NATIONAL LEGISLATIVE AND REGULATORY ACTIVITIES

Armenia

Radiation protection

Law Amending and Supplementing the 1999 Law for the Safe Utilisation of Atomic Energy for Peaceful Purposes (2004)

This law, which was adopted on 9 November 2004 and entered into force on 15 December 2004, amends and supplements the 1999 Law for the Safe Utilisation of Atomic Energy for Peaceful Purposes (see *Nuclear Law Bulletin* Nos. 60 and 63; the text of the law is reproduced in the *Supplement* to NLB No. 65).

Chapter 1 of the law, entitled "General Provisions" has been amended in its entirety. The Preamble has been repealed and Article 1 now sets out the objectives of the law, stated to be the regulation of atomic energy use for peaceful purposes, the safety of nuclear facilities and ionising radiation sources, radiation protection, radioactive waste management, physical protection, liability and compensation for nuclear damage, and other aspects of atomic energy use relating to the protection of workers, the public and the environment and in connection with national safety interests.

Revised Article 2 attaches particular importance to compliance with requirements of international treaties ratified by Armenia, and to the safety standards of the IAEA. Revised Article 3 on basic terms contains a much broader list of definitions.

Chapter 2 of the 1999 Law on the jurisdiction of state and local authorities in the field of atomic energy utilisation remains unchanged by this Amending Act. Only one minor change is made to Chapter 3 [Article 11] adding a provision whereby posts of importance in terms of nuclear safety must be occupied by Armenian citizens.

Chapter 4 (state regulation on safety in the field of atomic energy utilisation) has been entirely amended. An exhaustive list of fields covered by state regulation is now provided in Article 15, including site selection, designing, construction, commissioning, operation and decommissioning of atomic energy utilisation objects; practices involving nuclear or radioactive materials or equipment; import and export of nuclear and radioactive materials or equipment; accounting and control of nuclear and radioactive materials or equipment; radioactive waste management; physical protection; and personnel training.

New Articles 17(1) and 17(2) also contain some new provisions. In particular, 17(1-3) specifies that representatives of state authorities as well as international organisations and foreign experts may be involved in regulatory supervision practices. Article 17(2) provides that state inspectors of the

regulatory authority shall have a technical support organisation empowered to, in particular, conduct safety expertise in the utilisation of atomic energy, which shall be financed from the state budget.

The licensing provisions under Chapter 5 have been revised and now establish time frames within which the regulatory authority shall review licence applications, and grant or refuse a licence.

A new provision [Article 19(1)] has been added to Chapter 6 of the 1999 Law on the operation of atomic energy utilisation objects. It imposes requirements on the operators of installations concerning financial provision that must be made in respect of nuclear, radiation and technical safety, fire protection, physical protection, accounting and control, implementation of improvements to safety, scientific and technical support, storage of spent nuclear fuel, and decommissioning.

A few very minor changes are made to Chapters 7, 8 and 9 of the law and Chapters 10, 11 and 12 remain entirely untouched.

Regulations on nuclear trade

Government Decree on Licensing Procedures for Import/Export of Radioactive Materials (2004)

Decree No. 1760-N, adopted on 9 December 2004, governs licensing procedures in respect of export and import of ionising radiation generators, radioactive materials and equipment containing radioactive materials. It aims to prevent illicit trafficking and to protect the public against the harmful impact of ionising radiation.

Brazil

Organisation and structure

Order Setting up a Permanent Committee on Nuclear Emergency Response (2005)

Order No. 68, establishing a Permanent Committee for Nuclear Emergency Response in the Resende municipality – COPREN/RES, was adopted on 18 February 2005 by the Ministry of Sciences and Technology and published in the Official Gazette on 23 February 2005.

The Committee is designed to assist the Commission for Co-ordination of Protection of the Brazilian Nuclear Programme (COPRON) in relation to emergency response at the *Industrias Nucleares do Brasil* nuclear fuel factory, (FCN/INB) within the framework of the Protection System for the Brazilian Nuclear Programme (SIPRON) (see *Nuclear Law Bulletin* Nos. 27, 50, 53 and 60).

The Committee is responsible in particular for:

- examining proposals to amend standards and directives governing SIPRON activities in relation to the FCN/INB;
- drafting studies and reports relating to COPRON responsibilities in respect of SIPRON activities in relation to the FCN/INB;
- drafting proposals to update legislation governing SIPRON activities in relation to the FCN/INB;

- planning and submitting to the COPRON an annual Programme for SIPRON activities in relation to the FCN/INB;
- planning and co-ordinating activities relating to physical protection at the FCN/INB;
- planning, co-ordinating and assessing emergency response exercises at the FCN/INB, carried out under SIPRON's annual programme of work; proposing and adopting measures and procedures required for the improvement of existing standards;
- drafting and co-ordinating a quality control programme in respect of nuclear emergency response at the FCN/INB;
- following up and assessing the planning and implementation of public information programmes with regard to emergency situations at the FCN/INB;
- proposing staff training programmes regarding implementation of physical protection measures and emergency response at the FCN/INB.

Radiation protection

Resolution of the CNEN on Radiation Protection (2004)

Resolution No. 27 [NN 3.01] of the National Nuclear Energy Commission (CNEN) establishing basic radiation protection standards was published in the Official Gazette and entered into force on 26 January 2005. This resolution repeals and replaces Resolution CNEN 12/88 [NE 3.01] on the same subject (see *Nuclear Law Bulletin* Nos. 43 and 58).

This resolution lays down basic standards to protect people against the dangers resulting from ionising radiation. It also establishes practical measures and specifies requirements in relation to intervention procedures.

The practical measures apply to:

- the handling, production, supply and use of sources, as well as the transport, storage and disposal of radioactive materials, including all activities involving exposure to ionising radiation;
- exposure to natural sources of radiation, control over which is deemed necessary by the CNEN.

The provisions of this resolution also apply to exposure for medical purposes and to public exposure.

Situations where intervention is necessary include:

- those resulting from emergency situations where protective measures are necessary in order to reduce or avoid exposure to radiation;
- cases resulting from continued exposure which require repair or restorative measures;
- cases resulting from exposure to residues from activities which are not subject to CNEN regulatory control.

Resolution of the CNEN Regarding Security and Radiation Protection Measures in Industrial Mining Installations (2005)

Resolution No. 28 of the National Nuclear Energy Commission (CNEN) regarding security and radiation protection measures in industrial mining installations [NN 4.01] was published in the Official Gazette on 6 January 2005 and entered into force on the same day.

It is designed to establish security and radiation protection measures applicable to industrial mining installations which handle, process and store mineral ores, raw materials, residues and waste containing natural uranium and thorium radio-nucleides. Such installations may pose risk during their operation or even following closure, through exposure of workers and the public to ionising radiation.

France

Radiation protection

Order on Training, Missions and Activities of Persons Specialised in Medical Radiation Physics (2004)

This order, adopted on 19 November 2004 and published in the Official Gazette of 28 November 2004, governs the manner in which the person specialised in medical radiation physics, mentioned in Article R.1333-60 of the Code of Public Health, will be professionally trained and will perform his/her tasks.

This specialist's role in the preparation and completion of medical acts using ionising radiation has been reinforced. As is already the case for medical nuclear radiation therapies, his/her presence is now mandatory for all acts of radiology.

Decree on the Use by the IRSN of the National Identification Index of Natural Persons (2004)

Decree No. 2004-1489 of 30 December 2004, published in the Official Journal of 31 December 2004, authorises the Institute for Radiation Protection and Nuclear Safety (*Institut de radioprotection et de sûreté nucléaire* – IRSN) to use the ID numbers from the National Identification Index of Natural Persons in a system processing personal data relating to the health monitoring of workers exposed to ionising radiation. The IRSN centralises, operates, and maintains this information, and manages individual medical record cards.

This data processing system, entitled "Information System for the Monitoring of Exposure to Ionising Radiation" (*Système d'information de la surveillance de l'exposition aux rayonnements ionisants* – SISERI), concerns all persons who are or have been professionally exposed to ionising radiation and for whom dosimetric records have been taken.

This decree repeals Decree No 96-1108 of 17 December 1996 which authorised the Office for Protection against Ionising Radiation (since merged into the IRSN) to use the National Identification Repertory for identical purposes.

Order on Individual Medical Record Cards and Individual Dosimetric Information of Workers Exposed to Ionising Radiation (2004)

This order, adopted on 30 December 2004 and published in the Official Gazette of 31 December 2004, implements Article R.231-105 of the Labour Code concerning the individual medical record card to be provided by the company doctor to each worker exposed to ionising radiation. It also explains how the workers' dosimetric results should be notified and monitored, and how the radiation protection authorities and the workers themselves can exercise their right to information.

Order on the Army Radiation Protection Service (2005)

This order, adopted on 10 January 2005 and published in the Official Gazette of 2 February 2005, repeals the Order of 9 July 1980 on Radiation Protection in Units, Services and Establishments under the Ministry of Defence (see *Nuclear Law Bulletin* Nos. 26 and 40).

It sets out the functions of the Army Radiation Protection Service (*Service de protection radiologique des armées* – SPRA) and describes the manner in which it participates in the implementation of preventive measures against ionising radiation within Ministry of Defence bodies.

Interministerial Order on the Action of the Public Authorities in the Event of an Incident Resulting in a Radiological Emergency Situation (2005)

This Order of 7 April 2005 was published in the Official Gazette on 10 April 2005. It applies to all nuclear activities and installations, including those related to defence.

The Preamble refers to the necessity of ensuring satisfactory co-ordination between public authorities and efficient information of the authorities and the public in the event of a nuclear emergency. Such co-ordination and information are considered to facilitate the application of various measures to be taken and also to avoid unjustified public concern.

The order contains provisions relating to the permanent information of the public through three main communication channels. Institutional communication is carried out through the Local Information Boards (*Commissions locales d'information* – CLI) and the Information Boards (*Commissions d'information* – CI) and relates to the impact on health and environment of nuclear activities conducted in major nuclear installations and major nuclear installations classified as secret. The public is also informed during consultations organised before the establishment of the Off-site Emergency Response Plans (*Plans particuliers d'intervention* – PPI). Finally, the General Directorate for Nuclear Safety and Radiation Protection (*Direction générale de la sûreté nucléaire et de la radioprotection* – DGSNR), the delegate for nuclear safety and radiation protection for defence-related activities and installations (*Délégué à la sûreté nucléaire et à la radioprotection pour les activités et installations intéressant la défense* – DSND) and the Institute for Radiation Protection and Nuclear Safety (*Institut de radioprotection et de sûreté nucléaire* – IRSN) contribute to the general information of the public on issues relating to nuclear safety and radiation protection.

Regarding emergency management itself, the order distinguishes between three types of notification. The initial notification relating to the event may be made by any physical person or legal entity having knowledge of such event, for example the operator, the police authorities, the emergency services, the IRSN (through its radioactivity monitoring system) or the national weather service (especially in relation to international events). There is to be an immediate notification of the state

representative (the prefect), followed by relay notification to all bodies involved in emergency management in France plus certain other competent authorities. International notification is carried out pursuant to the requirements of the 1986 Convention on Early Notification of a Nuclear Accident and Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency.

Once the notification has been made, the emergency is managed at two levels. At the local and departmental level, two categories of persons are concerned. The operator of a nuclear installation is required to have drawn up and implemented an On-site Emergency Response Plan (*Plan d'urgence interne* – PUI), which contains further provisions concerning his responsibilities in the case of an incident. Moreover, the prefect, upon receiving a notification, immediately informs the Ministry of the Interior, and, if need be, takes over the lead of the emergency operations and orders measures of protection.

At central level, the prime minister, assisted by the secretary-general of national defence, is responsible for ministerial coordination and announces which ministry shall take the lead in operational management of government action, depending on the nature of the accident.

The order sets out further provisions on the responsibilities of the various bodies involved in emergency management, including the Ministry of the Interior, the DGSNR, the DSND, the IRSN, Météo-France and the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA). It also contains provisions relating to the training of persons involved in emergency management. Exercises shall be designed and organised to test response to radiological emergency situations thereby ensuring effective implementation of this interministerial order.

Italy

Organisation and structure

Decree on the Nuclear Installation Management Company SOGIN (2004)

A decree laying down a strategic and operative policy for the Nuclear Installation Management Company (*Società per la Gestione degli Impianti Nucleari* – SOGIN) was adopted on 2 December 2004 by the Minister for Productive Activities and published in the Official Journal of 15 January 2005. SOGIN is a body responsible for the management of activities related to the shut-down of nuclear power plants (see *Nuclear Law Bulletin* Nos. 66, 73 and 74). This decree stems from Article 13, paragraph 4 of Parliamentary Decree No. 79 of 16 March 1999, which implements Directive 96/92/EC of the European parliament and of the Council of 19 December 1996 concerning common rules for the internal market in electricity. The new policy provisions acknowledge the urgent need to remove spent fuel from temporary repositories, as well as to ensure consistency between SOGIN's activities and the general objectives of the government in the field of radioactive waste and spent fuel management.

In connection with the above, SOGIN is required:

- to ensure treatment and conditioning, within ten years, of all radioactive waste stored at the sites under its management, thus allowing for its transfer to the national repository;
- to put into full operation its commitments under reprocessing contracts with British Nuclear Fuel Ltd;

- to evaluate the possibility of temporary export, for treatment and reprocessing purposes, of spent fuel currently stored at nuclear power stations and storage sites;
- to carry out comparative analysis of short and long-term costs in relation to safety and environmental protection needs, leading to actions necessary for the safe storage of spent fuel;
- to participate in the decommissioning of the main nuclear installations, to take place within twenty years for fuel cycle installations and in the short term for other types of installation.

SOGIN is to submit a yearly status report to the Ministry for Productive Activities. It also co-operates with that Ministry and the Ministry for the Environment on identification of the national repository, promotion of information to the public in the vicinity of nuclear installations, plans to recover the productive potential of sites, rules and procedures relating to nuclear waste and spent fuel management as well as decommissioning, and rehabilitation of former nuclear sites.

Finally, pursuant to Act No. 239/04 Restructuring the Energy Sector (see *Nuclear Law Bulletin* No. 74), SOGIN is also required to be active on foreign markets on behalf of third parties, providing consultancy and services in general relating to the above-mentioned areas.

Radioactive waste management

Ordinance on Radioactive Waste Management (2005)

This ordinance was adopted on 4 March 2005 to extend the validity of the decree adopted on 7 March 2003 which was already extended once on 7 May 2004 (see *Nuclear Law Bulletin* Nos. 73 and 74). This ordinance governs the safe storage of radioactive material at nuclear power stations and at certain nuclear sites. The validity of the decree is hereby extended until 31 December 2005.

Japan

Organisation and structure

Japan Atomic Energy Agency Law (2004)

This law establishes the title, mission, and tasks of the Japan Atomic Energy Agency, created through the merger of the two major national nuclear R&D organisations, Japan Atomic Energy Research Institute (JAERI) and Japan Nuclear Cycle Development Institute (JNC). It was promulgated on 26 November 2004 and published on 3 December 2004.

This newly-created organisation, whose provisional title in English is the Japan Atomic Energy Agency – JAEA – will be operated as an independent administrative institution, i.e. a public organisation with a certain level of autonomous decision-making authority. Such institutions are used for the efficient implementation of projects which cannot be carried out by the private sector although they need not be carried out by the government itself. The JAEA is therefore subject to the general law establishing the principles applicable to all independent administrative institutions as well as to the Japan Atomic Energy Agency Law.

Like all other independent administrative institutions, the "medium-term objective" of the JAEA shall be adopted by the minister in charge of each individual independent administrative institution, in the case of the JAEA, the Minister of Education, Culture, Sports, Science and Technology and the Minister of Economy, Trade and Industry (hereinafter referred to as "Ministers"). This medium-term objective should identify the targets to be achieved by the JAEA within a three to five-year timeframe. In accordance with this objective, the JAEA shall establish its "medium-term plan" and submit it to the Ministers for approval along with its annual programme of work. The JAEA is subject to strict evaluation by a committee set up within the Ministry of Education, Culture, Sports, Science and Technology for this purpose.

The JAEA, whose headquarters are located in Ibaraki Prefecture, shall be responsible for the following activities:

- basic research on nuclear energy;
- activities necessary to ensure the technical feasibility of nuclear fuel cycle activities (development of the fast breeder reactor and related research, development of nuclear fuel materials for the fast breeder reactor and related research, development of technology for reprocessing of nuclear fuel materials and related research and development of technology for the treatment and the disposal of high-level radioactive waste);
- dissemination of information acquired from the above activities and the promotion of its utilisation;
- encouraging the use of its facilities and equipment by those involved in the development and utilisation of nuclear energy and, more broadly, those who undertake research and development on science and technology;
- contribution to human development in the nuclear field and to improving expertise amongst nuclear scientists and engineers;
- collection, categorisation and dissemination of information concerning nuclear energy.

The president of the JAEA will be appointed by the Minister in consultation with the Atomic Energy Commission. The tenure of the president will end with the completion of the period corresponding with each medium-term objective. One vice-president and up to seven executive directors may be appointed to support the president in the completion of his/her tasks.

The JAEA is scheduled to come into existence on 1 October 2005. On that date, all the rights and obligations of both JNC and JAERI will be taken over by the JAEA, except for a portion of JAERI's activities which will be taken over by RIKEN (a research institute in the field of science and technology) and other activities of JAERI which are not deemed necessary for the fulfilment of the objectives of the JAEA, and which are therefore transferred to the government.

Morocco

Third party liability

Act on Civil Liability for Nuclear Damage (2005)

The Act on Civil Liability for Nuclear Damage was promulgated on 7 January 2005. This act aims to ensure indemnification of damage which may be caused by certain peaceful uses of nuclear

energy pursuant to the provisions of the Vienna Convention on Civil Liability for Nuclear Damage. The text of this act is reproduced in the chapter "Texts" of this *Bulletin*.

The act is divided into six chapters. The first chapter, entitled General Provisions, sets out the objective of this act and takes up a number of the definitions contained in Article 1 of the Vienna Convention.

Chapters II and III deal respectively with the nature of liability and the exceptions to it, in similar terms to the Vienna Convention. The operator of a nuclear installation shall be solely liable for nuclear damage caused by a nuclear incident in his nuclear installation or involving nuclear material coming from or originating in his nuclear installation and occurring in certain circumstances. Specific provisions relating to the determination of liability apply where the damage occurs in the course of transport, where several operators are liable, or where nuclear damage and non-nuclear damage result from the same nuclear accident.

Pursuant to Chapter III, no liability shall attach to an operator for nuclear damage caused by a nuclear incident directly due to an act of armed conflict, hostilities, civil war or insurrection. Neither shall the operator be liable for nuclear damage to the nuclear installation itself, any other nuclear installation on the same site or to on-site property.

Chapter IV contains provisions on security for liability. The operator of a nuclear installation shall be required to have and maintain insurance or other financial security of 100 million Special Drawing Rights (SDRs). A lower amount may, under certain circumstances, be established, provided that it is not less than SDR 5 million.

Chapter V covers recourse and actions for compensation. The operator of a nuclear installation shall only have a right of recourse where this is expressly provided for by a contract in writing or where the incident results from an act or omission carried out with intent to cause damage. Priority is awarded to the compensation of loss of life and personal injury, which is subject to a 30-year limitation period. All other types of nuclear damage are subject to a 10-year limitation period.

Chapter VI sets out the applicable penalties that apply where the provisions of this act are breached.

Norway

Radiation protection

Regulations on Radiation Protection and Use of Radiation (2003)

These regulations of 21 November 2003 entered into force on 1 January 2004. They implement the Act of 12 May 2000 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).

The regulations reflect international standards in radiation protection as established in EU directives, IAEA safety standards, and recommendations from the ICRP and the ICNRP. They apply to the production, import, export, transfer, possession, installation, use, handling and disposal of radiation sources. Radioactive sources are basically regulated in two ways. Practices involving "strong" sources have to be licensed by the Norwegian Radiation Protection Authority while practices

involving weaker sources are subject to a notification requirement only, These various requirements are described in Chapter 2 of the regulations.

Chapter 3 sets out technical requirements governing ionising radiation sources, including shielding criteria, technical safety standards, requirements applicable to laboratories, as well as requirements regarding storage and labelling. Chapter 4 regulates occupational exposure to ionising radiation, establishing dose limits for workers, pregnant women and apprentices, and regulating classification and marking of the workplace. Chapter 5 contains special provisions on radioactive discharges into the environment, and on effluent and waste generated from practices using radioactive materials and sources. It requires that the "best available technology" be used to protect the environment.

Chapter 6 governs non-ionising radiation, providing that all exposure shall be kept as low as reasonably achievable. Chapter 7 deals with medical use of radiation for both diagnostic and therapeutic purposes. Patient protection is the central concern with an individual approach concerning both justification and optimisation. Requirements are set out in relation to the qualifications of all involved personnel. Further provisions concern dose measures and documentation, whether for diagnostic or therapeutic purposes, and quality assurance of equipment. Chapters 8 and 9 contain administrative provisions.

Poland

Radiation protection

Regulation on National Emergency Preparedness Plans (2005)

This regulation, adopted by the Council of Ministers on 18 January 2004, implements the requirements of Article 87 of the 2000 Atomic Energy Act (see *Nuclear Law Bulletin* Nos. 67 and 69; the text of the act is reproduced in the *Supplement* to NLB No. 68). It establishes a national emergency preparedness plan including procedures for co-operation of various authorities and services participating in the elimination of radiological emergencies and of their consequences. It also describes the principal components of regional emergency preparedness plans, indicating the elements essential for prompt response by the appropriate services.

Portugal

Organisation and structure

Decree-Law on the General Directorate for Geology and Energy (2004)

The General Directorate for Geology and Energy is a department of the Ministry of Economy and is responsible for the conception, promotion, and evaluation of policies related to energy and geological sources. Since the adoption of Decree-Law 165/2002 on 17 July 2002, it has been responsible for the licensing of nuclear fuel cycle facilities and for authorisations concerning the shipment of nuclear fuel between Portugal and other states (EU member states and others), and domestic transit. This new Decree-Law 15/2004, adopted on 14 January 2004, further clarifies the responsibilities of this Directorate.

Transport of radioactive materials

Decree-Law on the Transport of Dangerous Goods by Road (2003)

Decree-Law 267-A/2003, adopted on 27 October 2003, implements Commission Directive 2001/7/EC of 29 January 2001 and Commission Directive 2003/28/EC of 7 April 2003, both of which adapt to technical progress Council Directive 94/55/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road. It regroups in one single legal document all matters related to the transport of dangerous goods by road and repeals the 2000 Decree-Law on the Transport of Dangerous Goods by Road (see *Nuclear Law Bulletin* No. 70).

The decree-law defines "dangerous goods" and sets out conditions governing their transport by road. It identifies the legal entities which are responsible for the execution of the National Regulation for the Transport of Dangerous Goods by Road (published in annex) and the International European Agreement for the Transport of Dangerous Goods by Road. It also establishes an inspection regime and provides for penalties to be applied in the event of violations.

Romania

General legislation

Amendment to the Law on the Safe Conduct of Nuclear Activities (2004)

Law No. 549, published in Official Gazette Part I No. 1164 on 8 December 2004, amends Article 41 of the 1996 Law on the Safe Conduct of Nuclear Activities (see *Nuclear Law Bulletin* Nos. 59, 61 and 68; the text of the law is reproduced in the *Supplemen*t to NLB No. 59) in order to comply with European requirements regarding import licences and to eliminate the dual licensing requirements (by the National Commission for the Control of Nuclear Activities – CNCAN – and the Ministry of Economy and Trade) for import and export. Licences for the import and export of dual-use products and technologies are no longer granted automatically and shall be approved by the National Agency of Exports Control provided an import/export permit issued by the CNCAN is provided.

Radiation protection

Order Providing Specific Measures to Protect Individuals' Health Against Ionising Radiations during Medical Exposure (2004)

Order No. 1334, issued on 19 October 2004 by the Minister of Health and published in Official Gazette Part I No. 1014 on 3 November 2004, provides for specific actions designed to protect individuals' health against ionising radiation during medical exposure.

It provides that managers of units where diagnostic and interventional radiology, nuclear medicine and radiotherapy are carried out should draft their own specific regulations relating to the protection of individuals' health against ionising radiation during medical exposure, including the following elements:

- clearly determined responsibilities divided between physicians and practitioners;
- justification for the medical exposure of persons deliberately and voluntarily assisting in the course of other persons' medical exposure;

- written protocols and standardised techniques for each radiological practice, including criteria for patients selection, such as the patients' individual characteristics, the possibilities and limits of radiological procedures, and the existence of procedures which do not imply radiation exposure;
- documentation to be provided to justify the exposure of pregnant women and breast-feeding women, in the case of nuclear medicine;
- guarantees that patients undergoing radionuclide treatment shall receive written instructions relating to the dose limits of ionising radiation that can be received by a third party, such a family member.

Norms on Requirements to be Fulfilled by Licensed Operating Staff, Management Staff and Specific Training Staff in Nuclear Installations (2005)

Order No. 368, published in Official Gazette Part I No. 118 on 7 February 2005, implements Article 9, paragraph (3) of the Law on the Safe Conduct of Nuclear Activities and establishes Norms on requirements to be fulfilled by operating staff, management staff and specific training staff in nuclear power plants, research reactors and other types of nuclear installations in order to be granted a working permit.

Norms on Radiological Safety for Nuclear Medicine Practice (2005)

Order No. 358, published in Official Gazette Part I No. 139 on 15 February 2005, establishes norms on radiological safety for nuclear medicine practice. Such practices include the use of ionising radiation sources for therapeutic or diagnostic purposes, both in vitro and in vivo.

Regime of radioactive materials

Norms on Licensing Procedures for Nuclear Activities involving Dual-use Materials, Devices, Equipment and Data (2005)

Order No. 419, published in Official Gazette Part I No. 110 on 3 February 2005, implements the 1996 Law on the Safe Conduct of Nuclear Activities by laying down norms concerning the licensing procedures governing nuclear activities involving materials, devices, equipment and data that may be used for nuclear proliferation purposes.

Third party liability

Amendment to the 2001 Law on Civil Liability for Nuclear Damage (2004)

Law No. 470 adopted on 4 November 2004 and published in Official Gazette Part I. No. 1040 on 10 November 2004 modifies and completes the provisions of the 2001 Law on Civil Liability for Nuclear Damage (see *Nuclear Law Bulletin* No. 69, the text of this law is published in the *Supplement* to NLB 69).

The purpose of this amendment is to specify that the state shall be liable for nuclear damage which is the direct and immediate result of an act of terrorism in the nuclear field. Therefore

compensation for nuclear damage resulting from acts of terrorism shall be financed from public funds. This law repeals a July 2003 governmental Decision (Norm) that specifically included "any act of nuclear terrorism" as part of the operator's exoneration from liability for "hostilities".

Russian Federation

Third party liability

Law on the Ratification of the Vienna Convention on Civil Liability for Nuclear Damage (2005)

The State Duma (lower house of the Russian parliament) adopted on 2 March 2005 the Law on the Ratification of the 1963 Vienna Convention on Civil Liability for Nuclear Damage. This text was then approved by the Federation Council (upper house) on 11 March 2005 and signed by the president on 21 March 2005. By adopting this law the Russian Federation ratifies the 1963 Vienna Convention which it signed on 8 May 1996. The convention shall enter into force for the Russian Federation three months after the deposit of the instrument of ratification as provided by Article 24 of the convention.

Serbia and Montenegro

Regime of radioactive materials

Criminal Code of Montenegro (2003)

The 2003 Criminal Code of Montenegro was published in Official Gazette No. 70/2003. It contains certain provisions governing the use of nuclear substances. The code provides, under Articles 313 to 315, that anyone who unlawfully imports, transit or exports and transports radioactive materials and waste shall be liable to imprisonment for up to three years. The unlawful construction of nuclear facilities is also punished by imprisonment of six months to five years.

Under the chapter entitled "Criminal acts against general safety of people and property", Article 327 provides that anyone who unlawfully acquires, possesses, uses, transports or transmits nuclear materials shall be liable to imprisonment for up to three years. Articles 365 and 447 specify that penalties are increased if the use or threat to use nuclear substances is made with the intent to endanger life or to cause harm to a foreign state or organisation.

Slovenia

Organisation and structure

Amendment to the Act on State Administration (2004)

In *Nuclear Law Bulletin* No. 68, it was reported that responsibility for the energy sector had been transferred from the Ministry of Economy to the Ministry of the Environment and Spatial Planning. Pursuant to the Amendment to the Act on State Administration, adopted on 10 November 2004, the energy sector has been re-transferred back to the Ministry of Economy. Since the Nuclear Safety Administration however remains under the Ministry of the Environment and Spatial Planning, any possible conflict of interest between promotion and safety is avoided and the independence of the regulatory body competent for nuclear safety is maintained.

Radiation protection

Amendment to the Act on Protection Against Ionising Radiation and Nuclear Safety (2004)

An act amending the 2002 Act on Protection against Ionising Radiation and Nuclear Safety (see *Nuclear Law Bulletin* Nos. 70 and 71) was adopted on 30 April 2004 and published in Official Gazette RS 46/2004. The objective of this amendment is to harmonise requirements concerning the supervision and control of shipments of radioactive waste with European Union legislation.

Decree on Radiation Practices (2004)

This decree was adopted on 29 April 2004 and published on 30 April 2004 (Official Gazette RS 48/2004). It transposes certain requirements 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 which had not already been implemented in the 2002 Act on Protection against Ionising Radiation and Nuclear Safety.

Decree on Dose Limits, Radioactive Contamination and Intervention Levels (2004)

This decree was adopted on 29 April 2004 and published on 30 April 2004 (Official Gazette RS 49/2004). It determines the dose limits for exposed workers, apprentices, students, pregnant and breast-feeding women and members of the public. It also sets out the methods for measuring dose limits and the methods to be used for calculation and the use of dose constraints in radiation practice optimisation and planning. It further regulates the exposure of volunteers in medical examinations and treatment as well as in medical and bio-medical research. This decree also establishes limits governing the radioactive contamination of the air, surface or subterranean waters, the human body, surfaces in work premises, foodstuffs and other goods. Intervention levels and dose limits for emergency workers exposed during the implementation of intervention measures are also set out.

Regulation on the Use of Potassium Iodide Tablets (2004)

This regulation was adopted on 15 December 2004 and published on 30 December 2004 (Official Gazette RS 142/2004). It lays down the criteria for the distribution and preventive use of potassium iodide tablets in the event of a nuclear accident affecting national territory.

Radioactive waste management

Regulation on Shipments of Radioactive Waste into and out of the EU (2004)

This regulation was adopted on 24 May 2004 and published on 3 June 2004 (Official Gazette RS 60/2004). It transposes requirements of Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community as well as Commission Decision 93/552/Euratom establishing the standard document for the supervision and control of such shipments.

Switzerland

General legislation

Ordinance on Nuclear Energy (2004)

The new Ordinance on Nuclear Energy (*Ordonnance sur l'énergie nucléaire* – OENu), adopted on 10 December 2004, entered into force on 1 February 2005, at the same time as the new Federal Act on Nuclear Energy adopted on 21 March 2003 (see *Nuclear Law Bulletin* Nos. 71 and 72; the text of the act is reproduced in the *Supplement* to NLB No. 72) which it implements.

The OENu comprises seven chapters. The first chapter contains general provisions and lays down the definition of key terms used in the Law of 21 March 2003, some of which were not included in the Ordinance of 18 January 1984 on Definitions and Licences in the Atomic Energy Field, repealed by the OENu. This is for instance the case for "nuclear materials" which replaces the category of "nuclear fuel".

Chapter 2 reiterates the principles relating to nuclear security and safety as set out in the Law of 21 March 2003 and specifies requirements designed to ensure their implementation. In particular, it requires that the protection of nuclear installations and materials against acts of sabotage, acts of violence or theft be ensured through a defence system comprising measures of an architectural, technical, organisational, personal and administrative nature [Article 9].

Chapter 3 deals with nuclear articles and provides that the Federal Energy Office is the competent authority for granting licences to handle nuclear materials and lays down the procedure to follow in order to obtain a licence to transport, export, import or trade in technology or nuclear materials. In particular, at the request of an applicant, the Office may consider in advance whether it could grant a licence, and under which conditions, although this procedure does not lead to delivery of a licence [Article 16]. Licences are granted for 12 months, with a possibility of extension for a further six months. Licence holders are required to inform the Principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN) of certain events and records in particular concerning the safe and secure transport of nuclear materials.

Chapter 4 is devoted to nuclear installations and comprises four sections, relating to the various licences to be obtained by the operator of a nuclear installation and the various operating stages of the installation. In addition to the general licence [Section 1], it is necessary to obtain a construction licence and an operating licence: Sections 2 and 3 respectively list the documentation to be provided by the applicant for this purpose. In particular, a quality control programme which describes the organisation and schedule of the project is required; as is an implementation licence, for certain structures or elements of the installation or specific operating stages that are subject to the granting of such a licence pursuant to the construction or operating licence.

Section 4 of Chapter 4 governs the operations stage and lays down the obligations of the holder of an operating licence. He/she shall in particular establish systematic maintenance programmes for security or safety-related equipment. Every ten years, the licence holder shall conduct a thorough re-assessment of the security of nuclear power plants and shall update its decommissioning or closure plans. Licence holders required to stay abreast of scientific developments in the field and determine to what extent they could benefit the security of the installation. He/she shall submit to monitoring authorities periodic reports assessing the operating conditions of the installation and shall notify the DSN, before carrying them out, of specific activities, including the scheduled shut-down of a reactor, as well as certain events relating to safety. Section 5 contains provisions on the decommissioning

phase including documentary requirements. This section also specifies the content of the decommissioning decision, which describes in particular the importance of the decommissioning work and sets out an obligation to obtain an implementing licence for specific activities such as the conditioning of radioactive waste.

Chapter 5 comprises five sections on radioactive waste. Section 1, entitled "General provisions" lays down the principle of minimising waste, the various categories of waste and the content of the management programme to be defined by the persons in charge of waste disposal. Section 2 contains provisions relating to the release of materials and the conditioning of radioactive waste, which shall be carried out as quickly as possible. Section 3 contains rules regulating the handling of radioactive waste. It provides that the Office is the competent authority for granting the required licences and specifies the documents to be submitted with the licence application. The rules of Chapter 3 relating to the preliminary investigation, the validity of licences, record-keeping, and mandatory notifications are applicable to radioactive waste. Section 4 deals with geological studies. It specifies the documents to be provided to apply for a licence to carry out geological studies, including an investigation schedule, a geological report containing in particular a geological description of the region and an overview of geological studies which have already been undertaken in the region.

Section 5 contains specific provisions regarding deep geological disposal. It specifies documents to be provided to apply for a general licence to operate a deep geological repository in addition to the documents to be attached to an application for a general licence required for nuclear installations [Chapter 4]. It also provides that specific measures shall be taken to ensure the safety and monitoring of the repository and lays down in particular the modalities and purpose of experimental zones and test repositories which are used to study the behaviour of the stored waste, filling material and rock in which the repository will be operated, up to the end of the observation phase. Section 5 sets out obligations to be fulfilled by the owner of a deep geological repository, who shall be required to describe the measures planned to monitor the repository after disposal of the waste, and shall establish a file for long-term record-keeping on the repository.

Chapter 6 is entitled "Procedures, information and incentives". It contains provisions relating to the time limit within which supervisory authorities shall consider licence applications or approve a project, ranging from one month, from the date on which the completed application is received to its transmission to cantons and the competent federal services, or to the publication or the opening of the public investigation; to six months, from the end of the investigation procedure to the date on which the decision is made. It also provides details on the public information obligation of the DSN as regards specific events and records relating to nuclear security.

Chapter 7 contains penal provisions and final provisions. It provides that a sanction shall be imposed on anyone who, intentionally or by negligence, does not comply with the obligation to retain documents on the basis of which licences to handle nuclear articles, or to construct and operate nuclear installations, were granted.

Ukraine

Regime of nuclear installations

Law on Questions Relating to Maintenance of Nuclear Safety (2004)

The Law on Questions Relating to Maintenance of Nuclear Safety was signed by the president of Ukraine on 24 June 2004. The law defines legal and organisational principles governing financial

provisions for the maintenance of nuclear safety during the shutdown and decommissioning of nuclear installations. It provides for the establishment of a financial reserve (special fund) for financing actions for the shutdown and decommissioning of nuclear installations. This special account shall be opened by the nuclear operator in a bank authorised by the Cabinet of Ministers of Ukraine.

Third party liability

Establishment of a Nuclear Insurance Pool (2003)

The Nuclear Insurance Pool of Ukraine was established on 19 March 2003. The members of the pool are the 21 insurance companies of Ukraine. The contract covering civil liability insurance for Energoatom was signed on 27 April 2004. The general insurance sum covers SDR 150 million. The Energoatom reinsurance contract was signed on 25 May 2004 with the Russian nuclear insurance pool which has accepted liability at a rate of SDR 40 million.

United Kingdom

Organisation and structure

Radioactive waste management

Energy Act (2004)

The 2004 Energy Act received Royal Assent on 22 July 2004. It comprises four parts with 23 schedules. Only the first part is dedicated to the civil nuclear industry.

Part 1 contains provisions designed to:

- establish the Nuclear Decommissioning Authority ("the NDA"), a new public body with the primary role of ensuring the decommissioning and cleaning-up of Britain's civil public sector nuclear sites;
- create a new Civil Nuclear Police Authority to oversee a reconstituted nuclear constabulary;
- amend the Radioactive Substances Act 1993 (see *Nuclear Law Bulletin* No. 54) so as to allow the Environment Agency and equivalent authorities in Scotland and Northern Ireland to use a streamlined and simplified process in dealing with applications for the transfer of radioactive discharge authorisations when there is a change of operator at a nuclear site;
- extend the regulation of the security of uranium enrichment technologies and sensitive nuclear information;
- provide statutory authority for the Secretary of State to spend money to acquire British Energy Plc power stations and/or its stake in Nirex Limited. Nirex Limited is a company owned by the major nuclear industry waste producers and tasked with investigating feasibility of a deep intermediate and low level waste disposal facility.

The NDA's principal function (under Section 3) is to be responsible for securing:

- the operating of designated nuclear installations pending commencement of their decommissioning;
- the decommissioning of those and other designated nuclear installations;
- the cleaning-up of designated nuclear sites;
- the operation of designated facilities for treating, storing, transporting or disposing of hazardous material (which includes nuclear matter and radioactive waste);
- the treatment, storage, transportation and disposal, in designated circumstances, of hazardous material; and
- the decommissioning of designated installations comprised in facilities which are being or have been used in connection with the storage, disposal or treatment of hazardous material and which are facilities for which the NDA has, or has had, operational responsibility.

Sites and facilities are designated for these purposes by means of directions given by the Secretary of State to the NDA. Such directions also give the NDA responsibility for treating, storing and disposing of nuclear matter in particular circumstances. A number of designations have been made and came into force on 1 April 2005.

The act defines "cleaning-up" (which relates to sites) and "decommissioning" (which relates to nuclear installations) to include the treatment, storage, transportation and disposal of hazardous material and of other matter that needs to be dealt with in order to make the site or installation suitable for use for other purposes, as well as the construction of buildings and other structures to be used in connection with such activities. "Hazardous material" is nuclear matter, radioactive waste and any other article which has been and remains contaminated, radioactively or chemically, as a result of nuclear activities.

Sections 11 and 12 place a duty on the NDA to prepare a strategy for carrying out its functions and to keep that strategy under review. Whenever the NDA is given a new responsibility for securing the decommissioning or cleaning-up of an installation or site, it is required to review the relevance of its strategy for that purpose and, if need be, revise its strategy accordingly.

Section 13 requires the NDA to prepare a plan for each financial year showing how it intends to carry out its functions during that year. The NDA is also required under Section 14 to produce an annual report on the discharge of its responsibilities and on the carrying out of its other functions during each financial year.

Section 15 sets out what the NDA has to do in order to discharge a responsibility it is given for securing the decommissioning of an installation or the cleaning-up of a site. The NDA has a specific duty to take all such steps as it considers appropriate for securing the implementation of its strategy and annual work plan in relation to that installation or site.

Only where a site is a "contaminated site" rather than a "principal nuclear site" is the NDA's duty subject to directions given by ministers. The NDA is not subject to such directions in respect of the cleaning-up of a "principal nuclear site" or the decommissioning of an installation on such a site. The act defines "principal nuclear site" to include sites where a nuclear site licence is in force (granted under the Nuclear Installations Act 1965, see *Nuclear Law Bulletin* Nos. 3, 4, 15, 31, 32, 33 and 46. The text of the act as amended in 1983 is reproduced in the *Supplement* to NLB No. 33). A site is a

“contaminated site” if it is not a “principal nuclear site” but has become contaminated as a result of nuclear activities.

The position is different where the NDA has responsibility for securing the operation of an installation or for the treatment, storage, transportation or disposal of hazardous material, or for the management of any land not comprised in a site designated to be cleaned-up. In these circumstances, Section 16 places a duty on the NDA to carry out these tasks in accordance with such general and specific directions as may be given to it by ministers (as well as in accordance with its strategy and annual plan). Some of the directions made by the Secretary of State which came into force on 1 April 2005 include specific directions under this section of the act.

Section 7 gives the NDA other functions. The NDA must consider whether and to what extent it is appropriate to carry out these functions. The functions include the carrying out and promotion of research into matters relating to the NDA’s other functions.

Also under Section 7 the Secretary of State has the power to require the NDA to act on her behalf in relation to agreements to which she is a party. Ministers can also require the NDA to give advice about any of the things in which the NDA requires an expertise for carrying out its functions, and the NDA can provide general advice on its own initiative to ministers in respect of such things.

Section 9 imposes general duties on the NDA when carrying out its functions. The NDA has four overriding duties, which are:

- to have particular regard both to relevant government policy and to the regulatory framework in respect of the environment, health and safety and nuclear security;
- to promote the development of a competitive market for clean-up and other contracts;
- to ensure the availability of a skilled workforce capable of sustaining its work programmes over the long-term; and
- to secure the adoption of good practice across its sites.

Subject always to these four overriding duties, section 9 provides that the NDA also has a duty to secure value for money in its dealings with others.

Section 9 also provides that, in carrying out its functions with respect to the operation and management of designated sites, the NDA has a duty to act in the manner that it considers is most beneficial to the public.

Section 10 gives the NDA the general and specific powers it needs in order to carry out its functions. There is a broad power for the NDA to do all such things as appear to it to be likely to facilitate the carrying out of its functions or to be incidental to carrying them out. Section 10 identifies some particular powers. They include powers to make grants or loans for the benefit of socio-economic development or other activities that produce environmental benefits or for research into decommissioning and cleaning-up; and a power to enter into contracts for others to secure the things that the NDA has a function of securing (in other words, a power to subcontract). However, the NDA cannot do anything which is not required for the purpose of, or in connection with, the carrying out of its functions under the act.

Section 17 ensures that designated installations, sites and facilities are used for the purposes of the NDA. It does so by obliging any “person with control” of a designated installation, site or facility to secure that it (or any related right or interest) is not used or disposed of except for purposes which

facilitate the discharge of the NDA's responsibilities. "Person with control" is defined in Section 36(3) and includes the holder of a nuclear site licence. Except where the NDA otherwise directs, or where the NDA is charging for the work it is doing, the person with control must pay to the NDA any sums and other benefits received as a consequence of operating the site, installation or facility or the disposal of any interest or right in relation to the site, installation or facility. The main purpose of this is to ensure that where the NDA is funding the operation of an installation it also receives the income generated. The NDA is required in turn to pay the money received to the Secretary of State.

Section 18 places a duty on the person with control of a designated principal nuclear site, a nuclear installation, a facility situated in or on a principal nuclear site, or an installation comprised in an NDA facility, to prepare such plans for the discharge of the NDA's responsibilities in relation to that site, installation or facility as the NDA may direct, to submit those plans to the NDA for approval and to comply with any further directions the NDA may give in accordance with Section 18(3). The directions may only be given by the NDA for the purpose of giving effect to its strategy and annual work plans.

Section 21 gives the NDA financial responsibility for the decommissioning, operation or cleaning-up of installations and sites or related sites which, at the time the relevant designation is made under Section 3, are controlled by one of a number of specified persons. The specified persons include British Nuclear Fuels plc (BNFL).

Where Section 21 applies but the person in control of the site, installation or facility is not the NDA itself, it is provided that the NDA must ensure that the other person is not liable (and cannot become liable) to meet the costs of the discharge of the NDA's responsibilities in relation to that site, installation or facility. Therefore the NDA cannot impose charges on the person with control in such situations, and must meet the costs of that person incurred in discharging its obligations under Sections 17 and 18. Further, the NDA must make such arrangements as it sees fit for securing that the person with control is able to meet its liabilities in respect of NDA responsibilities as they fall due. However, Section 21(9) provides that the provisions of Section 21 have effect subject to the terms of any agreement between the person with control (or its parent company) and the NDA. So it is possible to apportion financial responsibility as between the NDA and the site licensee in respect of clean-up, decommissioning or operational obligations. This will not, however, limit the NDA's overall obligations to clean-up and decommission under the act.

Section 22 sets out how the NDA is to be put in funds and the arrangements for handling any income it generates. Section 22(2) enables the Secretary of State to fit the payment of grants to the requirements of the NDA so that the NDA has the funds it needs as and when required. Section 22(3) provides that the NDA must pay to the Secretary of State all sums received by it other than grants made to it by the Secretary of State.

Section 23 sets out the framework for the NDA to borrow money from the Secretary of State. This is principally to enable the NDA to support the carrying on of normal business practices which optimise the contractual arrangements which are necessary to support the decommissioning, cleaning-up and operational activity of the persons with control of designated sites, installations and facilities which it funds. The NDA is permitted to borrow from other sources, but this is subject to the approval of the Secretary of State and HM Treasury. The NDA's borrowing limit is GBP 2 000 million (which can be altered by order of the Secretary of State). The Secretary of State may guarantee the borrowing of the NDA on such terms as she thinks fit.

Section 26 provides that the NDA must keep proper accounts and accounting records and prepare a statement of accounts in respect of each accounting year.