Measures against Accidents in Nuclear Installations (HaO)

In the context of the amendments to the NEO, the HaO also has been amended. The aim of the changes of the HaO have essentially been to take over the amendments of NEO, Article 8.

Radiological Protection Ordinance (RPO)

In the context of the amendments to the NEO, there have also been amendments to the RPO. The new Article 9(j) states that the decay storage of nuclear waste from nuclear facilities that are located outside of nuclear facilities requires a radiation protection licence. The new Article 11(2)(f) states that ENSI becomes the granting authority for the radiation protection licence for the decay storage of radioactive waste of nuclear facilities and all activities related to it. In consequence, ENSI is the granting authority for licences based on both the nuclear energy legislation and radiological protection legislation for decay storage and to all activities related to it. It grants the approval for the transport of nuclear waste from the nuclear plant to the decay storage facility and the licence for the operation of the decay storage facility, and it confirms the clearance measurement.

As in the general rule, ENSI's responsibility over the nuclear power plant includes not only the control with regard to the nuclear energy legislation but also with regard to the radiological protection legislation (see Article 184(3)). In the field of decay storage, ENSI only grants separate radiological protection licences for the transport of nuclear waste from the nuclear power plant to the decay storage facility. The new Article 117(5) appoints ENSI to define the technical requirements for decay storage facilities and the activities related to the decay storage. The new Article 184(3)(d) states that ENSI is the supervisory authority for the decay storage of nuclear waste and for all activities related to it.

*Comprehensive revision of the Ordinance on Protection of the Population in the Vicinity of Nuclear Installations in the Case of an Emergency (Emergency Preparedness Ordinance – OPU)*²⁷

The Ordinance on Protection of the Population in the Vicinity of Nuclear Installations in the Case of an Emergency (Emergency Preparedness Ordinance – OPU) came into force on 1 January 2019. It regulates the provisions for emergency preparedness in the event of accidents occurring at Swiss nuclear power plants during which the release of large quantities of radioactive materials cannot be ruled out.

On 4 May 2011, in the wake of the nuclear disaster at the Fukushima Daiichi nuclear power plant, the Federal Council created the IDA NOMEX interdepartmental working group. The working group was convened to review whether the existing legislative and organisational measures in the area of emergency preparedness measures needed adapting, and if so how, especially with regard to emergency preparedness for the areas surrounding nuclear installations. The main points of the revision are:

- **Strengthening of planning assumptions:** the reference scenarios describe potential events and their consequences. Concerning emergency preparedness, the reference scenarios are used to set out strict rules on the preparation and strengthening of measures enabling the optimal management of an incident. Henceforth, the reference scenario based on a failure resulting in significant core damage, containment building failure, and the unfiltered release of a non-negligible amount of radioactive materials is applied (this is reference scenario A4). This scenario corresponds to a Level 7 event on the International Nuclear and Radiological Event Scale (INES), which is the highest classification on the international scale of safety significance developed by the IAEA. During a Level 7 event, emergency preparedness measures may be required in regions situated well outside emergency protection zone 2 (radius of 20 km around the installation). Accordingly, measures would be necessary in the rest of Switzerland (zone 3 until now) and more actors should be involved in emergency preparedness measures.

The comprehensive revision of the OPU specifies and, where necessary, supplements the obligations for cantons, some of which are located within protection zones 1 (radius of 3 to 5 km around the installation) and 2, thereby meeting the increasingly demanding requirements that are applicable within

27. For more information on the revision of the Emergency Preparedness Ordinance, see DETEC/OFEN (2017), *Révision complète de l'ordonnance sur la protection d'urgence (OPU) Rapport explicatif* [Comprehensive Revision of the Emergency Preparedness Ordinance: Explanatory Report], available at: www.admin.ch/ch/f/gg/pc/documents/2867/OPU_Rapport-expl_fr.pdf. See also, Département fédéral de la défense, de la protection de la population et des sports (DDPS), Office fédéral de la protection de la population OFPP (2015), *Concept de protection d'urgence en cas d'accident dans une centrale nucléaire en Suisse* [Emergency preparedness concept in the event of an accident at a nuclear power plant in Switzerland], available at: www.newsd.admin.ch/newsd/message/attachments/40199.pdf.

the framework of existing organisations. As a result, cantons, regions and communes are given duties within the rest of Switzerland.

- Regulations governing evacuation: the comprehensive revision of the OPU attaches greater weight to large-scale evacuation. The cantons containing some communes within protection zones 1 and 2, as well as the cantons in the rest of Switzerland, need to be involved. In particular, the latter have to guarantee the evacuation of the population exposed to danger along with the provision of accommodation and assistance to evacuees.
- Changes in terminology: the current “zones” have been renamed “emergency preparedness zones”. “Zone 3” (the rest of Switzerland) no longer exists under this nomenclature. Moreover, the term “planning zones” has been introduced. In the event of an incident, specific preparedness measures are ordered for these zones.

Radioactive waste management

Sectoral Plan for Deep Geological Repositories, third stage

- General

The search for suitable repository sites is regulated in the Sectoral Plan for Deep Geological Repositories.²⁸ The search is carried out in three stages in which the selection of geological siting areas is gradually narrowed down. At the end of each stage, the Federal Council decides on the next steps in the process. The SFOE bears the overall responsibility for the procedure, in which the protection of people and the environment is the top priority. The regional participation established within the sectoral plan enables the participation of the cantons, communes and neighbouring states (Germany) at an early stage in the process.

- Stage 2

In Stage 2, the task of the National Cooperative for the Disposal of Radioactive Waste (Nagra) was to propose at least two geological siting areas per type of repository (for high-level radioactive waste (HLW) and low- and intermediate-level radioactive waste (L/ILW)). Nagra proposed Jura Ost and Zürich Nordost as geological siting areas in which one repository for each category or a single repository for both categories would be feasible. Following its detailed study, the Swiss Federal Nuclear Safety Inspectorate came to the conclusion that, in addition to the two proposed geological siting areas, Nördlich Lägern should also be examined more closely. This view was also shared by the Federal Nuclear Safety Commission. Following a public consultation, Stage 2 was concluded on the basis of the decision by the Federal Council (end of 2018). In Stage 2, in addition to narrowing down the selection, Nagra is working closely together with the proposed siting regions in order to identify and designate potential sites for placement of the surface facilities.²⁹

- Stage 3

Stage 3 is the last stage in the Sectoral Plan for Deep Geological Repositories. During this stage, the remaining sites will be studied in detail and compared to each other. Nagra will use this as a basis on which to submit general licence applications for the construction of the deep geological repositories, most likely at the end of 2024. After a

28. For more information on the Sectoral Plan for Deep Geological Repositories see SFOE (n.d), “Deep Geological Repository’ sectoral plan (SDGR)”, www.uvek-gis.admin.ch/BFE/storymaps/EA_SachplanGeologischeTiefenlager/?lang=en (accessed 12 Apr. 2019).

29. For more information on the Stage 2 process, see NEA (2018), “Sectoral plan for deep geological repositories and Stage 2 consultation”, NLB, No. 100, OECD, Paris, pp. 102-103.

review by the relevant Federal authorities and upon completion of a consultation procedure, the Federal Council will be able to award the appropriate general licences and designate the siting location for the deep geological repositories. It will submit the rulings on the general licences to Parliament for approval. The decision on the approval of the general licences, which is expected in around 2030, is subject to a referendum.

After the award of the general licence, substructure geological analyses will be performed in the siting locations (construction of a rock laboratory). These investigations will provide important information for the construction of the repository. The next step is to apply for a construction licence and then an operating licence. Based on the current plan, the commissioning of a repository for L/ILW could take place as of 2050 and a repository for HLW as of 2060.

It is customary in the course of infrastructure projects such as deep geological repositories to involve all the relevant parties. This principle also applies to the aforementioned sectoral plan. Accordingly, regional conferences (RC) were put in place in Stage 2. Organised in associations, they will continue to represent the interests of the different siting regions in Stage 3 and draw up opinions, questions and requests. Their members represent the interests of the communes, planning associations, organisations and the population. In particular, the RCs will pay close attention to the realisation of the surface infrastructures and address issues related to regional development and security. Regional participation takes place with the support and under the aegis of the SFOE. The siting cantons are also involved, as are the other federal authorities such as ENSI and Nagra.

- Geological investigations

Geological investigations aim to further knowledge of the substructure in potential locations for a deep geological repository. The Nuclear Energy Act states that a licence is required from DETEC to carry out such investigations. Such boreholes provide more accurate information on the rock strata in the area of the potential repository, so that a profile of the geological situation can be drawn up with regard to all types of repository possible at the location (L/ILW, HLW and combined repositories). Quaternary boreholes also require a licence. These bore down to a lesser depth than exploratory boreholes and are used to obtain field data on matters relating to long-term geological evolution.

The SFOE is responsible for the licensing procedure in conjunction with the federal agencies and cantons concerned. A licensing procedure is conducted for each bore site. The application to bore is published at the beginning of each procedure and can be downloaded from this website. Persons affected by boreholes may appeal to the SFOE against the planned measures.³⁰

Nagra submitted 23 applications for boreholes in the potential siting areas with the SFOE: 8 for Jura Ost, 8 for Zürich Nordost and 7 for Nördlich Lägern. Public consultations were launched for all of the applications. They resulted in 472 objections for Jura Ost, 99 for Zürich Nordost and 132 for Nördlich Lägern.

30. For more information related to the licensing of the bore sites, see SFOE (2018), "Global investigations", www.bfe.admin.ch/bfe/en/home/supply/nuclear-energy/radioactive-waste/geological-investigations.html (accessed 12 Apr. 2019).

United States

General legislation, regulations and instruments

Nuclear Energy Innovation and Modernization Act

On 14 January 2019, the President signed into law the Nuclear Energy Innovation and Modernization Act (NEIMA),³¹ a statute that affects the US Nuclear Regulatory Commission (NRC) in a variety of ways. One of the most prominent sections of the new law requires the NRC to enhance its licensing process for commercial advanced nuclear reactors.³² First, working within the scope of the NRC's existing regulations, the NRC must provide for staged licensing and develop risk-informed, performance-based licensing evaluation techniques for commercial advanced nuclear reactors. Second, the NRC must undertake a rulemaking, to be completed by the end of 2027, to establish a technology neutral regulatory framework for optional use by commercial advanced nuclear reactor applicants.

The law also addresses research and test reactor licensing. Specifically, it requires the NRC to develop strategies and guidance for predictable, efficient and timely licensing reviews for research and test reactors and to apply a new cost recovery-percentage standard to distinguish between commercial facilities and non-commercial facilities.³³ Under the new cost-recovery standard, the NRC could issue a non-commercial licence for a reactor useful for research and development that also engages in commercial activities so long as the licensee recovers no more than 75% of its annual owning and operating costs through its commercial activities, with no more than 50% coming through sales of energy.³⁴

In addition, the law will require the NRC to adjust its approach to determining the fees it charges for its regulatory work. Although the NRC is not directly funded through fees – like most agencies in the US Government, the NRC receives appropriations each year from the US Treasury pursuant to appropriations laws enacted by the US Congress – the NRC has been required by law to charge fees to its licensees, applicants and others to whom it provides services, with those fees then being used to reimburse the US Treasury for a substantial portion of the NRC's budget.³⁵ The new law continues this basic approach, with certain adjustments, most of which will take effect in October 2020.³⁶

The law also addresses certain other budgetary and administrative matters involving the NRC, including requiring the NRC to develop performance metrics and milestone schedules for NRC activities being undertaken at the request of licensees or applicants and reporting certain delays to the NRC's Commission and to the US Congress, and requiring the NRC to train its staff and hire experts, as necessary, to support the licensing process improvement initiatives discussed above.³⁷ Finally, the law requires the NRC to develop and submit to the US Congress a number of reports on a variety of topics, including: 1) the commercial advanced nuclear reactor and research and test reactor licensing process improvement initiatives required by the law; 2) baffle-former bolt guidance; 3) evacuations in the event of emergencies;

31. Pub. L. No. 115-439, 132 Stat. __ (2019).

32. See *ibid.*, Sec. 103.

33. *Ibid.*, Sec. 103(a)(3), 106.

34. *Ibid.*, Sec. 106(b)(2) (amending the Atomic Energy Act of 1954, Sec. 104c. (42 USC 2134(c))).

35. See Omnibus Budget Reconciliation Act of 1990, Sec. 6101 (42 United States Code (USC) 2214).

36. Pub. L. No. 115-439, Sec. 102(b), 132 Stat. __ (2019); see also *ibid.*, Sec. 202 (requiring the NRC to complete a voluntary pilot initiative related to uranium recovery licensing fees).

37. *Ibid.*, Sec. 102(c).

4) accident tolerant fuel; 5) best practices for local community advisory boards associated with nuclear power reactor decommissioning; 6) the NRC's response to a study on reprisal and chilling effect at the NRC; and 7) improving the efficiency and transparency of, and examining a potential new fee approach for, uranium recovery licensing reviews.³⁸

Nuclear Energy Innovation Capabilities Act of 2017

On 28 September 2018, the President signed into law the Nuclear Energy Innovation Capabilities Act of 2017.³⁹ The law is directed primarily at the US Department of Energy (DOE), which has responsibility within the US Government for, among other things, promotion of commercial nuclear technologies, but the law does include certain provisions that address the NRC. One such provision requires the NRC to enter into a memorandum of understanding with the DOE that would address interactions between the two agencies regarding technical expertise, modelling and facilities related to advanced reactors.⁴⁰ The law also authorises the DOE and the NRC to enter into a memorandum of understanding relating to the National Reactor Innovation Center – a DOE programme authorised by the law for enabling the testing and demonstration of reactor concepts that would be proposed and funded, at least in part, by the private sector – to facilitate sharing of technical expertise and knowledge between the two agencies through a variety of means.⁴¹ The law additionally confirms that the NRC would remain responsible for licensing DOE reactors for commercial demonstration purposes as specified in pre-existing law (specifically, Section 202 of the Energy Reorganization Act of 1974 (42 USC 5842)).⁴²

As to the law's provisions directed more exclusively towards the DOE, they include, among other things, a requirement that the DOE assess the mission need for, as well as plan for and construct, a versatile reactor-based fast neutron source, with a goal of commencing operations by the end of 2025, and a requirement that the DOE execute a programme that would use high-performance computation modelling and simulation techniques to enhance US capabilities for developing new reactor technologies.⁴³

Radioactive waste management

Consolidated Interim Storage Facility applications pending before the NRC

The NRC is currently reviewing two applications to construct and operate a Consolidated Interim Storage Facility (CISF). The applicants, Interim Storage Partners/Waste Control Specialists (ISP) and Holtec International Inc. (Holtec), are requesting to store spent nuclear fuel in Andrews County, in the state of Texas, and Lea County, in the state of New Mexico, respectively.⁴⁴ The requested 10 *Code of Federal Regulations* Part 72 licences would authorise possession and storage of spent nuclear fuel for 40 years.

Several organisations have filed intervention petitions and requests for hearing on these applications, raising a variety of environmental, safety and legal contentions.

38. *Ibid.*, Sec. 103(b)-(e), 104-105, 107-109, 201-202.

39. Pub. L. No. 115-248, 132 Stat. __ (2018).

40. *Ibid.*, Sec. 2(h).

41. *Ibid.*

42. *Ibid.*

43. *Ibid.*, Sec. 2(e)(2), 2(g).

44. More information on the applications is available at NRC (2018), "Interim Storage Partners", www.nrc.gov/waste/spent-fuel-storage/cis/waste-control-specialist.html (accessed 3 Apr. 2019) and NRC (2018), "Holtec International – HI-STORE CISF", www.nrc.gov/waste/spent-fuel-storage/cis/holtec-international.html (accessed 3 Apr. 2019).

An Atomic Safety and Licensing Board (ASLB) has been established for each proceeding. Oral argument on standing and contention admissibility in the Holtec proceeding was held on 23-24 January 2019.⁴⁵

45. More information on the proceedings is available on the NRC's Electronic Hearing Docket at: <https://adams.nrc.gov/ehd/>.

