

# NATIONAL LEGISLATIVE AND REGULATORY ACTIVITIES

## **Argentina**

### *Organisation and Structure*

#### *Reorganisation of the National Atomic Energy Commission (2001)*

Decree No. 20/99 of 13 December 1999 transferred the National Atomic Energy Commission (*Comisión Nacional de Energía Atómica – CNEA*), previously under the control of the President of the Republic, under the authority of the Secretariat for Science and Technology which reports to the President. A new Decree No. 250 of 28 February 2001 places the Commission and the Nuclear Regulatory Authority (*Autoridad Regulatoria Nuclear – ARN*) under the direct authority of the President as was originally the case.

## **Canada**

### *Regime of Radioactive Materials (including Physical Protection)*

#### *Order aiming to increase security at major nuclear installations (2001)*

This Order was made on 18 October 2001 by the Canadian Nuclear Safety Commission (CNSC) pursuant to Section 47 of the Nuclear Safety and Control Act (see *Nuclear Law Bulletin* Nos. 60, 65 and 66; the text of this Act is reproduced in the Supplement to *Nuclear Law Bulletin* No. 60), which allows the Commission to make any order that it considers necessary to protect the environment or the health and safety of persons or to maintain national security and compliance with Canada's international obligations.

This Order aims to increase security at Canada's major nuclear installations and imposes specific security arrangements and measures on the five leading nuclear operators (i.e. Bruce Power, Ontario Power Generation, Atomic Energy of Canada Limited, New Brunswick Power and Hydro-Québec). The Order provides for increased screening of personnel (background checks), more stringent measures to verify the identity of personnel entering the facilities, the presence of armed persons on site for security reasons, improved equipment for security personnel, enhanced measures to prevent forced entry by vehicles and more effective searching of personnel and vehicles entering a facility site.

## France

### *Organisation and Structure*

#### *Establishment of the French Agency for Environmental Health Safety and the Institute for the Protection of Nuclear Safety (2001)*

Act No. 2001-398 of 9 May 2001 aims to strengthen the institutional regime governing health safety, monitoring and warning systems in relation to the environment. It sets up the following bodies:

- the French Agency for Environmental Health Safety (*Agence française de sécurité sanitaire environnementale* – AFSSE), a new State body responsible for developing and strengthening the capacity and coherence of expertise relating to health risks linked to the environment;
- the Institute for Radiation Protection and Nuclear Safety (*Institut de radioprotection et de sûreté nucléaire* – IRSN), which has been established through the merger of the Office for Protection against Ionising Radiation (*Office de protection contre les rayonnements ionisants* – OPRI) and the Institute for Protection and Nuclear Safety (*Institut de protection et de sûreté nucléaire* – IPSN) into a new public utility company.

The Act provides that a Decree of the Council of State will establish details concerning the conditions and timetable for the establishment of the IRSN, as well as the definition of its functions and subsidiary bodies.

#### *Amendment of the Decree on the Holding Company of the Atomic Energy Commission (2001)*

Decree No. 83-1116 of 21 December 1983 on the Holding Company of the Atomic Energy Commission (*Société des participations du Commissariat à l'énergie atomique* – CEA) which is named *CEA-Industrie* was amended by Decree No. 2001-342 of 19 April 2001, which entered into force on 21 April 2001. Pursuant to this new Decree, the Atomic Energy Commission is required to hold more than half of the capital of *CEA-Industrie*. It was previously required to hold at least 67%; however in reality, 95% of the capital of *CEA-Industrie* was held by the CEA.

The Decree furthermore provides that the Head of the Control Mission within the CEA exercises the role of State controller over *CEA-Industrie*.

#### *Decree on the Special Commission for Major Nuclear Installations Classified as Secret (2001)*

Decree No. 2001-417 of 11 May 2001 sets out the composition of the Special Commission for Major Nuclear Installations Classified as Secret, established by Section 4 of the Decree of 11 October 1999 on these installations (see *Nuclear Law Bulletin* No. 65). This Commission is comprised of:

- a member of the Council of State (*Conseil d'État* – Supreme Administrative Court in France) holding (at least) the position of councillor or president;

- the High Commissioner for Atomic Energy;
- the Director for the Safety of Nuclear Installations;
- seven representatives of the Ministry of Defence, at least six of whom belong to, respectively, the Armies General Staff, the Navy, the Air Force, the Procurement Agency, the General Controller of the Army, and the Shipbuilding Directorate (*Direction des constructions navales*);
- the Senior Civil Servant for Defence at the Ministry for Industry;
- a representative of the Minister of the Interior;
- a representative of the Minister responsible for Labour;
- a representative of the Minister responsible for the Environment;
- a representative of the Minister responsible for Health;
- a representative of the Atomic Energy Commission (CEA);
- a representative of the General Company for Nuclear Materials (COGEMA);
- two members chosen for their particular expertise in the nuclear field, to be proposed by the Minister of Defence and the Minister of Industry, respectively;
- deputy members for all of the above members.

The members of the Commission are nominated for a maximum duration of five years.

### ***Radiation Protection***

#### *Ordinance on the Implementation of EU Directives in the Field of Protection against Ionising Radiation (2001)*

Ordinance No. 2001-270 of 28 March 2001 aims to implement the following EU directives into French law:

- Council Directive 90/641/Euratom, of 4 December 1990, on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (see *Nuclear Law Bulletin* No. 47);
- Council Directive 96/29/Euratom of 13 May 1996 setting forth basic standards for the protection of the health of both workers and the public against the dangers resulting from ionising radiation (see *Nuclear Law Bulletin* No. 58);
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposures, and repealing Directive 84/466/Euratom (see *Nuclear Law Bulletin* No. 60).

The provisions of this Ordinance amend the Public Health Code and the Labour Code by inserting modifications related to both public protection (Sections 1 to 7 of the Ordinance) and to the protection of workers (Sections 8 to 10).

Ordinance No. 2001-270 covers all activities involving a risk of exposure of persons to ionising radiation, whether for medical, industrial or research purposes, and which it refers to as “nuclear activities”. It introduces the fundamental principles of radiation protection into the Public Health Code, i.e. the justification, optimisation and dose limitation principles. The provisions governing prohibitions on or authorisations for the use of ionising radiation is modernised and accompanied by a new set of criminal penalties. Furthermore, the rules governing the management of radio-nuclides have been made more stringent and take into account exposure to natural radiation.

This revision effectively places the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA) under the general legal regime, whereas previously it benefited in certain cases from an exceptional regime concerning permanent licensing for the preparation, import or export of artificial radio-elements. Article L 1333-20 of the Public Health Code is in fact repealed from the date of entry into force of the implementing decrees governing prohibitions and regulations and also those setting out conditions governing the licensing or declaration regime. Such entry into force will take place at the latest one year after the publication of this Ordinance. These measures also result in the disbandment, by the same date, of the Interministerial Committee for Artificial Radioelements (*Commission interministérielle des radioéléments artificiels* – CIREA) (see *Nuclear Law Bulletin* No. 23) for which the CEA and the Institute for Protection and Nuclear Safety provide permanent secretariat services.

The provisions of Title II of the Ordinance aim to improve the protection of exposed workers, in particular non-salaried workers and short-term workers. Although Directive 90/641 had already been implemented by Decree No. 97-137 of 13 February 1997 (see *Nuclear Law Bulletin* No. 59) and Decree No. 98-1186 of 26 December 1998 (see *Nuclear Law Bulletin* No. 63), specific provisions are introduced to cover non-salaried workers and workers holding either a fixed-duration contract or an interim post. Thus, Section 8 of the Ordinance provides that fixed-term contracts and interim contracts shall be extended or renewed in order to avoid the situation where intensive exposure suffered in the workplace would limit their possibilities of future work for these short-term workers. These provisions apply to contracts concluded after their entry into force.

#### *Decree on Information of the Public (2001)*

Decree No. 2001-470 of 28 May 2001, which amends Decree No. 88-622 of 6 May 1988 on Emergency Plans, establishes measures providing for the information of the public which must be activated during the On-site Emergency Plan (*plan particulier d'intervention*) and emergency measures for installations which may cause a radiological emergency situation.

#### ***Regime of Nuclear Installations***

#### *Decree governing the Safety and Radiation Protection of Nuclear Installations and Activities used for Defence Purposes (2001)*

Decree No. 2001-592 of 5 July 2001 establishes the legal framework governing the safety of nuclear installations and activities used for defence purposes, including for example major nuclear

installations classified as secret (*installations nucléaires de base secrètes*), armaments systems, and nuclear ships (hereinafter referred to as “military nuclear systems”), sites and installations used for nuclear experiments for defence purposes, or the transport of fissile or radioactive material for military use.

The Decree provides for the nomination of a Delegate for nuclear safety and radiation protection for activities and installations used for defence purposes. This Delegate is nominated by decree, upon joint proposal of the Minister for Defence and the Minister responsible for Industry to whom he reports, for a renewable period of five years. He is responsible in particular for putting forward draft regulations on nuclear safety applicable to nuclear installations and activities used for defence purposes to the Minister of Defence and the Minister responsible for Industry, and to control the application of such regulations by inspection. He furthermore proposes technical provisions governing protection against ionising radiation, deals with licensing applications for the construction of a major nuclear installation classified as secret or for new types of military nuclear systems, and takes any measures necessary to prevent nuclear accidents and limit their consequences.

The construction of a major nuclear installation classified as secret is subject to a licence which may be granted upon the opinion of the special commission for major nuclear installations classified as secret. The establishment of a new type of military nuclear system is also subject to delivery of a licence by the Prime Minister. The Decree sets out the procedure which should be followed in each of these cases.

### ***Transport of Radioactive Material***

#### *Order on Postal Deliveries of Radioactive Materials (2001)*

The Order of 22 March 2001 sets out special rules governing postal deliveries of radioactive materials in France. It repeals and replaces the Order of 18 August 1972 as amended on deliveries by post of radioactive materials which are exempt from special transport conditions. It aims to ensure the protection of personnel involved in handling and transporting postal deliveries and the protection of the environment with regard to the risks posed by radioactive materials.

This Order only applies to national postal deliveries of “exempted” packages which contain very low quantities of radioactive materials (international postal deliveries of such materials is prohibited). Radioactive materials may be accepted for postal delivery subject to the terms of the ADR (carriage of dangerous goods by road), RID (carriage of dangerous goods by rail) and OPS 1 (technical conditions governing the use of aircraft by public air transport companies) Agreements where they are not in contradiction with the terms of the present Order, and with the exception of provisions governing transport documents.

Postal deliveries of radioactive materials accepted for such delivery pursuant to the terms of this Order must be carried out by a carrier authorised by the competent authority in a special consignment office designated for this purpose by the authorisation. Carriers which are already authorised under the terms of the above-mentioned Order of 18 August 1972 are permitted to continue their deliveries whilst conforming to the requirements of the new Order within a period of one year from the date of its publication.

### *Order on the Carriage of Dangerous Goods by Road (“ADR Order”) (2001)*

The ADR Order, which was adopted on 1 June 2001 and entered into force on 1 July 2001, amends the ADR Order of 5 December 1996 on the same subject which aimed to allow application on French territory of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR Agreement).

The 2001 Order aims to incorporate into French law the 2001 Amendment of the ADR Agreement and to modify the national specifications which France had retained. The Order takes into account the complete re-structuring of the ADR Agreement. It contains four annexes (A, B, C, D), Annexes A and B of which correspond to Annexes A and B of the ADR Agreement including its amendments which entered into force on 1 July 2001.

### *Order on the Transport of Dangerous Goods by Rail (“RID Order”) (2001)*

This Order of 5 June 2001 repeals the RID Order of 6 December 1996 and its 1997 and 1998 amending texts (see *Nuclear Law Bulletin* Nos. 61 and 63). It aims to implement the 2001 amendment to the Regulation on the International Carriage of Dangerous Goods by Rail into French law while keeping the national French specifications. This Order entered into force on 1 July 2001 but the rules in force as of 30 June 2001 may continue to be applied until 31 December 2001 for goods from Class 7 (radioactive materials) and until 31 December 2002 for other goods.

## **Germany**

### ***General Legislation***

#### *Agreement on the phase-out of nuclear energy (2001)*

On 11 June 2001, the German Government and the leading electricity-generating companies signed an Agreement on the phase-out of nuclear energy. This Agreement formalises the terms of the agreement which the utilities and the Government reached on 14 June 2000 (see *Nuclear Law Bulletin* No. 66).

This Agreement, which confirms the ban on the construction of new nuclear power plants, the limitation to 32 years of the average life-span of the 19 German nuclear power plants, the prohibition from 1 July 2005 of nuclear waste reprocessing, and the obligation to set up and use interim storage facilities in the vicinity of the plants, paves the way for consideration by the Parliament of a draft law to amend the 1959 Act on Peaceful Uses of Nuclear Energy (the text of which is reproduced in the Supplement to *Nuclear Law Bulletin* No. 36).

## ***Radiation Protection***

### *Ordinance implementing Euratom Directives on Radiation Protection (2001)*

On 20 July 2001, the Federal Government issued an Ordinance for the Implementation of Euratom Directives on Radiation Protection (*Bundesgesetzblatt I* p.1714). The main legal basis for this Ordinance lies in the authorisations granted to the Federal Government by the Atomic Energy Act, in particular following its amendment by the Act of 3 May 2000 (see *Nuclear Law Bulletin* No. 67; see also *Bundesgesetzblatt* 2001 I p. 1847).

The main purpose of this Ordinance is to amend the 1989 Radiation Protection Ordinance (see *Nuclear Law Bulletin* Nos. 44, 52 and 59) but numerous other ordinances require consequential amendments, namely:

- Nuclear Installations Procedural Ordinance (Supplement to *Nuclear Law Bulletin* No. 30; also see *Nuclear Law Bulletin* No. 55);
- Financial Security Ordinance (Supplement to *Nuclear Law Bulletin* No. 18);
- Reliability Assessment Ordinance (see *Nuclear Law Bulletin* No. 65);
- Ordinance on Advanced Financial Contributions towards Final Disposal Facilities (see *Nuclear Law Bulletin* Nos. 30, 39, 41 and 46);
- Ordinance on Persons Responsible for Nuclear Safety (see *Nuclear Law Bulletin* No. 51);
- Ordinance on the Shipment of Radioactive Waste (see *Nuclear Law Bulletin* No. 63);
- Ordinance on Nuclear Costs (see *Nuclear Law Bulletin* Nos. 29 and 51);
- Ordinance on Weights and Measures (*Eichordnung*);
- Ordinance on X-rays (see *Nuclear Law Bulletin* Nos. 39, 47 and 59).

The amendment of the Radiation Protection Ordinance results in an entirely new version of that Ordinance. The old Radiation Protection Ordinance of 13 June 1989 as last amended on 18 August 1997 (*Bundesgesetzblatt* 1989 I. p. 1321, 1326; 1997 I p. 2113) expired on 1 August 2001 when the amending Ordinance came into effect.

The new Radiation Protection Ordinance comprises 118 Sections and 14 Annexes. It is comprised of the following parts:

- Part 1: General.
- Part 2: Protection of man and the environment against radioactive substances or ionising radiation from goal oriented uses in connection with certain activities.
- Part 3: Protection of man and the environment against natural radioactive substances and ionising sources in connection with activities not covered by Part 2.

- Part 4: Protection of consumers in connection with the addition of radioactive substances to products.
- Part 5: Joint provisions applicable to all Parts.

The Ordinance aims to implement Council Directives 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 (Official Journal L159 of 29 June 1996, p. 1; see *Nuclear Law Bulletin* No. 58) and 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (Official Journal L180 of 9 July 1997, p. 22; see *Nuclear Law Bulletin* No. 60). The Ordinance also implements additional elements of Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (Official Journal L 357, p. 31). This latter amendment is a consequence of a procedure against the Federal Republic of Germany pending before the European Court of Justice in which the Commission claims that Germany has not properly implemented the said Directive.

Details of the new Radiation Protection Ordinance are set out in a study by Dr. Martina Palm in Chapter “Studies” of this *Bulletin*.

## Greece

### *Radiation Protection*

#### *Radiation Protection Regulations (2001)*

These new Regulations were adopted by Ministerial Order No. 1014 (FOR) 94, and entered into force on 6 March 2001. Designed to protect the workers and the public against the risks resulting from ionising radiation, they replace the Regulations of 17 July 1991, approved by Ministerial Order No. 14632 (FOR) 1416.

Amendment of the former Regulations had become necessary in order to take into account the Recommendation of the International Commission on Radiological Protection set out in its Publication No. 60, the international basic safety standards, and also to implement 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* No. 58) and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (see *Nuclear Law Bulletin* No. 60).

The new Regulations is comprised of 12 Parts dealing respectively with principles of radiological protection; licensing of ionising radiation laboratories; radio-diagnostic laboratories; nuclear medicine diagnostic and therapeutic laboratories; radiotherapy laboratories; management and disposal of radioactive waste; radiological laboratories for research, training and applications of ionising radiation; industrial radiographic laboratories; sealed source irradiation installations; particle accelerators; transport of radioactive materials; and annexes.

The main changes made by the Regulations are as follows:

- Reduction of the annual dose limits for occupationally exposed workers and the public to 20 mSv and 1 mSv respectively.
- Establishment of a distinction between practices and interventions: practices are human activities which may result in an increase of exposure to ionising radiation; interventions are human activities which aim to reduce or prevent exposure resulting from a radiological emergency or from past practices of professional activities.
- Introduction of the concept of intervention as a legal instrument in radiation protection legislation.
- Taking into account exposures resulting from professional activities involving natural sources of radiation: such exposures may justify special attention or protective measures.
- Introduction of the concept of “dose constraints” in relation to the optimisation procedures: dose constraints may be established and used for a given source, practice or activity in order to optimise protection at the design or planning stage. Dose constraints may be set out by the Greek Atomic Energy Commission (GAEC). Generic and specific dose constraints are set out in the Regulations.
- Obligation to justify new practices and some previous ones. In the medical field, justification of new practices or of previous practices made necessary in the light of new information is approved by a seven-member committee established under the Minister for Health. For all other practices, justification is approved by the GAEC.

## Italy

### *Radiation Protection*

#### *Amendment of the Decree implementing the Euratom basic radiation protection standards (2001)*

Parliamentary Decree No. 241 of 26 May 2000 (see *Nuclear Law Bulletin* No. 66), adopted in order to implement Council Directive 96/29/Euratom of 13 May 1996 setting forth basic standards for the protection of the health of both workers and the public against the dangers resulting from ionising radiation (see *Nuclear Law Bulletin* No. 58), was amended by Parliamentary Decree No. 257 of 9 May 2001 (published in Official Journal No. 153 of 4 July 2001). The amendments introduced essentially aim to rectify certain technical provisions, including one governing the establishment of particular technical conditions related to the licensing (or the exemption from licensing) of X-ray equipment and other radioactive sources. However, certain fundamental provisions, such as those governing the licensing of certain activities or ionising radiation sources, have also been amended. Other modifications include the introduction of limitations or special bans on the use or importation of certain products containing naturally radioactive materials, or the procedures which should be followed upon the termination of certain activities.

### *Implementation of the European Directive on the Quality of Water Intended for Human Consumption (2001)*

Parliamentary Decree No. 31 of 2 February 2001 (published in the Official Journal – Ordinary Supplement – No. 53 of 3 March 2001) which implements Council Directive 98/83/EC of 3 November 1998 on the Quality of Water Intended for Human Consumption sets out the minimum conditions which must be observed in respect of water for human consumption. The Decree therefore establishes the radioactive content (tritium, potassium-40, radon and its decay products) and the parameter levels (100 Becquerel/litre for tritium) which must be observed. It also organises a control mechanism governing these standards and sets out the frequency, methods and competent authorities (the regions, and at national level, the Minister for Health) for such control.

## **Japan**

### *Radiation Protection*

#### *Revision of the Nuclear Disaster Prevention Guidelines (2000)*

On the basis of the lessons learned from the criticality accident which occurred at the Tokai-mura nuclear fuel fabrication plant in 1999 and the Special Law on Emergency Preparedness for Nuclear Disaster (see *Nuclear Law Bulletin* No. 65), the Guidelines describing the technical aspects of nuclear disaster prevention measures were revised in May 2000. The main features of the revision are as follows:

- The Guidelines are adjusted to comply with the new legal framework governing nuclear disaster prevention measures as set out by the above-mentioned Special Law.
- They now cover research reactors and other nuclear fuel facilities, including nuclear power plants and reprocessing plants.
- They apply to an accident resulting in release of nuclear fuel particles into the environment, a criticality accident, and an accident accompanied by a release of noble gas and iodine into the environment.

## **Republic of Korea**

### *Third Party Liability*

#### *Amendments to the Act on Compensation for Nuclear Damage (2001)*

New amendments were made to the 1969 Act on Compensation for Nuclear Damage with the adoption of Act No. 6350 on 16 January 2001 (see *Nuclear Law Bulletin* No. 67). The text of this Act, as amended, is reproduced in the Supplement to this *Bulletin*.

## **Lithuania**

### ***General Legislation***

#### *Regulations for the Classification of Legal Acts Regulating Nuclear Safety (2001)*

By Order No. 34 of 11 July 2001, the Nuclear Power Safety Inspectorate (VATESI) approved the Regulations for the Classification of Legal Acts Regulating Nuclear Safety. These Regulations set out a hierarchy between the various instruments listed (legal acts, general requirements, regulations, rules, recommendations, etc.) and specify their binding or non-binding character.

### ***Radiation Protection***

#### *Hygiene Standard "Radiation Safety in Nuclear Power Plants" (2001)*

By Order No. 120 of 19 February 2001, the Minister of Health Protection approved this Standard HN 87:2001. It establishes the radiation safety requirements to be observed during the operation of nuclear power plants with a view to ensuring the protection of employees of nuclear power plants and of the public living in the surrounding areas.

#### *Guidelines governing the Procedure on Radiological Monitoring and Limitation of Releases of Radionuclides into the Environment from Nuclear Facilities (2001)*

By Order No. 60 of 23 January 2001, the Minister for the Environment approved Document LAND 42-2001. This Document sets out guidelines which apply to the design, construction and operation of nuclear facilities, the activities of which involve radionuclides which could be released into the environment, as well as to the decommissioning of such facilities.

### ***Regime of Nuclear Installations***

#### *Law on the Decommissioning Fund for the Ignalina Nuclear Power Plant (2001)*

This Law was adopted on 12 July 2001 by the Seimas (Parliament) of the Republic of Lithuania and will enter into force on 1 January 2002. It provides for the establishment of a new Ignalina NPP Decommissioning Fund (see *Nuclear Law Bulletin* No. 66).

This Fund shall be financed in particular from a percentage of the profit made by Ignalina NPP through electricity production; voluntary contributions from foreign countries, international organisations, financial institutions and legal entities of Lithuania; and income gained from the sale of property during decommissioning.

The Law states that the Foundation shall be managed by the Fund Council, consisting of seven members appointed by the Government. The Law sets out the tasks of the Council, including in

particular decisions as to which decommissioning measures will be financed from the assets of the Fund.

The assets of the Fund shall be used to finance technical and social projects related to the decommissioning of Ignalina NPP; management, final disposal and long term storage of radioactive waste and spent fuel from Ignalina NPP; and compensation for nuclear damage.

Finally, the Law provides that the assets currently available in the Fund for the Decommissioning of the State Enterprise Ignalina Nuclear Power established by Governmental Resolution No. 1403 of 2 November 1995 shall be transferred to the Ignalina NPP Decommissioning Fund.

### ***Radioactive Waste Management***

#### *Order approving the Requirements on Management of Radioactive Waste in Nuclear Power Plants before Disposal (2001)*

Order No. 38 was adopted by the Nuclear Power Safety Inspectorate (VATESI) on 27 July 2001. These requirements aim to ensure the safe management before disposal of radioactive waste generated during operation and decommissioning of nuclear power plants, as well as other types of radioactive waste, e.g. radioactive waste transferred to nuclear power plants for storage and/or reprocessing.

## **Luxembourg**

### ***Radiation Protection***

#### *Grand-ducal Regulations relating to the Health Protection of Individuals against the Dangers of Ionising Radiation in relation to Medical Exposures (2001)*

The promulgation on 16 March 2001 of new Grand-ducal Regulations relating to the Medical Uses of Ionising Radiation, designed to replace the Grand-ducal Regulations of 17 February 1987 on the same subject (see *Nuclear Law Bulletin* No. 41), was necessary due to the repeal, on 5 May 2000, of Directive 84/466/Euratom of 3 September 1984 laying down Basic Measures for the Radiation Protection of Persons Undergoing Medical Examination or Treatment (see *Nuclear Law Bulletin* No. 34), and its replacement by Council Directive 97/43/Euratom of 30 June 1997 on Health Protection of Individuals against the Dangers of Ionising Radiation in relation to Medical Exposure (see *Nuclear Law Bulletin* No. 60).

It was necessary to draft this new Directive for several reasons:

- Exposures for medical reasons remain the principal source of exposure to artificial ionising radiation for citizens of the European Union.
- Medical uses of ionising radiation have led to important developments in numerous medical fields, in particular through the introduction of new techniques and technologies.

However, often these new techniques in fact administer high doses (CAT scans, interventional radiology). The use of such new procedures during medical treatment necessitates exposure which must be carried out in optimal conditions of radiation protection.

- The International Commission on Radiological Protection (ICRP) published recommendations in 1996 on the radiological protection of patients exposed to ionising radiation for medical purposes (ICRP 73). These recommendations emphasise the importance of the principles of justification and optimisation of medical exposure.
- Harmonisation at European level of the protection of patients exposed to ionising radiation for medical purposes became desirable: in reality, radiological practices in European countries can vary substantially.

These new Regulations comply in general with the provisions set out in Directive 97/43/Euratom and in the Act of 10 August 1983 concerning the Medical Uses of Ionising Radiation (see *Nuclear Law Bulletin* No. 34).

The most important modifications and the main new elements introduced by these Regulations are as follows:

- **Justification:** Each individual exposure and all new and existing practices must be justified generically. This implies that both prescribers and practitioners are involved in the justification process. The two parties must decide whether the potential health benefits for the patient resulting from the examination are greater than the risks caused by the exposure. In order to assist prescribers in their judgement, it is planned to establish prescription criteria governing exposure for medical purposes.
- **Optimisation:** all medical exposure for radiodiagnostic purposes, with the exception of therapeutic procedures, must be maintained at the lowest level reasonably possible. This process of optimisation focuses on the choice between different equipment, the establishment of adequate diagnostic information or therapeutic results, practical aspects, insurance, quality control, and the evaluation of doses administered to patients. Reference levels (dose levels) for examinations for radiodiagnostic purposes remain to be established.

The Regulations set out rules governing exposure for therapeutic purposes, for research purposes or as part of medico-legal procedures.

- **Training:** theoretical and practical training in radiation protection is compulsory for all persons who are authorised to use ionising radiation on humans. This basic training must be complemented by continuing education on the subject.
- **Equipment:** equipment used must be subject to strict radiation protection control. Recommended means of control are quality assurance programmes which involve periodical performance control of equipment, to be carried out by an expert in medical physics, as well as tests to be carried out periodically by the operator of the installation.

- Special practices: particular attention is paid to special practices which require appropriate techniques, equipment and accessories. These measures concern in particular:
  - children;
  - health screening programmes;
  - interventional radiology and computed tomography (CAT scan);
  - radiotherapy.

The Regulations provide that these special techniques should be accompanied by specific quality assurance programmes and continued training for users.

- Clinical audits: the Regulations provide that clinical audits should be used to allow evaluation, by users, of existing quality assurance programmes in order to carry out improvements in the case of marked deficiencies.

## **Morocco**

### ***Organisation and Structure***

#### *Decree on the Construction Licence for the Maâmora Nuclear Research Centre (1999)*

Pursuant to this Decree No. 2-99-111 of 26 February 1999, the National Centre of Nuclear Energy, Science and Techniques (*Centre national de l'énergie, des sciences et des techniques nucléaires* – CNESTEN) is licensed to build a Nuclear Research Centre on the Maâmora site, located in the province of Kénitra. The establishment of this Centre aims to fulfil one of the principal tasks of the CNESTEN as set out in Act No. 17-83 of 14 November 1986 setting up the CNESTEN, as amended by Act No. 12-97 of 2 August 1997 (see *Nuclear Law Bulletin* No. 51). These tasks include the promotion of nuclear techniques in different socioeconomic sectors; research and development activities in the field of nuclear energy, science and techniques; monitoring technological development in the electronuclear field; providing support and advice to the State (through the Nuclear Research Centre) in relation to nuclear and radiological safety; training in the nuclear field; production and commercialisation of radioisotopes and radiopharmaceuticals; and the management of radioactive waste.

The 1999 Decree describes the installations (called modules) making up the Nuclear Research Centre and in respect of which the CNESTEN is to be the operator. These include a research reactor called Triga Mark II, a laboratory and modules for safety, technology, waste and technical and administrative support.

The Decree sets out particular technical criteria which must be observed by the CNESTEN, governing the quality of the Nuclear Research Centre installations, the protection of these installations against earthquakes, fires and attacks of internal or external origin, changes in the environment around the Centre, the confinement of radioactive materials in its installations, etc.

The Decree prohibits the final disposal of radioactive waste on the site of the Maâmora Nuclear Research Centre. However, it does provide that installations for the management of radioactive waste will reduce the volume and the noxiousness of waste generated within and outside the Centre.

The Decree also contains provisions governing the transport of radioactive materials. It furthermore sets out a number of the responsibilities of the CNESTEN. These include, for example, controlling the releases from the installations of the Centre and their potential consequences on the environment; presenting certain documents to the Minister responsible for Energy, i.e. a provisional safety analysis report in support of an application to authorise initial tests, a definitive safety report to accompany the application for an operating licence and a document setting out the appropriate measures which will be taken in relation to the physical protection of the installations; the establishment of a system of accounting of nuclear materials on the site of the Nuclear Research Centre, the notification of the Ministers for Energy, State, the Interior, Health and the Environment within 24 hours of any nuclear accident occurring in the installations of the Centre. The CNESTEN is entirely responsible for nuclear safety in its installations and it should demonstrate to the Minister responsible for Energy that measures are in place governing third party liability for nuclear damage.

## **Norway**

### ***Radiation Protection***

#### *Act on Radiation Protection and Use of Radiation (2000)*

This Act was adopted on 12 May 2000 and entered into force on 1 July 2000 (see *Nuclear Law Bulletin* No. 67). The text of the Act is reproduced in the Supplement to this *Bulletin*.

## **Poland**

### ***General Legislation***

#### *Atomic Energy Act (2000)*

This Act was adopted on 29 November 2000 and will enter into force on 1 January 2002 (see *Nuclear Law Bulletin* No. 67). The text of the Act is reproduced in the Supplement to this *Bulletin*.

## **Romania**

### ***General Legislation***

#### *Amendment to the Law on the Safe Conduct of Nuclear Activities (2001)*

Section 8 of Law No. 11/1996 on the Safe Conduct of Nuclear Activities of 10 October 1996 (the text of which is reproduced in the Supplement to *Nuclear Law Bulletin* No. 59) was amended by Law No. 384 of 10 July 2001. This amendment introduces a new paragraph into this Section to allow not only the legal entities but also certain legally constituted bodies without legal personality as listed in a new Annex 4 to the Law, to carry out nuclear activities in Romania.

### ***Radiation Protection***

#### *Regulation on the Operational Protection of Outside Workers Exposed to the Risk of Ionising Radiation during their Activities in Controlled Areas (2001)*

This Regulation, which was adopted on 20 August 2001, implements Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (see *Nuclear Law Bulletin* No. 47). Pursuant to this Regulation, outside undertakings are required to comply with reporting requirements and to provide information, training and individual radiological monitoring documents, issued by the National Commission for Nuclear Activities Control (CNCAN). The Regulation establishes a system of prior authorisation of outside undertakings by the CNCAN. Operators of controlled areas must ensure protection of outside workers. Finally, the Regulation sets out in its Annex the individual radiological monitoring document, issued by the CNCAN, which bears an identification number.

## **Russian Federation**

### ***Organisation and Structure***

#### *Reorganisation of Rosenergoatom (2001)*

In the context of the reform of the energy industry and pursuant to a Decree of 11 July 2001, the Russian State Agency for the Generation of Electric and Thermal Power at Nuclear Power Plants (*Rosenergoatom*) was reorganised by a governmental Order of 8 September 2001. According to this Order, 20 individual enterprises in the nuclear sector, including nine nuclear power plants in operation, six nuclear units under construction, three enterprises for repair and maintenance of NPPs, a firm specialised in NPP management training and consulting, and the Research and Development Institute of NPP Operation, are to merge with *Rosenergoatom*. This is the case in particular of the Leningrad plant which was not until now under its control. Accordingly, *Rosenergoatom* will be the sole nuclear utility in the Russian Federation to fulfil the role of nuclear operator and nuclear generating company.

## ***Regulations on Nuclear Trade***

### *Laws allowing the import of spent nuclear fuel for storage and reprocessing (2001)*

On 6 June 2001 the Duma adopted three Laws allowing the import of spent nuclear fuel for storage and reprocessing. These Laws were signed by the President of the Russian Federation on 10 July 2001, together with a Decree setting up a special commission for the import of spent nuclear fuel. This Commission will comprise 20 members (five each nominated by the President, the Duma, the Council of Federation and the Government).

The first Law amends Section 50 of Law No. 2060-1 on Environmental Protection of 19 December 1991, which prohibited the import of spent fuel and radioactive waste except from Russian-made reactors. The 2001 Law states that import of spent fuel from foreign countries to the Russian Federation for storage and/or reprocessing is allowed. Such imports are subject to governmental assent and to the provisions of international treaties to which the Russian Federation is a Party. The principles of non-proliferation, environmental protection and economic interest of the project shall also be taken into account.

The second text introduces amendments and additions to the Law on the Use of Atomic Energy of 21 November 1995 (see *Nuclear Law Bulletin* No. 58; the text of this Law is reproduced in the Supplement to *Bulletin* No. 57). It defines the terms “fuel assembly” and “spent fuel assembly” and states that their export and import will be governed by the terms of civil contracts.

Finally, the Law on Special Ecological Programmes for the Rehabilitation of Radioactively Contaminated Areas establishes the legal framework governing such Programmes. The Special Ecological Programmes aim to ensure radiation protection of the public, general decrease of the risk posed by radiation and improvement of the ecological situation in radioactively contaminated areas. Measures of rehabilitation of such areas shall be implemented and radioactive materials taken out of operation shall be disposed of. These programmes shall be financed from income generated by foreign trade transactions involving spent nuclear fuel assemblies. The funds collected will be transferred to a special account of the Ministry of Atomic Energy (Minatom). Such foreign trade transactions shall be approved by the Government and 75% of income generated shall be used to finance special ecological programmes. The Government shall prescribe the maximum number of spent fuel assemblies which may be imported per year into the Russian Federation, upon agreement with the authorities on the territory of which the spent fuel reprocessing installation is located.

## **Slovenia**

### ***Organisation and Structure***

#### *Transfer of responsibilities in the energy sector (2001)*

Pursuant to the Act on the Organisation and Assignment of Ministerial Responsibilities, as amended on 12 April 2001, the energy sector was transferred from the Ministry of Economy to the Ministry of the Environment and Spatial Planning.

## **Spain**

### ***Radiation Protection***

#### *Royal Decree approving the Regulations on Health Protection against Ionising Radiation (2001)*

A Royal Decree No. 783/2001 approving Regulations on Health Protection against Ionising Radiation was adopted on 6 July 2001. This text, which repeals Decree No. 53/1992 of 24 January 1992 on the same subject (see *Nuclear Law Bulletin* No. 49), aims to implement 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* No. 58). To this effect, it establishes standards governing radiation protection, covering in particular the principles of justification, optimisation and dose limitation.

## **Ukraine**

### ***Organisation and Structure***

#### *Decree establishing Chernobyl Nuclear Power Plant (2001)*

Following the adoption of the Presidential Decree of 25 September 2000 concerning the planned shut-down of the Chernobyl nuclear power plant, the Cabinet of Ministers adopted Decree No. 399 establishing a state-owned specialised company called Chernobyl Nuclear Power Plant on 25 April 2001.

While the plant was previously a division of the National Nuclear Energy Generating Company (*Energoatom*), Chernobyl Nuclear Power Plant, which will inherit property and responsibilities from *Energoatom*, is now to be under the direct supervision of the Ukrainian President and will report to the Minister of Fuel and Energy, who appoints its Director.

The Chernobyl Nuclear Power Plant's main tasks will be the following:

- ensuring the safe decommissioning of the Chernobyl site's three nuclear units and other nuclear units;
- transforming the sarcophagus at the destroyed fourth unit into an ecologically safe system;
- managing the radioactive waste and spent fuel generated by the Chernobyl nuclear power plant; and
- participating in international decommissioning projects.

## United States\*

### *Radiation Protection*

#### *Public Health and Environmental Radiation Protection Standards for Yucca Mountain (2001)*

The 1992 Energy Policy Act (EPACT; see *Nuclear Law Bulletin* No. 51) directed the Environmental Protection Agency (EPA) to develop site-specific radiation standards for a repository at Yucca Mountain, Nevada,<sup>1</sup> based on recommendations of the National Academy of Sciences.<sup>2</sup> The Nuclear Regulatory Commission (NRC) would then modify its criteria consistent with those of the EPA.<sup>3</sup> On 13 June 2001 the EPA published “Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada” which address all potential sources of exposure (air, ground-water and soil) and limit an individual’s annual radiation exposure from all pathways (ingestion, inhalation and physical contact) to 15 millirem (mrem) for a 10 000 year compliance period.<sup>4</sup> The new standards include separate ground-water protection criteria whereby radionuclide releases at Yucca Mountain may not cause radioactivity to exceed “4 mrem per year to the whole body or any organ based on drinking two liters of water per day from the representative volume” over the 10 000 year period.

#### *Standards for storage (Subpart A Parts 197.1-197.5)*

While the Department of Energy currently conceives of the Yucca Mountain repository as a facility for permanent disposal, the EPA decided to develop storage and disposal standards on the grounds that the situation could change. Radioactive material stored inside the repository is subject to the new standards while EPA generic standards at Subpart A of 40 C.F.R. Part 191 would apply to material that the Department might handle and store above ground at the Yucca Mountain site.<sup>5</sup> Under

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\* This note was kindly submitted by Ms. Sophia Angelini, Attorney Adviser, Office of Civilian Nuclear Programs, Department of Energy.

1. The Nuclear Waste Policy Act established the Federal Government’s responsibility to dispose of spent nuclear fuel and high-level radioactive waste and provided for a geologic repository which would be operational by 1998. Yucca Mountain is the Department of Energy’s potential geologic repository designed to store and dispose of spent nuclear fuel and high-level radioactive waste.
2. The EPA proposed “Environmental Radiation Protection Standards for Yucca Mountain, Nevada”, 64 Fed. Reg. 46976 (1999) (to be codified at 40 C.F.R. Part 197).
3. The NRC proposed “Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada”, 64 Fed. Reg. 8640 (1999) (to be codified at 10 C.F.R. Part 63).
4. 66 Fed. Reg. 32074 (2001) (40 C.F.R. Part 197). Detailed analysis and documents relevant to this rulemaking are available at [www.epa.gov/radiation/yucca](http://www.epa.gov/radiation/yucca).
5. Subpart A of 40 C.F.R. Part 191 requires that the Department manage and store spent nuclear fuel, high-level radioactive waste and transuranic radioactive wastes at a site, such as Yucca Mountain, in a manner that provides “reasonable assurance” that the annual dose equivalent to any member of the public in the general environment will not exceed 25 mrem/year to the whole body.

Part 197, combined doses incurred by any individual in the general environment at Yucca Mountain from waste storage inside and outside the repository must not exceed 15 mrem “committed effective dose equivalent” (CEDE) per year (Part 197.4).<sup>6</sup>

*Standards for disposal (Subpart B Parts 197.12-197.36)*

Individual-protection standard (197.20 and 197.25) specifies the maximum dose that a “reasonably maximally exposed individual” (RMEI)<sup>7</sup> may receive from releases from the Yucca Mountain disposal system. The EPA established a dose limit of 15 mrem CEDE per year individual-protection standard, corresponding approximately to about 8,5 fatal cancers per million members of the population per year.<sup>8</sup>

Ground-water protection standards (Part 197.30) specify that the Department must demonstrate a reasonable expectation that for 10 000 years after disposal, releases of radionuclides from the disposal system will not cause radioactivity in the representative volume of water to exceed 4 mrem per year to the whole body or any organ based on drinking two litres of water per day from the representative volume.

Human-intrusion standard (Part 197.25) specifies that the Department must determine when the waste package would degrade sufficiently such that human intrusion could occur without recognition by the drillers. The Department must demonstrate a reasonable expectation that the RMEI would receive no more than an “annual committed effective dose” of 15 mrem as a result of human intrusion.<sup>9</sup>

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6. “CEDE” is defined at Part 197.2 as “the effective dose equivalent received over a period of time (e.g. 30 years), as determined by the NRC, by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides”. 40 C.F.R. part 197.2 contains other definitions applicable to Subpart A.

7. The EPA describes its model of an RMEI as a theoretical individual representative of a future population group or community termed “rural residential”. This speculative RMEI would, *inter alia*, live in the vicinity of Yucca Mountain and Amargosa Valley, do personal gardening and drink two liters per day of water contaminated with radionuclides.

8. The EPA rejected the risk-based standard recommended by the National Academy of Science.

9. “Annual committed effective dose equivalent” defined as the effective dose equivalent received by an individual in one year from radiation sources external to the individual plus the committed dose equivalent. “Committed effective dose equivalent” is defined as the effective dose equivalent received over a period of time (e.g., 30 years) as determined by the NRC, by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides.