

National legislative and regulatory activities

France

General legislation, regulations and instruments

Nuclear Safety Authority (ASN) Resolution No. 2015-DC-0523 of 29 September 2015 establishing a classification for basic nuclear installations according to the risks and disadvantages they present with regard to the interests mentioned in Article L. 593-1 of the French Environmental Code

With a view to enhancing the effectiveness of the control it exercises over basic nuclear installations [*installations nucléaires de base*] (INBs), the French Nuclear Safety Authority (ASN) considers that such control must be proportionate to the scale of the risks and disadvantages of INBs with regard to the interests mentioned in Article L. 593-1 of the French Environmental Code (namely public security, health and safety, protection of nature and the environment).

Under this decision, the ASN sets out the technical criteria for the classification of INBs into three categories, in descending order of importance of the risks and disadvantages.

On the basis of these criteria, the ASN must henceforth publish an annual list of INBs by category.

Ordinance No. 2016-128 of 10 February 2016 pertaining to various provisions on nuclear material¹

Issued pursuant to the authorisations granted to the French government under Law No. 2015-992 of 17 August 2015 on the energy transition for green growth, this ordinance amends the “nuclear” provisions governing France’s Environmental Code, Public Health Code, Labour Code and Defence Code. It comprises four chapters:

- Chapter I: responsible and safe management of spent fuel and radioactive waste;
- Chapter II: nuclear safety, transparency and basic nuclear installations;
- Chapter III: nuclear activities under the public health code; and
- Chapter IV: proportionate control and sanction of provisions relating to the protection of nuclear materials.

In particular, the ordinance broadens the ASN’s field of competence in the area of nuclear activities and protection against malicious acts, and significantly strengthens the provisions of the aforementioned codes relating to control and sanctions, at both the administrative and the criminal level.

Note that the provisions of Chapter III, which fully rewrite the provisions of the Public Health Code relative to nuclear activities (Articles L. 1333-1 et seq.), will enter into force on a date that will be specified in a decree issued through the *Conseil d’État*, and no later than 1 July 2017.

1. *Journal officiel “Lois et Décrets”* [Official Journal of Laws and Decrees] (J.O.L. et D.), JORF n° 0035 of 11 February 2016, text no. 8.

Ministerial Order of 15 January 2016 regarding the objective cost of the implementation of long-term management solutions for long-lived medium and high-level radioactive waste²

French Nuclear Safety Authority Opinion No. 2015-AV-0227 of 10 February 2015 regarding the evaluation of the reference cost of the Cigéo project for the deep geological storage of radioactive waste

The Ministerial Order of 15 January 2016 establishes an evaluation of the cost of the storage of long-lived medium and high-level radioactive waste in a deep geological repository, as part of the “Cigéo” project, at EUR 25 billion over a period of 140 years as of 2016.

In accordance with the opinion of the ASN, it makes provisions for a mechanism to regularly update the reference cost, at least during the project’s key development phases.

On 10 February 2015, the ASN issued an opinion (published in January 2016) on the evaluation of the reference cost of the Cigéo project by the French National Radioactive Waste Management Agency (ANDRA).

Given that the previous evaluation of the project dated back to 2005, ANDRA’s decision was viewed favourably by the ASN, which observed that the technical file containing the documented and substantiated cost figures was a “significant improvement” on the 2005 file. The ASN also highlighted the importance in this evaluation of co-operation between ANDRA and the producers of nuclear waste, while insisting on the importance of establishing a framework for said co-operation. Nevertheless, given that some of the assumptions made by ANDRA seem overly optimistic and significantly affect the overall figures, the ASN suggested that a more prudent account be taken of the “opportunities”, which tend to reduce the cost of the project. Lastly, the ASN considered that the reference cost should be updated regularly, at least during the project’s key development phases.

Nuclear trade (including non-proliferation)

Act No. 2016-113 of 5 February 2016 implementing the Additional Protocol to the Agreement between France, the European Atomic Energy Community and the International Atomic Energy Agency regarding the application of safeguards in France, signed in Vienna on 22 September 1998³

The Additional Protocol to the Agreement on Safeguards of 22 September 1998 with the European Atomic Energy Community and the International Atomic Energy Agency (IAEA) supplements the measures set out in the safeguards agreement providing for verification by the IAEA of declared nuclear material accountancy.

The Act of 5 February 2016 establishes the implementing provisions for the additional protocol, which imposes new obligations on operators in the nuclear sector, especially in terms of declarations.

In addition, it organises and governs the conduct of international verifications in France and provides for criminal sanctions in the event of a failure to provide information referred to in the Act or a refusal by an operator to comply with an international IAEA verification authorised by the national court.

2. J.O.L. et D., JORF n° 0014 of 17 January 2016, text no. 3.

3. J.O.L. et D., JORF n° 0031 of 6 February 2016, text no. 1.

International co-operation

Decree No. 2015-1122 of 7 September 2015 publishing the Co-operation Agreement between the Government of the French Republic and the Government of the United Mexican States for the Development of Peaceful Uses of Nuclear Energy (together constituting an agreement by exchange of notes verbales signed in Mexico City on 29 September and 16 October 2014, repealing the nuclear co-operation agreement of 2 March 1979), signed in Mexico City on 30 July 2014⁴

Under this agreement, France and the United Mexican States indicate their willingness to develop technical and scientific co-operation in the field of peaceful uses of nuclear energy, in accordance with the principles provided for in their respective legislations and nuclear policies, and in compliance with international commitments concerning the non-proliferation of nuclear weapons.

This co-operation may cover in particular:

- the use of nuclear energy for electricity production, including the design, construction, operation and decommissioning of nuclear facilities;
- the training of human resources in the field of peaceful uses of nuclear energy;
- the management of spent nuclear fuel and radioactive waste, including the design, construction and operation of storage facilities or repositories for radioactive waste in Mexico;
- nuclear technological safety, radiological safety, safety culture and environmental protection;
- nuclear security; and
- prevention and response to emergencies related to radiological or nuclear accidents.

This Agreement shall remain in force for a period of 20 years after the date of its entry into force on 1 August 2015.

India

Licensing and regulatory infrastructure

The Atomic Energy (Amendment) Act, 2015

The definition of “Government company” under Section 2(1)(bb) of the Atomic Energy Act, 1962 was amended.⁵ According to the amendment:

(bb) “Government company” means a company in which—

- (i) not less than fifty-one per cent. of the paid-up share capital is held by the Central Government; or
- (ii) the whole of the paid-up share capital is held by one or more of the companies specified in sub-clause (i) and which, by its articles of

4. J.O.L. et D., JORF n° 0208 of 9 September 2015, text no. 1.

5. The Atomic Energy (Amendment) Act, 2015 received the assent of the President on 31 December 2015 and was published in Official Gazette on 1 January 2016. The full text of the Amendment has been reproduced in this edition of the *Nuclear Law Bulletin* and can be found in Chapter 6 (“Documents and Legal Texts”).

association, empowers the Central Government to constitute and reconstitute its Board of Directors.

The amendment also added two additional sub-sections to Section 14 of the Atomic Energy Act, 1962 to make it mandatory that “No licence ... shall be granted to a person other than a Department of the Central Government or any authority or an institution or a corporation established by the Central Government or a Government Company” and “Any license granted ... shall stand cancelled in case the licensee ceases to be a Government company and, notwithstanding anything contained in any other law for the time being in force, all assets thereof shall vest in the Central Government free from any liability”.

Liability and compensation

Nuclear Liability Fund Rules, 2015

The Central Government has notified the Nuclear Liability Fund Rules, 2015 in exercise of its powers under Section 7(2) of the Civil Liability for Nuclear Damage Act, 2010.⁶ The Nuclear Liability Fund is established by the Central Government and is comprised of the levy collected from operators of nuclear installations.⁷ The operator must pay the levy on a quarterly basis for every unit of electricity sold to its customers until the total amount reaches INR 2 000 crores and the levy shall be resumed in the event of any withdrawals to ensure that the Fund balance remains at INR 2 000 crores at any given time.⁸ In case there is a delay in payment by the operator, the operator will be charged on a daily basis an interest calculated at the rate of 18% per annum.⁹ The Fund shall be managed in accordance with the rules and instructions relating to the management of Public Accounts of the Central Government and for payment out of the Fund, the Central Government shall ascertain the payment to be made and obtain the Parliament’s approval for making such a payment.¹⁰

Ireland

Nuclear safety and radiological protection (including nuclear emergency planning)

European Union Environmental Objectives (Surface Waters) (Amendment) Regulations 2015, Statutory Instrument (S.I.) No. 386 of 2015

These above named regulations amend the European Communities (Water Policy) Regulations 2003 (S.I. No. 722 of 2003) and the European Communities Environmental Objectives (Surface Waters) Regulations 2009 (S.I. No. 272 of 2009). The purpose of the 2015 Amendment is to give effect to the requirements of

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6. The Nuclear Liability Fund Rules, 2015 came into force on the date of publication in the Official Gazette (8 December 2015). The full text of the Fund Rules has been reproduced in this edition of the *Nuclear Law Bulletin* and can be found in Chapter 6 (“Documents and Legal Texts”).
 7. Fund Rules, *supra* note 6, Rules 3(1) and (2). The Rules provide that the operator shall pay to the Fund a levy at the rate of INR 0.05 (five paise) or a levy at such rate between INR 0.05 to 0.10 (five paise to ten paise) for every unit of electricity sold to its customers. *Ibid.*, Rule 3(3).
 8. *Ibid.*, Rules 3(3) – (5).
 9. *Ibid.*, Rule 5.
 10. *Ibid.*, Rule 4.

Directive 2013/39/EU,¹¹ Commission Decision 2013/480/EU¹² and Commission Implementing Decision (EU) 2015/495.¹³

The 2015 Amendment revises the environmental quality standards for a number of priority substances, adds 12 new substances to the original list and includes additional environmental quality standards for biological quality elements. The Regulations also provide for the establishment of a watch list to monitor concentrations of emerging pollutants and other substances of concern in the aquatic environment, to be updated every 24 months.

Of note, the 2009 Regulations are amended in Schedule 1 by the deletion of “The Radiological Protection Institute of Ireland” in the list of relevant public authorities.

European Union (Drinking Water) Regulations 2014, S.I. No. 122 of 2014

The above named Drinking Water Regulations were enacted to prescribe applicable quality standards and related supervision and enforcement procedures in relation to supplies of drinking water, including requirements for sampling frequency, methods of analysis, the provision of information to consumers and related matters. The Regulations update the European Communities (Drinking Water) (No. 2) Regulations, which are duly revoked.

Transport of radioactive material

European Union (Transport of Dangerous Goods by Rail) (Amendment) Regulations 2015, S.I. No. 360 of 2015

The purpose of this Amendment is to transpose Commission Directive 2014/103/EU,¹⁴ in so far as it relates to transport of dangerous goods by rail, into national law through amendment of the European Communities (Transport of Dangerous Goods by Rail) Regulations 2010 (as amended by S.I. No. 201 of 2013).

Of note, the 2010 Regulations are amended by substituting the Environmental Protection Agency as the competent authority for the purposes of Regulation 4(1)(c), rather than the Radiological Protection Institute of Ireland.

European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) (Amendment) (No. 2) Regulations 2015, S.I. No. 288 of 2015

Amendment No. 2 transposes into Irish law Commission Directive 2014/103/EU,¹⁵ adapting for the third time the Annexes to Directive 2008/68/EC¹⁶ to scientific and technical progress (insofar as that Directive relates to the transport of dangerous

11. Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy, *Official Journal of the European Union* (OJ) L 226 (24 August 2013).

12. Commission Decision 2013/480/EU of 20 September 2013 establishing, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, the values of the Member State monitoring system classifications as a result of the intercalibration exercise and repealing Decision 2008/915/EC, OJ L 266 (8 November 2013).

13. Commission Implementing Decision (EU) 2015/495 of 20 March 2015 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council, OJ L 78 (24 March 2015).

14. Commission Directive 2014/103/EU of 21 November 2014 adapting for the third time the Annexes to Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods to scientific and technical progress, OJ L 335/14 (22 November 2014).

15. *Ibid.*

16. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods, OJ L 260 (30 September 2008).

goods by road). Commission Directive 2014/103/EU gives effect to the changes to the European Agreement Concerning the International Carriage of Dangerous Goods by Road that came into force on 1 January 2015.

Amendment No. 2 also gives further effect to Directive 2008/68/EC¹⁷ and amends for the third time the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 (S.I. No. 349 of 2011).

Nuclear trade (including non-proliferation)

Nuclear Test Ban Act 2008 (Commencement) Order 2015, S.I. No. 134 of 2015

On 30 March 2015, the Minister for Environment, Community and Local Government signed into law the above Commencement Order. This Order brings into operation, with effect from 2 April 2015, the Nuclear Test Ban Act 2008. This Act provides the legislation needed to enable Ireland to implement its obligations under the Comprehensive Nuclear Test-Ban Treaty.¹⁸

Lithuania

Licensing and regulatory infrastructure

On 29 January 2016, the Head of the State Nuclear Power Safety Inspectorate (VATESI) approved a new version of the requirements for the management systems of licensees: Nuclear Safety Requirements BSR-1.4.1-2016 “Management System”.¹⁹ The most significant changes are:

- broadened scope of application: these requirements are now mandatory for persons with a licence for the shipment of nuclear fuel cycle materials, nuclear materials and fissile materials and for the acquisition, possession and usage of nuclear materials and fissile materials in quantities established in Annex 1 of the Law on Nuclear Safety;
- introduction of requirements for security culture; and
- transposition of the safety reference levels for existing reactors, issued by the Western European Nuclear Regulators Association (WENRA) on 30 May 2014.

Along with these requirements, the amendments of ten other Nuclear Safety Requirements were adopted to harmonise the older legislation with the new requirements. The requirements and associated amendments come into force on 1 May 2016.

Nuclear safety and radiological protection (including nuclear emergency planning)

On 29 January 2016, the Head of VATESI approved a new version of requirements for inspections: Nuclear Safety Requirements BSR-1.1.3-2016 “Inspections Conducted by

17. *Ibid.*

18. Comprehensive Nuclear-Test-Ban Treaty (1996) (not yet entered into force), available at: www.ctbto.org/fileadmin/content/treaty/treaty_text.pdf (Nuclear Test Ban Treaty).

19. Order No. 22.3-13 (2016) of the Head of VATESI, “On the Amendment of the Order No. 22.3-56, 21st of June, 2010, of the Head of State Nuclear Power Safety Inspectorate on the Approval of Nuclear Safety Requirements BSR-1.4.1-2010 ‘Management System Requirements’”, available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/1845c0d0c68611e583a295d9366c7ab3.

the State Nuclear Power Safety Inspectorate.”²⁰ The requirements come into force on 1 May 2016. The most significant changes are:

- replacement of the existing classification of inspections with the following: regular inspections (carried out according to the schedules or other aspects of ordinary activities carried out by an economic entity), technical inspections (participation in technical checks of nuclear facilities’ structures, systems and components or equipment carried out by an economic entity) and special inspections (other inspections, aimed at inspecting the specific aspects of safety or responding to the existing unexpected, unplanned, unusual situations, occurred unusual event or obtained specific information);
- introduction of streamlined procedures for inspecting suppliers of licensees and permit holders;
- the right of licensees or temporary permit holders to declare the compliance of their nuclear energy activities with sources of ionising radiation with the legal acts regulating radiological protection by submitting the declaration of compliance with the established radiological protection requirements. The submittal of the declaration results in the possibility to decrease the number of inspections of the aforementioned activities;
- revision and amendment of the procedures and forms, taking into account the existing practice, for more comprehensible and transparent requirements;
- the application of a graded approach to inspection activities for the various facilities and activities was highlighted; and
- updates to the principles for determining of periodicity of regular inspections.

Radioactive waste management

On 30 November 2015, the Head of VATESI approved new requirements for decommissioning of nuclear facilities: Nuclear Safety Requirements BSR-1.5.1-2015 “Decommissioning of Nuclear Facilities”.²¹ The requirements come into force on 1 May 2016. The new requirements include the following main changes as compared to previous legislation:

- the list of definitions was significantly updated (see e.g. decommissioning project, surrogate radionuclides, background radiation);
- the provisions for performing various radiological surveys during decommissioning of nuclear facility were clarified (see e.g. Characterization, Scoping, Final status, Verification radiological surveys);
- the requirements were harmonised with the IAEA’s General Safety Requirements Part 6 “Decommissioning of Facilities” and WENRA’s safety reference levels for the decommissioning of nuclear facilities;

20. Order No. 22.3-24 (2016) of the Head of VATESI “On the Amendment of Order No. 22.3-82, 25th of August, 2011, of the Head of State Nuclear Power Safety Inspectorate on the Approval of Nuclear Safety Requirements BSR-1.1.3-2011 ‘Inspections Conducted by the State Nuclear Power Safety Inspectorate’”, available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/5f74ac60c68511e583a295d9366c7ab3.

21. Order No. 22.3-216 (2015) of the Head of VATESI, “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/10df96e0983711e5a6f4e928c954d72b.

- the requirements for decommissioning projects, safety analysis and justification of decommissioning of nuclear facilities were laid out in more detail; and
- based on experience gained during the Ignalina nuclear power plant's dismantling and decontamination activities, the requirements for dismantling and decontamination activities; removal of structures, systems and components; and other preparatory actions for decommissioning during the period of transition between permanent shutdown and the issuing of the license for decommissioning were streamlined.

Luxembourg

Nuclear safety and radiological protection (including nuclear emergency planning)

Decree of 16 December 2015

The Decree of 16 December 2015 amending the Decree of 7 October 2002 on the quality of water intended for human consumption and the Decree of 14 December 2000 concerning the protection of the population against the dangers arising from ionising radiation²² transposed Council Directive 2013/51/Euratom²³ into the laws of Luxembourg.

Slovak Republic

International co-operation

Details about international agreements concluded by the Slovak Republic

The Slovak Republic has not signed, ratified, acceded to or terminated any treaty in the field of nuclear energy since the last edition of the *Nuclear Law Bulletin*, No. 96.

General legislation, regulations and instruments

As of 1 March 2016, six amendments to the existing Nuclear Regulatory Authority of the Slovak Republic (NRA) regulations entered into force. These amendments are largely based on the outcomes of the International Regulatory Review Service (IRRS) mission of the International Atomic Energy Agency (IAEA) to the NRA, which was held in 2012, and on new requirements and recommendations formulated by the IAEA and the Western European Nuclear Regulators Association (WENRA).

Regulation No. 101/2016 Coll. amending Regulation No. 30/2012 Coll., laying down details of requirements for the handling of nuclear materials, radioactive waste and spent nuclear fuel

The amended regulation reflects on the “Waste and Spent Fuel Storage Safety Reference Levels” prepared by the Working Group on Waste and Decommissioning (WGWD) of WENRA. The aforementioned amendment incorporates the enhanced requirements as defined by the WENRA WGWD for storage of spent nuclear fuel, thus improving the existing national safety reference levels.

22. *Journal Officiel du Grand-Duché de Luxembourg*, A – N° 261, p. 6268 (29 December 2015), available (in French) at: www.legilux.public.lu/leg/a/archives/2015/0261/a261.pdf.

23. Council Directive 2013/51/EURATOM of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption, OJ L 296 (7 October 2013).

Regulation No. 102/2016 Coll. amending Regulation 58/2006 Coll., laying down details on the scope, contents and means of preparation of nuclear installation documentation necessary for individual decisions

The amendment harmonises the Slovak legal regulation with the requirements of the recommended structure of decommissioning documentation applicable in the respective phases of the life-cycle of a nuclear installation as defined by the actual IAEA recommendation on “Standard Format and Content for Safety Related Decommissioning Documents” (SRS No. 45). Hence, the regulation specifies further standards for the reference report on the:

- decommissioning method;
- preliminary plan for the management of radioactive waste and spent nuclear fuel (including their transport);
- preliminary conceptual plan for decommissioning;
- plan for the management of radioactive waste and spent nuclear fuel (including their transport);
- conceptual plan for the decommissioning of a nuclear installation from operation;
- decommissioning stage plan;
- decommissioning concept during the period after the end of the permitted decommissioning stage;
- plan for the management and transport of radioactive waste; and
- plan for the management of conventional waste from decommissioning.

Furthermore, the amendment replaces the original terms “beyond design basis accident”, “selected beyond design basis accident” and “selected heavy accident” with the term “accident in design extension conditions”. This adjustment in terminology aligns with the recommended terminology of the IAEA and WENRA.

Regulation No. 103/2016 Coll. amending Regulation No. 430/2011 Coll. on nuclear safety requirements

The regulation as amended incorporates the relevant provisions of the IAEA Safety Standards No. SSR-2/1 (“Safety of Nuclear Power Plants: Design”) into the Slovak legal order. It amends the original terminology (e.g. “emergency conditions”, “accident in design extension conditions”) to conform to the terminology used by the IAEA and WENRA. The categorisation of the status of a nuclear installation considered in the nuclear facility’s design is introduced by this amendment when it distinguishes its normal operation, abnormal operation and emergency conditions. Furthermore, it extends the definition of severe accident by including the condition of nuclear fuel meltdown that shall not necessarily be restricted to the active zone of a nuclear installation. By adoption of this amendment, the Slovak Republic implements one of the suggestions (S 10) proposed by the IRRS mission of the IAEA.

Regulation No. 104/2016 Coll. amending Regulation No. 431/2011 Coll. on a quality management system

This amendment improves the existing quality management system by specifying the requirements for ensuring computer system and network security and those for assessment and approval processes and procedures for operative changes to technical documentation of selected facilities during the construction and commissioning of nuclear installations. The amended regulation also reflects on

changing terminology by replacing the term “selected beyond design basis accident” with the term “accident in design extension conditions without serious damage to nuclear fuel”.

Regulation No. 105/2016 Coll. amending Regulation No. 57/2006 Coll., laying down details of requirements for the transport of radioactive materials

This amendment improves the protection of personnel participating in the transport of radioactive material, as well as the general public and the environment, against the possibility of internal contamination (ingestion or inhalation of radionuclides) in the case of leakage of highly dispersible radioactive material from a consignment during the transport.

The regulation now specifies the content of the plan for the provision of physical protection and introduces the requirement to prepare the emergency plan addressing possible incidents during the transport that are related to the breach of the physical protection of transported radioactive material due to the unauthorised activity or sabotage. The need to implement such measures into the legal order of the Slovak Republic stems from the IAEA’s “Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5)”.

The new legal regime on the transport of nuclear material introduced by the aforementioned amendment extends the list of entities responsible for the transport of the consignment by including the originator, owner, shipper, or any other natural or legal person participating in the transport. Hence, the amendment adjusts the legal requirements to those stated by the Atomic Act in line with the relevant provisions of Council Directive 2006/117/EURATOM²⁴ and the Convention concerning International Carriage by Rail (COTIF) and its Regulation concerning the International Carriage of Dangerous Goods by Rail (RID).

Regulation No. 106/2016 Coll. amending Regulation No. 33/2012 Coll. on the regular, comprehensive and systematic evaluation of the nuclear safety of nuclear installations

This amendment implements the IAEA Specific Safety Guide (SSG-25) on “Periodic Safety Review for Nuclear Power Plants” and the “Report: WENRA Safety Reference Levels for Existing Reactors” prepared by the Reactor Harmonisation Working Group (RHWG) of WENRA. The amended regulation states that the periodic safety review shall demonstrate that the required level of nuclear safety is ensured until the next periodic evaluation, which shall be based on an overall evaluation of the safety of the nuclear installation. It modifies the requirements for the periodic review by adding and specifying the conditions for the deterministic safety analyses, probabilistic safety evaluations and unintentional internal and external threats to nuclear installations to the list of areas under review. The amendment also explicitly introduces the term “safety culture” into the text of the regulation.

24. Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel, OJ L 337 (5 December 2006).

Spain

Radioactive materials (including physical protection)

Royal Decree 1086/2015, of 4 December, amending Royal Decree 1308/2011, of 26 September, on the physical protection of facilities, nuclear materials and radioactive sources (published in the Official State Gazette of 18 December 2015)²⁵

Royal Decree 1308/2011, of 26 September 2011, on the physical protection of facilities, nuclear materials and radioactive sources (Official State Gazette of 7 October 2011), incorporated into Spanish legislation the commitments accepted by Spain on physical protection matters, particularly the Amendment to the Convention on the Physical Protection of Nuclear Materials²⁶ (approved in July 2005), the International Convention for the Suppression of Acts of Nuclear Terrorism²⁷ (ratified in January 2007) and United Nations Security Council Resolution 1540²⁸ on non-proliferation of nuclear, chemical and biological weapons. It repealed the former Royal Decree 158/1995, of 3 February 1995, on the physical protection of nuclear materials.

Its most important contribution was the enhancement of the previous physical protection system in Spain, defining the concepts that are used in the physical protection systems for nuclear facilities and materials. It reinforced the regulation of protection measures for these materials and above all addressed the prevention of sabotage of facilities, the protection of significant radioactive sources, the management of illicit trafficking events, the limitation of powers between authorities and the protection of physical protection information.

One of the obligations introduced by Royal Decree 1308/2011 was the establishment by the competent authorities of the Design Basis Threat (DBT) to be applied in order to design the physical protection systems of facilities and materials within the scope of the Royal Decree. To comply with this legal requirement, the DBT for Spanish nuclear power plants (NPP) and the Centralised Temporary Storage for High Level Radioactive Waste and Spent Fuel (CTS) was defined and it highlighted the need for establishing on-site response teams formed by public law enforcement agents (Civil Guards) in the NPP.

To that end, the most relevant amendment introduced by Royal Decree 1086/2015 is the presence of Civil Guards in the aforementioned facilities. This Royal Decree defines the term “Site Response Team”, its main responsibilities and the co-ordination to be carried out with the rest of actors involved in the physical protections systems of the NPPs.

The cost associated with this newly integrated security model for NPPs will be paid by operators pursuant to a fee that has been fixed by Law 34/2015, of 21 September 2015, amending Law 58/2003 (General Tax Law).

Moreover, Royal Decree 1086/2015 establishes the integration of the Operator Specific Protection Plans (introduced by Royal Decree 704/2011, of 20 May 2011, approving the Regulation on the Protection of Critical Infrastructures) into the existing Physical Protection Plans under Royal Decree 1308/2011.

25. Available (in Spanish) at: www.boe.es/boe/dias/2015/12/18/pdfs/BOE-A-2015-13784.pdf.

26. Amendment to the Convention on the Physical Protection of Nuclear Material (2005), IAEA Doc. GOC/INF/2005/10-GC(49)/INF/6, entered into force on 8 May 2016, pp. 3-11.

27. International Convention for the Suppression of Acts of Nuclear Terrorism (2005), 2445 UNTS 137, entered into force 7 July 2007 (Nuclear Terrorism Convention).

28. United Nations Security Council Resolution (UNSCR) 1540 (2004), S/RES/1540 (2004).

Finally, this Royal Decree also takes into account revision 5 of INFCIRC/225 “Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities” that provides cyber security recommendations, among others.

Radioactive waste management

Ministerial Order IET/458/2015, of 11 March, regulating allocations to municipalities in the vicinity of nuclear facilities from the Fund for the financing of activities included in the General Radioactive Waste Plan²⁹

Since 1989, ENRESA (the public company responsible for the management of spent fuel and radioactive waste and for the decommissioning of nuclear facilities) is authorised to allocate funds to municipalities in the vicinity of nuclear facilities, particularly centralised facilities conceived for the storage of radioactive waste, and nuclear power plants storing spent fuel generated by them or in the process of decommissioning. These funds are charged to the “Fund for the financing of activities included in the General Radioactive Waste Plan”, managed by ENRESA, according to Law 54/1997. The allocations have been regulated by several Ministerial Orders throughout the years.

The amount of the funds to be allocated in each municipality depends on the category of the facility and is calculated according to a formula that takes into account the distance between the municipality and the facility, as well as its inhabitants. The funds allocated annually consist of a fixed term and of a variable term, depending on the increase of the spent fuel stored the prior year or on the amount of radioactive waste received the prior year in the facility, as the case may be.

Ministerial Order IET/458/2015 of 11 March 2015 revises the regulation of these allocations and repeals the former Ministerial Order of 13 July 1998 which governed those allocations since 1998. Apart from the amendment of some criteria involved in the allocation of the existing funds, the most relevant amendment introduced by the Ministerial Order is the creation of a new type of funds, which do not replace the existing funds, and must be dedicated to the financing of local development projects in order to promote the establishment of alternative economies other than those associated with the nuclear facilities.

On an annual basis, each municipality can make a request for these new funds by presenting investment projects to be undertaken during the coming year(s), and that must be approved by the Director-General for Energy Policy and Mines of the Ministry of Industry, Energy and Tourism (MINETUR). The projects are evaluated by an Assessment Commission formed by representatives from the MINETUR, ENRESA and the municipalities, prior to the approval of the MINETUR. ENRESA is the entity responsible for paying the funds and monitoring the projects.

United States

Licensing and regulatory infrastructure

Commission approves final procedures for hearings on inspections, tests, analyses, and acceptance criteria (ITAAC) for combined licenses

ITAAC are verification requirements included in the combined license process in Title 10 of the Code of Federal Regulations (10 CFR) Part 52.³⁰ Pursuant to the Atomic

29. Available (in Spanish) at: www.boe.es/boe/dias/2015/03/17/pdfs/BOE-A-2015-2872.pdf.

30. NRC (2015), “Final Procedures for Hearings on Conformance with the Acceptance Criteria in Combined Licenses”, 20 January, available at: www.nrc.gov/docs/ML1434/ML14343A747.pdf.

Energy Act of 1954, as amended (AEA), the US Nuclear Regulatory Commission (NRC) is required to make a predictive finding that a nuclear facility will be constructed and operated in accordance with the AEA and NRC rules and regulations.³¹ The ITAAC are included in a combined license to verify prior to operation that the facility has been constructed and will be operated in accordance with these requirements.³² Per the AEA, a combined license facility cannot start operation until the NRC finds that the acceptance criteria in the ITAAC are met.³³ Section 189a.(1)(B) of the AEA provides that the public has an opportunity to request a hearing on the licensee's conformance with the ITAAC acceptance criteria.³⁴ NRC regulations previously did not address detailed procedures for ITAAC hearings.³⁵ The Commission, on 1 April 2016, approved final procedures for hearings on ITAAC acceptance criteria.³⁶

Hearing requests "shall show, prima facie, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety."³⁷ A petitioner may put forth a "claim of incompleteness" to indicate that a licensee's ITAAC notification is incomplete and that such incompleteness prevents the petitioner from making the necessary prima facie showing.³⁸ These claims are not considered "contentions", as the prima facie requirement for the contention has not been satisfied, but claims of incompleteness could result in the petitioner receiving the information necessary to make the required prima facie showing.³⁹ Under 10 CFR 2.310(j) and the approved final procedures, the Commission retains the ability to designate procedures for ITAAC hearings on a case-specific basis.⁴⁰

Congress intended that ITAAC hearings not delay plant operation unnecessarily.⁴¹ Major features of the final procedures for hearings on ITAAC criteria include requirements for the NRC to publish the notice of intended operation up to 105 days earlier than the AEA requires to provide additional assurance that the hearing will be completed prior to operation.⁴² The final procedures will also require that the NRC complete ITAAC hearings much faster than other hearings and will include 60 days for hearing requests, 25 days for answers to hearing requests and up to 125 days for the NRC to render a decision on the hearing request, complete pre-hearing activities, hold the hearing and issue an initial decision.⁴³ Finally, the final procedures include a process for allowing interim operation pending the completion of a hearing should the hearing decision not be issued before operation is scheduled to begin.⁴⁴

31. *Ibid.*, p. 2.

32. *Ibid.*

33. *Ibid.*

34. *Ibid.*

35. *Ibid.*

36. NRC (2016), "Staff Requirements – SECY-15-0010 – Final Procedures for Hearings on Conformance with the Acceptance Criteria in Combined Licenses", 1 April.

37. US Atomic Energy Act of 1954 § 189a(1)(B)(ii), 42 USC § 2239 (1983).

38. NRC, *supra* note 30, at 3.

39. *Ibid.*

40. NRC, *supra* note 36, p. 1.

41. NRC, *supra* note 30, p. 4.

42. *Ibid.*, p. 9.

43. *Ibid.*, p. 3.

44. *Ibid.*, pp. 3-4.