

# NATIONAL LEGISLATIVE AND REGULATORY ACTIVITIES

## Belgium

### *Organisation and structure*

#### *Amendment to the Royal Order on the Scientific Board for Ionising Radiation (2006)*

This Royal Order of 1 May 2006 amends the Royal Order of 18 December 2002 setting out the composition and powers of the Scientific Board for Ionising Radiation established alongside the Federal Agency for Nuclear Control (see *Nuclear Law Bulletin* No. 71). It provides that 16 Members of the Board will be nominated by the competent Minister (holding authority over the Federal Agency for Nuclear Control) and 2 each will be nominated by the Flemish Government, the Wallon Government and the Government of the Region of Brussels-Capital. It sets out further requirements in relation to the qualifications and linguistic capabilities of all members of the Board, and provides details on the terms and conditions of their nomination.

### *Radiation protection*

#### *Amendment to the Royal Order on Radiation Protection (2006)*

This Royal Order of 24 January 2006 was adopted in implementation of the 1994 Act on Protection of the Public, Workers and the Environment against the Dangers of Ionising Radiation and Relating to the Federal Agency for Nuclear Control (see *Nuclear Law Bulletin* Nos. 53, 54 and 59).

It amends the Royal Order of 20 July 2001 establishing General Regulations for the Protection of the Public, Workers and the Environment against the Dangers of Ionising Radiation (see *Nuclear Law Bulletin* No. 69) by setting out specific provisions with regard to the elimination of lightning rods containing radioactive materials.

#### *Amendment to the Royal Order Establishing General Regulations for the Protection of the Public, Workers and the Environment Against the Dangers of Ionising Radiation (2006)*

This Royal Order of 23 May 2006 amends the Royal Order of 20 July 2001 (see *Nuclear Law Bulletin* No. 69). It implements Council Directive 2003/122/Euratom of 22 December 2003 on the Control of High-activity Sealed Radioactive Sources and Orphan Sources (see *Nuclear Law Bulletin* Nos. 72 and 73). It contains in particular more specific information on the definitions of “sealed source”, “high-activity source which is no longer used” and “orphan source”.

#### *Directives on the Use of Walk-through Radioactivity Detectors in the Non-nuclear Sector (2006)*

These directives were adopted by the Federal Agency for Nuclear Control and published on 4 September 2006. They are designed to apply to anyone using walk-through radioactivity detectors in their establishments and, if necessary, to experts who may be required to carry out maintenance. They establish threshold levels and describe the procedure to be followed by the person operating this device when the alarm sounds. They further describe radiation protection measures to be taken by personnel in the case of intervention and information that the operator of such detectors should provide to the Federal Agency for Nuclear Control.

#### *Directives on the Use of X-rays for Medical Purposes – Dosimetry of Patients (2006)*

These directives, adopted by the Federal Agency for Nuclear Control on 12 October 2006, set out specific criteria with regard to the use of X-rays for medical purposes, in particular in relation to the dosimetry of patients. They establish measures regarding the frequency of dose verifications for patients and the evaluation of individual doses.

#### ***Transport of radioactive materials***

##### *Order on the Appointment of Safety Advisors for the Transport of Dangerous Goods (2006)*

This Royal Order of 5 July 2006 implements Council Directive 96/35/EC of 3 June 1996 on the Appointment and Vocational Qualification of Safety Advisors for the Transport of Dangerous Goods by Road, Rail and Inland Waterway, and Directive 2000/18/EC of the European Parliament and of the Council of 17 April 2000 on Minimum Examination Requirements for Safety Advisors for the Transport of Dangerous Goods by Road, Rail or Inland Waterway, into Belgian law. In line with Article 1 of Directive 96/35/EC, it provides that undertakings the activities of which include the transport, or the related loading or unloading, of dangerous goods by road, rail or inland waterway each appoint one or more safety advisors for the transport of dangerous goods, responsible for helping to prevent the risks inherent in such activities with regard to persons, property and the environment. It sets out further details with regard to the qualifications and examinations necessary to exercise these activities.

## **Brazil**

### ***General legislation***

#### *Decree Implementing the Co-operation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (2006)*

On 5 September 2006, Decree No. 5885 implementing the Co-operation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (ARCAL) was adopted. ARCAL was originally adopted under the aegis of the International Atomic Energy Agency (IAEA), in Vienna, on 25 September 1998. Brazil deposited its instrument of ratification on 27 March 2006.

States Parties to this agreement, under the auspices of the IAEA, undertake to promote, foster, co-ordinate and implement co-operation activities for training, research, development and applications

of nuclear science and technology in the Latin America and the Caribbean region through their competent national institutions. Activities are carried out under the primary supervision of the ARCAL Board of Representatives, with the assistance of a Technical Co-ordination Board.

The ARCAL Agreement entered into force on 5 September 2005 following the deposit of the instruments of ratification of ten IAEA Member States. It shall remain in force for ten years and may be extended by periods of five years if the Member States so agree.

## Canada

### *Regime of radioactive materials (including physical protection)*

#### *Regulations Amending the Nuclear Security Regulations (2006)\**

##### *Background*

The Nuclear Safety and Control Act<sup>1</sup> (hereinafter referred to as “the NSCA”; the text of this instrument was reproduced in the Supplement to *Nuclear Law Bulletin* No. 60), is the framework legislation that governs the safe and peaceful use of nuclear energy and nuclear substances in Canada. It requires those carrying out nuclear related activities to be licensed in order to protect health, safety and the environment, to prevent unreasonable risk to national security and to respect Canada’s international obligations.<sup>2</sup>

The NSCA establishes the Canadian Nuclear Safety Commission (CNSC) as the regulatory Agency responsible for the implementation of the requirements set out in the NSCA and associated regulations. The areas subject to regulatory oversight include nuclear power reactors, non-power reactors, nuclear research and test facilities, uranium mines and mills, uranium refineries, nuclear substance processing facilities, irradiators, medical and non-medical accelerators, and a wide variety of nuclear substances and prescribed equipment.

At the time the NSCA came into force on 31 May 2000, specific regulations were made in which the more detailed requirements applicable to the Canadian nuclear industry were outlined. Included in this set of regulations were the Nuclear Security Regulations (hereinafter referred to as “the 2000 NSR”).<sup>3</sup> They set out the baseline requirements applicable to Category I, II and III material and nuclear reactors that could exceed 10 MW thermal power during normal operation.

As a result of the heightened threat posed to Canadian nuclear facilities following the terrorist events of 11 September 2001, the CNSC issued two orders<sup>4</sup> that required affected licensees to

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\* This Information Note was kindly submitted by Samantha Maislin Dickson, Counsel with the Department of Justice Canada. The author alone is responsible for the facts mentioned and opinions expressed herein.

1. S.C. 1997, c. 9, which came into force on 31 May 2000.
2. S. 3 (Purpose) and 9 (Object) of the NSCA.
3. SOR/2000-209.
4. The first order, CNSC Order Number 01-1, was issued by a full panel of the tribunal component of the CNSC (the Commission), to facilities considered high-risk (e.g. nuclear power plants and nuclear research and test establishments) under its powers to issue emergency orders pursuant to s. 47 of the NSCA. The second order, Designated Officer Order Number 01-D1, was issued by a Designated Officer, a person authorized by the Commission to exercise certain decision-making functions under the NSCA, in

implement specific physical protection measures considered necessary to strengthen security at their facilities. Subsequent to these orders being issued, the CNSC undertook a thorough review of the 2000 NSR, taking into consideration the findings of earlier studies on the security of nuclear facilities in Canada<sup>5</sup> and the increased threat of terrorist action against high-profile nuclear facilities.

#### *Amendment to 2000 NSR*

Following extensive public consultation, in particular with affected licensees, the Regulations Amending the Nuclear Security Regulations were made by the CNSC on 16 August 2006. They were approved by the Governor in Council on 29 August 2006, and published in a special edition of the *Canada Gazette*, Part II (Official Regulations) on 7 September 2006.<sup>6</sup> The amended regulations (“the 2006 NSR”) will come into force on 27 November 2006 as a three month transition period was included in order to provide affected licensees time to comply with the new requirements.<sup>7</sup>

The 2006 NSR decisively strengthen the regulatory regime for the physical protection of nuclear facilities, nuclear material and nuclear substances in Canada, by taking into account the results of the regulatory reviews and incorporating the requirements of the orders that had been issued following the events of 9/11. Like the 2000 NSR, the 2006 NSR categorise nuclear materials according to potential risk of their use in a nuclear explosive device, with Category I nuclear material being the highest risk and Category III nuclear material being the lowest.

The amended regulations are divided into two parts, with Part 1 applying to high security sites<sup>8</sup> and facilities containing Category III material and Part 2 applying to lower risk facilities regulated by the CNSC.<sup>9</sup> The additional physical protection requirements contained in the 2006 NSR touch on all aspects of the physical protection of nuclear material and nuclear substances, and include:

For licensees subject to Part 1:<sup>10</sup>

- **On-site nuclear response force** – Licensees must establish an armed response force available at all times and capable of making an immediate and effective intervention to counter threats to nuclear facilities and nuclear material.
- **Design basis threat analysis** – Licensees must incorporate the national design basis threat, established by the CNSC, in the design of their physical protection system to

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accordance with his power to issue orders under s. 35 and para. 37(2)(f) of the NSCA. This second order applied to a group of facilities having a lower risk profile (e.g. nuclear substance processing facilities, uranium refineries and nuclear fuel fabrication facilities).

5. These studies examined the recommendations of the IAEA contained in the International Atomic Energy Agency’s *Physical Protection of Nuclear Material and Nuclear Facilities* INFCIRC/225/Rev.4 (Corrected).
6. SOR/2006-191.
7. S. 43 of the 2006 NSR.
8. Essentially those facilities captured by the CNSC Order Number 01-1, *supra*, note 4.
9. Those facilities captured by Designated Officer Number 01-D1, *supra*, note 4.
10. Licensees possessing, using or storing Category III material are subject only to certain requirements found in Part 1 of the 2006 NSR, the bulk of these requirements applying to “high security sites”, the facilities that were captured by Commission Order CNSC Number 01-1.

protect against the unauthorised removal of nuclear material and sabotage of nuclear facilities and nuclear material.

- **Threat and risk assessment** – Licensees must carry out a threat and risk assessment to identify local threats to their facility and take any credible threats into account in the design of their physical protection system.
- **Identification and protection of vital areas** – Licensees must identify and apply physical protection measures to areas which contain equipment, systems or devices, or nuclear substances where sabotage could directly or indirectly lead to unacceptable radiological consequences.
- **Uninterrupted power supply** – Licensees must have an uninterrupted power supply (i.e. back-up battery power) to maintain the operation of alarm systems, alarm assessment systems and the various essential monitoring functions of the security monitoring room.
- **Certificates for medical fitness, physical fitness and psychological fitness** – Licensees must obtain three separate certificates confirming that persons employed as nuclear security officers are medically, physically and psychologically fit to carry out their duties.
- **Contingency planning, drills and exercises** – Licensees must test physical protection systems through regular drills, and develop and exercise contingency plans to manage anticipated security related emergencies.
- **Responsibility for granting authorisations** – Licensees are now responsible for granting certain access authorisations (this responsibility was transferred from the CNSC, recognizing that the licensees are responsible for nuclear security).

Requirements applicable to licensees subject to Part 1 and Part 2:

- **Access control** – Licensees must have procedures and devices in place to positively identify and screen persons entering a nuclear facility.
- **Supervisor awareness programme** – Licensees must train supervisors to recognise behavioural changes in facility personnel, including contractors, which may indicate an increase in risk to the security of the facility.
- **Predetermination of trustworthiness** – Employees and other persons with unescorted access to the licensee’s facility must obtain a security clearance or an authorisation appropriate to their level of access.

In addition to the 2006 NSR, the CNSC continues to regulate some aspects of the physical protection of nuclear material and nuclear substances by way of its licensing authority.<sup>11</sup> In contrast to regulations, licence conditions that are contained in licences not publicly available are a more appropriate regulatory mechanism to address security sensitive requirements<sup>12</sup> as well as those that are facility specific.

As part of its compliance and enforcement programme established under the NSCA, the CNSC monitors compliance with its regulatory regime, including the 2006 NSR. CNSC inspectors and staff

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11. S. 24 and ss. 37(2) of the NSCA.

12. Pursuant to para. 21(1)(c) of the General Nuclear Safety and Control Regulations [SOR/2000-202], the security arrangements, security equipment, security systems and security procedures established by a licensee are considered “prescribed information” and can only be made public in certain circumstances.

of the Nuclear Security Division verify compliance with the 2006 NSR and the effectiveness of licensees' physical protection programmes. There are a variety of regulatory tools available to the CNSC, including written notices, increased regulatory scrutiny, licensing actions<sup>13</sup> and the issuance of orders.<sup>14</sup>

Finally, the NSCA creates offences for non compliance with regulatory requirements such as failure to comply with a licence condition, the NSCA or any regulation made pursuant to the NSCA.<sup>15</sup> The penalties associated with these offences include fines not exceeding 1 million of CAN dollars (CAD) or a prison term not exceeding five years, or both, if the matter is prosecuted by way of indictment.<sup>16</sup> If the Crown elects to prosecute by way of summary conviction, the offence is punishable by a fine not exceeding CAD 500 000 or imprisonment for a term not exceeding 18 months, or both.<sup>17</sup>

## France

### *Radiation protection*

*Decree Establishing Criteria Governing the Nomination, Clearance and Swearing in of Radiation Protection Inspectors (2006)*

Decree No. 2006-694, adopted on 13 June 2006, sets out criteria governing the nomination of radiation protection inspectors pursuant to Articles L.1333-17 (civil installations) and L.1333-18 (installations classified for defense purposes) of the Public Health Code.

Radiation protection inspectors are nominated upon proposal of the Director General for Nuclear Safety and Radiation Protection, by Joint Order of the Ministers responsible for Health and for Labour. The order nominating an inspector specifies, *inter alia*, the fields in which (s)he may carry out activities: industrial applications of ionising radiation, medical applications of ionising radiation, or other applications.

Radiation protection inspectors mentioned at Article L.1333-18 are nominated as follows:

- by Order of the Minister for Defense or the Minister responsible for Industry, upon a proposal of the Delegate for nuclear safety and radiation protection for defense-classified activities and installations, for activities and installations falling within their respective field of authority, to which Decree No. 2001-293 of 5 July 2001 on the Safety and Radiation Protection of Defense-related Nuclear Installations and Activities applies;
- by Order of the Minister of Defense for the inspection of other defense-related installations, to which Article L.611-2 of the Labour Code applies.

Proposals for nomination are submitted to the Director General of Nuclear Safety and Radiation Protection for comment. In order to nominate someone as a radiation protection inspector, the

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13. *Ibid.*

14. S. 35, para. 37(2)(f), ss. 46(3) and s. 47 of the NSCA.

15. S. 48 of the NSCA.

16. Para. 51(3)(a) of the NSCA.

17. Para. 51(3)(b) of the NSCA.

authorities take into account that person's level of training, professional experience and legal and technical knowledge in the radiation protection field, in light of the qualifications necessary to fulfill the inspection role.

*Order on Dosimetric Information to Be Contained in Written Reports of Medical Acts Involving Ionising Radiation (2006)*

This Order of 22 September 2006 provides that any medical acts which involve the application of ionising radiation must be the subject of a written report established by the practitioner who administered the act and must contain the following information:

- the identification of the patient and the administering practitioner;
- the date upon which the act was administered;
- the facts justifying the administration of this act and the procedure followed, in light of the guides on prescriptions and on procedures mentioned in Articles R.1333-69 and R.1333-70 respectively of the Public Health Code;
- information identifying the material used in the case of the most irradiating techniques: interventional radiology, CT scans and radiotherapy;
- information useful to estimate the dose received by the patient during the procedure.

With regard to acts of nuclear medicine, including in internal vectorised radiotherapy, the written report shall contain the name of the radiopharmaceutical(s) administered, specifying the radionuclide used, the activity administered and the mode of administration.

## **Latvia**

### ***Radiation protection***

*Regulations on Radiometric Control of Goods and Vehicles on the State Border (2005)*

These Cabinet Regulations (No. 233) were adopted on 5 April 2005 in implementation of Council Directive 2003/122/Euratom of 22 December 2003 on the Control of High-activity Sealed Radioactive Sources and Orphan Sources (see *Nuclear Law Bulletin* Nos. 72 and 73). They provide in particular for supplementary training and retraining for the staff of different state institutions who are involved in relevant activities where orphan sources are most likely to be found – at significant transit points e.g. customs posts and border crossing points.

*Amendment of the 2001 Regulations on the Procedure for the Issue of a Special Permit (Licence) (2006)*

These Cabinet Regulations (No. 301) on the Procedure for the Issue of a Special Permit (Licence) or Permit for Activities Involving Ionising Radiation Sources and the Procedure for Public Dispute on the Establishment of Ionising Radiation Facilities of State Significance or on Essential Modifications thereto, adopted on 3 July 2001 (see *Nuclear Law Bulletin* No. 70) have recently been amended. The first amendment extends to five years the period of validity for licences in respect of low-risk practices such as dental X-ray, provided that during the previous licence there were no

violations of requirements. The second amendment was adopted in implementation of the Council Directive 2003/122/Euratom of 22 December 2003 on the Control of High-activity Sealed Radioactive Sources and Orphan Sources (see *Nuclear Law Bulletin* Nos. 72 and 73). It concerns in particular requirements for owners and potential owners to provide the competent authority with detailed plans on proposed activities involving spent sealed sources.

*Amendment of the 2001 Regulations on the Procedure for Packaging and Marking of Ionising Radiation Sources (2006)*

These Cabinet Regulations (No. 406), adopted on 18 September 2001 (see *Nuclear Law Bulletin* No. 70), were recently amended in implementation of the Council Directive 2003/122/Euratom of 22 December 2003 on the Control of High-activity Sealed Radioactive Sources and Orphan Sources. Specific requirements include the marking of high-activity sources by engraving or stamping.

*Amendment of the 2001 Regulations on Activities Involving Ionising Radiation Sources Which Do not Require a Special Permit (Licence) or Permit (2006)*

These Cabinet Regulations (No. 288), adopted on 3 July 2001, were recently amended in implementation of Council Directive 96/29/Euratom of 13 May 1996 Laying Down Basic Safety Standards for the Protection of the Health of Workers and the General Public Against the Dangers Arising From Ionising Radiation (see *Nuclear Law Bulletin* Nos. 52, 58 and 61).

## **Republic of Moldova**

### ***Radiation protection***

*Law on the Safe Deployment of Nuclear and Radiological Activities (2006)\**

Law No. 111-XVI on the Safe Deployment of Nuclear and Radiological Activities was adopted on 11 May 2006 and entered into force on 30 September 2006. It repeals the 1997 Law on Radiation Protection and Safety. The main purpose of this new legislation is to improve the regulatory framework in the field of radiation protection and to establish a regulatory authority in the Republic of Moldova. The law contains 42 Articles divided into 8 Chapters.

Chapter I “General Provisions” contains requirements governing the safe deployment of nuclear and radiological activities and establishes that those activities must be performed exclusively for peaceful purposes, in line with the obligations contained in the international treaties to which the Republic of Moldova is Party.

The scope of the law is defined as follows:

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\* This Information Note was kindly provided by Ms. Maria Corfanenco, Head of the Division of Personnel, Legal and Foreign Affairs at the Department of Standardization and Metrology of the Republic of Moldova. Ms. Corfanenco took part in the 2005 Session of the International School of Nuclear Law at the University of Montpellier 1. Facts given and opinions expressed in this Note are the responsibility of the author alone.

- non-proliferation of nuclear weapons, of materials and equipment relevant for the proliferation of nuclear weapons and of other nuclear explosive devices;
- establishment of mechanisms to ensure the safety of nuclear and radiological activities;
- preventing the unauthorised deployment of nuclear and radiological activities, in compliance with the Republic of Moldova's obligations under the Treaty on Non-proliferation of Nuclear Weapons and other international treaties to which it is Party;
- protection of workers, the public, property and the environment against the harmful effects of ionising radiation, in compliance with international requirements in the field of radiation protection and nuclear safety.

Chapter II "National Agency" provides for the establishment of the national nuclear regulatory authority. The National Agency is a central public authority, attached to the Ministry of Ecology and Natural Resources. It has legal personality and holds the necessary level of independence and competence to perform regulatory functions in the field of nuclear and radiological activities [Art. 10]. The structure and statute of the National Agency are approved by the Government, and financial resources necessary for its activities are provided from the state budget, as well as from grants, technical assistance and international co-operation projects. The Head of the National Agency is also the State Chief Inspector in the field of nuclear and radiological activities and is appointed by the Government.

The principal functions of the National Agency are as follows:

- drafting laws in the field of nuclear and radiological activities;
- ensuring compliance with legislation in force and with the international treaties to which the Republic of Moldova is Party;
- ensuring the necessary regulatory framework establishing general requirements governing the safety of nuclear and radiological activities; radiation protection; quality control system; control on non-proliferation of nuclear weapons; physical protection and security of radiation sources, intervention and research in the event of radiological (nuclear) accidents;
- establishing requirements for licensing, supervision and control;
- reviewing and assessing licensing applications;
- maintaining the national register of radioactive sources, and the national register of natural and legal persons licensed to carry out activities in the field of nuclear and radiological activities;
- collaboration with the regulatory authorities of other countries and with international organisations competent in the field;
- accreditation of experts in the field of nuclear and radiological activities.

Pursuant to Article 12, the National Agency is entitled to unlimited access to sites where nuclear and radiological activities are carried out and to all information, technical and contractual data, in any form, necessary to carry out controls.

Chapter III "Competence of the Other Authorities Involved in the Regulatory Process" specifies the respective roles and responsibilities of other authorities in the fields of medicine, emergency situations, environmental protection, agriculture, customs, standardisation and metrology.

Chapter IV “Licensing of Nuclear and Radiological Activities” states that authorisation is issued in the form of a licence or registration, depending on the categorisation of sources in accordance with International Atomic Energy Agency recommendations. Licences for Category I-III sources are issued by the Licensing Chamber. Registration is sufficient for Categories IV-V and is performed by the National Agency. This Chapter also sets out dose limits and criteria for exemptions from the authorisation and control procedure and establishes conditions governing the licensing of the import and export of radiation sources.

Chapter V “Obligations and Rights of the Public and of Licensees” sets out various provisions on the obligations of the public (to observe the legislation and regulations in force, take the necessary precautionary measures established by radiation protection standards etc.) and their corresponding rights (to safe working conditions, transparent information on the radiological situation, and compensation in the event of an accident etc.). Similarly, it sets out the rights and obligations of licensees. Licensees are required to ensure:

- nuclear and radiological safety, radiation protection, physical protection, intervention in the event of a radiological (nuclear) accident, maintenance of a quality control system for the activities performed;
- registration of radioactive and nuclear materials, and of ionising radiation sources;
- compliance with licence conditions; submission of information to the National Agency regarding any exceeding of dose limits established by the regulations in force;
- establishment of internal regulations, roles and instructions in order to ensure the safe deployment of its activities;
- where an activity generates waste, safe management of that waste and financing of its collection, manipulation, transportation, treatment, conditioning and storage.

Chapter VI “State Control and Supervision of Nuclear and Radiological Activities” provides that state control and supervision is performed in relation to the issuing of a licence; during the validity of that licence, periodically or incidentally; on the basis of a notification and/or at the request of licensees; and when information comes to light that radiological and nuclear activities are being performed without a licence.

Chapter VII “Responsibility for violation of legislation in the field of nuclear and radiological activities” sets out general provisions with regard to liability for violations. Information on specific offences is set out in other legislation. Article 38 provides that the licensee is entirely responsible for nuclear damage caused, in accordance with the national legislation and with the 1963 Vienna Convention on Civil Liability for Nuclear Damage, to which the Republic of Moldova is a Party.

Chapter VIII “Final Clauses” provides that licences, authorisations and permits issued before the entry into force of this law shall remain valid for the period for which they were issued, provided that they are registered by the National Agency within 30 days after entry into force of this legislation. It further provides that the Government will submit proposals to the Parliament to harmonise the legislation in force and its own normative acts with this new law and will create the National Agency.

## **Morocco**

### ***Third party liability***

#### *Decree Granting a State Guarantee to CNESTEN (2006)*

In June 2006, the research reactor TRIGA MARK II, with a capacity of 2 MW, located at the Nuclear Research Centre on the Maâmora site (*Centre d'études nucléaires de la Maâmora – CENM*), was commissioned. This installation is designed to produce radioisotopes for medical and industrial uses, to analyse the irradiation of mining, biological and material samples, and to carry out scientific research.

Pursuant to the Protocol to Amend the Vienna Convention on Civil Liability for Nuclear Damage, ratified by Morocco on 6 July 1997 and which entered into force on 4 October 2003, the National Centre of Nuclear Energy, Science and Techniques (*Centre national de l'énergie, des sciences et des techniques nucléaires – CNESTEN*), as operator of a nuclear installation, is required to have insurance or other financial security.

This obligation is established in a Decree of the Prime Minister of 26 February 1999 on the Construction Licence for the CENM and is implemented by Act No. 12-02 on Civil Liability for Nuclear Damage, promulgated on 7 January 2005 (the text of the Act is reproduced in *Nuclear Law Bulletin* No. 75).

In order to enable CNESTEN to meet its insurance obligation, the Moroccan State has provided a financial guarantee. The State is indeed entitled to provide a guarantee to cover the third party liability of an operator when it cannot meet its obligations, totally or partially, pursuant to Article 24 of the Act on Civil Liability for Nuclear Damage.

Article 22 of this law provides that, having regard to the nature of the nuclear installation, the administrative authorities may fix the operator's liability at an amount lower than the basic amount [100 million Special Drawing Rights (SDR)]. Therefore, as regards the CENM installation, the amount is fixed at SDR 5 million.

This State guarantee is granted to CNESTEN pursuant to a Decree of 1 February 2006 (No. 2-06-84).

## **Norway**

### ***Radiation protection (including nuclear emergency planning)***

#### *Amendments to the Act on Radiation Protection and Use of Radiation (2005)*

Potential nuclear and radiological threat scenarios have changed considerably during the last decade. They now include not only nuclear or radiological accidents or incidents but also other threats resulting from malevolent acts such as sabotage of nuclear facilities, the use of “dirty bombs” or dispersal of radioactive sources in populated areas.

In order to clarify that the provisions of the 2000 Act on Radiation Protection and Use of Radiation (see *Nuclear Law Bulletin* No. 67; the text of the Act is reproduced in the Supplement to *NLB* No. 68) include all these threat scenarios, the term “nuclear accident” in Section 16 of the Act has

been replaced by “nuclear accident and other events which may involve ionising radiation or dispersion of radioactivity”. Consequently, the term “emergency preparedness against nuclear accidents” in Sections 15 and 16 has been replaced by “nuclear and radiological emergency preparedness.”

Furthermore, the Radiation Protection Act now clearly states (in Section 16) that the purpose of nuclear and radiological emergency preparedness is to protect life, health, the environment or other important social interests.

## **Romania**

### ***Regime of nuclear installations***

#### *Decision on Procedures for Environmental Impact Assessment (2006)*

Government Decision No. 1213 of 6 September 2006 was published in the Official Gazette of Romania (Part I, No. 802) of 25 September 2006. This Decision establishes a standard procedure for the assessment of the environmental impact of certain public and private projects that may have a significant impact on the environment. This assessment is an integral part of the licensing procedure. The competent authorities to enforce the provisions of this Decision are, as appropriate, the central environmental authority – the National Agency for Environmental Protection – or the regional and local agencies for environmental protection. Projects that due to their nature, magnitude or position, amongst other factors, may have a significant impact on environment, are required to have their environmental impact assessed prior to the issuance of an environmental approval.

A list of projects that have undergone an environmental impact assessment is set out in Annex 1 to the decision. They include nuclear power plants and other nuclear installations, including their decommissioning and dismantling, (excluding, however, research installations dedicated to the production and conversion of fissionable and radioactive materials whose maximum capacity does not exceed 1 kW of continuous thermal power); installations for the reprocessing of spent nuclear fuel, the production or enrichment of nuclear fuel, the processing of spent nuclear fuel or highly radioactive waste, the final storage of spent nuclear fuel or radioactive waste, the storage of spent nuclear fuel or radioactive waste at a location different from the production facility for a time-period that exceeds 10 years. Annex 2 to the decision sets out a list of the projects for which the eligibility for environmental impact assessment remains to be determined. Among such projects are installations for the processing and storage of radioactive waste, other than those listed in Annex 1.

### ***Radioactive waste management***

#### *Amendment of the Ordinance on the Management of Spent Nuclear Fuel and Radioactive Waste (2006)*

Ordinance No. 31 of 19 July 2006 amending Ordinance No. 11/2003 on Radioactive Waste and Spent Fuel Management (see *Nuclear Law Bulletin* Nos. 71 and 72) was published in the Official Gazette of Romania (Part I, No. 663) of 2 August 2006. The main amendments to the ordinance are as follows:

- The title of the ordinance has been modified to “Ordinance on the Safe Management of Radioactive Waste”.

- In accordance with the new wording of Article 1, the management of radioactive waste is to comply with national norms and regulations as well as with international agreements and conventions to which Romania is a Party, with regard to nuclear safety and protection against ionising radiation for the public, workers, the environment and property.
- The objective of this ordinance is now to set out the responsibilities of the various bodies involved in radioactive waste management and to allocate the financial resources necessary for decommissioning and radioactive waste management during the life-time of nuclear and radiological installations, in order to ensure nuclear and radiological safety for the public, workers, the environment and property, without jeopardising the needs and expectations of future generations.
- The scope of the ordinance has been amended. It now applies to the safe management of both radioactive waste resulting from the nuclear fuel cycle and radioactive waste resulting from nuclear applications and technologies in industry, medicine, agriculture and other fields of social-economical interest, including waste resulting from decommissioning.
- The principles underlying the management of radioactive waste, including final storage, are a) to use only processes and methods of management that guarantee an acceptable level of protection against ionising radiation for human health and the environment, including possible transboundary effects; b) the polluter pays principle; c) the liability of the party generating the radioactive waste; d) the use of the most effective methods available that do not involve excessive costs for future generations; e) to maintain the lowest possible level of activity and volume of radioactive waste.
- Activities related to the safe management of radioactive waste generated are to be performed in compliance with the national strategy, which is part of the National Nuclear Development Strategy. Radioactive waste is to be classified according to the norms issued by the National Commission for the Control of Nuclear Activities (CNCAN). The parameters defining the limits and technical conditions in relation to the final storage of radioactive waste are to be defined by the National Agency for Radioactive Waste (ANDRAD) and approved by Joint Order of the Chairpersons of ANDRAD and CNCAN.
- ANDRAD is responsible for the final storage of spent nuclear fuel and radioactive waste, including waste resulting from the decommissioning of nuclear or radiological installations.
- The funding required to implement these activities derives partly from direct annual contributions due by licence-holders and partly from the State budget. There are also some other sources in the form of donations, sponsorships or financial assistance.

## **Slovak Republic**

### ***Radiation protection***

#### *Act on Public Healthcare (2006)*

Act No. 126/2006 on Public Healthcare entered into force on 1 June 2006. It implements, *inter alia*, EU directives in the field of radiation protection and radiation sources. Pursuant to this new Act, the Ministry of Health has issued the following regulations:

- Regulation No. 334/2006 on the Management of Institutional Radioactive Waste.

- Regulation No. 345/2006 on Basic Safety Requirements on the Health Protection of Workers and the Public Against Ionising Radiation.
- Regulation No. 346/2006 on the Radiation Protection of Outside Workers Exposed to the Risk of Ionising Radiation in Controlled Areas.
- Regulation No. 347/2006 on the Radiation Monitoring Network.
- Regulation No. 348/2006 on the Control of High-activity Radioactive Sources and Orphan Sources.
- Regulation No. 349/2006 on Radiation Protection During the Shipment of Radioactive Sources and Radioactive Substances.
- Regulation No. 350/2006 on the Elimination of Exposure to Natural Radiation.

### ***Radioactive waste management***

#### *Act establishing a Nuclear Decommissioning Fund (2006)*

A new Act on a Fund for the Decommissioning of Nuclear Installations and for the Management of Spent Fuel and Radioactive Waste (No. 238/2006) has replaced the previous Act on the State Nuclear Fund No. 254/1994. This new legislation has already been amended by Act No. 258/2006.

Pursuant to this act, a completely new fund has been established. The most important change is that financial contributions are collected separately on individual accounts for each nuclear installation in the Slovak Republic. These contributions may only be used to cover reasonable expenses arising from decommissioning, and from the management of spent fuel and radioactive waste originating from the relevant nuclear installation. This act only applies to the decommissioning of nuclear installations and management of their radioactive waste and does not apply to radiation sources used in medicine or industry.

During the drafting of this legislation, the question arose as to how to finance the decommissioning of the NPP Bohunice A1<sup>1</sup>, NPP Bohunice V1<sup>2</sup> and the management of spent fuel and radioactive waste arising therefrom. These nuclear installations have been always operated by the State to provide electricity. Up to 1994, no financial contributions or fees to cover future decommissioning were charged. Furthermore, contributions paid by operators since 1994 have been deemed to be insufficient.

Pursuant to the new act, the operators of electricity distribution networks are obliged to transfer to the State budget a percentage of the monies they receive from electricity customers. This tax is one of the most important sources of the Nuclear Decommissioning Fund and is credited directly and exclusively to the NPP Bohunice A1 and V1 accounts.

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1. This plant was in operation for four years and was shut down in 1977 after a nuclear accident.
  2. This plant's two reactors have been in operation since 1978-80, and are to be shut down before 2008.

## ***Environmental protection***

### *Act on Environmental Impact Assessment (2006)*

The 1998 Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (see *Nuclear Law Bulletin* No. 62) entered into force for the Slovak Republic on 5 March 2006. This new Act on Environmental Impact Assessment No. 24/2006 replaces the previous legislation on the same subject (Act. No. 127/2004) and implements Council Directive 85/337/EC of 27 June 1985 on the Assessment of the Effects of Certain Public and Private Projects on the Environment and Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the Assessment of the Effects of Certain Plans and Programmes on the Environment.

## **Slovenia**

### ***Radiation protection***

#### *Regulation on Approved Experts for Radiation and Nuclear Safety (2006)*

This Regulation was adopted on 8 March 2006 and was published in Official Gazette No. 51/06. With respect to the procedure for obtaining a licence to carry out the work of an approved expert for radiation and nuclear safety, the regulation establishes a verification programme to ensure that the necessary conditions are fulfilled and it appoints a special three-member expert commission to examine the fulfilment of these conditions. It also defines the method to be used for keeping records on approved experts, the format and extent of regular and exceptional reports and other conditions that approved experts must meet to assess radiation and nuclear safety.

### ***Radioactive waste management***

#### *Regulation on the Classification of Radioactive Waste (2006)*

This Regulation, adopted on 6 March 2006 and published in Official Gazette No. 49/06, provides a classification of radioactive waste with regard to the level and type of radioactivity. It defines radioactive waste and spent fuel management and sets out requirements with regard to reporting on the production of radioactive waste and spent fuel. Furthermore it determines the method to be used to maintain the central records on the production of radioactive waste and spent fuel and to administer the records on radioactive waste and spent fuel in storage or disposal.

## **Spain**

### ***Radiation protection***

#### *Decree on the Control of High-activity Sealed Radioactive Sources and Orphan Sources (2006)*

Royal Decree 229/2006, adopted on 24 February 2006, implements Council Directive 2003/122/Euratom of 22 December 2003 on the Control of High-activity Sealed Radioactive Sources and Orphan Sources (see *Nuclear Law Bulletin* Nos. 72 and 73).

The aim of this decree is to prevent exposure of workers and the public to ionising radiation arising from inadequate control of high-activity sealed radioactive sources or orphan sources. Orphan sources are sealed sources which have never been under regulatory control or which have been abandoned, stolen, lost, misplaced or transferred without proper notification of the competent authority.

This royal decree is to be applied in conjunction with other instruments, such as the 1999 Regulations on Nuclear and Radioactive Installations (see *Nuclear Law Bulletin* No. 66) and the 2001 Regulations on Health Protection against Ionising Radiation (see *Nuclear Law Bulletin* No. 68). Both of these instruments implement Directive 96/29/Euratom Laying Down Basic Safety Standards for the Protection of the Health of Workers and the General Public Against the Dangers Arising From Ionising Radiation.

### ***Regime of radioactive materials***

#### *Order on Activities in the Front End of the Nuclear Fuel Cycle (2005)*

This Order of the Ministry of Industry, Tourism and Trade ITC/2821/2005, adopted on 7 September 2005, amends the quantities laid down in Article 3(c) of Royal Decree No. 1464/1999 on Activities Comprising the Front End of the Nuclear Fuel Cycle (see *Nuclear Law Bulletin* No. 67).

It aims to adapt the reserves of enriched uranium to the actual situation with regard to uranium concentration, conversion and enrichment. This reserve was established by the Royal Decree of 1999, which provided for subsequent modification of the quantities of this reserve through Order of the Ministry of Industry and Energy (now the Ministry of Industry, Tourism and Trade).

### ***Radioactive waste management***

#### *Decree-Law on Urgent Reforms to Promote Productivity and Improve Public Contracting (2005)*

Article 25 of this Royal Decree-Law 5/2005, adopted on 11 March 2005, modifies the Sixth Addendum of Law 54/1997 on the Electricity Sector, which regulates the funds financing the activities of the General Radioactive Waste Plan, managed by the National Enterprise for Radioactive Waste (ENRESA).

This decree-law modifies the system of financing the management of radioactive waste and spent fuel and the decommissioning of nuclear power plants. It provides that licensees must finance in advance, during the operative lifetime of the nuclear power plants, the future costs for decommissioning, spent fuel and waste management. This obligation is applicable as from 1 April 2005.

To fulfil this obligation, ENRESA bills licensees the sum resulting from multiplying the gross kilowatt-hour (kWh) generated by each nuclear power plant during each calendar month by a unit value specific to each plant, calculated on the basis of criteria such as remaining lifetime or the volume of waste generated. The system is made more flexible by the fact that the said unit values are revised annually.

This decree-law further provides that the State will become the owner of radioactive waste once it has been sent for definitive disposal. The State will also be responsible for surveillance following

the decommissioning of a nuclear or radioactive facility, once the period of time established in the Statement of Closure has expired. This applies in particular to uranium mines.

#### *Law on Reforms for the Promotion of Productivity (2005)*

Article 8 of this Law 24/2005, adopted on 18 November 2005, adds a Sixth Addendum *bis* to Law 54/1997 on the Electricity Sector, establishing a new Corporate Public Entity (*Entidad Pública Empresarial*) to replace the National Enterprise for Radioactive Waste ENRESA. Upon approval of the Statutes of this new Corporate Public Entity ENRESA by Royal Decree, the existing *Empresa Nacional de Residuos Radiactivos, S.A.* (ENRESA) will be dissolved. The new Corporate Public Entity will legally succeed ENRESA in all its rights and duties. Its dissolution and liquidation shall be approved by agreement of the Council of Ministers.

This law further declares spent fuel and radioactive waste management, including decommissioning of radioactive and nuclear installations, to be a public service. Pursuant to Article 128.2 of the Spanish Constitution, essential resources or services, particularly in the case of monopoly, may be reserved by law to the public sector. Accordingly, this public service will be directly managed by the Corporate Public Entity ENRESA, following the instructions set out in the General Radioactive Waste Plan approved by the Government.

A series of fees are established to pay for the services of this public entity, which will be invested in the Fund for the financing of the activities of the General Radioactive Waste Plan. The Government is enabled to revise the elements of determination of the fees' quota through a Royal Decree, upon the information of an annual financial report about the activities of the General Radioactive Waste Plan.

Article 14 of this Law modifies Addendum Seven of Law 54/1997 on the Electricity Sector with regard to the transfer of the property of nuclear power plants under moratorium. Following the principle of free competition, it is established that the market value of the land on which these installations are situated will be determined by public auction or tender. The licensee of the installation is entitled to participate in this process.

Article 16 of this Law modifies the 1964 Act on Nuclear Energy (see *Nuclear Law Bulletin* No. 2) with the addition of new obligations in the area of nuclear safeguards and physical protection of nuclear materials.

Article 17 of this Law amends the 1980 Act setting up a Nuclear Safety Council – *Consejo de Seguridad Nuclear* (see *Nuclear Law Bulletin* Nos. 25, 66 and 69) by providing that instructions emitted by this public body shall be binding when they are notified or published in the Spanish Official Journal.

## **Switzerland**

### ***General legislation***

#### *Second Set of Ordinances on Nuclear Energy (2006)*

The Federal Act on Nuclear Energy, adopted in March 2003 (see *Nuclear Law Bulletin* Nos. 71 and 72; the text of the law is reproduced in the Supplement to NLB No. 72) and the Ordinance on

Nuclear Energy adopted in December 2004 (see *Nuclear Law Bulletin* No. 75) entered into force on 1 February 2005. The Ordinance on Nuclear Energy contains a large number of the provisions necessary to implement the Act on Nuclear Energy.

On 1 July 2006, ordinances of the Federal Council regulating other fields entered into force. They are as follows:

- Ordinance on the Qualifications of Personnel of Nuclear Installations:

This ordinance sets out criteria with regard to the qualifications, training and professional capacity of personnel of nuclear installations who are involved in nuclear safety.

- Ordinance on Security Controls of Persons in the Field of Nuclear Installations:

The Act on Nuclear Energy sets out a formal legal basis for the security control of persons who carry out activities in nuclear installations. This is an important means of preventing risk. Another ordinance already in force applies only to personnel of the Confederation and military personnel, along with third parties. Further rules have been established in this new ordinance to cover persons working for operators of nuclear installations.

- Ordinance on Surveillance Teams in Nuclear Installations:

In order to protect themselves from malevolent acts, Swiss nuclear power plants and the intermediate repository of Würenlingen, in the canton of Argovie, already have surveillance teams. The criteria applicable to these surveillance teams was previously set out in a Directive of the Federal Office of Energy. The new ordinance now comprehensively covers the duties and obligations of surveillance teams, and regulates their equipment and arms. The training of surveillance personnel is carried out by the cantons in co-operation with the competent federal bodies.

- Ordinance on Recipients and Pipes Classified for Safety Purposes in Nuclear Installations:

In addition to the terms of the Act on Nuclear Energy and the Ordinance on Nuclear Energy, this ordinance sets out specific criteria for the safety and periodical control of recipients and pipes. It replaces out-of-date provisions on the technical safety of recipients and other gas-pressured machinery and consolidates in one legal instrument the most important rules previously set out in directives.