

NATIONAL LEGISLATIVE AND REGULATORY ACTIVITIES

China (People's Republic of)

Radiation Protection

Law on Protection from Radiation Contamination (2003)

The Law on Protection from Radiation Contamination was adopted on 28 June 2003, and came into force on 1 October 2003. This Law is composed of eight chapters and 63 articles. Generally, it covers: supervision and administration organisations; prevention and control of radiation contamination at nuclear installations, uranium ore extraction sites and any place where radiation applications are used; management of nuclear waste and legal liability. A translation of this Law in English will be made available shortly, upon which time a more detailed description of the Law will appear in the *Nuclear Law Bulletin*.

France

Organisation and structure

Decree on the Creation of the Interministerial Committee on Nuclear and Radiological Crisis (2003)

This Decree No. 2003-865, adopted on 8 September 2003, modifies the general rules governing the organisation and implementation of nuclear security. The Interministerial Committee on Nuclear and Radiological Crisis (ICNRC) replaces the Interministerial Committee on Nuclear Security (ICNS) created by Decree No. 75-713 of 4 August 1975 (see *Nuclear Law Bulletin* No. 16) which is repealed by the present Decree.

In accordance with Article 1 of the Decree, the mission of the ICNRC is to suggest measures to the Prime Minister “in case of an accident in a major nuclear installation, a nuclear installation classified as secret, during the transport of nuclear or radiological material which concerns the civil or defence sector and above all a military nuclear system, as well as in case of attack or threat of attack having or capable of having nuclear or radiological consequences.” The ICNRC may assemble on the initiative of the Prime Minister, on the basis of the need to manage a nuclear or radiological crisis affecting the civil or defence sectors or even as a defensive measure in the case of a threatened attack. The ICNRC assembles the Prime Minister and the Ministers of Foreign Affairs, Defence, Environment, Industry, Health and Transportation. The Secretary General of National Defence

governs an operating Secretariat. In addition, other agencies and interested organisations as well as the nuclear operators concerned may be invited to meetings of the ICNRC. However, the Prime Minister may move to limit participation in ICNRC meetings.

Working together with the ministries and agencies concerned, the Secretary General of National Defence has as its mission (Article 2) to co-ordinate, organise and follow-up on the coherence of every plan of action which aims to prevent the situations provided for in Article 1 of the Decree, and of the means of action implemented in case of a nuclear or radiological crisis. The Secretary General of National Defence is, in addition, informed without delay in the event of an accident, attack or threat of a nuclear or radiological nature. It is his responsibility to prepare a follow-up report of the incident for the President of the Republic and the Prime Minister.

Finally, the Decree specifies that the respective ministries, organisations, consultative bodies and interested nuclear operators furnish assistance, as far as needed, to the Secretary General of National Defence in the carrying out of its above mentioned responsibilities.

Nuclear Material Regime (including Physical Protection)

Order Regarding the Protection of National Defence Secrecy in the Field of Nuclear Material Control and Protection (2003)

This Order, adopted on 24 July 2003 by the Ministry of Economy, Finance and Industry, provides that all information pertaining to surveillance measures, physical protection and monitoring of nuclear materials is classified as a national security secret. Likewise, all information pertaining to the transportation of nuclear materials and the preparation of crisis exercises related to the protection of nuclear materials within official places or installations is classified as a national security secret. Accordingly, such information must be protected by measures that assure restricted distribution.

Hungary

Organisation and Structure

Decree on the Scope of Duties, Authority and Competence to Impose Penalties of the Hungarian Atomic Energy Authority, and on the Activities of the Atomic Energy Co-ordination Council (2003)

This Government Decree No. 114/2003 was adopted on 29 July 2003 and entered into force on 1 August 2003. It implements the provisions of the 1996 Atomic Energy Act (see *Nuclear Law Bulletin* No. 60; the text of this Law is reproduced in the Supplement to *NLB* No. 60), defining the statutes of the Hungarian Atomic Energy Authority (HAEA), and the Atomic Energy Co-ordination Council, and provides HAEA with regulatory independence.

The main function of the HAEA is to co-ordinate and fulfil regulatory duties with respect to the safety of the peaceful use of atomic energy. The HAEA is entitled to conduct inspections at the installation of any user of atomic energy and is responsible for the management of the Central Nuclear Financial Fund. The HAEA is also empowered to fine any licensee for violation of legal regulations or safety rules, or for any failure to comply with the provisions laid down in the licence. The Director

General of the HAEA shall prepare an annual report on the safe use of atomic energy to the Government and to Parliament in co-operation with the relevant ministries, and also other competent central state organisations.

An Emergency Response Organisation shall also be set up and operated by the HAEA. This Organisation shall be designed to carry out the duties relating to emergency preparedness and response to nuclear accidents. The HAEA is assisted by the Scientific Council, composed of 12 experts with nation-wide reputation in the field of atomic energy. The Scientific Council shall convey its opinion in connection with nuclear safety, radiation protection, emergency response and preparedness related to nuclear accidents.

Finally, the Atomic Energy Co-ordination Council, established by the Government, intends to co-ordinate the activities of ministries and central administration organisations vested with regulatory powers under the 1996 Atomic Energy Act in the field of safe use of atomic energy, nuclear safety and radiation protection. This Council is chaired by the Director General of the HAEA.

Radioactive Waste Management

Order on some Aspects of the Interim Storage and Final Disposal of Radioactive Waste and on the Radiological Aspects of Radioactive Materials Arising from Industrial Activities and Naturally Occurring Radioactive Materials (2003)

This Order No. 47/2003 was adopted on 8 August 2003 by the Ministry of Health, Social and Family Affairs. It sets out the procedure and conditions to obtain a license to establish an interim storage facility or final depository of radioactive waste. It also regulates the conditions of processing radioactive materials arising from industrial activities and naturally occurring radioactive materials.

Italy

Organisation and structure

Legislative Decree on the Organisational Statute of the ENEA (2003)

Legislative Decree No. 257/03, adopted the 3 September 2003, and published in the Official Journal No. 213 on 13 September 2003, repeals and replaces the previous organisational statute (Decree No. 36/99) of the National Committee for Research and Development of Nuclear and Alternative Energies (ENEA). Unlike the previous organisational statute, Decree 257/03 specifically addresses nuclear energy.

Article 2 of the Decree stipulates that the ENEA is a public body, which acts to support policies of competitiveness and sustainable development in the areas of energy, the environment and new technologies.

In order to pursue the above mentioned objectives, Article 3 states that ENEA is to promote and carry out basic and applied research activities, including the production of prototypes, the industrialisation of items in the area of nuclear technologies and the applications of technologies

pertaining to ionising radiation. ENEA is in particular responsible for the scientific and technological know-how in the matter of nuclear energy. More generally, ENEA is also in charge of the various activities necessary for the accomplishment of the tasks conferred to it.

Latvia

Radiation Protection

Regulations on the Requirements for Emergency Preparedness and Response (2003)

The Cabinet of Ministers approved Regulations on the Requirements for Emergency Preparedness and Response and the National Emergency Preparedness Plan on 8 April 2003. These documents describe both the on-site and off-site emergency plans and response actions, including the large-scale actions to be taken in the event of an accident in the neighbouring countries. The governmental bodies co-ordinating response actions in the case of a radiological emergency are the State Fire and Rescue Service and the Radiation Safety Centre. The Radiation Safety Centre is responsible for the supervision of operative actions at the accident site, while the State Fire and Rescue Service is responsible for larger scale accident activities.

Regime of Radioactive Materials (including Physical Protection)

Regulations on Physical Protection of Ionising Radiation Sources (2002)

These Regulations, issued on 4 November 2002, establish several groups according to their importance for physical protection and introduce the basic approach for simultaneously applicable protection methods: detection, assessment, delay and response. These Regulations are based upon the IAEA Recommendations for physical protection of nuclear facilities and nuclear materials.

Portugal

Organisation and Structure

Decree-Law approving the Organic Law of Ministry for Towns, Territorial Planning and Environment (2003)

This Decree-Law No. 97/03, adopted on 7 May 2003, defines, *inter alia*, the competence of the Environment Institute, a public entity created under the Ministry for Towns, Territorial Planning and Environment responsible for continuing environment and sustainable development policies. The Environment Institute also co-ordinates the activities related to environment and public security. In this respect, it is responsible for early notification in the event of a nuclear accident and is responsible for the assessment of the risks of radiation emissions. The Environment Institute is chaired by a president and two vice-presidents. Decree-Law 113/2003 details the internal structure of the Environment Institute.

Romania

General Legislation

The Romanian Constitution vests the government with the authority to enact ordinances, on select matters, which produce the same effect as statutes and are enforced as such until the Parliament votes for or against them. If the Parliament passes the ordinance it becomes a statute. Pursuant to this procedure, the Romanian Parliament has recently passed laws that approve government ordinances regarding the use of nuclear energy for peaceful purposes and the safe management of nuclear waste and spent fuel.

Law for the approval of the Government Ordinance on the Use of Nuclear Energy Exclusively for Peaceful Purposes (2003)

The Law No. 321/2003 was published in the Official Gazette (*Monitorul Oficial*, Part I, No. 509) on 15 July 2003, for the purpose of approving and simultaneously amending Government Ordinance No. 7 on the use of nuclear energy exclusively for peaceful purposes (see *Nuclear Law Bulletin* No. 71).

Law No. 321/2003 amends the scope of Ordinance No. 7 by stating that the promotion and organisation of activities in the nuclear field is to be achieved through promoting research, development and use of nuclear applications for peaceful purposes and to secure nuclear energy resources.

The Law also modifies Article 5 of the Ordinance by requiring that the siting, construction, transfer of property and decommissioning of power and research reactors, as well as final storage facilities shall be approved by Government Decision issued by the Romanian government.

The most important amendment of Government Ordinance No. 7 is the creation of a Romanian Nuclear Agency – called the Nuclear Agency – by the reorganisation of the National Agency for Atomic Energy within the Ministry of Education, Research and Youth for the purpose of harmonising the strategies in the nuclear field and the monitoring of the National Nuclear Plan's implementation.

The Nuclear Agency is a specialised body of the central administration; a legal person in its own right, subordinated to the Prime Minister. Its main purpose is to provide technical counsel to the government in making nuclear policy, as well as the promotion and monitoring of nuclear activities in Romania. The Nuclear Agency shall be administered by a Board of Directors whose members should be representatives of the ministries having responsibilities in the nuclear field. The Nuclear Agency's Chairman shall be appointed and dismissed by decision of the Prime Minister.

The Nuclear Agency co-ordinates the promotion of nuclear activities in Romania, based on the Nuclear Development Strategy, Operational Plan and National Nuclear Plan. The Nuclear Agency also promotes international partnership by co-operating with the International Atomic Energy Agency (IAEA) and other international or regional organisations operating in this field, as well as by concluding research and development, technical assistance, evaluation, training agreements and contracts, after consulting the ministries managing specific activities or having responsibilities in the nuclear field.

Amendment to the Law on the Safe Conduct of Nuclear Activities (2003)

Law No. 111/1996 was initially published on 29 October 1996 (the text of this Law is reproduced in the Supplement to the *Nuclear Law Bulletin* No. 59). Several amendments have been made to the Law, the latest being Law No. 193 of 13 May 2003, published in the Official Gazette (*Monitural Oficial*, Part I, No. 343) on 20 May 2003. The object of the Law, in general, is the safe conduct of nuclear activities for exclusively peaceful purposes so that they meet safety conditions set for the protection of professionally exposed personnel, the general population, the environment and property. Further, the Law aims to minimise the risks associated with nuclear activities through a regime of regulatory requirements and international conventions. The Law on Safe Conduct of Nuclear Activities will soon be republished in the Official Gazette of Romania with a new numerical assignation to the text.

The National Commission for the Control of Nuclear Activities (CNCAN) is the national authority competent to exercise the regulatory powers provided for under Law No. 111/1996. The new amendments serve to enhance the CNCAN's administrative capacity by providing for:

- the recognition of CNCAN personnel who develop activities in radiological areas as exposed workers [in accordance with the provisions of Council Directive 96/29 Euratom of 13 May 1996 laying down the 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)];
- the establishment of technical support organisations for CNCAN including a forthcoming National Institute for Nuclear Safety;
- the authority of CNCAN inspectors to order that activities posing unauthorised risk to nuclear installations cease, and the power to close nuclear installations not complying with legal requirements;
- the complete financing of the CNCAN budget by tariffs and fees received for the authorisation and control of nuclear activities.

Other noteworthy amendments found in Law No. 193/2003 include:

- allowance for the transit of radioactive waste in Romania, transposing the provisions of Directive 92/3/Euratom of 3 February 1992 on control of Radioactive Waste Shipments (see *Nuclear Law Bulletin* No. 69) into national legislation by Order No. 183/2003;
- a definition of nuclear related terrorist acts and specific sentences for each act;
- and criminal sanctions for unauthorised decommission of nuclear installations and radioactive sources, and the unauthorised cessation of nuclear activities.

Radioactive Waste Management

Law for the approval of the Government Ordinance on the Management of Spent Nuclear Fuel and Radioactive Waste, Final Storage Included (2003)

Law No. 320/2003 was published in the Official Gazette (*Monitural Oficial*, Part I, No. 527) on 22 July 2003, and has the effect of simultaneously approving and modifying Government Ordinance No. 11 of 30 January 2003 (see *Nuclear Law Bulletin* No. 71). The Law came into force 22 August 2003, and is to be re-published in the Official Gazette of Romania with a new number assignation to the texts.

The modified object of Ordinance No. 11/2003 is to regulate activities relating to the management of spent nuclear fuel and radioactive material so as to secure safe conditions for professional personnel at risk, the general population, the environment and property, at present and in the future, without jeopardising the needs and expectations of future generations.

Nuclear operators are required to manage the spent nuclear fuel and radioactive waste that they generate in compliance with national regulations and the international agreements to which Romania is a Party. To this end, licensees must annually report the quantities and types of spent nuclear fuel and radioactive waste generated over the current year and an estimate for the following year. Operators are required to provide funds for the purpose of final storage of spent nuclear fuel and radioactive waste that results from the operation, maintenance and repair of nuclear and radiological installations.

Finally, the Law prohibits the import of spent nuclear fuel and radioactive waste for the purpose of final storage, and specifies sanctions for violation of this provision.

Third Party Liability

Norms for the Enforcement of the Law on Civil Liability for Nuclear Damage (2003)

The Methodological Norms for the enforcement of Law No. 703/2001 on Civil Liability for Nuclear Damage (the text of this Law is reproduced in the Supplement to *Nuclear Law Bulletin* No. 69) were published in the Official Gazette (*Monitural Oficial*, Part I, No. 580) on 14 August 2003 and came into force on 14 September 2003. The Norms provide that nuclear operators must present the insurance policy or the financial security set out in Law No. 703/2001 to the CNCAN by 14 March 2003. Also the Insurance Supervision Commission is to issue specific prudential Norms with respect to the underwriting of risks for nuclear accidents which are to be published in the Official Gazette by 14 November 2003.

The Methodological Norms require that insurance policies or financial securities acquired under the provisions of Law No. 703/2001 must provide cover against civil liability for nuclear damage. In case of nuclear installations and radioactive materials that do not present a risk of criticality, an insurance policy or financial security is not mandatory. Risk of criticality is defined as the risk of an uncontrolled chain-process of nuclear fission. A nuclear installation is deemed to present a risk of criticality when the quantity of fissionable material held, deposited, handled, used or transported can sustain a chain-process of nuclear fission. According to the provisions of Law No. 111/1996 on the Safe Deployment of Nuclear Activities, the licensee should make the request for such an exemption during the licensing procedure and it shall be explicitly set-out in the license issued by the CNCAN.

The sum insured under the insurance policy or guaranteed through the financial security shall also be explicitly set-out in the license issued by the CNCAN.

The insurance policy or the financial security provided for in Law No. 703/2001 must be acquired from an insurer/financial institution registered with the national authority competent in the nuclear field. The insurer may conclude insurance policies with a nuclear operator only subsequent to its authorisation and in accordance with the relevant prudential norms regarding underwriting risks relating to civil liability for nuclear damage. The financial security may also be created as a deposit placed with the State Treasury. The CNCAN shall be notified as to the creation of such security set out in the previous paragraph within 48 hours of its creation. The said security may be modified or liquidated only with CNCAN approval. In such cases the operator may withdraw the amounts deposited in excess of the minimum amount required.

The nuclear operator shall immediately notify the CNCAN and the insurer as to any nuclear occurrence susceptible to cause nuclear damage. Within ten days of such an occurrence, the nuclear operator shall transmit to the CNCAN and to the insurer a preliminary report assessing any potential damage. The nuclear operator shall keep good record of any claim for damages made against it and register the identity of the claimant, the nature, type and size of the damages claimed. The nuclear operator shall notify the CNCAN as to the method of compensation and the amount of damages awarded by the insurer.

Subsequent to a nuclear occurrence the CNCAN is to set-up a special commission whose tasks are to: determine the causes and consequences of the nuclear occurrence; examine and assess nuclear damage; issue recommendations as to the compensation, assistance and reconstruction measures; and issue recommendations as to the improvements to the nuclear installation with respect to nuclear and radiation emission safety. The conclusions and recommendations presented in the report are to be disclosed to the media.

The competent court may take into consideration the above mentioned examination reports and recommendations made by the Commission with respect to compensation to make a correct allotment, consistent with the type of damage and number of victims. The Court may order ten percent of the total coverage against nuclear damage to be set-aside for potential nuclear damage until the statutory limit tolls.

Slovak Republic

Regime of Nuclear Installations

Decree on Nuclear Safety Requirements for Nuclear Installations (2003)

This Decree No. 167/2003 was adopted on 5 March 2003 by the Nuclear Regulatory Authority of the Slovak Republic and entered into force on 1 June 2003. It lays down the requirements for nuclear safety of nuclear installations during siting, design, commissioning, operation and decommissioning. The Decree details, *inter alia*, the properties of the land for the siting of a nuclear installation; depth protection, nuclear safety functions and characteristics; radiation protection; research in the field of nuclear safety, equipment faults, fire prevention; safety systems and control systems; containment system, nuclear material management; basic requirements for the start-up and principles of operation of a nuclear installation.

Decree on Nuclear Safety Assessment (2003)

This Decree No. 121/2003 was adopted by the Nuclear Regulatory Authority of the Slovak Republic on 5 March 2003 and entered into force on 1 June 2003. It regulates the intervals and performance scope of complex and systematic assessments of nuclear safety during the operation of a nuclear installation.

Slovenia

Organisation and Structure

Regulation on the Organisation and Assignment of Ministerial Responsibilities (2003)

This Regulation was adopted by the Government on 12 June 2003 and entered into force on 27 June 2003. It contains, *inter alia*, a description of the responsibilities of the Radiation Safety Administration, established on 27 February 2003 as a regulatory body within the Ministry of Health, and of the Slovene Nuclear Safety Administration. The Radiation Safety Administration performs specialised technical and development administrative tasks and inspection supervision related to practices involving radiation or the use of radiation sources in medical and veterinary applications; the protection against ionising radiation; systematic monitoring of living and working conditions in relation to exposure from natural radiation sources; monitoring of radioactive contamination of foodstuffs and drinking water; restriction, diminution and prevention of damage to health resulting from non-ionising radiation; and control of the qualifications and competence of radiation protection experts.

Switzerland

General Legislation

Law on Nuclear Energy (LENu) (2003)

This Law was adopted on 21 March 2003 (see *Nuclear Law Bulletin* No. 71. The Law is foreseen to take effect on 1 January 2005, at the same time as its implementing Ordinance (OENu), which is to be approved by the Federal Swiss Council near the end of the year 2004. The text of the Law is reproduced in the Supplement to this edition of the *Bulletin*.

Ukraine

Third Party Liability

Decree on Compulsory Insurance of Civil Liability for Nuclear Damage (2003)

This Decree No. 953 was adopted by the Cabinet of Ministers on 23 June 2003, following the entry into force of the 2001 Law on Civil Liability for Nuclear Damage and its Financial Security (see *Nuclear Law Bulletin* No. 69; the text of this Law is reproduced in the Supplement to *NLB* No. 69). It approves the procedures and rules for the compulsory insurance of civil liability for nuclear damage, specific licensing terms for activities requiring civil liability insurance for nuclear damage, a statute on a national nuclear insurance pool, a standard form of agreement for mandatory civil liability insurance for nuclear damage and a procedure for calculating premiums for such insurance.

Uruguay

Radiation Protection

Regulations on Radiation Protection (2002)

The following regulations were approved by Resolution of the Ministry of Industry, Energy and Mining (*Ministerio de Industria, Energia y Minería*) on 28 June 2002.

Regulation UY 101 establishes minimum-security requirements for the operation of industrial gammagraphy equipment.

Regulation UY 102 establishes minimum radiological security requirements applicable to the authorisation of non-dispersible solid radioactive sources with therapeutics, interstitial brachytherapy applications and superficial intracavitaries. This Regulation applies to all activities related to the use of non-dispersible solid radioactive sources in brachytherapy.

Regulation UY 103 establishes minimum radiological security requirements in the operation of electron linear accelerators for medical use. This Regulation applies to all installations that have electron linear accelerators for medical purposes, with an energy rank between 4 and 40 MeV.

Regulation UY 104 establishes the radiological security requirements applicable to the operation of telecobalt therapy equipment used for the treatment of human beings.

Regulation UY 105 establishes minimum radiological safety requirements for the use of non-sealed radioactive sources in nuclear medicine. This Regulation is applicable to the operation of any installation or the realisation of nuclear medicine training that uses non-sealed radioactive sources for therapeutic purposes.

Regulation UY 108 guarantees effective inspections over the use of medical or odontological radio-diagnostics in order to avoid any unnecessary exposures of workers and the public. In addition it aims to limit the possibility of accidents and exposure to patients where a minimum is necessary to

achieve the objective of the diagnostic required, taking into account the International Basic Standards for Protection against Ionising Radiation and for Safety of Radiation Sources (Safety Series No. 115). Annex to Regulation UY 108 guarantees an effective control of X-ray equipment used in the baggage and cargo inspection to avoid unnecessary exposure of workers and public, as well as to limit the possibility of accidents.

Radioactive Waste Management

Regulation on Radioactive Waste Management (2002)

Regulation UY 106, approved by Resolution of the Ministry of Industry, Energy and Mining on 20 June 2002, establishes general requirements pertaining to radioactive waste management for the purpose of maintaining an adequate level of radiological protection of people and the environment for present and future generations. This regulation is applicable to waste management installations and training under the control of the Regulatory Authority.

Transport of Radioactive Materials

Regulation on the Transport of Radioactive Materials (2002)

Regulation UY 107, approved by Resolution of the Ministry of Industry, Energy and Mining on 28 June 2002, establishes minimum safety requirements for the protection of people, goods and the environment from harmful effects of ionising radiation during the transport of radioactive materials.