

National legislative and regulatory activities

Canada

General legislation, regulations and instruments

Impact Assessment Act – Comprehensive changes to the federal environmental assessment process

On 21 June 2019, the Government of Canada adopted the Impact Assessment Act (IAA).¹ The impetus for the changes originated from the government’s commitment during the last election campaign to reform federal environmental and regulatory processes to address concerns raised regarding meaningful engagement, inefficiencies, concern for public trust and the need to balance the country’s environmental goals with the desire to remain competitive. Following a comprehensive consultation process that included recommendations from an expert review panel, the government tabled its proposed legislation (Bill C-69) on 8 February 2018. Following further reviews by the House of Commons and the Senate, the revised legislation received Royal Assent on 21 June 2019 and it came into force on 28 August 2019.

The focus of the IAA differs significantly from the prior, over 40-year old environmental assessment legislation in Canada. Previously, the focus of the environmental assessment was to determine potential adverse effects and their significance. Before a project in relation to which significant adverse impacts were identified was allowed to proceed, the Governor in Council (GIC) determined whether the “significant adverse environmental effects” could be “justified”.

The new approach moves away from focusing on assessing biophysical environmental effects and their significance. The expanded factors,² in addition to biophysical environmental effects, include health impacts, purpose and need, economic opportunities, social issues, cultural concerns, Indigenous knowledge and potential impact on the rights of Indigenous peoples. The assessment must also consider how the project contributes to sustainability³ and the extent to which the effects of the project hinder or contribute to Canada’s ability to meet its environmental obligations. Projects must also undergo a gender-based analysis to assess how a project could affect particular groups. The IAA enhances consultation opportunities with Indigenous peoples and recognition of Indigenous rights, interests and knowledge. The IAA also increases consultation and engagement opportunities for Indigenous groups throughout the impact assessment (IA), but notably during the “early planning phase”. This approach reflects a shift towards increased Crown-Indigenous consultation earlier in the process, rather than proponent-driven engagement.

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1. Statutes of Canada (S.C.) 2019, Chapter (c.) 28.
 2. IAA, Section 22 lists more than 20 factors that must be considered as part of an impact assessment of a designated project.
 3. IAA, Section 2 defines “sustainability” as “the ability to protect the environment, contribute to the social and economic well-being of the people of Canada and preserve their health in a manner that benefits present and future generations”.

Under the new legislation, as was the case in the law it repealed, only designated projects⁴ listed in the Physical Activities Regulations⁵ (the Project List) or projects specifically designated by the Minister are subject to the IAA. The Project List includes projects determined to have the greatest potential for adverse and complex effects in areas of federal jurisdiction. The Project List includes uranium mines and mills,⁶ certain nuclear and storage facilities,⁷ and long-term management or disposal facilities⁸ of various size, location or characterisation. Nuclear reactors with a combined thermal capacity of more than 900 megawatts thermal (MWt) located within the licensed boundaries of an existing Class IA nuclear facility or reactors with thermal capacity of more than 200 MWt located outside a Class IA nuclear facility boundary are included in the Project List.⁹

The legislation establishes a single federal agency, the Impact Assessment Agency (Agency) to lead or plan all assessments of designated projects. The Agency is responsible to co-ordinate consultations and to ensure opportunities for public participation. It also ensures that the IA is conducted and the IA report is submitted. Under the new legislation, the Canadian Nuclear Safety Commission (CNSC) is no longer the responsible authority for the conduct of impact assessment of designated projects that are regulated under the Nuclear Safety and Control Act (NSCA).¹⁰ Under the former environmental assessment legislation in Canada, the CNSC was the authority responsible for the conduct of the environmental assessment of projects that fell under the NSCA. As explained below, for these projects, the CNSC takes part in the assessment, but is not responsible for decision making on the assessment.

At the initial stage or planning phase, a proponent submits to the Agency an initial description of the intended project. Following a consultation process, the Agency provides the proponent a summary of the issues and comments received. The proponent will then submit a detailed revised project description that will include how it intends to address the issues raised by the Agency. In accordance with section 16 of the IAA, the Agency will then determine whether an assessment is required, taking into account such considerations as the potential adverse effects, as well as comments from the public and Indigenous groups. If an impact assessment of a designated project is required, the Agency has 180 days to provide the proponent with the Notice of the Commencement of the assessment and the information and/or studies that the Agency will require for the impact assessment. Under the new legislation, the Agency determines the scope of the factors to be considered in the impact assessment.

For a project that involves physical activities regulated under the NSCA, the Minister of the Environment must refer the project to a review panel to conduct the impact assessment.¹¹ Within 45 days after the publication of the Notice of Commencement, the Minister establishes the panel's terms of reference, in consultation with the President of the CNSC. The Agency must appoint within that period the chairperson and at least two other members. At least one panel member, but not the majority of the members of the review panel, is appointed from a roster

4. IAA, Section 2 states that "designated project" means "a physical activity or any physical activity incidental to the physical activity that is carried out in Canada or on federal lands and that is designated by regulations under the Act or designated in an order made by the Minister of the environment".

5. Statutory Orders and Regulations (SOR)/2019-285.

6. *Ibid.*, Sections 20, 21, 22 and 23.

7. *Ibid.*, Section 26.

8. *Ibid.*, Section 28.

9. *Ibid.*, Section 27.

10. S.C. 1997, c.9.

11. IAA, Section 43, "Obligation to refer".

of members of the CNSC.¹² The time limit for the review panel to submit a report must not exceed 600 days, subject to legislated provisions to extend the time limit.

At the end of the IA, the report, together with recommendations on conditions in relation to the adverse effects, is submitted to the GIC for decision. Under the previous assessment regime, the decision whether to approve a project was based on whether there were any significant adverse environmental effects and, if so, whether the effects were justified in the circumstances. Under the new legislation, the decision framework has shifted from whether significant adverse impacts are justified to a determination of whether a project is in the public interest. Section 63 of the IAA stipulates the factors that the GIC must consider to determine whether a project is in the public interest. The determination must consider:

- the extent to which the project contributes to sustainability;
- the extent to which identified adverse effects are significant;
- the implementation of appropriate mitigation measures;
- the impact the project may have on Indigenous groups and on Aboriginal Rights; and
- the extent to which the project hinders or contributes to Canada's environmental obligations and commitments related to climate change.

Should the GIC determine that the project is in the public interest, the Minister of the Environment will issue a decision statement that will include any conditions with which the proponent must comply, including any conditions that the Minister designates as part of the licence issued under section 24 of the NSCA.

Subsection 51(2) of the IAA stipulates that the review panel's report must also include "the information necessary for the licence to be issued" under section 24 of the NSCA in relation to the project that is the subject of the report. This reflects the intention to integrate the assessment process, to the extent possible, with the regulatory process for licensing that will follow a successful assessment. It is important to note that this does not empower the process under the IAA to substitute for the licensing process and decision making under the NSCA, which is conducted by the nuclear regulatory body, the CNSC. As with previous assessment processes, the licensing process for nuclear projects under the regulatory scheme follows the assessment process if it results in a positive decision. Since the review panel's assessment report is to contain the information necessary for licensing, this should facilitate to the extent possible the integration of the assessment with the subsequent licensing process.

The IAA transitional provisions stipulate that projects that commenced under Canadian Environmental Assessment Act, 2012 (CEAA, 2012),¹³ for which the notice of commencement was posted, are continued under the CEAA 2012 as if that Act had not been repealed.

12. *Ibid.*, Section 50, "Establishment of roster".

13. S.C. 2012, c. 19, s. 52.

France

Nuclear installations

Decree No. 2019-190 of 14 March 2019 codifying provisions concerning basic nuclear installations, the transport of radioactive substances and transparency in the field of nuclear energy¹⁴

The Decree codifies in the Environment Code numerous provisions relating to basic nuclear installations (BNI), especially the provisions of Decree 2007-1557 of 2 November 2017 (the so-called “Procedures Decree”) concerning BNI and the control of radioactive substances transport in the field of nuclear safety.

Accordingly, Title IX of Book V of the regulatory part of the Environment Code entitled “Nuclear Safety and Basic Nuclear Installations” now has four detailed chapters related to:

- the Nuclear Safety Authority (Autorité de sûreté nucléaire – ASN) and the National Institute for Radiological Protection and Nuclear Safety (Institut national de radioprotection et de sûreté nucléaire – IRSN) (Art. R. 592-1 to R. 592-61); it should be noted that some provisions already existed, but were supplemented and renumbered;
- BNIs (Art. R. 593-1 to R. 593-123): this chapter is divided into 17 sections: nomenclature of BNIs; general provisions; use of external contractors; creation of a BNI; commissioning of a BNI; ASN requirements; amendment of the decree authorising the creation of a BNI; significant modifications during operation coming under the ASN; periodic review; permanent shutdown, dismantling and decommissioning of a BNI; provisions pertaining to installations operating under a grandfather clause; general interest easement; applicable provisions in case of serious risk; installations located in the perimeter of a BNI; particular categories of BNIs; Radiological Protection Adviser; and provisions pertaining to short-term authorisations;
- radioactive substances transport (Art. 595.1 to R. 595.3); and
- controls and sanctions (Art. 596-1 to R. 596-17).

The decree also codifies provisions relating to public information procedures and effective transparency in the field of nuclear energy (Art. R. 125-49), local information commissions (Art. R. 125-50 to R. 125-76) and the High Committee for Transparency and Information on Nuclear Security (Haut Comité pour la transparence et l’information sur la sécurité nucléaire, Art. 125-77 to R. 125-87).

As of 1 April 2019, the date of the decree’s entry into force, the following decrees are repealed:

- Decree No. 2007-830 of 11 May 2007 relating to the nomenclature of BNIs;
- Decree No. 2007-831 of 11 May 2007 setting the procedures for the appointment and certification of nuclear safety inspectors;
- Decree No. 2007-1368 of 19 September 2007 relating to the part-time secondment of some civil servants at the Nuclear Safety Authority;

14. *Journal officiel “Lois et Décrets”* [Official Journal of Laws and Decrees] (J.O.L et D.), No. 64, 16 March 2019, text No. 3.

- Decree No. 2007-1557 of 2 November 2007 relating to BNIs and control, in the field of nuclear energy, of radioactive substances transport, except for Art. 65, 66, 67, 67-1, 68 and 69;
- Decree No. 2007-1572 of 6 November 2007 relating to technical investigations on accidents or incidents related to a nuclear activity;
- Decree No. 2008-251 of 12 March 2008 relating to the local information commissions of BNIs;
- Decree No. 2008-1108 of 29 October 2008 relating to the composition of the High Committee for Transparency and Information on Nuclear Security;
- Decree No. 2010-277 of 16 March 2010 relating to the High Committee for Transparency and Information on Nuclear Security; and
- Decree No. 2016-846 of 28 June 2016 relating to the modification, permanent shutdown and decommissioning of a BNI and to subcontracting, except for para. I and II of Article 13.

Decree No. 2019-67 of 1 February 2019 establishing an Interministerial Delegate for the future of the Fessenheim territory and the territories of coal-fired power plants¹⁵

Decree of 6 February 2019 appointing an Interministerial Delegate for the future of the Fessenheim territory and the territories of coal-fired power plants – Mr David Coste¹⁶

The Decree of 1 February 2019 establishes, under the Minister for Energy, an Interministerial Delegate for the future of the region near the Fessenheim site (Haut-Rhin) and the regions near coal-fired power plants. Mr David Coste was appointed Interministerial Delegate by the Decree of 6 February 2019. In this capacity, he is in charge of:

- preparing and co-ordinating, under the authority of the Minister for Energy, the operations necessary for the shutdown of the Fessenheim NPP as well as the operations necessary for the shutdown of the coal-fired units of the Gardanne (Bouches-du-Rhône), Cordemais (Loire-Atlantique), Saint-Avold (Moselle) and Le Havre (Seine-Maritime) power plants;
- conducting the development of a reconversion strategy for the livelihood and employment areas concerned, taking into account the impact of the permanent shutdown of these power plants on local economic activities, including contracting, and on the tax revenue of local communities.

In fulfilling this mission, the Interministerial Delegate liaises with the prefects of the departments and regions concerned and can appeal to state administration and national state establishments. The individual ensures that proper social dialogue and consultation take place at every stage with the stakeholders in the living and working areas concerned, especially with local communities, socio-economic actors and operators.

Decree No. 2012-1384 of 11 December 2012 establishing an Interministerial Delegate on the closure of the nuclear power plant and conversion of the Fessenheim site is repealed.

15. J.O.L. et D., No. 29, 3 February 2019, text No. 1, consolidated version in force as of 14 November 2019, available at: www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000038088256&dateTexte=20191114.

16. J.O.L. et D., No. 32, 7 February 2019, text No. 38.

Lithuania

Nuclear safety and radiological protection (including nuclear emergency planning)

Requirements for operating experience

Nuclear Safety Requirements BSR-1.4.4-2019 “Use of the Experience of the Individuals Operating in the Nuclear Energy Sector”¹⁷ were approved by the Head of State Nuclear Power Safety Inspectorate (VATESI) in 2019 and replaced Nuclear Safety Requirements BSR-1.8.1-2010 “Notification on Unusual Events at Nuclear Power Plants” and “Requirements on Operational Experience Feedback in the Field of Nuclear Energy” (P-2009-04). The new requirements were put into place pursuant to changes in legislation and VATESI’s regulatory experience and establish provisions on monitoring, evaluating and sharing operational experience in the nuclear energy sector, and also establish obligations for evaluation and reporting of unusual events. The new requirements came into force on 1 November 2019.

Requirements for Maintenance, Surveillance and In-service Inspections of Nuclear Facilities

Nuclear Safety Requirements BSR-1.8.6-2019 “Maintenance, Surveillance and In-service Inspection of Nuclear Facility’s Structures, Systems and Components Important to Safety”¹⁸ were approved by the Head of VATESI in 2019. These requirements gather provisions on maintenance, surveillance and in-service inspections within one document and are applicable to all nuclear facilities. The new requirements include provisions regarding planning, maintenance management, surveillance and in-service inspections, analysis of their results, and documentation. The new requirements came into force on 1 November 2019.

Transport of radioactive materials

Requirements for licensing of transport activities

New Nuclear Safety Requirements BSR-4.1.2-2019 “Requirements for the Documents which must be Provided with an Application to Obtain a Licence for Transport of Nuclear Fuel Cycle, Nuclear and Fissionable Materials”¹⁹ were approved by the Head of VATESI in 2019. The goal of this new document is to set requirements for the content of an application for a licence for transport of nuclear fuel cycle, nuclear and fissionable materials. The new requirements came into force on 1 November 2019.

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17. Order No. 22.3-148 (4 July 2019) of the Head of State Nuclear Power Safety Inspectorate, “On the approval of Nuclear Safety Requirements BSR-1.4.4-2019 ‘Use of the Experience of the Individuals Operating in the Nuclear Energy Sector’”, TAR, No. 11095 (4 July 2019) available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/4be2d5409e5011e9878fc525390407ce.
 18. Order No. 22.3-136 (3 July 2019) of the Head of State Nuclear Power Safety Inspectorate, “On the approval of Nuclear Safety Requirements BSR-1.8.6-2019 ‘Maintenance, Surveillance and In-service Inspection of Nuclear Facility’s Structures, Systems and Components Important to Safety’”, TAR, No. 10957 (3 July 2019), available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/50c601109d7c11e9878fc525390407ce.
 19. Order No. 22.3-169 (19 July 2019) of the Head of State Nuclear Power Safety Inspectorate, “On the approval of Nuclear Safety Requirements BSR-4.1.2-2019 ‘Requirements for the Documents which must be Provided with Application to Obtain Licence for Transport of Nuclear Fuel Cycle, Nuclear and Fissionable Materials’”, *Teisės AktyRegistras* (TAR – Register of Legal Acts), No. 11968 (19 July 2019), available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/1685a0b0a9e211e9964cdd77475976b0.

Luxembourg

Nuclear safety and radiological protection (including nuclear emergency planning)

Transposition of the Euratom Basic Safety Standards Directive

The new Law of 28 May 2019 on Radiological Protection [*Loi du 28 mai relative à la radioprotection*] and the Regulation of 1 August 2019 on Radiological Protection [*Règlement grand-ducal du 1^{er} août 2019 relatif à la radioprotection*] transposes the Euratom Basic Safety Standards Directive²⁰ and entered into force on 1 August 2019. The new framework repeals and replaces the former legal framework on those matters, namely the Framework Act of 25 March 1963 concerning the Protection of the Population against the Dangers arising from Ionising Radiation.

The main aspects from the previous framework have been maintained and strengthened, as the previous framework was in conformity with the 2014 amended Nuclear Safety Directive.²¹ The new framework also contains some provisions from the 2014 amended Nuclear Safety Directive to further strengthen compliance. The new law mainly aims to:

- modernise the national legislative framework for the control and monitoring of practices that use radiation sources, for example in nuclear medicine departments. The level of control takes into account a graded approach;
- simplify the administrative procedures for low-risk equipment, such as baggage screening scanners. For these practices, the law establishes a system of authorisation, inspections and sanctions by the regulatory body;
- define conditions relating, in particular, to the training and continuing education necessary for the exercise of a practice, the compulsory consultation of experts, the individual protection of workers and the information that must be provided to workers on the potential risks. Concerning experts, the law creates new professions of expert in medical physics and expert in radiological protection;
- specify the responsibilities of the requesting physician and the medical director in the field of medical exposures to radiation so as to ensure the optimisation and justification of any act of nuclear medicine and radiology for the protection of patients;
- broaden the scope of the law to include exposure from natural sources of radiation, including the protection of aircrews from cosmic radiation, radon exposure in dwellings and workplaces, exposure from building materials, and protection of workers from naturally occurring radioactive materials;
- clarify the responsibilities and criteria for the protection of the population in order to cope with the possibility of a nuclear or radiological accident. In this area, it strengthens the implementation of emergency response planning;

20. *Official Journal of the Grand Duchy of Luxembourg*, A389 (7 June 2019) and *ibid.*, A528 (5 Aug. 2019), implementing 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, *Official Journal of the European Union (OJ)* L 13/1 (17 Jan. 2014) (Euratom Basic Safety Standards Directive).

21. 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 219/42 (25 July 2014).

- establish closer collaboration among member states and ensure participation in international peer reviews concerning nuclear safety; and
- forbid some practices, such as the construction and operation of nuclear installations.

Portugal

Nuclear safety and radiological protection (including nuclear emergency planning)

New basic safety standards for protection against the dangers arising from exposure to ionising radiation

Decree Law 108/2018 of 3 December updates the standards regarding radiological protection, adapting them to the Euratom Basic Safety Standards Directive.²² It also appoints the competent authority and the supervisory authority for radiological protection and establishes its powers.

- Transposition of the Euratom Basic Safety Standards Directive

Decree Law 108/2018 transposes the Euratom Basic Safety Standards Directive, defining the regulatory framework applicable to planned and emergency exposure situations, determining a set of management, control, rapid notification and information mechanisms for the protection of members of the public from the risks of exposure to ionising radiation. Despite some minor arguable inconsistencies between the directive and its transpositions, the only aspects of the transposition that are to be singled out relate to the options of the Portuguese Government in relation to the institutional framework for the enforcement of this legal framework.

- Termination of COMRSIN

The previously existing Regulatory Commission for the Security of Nuclear Facilities (Comissão Reguladora para a Segurança das Instalações Nucleares – COMRSIN), created by Decree Law 30/2012 of 9 February 2012, is terminated and its powers are transferred to two public authorities under the new legal framework: the Portuguese Environment Agency (Agência Portuguesa do Ambiente – APA) and the Inspectorate-General for Agriculture, Sea, Environment and Territorial Planning (Inspeção-Geral da Agricultura, do Mar, do Ambiente e do Ordenamento do Território – IGAMAOT).

- Portuguese Environment Agency

The APA is now one of the two authorities responsible for ensuring the existence of a high level of radiological protection and of nuclear safety, the safe management of spent fuel and radioactive waste, as well as the issue of registrations and licences for practices or activities covered by the decree law. It has, in essence, received all the powers previously held by COMRSIN and by the Directorate General for Health, except those relating to control and inspections. In other words, it regulates and licenses, but does not verify compliance with the law.

Other than the powers received under Decree Law 108/2018, the APA's key roles are proposing, developing and implementing environmental and sustainable development policies, combating climate change, preserving nature, protecting air quality and restoring contaminated soils.

22. *Diário da República* (Official Register), Series 1, No. 232, p. 5490 (3 Dec. 2018). The Decree Law implements 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 13/1 (17 Jan. 2014) (Euratom Basic Safety Standards Directive).

- Inspectorate-General for Agriculture, Sea, Environment and Territorial Planning

Decree Law 108/2018 transferred inspection powers relating to radiological protection, nuclear safety, spent fuel and radioactive waste to IGAMAOT. IGAMAOT is thus entrusted with ensuring compliance with this legal framework. To this extent, it can order corrective measures, including the modification or revocation of issued permits and registrations, as well as operating conditions and procedures, and the temporary or permanent closure of installations.

Slovak Republic

General legislation, regulations and instruments

Draft Decree amending Decree No. 52/2006 Coll., on professional competence as amended by Decree No. 34/2012 Coll.

The Draft Decree of the Nuclear Regulatory Authority of the Slovak Republic (NRA SR) amending Decree No. 52/2006 Coll. on professional competence as amended by Decree No. 34/2012 Coll. was the subject of the approval procedure on 19 August 2019 by the Standing Working Commission on technical legal provisions of the Legislative Council of the Government of the Slovak Republic. Subsequently, this draft was open for comment in accordance with 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.²³ The draft decree was made available within the EU Technical Regulation Information System database through 23 November 2019. No comments were received from the European Commission or any other member states; therefore, the decree was published in the Official Journal of Law of the Slovak Republic on 29 November 2019 as Regulation No. 410/2019 Coll., and it came into force on 1 January 2020.

Quadrilateral meeting with the Czech, Hungarian and Slovenian regulatory authorities

The Slovenian town Ptuj hosted the quadrilateral meeting of the Czech, Hungarian, Slovak and Slovenian regulatory authorities from 3 to 4 April 2019. Meeting participants exchanged information on changes and current developments of their regulatory authorities and on the most important activities undertaken from the last meeting. Topics of discussion included issues of nuclear power plant (NPP) safety, legal and regulatory frameworks, international issues and safety culture. Part of the meeting included a consultation on international projects conducted within the common consortium.

Bilateral meeting with Austrian authorities

The bilateral meeting between Austria and the Slovak Republic was held in Piestany, Slovak Republic, from 17 to 19 June 2019. As stipulated in the bilateral treaty concluded between both countries, the topic of the meeting was issues related to nuclear safety and radiological protection. The Slovak delegation was led by Chairwoman Marta Žiaková of the Nuclear Regulatory Authority of the Slovak Republic. As the part of the official programme, the expert meeting on Mochovce NPP, units 3 and 4, was held on 17 June 2019. Heads of both delegations noted their appreciation for these regular

23. 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, OJ L 241/1 (17 Sept. 2015).

meetings as well as the opportunity for discussion on, and exchange of, current information, which reinforce confidence between both countries in the nuclear field.

Slovenia

Nuclear safety and radiological protection (including nuclear emergency planning)

New regulations adopted on the basis of Ionising Radiation Protection and Nuclear Safety Act from 2017

As reported previously,²⁴ on the basis of the 2017 Ionising Radiation Protection and Nuclear Safety Act,²⁵ four government decrees (denoted by the abbreviation “UV”), two Rules of the Minister responsible for the Environment (denoted by the abbreviation “JV”) and six Rules of the Minister responsible for Health (denoted by the abbreviation “SV”) were adopted by the end of July 2018.

The following additional regulations were recently adopted to implement the same act:

- Decree on verification of radioactivity of shipments that may contain radioactive sources of unknown origin (UV11), in February 2019 (*Official Gazette of the Republic of Slovenia*, No. 10/2019, 15 Feb. 2019); and
- Amendments to the Decree on the content and elaboration of protection and rescue plans, in April 2019 (*Official Gazette of the Republic of Slovenia*, No. 26/2019, 26 April 2019). Although the amended decree was actually adopted to implement the Protection against Natural and Other Disasters Act, it is important because it transposed some provisions of the Euratom Basic Safety Standards Directive.²⁶

With these two regulations, the process of transposition of the Euratom Basic Safety Standards Directive into the Slovenian legal system was completed. The Slovenian Nuclear Safety Administration continues to work on amendments to other regulations issued under the 2017 Ionising Radiation Protection and Nuclear Safety Act, which will be adopted in the coming months and years.

24. For more information, see NEA (2018), “New regulations adopted on the basis of Ionising Radiation Protection and Nuclear Safety Act from 2017”, *Nuclear Law Bulletin*, No. 101, OECD, Paris, pp. 87-88.

25. Ionising Radiation Protection and Nuclear Safety Act (ZVISJV-1), *Official Gazette of the Republic of Slovenia*, No. 76/2017 (22 Dec. 2017).

26. 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 13/1 (17 Jan. 2014) (Euratom Basic Safety Standards).

Switzerland

Nuclear installations

Opening of the cooling water discharge authorisation procedure for the Beznau nuclear power plant²⁷

Under the new legal provisions, the existing discharge authorisation for the two units of the Beznau nuclear power plant (NPP) should be reviewed for possible amendment or replacement. The Swiss Federal Office for Energy (Office fédéral de l'énergie – OFEN), which is the responsible authority, initiated a procedure for the possible amendment or replacement of the existing cooling water discharge authorisation for the Beznau NPP. On 4 July 2019, the OFEN also notified the Beznau NPP of provisional measures with immediate effect regarding cooling water discharge. By virtue of the OFEN decision, the Beznau NPP should henceforth observe the 25° C compulsory limit set for waterways as defined by the Order on water protection. Should the 25° C limit be exceeded or be at risk of being exceeded, the operating power should be lowered or the NPP should be temporarily shut down. During the 2018 heatwave, areas of the Aar River close to the NPP at times greatly exceeded the 25° C limit, sometimes for several days. The provisional measures aim to prevent this situation from reoccurring until the end of the procedure. Consequently, any appeal against the aforementioned measures will not suspend the procedures.

Radioactive waste management

Paul Scherrer Institute's Eastern Storage Area (OSPA): Entry into force of the combined construction and operation licence

The Paul Scherrer Institute (PSI) operates on its eastern site (Würenlingen, Argovie canton) the interim storage installation for packaged radioactive waste managed by the Swiss Confederation (waste from medical, research and industrial activities) and for radioactive waste generated by PSI's decommissioning activities. A new building dedicated to interim storage is now necessary for existing and future low and intermediate level radioactive waste until a deep geological repository is available in Switzerland to dispose of this waste. The PSI filed an application before the Confederation for a combined construction and operation licence in 2014. On 13 September 2018, the Federal Department for Environment, Transport, Energy and Communication (DETEC) granted the combined licence for the new interim storage building. The licence has now come into force.

United States

Nuclear safety and radiological protection (including nuclear emergency planning)

The NRC issues a final rule related to beyond-design-basis events

On 9 August 2019, the US Nuclear Regulatory Commission (NRC) published a final rule that amended its regulations to establish requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events.²⁸ The final rule made generically applicable the requirements in NRC orders for mitigation of

27. Swiss Federal Office for Energy (4 July 2019), "Interlocutory Decision with regard to proceedings concerning the possible adaptation or new approval of the Federal Council's approval of 15 December 1997 concerning the discharge of cooling water for the Beznau I and II nuclear power plants", available at: www.news.admin.ch/news/message/attachments/57706.pdf (in German).

28. Mitigation of Beyond-Design-Basis Events, Final Rule, 84 Fed. Reg. 39684 (9 Aug. 2019).

beyond-design-basis events²⁹ and for reliable spent fuel pool instrumentation³⁰ that were issued following the March 2011 Fukushima Daiichi nuclear power plant accident. Under the Final Rule, operating nuclear power plants must have mitigation strategies (also called “FLEX strategies”) to address beyond-design-basis events. Plants must also provide a reliable means to remotely monitor wide-range water level for each spent fuel pool, so that they can effectively prioritise event mitigation and recovery actions in the event of a beyond-design-basis external event with the potential to challenge both the reactor and spent fuel pool. Plants that have begun decommissioning only need to have mitigation strategies associated with maintaining or restoring spent fuel pool cooling capabilities, and they need not maintain the means to remotely monitor spent fuel pool water levels. When the spent fuel in a pool at a decommissioning plant has cooled sufficiently such that ad hoc action in response to an event can be taken to sustain the spent-fuel-pool cooling function indefinitely, licensees will not need to maintain mitigation strategies. The final rule went into effect on 9 September 2019.

Radioactive waste management

NRC issues regulatory basis for disposal of “Greater-than-Class-C” radioactive waste

On 22 July 2019, the NRC published in the Federal Register a notice requesting public comment on a draft regulatory basis³¹ to support the development of rulemaking for the disposal of greater-than-Class-C (GTCC) waste in a near-surface disposal facility.³² Under its regulations in Part 61 of Title 10 of the *Code of Federal Regulations* (10 CFR), the NRC classifies low-level radioactive waste (LLRW) into three classes based on the radiological hazard as determined by the concentration of radionuclides prescribed for each class, namely, Class A, Class B and Class C wastes. Class C is the most hazardous of the three categories, and LLRW streams that contain radionuclide concentrations exceeding the limits for Class C waste (and thus are more hazardous than Class C waste), are referred to as “greater-than-Class C” (GTCC) waste. Currently, NRC regulation 10 CFR 61.55(a)(2)(iv) directs that GTCC waste be disposed in a geological repository, although the Commission, on a site-specific basis, may approve a proposal to dispose of GTCC waste in a facility licensed under 10 CFR Part 61 (i.e. a “land disposal facility”).³³

In 2015, the Commission directed the NRC staff to develop a draft regulatory basis that would analyse whether all or some GTCC waste streams could be disposed of in a near-surface disposal facility, which is a facility in which LLRW is disposed of within the upper 30 metres of the earth’s surface.³⁴ The Commission further directed that the

29. NRC (12 March 2012), “Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design-Basis External Events (Effective Immediately)”, EA-12-049, 77 Fed. Reg. 16091 (19 March 2012).

30. NRC (12 March 2012), “Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation (Effective Immediately)”, EA-12-051, 77 Fed. Reg. 16082 (19 March 2012).

31. A draft regulatory basis is a pre-rulemaking document used by the NRC staff to develop a regulatory position on a given matter and to solicit public and other stakeholder comment as to whether the NRC should proceed with a notice-and-comment rulemaking, and if so, the scope of such rulemaking.

32. Greater-Than-Class-C and Transuranic Waste, 84 *Federal Register* (Fed. Reg.) 35037 (22 July 2019). The draft regulatory basis is available through the NRC’s Agencywide Documents Access and Management System (ADAMS) and is designated as ADAMS Accession No. ML19059A403. ADAMS may be accessed at www.nrc.gov/reading-rm/adams.html.

33. Land disposal facilities are used for the disposal of LLRW. LLRW buried at a land disposal facility would be disposed of at much shallower depths than if disposed of in a geological repository.

34. A “near surface disposal facility” is a type of “land disposal facility”. Both terms are defined in 10 CFR 61.2, “Definitions.”

staff consider whether Agreement States³⁵ could license near-surface disposal facilities that can accept GTCC waste, or whether there were any GTCC waste streams that were so hazardous that the disposal of such waste should be reserved solely to the NRC's regulatory oversight. The NRC staff's preliminary technical analyses found that most GTCC waste streams were potentially suitable for disposal in a near-surface disposal facility that could be licensed by an Agreement State. The presence of transuranic radionuclides in many GTCC waste streams, however, presents a regulatory issue as the current definition of low-level radioactive waste in 10 CFR 61.2 excludes transuranic waste.³⁶

As described in the draft regulatory basis, a potential rulemaking could remove the 10 CFR 61.55(a)(2)(iv) direction that the default disposal path for GTCC waste be in a geological repository, revise the definition of LLRW by removing the transuranic waste exclusion, and make other regulatory changes to accommodate an expanded licensing role for Agreement States. In addition to a potential rulemaking, the draft regulatory basis considered the no-action alternative and a guidance-only option, in which the NRC staff would issue guidance on GTCC waste disposal but no rule.

The public comment period ran until 19 November 2019.³⁷ The NRC staff will consider all written comments received and make a recommendation to the NRC Commission. If the NRC staff recommends, and if the Commission approves, proceeding with a GTCC waste disposal rulemaking, the NRC will then issue a proposed rule for public comment in accordance with the Administrative Procedure Act, 5 USC 553.

35. Section 274b of the Atomic Energy Act, as amended, 42 *United States Code* (USC) 2021(b), authorises the Commission to enter into an agreement with the governor of a state whereby the Commission relinquishes its regulatory authority, and the state assumes that authority, for the regulation of certain radioactive materials. A state that has entered into such an agreement with the NRC is defined as an "Agreement State".

36. The regulation defines the term "waste" as meaning:
those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct material* set forth in [10 CFR] § 20.1003 of this chapter.

37. In response to multiple requests, the NRC extended the public comment period by 60 days, from 20 September 2019 to 19 November 2019. Greater-Than-Class-C and Transuranic Waste, 84 Fed. Reg. 48309 (13 Sept. 2019).

