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# **NUCLEAR LEGISLATION: ANALYTICAL STUDY**

## **Regulatory and Institutional Framework for Nuclear Activities**

**2001 Update**

## ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed:

- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

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The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

Australia's basic legislation in the nuclear field consists of five Acts passed by the Federal Parliament. These Acts are as follows:

- the South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986];
- the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987];
- the Australian Nuclear Science and Technology Organisation Act [No. 3 of 1987];
- the Australian Nuclear Science and Technology Organisation Amendment Act 1992 [No. 83 of 1992]; and
- the Radiation Protection and Nuclear Safety Act [No. 133 of 1998].

The first two Acts were prompted by the need for domestic legislation to implement Australia's international obligations. The third arose from a long-standing recognition that the Atomic Energy Act 1953 was inappropriate as the legislative basis for the activities of Australia's national nuclear organisation. For its part, the 1992 Act introduced some necessary changes into the Australian Nuclear Science and Technology Organisation Act. Finally, the 1998 Act establishes a regime to regulate the operation of nuclear installations and the management of radiation sources, where these activities are undertaken by Commonwealth entities.

Each of these Acts will be discussed in more detail below but, briefly, their scope is as follows.

The South Pacific Nuclear Free Zone Treaty Act of 1986 implements Australia's obligations under the Treaty. The manufacture, possession and testing of nuclear weapons in Australia are prohibited, as is research and development relating to the production of nuclear weapons.

The Nuclear Non-Proliferation (Safeguards) Act of 1987 provides a legislative basis for Australia's safeguards system, implementing its obligations under the Nuclear Non-Proliferation Treaty, Australia's bilateral safeguards agreement with the International Atomic Energy Agency and the Convention on the Physical Protection of Nuclear Material. This Act regulates the possession, transport and communication of nuclear material, and associated material, facilities, equipment and technology.

The Australian Nuclear Science and Technology Organisation Act of 1992 transformed the Australian Atomic Energy Commission into the Australian Nuclear Science and Technology

Organisation (ANSTO). The change represented a move away from work on power generation and the nuclear fuel cycle, the basis of the Australian Atomic Energy Commission's charter, to focus instead on the development and utilisation of nuclear and associated technologies, concentrating in particular on radiation and radioisotope applications in medicine, industry, science and agriculture. ANSTO operates one nuclear research reactor to further its research in these areas.

The Australian Radiation Protection and Nuclear Safety Act of 1998 provided for the appointment of the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), who is entrusted to perform functions and exercise powers under the Act. The Nuclear Safety Bureau, which had been responsible for monitoring and reviewing the safety of ANSTO's nuclear plant under the ANSTO Act, was abolished. The CEO regulates, through a licensing system, nuclear installations from the time at which plans are drawn up for their construction through all stages of operation until decommissioning, as well as the use of radiation sources. The Act applies to the uses of radiation by Commonwealth entities. Other uses are controlled by the legislation of the relevant state or territory. The Act also established the Radiation Health and Safety Advisory Council and two supporting Committees. The Council's tasks include advising the CEO on matters relating to nuclear safety and radiation protection.

In addition, the Atomic Energy Act [No. 31 of 1953] is still partly relevant. Although substantial parts of it were repealed in 1987 when ANSTO replaced the Australian Atomic Energy Commission, a few provisions remain which are significant in the context of the regulatory regime governing uranium mining in the Northern Territory.

Another relevant federal Act, discussed below, is the Environment Protection (Sea Dumping) Act 1981 [Act No. 101 of 1981].

Because Australia is a federal state, with a division of power between the national (Commonwealth) government and the six state governments, the Commonwealth Government does not have the capacity to legislate on all aspects relevant to nuclear activities. For this reason, it will be necessary to discuss state laws in some areas, for example, radiation protection and transport. In addition to the states, Australia has two internal Territories (the Northern Territory and the Australian Capital Territory) whose constitutional position is different from that of the states. Essentially, the Territories have fewer legislative powers than the states and are subject to Commonwealth intervention in areas where the states are not. The legislative framework that exists in relation to the mining of uranium in the Northern Territory, is an illustration of this situation: the law governing the operations of the Northern Territory's uranium mines is a combination of Commonwealth and territory law.

## **2. Mining Regime**

Mining is an area over which the Commonwealth Government has no direct power under Australia's Constitution. However, uranium mines possess uranium and so require a permit under the Nuclear Non-Proliferation (Safeguards) Act (for further details, see *infra* under Section 8 "Non-Proliferation and Physical Protection"). The Commonwealth can also exercise indirect control over uranium mining because it does have constitutional power over Australia's international trade and commerce [Constitution, Article 51(i)], and therefore has the power to regulate or prohibit exports and imports. The Customs (Prohibited Exports) Regulations, made under the Customs Act [No. 6 of 1901], forbid the export of uranium and other source material, including thorium bearing ores such as monazite, except with a permit from the Minister for Industry, Science and Resources. In this way, the

Commonwealth Government is able, in practice, to control the decisions of state governments and of mining companies as to the establishment of uranium mines.

The regulatory system covering uranium mining in the Northern Territory is complicated by the constitutional position of this Territory. Under the Australian Constitution, the Commonwealth Government has plenary legislative power over the Territories [Article 122]. In 1978, the national Parliament passed the Northern Territory (Self-Government) Act [Act No. 58 of 1978], which enabled the Northern Territory to elect its own legislature, and conferred general powers on that legislature. In respect of certain subject matters, however, such as Aboriginal affairs and uranium mining, the Commonwealth Government has retained control, though not necessarily to the total exclusion of a role for the Territory's own legislature.

The specific effects of this in relation to uranium mining in the Northern Territory are as follows:

- The Commonwealth has retained ownership of all uranium found in the Territory [Atomic Energy Act No. 31 of 1953, Section 35].
- All discoveries of uranium and thorium must be reported to the Commonwealth authorities within one month [Atomic Energy Act, Section 36].
- The Ranger uranium mine venture is authorised by the Commonwealth Minister for Industry, Science and Resources [Atomic Energy Act, Section 41].

In addition, the Commonwealth has passed environmental protection legislation to cover the Alligator Rivers region, which contains the Ranger uranium mine, the now decommissioned Nabarlek uranium mine, and the Jabiluka and Koongarra uranium deposits. This Act, the Environment Protection (Alligator Rivers Region) Act 1978 [Act No. 28 of 1978], provides for the appointment of a Supervising Scientist, who is to report and provide advice to the Commonwealth Minister for the Environment and Heritage on the environmental effects of uranium mining in the region [Section 5].

However, the Northern Territory legislature is not excluded from the field of uranium mining. The Northern Territory Mining Act [No. 15 of 1980] establishes a system of licences and leases for mineral exploration and mining, "minerals" being defined broadly enough to include uranium [Section 4(1)]. However, since the Commonwealth has retained ownership of uranium in the Northern Territory, the Northern Territory provides that an authorisation in relation to uranium mining can only be issued at the direction of the relevant Commonwealth Minister [Section 175]. The Northern Territory also has its own environmental legislation, specifically aimed at the uranium mining activities carried on in the Territory. The Uranium Mining (Environment Control) Act [No. 46 of 1979] applies to the whole of the Alligator Rivers region. It stipulates that the owner or manager of any uranium mine within the region must appoint a qualified environment protection officer [Section 5]; mining and incidental activities can only be carried out if authorised by the Territory's Minister [Sections 8, 9, 10 and 12]; and the Minister may require the mine owner to rehabilitate land which has been affected by mining operations [Section 11]. The Act provides for inspectors to enforce compliance with the Act and with the conditions of ministerial authorisations [Section 19]. Contravention of the Act, of an authorisation or of an inspector's direction is a criminal offence [Section 27].

Uranium mining activities in South Australia are regulated primarily by South Australian legislation. In the case of the Olympic Dam Project, this is subject to separate legislation: the Roxby Downs (Indenture Ratification) Act 1982 (as amended). This Act ratifies the Olympic Dam and Stuart

Shelf Indenture, a detailed agreement between the operator and the Government of South Australia. The Act deals with matters such as protection of the rights of the project, streamlining of some administrative procedures, compliance with radiation protection codes, environmental protection requirements and enforcement of conditions. The Indenture overrides some general South Australian legislation, such as the Mining Act 1971, by granting a special mining lease for the Olympic Dam.

In contrast, the new Beverley uranium mine is regulated primarily under the Mining Act 1971 and the Radiation Protection and Control Act 1982. The Mining Act governs the granting of mining leases which are granted subject to compliance with certain terms and conditions, including environmental protection and rehabilitation requirements. A licence is required under the Radiation Protection and Control Act to carry out operations for the mining and milling of radioactive ores. The Beverley mine holds such a licence, with similar conditions to those prescribed for Olympic Dam. The proposed Honeymoon mine would operate under similar regulatory arrangements.

Commonwealth regulation and involvement is minimal, with interaction generally restricted to participation in consultative arrangements. For Olympic Dam, these consist of two consultative committees, the Olympic Dam Environment Consultative Committee (ODECC) and the Community Consultative Forum (CCF). ODECC, consisting of representatives of the state, the Commonwealth and the operator of the mine, exchanges information on environmental and related matters affecting the Olympic Dam project. The CCF includes Aboriginal, pastoralist, environmentalist and Roxby Downs township representatives, and provides the mechanism for a regular flow of information to the public on the project's environmental performance. The Beverley Environment Consultative Committee operates in a similar manner to ODECC, but also includes a process of public consultation.

In contrast to the situation in the Northern Territory and South Australia, two states have legislated to prohibit prospecting for and mining of uranium. Victoria passed its Nuclear Activities (Prohibitions) Act in 1983 [Act No. 9923] and New South Wales passed the Uranium Mining and Nuclear Facilities (Prohibitions) Act in 1986 [Act No. 194].

### **3. Radioactive Substances and Equipment**

The regulation of radioactive substances and equipment used in the medical and industrial contexts is largely a matter for the states. Each state, the Northern Territory and the Australian Capital Territory has legislation establishing a permit or licensing system to cover the sale, use, possession, disposal, etc., of radiation apparatus and radioactive substances (for further details on this subject, see, *infra*, Section 6 "Radiation Protection"). Where the substance involved is uranium, plutonium, thorium, heavy water or nuclear grade graphite, or where the equipment is related to the nuclear fuel cycle, the Nuclear Non-Proliferation (Safeguards) Act may be relevant (for further details, see, *infra*, Section 8 "Non-Proliferation and Physical Protection").

### **4. Nuclear Installations**

#### ***a) Licensing and inspection, including nuclear safety***

All nuclear installations are regulated by the Nuclear Non-Proliferation (Safeguards) Act (for further details, see, *infra*, Section 8 "Non-Proliferation and Physical Protection"). In addition, Commonwealth nuclear installations are regulated by the Australian Radiation Protection and Nuclear

Safety Act [No. 133 of 1998] while non-Commonwealth installations are governed by state or territory legislation.

The Australian Radiation Protection and Nuclear Safety Act prohibits the construction or operation by controlled persons of nuclear fuel fabrication plants, nuclear power plants, uranium enrichment plants and reprocessing facilities. Australia, however, has one research reactor and radioactive waste management facilities. Under the Act, the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency is the major authority in the regulation of the safety of those nuclear installations.

The CEO is empowered to issue facility licences which authorise controlled persons to prepare a site for, construct, have possession or control of, operate, decommission, dispose of, or abandon, nuclear installations. A “controlled person” means, under the Act, a Commonwealth entity or a person who has a contractual relationship with a Commonwealth entity [Section 32]. The facility licence is issued subject to the condition that any licensee allow the CEO, or a person authorised by him, to enter and inspect the site and the facility, and comply with any requirements specified in the regulations in relation to such an inspection. The licence is also subject to the conditions prescribed by the regulations or imposed by the CEO at the time of issue or amendment [Section 35]. Licences remain in force until cancelled by the CEO or surrendered by licensees [Section 37]. The CEO may suspend or cancel a licence on grounds prescribed in the Act, including for breach of a condition of the licence [Section 38]. Licence decisions made by the CEO can be reviewed by the Minister or the Administrative Appeals Tribunal at the request of applicants or licensees [Section 40].

The CEO may appoint an inspector who may enter any premises and exercise powers, with the consent of the occupiers of the premises or under a warrant issued by the magistrate in order to ensure compliance with this Act and the regulations [Sections 62 and 63]. An inspector may exercise powers by searching premises, inspecting, examining, taking measurements of, or conducting tests concerning anything on the premises which relates to controlled material, apparatus or facility [Section 67].

The Australian Radiation Protection and Nuclear Safety (Licenses Charges) Act [No. 134] requires licence-holders of both nuclear installations and radioactive materials to pay an annual charge, to be prescribed by regulation. The Australian Radiation Protection and Nuclear Safety (Consequential Amendments) Act [No. 135] repeals those provisions of the 1987 Australian Nuclear Science and Technology Organisation Act which concern the Nuclear Safety Bureau, and the 1978 Environment Protection (Nuclear Codes) Act [No. 38].

In 1999, the Australian Radiation Protection and Nuclear Safety Regulations (Statutory Rules No. 37) were proclaimed. They were amended by Statutory Rules No. 97 (for further details, see *infra* Section 6 “Radiation Protection”).

At the international level, Australia is a Party to the following conventions:

- 1994 Convention on Nuclear Safety, ratified on 24 December 1996;
- 1986 Convention on Early Notification of a Nuclear Accident, ratified on 22 September 1987; and
- 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, ratified on 22 September 1987.

## **b) Protection of the environment against radiation effects**

The Environment Protection and Biodiversity Conservation Act 1999 [No. 91], which is administered by the Commonwealth, establishes requirements for environmental impact assessment processes for actions in relation to seven defined matters of national environmental significance. One of those matters is the protection of the environment from “nuclear actions”. The definition of “a nuclear action” [Section 22] includes, *inter alia*, mining or milling uranium ore, transporting spent nuclear fuel, and establishing, significantly modifying, decommissioning or rehabilitating a research reactor. The Environment Protection and Biodiversity Conservation Regulations of 2000 define nuclear actions and installations by setting out the activity levels beyond which certain actions or installations are considered as nuclear actions or installations.

Under the Act, the proponent of a nuclear action must refer the proposal to the Commonwealth Minister for the Environment and Heritage who determines whether environmental impact assessment is required, and if so, the level of the assessment. The proponent must not take the action unless it has been approved by the Minister for the Environment and Heritage, subject to any conditions placed on the approval.

Each of the Australian States and Territories has also enacted environmental impact assessment legislation. The Environmental Protection and Biodiversity Conservation Act [Section 45] provides for the conclusion of a bilateral agreement between the Commonwealth and any State or Territory to minimise the duplication of environmental assessment and approval processes through the Commonwealth accreditation of the State or Territory process (or vice versa).

Section 140A of the Act specifically prohibits the Minister from approving actions involving the construction or operation of a nuclear fuel fabrication plant, a nuclear power plant, an enrichment plant, or a reprocessing facility.

## **5. Trade in Nuclear Materials and Equipment**

Australia’s trade in the uranium it produces is international, since there is no domestic nuclear power industry. As already mentioned, the Commonwealth Government exercises control over this trade by virtue of its constitutional power in relation to international trade and commerce. Specifically, the Customs (Prohibited Exports) Regulations, made under the Customs Act [No. 6 of 1901], prohibit the export of uranium unless the approval of the Minister for Industry, Science and Resources has been obtained. The Minister’s decision is affected by government policy and by the need to comply with Australia’s obligations under, for example, the Non-Proliferation Treaty, Australia’s network of bilateral safeguards agreements and the South Pacific Nuclear Free Zone Treaty. Australia’s membership of the Nuclear Suppliers’ Group and the Zangger Committee is also relevant in this regard. These restrictions extend to other nuclear materials and to nuclear equipment and technology, including items which also have non-nuclear applications.

## **6. Radiation Protection**

In 1998, the 1978 Environment Protection (Nuclear Codes) Act [No. 32], which aimed to provide for the protection of people and the environment from possible harmful effects associated with nuclear activities, was repealed. Under the new regime established by the Australian Radiation Protection and Nuclear Safety Act [No. 133 of 1998], the Chief Executive Officer (CEO) of the

Australian Radiation Protection and Nuclear Safety Agency is the regulatory authority in this field, in relation to radiation sources under Commonwealth control.

The CEO may issue a radiation source licence which authorises controlled persons to deal with a controlled apparatus or material [Section 33 of Act No. 133]. A “controlled apparatus” is defined as (a) an apparatus that produces ionising radiation when energised or that would, if assembled or repaired, be capable of producing ionising radiation when energised, (b) an apparatus that produces ionising radiation because it contains radioactive material or (c) an apparatus prescribed by the regulations that produces harmful non-ionising radiation when energised. “Controlled material” means any natural or artificial material, whether in solid or liquid form, or in the form of a gas or vapour, which emits ionising radiation spontaneously [Section 13]. The source licence is issued subject to the conditions that the licensee allow the CEO, or a person authorised by CEO, to inspect a controlled apparatus or material, and comply with any requirements specified in the regulations in relation to such an inspection [Section 35]. Sections 35, 37, 38, and 40 of the Act, which were described under Section 4 “Nuclear Installations” *supra*, are also applied to the delivery of source licences.

As already said *supra*, the Australian Radiation Protection and Nuclear Safety Regulations (Statutory Rules No. 37) were adopted in 1999 to implement Act No. 133. They were amended by Statutory Rules No. 97. These Regulations cover, *inter alia*, facility and source licences, exemptions and applications for licences. In this respect, they list matters that the CEO must take into account when issuing licences. Furthermore, the Regulations lay down the effective dose limit for occupational exposure, which is set at 20 mSv annually, averaged over five consecutive calendar years, and the effective dose limit for public exposure, set at 1 mSv annually.

The following Codes of Practice have been made under the Environment Protection (Nuclear Codes) Act [No. 38 of 1978] and are currently reflected in state and territory law:

- Code of Practice on the Management of Radioactive Waste from the Mining and Milling of Radioactive Ores (1982);
- Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores (1987);
- Code of Practice for the Safe Transport of Radioactive Substances (1990).

In addition to the Codes developed under the Environment Protection (Nuclear Codes) Act 1978, there are a number of other codes and standards relating to radiation protection which have been developed by organisations like the National Health and Medical Research Council, the National Occupational Health and Safety Council and Standards Australia (two such instruments were adopted in June 1995, based upon the 1990 Recommendations of the International Commission on Radiological Protection, Publication No. 60). The Codes formerly published by the National Health and Medical Research Council, and those published under the Environment Protection (Nuclear Codes) Act 1978, are now under review by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) through its Radiation Health Committee, with the aim of republishing a single ARPANSA Radiation Protection Series of publications. Although states are not obliged to adopt these

codes, most states have incorporated them, usually into licence or registration conditions implemented under their own radiation protection Acts.<sup>1</sup>

The Northern Territory and the Australian Capital Territory also have their own radiation protection legislation and adopt codes in a similar way.<sup>2</sup>

Although these Acts are not identical, they have a common approach and their major elements are as follows:

- a permit or licence is required before a person can make, store, transport, sell, possess or use radioactive materials and ionising radiation-emitting equipment;
- the permit will not be issued unless the responsible authority is satisfied that the person is properly trained and is in other respects a “fit and proper person”;
- the permit is granted for a limited period and may be made subject to conditions. If a condition is breached, or the permit-holder contravenes the legislation, the permit may be revoked;
- permit-holders must keep records indicating the nature, purpose, usage, manner of storage etc., of radioactive substances and radiation-emitting equipment in their possession;
- specified precautions must be adopted for the protection of workers and persons undergoing medical diagnosis or treatment;
- maximum limits of radiation dosage are prescribed for radiation workers and medical patients;
- controls are imposed on methods of radioactive waste disposal;
- compliance with the regulatory system is achieved through the appointment of inspectors with statutory powers to enter and search premises and to collect information;
- contraventions of the relevant Act or regulations are criminal offences.

With regard to the specific issue of radiation protection in relation to uranium mining, the Northern Territory Mines Safety Control (Radiation Protection) Regulations [S.I. No. 30 of 1981] set safety standards by direct reference to the Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores (as amended from time to time). In addition, it sets out its own safety precautions, imposing detailed duties on the owner and the manager of the mine and on the employees at the mine. The owner’s responsibilities include ensuring that new employees are instructed in the radiation risks in their work and how to avoid them; that regular inspections of safety facilities are made and recorded; that a radiation safety officer, responsible to the manager, is appointed; and that the health of employees is monitored regularly [Section 4]. Duties are also imposed on the employees;

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1. New South Wales: Radiation Control Act 1990; Queensland: Radiation Safety Act 1999; South Australia: Radiation Protection and Control Act 1982; Tasmania: Radiation Control Act 1977; Victoria: Health Act 1958 (as amended), Division 2AA Radiation Safety; Western Australia: Radiation Safety Act 1975.

2. Australian Capital Territory: Radiation Act 1983; Northern Territory: Radiation (Safety Control) Act 1979.

they are obliged to report any defect which may contribute to a radiation hazard, use the protective equipment that is provided to them and submit to health assessments as required by the Code [Section 5]. A person who contravenes any of the Regulations, whether owner, manager or employee, is guilty of an offence and may be fined.

## **7. Radioactive Waste Management**

Management of radioactive waste in Australia is the responsibility of the government in whose jurisdiction it is produced. Australia's radioactive waste comes from two main sources: mining activities and the use of radionuclides in research, medicine and industry.

Waste from uranium mining activities is managed and disposed of near the site of origin at the cost of the mine operator and in accordance with the requirements of the Code of Practice on the Management of Radioactive Wastes from the Mining and Milling of Radioactive Ores (1982). These requirements have been incorporated in the Northern Territory's Mines Safety Control (Radioactive Wastes Management) Regulations and, by reference, in South Australia's Roxby Downs (Indenture Ratification) Act of 1982.

Low-level and short-lived intermediate-level radioactive waste resulting from research and the medical and industrial uses of radionuclides is at present held at over 50 temporary storage sites throughout Australia. The Minister for Industry, Science and Resources has announced that a site located in the Woomera Prohibited Area in the central north region of South Australia has been selected as the preferred site to hold Australia's solid low level radioactive waste. The selection of the preferred site, and two alternative sites also in the same region, is the culmination of an Australia-wide search and public consultation process initiated by the Commonwealth Government in 1992 after general agreement by the States and Territories on the need for a central waste repository. The 1992 amendments to the ANSTO Act added to ANSTO's functions that of conditioning, managing and storing radioactive materials and waste, but only if the materials or waste had arisen either from ANSTO's own activities or from the activities of persons specified in the regulations [ANSTO Act, Section 5(1)]. The Act specifically states that ANSTO's premises are not to become a permanent national nuclear waste repository [Section 5(1)(a)]. The Code of Practice for the Near-Surface Disposal of Radioactive Waste in Australia (issued in 1992 by the National Health and Medical Research Council) sets out requirements for siting, design and operation of a new near-surface disposal facility. Separate licences to site, construct and operate the facility must be obtained from the Australian Radiation Protection and Nuclear Safety Agency before the repository can be constructed and commence operations. The licensing process will begin during 2001.

The State of Western Australia has established its own near surface disposal facility for low level radioactive waste. Regulations made under Western Australia's Radiation Safety Act 1975 have incorporated the requirements of the Code of Practice for the Near-Surface Disposal of Radioactive Waste in Australia.

The storage and disposal of radioactive substances and apparatus are also addressed by the Code of Practice for the Disposal of Radioactive Wastes by the User (1985) and by the radiation control Acts and Regulations of the states and territories.<sup>3</sup>

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3. New South Wales: Radiation Control Act 1990; Queensland: Radiation Safety Act 1999; South Australia: Radiation Protection and Control Act 1982; Tasmania: Radiation Control Act 1977; Victoria: Health

The Commonwealth's Environment Protection (Sea Dumping) Act [No. 101 of 1981] regulates the dumping at sea of radioactive material. Until 1986, the Act prohibited dumping of high level radioactive waste, but allowed dumping under permit of other radioactive wastes and materials. In 1986 amendments were made to the Act following Australia's ratification of the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (the London Convention, ratified on 21 August 1985) and of the 1985 South Pacific Nuclear Free Zone Treaty (the Rarotonga Treaty, ratified on 11 December 1986). The result of the amendments is that all dumping of radioactive material in Australia's territorial sea is now prohibited [Section 9(a)]. Australia ratified the 1996 Protocol to the London Convention on 4 December 2000.

"Radioactive material" is defined as material that has an activity of more than 35 becquerels per gram [Section 4(1)]. If radioactive material is dumped in contravention of the Act, the owner and the person in charge of the vessel, aircraft or platform from which the dumping occurred are both guilty of an offence, as is the owner of the material dumped [Section 9(a)]. The amendments did not alter the exemptions contained in the original Act. The Act does not apply to the disposal of wastes arising from exploration and exploitation of seabed mineral resources [Section 5], nor does it apply in relation to a vessel, aircraft or platform belonging to the defence forces of Australia or of a foreign country [Section 7].

In September 1995 Australia signed the 1995 Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes with the South Pacific Region (Waigani Convention). On 13 November 1998, Australia signed the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

## **8. Non-Proliferation and Physical Protection**

Australia has ratified the following international instruments in this field:

- 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 23 January 1973;
- 1985 South Pacific Nuclear Free Zone Treaty on 11 December 1986;
- 1996 Comprehensive Nuclear Test Ban Treaty on 9 July 1998; and
- 1979 Convention on the Physical Protection of Nuclear Material on 22 September 1987.

Other relevant international instruments are Australia's safeguards agreement of 10 July 1974 with the International Atomic Energy Agency (IAEA), Additional Protocol to that Agreement of 23 September 1997 and Australia's bilateral nuclear safeguards agreements with individual countries and Euratom.

The Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987] and the South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986] establish the legal framework that is required at a national level by the Non-Proliferation Treaty and the South Pacific Nuclear Free Zone Treaty. An account of each of these elements now follows.

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Act 1958 (as amended), Division 2AA Radiation Safety; Western Australia: Radiation Safety Act 1975; Australian Capital Territory: Radiation Act 1983; Northern Territory: Radiation (Safety Control) Act 1979.

**a) *Bilateral Safeguards Agreements***

The Commonwealth Government permits exports of nuclear material only to countries with which Australia has concluded a bilateral safeguards agreement. These agreements are designed to guarantee that Australian uranium can be used only in the civil nuclear fuel cycle of the importing state. This state undertakes that:

- Australian obligated nuclear material will not be used in the manufacture of nuclear weapons or other nuclear explosive devices, or in related research or development;
- Australian obligated nuclear material will not be used for any military purpose;
- Australian obligated nuclear material will be covered by IAEA safeguards;
- fallback safeguards will apply if at any stage IAEA safeguards cease to operate;
- the enrichment of Australian uranium beyond 20% U<sup>235</sup>, the reprocessing of spent fuel from Australian uranium, or the retransfer of Australian uranium to another country will not occur without prior Australian consent;
- physical security to internationally agreed levels to prevent theft of nuclear material will be applied;
- it will participate in consultations with Australia, as and when required, particularly in respect of reprocessing and plutonium use questions.

Each of these bilateral agreements is supplemented by an administrative arrangement which sets out details as to the manner in which the obligations under the agreement are to be performed, including arrangements for accounting for Australian obligated nuclear material as it passes through each phase of the recipient's fuel cycle.

**b) *International Atomic Energy Agency Safeguards Agreement***

In 1974 Australia concluded a safeguards agreement with the IAEA, as required by the Treaty on the Non-Proliferation of Nuclear Weapons. Although the main function of the Agreement is to establish a system of safeguards to apply to nuclear material within Australia, it also requires Australia to notify the IAEA of intended transfers of material subject to IAEA safeguards out of Australia. On 23 September 1997 Australia became the first country to sign a Protocol supplementing and strengthening its basic safeguards agreement with the IAEA, based on the Model Protocol developed by the IAEA's Programme 93+2.

**c) *The South Pacific Nuclear Free Zone Treaty Act***

The South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986] gives effect to all the substantive provisions of the Treaty. Its main provisions are contained in Part II (a series of prohibitions relating to nuclear explosive devices) and in Part IV (dealing with inspections to ensure Australia's compliance with the Treaty).

Part II of the Act prohibits the manufacture, production and acquisition of nuclear explosive devices [Section 8]. Research and development directed towards the manufacture of a nuclear explosive device is forbidden [Section 9], as is the possession of, or control over, such a device [Section 10]. It is an offence to station a nuclear explosive device in Australia [Section 11] or to carry out a test of such a device [Section 12]. Section 14 extends all these offence provisions to acts occurring outside Australia if those acts are committed by a commonwealth, state or territory government or government authority, or if those acts are committed on an Australian ship or aircraft. However, the Act does not seek to affect the visits of foreign ships or aircraft visiting Australia, navigating through Australian waters or flying through Australian airspace [Section 15]. The penalty for any of these offences is, in the case of an individual, a fine of 100 000 Australian dollars (AUD), a prison sentence of 20 years, or both, and, in the case of a body corporate, a fine of AUD 500 000 [Section 16].

Part IV of the Act provides for the appointment of special Treaty inspectors to investigate a complaint brought against Australia under the Treaty [Section 19]. While the Treaty inspectors are given certain powers to enter premises with the consent of the owner or occupier, to examine, take samples, make copies of documents, etc. [Section 22], it is envisaged that their inspections will be facilitated by Australian inspectors who have been appointed under the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987]. These Australian inspectors are given extensive powers, for example, to apply to a magistrate for a search warrant [Section 21] and to require information from a person suspected of committing an offence against the Act [Section 24].

#### *d) The Nuclear Non-Proliferation (Safeguards) Act*

Until the enactment of the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987], those aspects of the Non-Proliferation Treaty which required domestic implementation through control of the possession, use and transport of nuclear material were dealt with by means of the Customs Act [No. 6 of 1901] and regulations made under it, and by relying on co-operation from holders of nuclear items. The Safeguards Act now regulates the possession, use and transport of nuclear items in Australia. There are express provisions in the Act stating that its objects are to give effect to certain obligations under the Non-Proliferation Treaty and the Physical Protection Convention [Section 3], and that the Act will be administered in accordance with these Treaties [Section 70].

The Act establishes a national system regulating the possession of nuclear material, equipment and technology. In practice, the bodies chiefly affected by this system are uranium mining companies and ANSTO. The Act seeks to subject all nuclear material and associated items within Australia to a system of stringent and detailed controls.

“Nuclear material” is defined in Section 4(1) to mean any source or special fissionable material, as defined in Article XX of the IAEA Statute, but not including ore or ore residue. “Associated item” means associated material, associated equipment or associated technology [Section 4(1)]. Broadly speaking, this means:

- material of a kind specially suited for use in the construction or operation of a nuclear reactor;
- equipment or plant that is specially suited to the production of nuclear weapons or for use in other nuclear activities; and

- information (other than information available to the public) that is applicable primarily to nuclear weapons or to equipment for the enrichment of nuclear material, the reprocessing of irradiated material, or the production of heavy water [Section 4(1)].

The Minister has the power to exempt certain nuclear material and associated items from the Act [Section 11] and this has been done under the Nuclear Non Proliferation (Safeguards) Regulations [S.I. No. 75 of 1987]. The regulations exempt, for example, depleted uranium and heavy water in non-nuclear use; thorium incorporated in electronic components and aircraft parts; source material incorporated in ceramic glazes; and source material contained in certain chemical mixtures in which the uranium or thorium content is less than 0.05% of the weight of the mixture [Regulation 3].

The principle underlying the safeguards system is that all possession, use and transportation of nuclear material covered by the Act is prohibited unless it is carried out under a permit granted by the Minister for Foreign Affairs [Sections 13 and 16]. The procedure is described below.

A person may apply for a permit to the Director of Safeguards, who may request more information from the person. The Director then makes a report to the Minister in relation to the application [Section 12]. The Minister may not grant the permit unless the applicant has provided all the information required by the Director, and the Director is satisfied that:

- a) appropriate procedures can be applied at the nuclear facility concerned for the implementation of the Australian safeguards system; and
- b) adequate physical security can be applied to nuclear material and associated items at the facility [Section 14].

If the Minister grants the permit, it may be made subject to conditions and restrictions [Section 13(2)]. Customarily, the conditions will specify the following matters [Section 13(3)]:

- precisely what material is covered by the permit;
- the period of time for which the permit is valid;
- the procedures which must be followed if the material is to be transported (including notifying the Director or Minister);
- the measures which must be taken to ensure the physical security of the material;
- who is to be allowed access to the material;
- the steps to be followed, and the records to be kept, in order to account for the material;
- the permitted uses of the material;
- the inspections which must be permitted in relation to the material;
- the conditions under which any transfer of the ownership, possession or control of the material may take place;
- in the case of a permit to possess information covered by the Act, any restrictions on the communication of that information.

Similar procedures apply in relation to a transport permit and an authority allowing the communication of information that comes within the definition of “associated item” [Section 4(1)]. A permit to allow nuclear material to be moved from one specified location to another may be subject to conditions stipulating the means of transport, the route, physical security measures, records to be kept, reports to be made etc. [Section 16]. In the case of communication of information, an authority may be given subject to restrictions as to precisely what information may be passed on, to whom it may be given, and within what time period it may be given [Section 18].

Further control can be exercised over the holders of permits and authorities by means of ministerial orders and directions [Section 73]. Broadly speaking, these may deal with the same matters as those that are dealt with by the conditions which may be attached to a permit or authority (for example, requirements as to physical security measures to be taken, the permitted uses of the nuclear material, etc.).

If the holder of a permit or authority contravenes one of the conditions attaching to it, or a direction under Section 73, or is convicted of an offence against the Act, the permit or authority may be revoked by the Minister [Section 19]. A further deterrent is that any contravention of a condition or a Section 73 order or direction is itself an offence against the Act [Section 25], punishable by a fine or a prison sentence or both. The Act also ensures that safeguards can be maintained even if the permit-holder has failed to carry out his or her obligations. In such a situation, the Director may authorise an inspector to do anything necessary to ensure compliance with the condition, order or direction that has been contravened [Section 68]. Any costs incurred by the Commonwealth as a result of the inspector’s actions become a debt due to the Commonwealth by the permit-holder [Section 68(4)].

The safeguards system established by these provisions is supported by the creation of a number of offences. The basic offence is that of possessing nuclear material or an associated item without a permit granted under Section 13 or 16. The offence provision [Section 23] is drafted so as to extend to possession outside Australia if the material is on an Australian ship or aircraft or is in the course of a journey which began at a place in Australia. The communication of information covered by the Act without an authority under Section 18 is also made an offence [Section 26]. The Act creates several other related offences, all punishable by a fine, a term of imprisonment or both [Sections 25 and 28-31]. As is usual in Commonwealth law, the fine incurred by a company may be up to five times higher than the amount of the fine incurred by an individual.

Two final points should be noted regarding the permit and authority system. The first is that where the Minister has made an adverse decision (for example, refusing to grant a permit or revoking a permit), the person affected must be given reasons for the decision and has the right to have the decision reviewed by an independent administrative tribunal, which has the power to overturn the Minister’s decision [Section 22]. The second point concerns the relationship between the system of permits and authorities established under this Act, and any state or territory law that regulates radioactive substances, etc. The Commonwealth Act makes it quite clear that its requirements are additional to any that may exist under state law; the granting of a permit under this Act does not excuse the permit-holder from complying with relevant state law [Section 21].

In addition to establishing this system of permits and authorities, the Safeguards Act gave statutory recognition to the Australian Safeguards Office, which is part of the Australian Safeguards and Non-Proliferation Office (ASNO), and the Director of Safeguards, who is also the Director General of ASNO. The functions of the Director include ensuring the effective operation of the permit system, carrying out Australia’s safeguards obligations under its agreement with the IAEA and its

bilateral agreements, and monitoring compliance by Australia's partners in those bilateral agreements [Section 43].

Australia's agreement with the IAEA requires Australia to ensure that inspections on national territory can be carried out by the Agency. The Safeguards Act provides both for the appointment of Australian inspectors to ensure compliance with the Act and the Regulations, and also for the recognition by the Minister of inspectors who have been designated by the Agency for the purpose of making Agency inspections [Section 57].

Agency inspectors have powers to examine, take samples, verify the proper functioning of equipment, take measurements, install or operate a containment device or a surveillance device, take extracts from records and other documents, as well as a general power to do anything necessary to carry out an Agency inspection [Section 60]. Their powers are more limited than those of the Australian inspectors; for example they have no powers to enter premises without the consent of the owner. However, the Act provides that one of the functions of a local inspector is to facilitate an inspection by an Agency inspector [Section 59(1)(e)]. The Act envisages situations where a local inspector will obtain a search warrant [Section 59(6)] for the purpose of facilitating an Agency inspection, and the Agency inspector will then accompany the local inspector to the premises or land in question and carry out an Agency inspection [Section 60(3)].

The Safeguards Act contains a Division creating a number of offences relevant to the Convention on the Physical Protection of Nuclear Material. It is an offence to steal nuclear material or obtain it by false pretences [Section 33], to demand it by threats [Section 34] or to use or threaten to use it to cause serious personal injury and substantial property damage [Section 36]. These offences are punishable by a maximum fine of AUD 20 000 or imprisonment for a maximum of ten years or both. In addition, a court convicting a person of one of these offences may order the forfeiture of any article used in the offence [Section 39].

One of the regulation-making powers under the Act concerns the making of standards for the physical security to be applied with respect to nuclear material and associated items [Section 74(f)].

Finally, it should be noted that the Australian Radiation Protection and Nuclear Safety Act 1998 does not exclude the implementation of the Nuclear Non-Proliferation (Safeguards) Act. For example, a controlled person may be required by 1998 Act to hold a licence, and by 1987 Act to hold a permit, in respect of the same thing. The controlled person must satisfy the requirements of both Acts in so far as they are capable of being satisfied concurrently [1998 Act, Section 9].

## **9. Transport**

As previously mentioned, the Commonwealth controls the import and export of radioactive substances and requires a permit to be obtained before such substances can either leave or enter Australia [S.I. No. 90 of 1956 (dealing with imports) and S.I. No. 5 of 1958 (dealing with exports)].

In relation to transport within Australia, the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987] provides that conditions may be attached to a permit to possess nuclear material and that they may set out the procedures to be followed if the material is to be transported from one location to another [Section 13(3)(c)]. The Act also provides for a special transport permit, which may have detailed conditions attached to it [Section 16].

The Commonwealth has formulated a Code of Practice for the Safe Transport of Radioactive Substances. Originally formulated in 1982 and revised in 1990, the Code adopts the IAEA Regulations for the Safe Transport of Radioactive Material. The Code is currently being reviewed with the intention of adopting the IAEA 1996 Regulations for the Safe Transport of Radioactive Material (revised) (TS-R-1). Different aspects of the current Code are now reflected in various pieces of legislation dealing with different types of transport.

Transport of dangerous goods by sea is covered by the Navigation Act [No. 4 of 1913] and by regulations made under it.

Transport of dangerous goods by air is covered by the Crimes (Aviation) Act 1991 [No. 139 of 1991] and by regulations made under it.

The regulation of land transport is, generally speaking, a matter for States and Territory governments. The Code of Practice, insofar as it applies to land transport, is implemented by the States and Territories through regulations made under their respective transport Acts. As mentioned previously, requirements imposed by the States regarding the possession and transport of nuclear material operate in addition to those imposed under the Commonwealth's Safeguards Act (provided, of course, that the state requirements are not inconsistent with those of the Commonwealth).

## **10. Nuclear Third Party Liability**

There are no specific provisions in Australian legislation governing nuclear third party liability. Moreover, Australia is not a party to any of the conventions on nuclear third party liability although it has signed the 1997 Convention on Supplementary Compensation for Nuclear Damage.

## **II. INSTITUTIONAL FRAMEWORK**

### **1. Regulatory and Supervisory Authorities**

#### ***a) Minister for Industry, Science and Resources***

The Minister for Industry, Science and Resources has the power to allow or disallow the movement of uranium and other source material, and special fissionable material, out of Australia. The Customs (Prohibited Exports) Regulations, made under the Customs Act [No. 6 of 1901], forbid the export of uranium and related products except with a permit from the Minister [Regulation 9]. The Regulations were amended in 2000 to enable the Minister to issue permits subject to compliance with specified conditions.

The Minister is also responsible for those provisions of the Atomic Energy Act [No. 31 of 1953] which remain in force. All discoveries of uranium and thorium in Australia must be reported to the

Minister within one month [Section 36]. Provision is also made in this Act for the Minister to represent the Commonwealth's continuing interests in the Ranger uranium mining venture in the Northern Territory. The Minister may authorise a person to carry on operations in the Ranger Project Area on behalf of or in association with the Commonwealth and the Minister may vary or revoke the authority if satisfied that its conditions are not being met [Section 41(a)]. A person who has been given the authority may not assign his or her interest in the venture to another person without the consent of the Minister [Section 41(b)]. The Minister also has the power to renew the authority for a further period and to impose conditions and restrictions on the new authority [Section 41(c)].

The Australian Nuclear Science and Technology Organisation (ANSTO) is accountable to the Minister for Industry, Science and Resources. The Minister may direct ANSTO to undertake research and development in relation to matters specified by the Minister [Section 5(1)(a)(iii)]. The Minister may also give directions to the Board of Directors of ANSTO with respect to the performance of ANSTO's functions [Section 11], and may convene meetings of the Board [Section 16].

The Board of ANSTO is financially accountable to the Minister. It must prepare estimates of its receipts and expenditure for each financial year and submit them to the Minister [Section 28].

**b) *Minister for the Environment and Heritage***

The Minister for the Environment and Heritage has certain powers and functions under the Environment Protection (Alligator Rivers Region) Act [No. 28 of 1978]. The Minister may give directions to the supervising scientist and may request that he provides information in relation to the operation of the Act [Section 7]. The Minister receives advice from the supervising scientist on a range of environmental issues arising from the mining operations in the Alligator Rivers Region [Section 5(e)]. The Minister is obliged to lay before each House of Parliament a copy of the supervising scientist's annual report and any other reports that the supervising scientist has made to the Minister, except for reports made to the Minister in connection with scientific and technical advice on environmental matters outside the Alligator Rivers Region [Section 36]. Under the Environment Protection and Biodiversity Conservation Act [No. 91 of 1999] the Minister for the Environment and Heritage is responsible for assessing and approving nuclear actions as defined in that Act. The Minister may attach conditions to approvals.

**c) *Minister for Foreign Affairs***

Under the South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986], the Minister for Foreign Affairs is responsible for nominating a Treaty inspector for the purposes of the Act. The Minister will only make this declaration if the person has been appointed as a special inspector under the Treaty for the purpose of investigating a complaint brought against Australia pursuant to the Treaty [Section 19].

The Minister is responsible for the administration of the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987] (hereinafter referred to as "the Safeguards Act"). Under the Safeguards Act it is the Minister who grants or refuses to grant a permit for the possession of nuclear material, an associated item or associated technology [Sections 13, 16 and 18]. Similarly, it is the Minister who imposes conditions and restrictions on any permit or authority granted [Sections 13, 16 and 18] and who exercises the power to revoke the permit or authority in certain circumstances [Section 20]. The Minister has a further power to control the activities of permit-holders, in the shape of orders and

directions under Section 73. Under this Section, the Minister may make orders which are to be complied with by all permit-holders, and may also give directions to a particular permit-holder.

All these decisions of the Minister are subject to review by the Administrative Appeals Tribunal [Section 22]. This is an independent tribunal established by legislation for the purpose of reviewing a wide range of administrative decisions. Upon application by a person adversely affected by such a decision, the tribunal is empowered to examine the merits of the decision, as well as its procedural correctness [Administrative Appeals Tribunal Act, No. 91 of 1975]. The Safeguards Act envisages, however, that some ministerial decisions made under it may not be suitable for review by the Administrative Appeals Tribunal. Section 22(5) provides that the Minister can issue a certificate stating that it is in the public interest that responsibility for a particular decision should reside solely with the Minister, and that the Minister's decision should not be reviewable. The Minister is obliged to include in the certificate a statement of the grounds on which the certificate is issued [Section 22(6)], and must table the certificate before each House of Parliament [Section 22(9)].

The Minister has the power to issue directions to the Director of Safeguards and the Director must comply with any such directions in the performance of his or her functions under the Act [Section 44].

The Minister's other responsibilities under the Safeguards Act include the appointment of inspectors for the purposes of the Act, and the declaration of Agency inspectors where these have been designated by the IAEA [Section 57]. The Minister is also required to submit to Parliament the annual report made by the Director of Safeguards [Section 51].

The Minister has the power to delegate any of the functions mentioned above (except the power to certify that a decision is not subject to administrative review) to the Director of Safeguards or to an officer of the Ministry [Section 72]. The Minister has delegated many of these functions to the Director of Safeguards.

**d) *Minister for Health and Aged Care***

The Australian Radiation Protection and Nuclear Safety Agency is within the portfolio of the Minister for Health and Aged Care, which is responsible for providing protection, promoting the health of all Australians and minimising the incidence and severity of preventable mortality, illness, injury and disability. The Minister must, by notice in writing, give directions to the chief executive officer (CEO) with respect to the performance of the CEO's functions or the exercise of his powers, if it is in the public interest to do so. This Minister is one of the two ministers responsible for the issue of permits to import radioactive material and substances. The other minister who may exercise this power is the Minister for Customs [Customs (Prohibited Imports) Regulations, Section 4(r)].

**e) *Minister for Finance***

The Minister for Finance has various functions under the Australian Nuclear Science and Technology Organisation Act [No. 3 of 1987]. Parliament decides each year an amount of money to be provided for the purposes of ANSTO [Section 27(1)]. The Minister may give directions as to the times at which, and the amounts in which, that money will be paid to the organisation [Section 27(2)]. The Minister for Finance may also lend money to ANSTO on behalf of the Commonwealth [Section 32].

## **2. Advisory Bodies**

### ***a) Advisory Committees***

Section 41 of the ANSTO Act [No. 3 of 1987] allows the Minister to establish committees to give advice to the Board of Directors on a particular matter or classes of matter relating to the functions of ANSTO.

### ***b) Radiation Health and Safety Advisory Council***

The Radiation Health and Safety Advisory Council was established by the Australian Radiation Protection and Nuclear Safety Act [No. 133 of 1998] as a consultative body on radiation and nuclear safety [Section 19]. The Council examines issues of major concern to the community in relation to radiation protection and nuclear safety and advises the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) on these issues, as well as on the adoption of recommendations, policies and codes [Section 20]. The Radiation Health Committee and the Nuclear Safety Committee were established as advisory committees to the CEO and the Council [Sections 22 and 25]. Both Committees draft national policies, codes and standards in their respective fields and review their effectiveness periodically [Sections 23 and 26].

The membership of the Council includes the CEO of ARPANSA, two state/territory radiation control officers, a person to represent the interests of the general public and eight other members with expertise in the area. The Radiation Health Committee includes the CEO of ARPANSA, a radiation control officer from each state and territory, a Nuclear Safety Committee representative, a person to represent the interests of the general public, and two other members. The Nuclear Safety Committee includes the CEO of ARPANSA, a representative of local governments, a person to represent the interests of the general public, a Radiation Health Committee representative and eight other members. Each member of the Council, other than the CEO, is appointed by the Minister [Section 21]. Members of the Committees are appointed by the CEO.

## **3. Public and Semi-Public Agencies**

### ***a) Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)***

#### ***i) Legal Status***

The Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the statutory officer whose functions are laid down in the Australian Radiation Protection and Nuclear Safety Act [No. 133 of 1998].

#### ***ii) Responsibilities***

The functions of the CEO fall into the following categories [1998 Act, Section 15]:

- to promote uniformity of radiation protection and nuclear safety policy and practices;

- to provide advice and services concerning radiation protection and nuclear safety;
- to undertake research in relation to radiation protection, nuclear safety and related issues;
- to accredit persons with technical expertise for the purpose of this Act;
- to monitor the operations of ARPANSA, the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee and to report on their operations to the relevant minister and to the Parliament;
- to monitor compliance with the provision which deals with the prohibition of construction or operation of nuclear installations or possession of controlled material or controlled apparatus, without a licence.

The CEO must comply with the directions which are given by the Minister with respect to the performance of the CEO's functions or the exercise of his powers [Section 16]. The CEO may give written directions to controlled persons requiring them to take appropriate steps, in order to protect the health and safety of people or to avoid damage to the environment [Section 41].

### *iii) Structure*

The CEO is appointed by the Governor-General for a period up to five years [Section 45]. The CEO's appointment can be terminated only on certain grounds specified in the Act (for example, misbehaviour or incapacity) [Section 51]. The CEO may engage the staff or consultants to assist in the performance of any of its functions [Section 58].

### *iv) Financing*

The ARPANSA Reserve was established to make payments for the implementation of the Australian Radiation Protection and Nuclear Safety Act and otherwise in connection with the performance of the CEO's function. The Reserve consists of money appropriated by Parliament for the purposes of the CEO and amounts equal to amounts received by the Commonwealth in connection with the performance of the CEO's functions under this Act or regulations [Section 56].

## ***b) Australian Safeguards and Non-Proliferation Office***

### *i) Legal Status*

The Australian Safeguards Office was established by Section 54 of the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987], and consists of the Director of Safeguards and staff. This Office combined with the Chemical Weapons Convention Office and the Australian Comprehensive Test Ban Office to make up the Australian Safeguards and Non-Proliferation Office (ASNO). The Director General of ASNO is also the Director of each of the constituent organisations.

*ii) Responsibilities*

The statutory functions of the Director are, with the assistance of the staff, to ensure the effective operation of the Australian safeguards system; to carry out Australia's reporting obligations under the IAEA Agreement and bilateral agreements in relation to the Australian safeguards system; to monitor compliance by Australia's bilateral agreement partners; to undertake research and development in relation to nuclear safeguards; and to advise the Minister for Foreign Affairs on matters relating to the operation of the Australian safeguards system. The Director is required to make an annual report to the Minister, which must include details of all nuclear material and associated items of Australian origin transferred from Australia to any foreign jurisdiction, their quantities and their intended end-use [Section 51].

*iii) Financing*

The Australian Safeguards and Non-Proliferation Office is funded by money appropriated by the Parliament. Two amending Acts, the Nuclear Non-Proliferation (Safeguards) Amendment Act [No. 33 of 1993] and the Nuclear Safeguards (Producers of Uranium Ore Concentrates) Charge Act [No. 34 of 1993] provide for the imposition of a charge on commercial uranium producers in Australia in order to recover some of the costs of the Office's activities. However, the charge collected goes directly to Consolidated Revenue and has no effect on ASNO's budget.

*c) Australian Nuclear Science and Technology Organisation (ANSTO)*

*i) Legal Status*

On 27 April 1987 the Australian Atomic Energy Commission became the Australian Nuclear Science and Technology Organisation (ANSTO) [Australian Nuclear Science and Technology Organisation Act (No. 3 of 1987), Section 4]. ANSTO is a body corporate, with the capacity to sue and be sued [Section 4(2)]. It can enter into contracts, own property and form, or participate in the formation of, companies [Section 6]. Its participation in companies is subject to certain limitations and to the approval of its supervisory Minister.

*ii) Responsibilities*

The functions of ANSTO fall into the following general categories:

- undertaking research and development in relation to nuclear science and technology and in relation to the production and use of radioisotopes, the use of isotopic techniques and nuclear radiation, for medicine, science, industry, commerce and agriculture;
- conditioning, managing and storing specified radioactive materials and radioactive waste;
- encouraging and facilitating the application and utilisation of the results of such research and development;
- providing and selling goods and services in connection with ANSTO's activities;

- liaising between Australia and other countries, and between other Commonwealth and state authorities in relation to its activities;
- providing advice on aspects of nuclear science and nuclear technology;
- making available to other people, on a commercial basis, ANSTO's knowledge, equipment and facilities;
- publishing scientific and technical reports, periodicals and papers; and
- arranging and encouraging training in matters related to its activities [Section 5].

In undertaking its statutory functions, ANSTO is required to have regard to the government's national science, technology and energy policy objectives and to its commercialisation objectives for public research institutions [Section 5(3)].

### *iii) Structure*

The Organisation consists of a board of directors, and an executive director and staff. The board consists of the executive director and at least two other members. The total maximum number of members is seven [Section 9]. The members, other than the executive director, are appointed by the Governor-General for a term of up to five years, and they can be dismissed from office only by the Governor-General, on the ground of misbehaviour or physical or mental incapacity [Sections 9 and 14].

The board's role is to ensure the proper and efficient performance by ANSTO of its functions, and in doing so, the board is to have regard to the policies of the Commonwealth Government insofar as they are relevant to ANSTO's work [Section 10]. ANSTO's Minister may give directions to the board about the performance of ANSTO's functions, if satisfied that it is in the public interest to do so [Section 11].

The Executive Director of ANSTO is appointed by the board of directors [Section 18] to manage the affairs of the Organisation subject to the directions, and in accordance with the policies, of the board [Section 19].

The Executive Director is empowered to appoint such staff as the board considers necessary for the purposes of the Act [Section 24].

### *iv) Financing*

ANSTO is funded by money appropriated by Parliament for the purposes of the Organisation. The Minister for Finance may give directions as to the amounts in which, and the times at which, the money appropriated is to be paid to ANSTO [Section 27]. The Organisation may also borrow Commonwealth money from the Minister for Finance, on conditions determined by the Minister [Section 32], and may deal with securities, with the approval of the Treasurer [Section 34]. ANSTO may also accept gifts and bequests made to it [Section 38]. Lastly ANSTO is empowered to provide and sell goods and services, and a significant proportion of the Organisation's revenue is earned in that way [Section 5(1)(c)].

*d) Supervising Scientist*

The Environment Protection (Alligator Rivers Region) Act [No. 28 of 1978] creates the position of Supervising Scientist for the Alligator Rivers Region [Section 4]. This area of the Northern Territory contains the Ranger uranium mine, the now decommissioned Nabarlek uranium mine and the Jabiluka and Koongarra uranium deposits. The functions of the Supervising Scientist in relation to the protection of the environment were originally confined to the effects of uranium mining in the region, but the Act was amended in 1987 [Act No. 17] to extend these functions to all mining operations in an area declared to be a conservation zone. The Supervising Scientist's general functions include the following:

- developing research and information programmes on the environmental effects of mining in the areas concerned;
- developing and promoting standards and procedures in relation to mining for the protection of the environment in the areas concerned;
- supervising the implementation of Commonwealth and Northern Territory laws relating to environmental protection of the areas from the adverse effects of mining; and
- advising the Commonwealth Minister for the Environment and Heritage on all these matters [Sections 5 and 5A].

The Supervising Scientist is also a member of the Advisory Committee established under the Act. The other members of the Committee are:

- a chairperson appointed by the Minister for the Environment and Heritage;
- the Director of the Commonwealth's National Parks and Wildlife Service;
- a member appointed by the Minister for the Environment and Heritage on the nomination of the Northern Territory government;
- a member appointed by the Minister for the Environment and Heritage on the nomination of the appropriate Aboriginal Land Council; and
- such other members as are appointed by the Minister for the Environment and Heritage from time to time.

The Advisory Committee provides a formal forum for consultation on the effects of uranium on the environment in the Alligator Rivers Region and on matters relating to environmental research conducted in the region and referred to it by the Technical Committee.

Associated with the Advisory Committee is the Technical Committee, appointed by the Minister for the Environment and Heritage. The Technical Committee considers environmental research needs in relation to uranium mining in the region, reviews research programmes, refers matters relating to such programmes to the Advisory Committee, and makes recommendations to the Minister on the nature and extent of research necessary, and on the appropriate organisation to conduct the research.

Finally, the Supervising Scientist is charged with the management of the Environmental Research Institute of the Supervising Scientist. The functions of the Institute are, in general terms, to support the Supervising Scientist in the research and information functions conferred under Sections 5 and 5A [Section 24]. It is also permitted to undertake research on matters outside the region on a commercial basis.

# CANADA

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

Nuclear power provides approximately 14% of Canada's total electricity supply, produced by the 14 power reactors that are currently in operation. Eight further units have been placed in a state of approved shutdown pending refurbishment. Most of Canada's power reactors are owned and operated by Ontario Power Generation Inc., a corporation owned by the Government of Ontario. Its twenty reactors are located at three major sites: Pickering, Bruce and Darlington. Hydro Quebec also owns and operates a power reactor at Gentilly and New Brunswick Power Corporation owns and operates a reactor at Pt. Lepreau. There are, in addition, eight operating research reactors in Canada: two at the Chalk River Laboratories site of Atomic Energy of Canada Limited (AECL) and six at various universities across the country. There is also a subcritical assembly at École Polytechnique, and two MAPLE reactors being commissioned at AECL's Chalk River Laboratories.

On 20 March 1997, Canada's Nuclear Safety and Control Act [S.C. 1997, c.9] (hereinafter referred to as "the Act") received Royal Assent and on 31 May 2000, it came into force. This comprehensive legislation replaces the Atomic Energy Control Act, first adopted in 1946, as the means by which the Canadian nuclear industry is to be regulated and by which Canada will comply with its international commitments with respect to the peaceful uses of nuclear energy. It dissolves the former Atomic Energy Control Board (AECB), establishes a new Canadian Nuclear Safety Commission (hereinafter referred to as "the Commission" or CNSC) and clearly distinguishes the regulatory role of the new Commission from that of the federal research, development and marketing organisation known as Atomic Energy of Canada Limited (AECL). The Act is binding upon the Crown, both federal and provincial and upon the private sector.

Under the Act, the Commission has a clear mandate to establish and enforce health, safety, security and environmental protection standards in connection with nuclear activities. The objectives of the Commission also extend to achieving compliance with Canada's international commitments regarding nuclear non-proliferation, safeguards and security. Equally, it is charged with providing objective scientific, technical and regulatory information to the public concerning its own activities and concerning the effects of the nuclear industry on health, safety and the environment [Section 9]. Like its predecessor, the Commission has extensive authority to regulate a broad range of activities involving nuclear energy or nuclear materials in Canada including the import, export and transportation of nuclear materials and other prescribed substances, nuclear equipment and nuclear technology [Section 44].

#### a) *Licensing System*

The principal regulatory mechanism used by the Commission is a licensing system. Section 26 of the Act prohibits almost every activity associated with nuclear substances, prescribed equipment, prescribed information and nuclear facilities, except in accordance with a licence issued by the

Commission; the Commission is also empowered to issue, renew, suspend, amend, revoke or replace a licence, subject to any term or condition that it considers necessary and subject to the payment of the prescribed fee [Nuclear Safety and Control Act, Section 24]. In Canada, there are over 4 000 licensees carrying out activities in the areas of power and research reactors, uranium mines and mills, accelerators, waste management facilities, nuclear medicine, packaging and transport of radioactive materials, industrial gauges and research involving radioisotopes.

The general requirements applicable to all licence applications are found in Section 3 of the General Nuclear Safety and Control (GNSC) Regulations [SOR/2000-202; 31 May 2000].<sup>1</sup> An applicant must, in particular, provide information on proposed measures for complying with radiation protection and nuclear security regulations and for properly managing and disposing of any radioactive waste. It must also submit information on its organisational management structure to the extent that such structure may affect its compliance with the Act and any regulations made thereunder. Additional information requirements are imposed upon an applicant for a licence to abandon a licensed activity, for the renewal, amendment, revocation or replacement of a licence [Sections 4-6].

The GNSC Regulations also impose a number of general obligations on all licensees, such as taking all reasonable precautions to protect the environment, to maintain security, to protect the health and safety of persons, and to control the release of radioactive nuclear substances or hazardous substances into the environment. Licensees are equally obliged to train and instruct their workers properly and to ensure that they observe all required safety and health procedures, to implement measures for alerting the licensee to acts of sabotage and to take all necessary measures to facilitate Canada's compliance with safeguards agreements [Section 12]. Obligations are also specifically imposed upon workers to ensure that they, too, comply with and respect the measures and precautions implemented by the licensee for whom they work [Section 17].

There are extensive reporting requirements imposed upon all licensees [Sections 27 *et seq.*], including the obligation to file both preliminary and full reports with the Commission of any potentially dangerous situation, such as unauthorised releases of radioactive nuclear substances, excessive exposure of persons to radiation, a breach of security or attempted act of sabotage, any component or system failure which could have serious adverse effects on the environment or is likely to constitute a serious risk to the health and safety of persons or the maintenance of security and any situation which could interfere with or interrupt the operation of safeguards equipment including theft, loss, sabotage, damage, illegal use, possession or removal of safeguards equipment or samples.

As a result of Canada's federal system, certain nuclear activities have sometimes been subjected to overlapping or duplicative regulation by both the federal and provincial governments. In order to address this concern, the Commission is empowered to establish administrative arrangements with other provincial legislative requirements. The Act, for example, authorises the Commission to enter into agreements with other jurisdictions that may provide for an integrated regulatory regime in respect of specific activities. It also recognises the possibility of incorporating provincial laws, standards and codes into the Commission's regulations [Section 44(6)]. The Commission also co-chairs the Federal-Provincial-Territorial Radiation Protection Committee that provides a national forum on radiation protection issues and develops standards and practices to protect people from radiation exposure.

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1 . SOR = Statutory Orders and Regulations.

## ***b) Offences, Compliance and Enforcement***

Under Section 48 of the Act, it is an offence to alter, except as permitted by the regulations or a licence, or to misuse any thing whose purpose is to protect the environment or the health or safety of persons from any risk associated with the development, production or use of nuclear energy or from any risk associated with the possession or use of a nuclear substance, prescribed equipment or prescribed information. It is equally an offence to so alter or misuse any thing whose purpose is to maintain national security or implement international obligations to which Canada has agreed, at a nuclear facility or place where nuclear substances are located. There are, in addition, many other designated offences, including failing to comply with the Act, the regulations made thereunder or a licence condition, unauthorised disclosure of prescribed information, failure to comply with an order of the Commission and falsifying records required to be kept under the Act.

The Commission is empowered under the Act [Section 29] to designate trained inspectors who are authorised to inspect nuclear facilities and places where nuclear substances, prescribed equipment or prescribed information may be kept, for the purpose of verifying compliance with the Act, any regulation, order, or decision made under the Act, or any licence condition. Amongst other things, inspectors are empowered to order a licensee to take any measures considered necessary to protect the environment or the health or safety of persons or to maintain national security or compliance with Canada's international obligations [Section 35]. Nuclear power plant licensees have resident inspectors from the Commission working full-time on site at their facilities.

In addition, the Commission has the authority to nominate and empower designated officers to perform a variety of duties, including certification of prescribed equipment, issuing, renewing, suspending, amending, revoking or replacing a licence, making any remedial action order that an inspector may make and confirming, amending, revoking or replacing any order made by an inspector [Section 37]. In most cases, orders by inspectors or designated officers must be made in accordance with prescribed rules of procedure [Section 38] and it is an offence under the Act to fail to comply with an order of a designated officer or an inspector [Section 48(e)].

Violations can be penalised by an escalating range of actions, including warnings, orders by inspectors or designated officers, licence suspension and prosecution. In addition, for offences under the Act, a convicted offender may be required by the court to pay compensation to any person who has suffered loss of, or damage to property as a result of the offence [Section 62]. Punishment for summary conviction offences consists of fines ranging up to 500 000 Canadian dollars (CAD) or imprisonment for up to 18 months or both, whereas for indictable offences the punishment ranges from fines up to CAD 1 000 000 or imprisonment for up to 5 years or both [Section 51(3)]. For unauthorised possession of a nuclear substance, prescribed equipment or prescribed information capable of being used to produce a nuclear weapon or a nuclear explosive device, the punishment is imprisonment for up to ten years [Sections 50 and 51(2)]. For all offences except the last, the defence of having exercised due diligence to prevent its commission is available [Section 51.1].

The AECB Cost Recovery Fees Regulations 1994, which have been continued in force by Section 80 of the Act, implement the Commission's authority under Section 44 of the Act to prescribe fees that may be charged for the provision of information, products and services by the Commission and for licences or a class of licence. The Regulations apply to most licence applications although publicly funded health care and educational institutions and federal departments and agencies are exempt from the fees.

**c) *Regulatory Documents***

The Commission operates within a legal framework that includes both legally enforceable instruments such as acts, regulations, licences and directives, and regulatory documents that are used to support and provide further information on these instruments. Regulatory documents are a means of informing applicants of the Commission's regulatory expectations. During the development of each regulatory document, the Commission engages in extensive consultation on all aspects of the document with all those who will be affected by it. These documents are classed as follows:

- *Regulatory policy*: a document that describes the philosophy, principles and fundamental factors used by the Commission in its regulatory programme.
- *Regulatory standard*: a document that is suitable for use in compliance assessment and describes rules, characteristics or practices which the Commission accepts as meeting the regulatory requirements. Regulatory standards can become legally enforceable when incorporated as conditions in a licence.
- *Regulatory guide*: a document that provides guidance or describes characteristics or practices that the Commission recommends for meeting regulatory requirements or improving administrative effectiveness.
- *Regulatory notice*: a document that provides case-specific guidance or information to alert licensees and others about significant health, safety or compliance issues that should be acted upon in a timely manner.
- *Regulatory procedure*: a document that describes work processes that the Commission follows to administer the regulatory requirements for which it is responsible.

**d) *Other Relevant Legislation***

Certain activities that are regulated by the Commission also require an environmental assessment under the Canadian Environmental Assessment (CEA) Act of 23 June 1992 [C-15.2]. This Act requires, subject to specific exclusions [Section 7], that an environmental assessment be carried out in respect of projects for which federal, provincial or territorial government approval is needed or for which federal land or funding is needed [Section 5]. The assessment identifies whether the project is likely to cause significant adverse environmental effects and an "environmental effect" is defined as any change that a project may cause to land, water, air, living organisms or to the natural system in which these components interact. If possible adverse effects can be identified before they occur, then decision-makers can modify the project so as to mitigate such effects.

Under both the CEA Act and the Commission licensing process, the public is given ample opportunity to participate. The Commission maintains up-to-date information on all of its current environmental assessments and the Canadian Environmental Assessment Agency, which is established under the CEA Act [Section 61], maintains a public registry of all environmental assessments conducted by Canadian Government departments and agencies, including the Commission [Section 55].

The Commission also monitors the environmental performance and compliance of its licensees to ensure that their activities are consistent with Commission licence conditions and Canada's international obligations.

There are, in addition, the Transportation of Dangerous Goods Act 1992 [T-19.01] and the Transportation of Dangerous Goods Regulations [SOR/85-77]. These Regulations establish classes of dangerous goods, an identification list of common dangerous goods and the safety requirements for identification, packaging and shipment of these dangerous goods in a manner similar to the United Nations Recommendations on the Transport of Dangerous Goods. For radioactive material, the Act and Regulations refer to the Nuclear Safety and Control Act and the Packaging and Transport of Nuclear Substances Regulations 1983 [SOR/83-740] for the specifics of health and safety protection requirements for packaging and transport. For international air and sea transport, the Transportation of Dangerous Goods Regulations refer to the appropriate international regulations of the International Civil Aviation Organisation (ICAO) and the International Maritime Organisation (IMO).

Another important Canadian statute passed by the Canadian Parliament in 1970 is the Nuclear Liability Act [R.S.<sup>2</sup> 1985, c. N-28]. This legislation addresses the issue of civil liability for damage suffered by third parties as a result of nuclear incidents at defined nuclear installations. The Act is based upon the same principles that form the basis of international conventions in this field, even though Canada is not party to any such conventions. However, in light of the rather low operator liability limit that is provided for, it is likely that the Act will be amended in the future.

## **2. Mining Regime**

Canada's constitutional arrangements result in a division of jurisdiction between the federal and the provincial governments in relation to uranium mining and milling activities. While the federal government has jurisdiction to legislate in respect of the uses of uranium, the provincial governments are responsible for enacting legislation in respect of the exploitation of all mineral resources (including uranium). As a result, uranium mining and milling activities have sometimes been subjected to regulation by both levels of government. In order to avoid such situations in the future, the Nuclear Safety and Control Act authorises the incorporation by reference of provincial laws, standards and codes into the regulations of the Canadian Nuclear Safety Commission [Section 44(6)] and authorises the Commission to enter into arrangements with provincial jurisdictions that may provide for an integrated regulatory regime in respect of specific activities [Section 21(1)(a)].

In November 2000, the President of the Commission and the Ministers of Saskatchewan Environment and Resource Management and Saskatchewan Labour signed a Memorandum of Understanding under which the Commission and the provincial regulators agreed to collaborate in the development and implementation of a harmonised regulatory regime for uranium mines and mills in Saskatchewan. Discussions between staff of the Commission and officials from the Province are currently underway.

In addition, Human Resources Development Canada, which is responsible under the Canada Labour Code for regulating labour standards, labour relations and conventional (non-nuclear) occupational health and safety matters at nuclear facilities, has, in consultation with Saskatchewan Labour, finalised regulations excluding Saskatchewan uranium mines and mills from application of Part II (occupational health and safety) of the Code, and incorporating by reference in its place a number of provincial statutes regulating conventional occupational health and safety. The administration of these regulations will be delegated to Saskatchewan Labour.

The Commission is also given the authority to make regulations respecting the mining, production and refinement of a nuclear substance [Nuclear Safety and Control Act, Section 44(1)(b)], and the term "nuclear substance" is defined in Section 2 of the Act to specifically include "uranium".

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2 . R.S. = Revised Statutes.

The Act prohibits anyone from, *inter alia*, mining, producing or refining a nuclear substance except in accordance with a licence [Section 26(b)]. The Commission is authorised to issue, renew, suspend, amend, revoke or replace licences for that purpose [Section 24(2)] and to attach conditions to those licences [Section 24(5)].

In exercising its authority under the Act, the Commission has made the Uranium Mines and Mills Regulations [SOR/2000-206; 31 May 2000] which comprise, essentially, the same requirements as were contained under the now repealed Uranium and Thorium Mining Regulations [SOR/88-243, as modified]. The Regulations do not apply to uranium prospecting or surface exploration activities [Section 2(2)], but they do impose comprehensive licensing requirements upon anyone who wishes to prepare a site for, construct, operate, decommission or abandon a uranium mine or mill.

Licence applications must be accompanied by detailed information on the activity to be licensed, the plan and description of the facility, associated environmental and waste management measures, health and safety concerns and security measures [Sections 3 and 5-8]. In addition, licence applicants (other than a licence to abandon) must provide a Code of Practice that describes the measures and procedures which the applicant will take where a specific dose of radiation or other parameter is reached, possibly indicating a loss of control of part of a licensee's radiation protection programme or environmental protection programme, and triggering a requirement for a specific action to be taken [Section 4].

In addition to setting out licensing requirements, the Regulations impose a number of specific obligations upon licensees with respect to operating procedures, worker training programmes, maintenance of ventilation systems, use of respirators, gamma radiation dose rate notices, and maintenance and availability of records required to be kept in respect of the licensed activity [Sections 9-16].

### **3. Nuclear Substances and Radiation Devices**

Under the Nuclear Safety and Control Act, the Commission is authorised to make regulations respecting, *inter alia*, the conversion, enrichment, processing, reprocessing, possession, import, export, use, packaging, transport, management, storage, disposal and abandonment of nuclear substances [Section 44(1)(b)]. Pursuant to that authority, the Commission has made the Nuclear Substances and Radiation Devices Regulations [SOR/2000-207; 31 May 2000], supplementing the General Nuclear Safety and Control Regulations, and applying to all nuclear substances, sealed sources and radiation devices not already covered by other regulations.

A "nuclear substance" is broadly defined as: deuterium, thorium, uranium, an element with an atomic number greater than 92 or any derivative or compound of any of them, a radioactive nuclide, a substance prescribed by regulation as being capable of releasing nuclear energy or as being required for the production or use of nuclear energy, a radioactive by-product of the development, production or use of nuclear energy; and a radioactive substance or thing that was used for the development or production, or in connection with the use, of nuclear energy [Nuclear Safety and Control Act, Section 2(2)]. A "radiation device" is defined under these new Regulations to mean a device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties, as well as a device that contains a radium luminous compound [Section 1]. The new Regulations also contain criteria for consumer products such as smoke detectors and safety signs using tritium. Given their broad application, these Regulations apply to almost every licensee.

In general, the Regulations reflect international practice but there are some minor variations based upon Canadian policy and circumstances. Licence applicants must provide very detailed information concerning the substance or device in respect of which a licence is sought, including information on the methods, procedures and equipment to be used to carry on the licensed activity, to be used during or following an accident to monitor nuclear substance releases, to detect and record radiation dose rates and quantities and to limit the spread of radioactive contamination within and from the site. Information is also required on the methods, procedures and equipment used to calibrate radiation survey meters and dosimeters and to conduct leak tests and surveys as well as on equipment and system inspection programmes, instructions for dealing with accidents, worker training programmes and a number of other safety related matters [Section 3(1)].

Activities that are exempt from the licensing requirements are set out in Sections 5-8 of the Regulations. Generally, they include activities involving a nuclear substance which does not exceed its exemption quantity as set out in the Schedule to the Regulations or where the quantity is considered to be an acceptable function of that exemption factor [Section 5]. In addition, exempted activities extend, under specified conditions and circumstances, to smoke detectors containing a nuclear substance [Section 6], tritium-activated self-luminous safety signs [Section 7] and other devices containing a radium luminous compound [Section 8].

Many of the Regulations' provisions deal specifically with radiation protection in the context of industrial radiography [Sections 30-35]. They impose detailed obligations on licence holders in respect of the use or possession of radiography equipment including qualifications and training of the licensee's staff, dose limits applicable to workers and non-workers, the levels of maintenance and security to be observed in relation to the equipment, procedures to be followed by anyone operating the equipment, and measurement and recording of radiation doses received by anyone who has operated the equipment. They also provide for the certification of radiation devices [Sections 11-15] and impose general obligations upon licensees with respect to the safe and proper use of nuclear substances and radiation devices by workers or others who might come into contact with such substances and devices [Sections 16-23].

Specific requirements are set out for the operation of exposure devices [Sections 24-34], including radiation sources used to radiograph structures such as pipeline welds, aircraft components and pressure vessels. The new regulations require all exposure device operators to wear an audible alarming dosimeter to alert them to dangerous levels of radiation before significant exposures occur. Previously only trainees were required to wear these devices.

Every licensee is required to keep and retain detailed records of nuclear substances in its possession or which it received, disposed of or abandoned, of workers who handled nuclear substances and the training they received, and of inspections and servicing performed by the licensee [Section 36(1)]. Similarly detailed record-keeping requirements are imposed on licensees of exposure devices [Section 37]. Finally, licensees who become aware of potentially dangerous situations, such as where an exposure device or sealed source assembly is lost, are required to make both preliminary and full reports to the Commission concerning the circumstances of the situation and what corrective or remedial measures the licensee has taken or proposes to take [Section 38].

#### **4. Nuclear Facilities**

Under the Nuclear Safety and Control Act, the definition of nuclear facilities includes reactors, particle accelerators, uranium processing plants, waste management facilities and, because their level or risk falls within the range of other nuclear facilities, plants that possess, process or use large quantities of radioactive material [Section 2]. However, since licensing criteria vary significantly for

these various facilities, they are divided into two classes of facilities, with the Class I Nuclear Facilities Regulations [SOR/2000-204; 31 May 2000] applying to major facilities such as reactors, high-energy accelerators and uranium processing facilities, and Class II Nuclear Facilities and Prescribed Equipment Regulations [SOR/2000-205; 31 May 2000] covering such things as low-energy particle accelerators, irradiators and radiation therapy installations because of the low risk these types of facilities represent.

The licensing requirements for both Class I and Class II are essentially the same as those applicable under the former legislation. Separate licences are required for constructing, operating and decommissioning the facility. In respect of Class I nuclear facilities, separate licences are also required in respect of preparing the site for the facility [Class I Nuclear Facilities Regulations, Section 4] and for abandoning the facility [Section 8]. A licence is also required in respect of the use of Class II prescribed equipment [Class II Nuclear Facilities and Prescribed Equipment Regulations, Section 6] and the equipment must either be certified by the Commission or a designed officer authorised under the Act, or be used in accordance with a licence authorising its use for development purposes [Section 10].

The Regulations set out detailed information requirements in respect of all such licence applications. These include (i) the general requirements provided for in Sections 3 and 4 of the General Nuclear Safety and Control Regulations; (ii) more specific requirements such as providing a site description and plan, quality assurance programme, proposed worker health and safety policies, environmental protection policies and decommissioning plans; and finally (iii) the precise requirements relevant to each particular type of licence, as set out in Sections 4-8 of the Class I Nuclear Facilities Regulations and in Sections 3-6 of the Class II Nuclear Facilities and Prescribed Equipment Regulations. In addition, the Class II Regulations set out special radiation protection requirements for both nuclear facilities [Sections 15-17] and prescribed equipment [Sections 18-20] to ensure personal safety of both the user of the facility or equipment and the recipient of the radiation dose administered.

The Class I Nuclear Facilities Regulations provides that senior control room staff of nuclear power reactors will now need to be re-certified as competent every five years. In order to attain such re-certification, the staff will be required to successfully complete a continuing training programme and re-qualification tests, both of which are to be administered by the licensee and evaluated regularly by the Commission [Section 9].

The Class II Nuclear Facilities Regulations requires nuclear safety service providers to be licensed. In the past, there was no regulatory control over the work performed by companies who provided technical services to Class II nuclear facility operators and to nuclear substance licence holders, such as repairing safety systems. The new Regulations now require such service providers to be licensed where they are providing nuclear-safety related services and the information required to be submitted in respect of a licence application is set out in Section 3 of the General Nuclear Safety and Control Regulations and in Section 7 of the Class II Nuclear Facilities Regulations.

Extensive record keeping requirements are imposed upon licensees of both Class I and Class II nuclear facilities and Class II prescribed equipment. For Class I facilities, these relate primarily to the results of effluent and environmental monitoring programmes, operating and maintenance procedures, the nature and amount of radiation, nuclear substances and hazardous substances within the facility, the status of each worker's qualifications and training and special reports in respect of the decommissioning of the facility [Section 14]. For Class II facilities and equipment, records shall be kept of, amongst other things, radiation surveys, radiation output from equipment, employee training, the transfer of equipment, and sealed source leak test results [Section 21].

At the international level, Canada is a Party to the 1994 Convention on Nuclear Safety, ratified on 12 December 1995. It also ratified the 1986 Convention on Early Notification of a Nuclear Accident on 18 January 1990.

## **5. Trade in Nuclear Materials and Equipment**

The import or export of prescribed equipment, prescribed information or a nuclear substance is prohibited except in accordance with a licence [Nuclear Safety and Control Act, Section 26]. The Commission is authorised to issue licences for those activities [Section 24]. In addition, the Commission is authorised to make regulations respecting the import and export of nuclear substances, prescribed equipment and prescribed information [Section 44]. That authority has resulted in the Nuclear Non-proliferation Import and Export Control Regulations [SOR/2000-210; 31 May 2000] which apply to the import and export of controlled nuclear substances, controlled nuclear equipment and controlled nuclear information [Section 2]. These include nuclear-related dual-use items.

Controlled nuclear substances are listed in the Schedule to the Regulations as including in Part A certain categories of special fissionable material, source material, deuterium and heavy water, nuclear grade graphite and tritium. Controlled nuclear equipment is shown in the same Schedule to include nuclear reactors, plants for the reprocessing of irradiated fuel elements, plants for the fabrication of nuclear reactor fuel elements, plants for the separation of isotopes of uranium, plants for the production or concentration of heavy water, deuterium and deuterium compounds, plants for the conversion of uranium and certain equipment especially designed or prepared for such reactors and plants together with parts for such reactors and plants. “Controlled nuclear information” is defined to include technical data of any kind and in any form, other than data available to the public, respecting any item listed as a controlled nuclear substance or controlled nuclear equipment. Part B of the Schedule includes nuclear-related dual-use items.

Applicants for a licence to import or export any controlled substance, equipment or information must submit an application containing specific information such as its origin, its description, its supplier and final consignee, its intended end-use and its intended end-use location [Section 3]. In general, the new Regulations increase the number of items for which import licences are required so that Canada will be in a better position to implement its international obligations with respect to the control of nuclear equipment. However, in practice, Canada imports relatively little of this equipment. Certain activities are exempt from licensing, such as the import of a controlled nuclear substance that is classified as a dual-use item and that is not a radioactive nuclide, or the import of controlled nuclear equipment that is classified as parts or a nuclear-related dual-use item [Section 4].

### **a) Exports**

Canada is a Party to the Treaty on the Non-Proliferation of Nuclear Weapons. Canada’s exports of uranium, heavy water and nuclear equipment and technology for nuclear fuel cycle use are subject to Canada’s nuclear non-proliferation policy (see Section 8 “Non-Proliferation and Nuclear Security”, *infra*).

Canada exports uranium, heavy water, nuclear reactor and other fuel cycle equipment and technology for nuclear power use. Canada also exports radioisotopes, deuterium and uranium for agricultural, medical and industrial use. Apart from the Nuclear Safety and Control Act and the Nuclear Non-proliferation Import and Export Control Regulations, Canada’s nuclear export activities are governed by the Export and Import Permits Act [R.S. 1985, c. E-19]. That Act permits the government to establish an Export Control List, whose basic purpose is to prevent the export of

articles with “a strategic nature or value” if such export could be detrimental to Canada’s security. It also permits Canada to implement its international commitments, and control the export of its natural resources [Section 5]. Anyone wishing to export an item on the Export Control List must apply to the Minister of Foreign Affairs for a permit which may be made subject to specific terms and conditions [Section 7]. Administrative arrangements ensure that terms and conditions of the permit issued under the Export and Import Permits Act do not duplicate conditions imposed on the licence issued by the Commission.

**b) Other Imports**

The possession, sale and importation of certain categories of equipment emitting radiation, but not intended for the production of nuclear energy within the meaning of the Nuclear Safety and Control Act, are governed by the Radiation Emitting Devices Act (REDA) [R.S. 1985, c. R-1]. The Minister of Health and Welfare is responsible for implementing this Act. The REDA regulates the sale, lease and importation of all devices capable of producing and emitting radiation except those that are designed primarily for the production of nuclear energy [Section 3]. The Act creates various classes of device, and regulations made under the Act prescribe standards relating to the design, construction and functioning of each class. The sale, lease or importation of a radiation emitting device that does not comply with the appropriate standard is prohibited [Section 4]. The prohibition is reinforced by the criminal law; a person convicted of an offence under the Act may be fined or imprisoned or both [Section 14].

**6. Radiation Protection**

The Radiation Protection Regulations [SOR/2000-203; 31 May 2000] contain the radiation protection requirements applicable to all licensees as well as others who fall under the jurisdiction of the Commission. Their primary focus is the protection of nuclear energy workers from the effects of ionising radiation and minimising health risks to the general public. The Regulations do not apply to medical doses, doses to non-professional caregivers and doses to volunteers in biomedical research [Section 2(2)].

Every licensee is required to implement a radiation protection programme which includes keeping the amount of exposure to radon progeny (defined as specific radioactive decay products of radon 222) and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account [Section 4]. Amongst other obligations, licensees must also ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity, and must comply with specific obligations regarding methods of ascertaining and recording doses of radiation, actions to be taken when a specific dose of radiation is reached (action level), and providing nuclear energy workers with full particulars of the risks associated with radiation to which they may be exposed [Sections 5-9].

The Regulations prescribe the maximum permissible doses and exposures for nuclear energy workers, pregnant nuclear energy workers and members of the public [Sections 13 and 14 and Schedules I and II]. Except with respect to pregnant nuclear energy workers, the new dose limits reflect the 1991 Recommendations of the International Commission on Radiation Protection (ICRP) which call for lowering the dose limits for nuclear energy workers from 50 millisievert (mSv)/year to 100 mSv for five years and for members of the public from 5 mSv/year to 1 mSv/year. As regards pregnant nuclear energy workers, the maximum effective dose to the worker during the period of

pregnancy is set at 4 mSv/year.<sup>3</sup> The Regulations provide for exceptions to the dose limits in emergency situations [Section 15], as well as prescribing actions to be taken by licensees when the dose limits received by any person exceed the applicable limit [Sections 16 and 17].

Sections 18 and 19 of the Regulations prescribe the requirements for a licence application in respect of the operation of a dosimetry service as well as the obligations imposed upon the licensee who operates such services. The latter include the obligation to file with the National Dose Registry of the Department of Health, specified information with respect to each nuclear energy worker for whom it has measured and monitored a dose of radiation.

Finally, Sections 20-22 of the Regulations set out the labelling requirements in respect of containers or devices that contain a radioactive nuclear substance, together with the radiation warning symbol and sign posting requirements in respect of an area, room, enclosure or vehicle where there are specified quantities of radioactive nuclear substances or where there is a reasonable probability that a person will be exposed to a specified dose rate.

## **7. Radioactive Waste Management**

Section 26 of the Nuclear Safety and Control Act prohibits the storage or disposal of nuclear substances, the abandonment of prescribed equipment, and the decommissioning or abandonment of a nuclear facility or a nuclear-powered vehicle except in accordance with a licence issued by the Commission. Disposal must be carried out in accordance with the conditions of a licence that has been issued by the Commission in relation to that particular substance, equipment or facility. Licence conditions in relation to waste management are aimed at ensuring the protection of health, safety, security and the environment.

Radioactive waste management facilities are nuclear facilities for the purposes of the Nuclear Safety and Control Act [Section 2], and therefore can only be operated according to the terms and conditions of a licence issued under the relevant Regulations.

In 1987, the Atomic Energy Control Board, predecessor to the Commission, issued a Regulatory Policy Statement entitled “Regulatory objectives, requirements and guidelines for the disposal of radioactive wastes – long term aspects” [Regulatory Document R-104]. The Statement sets out the objectives of radioactive waste disposal regulation as minimising the burden on future generations, protecting the environment and protecting human health and goes on to list the basic factors which must be addressed by any waste disposal proposal.

An important innovation in the licensing system under the new legislation is the authority given to the Commission to impose a licence condition requiring a licensee to provide a financial guarantee for decommissioning and waste management costs associated with the licensed nuclear facility [Nuclear Safety and Control Act, Section 24(5)]. This requirement is implemented through the General Nuclear Safety and Control Regulations that require licence applicants to provide information on proposed financial guarantees and to describe their plans for decommissioning and waste management at the end of the life of the nuclear facility [Section 3(1)]. Substantial flexibility is permitted in the ways in which licensees can meet these financial requirements, but the objective

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3. The 1991 ICRP Recommendations call for lowering the dose limits for pregnant nuclear workers from 10 mSv/year to 2 mSv/year. However, in light of comments received concerning the extent to which such a significant reduction could affect employment opportunities for women in the nuclear industry, and as a result of a comprehensive consultation process and a thorough review of the risks of radiation, the maximum effective dose was set at 4 mSv in the new Regulations.

remains constant: to eliminate the risk of such liabilities having to be borne by the public such as might occur in the case of a licensee's insolvency.

In June 2000, the Commission issued two related regulatory guides, G-219, "Decommissioning Planned for Licensed Activities", and G-206, "Financial Guarantees for the Decommissioning of Licensed Activities". Together they provide guidance regarding the preparation of decommissioning plans for activities licensed by the Commission and the criteria used to evaluate financial guarantee mechanisms that a licence applicant may propose.

At the international level Canada ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 7 May 1998. Canada is also party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter (ratified on 13 November 1975) and to its 1996 Protocol (ratified on 15 May 2000). Canada has ocean dumping control legislation<sup>4</sup> which reflects its obligations under the Convention, that is, the prohibition of dumping of high-level radioactive waste, but the legislation provides for the licensing of dumping low-level radioactive waste at sea. Recent amendments to the Convention extending the ban on dumping to low-level radioactive waste,<sup>5</sup> mean that Canada is now obliged to prohibit the dumping at sea of all radioactive waste.

## **8. Non-Proliferation and Nuclear Security**

Canada ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 8 January 1969, as well as the 1996 Comprehensive Nuclear Test Ban Treaty on 18 December 1998 and it participates actively in international atomic energy control measures. The Department of Foreign Affairs and International Trade is responsible for negotiating Canada's bilateral nuclear co-operation agreements with other countries, covering trade in nuclear materials, equipment and technology, and it does so with the participation of the Canadian Nuclear Safety Commission. It is the Commission, however, which administers them and there are currently 38 such agreements signed by Canada. In accordance with Canada's nuclear non-proliferation policy, nuclear co-operation will be authorised only for those non-nuclear weapon states that have either ratified the NPT or have taken an equivalent binding step and have thereby accepted the International Atomic Energy Agency (IAEA) safeguards on the full scope of their nuclear activities. Furthermore, nuclear exports can go forward only to those states (both nuclear and non-nuclear weapon states) that have undertaken to accept in a formal nuclear co-operation agreement a number of additional requirements designed to minimise the proliferation risk associated with Canadian nuclear exports.

Safeguards inspectors from the IAEA carry out regular inspections of Canadian nuclear installations to ensure that Canada complies with its own NPT-type full scope safeguards agreement with the Agency. The Commission facilitates the implementation of this agreement [IAEA: INFCIRC/64] by providing information on and access to nuclear material for accounting and verification.

Canada ratified the 1979 Convention on the Physical Protection of Nuclear Material on 21 March 1986. As a result of Canada's obligations as a party to that Convention, and having regard to IAEA recommendations, the Physical Security Regulations [SOR/83-77] were made under Section 9 of the now repealed Atomic Energy Control Act. With the replacement of that Act by the Nuclear

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4. The Canadian Environmental Protection Act, assented to 14 September 1999 (R.S. 1999, c. 33).

5. The ban, which is to remain in force for 25 years, became effective on 20 February 1994.

Safety and Control Act came the replacement of those Regulations by the Nuclear Security Regulations [SOR/2000-209; 31 May 2000].

The new Regulations define the licensing requirements and security measures required for the physical protection of certain nuclear materials and of nuclear reactors that may exceed 10 MW thermal power during normal operation [Section 2]. These nuclear materials are divided into Categories I, II or III, depending upon their level of risk. The composition of the three categories is set out in the Schedule to the Regulations.

A licence is required for all nuclear materials and reactor facilities covered by the Regulations [Sections 3 and 4]. In all cases, except for Category III nuclear materials which pose the least risk, the applicant must provide, amongst other information, a security plan which describes its protection arrangements with a response force, a description of its proposed security equipment, systems and procedures, its on and off-site communications equipment, system and procedures, the structure and organisation of its nuclear security guard services and its proposed plan and procedures to respond to breaches of security [Section 3].

A separate licence is required for the transport of Category I, II or III nuclear material. Applicants must submit, in particular, a transportation security plan that includes a threat assessment, proposed security measures, communications arrangements between the licensee, the vehicle operator, the recipient of the material and any response force along the route, arrangements with that response force and planned and alternate emergency routes [Section 5].

The Regulations also impose general obligations upon licensees with respect to the areas in which licensed nuclear materials may be processed, used and stored: an inner area for Category I material, a protected area for Category II material, and either a controlled access, visually surveyed or protected area for Category III material [Section 7]. Nuclear facilities to which the Regulations apply must also be located in a protected area [Section 8]. The requirements concerning the physical protection of both protected areas and inner areas are specifically set out in the Regulations as are the measures to be taken in respect of entry into and exit from those areas.

A protected area must be enclosed by a barrier constructed to prohibit any unauthorised entry into that area [Section 9] and be surrounded by an unobstructed area, maintained to ensure that the barrier is not breached [Section 10]. Protected areas must be continuously illuminated and equipped with devices that detect any intrusion and that facilitate an immediate assessment of the cause of the alarm [Section 11]. Inner area requirements are more stringent, and include a barrier constructed to prevent unauthorised access to the area or removal of Category I material therefrom before a response force can effectively intervene, more tightly secured access requirements in respect of openings in the barrier, and greater security requirements in respect of intrusion detection devices [Sections 13 and 14].

The Regulations prohibit unescorted access of any person into a protected area except with the written authorisation of the licensee [Section 17]. Unescorted access into an inner area is only allowed with the written authorisation of the Commission [Section 18]. Both the licensee and the Commission are given the power to revoke authorisations to enter a protected area or an inner area [Sections 21 and 22]. Special provisions in the Regulations exempt Commission appointed inspectors from the authorisation requirements regarding entry into protected and inner areas [Section 29].

New security requirements under these Regulations mean that licensees must install and continuously maintain additional alarm assessment equipment in protected areas and an alarm assessment system in inner areas to facilitate the immediate assessment of the cause of the alarm. In addition, licensees are required to search or otherwise monitor persons without an authorisation, and

their possessions, when entering or leaving a protected and inner area. Searches can be carried out by technical means and are similar to Canadian airport security standards [Section 27].

In respect of nuclear facilities covered by the Regulations, the licensee is required to have available a sufficient number of trained security guards to enable him to comply with the Regulations [Section 30] and the Commission must give its consent to the appointment of such guards upon application by the licensee [Section 31]. The licensee must also make written arrangements with a response force to provide for the protection of Category I and II nuclear materials and nuclear facilities [Section 35], and in addition, he must conduct security drills every six months to test the operation of security equipment, systems and procedures [Section 36].

## **9. Transport**

The Commission has the power to make regulations governing the transport of nuclear substances [Nuclear Safety and Control Act, Section 44(1)] and it has principally exercised this power by making the Packaging and Transport of Nuclear Substances Regulations [SOR/2000-208; 31 May 2000]. These Regulations revise the Transport Packaging of Radioactive Materials Regulations, 1983 [SOR/83-740], and are based upon the 1985 IAEA Recommendations for such packaging requirements, as amended in 1990. In fact, since these new Regulations make such numerous references to the IAEA Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6), the Commission has reproduced that reference material with the IAEA's approval, and it is freely available to all licence applicants.

The Regulations apply to all aspects of the packaging and transport of nuclear substances, including the design, production, use and maintenance of packaging and packages, and the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination and unloading of packages [Section 2(1)]. They require a licence for the transport of Category I, II and III nuclear material in accordance with the Nuclear Security Regulations (see Section 8 "Non-Proliferation and Nuclear Security" *supra*), except where the nuclear substances are in transit or are packaged and transported under a "special arrangement" as defined in the IAEA Regulations [Section 3]. In these latter two cases, for which licences are also required, Sections 4 and 5 describe the extensive information requirements imposed upon licence applicants.

The Regulations impose general obligations and divide nuclear materials into various categories; one category covers all fissile material while other categories apply to radioactive material of differing levels of activity. The Regulations stipulate different packaging requirements for each category of substance to be transported and set out in great detail the specifications for each type of package. Radioactive material must not be transported unless it is contained in a package whose design has been approved by the Commission. The certificate may be made subject to any limitations or conditions on the use or transport of the package that the Commission considers to be necessary in the interest of health, safety or security.

For packages originating in a foreign country, the Commission may issue a Canadian certificate that has the effect of endorsing a certificate issued by a competent authority in that country. The endorsement indicates that the Commission accepts that the design of the package meets requirements substantially equivalent to the requirements of the Canadian Regulations.

The Regulations also provide for various different safety marks which must be affixed to any package or container containing radioactive material.

## 10. Nuclear Third Party Liability

The Nuclear Liability Act [R.S. 1985, c. N-28] was passed by the Canadian Parliament in 1970 and it came into force on 11 October 1976.<sup>6</sup> It provides for compensation on a no-fault basis to third parties who have suffered injuries or damages as a result of a nuclear incident that has occurred at a designated nuclear installation or in the course of transport. The Canadian Nuclear Safety Commission is empowered under the Nuclear Safety and Control Act to designate nuclear facilities as “nuclear installations” for the purposes of the Nuclear Liability Act. Although Canada is not a party to any of the international conventions on nuclear third party liability, the Nuclear Liability Act is largely based on the principles laid down in the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy as amended, and in the 1963 Vienna Convention on Civil Liability for Nuclear Damage, as amended.

The major elements of the Act are described below.

### *i) Transboundary damage*

The operator of a nuclear installation in Canada is not liable for damage occurring outside Canada. However, the Act contains a mechanism for the making of reciprocal arrangements with other countries [Section 33(3)]. This mechanism was used in 1976, resulting in the Canada-United States Nuclear Liability Rules. Under these Rules, Canadian operators are liable for injury or damage that is suffered in the United States but caused by a nuclear incident occurring in Canada.

### *ii) Nature of liability*

The operator of a nuclear installation has a duty to ensure that no personal injury or property damage is caused by nuclear material within that operator’s control [Section 3]. In the event of a breach of this duty, the operator’s liability is absolute; in other words, there is no need to establish fault on the operator’s part [Section 4].

Two or more operators may be jointly and severally liable, but apart from this case, the operator’s liability is exclusive; no other person is liable for the damage [Section 11].

### *iii) Time limits for making claims*

A person seeking compensation from an operator of a nuclear installation for injury (other than loss of life) or for property damage must bring an action within three years from the date on which the person knew, or ought reasonably to have known, of the injury or damage; in the case of a claim for loss of life, the action must be brought within three years of the death. Regardless of these three-year rules, no action can be commenced after the end of the period of ten years from the date of the breach of the operator’s duty [Section 13].

### *iv) Insurance and other financial arrangements*

The Canadian Nuclear Safety Commission, with the approval of the Treasury Board, prescribes a basic level of insurance for each designated nuclear installation. The amount prescribed is not to

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6. A consolidation of the Act was passed in 1985 [R.S. 1985, c. N-28].

exceed 75 million Canadian dollars (CAD) [Section 15]. Where the basic insurance amount for a particular facility is less than CAD 75 million, supplementary insurance to make up the difference must be obtained, with the Canadian Government acting as reinsurer [Section 16].

The Act allows for the possibility of state intervention to provide compensation where either the CAD 75 million is likely to be insufficient to meet the claims, or the nuclear incident is such that it is in the public interest for special compensation measures to be provided [Section 18]. In such a situation, the operator's liability to claimants ceases, but in its place a liability arises to indemnify the government for amounts awarded by the Nuclear Damage Claims Commission [Sections 19 and 20]. The Commission, consisting of judges or experienced barristers, has exclusive jurisdiction to hear every claim arising from the nuclear incident and to award amounts of compensation [Section 24].

Where there is no state intervention, a person seeking compensation as a result of a nuclear accident must bring an action against the operator of the nuclear installation that caused the accident. The action must be brought in a court exercising jurisdiction in the place in Canada where the injury or damage was suffered, or, if this would result in several courts hearing claims in respect of the same incident, in a court exercising jurisdiction in the same place as the nuclear facility which caused the incident [Section 14].

## **II. INSTITUTIONAL FRAMEWORK**

In Canada, the Canadian Nuclear Safety Commission (hereinafter referred to as "the Commission") has the power to regulate nuclear activities and it exercises this power in co-operation with other federal and provincial government departments concerned. However, with regard to promoting the peaceful uses of nuclear energy, it is the Crown Corporation, Atomic Energy of Canada Ltd. which is responsible for ensuring the transfer of nuclear technology for the benefit of private industry, and for supporting the Canadian nuclear industry in international markets.

### **1. Regulatory and Supervisory Authorities**

#### ***a) Governor in Council***

Regulations made by the Canadian Nuclear Safety Commission concerning the development, production and use of nuclear energy or any other matter in respect of which it is empowered to make regulations under the Nuclear Safety and Control Act, are subject to approval by the Governor in Council. The Governor in Council appoints the members of the Commission and designates one of them as the Commission's President.

The Governor in Council may issue, by order, directives to the Commission on broad policy matters with respect to the objectives of the Commission. Such orders are binding upon the Commission and must be presented to each House of Parliament (Senate and House of Commons) [Nuclear Safety and Control Act, Section 19]. In addition, the Governor in Council is empowered to

make regulations as are considered necessary for carrying out the purposes of the Nuclear Safety and Control Act [Section 44(5)].

**b) *Minister of Natural Resources***

The Minister of Natural Resources is currently the Minister for the purposes of the Nuclear Safety and Control Act and for the Nuclear Liability Act.

Both the Canadian Nuclear Safety Commission and Atomic Energy of Canada Limited report to Parliament through annual reports submitted to the Minister of Natural Resources.

**c) *Other Ministerial Authorities***

Various other departments of the federal government have powers or functions that may relate to the nuclear energy field, the most important of which are Health, Environment, Foreign Affairs and International Trade, Human Resources Development, and Transport.

**d) *Canadian Nuclear Safety Commission (CNSC)***

The Canadian Nuclear Safety Commission is established under the Nuclear Safety and Control Act as an independent agency of the Government of Canada, replacing the Atomic Energy Control Board. It governs the use of nuclear energy and materials to protect health, safety, security and the environment and to respect Canada's international commitments on the peaceful uses of nuclear energy.

**i) *Legal status***

The Commission is a departmental corporation. It is for all purposes an agent of the federal Crown and may only exercise its powers in that capacity. While it submits annual reports on its activities to the Minister of Natural Resources, who in turn submits those reports to Parliament, the Commission remains an independent agency and is not under the supervision of the Minister.

**ii) *Responsibilities***

The Commission is responsible for regulating the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information. It does so in order to prevent unreasonable risk to the environment, to the health and safety of persons and to national security, and in order to achieve conformity with control measures and international obligations to which Canada has agreed. The Commission is also responsible for disseminating objective scientific, technical and regulatory information to the public concerning its activities, and concerning the environmental, health and safety effects of the activities which it regulates [Nuclear Safety and Control Act, Section 9].

### *Regulatory Powers*

The Commission has the authority to regulate a broad scope of activities involving the development, production and use of nuclear energy in Canada. With the approval of the Governor in Council, it may make regulations covering activities in all stages of the nuclear fuel cycle, from the mining of nuclear substances to the disposal of a major nuclear facility and including the import, export and transportation of nuclear materials. It is also empowered to make regulations respecting measures to ensure national security and compliance with Canada's international obligations in the development, production and use of nuclear energy. A detailed description of its regulatory powers is provided in Part I of this study "General Regulatory Regime".

### *Administrative Powers*

The Nuclear Safety and Control Act makes the Commission a court of record and it has all the powers necessary to carry out its duties with respect to the appearance, summoning and examination of witnesses, the production and inspection of records, the enforcement of its orders, and any other matter necessary for the due exercise of its jurisdiction [Section 20]. In particular, any decision or order of the Commission may, for the purposes of enforcement, be made a rule, order or decree of the Federal Court or of a superior court of a province and be enforced accordingly.

The Nuclear Safety and Control Act requires the Commission to hold public hearings in certain specified situations and to give a reasonable opportunity for affected parties to be heard. Section 40 of the Act, for example, sets out the circumstances in which the Commission is required to provide an opportunity to be heard in accordance with rules of procedure prescribed by it; for example, before refusing to issue or renew a licence, or before confirming an order made by an inspector or a designated officer requiring a licensee to take measures to protect the environment or the health or safety of persons. This Section also sets out the circumstances under which the Commission may, on its own initiative, conduct proceedings in accordance with prescribed rules of procedure and under which it must hold public hearings. The Canadian Nuclear Safety Commission Rules of Procedure are contained in P.C. 2000-791 of 31 May 2000. Additional provisions in the Act address the Commission's powers to rehear and redetermine decisions and orders and to hear appeals in specified cases [Section 43].

Pursuant to Section 15 of the Act, the Commission has made by-laws with regard to the management and conduct of its affairs [SOR/2000-213; 31 May 2000]. These by-laws determine the procedures to be followed in proceedings other than those to which the Canadian Nuclear Safety Commission Rules of Procedure apply. The by-laws are used for administrative requirements, such as when the Commission meets on internal matters or makes regulations or policies, or when it wishes to discuss matters of general applicability.

### *Other activities*

The Commission intends to continue the practice of its predecessor, the Atomic Energy Control Board, of granting public access to information on regulatory matters such as the granting of licences. Under this practice, the public may examine documents supporting licence applications, the reports of advisers to the Commission and the final report by the Commission's staff on any licence application, as well as the reports that licence holders are required to submit under the General Nuclear Safety and Control Regulations or the terms of licence. In addition, the Commission reports regularly, through the media, on the process of issuing licences for nuclear installations, on important events requiring that

remedial action be taken or ordered and on situations where the Commission is aware of any present or future concern for the public and the environment.

Dissemination of this information to the public is controlled by the Commission and respects the Access to Information Act [R.S. 1985, c. A-1] and the Privacy Act [R.S. 1985, c. P-21].

### *iii) Structure*

The Canadian Nuclear Safety Commission consists of seven permanent members each of whom are appointed by the Governor in Council for a term of five years which may be renewed. The President of the Commission, designated to hold that office by the Governor in Council, is a full-time member of the Commission and is its Chief Executive Officer.

The President may establish a panel of the Commission, consisting of one or more members, to exercise or perform certain powers, duties and functions of the Commission [Nuclear Safety and Control Act, Section 22].

The Commission staff implements the policies of the Commission and makes recommendations to it concerning the issuing of licences, and other regulatory matters. Some aspects of licensing are delegated to “designated officers” on the staff of the Commission.

### *iv) Financing*

The Commission’s financial resources derive in part from appropriations voted by Parliament, but as well from licensing fees or through fees charged for the provision of information, products or services. Such fees are authorised by Section 44 of the Act and are prescribed in the Cost Recovery Fees Regulations, 1994 which have been continued in force pursuant to Section 80 of the Act.

The Auditor General of Canada is responsible for auditing the Commission’s accounts and financial statements.

## **2. Public and Semi-Public Agencies**

### *a) National Research Council (NRC)*

Created in 1916 under the National Research Council Act [R.S. 1985, c. N-15] the National Research Council (NRC) is a departmental Crown corporation reporting to Parliament through a designated minister. Since its inception, the NRC has played a major role in Canada’s scientific development. Today, it constitutes a national scientific laboratory which performs much of its research in collaboration with industry and universities. It also operates a national library for science and engineering and provides support to industrial research through financial contributions and technical assistance.

The President of the NRC is currently an appointed member of the Canadian Nuclear Safety Commission, but is no longer an ex-officio appointee as was the case under predecessor legislation.

**b) *Natural Sciences and Engineering Research Council***

Formed in 1978, the Natural Sciences and Engineering Research Council is a departmental Crown corporation under the Natural Sciences and Engineering Research Council Act [R.S. 1985, c. N-21] and reports to Parliament through a designated minister. The Council promotes and supports research in the natural sciences and engineering, except the medical sciences, and advises the Minister on aspects of such research, on request.

**c) *Atomic Energy of Canada Ltd. (AECL)***

*i) Legal Status*

Atomic Energy of Canada Limited (AECL) was incorporated by the Minister of Natural Resources pursuant to powers granted under Section 10(2) of the former Atomic Energy Control Act, now renamed the Nuclear Energy Act [Nuclear Safety and Control Act, Section 89]. Its incorporation was carried out by way of patent letters issued in 1952 and, since 1977, AECL has continued its corporate status under the Canada Business Corporations Act. It is a Crown corporation wholly owned by the Government of Canada.

*ii) Activities*

AECL is a vendor of CANDU® power reactors, MAPLE (Multipurpose Applied Physics Lattice Experiment) research reactors and the MACSTOR advanced spent fuel storage systems. It engages in a wide range of research and development activities and provides nuclear engineering products and services to customers world-wide in nuclear and related industries.

AECL is currently commissioning two 10 MWth MAPLE reactors, both located at its Chalk River Laboratories. AECL designed and built the reactors, which are dedicated to the production of medical isotopes, and will operate them for MDS Nordion Inc., who will own the reactors following acceptance tests. AECL is also planning a “Canadian Neutron Facility”, a 40 MWth reactor based on MAPLE technology, to be used for fuels and materials testing and neutron research and to replace the NRU reactor’s research and materials testing capability.

*iii) Structure*

AECL is managed by a board of directors, comprising 13 members who are appointed by the Governor in Council for a three-year term that is renewable. The chairperson of the board and the president and chief executive officer of AECL are equally appointed by the Governor in Council. The appointment of subordinate officers is the prerogative of the board of directors and there are currently seven vice-presidents responsible for various aspects of the corporation’s activities.

AECL has more than 3 500 staff at its head office and engineering design centre in Mississauga, Ontario. Most of AECL’s nuclear projects are managed from this location, as are AECL’s international marketing initiatives. It also has major research and development laboratories at Chalk River, Ontario, and at Pinawa, Manitoba. It has business offices in Ottawa, Ontario and Montreal, Quebec.

AECL also has international offices in Seoul, Republic of Korea; Beijing, China; Bucharest, Romania; Ankara, Turkey; Jakarta, Indonesia; Bangkok, Thailand; and Buenos Aires, Argentina.

iv) *Financing*

The financial resources of AECL come from two primary sources: moneys which are appropriated by Parliament and revenues derived from supplying goods and services to Canadian and foreign utilities and to other companies requiring nuclear or nuclear related goods, services or technology.

Despite AECL's commercial mandate, it is an agent of the federal Crown. As a result, its research and development expenditures, capital expenditures, loans, and major transactions or undertakings are ultimately subject to either government or parliamentary approval.

AECL's annual financial statements are audited by the Auditor General of Canada and both the financial statements, together with the Auditor General's report, are submitted annually to Parliament by the Minister of Natural Resources.

# HUNGARY

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

At present there is one nuclear power station in Hungary, located at Paks, which is operated by Hungarian Power Companies Ltd. (*Magyar Villamos Művek Részvénytársaság* – formerly MVM, now MVM Rt.). The station's four units have a capacity of 1 840 MWe, generating about 40% of the country's domestic electricity production. The first Atomic Energy Act was promulgated in 1980 at the time of construction of this power station to ensure regulation of the industry. The four units at Paks came into service between 1983 and 1987 and have been subjected to what amounts to a continuous process of upgrading.

The legal regime applicable to nuclear activities in Hungary was previously governed by the Atomic Energy Act of 1980. On 10 December 1996, the Hungarian Parliament adopted a new Atomic Energy Act, which replaced the 1980 Act. The Atomic Energy Act of 1996 (hereinafter referred to as "the Act"), while preserving the basic principles of the 1980 Act, aims to conform to recent international rules and recommendations as promulgated by the International Atomic Energy Agency (IAEA) and the OECD Nuclear Energy Agency (OECD/NEA). It entered into force six months after its promulgation *i.e.* on 1 June 1997, with the exception of Sections 62-64 (concerning the Central Nuclear Financial Fund), which entered into force on 1 January 1998. As with the 1980 Act, different ministers are responsible for implementing the Act in their respective fields of jurisdiction by means of separate legal regulations. New regulations have been enacted since 1997 and thus the regulations which existed prior to that date are no longer applicable, with the exception of certain provisions of Ordinance No. 7 of 20 July 1988 regarding radioactive waste management, pending adoption of new regulations in this field.

The aim of the Act is not only to modernise Hungarian nuclear law, but also to harmonise Hungarian national law with international treaties to which Hungary is a party. The basic principles of the Act are to protect the population and the environment against the hazards generated by the peaceful uses of nuclear energy, and to improve the safety of all nuclear activities.

The Act provides that nuclear energy may only be used in the manner set out in legal regulations and under regular control by the authorities. The regulatory authorities are required, under the Act, to be independent from organisations having an interest in the promotion and development of the uses of nuclear energy [Section 5(2)].

The powers to implement the government's responsibility under the Act for the control and supervision of the safe utilisation of nuclear energy are vested in the Hungarian Atomic Energy Commission – HAEC (*Országos Atomenergia Bizottság*) and the Hungarian Atomic Energy Authority – HAEA (*Országos Atomenergia Hivatal*), as well as the ministers concerned [Section 6(2)]. The HAEC is concerned with the development of policy, as well as the overall co-ordination and monitoring of activities in the nuclear field. Its members are comprised of senior

officials of the ministries and public organisations performing regulatory tasks under the Act [Section 8]. The HAEA, on the other hand, is a regulatory authority and, as such, co-ordinates or performs the particular regulatory tasks necessary to ensure the safe application of nuclear energy [Section 17]. The responsibilities of the HAEA and HAEC are established in Government Decree No. 87/1997 (V.28) Korm.,<sup>1</sup> on Duties and Scope of Authority of the HAEC and on the Scope of Duty, Authority, and Jurisdiction for Imposing Penalties, of the HAEA. The Decree came into effect on 1 June 1997.

Various ministers and other authorities are responsible for enforcing those aspects of any particular licence granted by the HAEA which fall within their jurisdiction [Sections 19(2), 21-28 and 68]. These ministers and authorities are described, *infra*, in Part II of this study “Institutional Framework”, Section 1 “Regulatory and Supervisory Authorities”.

## **2. Mining Regime**

No radioactive ores are mined in Hungary and, accordingly, there is no legislation dealing specifically with the prospecting for and mining of such ores. General mining legislation would, therefore, apply [Act No. XLVIII of 1993, as amended by Act No. XII of 1997].

Under the Atomic Energy Act of 1996, the President of the Hungarian Mining Authority (*Magyar Bányászati Hivatal*) is empowered to enforce technical and safety aspects of mining, in so far as they relate to the activities licensed by the HAEA [Section 19(2)(h)] or licensed by the Minister for Health [Section 21(1)(g)].

## **3. Radioactive Substances, Nuclear Fuel and Equipment**

The Act states, as a general principle, that the user of nuclear energy is responsible for its safe application and compliance with safety standards [Section 10(1)]. Furthermore, the user is expressly obliged to provide the resources required for the safe use of nuclear energy [Section 10(2)].

To ensure that the user fulfils this obligation, a general regime of licensing is established under Chapter III of the Act. Where not regulated by this Act, the provisions of Act No. IV of 1957 on the General Rules of State Administration Procedures apply to the use of nuclear energy [Section 12(1)].

As regards the general regime under the Act, the HAEA has a co-ordinating role in regulating nuclear activities [Section 17(1)]. It has general responsibility for activities such as accountancy and control of nuclear materials, licensing the transport of radioactive materials as well as approval and inspection of transport packaging, co-ordination of research and development related to the safe use of nuclear energy and co-ordination of international co-operation related to the use of nuclear energy [Section 17(2)].

As will be discussed below in more detail (see, *infra*, Section 4 “Nuclear Installations”), the HAEA has particular responsibility for licensing and supervision of nuclear facilities [Section 17(2)(a)] and nuclear equipment. It also monitors the existence of a quality assurance system as prescribed in Section 11(2) of the Act.

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1. “Korm.” is the abbreviation of the Hungarian word for “government”.

The Minister for Health has responsibility for the licensing and monitoring of a wide variety of other nuclear activities. These include the ownership, manufacture, possession, storage, use and distribution of radioactive materials, as well as, *inter alia*, the ownership and use of facilities and equipment generating ionising radiation [Section 20(1)(a) and (c)]. This Minister has particular responsibility for radiation hygiene and for radioactive waste disposal facilities [Section 20(1)(d)-(h)] (see, *infra*, Section 6 “Radiation Protection” and Section 7 “Radioactive Waste Management”).

The Act does not apply to activities related to radioactive materials, nor to equipment which – due to the character and extent of ionising radiation that it can produce – does not qualify as hazardous to human life and health, or to the animate and inanimate environment [Governmental Decree No. 124/1997 (VII.18) Korm. on Radioactive Materials and Equipment Generating Ionising Radiation Exempted from the Scope of the Atomic Energy Act No. CXVI of 1996; Ordinance of the Minister for Health No. 23/1997 (VII.18) NM defining the Exemption Levels (Activity Concentrations and Activities) of Radionuclides].

In respect of both the licences issued by the HAEA and the licences issued by the Minister for Health, certain other ministers and authorities are empowered to enforce those aspects of the licence which fall within their jurisdiction. Similarly, there are provisions in the Act which give nominated ministers and authorities, some of which are the same as those nominated in the licensing provisions, the specific power to conduct inspections of or otherwise regulate those aspects of nuclear activities which fall within their jurisdiction. These various other ministers and authorities, and their respective areas of responsibility, are described in Sections 19(2), 21-28 and 68 of the Act.

In Hungary there is an itemised national accounting scheme, beginning with the production of radioactive materials, through to their disposal as radioactive waste. Under the executive orders of the Act, the Department of Nuclear and Radioactive Materials of the HAEA is responsible for the Central Registry of radioactive material as well as for the State System of Accountancy and Control of nuclear material through which the national accounting systems are maintained [Ministerial Ordinances No. 25/1997 (VI.18) IKIM and No. 39/1997 (VII.1) IKIM].

#### **4. Nuclear Installations**

##### ***a) Licensing and inspection, including nuclear safety***

In the definition section of the Act, a nuclear facility is defined as including a nuclear power plant, a nuclear district heating plant and a nuclear reactor for research and training [Section 2(g)]. Parliament’s preliminary approval is required to initiate activities for the construction of a new nuclear facility, or the addition of a further unit to an existing power plant [Section 7(2)].

Under the general regime of licensing, the HAEA is the regulatory body responsible for licensing the siting, construction, enlargement, commissioning, operation, modification, shutting down and decommissioning of a nuclear facility [Section 17(2)(a)]. The processing period for each of these licences should not exceed six months [Section 12(2)].

In addition, the HAEA is the regulatory authority for licensing of structures connected to nuclear facilities [Section 17(2)(c)]. The Act leaves many of the details of the regulatory scheme to be governed by separate regulations. Thus, a government decree was adopted to deal with nuclear safety and the procedures the HAEA should follow to ensure compliance with the legislation [Decree

No. 108/1997 (VI.25) Korm.]. Under this Decree, the Nuclear Safety Directorate (NSD) of the HAEA is nominated as the nuclear safety regulatory body, which makes decisions in the first instance in licensing, inspection and enforcement matters.

In respect of nuclear facilities, a permit from the NSD is required for: siting, construction (or enlargement), commissioning, operation, modification, permanent shutdown and decommissioning.

In respect of the equipment and nuclear fuel used in nuclear facilities, the NSD grants a general or specific permit for: manufacturing, importation, installation, commissioning (and operation), modification and decommissioning.

The NSD also grants permits for the construction, commissioning, maintenance, remodelling, rehabilitation, modification, expansion, use (other than for its original function) and demolition of nuclear buildings and structures.

In the interests of ensuring nuclear safety, the NSD is required, in all phases during the life cycle of nuclear facilities, to routinely inspect the following:

- the observance of provisions prescribed in applicable laws and regulations, including the quality assurance system of the nuclear facility;
- the fulfilment of conditions attached to licences; and
- the execution of instructions issued by the NSD.

The following nuclear safety regulations are set out in a five-volume appendix to the Decree, describing the mandatory safety requirements for nuclear facilities:

- Regulatory Procedures of Nuclear Power Plants;
- Quality Assurance of Nuclear Power Plants;
- Design Requirements of Nuclear Power Plants;
- Operation Requirements of Nuclear Power Plants;
- Regulation of Research Reactors.

Under the Act, a licence may be granted for a limited or an unlimited period of time and may be issued subject to conditions. A licence granted for a limited period may be extended upon request. A licence becomes void if it expires, if the conditions set out in the licence are not complied with, or if the nuclear equipment or facility is continuously out of operation beyond a period specified in the licence. The HAEA may withdraw a licence or limit its period of validity if the Authority determines that there has been a change in the safety conditions and level of risk which had served as the basis for issuing the licence in the first instance. Similarly, the HAEA may withdraw a licence, or limit its period of validity, if modifications to a nuclear facility or to nuclear equipment or systems are in breach of the licence to undertake the modifications [Section 14]. It should also be noted that the area surrounding a nuclear facility may be designated an exclusion zone, with restrictions on mining, land use and water usage [Sections 34-37]. Governmental Decree No. 213/1997 (XII. 1) Korm. on the Exclusion Zone of a Nuclear Facility and a Radioactive Waste Disposal Facility contains detailed provisions on this matter.

In addition to the enforcement powers set out above, the HAEA is obliged to monitor compliance with licence conditions and safety regulations, keep records of inspections and, in the event of violations, may impose fines as prescribed by separate regulations [Section 15(1)-(4)]. The Act provides that no fine can be imposed beyond six months from the date the HAEA learns of the breach, or beyond two years from the date when the licensee should have complied with its obligations [Section 15(5)].

As part of the HAEA's licensing process, other relevant administrative bodies are authorised to participate within the scope of their responsibility as defined by separate regulations [Section 17(3)]. Some of the more important ministers and bodies involved in this process are expressly provided for, with reference in the Act to their areas of competence [Section 19(2)] (for details of their responsibilities see, *infra*, Part II of this Study "Institutional Framework", Section 1 "Regulatory and Supervisory Authorities"). The applicant is obliged to attach the other prescribed regulatory licences and approvals to the licence application [Section 19(3)].

The Act also provides that the HAEA is responsible for the nuclear safety inspection of nuclear facilities [Section 17(2)(b)]. As with the licensing function, this is intended to be supplemented by inspection and regulatory powers granted under the Act to other specified ministers and administrative bodies with particular areas of interest, most of whom are referred to in the previous paragraph [Sections 22-26]. The details of these inspection powers are as determined in separate legal regulations.

In addition, it is necessary under the Act to obtain the relevant licence from the Hungarian Energy Office (*Magyar Energia Hivatal*), pursuant to Act No. XLVIII of 1994 on the Production, Transport and Supply of Electric Energy, for the construction and lawful operation of a nuclear power plant [Section 33].

Personnel operating the Paks nuclear plant receive between two and three years of classroom and on-the-job training. They must also successfully complete five weeks of simulator training on the plant's full-scope simulator before taking the qualifying examination. Once qualified, the personnel receive a day of refresher training every five weeks and about 80 hours of simulator training every year. The regulatory requirements for education, training and retraining of employees is set out by Joint Ordinance No. 49 of 2 June 1998 of the Minister for Industry, Trade and Tourism and the Minister for Culture and Public Education.

Hungary was the first Eastern European country to request an Operational Safety Review Mission of its nuclear plant organised by the International Atomic Energy Agency, which was followed by other international review missions *e.g.* on safety upgrading, independent peer review of probabilistic safety assessment etc. The general judgement was that the design of the Paks nuclear power plant is up to the safety level of other western nuclear power plants constructed at the same time and that it is operated in a safe manner.

At the international level, Hungary ratified the 1994 Convention on Nuclear Safety on 18 March 1996.

#### **b) *Emergency response***

Chapter IV of the Act deals with measures for the prevention of abnormal events and the elimination of their consequences. The user of nuclear energy is obliged to take immediate appropriate measures if an abnormal event occurs in the course of its activities and the level of ionising radiation released is or may be higher than the level permitted by the authorities [Section 42].

The termination of an abnormal event, the investigation of its causes, and the execution of measures necessary to prevent its repeated occurrence are primarily the responsibility of the user of nuclear energy. In order to prevent the occurrence of a nuclear emergency, to respond to or limit the consequences of an event that has occurred, as well as to restore the situation, the user of nuclear energy is obliged to:

- prepare a plan for emergency preparedness which has to be approved by the relevant authorities;
- establish the required conditions and verify the suitability of those conditions from time to time for an efficient emergency response; and
- co-operate with the relevant authorities to ensure adequate external assistance if the need arises [Section 43].

To the extent that the capabilities of the user of nuclear energy are exceeded in the event of a nuclear emergency, the necessary response measures become the responsibility of the authorities identified in the emergency preparedness and response plan [Sections 44 and 46].

The emergency management plan has undergone an essential change following the entry into force of Act No. LXXIV of 1999 on the Control and Organisation of the Protection against Catastrophes on 1 January 2000. Pursuant to this Act, a single leading body, the Governmental Co-ordination Committee, has been set up to deal with all types of catastrophe, as opposed to the former system where the leading role was assigned to different bodies depending on the nature of the emergency (in the case of nuclear accidents, a specific governmental committee was in charge of nuclear emergency preparedness). The Minister for the Interior heads the Governmental Co-ordination Committee; his deputy in the event of nuclear emergencies is the Director General of the HAEA (for details, see, *infra*, Part II of this Study “Institutional Framework”, Section 1 “Regulatory and Supervisory Authorities”).

Under the Act, the user of nuclear energy is obliged to report all abnormal events, or any accident resulting in personal injury, to the mayor with jurisdiction over the area, or the county or Budapest office of the State Public Health and Medical Officer’s Service (*Állami Népegészségügyi és Tisztiorvosi Szolgálat – SPHMOS*) with jurisdiction over the area, the police and the HAEA [Section 45]. The HAEA may stipulate further reporting obligations applying to nuclear facilities [Section 45(3)]. If the environment is contaminated, additional authorities must be notified [Section 45(1) and (2)].

The Act lays down the obligations of the State Public Health and Medical Officer’s Service in the event of an emergency, to prevent the proliferation of radioactive contamination and to avoid radiation injury [Section 47].

Hungary is a Party to the following conventions in the field of nuclear emergencies:

- 1986 Convention on Early Notification of a Nuclear Accident, ratified on 10 March 1987;
- 1986 Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency, ratified on 10 March 1987.

## 5. Trade in Nuclear Materials and Equipment

Hungarian controls over the export and import of nuclear materials are in line with the provisions of the Treaty on the Non-Proliferation of Nuclear Weapons. The governmental Decree on Nuclear Exports and Imports [Decree No. 121/1997 (VII.17) Korm.] updates the previous Decree of 1986. It includes the requirements and the trigger list of the Nuclear Suppliers Group (“London Club”), as well as the list of materials and equipment covered by the Non-Proliferation Treaty (“Zangger Committee List”). It also takes into account the regulations of the European Union. The HAEA is responsible for the licensing of nuclear exports and imports [Section 17(2)(h)]. For details on licensing of transport and approval of packaging, see, *infra*, Section 9 “Transport”.

## 6. Radiation Protection

The HAEA has responsibility for licensing nuclear equipment with regard to ionising radiation protection requirements, as well as for monitoring the quality assurance system prescribed under the Act [Section 17(2)(d) and (e) of the Act]. This function is performed by the Nuclear Safety Directorate of the HAEA, which is entitled to conduct inspections at licensees’ and suppliers’ premises [Decree No. 108/1997 (VI.25) Korm.].

The Minister for Health is responsible for enforcing the health and radiation protection considerations arising from the activities licensed by the HAEA [Section 19(2)(f) of the Act]. In addition, through the State Public Health and Medical Officers Service, the Minister, as part of the radiation safety procedures, carries out:

- licensing and monitoring of all activities with radioactive materials; and
- licensing and inspection of non-nuclear facilities in which ionising radiation or radioactive material is utilised (including radioactive waste repositories) [Section 20(1)(a)-(d)].

The Minister also oversees radiation protection services established in facilities utilising nuclear energy, compliance with occupational safety requirements in the field of radiation protection and data collection and evaluation relating to the national radiation situation [Section 20(1)(e)-(h)].

The area surrounding a nuclear installation may be designated an exclusion zone, comprising restrictions on mining, and on land and water usage [Sections 34-37] (see also, *supra*, Section 4(a) “Licensing and inspection, including nuclear safety”).

Ordinance No. 16/2000 (VI.8) EüM of the Minister for Health on the Execution of Certain Provisions of the Act on Atomic Energy prescribes the health requirements and radiation protection standards applicable to all activities involving the use of atomic energy, in order to protect workers and the general public against the harmful effects of ionising radiation. According to this Ordinance, practices involving the release of ionising radiation shall not be licensed and maintained, unless it can be justified that the benefit for society offsets the radiation harm that they may cause. During practices applying any radiation source, except for therapeutic medical exposures, protection and safety shall be optimised in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposure be kept as low as reasonably achievable. In the course of optimisation, economic and social factors shall be taken into account. The persons in charge of an establishment using atomic energy are required to draw up internal rules on radiation protection and to establish a radiation protection service [Section 10].

Maximum permissible doses of ionising radiation are set out for workers and certain members of the public [Section 3 and Annex 2]. Training of staff engaged in activities involving the use of atomic energy is also provided for [Section 8].

## 7. Radioactive Waste Management

Under the Act, the Parliament's preliminary approval is required for the establishment of a new radioactive waste disposal facility [Section 7(2)].

The Minister for Health, through the State Public Health and Medical Officer Service, is responsible for licensing and monitoring the siting, construction, commissioning, operation, modification and closing of radioactive waste disposal facilities [Section 20(1)(d)]. Pursuant to Section 21 of the Act, other ministers and authorities are responsible for enforcing specified aspects associated with the licensing of the waste disposal facility. For details, see, *infra*, Part II of this Study "Institutional Framework", Section 1 "Regulatory and Supervisory Authorities".

A licence for the application of nuclear energy will only be granted if the safe interim storage or final disposal of the radioactive waste or spent fuel can be assured in accordance with the most recent scientific knowledge and experience [Section 38(1)]. Under the Act, the interim storage and final disposal of radioactive waste and spent fuel shall be considered safe if (a) the protection of human health and the environment is ensured during the whole period of these activities, and (b) the effect on human health and the environment is not higher beyond the country's borders than that accepted within the country [Section 38(2)].

Facilities for the interim storage or final disposal of spent fuel are nuclear facilities and the Nuclear Safety Directorate of the HAEA may regulate their operation. The interim storage of radioactive waste and spent fuel is licensed only for a limited period of time [Section 39]. In recognition of the importance of this issue on the national scale, the Act provides that the performance of tasks related to the final disposal of radioactive waste, as well as the interim storage and final disposal of spent fuel and decommissioning of a nuclear facility, will be restricted to an organisation designated by the government [Section 40].

The licensee is liable to cover the costs of the final disposal of radioactive waste, as well as the interim storage and final disposal of spent fuel (or, in the case of organisations funded by the national budget, the costs will be funded by the budget) [Sections 41 and 63(1)]. For this purpose the Central Nuclear Financial Fund (*Központi Nukleáris Pénzügyi Alap*) was established (as of 1 January 1998). The fund is managed by the HAEA and is a separate state fund pursuant to Act XXXVIII of 1992 on Public Finance, exclusively earmarked for financing the construction and operation of facilities for the final disposal of radioactive waste, as well as for the interim storage and final disposal of spent fuel, and the decommissioning of nuclear facilities [Section 62]. Payments into the fund by licensees of nuclear facilities will be determined in such a way that the fund fully covers all the costs arising from the waste management, interim storage and final disposal of spent fuel, both during the operation of the facility and at the time of its decommissioning [Section 63(2)]. In the case of a nuclear power plant, payments made by the licensees to the fund should be taken into account when pricing electricity [Section 63(4)]. Order No. 67/1997 (XII.18) IKIM of the Minister for Industry, Trade and Tourism specifies the rules on the operation and administration of this Fund.

Governmental Resolution No. 2414/1997 (XII.17) Korm. authorises the Director-General of the HAEA to establish the Public Agency for Radioactive Waste Management (PURAM). In accordance with the relevant government decrees and resolutions [see Governmental Decree No. 240/1997 (XII.18) Korm. on Establishment of the Organisation Designated for Implementing Radioactive Waste

Disposal and Spent Fuel, as well as Decommissioning of Nuclear Installations, and on the Financial Resources Necessary to Perform these Tasks], the PURAM attends to the planning, construction and management duties associated with the storage and disposal of radioactive waste and spent fuel. It is also responsible for activities related to the decommissioning of nuclear facilities, as well as for the operation of the Püspökszilágy Radioactive Waste Treatment and Disposal Facility and the Interim Storage Facility for Spent Fuel located at the Paks Nuclear Power Plant. The PURAM's duties include preparation of the annual, intermediate and long-range plans for the Central Nuclear Financial Fund.

Detailed regulations for radioactive waste management will be set out in a special Ministerial Ordinance currently under preparation. Until its entry into force the regulations laid down in Ordinance No. 7 of 20 July 1988 of the Minister for Health remain applicable, with the exception of those parts of Ordinance No. 7 which were already replaced by Ordinance No. 16/2000 (VI.8) EüM. Some special geological aspects are regulated by the Ordinance of the Minister for Industry, Trade and Tourism No. 62/1997 (XI.26) IKIM on the Geological and Mining Requirements for the Siting and Planning of Nuclear Facilities and Radioactive Waste Disposal Facilities.

In the past, spent fuel from the Paks plant was sent back to Russia for reprocessing. In 1992, however, Russia passed legislation prohibiting the import of foreign radioactive waste, and since that time the reshipment has required lengthy, case by case, negotiation. At the same time Ukraine became a transit state and a trilateral governmental agreement was concluded between the Russian Federation, Ukraine and Hungary to provide an appropriate legal framework for the shipments. With storage space in its spent fuel pools running low, and future acceptance of spent fuel by Russia uncertain, the Paks plant awarded a contract to GEC Alstom Engineering Systems in 1992 for the construction of a modular vault dry storage system. The HAEC issued a licence for the commissioning of the facility in February 1997. The first fuel assemblies were received by the facility in September 1997, and seven modules are currently in operation (each of which can store 450 assemblies) with a further four modules under construction.

In 1993, a national project was launched to select a site for the disposal of low and intermediate level waste from the nuclear power plant, and exploratory work is now under way to identify a site for detailed research. A site for a high-level waste repository in the Mecsek Mountains is also under preliminary study.

On 2 June 1998, Hungary ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. It has also been a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter since 6 March 1976, following its ratification on 5 February 1976.

## **8. Non-Proliferation and Physical Protection**

Hungary ratified both the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 27 May 1969, and the 1996 Comprehensive Nuclear Test Ban Treaty, on 13 July 1999. It also ratified the 1979 Convention on the Physical Protection of Nuclear Material on 4 May 1984.

As a non-nuclear weapon state it has subjected all of its nuclear activities to the provisions of the safeguards agreement, which it signed with the IAEA on 30 March 1972, and obliged itself to keep strict accountancy and control of all nuclear materials. The Act and its executive orders make the Director-General of the HAEA responsible for these actions. The General Nuclear Directorate (more precisely, the Department of Nuclear and Radioactive Materials) of the HAEA runs the State System of Accountancy and Control. Hungary signed the Additional Protocol to the Safeguards Agreement with the IAEA [Act No. XC of 1999] and it entered into force on 4 April 2000.

Hungary also contributes to the international control of nuclear materials through its export and import controls, which include the requirements and the trigger list of the Nuclear Suppliers Group, as well as the Zangger Committee list. It also takes into account similar regulations and controls of the European Union. Pursuant to Decree No. 121/1997 (VII.17) Korm. issued under the Act, in the case of nuclear exports or imports, the prior approval of the Department of Nuclear and Radioactive Materials of the HAEA is required in the general licensing procedure for internationally controlled goods and technologies carried out by the Export Control Office of the Ministry for Economic Affairs.

Express provision is made in the Act for the guarding and protection of nuclear facilities. This is stated to be the responsibility of the licensee, as required in separate regulations, through the use of armed security guards [Section 30(1)]. In addition, the Act provides for the possibility of protection of nuclear facilities, pursuant to separate legislative provisions, by the national security services [Section 30(2)]. The Act empowers the police to monitor compliance with regulations relevant to public security and domestic order [Section 30(3)]. The police, pursuant to separate regulations, are also responsible for issuing an approval, as a special authority, for nuclear facilities and facilities used for the final disposal of radioactive waste [Section 30(4)]. Similarly, the police, under separate regulations, issue licences for transporting fresh and spent nuclear fuel within Hungary and across its borders [Section 30(5)]. Further details are governed by separate regulations, namely Ordinance No. 47/1997 (VIII.26) BM of the Minister for the Interior on the Tasks of the Police in connection with the Use of Atomic Energy.

## **9. Transport**

The HAEA is responsible under the Act for the licensing of nuclear exports and imports, transport of radioactive materials in accordance with the regulations for the transport of dangerous goods, and for the approval and inspection of packaging of radioactive materials [Section 17(2)(h)-(j)]. The approval of the packaging and the notification of their transport are performed by the Department of Nuclear and Radioactive Materials of the HAEA, with the expert support of the Institute of Isotopes and the Surface Chemistry Research Centre of the Hungarian Academy of Sciences.

There are a number of relevant international transport regulations in force, implemented by the following:

- Ordinance No. 20/1979 (IX.18) of the Minister for Transport, Communication and Water Management, which implements the provisions of the European Agreement concerning the International Carriage of Dangerous Goods by Road;
- Ordinance No. 2/1982 (II.22) of the Minister for Transport, Communication and Water Management, which implements the provisions of the draft European Agreement on the International Carriage of Dangerous Goods by Inland Waterway; and
- Ordinance No. 12/1990 (IV.30) of the Minister for Transport, Communication and Water Management, which implements the provisions of the International Regulations concerning the Carriage of Dangerous Goods by Rail.

Further Ordinances by the Minister for Transport and Water Management include:

- No. 13/1997 (IX.3) KHVM on Promulgation of the Regulation on the Safe Transport by Railway of Spent Nuclear Fuel;
- No. 14/1997 (IX.3) KHVM on Transport, Carriage and Packaging of Radioactive Material, as amended by Ordinance No. 11/2000 (XI.10) KöViM.

## **10. Nuclear Third Party Liability**

Hungary was the first Eastern European State to become a Party to the 1963 Vienna Convention on Civil Liability for Nuclear Damage (accession on 28 July 1989) and to the 1988 Joint Protocol on the Application of the Vienna Convention and the Paris Convention (approved on 26 March 1990).

Chapter V of the Act implements these international obligations. Thus, there is strict liability, channelled to the licensee (operator) of the nuclear facility, for all nuclear damage, except as provided for by the Act [Sections 48(1) and 51]. In the case of international carriage, the location where the liability is transferred is required to be stated in the contract [Section 48(2)]. Exemptions from liability are limited to external causes (armed conflict, war, civil war, armed uprising or a grave natural disaster of an extraordinary character) or if the damage suffered by the injured party was caused by the injured party's gross negligence, or is the consequence of a wilful and unavoidable act or omission of the injured party which was expressly aimed at creating the danger [Section 49].

The liability of the licensee is limited to Special Drawing Rights (SDR) 100 million per nuclear accident arising in a nuclear facility, and SDR 5 million per accident arising during the transport or storage of nuclear fuel. Nuclear damage in excess of this amount will be compensated by the state, provided the total amount does not exceed SDR 300 million. Compensation will be paid in Hungarian currency, based on the official exchange rate with the SDR [Section 52].

Where damage is caused by another event jointly with the nuclear accident, and the two cannot be separated, the damage caused by the other event will be classed as nuclear damage. Two or more nuclear facilities operated at the same site by the licensee will be treated as one nuclear facility for the purposes of compensation [Section 53(4)].

If there is nuclear damage falling outside the scope of the Act, the person responsible for the release of ionising radiation is liable therefor under Section 345 of the Civil Code [Section 53(1)].

The licensee is obliged to provide for insurance or another form of financial security up to the amount of compensation specified in Section 52 of the Act [Section 54(1)]. The insurer or financial guarantor is not permitted to suspend or cancel the insurance or financial security without giving at least two months notice in writing to the HAEA and the licensee [Section 54(2)], or in the case of carriage of nuclear materials, it may not be cancelled or suspended during the period of carriage [Section 54(3)].

The amount of liability under Section 52 of the Act does not include the interest and costs associated with the nuclear damage, as determined by the relevant court [Section 56(1)]. If the amount available for compensation is not enough to satisfy the entitlements of the injured parties, then the amount due to each of them will be reduced proportionately [Section 56(3)].

Injured parties may claim their right to compensation within a three year limitation period, commencing on the date when the injured party learned or could have learned of the occurrence of the

damage and the identity of the licensee responsible; the licensee shall not be liable for damage after ten years from the date of the occurrence of the nuclear accident [Section 57(1) and (2)]. If the nuclear damage was caused by an abnormal event resulting from nuclear material which was stolen, lost, jettisoned or abandoned at the time of the abnormal event, the period of limitation shall commence from the date of the abnormal event, but shall not exceed twenty years from the date of the events listed [Section 57(3)].

No compensation is due to any party that has received full compensation for the same nuclear damage under any other cause of action [Section 59]. The Municipal Court of Budapest has exclusive jurisdiction to judge compensation claims under the Act [Section 65(1)] Governmental Decree No. 227/1997 (XII.10) Korm. on the Features, Conditions and Amounts of the Insurance or Other Financial Security related to Liability for Nuclear Damage provides for further details.

As regards insurance against nuclear liability claims, eleven Hungarian Insurers representing the vast majority of the Hungarian insurance market's non-life capacity, established the Hungarian Nuclear Insurance Pool at the end of 1996, the so-called "Hungarian Atomic Pool". The Pool is based on the fundamental principles common to all nuclear pools and is organised and managed by the Hungaria Insurance Co., the largest of such companies. The Hungarian Pool provides third party liability coverage for the Paks nuclear power plant in accordance with the Act. Property insurance is expected to be provided in the future as well. The Paks nuclear power plant is the first Russian designed plant to have third party liability insurance cover.

## II. INSTITUTIONAL FRAMEWORK

### 1. Regulatory and Supervisory Authorities<sup>2</sup>

#### a) *Hungarian Atomic Energy Commission (HAEC)*

Under the Act, the Hungarian Atomic Energy Commission – HAEC (*Országos Atomenergia Bizottság*), as a governmental committee, has various roles which are described in broad terms [Section 8(2)]. In its policy role, it is obliged to take a position on government proposals and programmes involving the use of nuclear energy and on issues of national and international significance related to regulating the use of nuclear energy, nuclear safety and radiation protection. It is also required to monitor international trends in the field of nuclear energy and make proposals to the government for corresponding domestic measures [Section 8(2)(a)]. The HAEC co-ordinates activities related to the safe use of nuclear energy which fall within the scope of authority of the government, the HAEA and other bodies stipulated in the Act [Section 8(2)(b)]. Finally, in its role as controller, it monitors in particular the enforcement of regulations related to the use of nuclear energy, and, based

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2. In addition to the ministers and authorities specifically listed, the building authority responsible for the area concerned is responsible for enforcing the general considerations related to regional planning and building [Sections 19(2)(g) and 21(f)].

on the findings arising out of its inspections, it initiates actions and makes proposals for amendment of the applicable legislation or draws up new draft legislation [Section 8(2)(c)].

The President of the HAEC is appointed by the Prime Minister. The members of the HAEC are senior officials of the Ministries and central public administration organisations performing regulatory tasks pursuant to the Act. They are appointed by the ministers and directors of the organisations concerned, with the agreement of the President of the HAEC [Section 8(1)]. The President of the HAEC presents an annual report to the National Assembly on the safe use of nuclear energy [Section 8(7)]. Presently, the President of the HAEC is the Minister for Economic Affairs, who performs this task independently of his responsibilities as Minister.

**b) *Hungarian Atomic Energy Authority (HAEA)***

The Hungarian Atomic Energy Authority – HAEA (*Országos Atomenergia Hivatal*) plays a central role in the regulation of the use of nuclear energy in Hungary [Section 6]. Pursuant to the Act, it regulates certain activities (in particular, the licensing of nuclear facilities) and co-ordinates the regulation of other activities by Ministries and administrative bodies specified under the Act and regulations [Sections 17 and 19].

The Director-General and the Deputies of the HAEA are appointed by the Prime Minister. The government exercises supervision over the HAEA through the President of the HAEC [Section 8(6)], who is one of the members of the government [Section 8(1)].

Within the HAEA, the Nuclear Safety Directorate (NSD) makes decisions in the first instance on licensing and enforcement matters. The Director-General of the HAEA is the decision maker in the event of an appeal against the decision of the NSD and there is the further possibility of a final appeal to the administrative court.

The NSD established a multipurpose Centre for Emergency Response, Training and Analysis equipped with hardware and software tools for independent analysis of abnormal events and accidents, giving estimations on the duration of incidents, and the possible escalation of the consequences of accident scenarios (by calculating source term), and by predicting environmental effects and proposing appropriate interventions. The centre also serves for the training of regulatory staff members using simulators and provides them with Probabilistic Safety Assessment based tools to assist in their everyday decision-making work.

The General Nuclear Directorate of the HAEA, through its Department of Nuclear and Radioactive Materials, runs the State System of Accountancy and Control of nuclear materials and the Central Registry of radioactive materials from their production to their disposal as radioactive waste.

The HAEA co-ordinates and supervises research and development in all fields of nuclear safety. It is also responsible for financing the scientific and technical work as support for the regulatory and nuclear emergency preparedness tasks.

**c) *Minister for Health***

The Minister for Health has responsibility for the licensing and monitoring of a number of nuclear activities specified in the Act [Section 20]. These include the ownership, production, possession, storage, use, and distribution of radioactive materials, as well as, *inter alia*, the ownership and use of equipment generating ionising radiation [Section 20(1)(a) and (c)]. Of particular importance

is the Minister's power to licence and monitor radioactive waste disposal facilities [Section 20(1)(d)] and to supervise occupational radiation protection services and other matters related to radiation hygiene [Section 20(1)(e)-(h)].

**d) *Minister for the Interior***

The Minister for the Interior, through the offices of the National Police Force and the Directorate General for National Emergency Management (including the Fire Protection and Civil Defence Service), enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities relating to public and domestic order, fire protection, physical protection, security, civil defence and nuclear emergency management [Sections 19(2)(a), 21(a) and 22].

**e) *Minister for Agriculture and Regional Development***

The Minister for Agriculture and Regional Development, through the offices of the Animal Health and Food Control Stations, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities associated with the use of nuclear energy relating to food, plant and animal hygiene, as well as soil protection [Sections 19(2)(b), 21(b) and 23].

**f) *Minister for Economic Affairs***

The Minister for Economic Affairs, through the Hungarian Geological Survey, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities relating to geology [Sections 19(2)(c) and 21(c)] and generally is responsible for the inspection of radioactivity of raw materials used or imported for the production of building materials [Section 24].

**g) *Minister for Transport and Water Management***

The Minister for Transport and Water Management, in respect of HAEA licences, enforces those licensing aspects of nuclear facilities and nuclear equipment and radioactive materials associated with water utilisation, protection of ground water and mitigation of water damage [Section 19(2)(d)] and, in respect of licences issued by the Minister for Health, including licences issued for radioactive waste disposal facilities, enforces those aspects related to traffic and transport as well as the previously mentioned matters relating to water supplies [Section 21(e)].

**h) *Minister for the Environment***

The Minister for the Environment, in respect of licences issued by the HAEA and by the Minister for Health, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities relating to environment protection, nature conservation and water quality protection [Sections 19(2)(e) and 21(d)] and is generally responsible for the inspection of the radioactive contamination of the air, land and water environments [Section 25].

***i) Minister for Defence***

The Minister for Defence, as detailed in separate regulations, is responsible in defence matters for the control of handling of radioactive materials, as well as for the construction, operation and closing down of military facilities and equipment which fall within the scope of the Act. In respect of the Hungarian Army, the Medical Officer's Service of the Army performs the same tasks handled by the Minister for Health in the civilian context under Section 20 of the Act, other than in respect of radioactive waste disposal facilities or the central collection and processing of data relating to a national radiation situation [Section 26].

***j) Minister for Education***

The Minister for Education is responsible for integrating into the National Master Curriculum the requirement to provide education on the scientific, technical and radiation protection aspects of the use of nuclear energy. The Minister also regulates higher and postgraduate education in the field of the application of nuclear energy in co-operation with the relevant professional institutions and ministers [Section 28].

***k) President of the Hungarian Mining Authority***

The President of the Hungarian Mining Authority (*Magyar Bányászati Hivatal*) is responsible for enforcing the technical and safety considerations relating to mining under the licence regime administered by the HAEA [Section 19(2)(h)] and the licensing regime administered by the Minister for Health [Section 21(g)].

***l) President of the National Measurement Authority***

The President of the National Measurement Authority (*Országos Mérésügyi Hivatal*), as determined in separate regulations, is required to perform the regulatory tasks related to measuring instruments in connection with the use of nuclear energy [Section 27].

***m) Governmental Co-ordination Committee***

The Governmental Co-ordination Committee, responsible for emergency management, is headed by the Minister for the Interior; his deputy in the event of nuclear emergencies is the Director General of the HAEA. The Committee consists of high-ranking representatives of the ministries and national organisations involved in the particular catastrophe. Two sub-committees of the Governmental Co-ordination Committee – the National Defence Committee and the Operational Staff – serve as vehicles to assist decision-making in the event of a nuclear emergency. These sub-committees include expert representatives of the ministries and national organisations involved in nuclear emergencies among their members.

The Directorate General for National Emergency Management manages a Nuclear Emergency Information Centre which is also responsible for decision-making, together with the National Environmental Radiation Monitoring System and the Centre of Emergency Response, Training and Analysis of the HAEA. The HAEA furthermore serves as the International Contact Point.

## 2. Advisory Bodies

### *Scientific Board*

The Scientific Board is the advisory body of the HAEC and the HAEA on all matters of importance concerning the safe use of nuclear energy. It consists of prominent members of the Hungarian Academy of Sciences, research institutions and universities. It is convened two or three times a year and formulates directives on current issues.

## 3. Public and Semi-Public Agencies

### a) *Institute for Electric Power Research (VEIKI)*

VEIKI was established in 1964. It has been functioning as a company with share capital since 1 January 1993, with its shares being fully owned by the state. The capital of the company is 330 million Hungarian Forint (HUF).

VEIKI is responsible for solving the operational problems of power plants (both conventional and nuclear). In the nuclear field its main duty is the independent evaluation of safety of VVER-type nuclear power plants, as well as the development of methods necessary for the evaluations. VEIKI acts as one of the technical support organisations of the HAEA.

About 10% of VEIKI's annual income comes from the state budget, with the major part of the remainder coming from contracts with domestic industry. Less than 10% of its budget is derived from international projects (PHARE, US DOE, IAEA, bilateral contracts).

### b) *Atomic Energy Research Institute (AEKI)*

AEKI is one of the research institutes of the Hungarian Academy of Sciences. It is responsible for independent nuclear safety research in Hungary and for the operation of the Budapest Research Reactor. An additional responsibility of AEKI is to act as the technical support organisation of the HAEA.

This Institute takes part in various European Union projects (4<sup>th</sup> and 5<sup>th</sup> Framework Programmes etc.).

### c) *Institute of Isotope and Surface Chemistry*

The Institute of Isotope and Surface Chemistry, within the Chemical Research Centre of the Academy of Sciences, provides expert advice through its laboratories to the HAEA and conducts related research and development in the following areas:

- illicit trafficking of nuclear and radioactive materials;
- safeguards-related measurement techniques;
- computerised accountancy of radioactive materials at national level;

- nuclear material accountancy at the level of a material balance area.

**d) *Department of Physical Chemistry of the University of Veszprém (Ve)***

The Department of Physical Chemistry of the University of Veszprém was established in 1950. The research activity of the Department in the field of nuclear corrosion processes started in 1980. During the initial period, special attention was paid to the water chemistry problems of VVER-type reactors, and a close relationship was built up between this Department and the Paks Nuclear Power Plant during the years. Since the early nineties, the Department has also developed co-operation activities with the Department for Energy of the Technical University of Budapest, resulting in the development of new secondary water chemistry of the Paks NPP.

In 1998, the Department became the technical support organisation for the HAEA. Its main research fields are primary and secondary water chemistry of VVER-type reactors, corrosion problems of stainless steel, concrete, and coatings.

**e) *Hungarian Power Companies Ltd. (MVM Rt.)***

The MVM company was restructured as part of the country's move towards a market economy. It became a company with share capital on 1 January 1992, with the government holding all the shares. MVM Rt. was a holding company with its subsidiaries consisting of eight generating corporations, six regional distribution corporations and one transmission system corporation. In April 1994, the Hungarian Parliament adopted a new electricity law, clearing the way for the sale of MVM Rt.'s non-nuclear subsidiaries.

In recent years there have been significant changes in the Hungarian power system and in the environment determining its operation. The system has operated under new regulations since 1995. The first phase of privatisation, which concerned each of the six regional power distribution companies and six of the eight power plant companies, has been completed. The majority of these companies have become the property of trade investors. The nuclear power station (Paks Nuclear Power Plant Ltd.) and the transmission system company (National Power Line Company Ltd.) are almost 100% owned by MVM Rt. The new regulations and the privatisation created the necessary conditions for operating the electricity industry in a competitive environment. The transformation of the industry was performed without jeopardising the security of the consumers' supply.

According to the regulations in force, the basic role of MVM Rt. is to control the operation of the national power system, as well as electricity transmission and wholesale. This includes *inter alia* electricity export and import. MVM Rt. purchases electricity from the power plants or import sources, and sells it to the distribution companies. During its operation, MVM Rt. must ensure the optimal utilisation of the power plants and the national grid, at the lowest possible cost.

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

In Italy, the regulatory regime for nuclear activities is based largely on four legislative instruments:

- The first, Framework Act No. 1860 of 31 December 1962 on the Peaceful Uses of Nuclear Energy, introduced a general regime based on a series of procedural requirements such as notifications and licences. This Act was amended by Presidential Decree No. 1704 of 30 December 1965. Other amendments were subsequently made under which small quantities of special fissile materials, raw materials and other radioactive materials laid down by Ministerial Decree were no longer subject to such formalities [Act No. 1008 of 9 December 1969; Ministerial Decree of 15 December 1970];
- The second basic text is Legislative Decree No. 230 of 17 March 1995. This Decree, which came into force on 1 January 1996, mainly deals with matters related to the safety of nuclear installations and the protection of workers and the general public against the hazards of ionising radiation arising from the peaceful uses of nuclear energy. Decree No. 230/95 provided, *inter alia*, for the implementation of existing Euratom Directives on radiation protection.
- The third text is Legislative Decree No. 241 of 26 May 2000, which entered into force on 1 January 2001. This Decree amends and completes Decree No. 230/95 while taking into account the provisions 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, in particular with regard to natural sources of ionising radiation, interventions and possible exposure.
- The fourth instrument is Legislative Decree No. 187 of 26 May 2000, which implements 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, and repealing Directive 84/466/Euratom. This Decree entered into force on 1 January 2001 and repealed those provisions governing medical exposure which were set out in Decree No. 230/95.

A series of decrees has been made in implementation of Act No. 1860/62 and other decrees are expected to implement Decree Nos. 230/95, 241/00 and 187/00. Pending the adoption of these implementing Decrees, the technical annexes to the above-referenced Decrees remain in force.

These instruments, in addition to other acts, decrees and regulations which do not concern nuclear activities exclusively, constitute the framework for nuclear legislation in Italy.

At the end of the 1980s, important changes were made to the traditional legislative procedure. The key stage in this process was the adoption of Act No. 86 of 9 March 1989, pursuant to which Italy can incorporate European Union regulations, including Euratom regulations, into its internal legislation by means of a simplified and quasi-automatic procedure. More specifically, Parliament adopts a Community Act each year reporting on the situation and authorising the government to take the measures required to implement Community law. Such measures allow national rules, no longer in conformity with EU requirements, to be amended or repealed as necessary, and provide for the adoption of new provisions. The essential aim of this procedure to accelerate the incorporation of Community regulations is to bring legislation up to date as quickly as possible.

With regard to radiation protection, the first Act [No. 212], adopted on 30 July 1990, provided, *inter alia*, for the implementation of Council Directives 80/836/Euratom, 84/467/Euratom and 84/466/Euratom. Since the Community Act for the year 1990 [No. 428 of 29 December 1991] did not refer to these Directives, in order to allow the government additional time for their implementation, they were incorporated into the Community Act for the year 1991 [No. 142 of 19 February 1992]. The above-mentioned Directives have been supplemented from time to time by the most recent Directives on radiation protection, *i.e.* Council Directives 89/618/Euratom, 90/641/Euratom, 92/3/Euratom, 96/29/Euratom and 97/43/Euratom. Pursuant to the Community Acts, the government has to adopt legislative decrees with a view to implementing the requirements prescribed by these Directives into domestic law. Therefore, Decree No. 230, as cited above, was amended by Decrees Nos. 241/00 and 187/00 successively, pursuant to Community Act No. 25 of 5 February 1999 which refers to Council Directives 96/29/Euratom and 97/43/Euratom.

Furthermore, in respect of the institutional framework, mention should be made of Act No. 933 of 1 August 1960 establishing the National Nuclear Energy Commission (*Comitato Nazionale per l'Energia Nucleare* – CNEN). Following its first re-structuring in 1971 [Act No. 1240 of 15 December 1971], the Commission was extensively re-organised again through an Act of 1982, which changed its name and extended its powers. The CNEN became the ENEA, namely the National Commission for Research and Development of Nuclear and Alternative Energy Sources (*Comitato Nazionale per la Ricerca e per lo Sviluppo dell'Energia Nucleare e delle Energie Alternative*). Hence, the ENEA's activities were extended to other energy sources (except for hydrocarbons) [Act No. 84 of 5 March 1982]. However, this latter reform was also of short duration. Act No. 282 of 25 August 1991 redefined the ENEA's goals and responsibilities and renamed it as the National Agency for Nuclear Technologies, Energy and the Environment (*Ente per le Nuove Tecnologie, l'Energia e l'Ambiente*). In addition to its previous responsibilities in relation to nuclear safety and radiation protection, it now also deals with environmental questions and new technologies. In January 1999, the ENEA was further re-structured (see *infra*, Part II “Institutional Framework”).

Mention should also be made of the three referenda organised in 1987, when the anti-nuclear coalition won a resounding majority, obliging Parliament to announce a five-year moratorium on the construction of new power plants [Decision of 18 February 1987]. Although the moratorium came to an end in 1992, no official decision has yet been taken in this respect by the Italian authorities. At the present time, Italy's nuclear energy output is zero since its reactors in service have been closed down (*Caorso*) and are in the process of being decommissioned (*Trino*, *Latina* and *Garigliano*) since 1990. Lastly, the as yet unfinished power plant of *Montalto di Castro* has been reconverted into a multi-fuel plant equipped with gas turbines.

## 2. Mining Regime

Concessions for the mining of radioactive ores listed in Article 197(4) of the Euratom Treaty are granted in accordance with the provisions of a Royal Decree of 1927 on Mines, as amended by Presidential Decree No. 620 of 28 June 1955 [Section 2 of Act No. 1860/62]. This Decree lays down rules for the granting of permits for prospecting and mining concessions for ores in general. Concessions are granted following consultations with the Higher Council for Mines.

Furthermore, the protection of workers in mines against ionising radiation is regulated by the above-mentioned Legislative Decree No. 230/95 and, in greater detail, by a Ministerial Decree of 13 May 1978 (made in implementation of the above-mentioned Presidential Decree No. 185/64) on the Radiation Protection of Miners (see *infra*, Section 6 “Radiation Protection”).

## 3. Radioactive Substances, Nuclear Fuel and Equipment

Regulations governing activities connected with radioactive substances, nuclear fuels and nuclear equipment are set out in Act No. 1860/62 on the Peaceful Uses of Nuclear Energy, in the decrees implementing Presidential Decree No. 185/64, as well as in Legislative Decrees Nos. 230/95 and 241/00.

The Minister for Industry, Commerce and Crafts (hereinafter referred to as “the Minister for Industry”) is the competent authority for such activities. Pursuant to Act No. 1008 of 19 December 1969, amending Act No. 1860/62, persons in possession of small quantities of special fissile materials, raw materials or other radioactive materials are exonerated, by Ministerial Decree of 15 December 1970 (in implementation of Act No. 1008/69) from the general declaration requirement. This gives more flexibility than the procedure established under the 1962 Act which required persons in possession of the above-mentioned materials to report them to the Minister within five days, irrespective of the quantity of materials held [Section 3]. However, in relation to radioactive materials, this same Section of Act No. 1860/62, as amended by Decree No. 1704/65, requires a declaration from persons in possession of radioactive materials such that the total radioactivity or mass exceeds the levels laid down in one of the decrees implementing Presidential Decree No. 185/64.

Under the terms of Decree No. 241, an advance declaration of practices involving materials and equipment that emit ionising radiation must also be made to the local authorities of the National Health Service and to other relevant local authorities. An implementing decree will establish the technical details in relation to the obligation to declare materials and equipment. Decree No. 241 also establishes the conditions governing exemptions from the declaration obligation.

Section 13 of Act No. 1860/62, as amended by Decree No. 1704/65, lays down the procedure regulating the use of radioisotopes. All such use requires a licence from the Minister for Industry. In addition, other ministers are involved depending on the use to which the substances are to be put. This provision has been supplemented by a Ministerial Decree of 1 March 1974 which contains detailed instructions on the information to be included in licensing applications: information relating to the applicant, the intended use of the radioisotopes (industrial, agricultural, medical or scientific), the location of the premises involved, the professional qualifications of personnel, etc.

Moreover, according to Decrees Nos. 230/95 and 241/00, the use of radioactive materials and radiation-emitting devices is divided into two categories (A and B) requiring a licence from the Minister for Industry (category A) and clearance certificates from the Prefect of the province (category B) with the agreement of other competent authorities. The criteria and procedure applicable

to this division into categories shall be laid down in a decree of the Prime Minister, made in agreement with the ministries concerned. However, authorities responsible for medical uses of such materials and devices shall be set up under regional legislation. Use includes trade in materials as well as activities related to their use, such as handling, treatment and the eventual disposal of waste into the environment [Sections 27 to 29 of Decree No. 230/95].

#### **4. Nuclear Installations**

Italy's nuclear power programme has been suspended since 1987. Following governmental decisions, it was decided that the former National Electricity Company, which has since become the National Electricity Company (*Ente Nazionale per l'Energia Elettrica* – ENEL), and building firms working in the nuclear sector had to be compensated for the costs and losses incurred following interruption of the Italian nuclear programme [Section 33 of Act No. 9 of 9 January 1991].

##### **a) Licensing and inspection, including nuclear safety**

The legislative and regulatory provisions applying to the construction and operation of nuclear installations in Italy are principally set out in Act No. 1860/62 on the Peaceful Uses of Nuclear Energy and to a large extent reiterated in Legislative Decree No. 230/95 containing technical and administrative licensing procedures as regards nuclear safety and radiation protection.

While nuclear power plants are excluded from the scope of Act No. 1860/62, in accordance with Decree No. 230/95, they remain subject to licensing by the Ministry for Industry, with ENEL as liable operator. The prior opinion of the National Environmental Protection Agency (*Agenzia Nazionale per la Protezione dell'Ambiente* – ANPA) is also required (see *infra*, Part II “Institutional Framework”, Section 3).

When filing a licensing application, the operator must submit detailed documentation concerning the siting of the installation, arrangements for release and disposal of radioactive waste, the cost and time required for construction and the financial security at his disposal. In short, the operator must show that he possesses the technical and financial resources required to ensure maximum safety.

A special administrative procedure for the prior selection of the site for nuclear electricity-generating plants was introduced by Act No. 393 of 2 August 1975. This Act establishes a special siting procedure involving the co-operation of the CIPE (Interministerial Committee for Economic Planning), the ENEA and the regional and local authorities. It also takes into consideration the administrative decentralisation policy giving the regions wider responsibilities in environmental protection and land-use planning.

The procedure introduced by Act No. 393/75 was at the centre of the referendum debate on the siting of nuclear power plants. The outcome of the referendum led to the repeal of paragraph 13 of the only Section of Act No. 8 of 10 January 1983 (which amended the Act of 1975). This provision specified that if, in the context of the siting procedure for electricity-generating power plants, the local authorities could not agree within a period of 150 days on a suitable site, the siting decision was to be taken by the CIPE. Following the repeal of this provision, no new provisions governing this issue were adopted.

As far as the licence itself is concerned, Act No. 393/75 did not change the technical and administrative procedures for the licensing of nuclear installations as provided for by Presidential

Decree No. 185/64, nor those of Decree No. 230/95 which replaced it. The operator submits the plans for the construction of the installation to the Minister for Industry [Section 5] who, after obtaining the opinion of the ANPA, decides for or against licensing by means of a decree.

Following delivery of the clearance certificate (or the building permit), construction proceeds under the technical supervision of the ANPA. The operating licence is then granted on satisfactory completion of the non-nuclear and nuclear tests.

Specific provisions concerning the decommissioning of nuclear installations are an important new addition to Decree No. 230/95, since no such provision appears in Presidential Decree No. 185/64, and this omission had led the competent authorities to apply by analogy the legal instruments relative to construction and operation. The operations involved in decommissioning are now licensed, as appropriate, in stages set forth in the provisions in question. The Ministry for Industry determines the requirements concerning the status of the installation and of the site on the basis of a final report provided by the operator.

Section 10 of Decree No. 230/95 governs the inspection of activities covered by this Decree. It is the responsibility of the ANPA to check that the installation is constructed in accordance with the initially approved project and to supervise the carrying out of the nuclear tests. For this purpose, the ANPA inspectors, appointed by the ANPA Chairperson, are vested with wide powers, as regards both inspection of the installations and access to documents. They are also empowered to undertake regular inspections of installations during operation. The competent authorities are also given powers of inspection under Decree No. 230/95 (Inspectorate of Labour, National Health Service, etc.). Under Act No. 349 of 8 July 1986 setting up the Ministry for the Environment, this Ministry is responsible for carrying out technical controls on the state of air, water and land pollution [Section 8]. Although nothing specific is said about nuclear installations, the way in which this Section is drafted could enable experts appointed by this Ministry to become involved in inspection.

It is relevant to note that, at the international level, Italy ratified the 1994 Convention on Nuclear Safety on 15 April 1998.

***b) Protection of the environment against radiation effects***

Although the Act setting up the Ministry for the Environment [Act No. 349 of 8 July 1986] contains no express provisions on nuclear activities and radiation protection, the role of this Ministry in the nuclear field is defined implicitly in some of the general provisions in Act No. 349/86.

Pending incorporation into national law of the provisions of Council Directive 85/337/EC on the assessment of the effects of certain public and private projects on the environment, Section 6 of the Act described, in a provisional manner, the impact assessment procedure to which installations capable of producing significant changes to the natural environment are subject. Pursuant to Section 6(2), an implementing Decree sets out the categories of installations subject to impact studies [Decree No. 377 of 10 August 1988]. The list includes nuclear power plants and other nuclear reactors (except for research reactors with a capacity less than 1 kw of constant thermal heat) as well as facilities for the long-term storage or final disposal of radioactive waste [Section 1].

A Decree of April 1999, which introduced technical standards concerning the impact assessment, fully implemented the 1985 Directive into national law.

A Presidential Decree of February 1998 supplementary to Decree No. 377/88 implemented most of the provisions of Council Directive 97/11/EC of 3 March 1997 which amended Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment. In particular, this Decree extended the list of installations subject to the impact study procedure to, *inter alia*, installations for the storage of nuclear fuel or the treatment of nuclear materials. A Decree of September 1999 in turn completed the Decree of February 1998 by introducing detailed technical provisions, thus ensuring the full implementation of Directive 97/11/EC.

Decree No. 377/88 also specifies that environmental impact studies should be carried out prior to applications for licences and clearance certificates and, in any event, before invitation to tender.

Such studies must include information relating to [Sections 2 *et seq.* of Decree No. 377/88]:

- the possible siting of the installation, having due regard to the effects on the surrounding environment;
- the disposal sites to be used for liquid waste, and to the characteristics and quantities of solid, liquid and gaseous waste generated by the installation;
- prevention and emergency plans in the event of damage to the environment caused during the construction or operation of the installation.

After receiving the backing of the Minister for the Environment, the project must be published in two newspapers, one local and the other national.

The entire regime as described above is to be incorporated into a framework act on the environment, a draft of which is currently under examination by the Parliament.

### **c) *Emergency response***

Regarding the general protection of the public, a Presidential Decree of 1981 provides for measures to ensure assistance for the public in the event of a disaster. The provisions of this Decree are of general application and therefore cover nuclear accidents. The Decree aims to set up a framework for assistance at regional level, given the process of decentralisation which followed the creation, in 1972, of autonomous regional authorities.

In 1983, the Minister for Health sent a Circular on Emergency Situations to the regional health authorities on whose territory nuclear installations were located [Circular No. 53 of 2 June 1983]. The Circular specifies that the health authorities are responsible for organising plans to deal with emergency situations involving radiation. This task is performed in conjunction with the provincial committees set up under Presidential Decree No. 185 of 13 February 1964. The Circular describes different possible situations, the location of emergency centres and the health measures to be taken to treat victims and to protect the public.

A commission to study problems arising from emergency situations has been established [Decree of 2 July 1986]. Its primary role is to advise the Minister for Civil Protection in the event of an emergency situation. The risks covered by the Decree include nuclear risks as well as those arising from the transport of hazardous materials. The regime applicable to emergency situations has been substantially modified since specific new provisions concerning nuclear emergencies came into force.

Like Presidential Decree No. 185 of 13 February 1964, Chapter X of Decree No. 230/95 deals with nuclear emergencies [Sections 115 to 135]. These Sections describe the procedure to be followed in preparing “external emergency plans” to be put into action when an accident occurs in a nuclear installation and involves a risk for the local population. These provisions deal essentially with information required as to the content of the plan and its approval, and with the obligation to declare a state of emergency and to inform neighbouring regions of the danger. Chapter X differs from the previous regime, in that it incorporates the nuclear emergency plans into the national planning of protective measures in the event of a radiation emergency covering the entire country. This form of planning is the responsibility of the Department for Civil Protection assisted by the ANPA. Decree No. 241/00 repeals and replaces Section 115 of Decree No. 230/95 and introduces supplementary provisions [Sections 115 *bis* to 115 *quinquies*] which take into account the new Euratom Basic Standards in the fields of intervention, possible exposure and prolonged exposure. Decrees of the Prime Minister, upon the proposal of the Minister for Health and in consultation with the other ministries and organisations concerned, as well as Decrees adopted by the Minister for the Environment under a similar procedure, lay down the applicable intervention levels in the event of an emergency and also the corresponding levels applicable to foodstuffs and beverages.

Decree No. 230/95 furthermore introduced provisions implementing Council Directive 618/89/Euratom concerning public information. A standing committee of the Ministry for Health is responsible for preparing, updating and disseminating this information. Finally, a centre for preparing and evaluating data concerning radiation emergencies has been set up within the ANPA.

At the international level, Italy ratified the 1986 Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency on 25 October 1990 [Act No. 92 of 9 April 1990], and the 1986 Convention on Early Notification of a Nuclear Accident on 8 February 1990.

## **5. Trade in Nuclear Materials and Equipment**

### **a) General provisions**

Framework Act No. 1860 of 1962 on the Peaceful Uses of Nuclear Energy [Section 4] and the Ministerial Decree of 30 October 1990 listing goods subject to an import licence establish the regime governing the import of goods. Radioisotopes and ionising radiation-emitting equipment are amongst those goods which require an import licence. Legislative Decree No. 89, adopted on 24 February 1997, sets out the list of dual-use goods subject to licensing, in accordance with Council Regulation (EC) No. 3381/94 of 19 December 1994 setting up a Community regime for the control of exports of dual-use goods.

Trade in radioactive ores, source materials and substances is subject to a licence from the Minister for Industry. Import and export licences, where required under the trade regulations applicable, are granted by the Minister for Foreign Trade after consultation with the Minister for Industry. The state has a right of pre-emption as regards source materials, a right which must be exercised within 30 days of the licence application [Section 4 of Act No. 1860/62]. Pursuant to Act No. 1008/69 which amended Act No. 1860/62, certain exemptions from the requirement to obtain a licence from the Ministry for Industry licensing are set out in a Decree of 15 December 1970 implementing Act No. 1008/69.

Furthermore, under the terms of Decree No. 230/95, the import and production for commercial purposes of radioactive materials, products and equipment containing such materials, are subject to

prior notification to the Ministries for the Environment and Industry and other ministries concerned, as well as to the ANPA, except for certain exemptions which are determined by the Minister for Industry on the advice of these ministries and of this Agency [Section 18]. Pursuant to Decree No. 241/00, Section 18 of Decree No. 230/95 was completed by further provisions setting out a compulsory licensing procedure, subject to exemptions and according to procedures similar to those mentioned above, for the use of radioactive materials during the manufacture, import and export of consumer goods.

All persons engaging in trade in ores, source materials or other radioactive materials must keep a special register containing records of their commercial operations [Section 20].

With regard to radiation protection, commercial operations are governed by the regime established in Decree No. 230/95. Also, decrees made by the Minister for Health, in agreement with the Minister for Industry, in implementation of Section 98 of Decree No. 230/95, specify those activities which are exempt from the prohibitions laid down in this Section, and those for which a licence can be granted. The main criterion used is that of the level of radioactivity of the products or equipment involved. The prohibitions apply to certain products and articles that contain radioactive materials (such as cosmetics, toys, lightning conductors, etc.), the manufacture, import, sale, use or possession of which are prohibited in principle.

Circular No. 228 of the Minister for Industry of 20 October 1993 incorporates Council Regulation (Euratom) No. 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States into Italian law. These Community provisions were adopted to allow the national authorities responsible for controlling radioactive substances to maintain a level of information identical to that existing before the abolition of border controls within the Community.

Following the adoption of Decree No. 230/95, which also implements 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, Circular No. 228 remains in force only in respect of sealed sources, to which it applies subject to the amendments adopted to the regime established in Decree No. 230/95. In this context, the Circular sets out the procedures relating to the type of commercial operation to be undertaken and to the prior licences required (for radioactive wastes, see *infra*, Section 7 “Radioactive Waste Management”).

## **b) Patents**

Patents and industrial designs and models are subject to the rules laid down in Royal Decree No. 1127 of 29 June 1939, those contained in international conventions and incorporated into Italian legislation on the protection of industrial property rights and, since 1958, those in the Act ratifying and implementing the Euratom Treaty.

The Central Patents Office of the Ministry for Industry is responsible for carrying out the formalities required under Article 16 of the Euratom Treaty [Act No. 933 of 1 August 1960].

The Central Patents Office must forward to the ENEA all applications for patents for inventions or industrial models acknowledged as being specifically nuclear in nature or directly related and essential to the development of nuclear energy [Section 26 of Act No. 1860/62].

## 6. Radiation Protection

Legislative Decree No. 230/95, as completed by Decree No. 241/00, replaces Presidential Decree No. 185/64 as the basic text in Italy governing radiation protection. In furtherance of the general framework established by Act No. 1860/62, Decree No. 230/95 also introduces a regime for supervising the safe conduct of nuclear activities and, in general, all activities involving the use of ionising radiation. This regime will be supplemented by the adoption of a number of implementing Decrees, in the same manner as those made in implementation of Presidential Decree No. 185/64.

Several examples may be mentioned. A Decree of the Prime Minister is to prescribe the numerical values and other conditions which determine the scope of application of Decree No. 230/95. This implementing Decree will be made on the proposal of the Ministries for the Environment and Health, in conjunction with the other ministries, and following consultations with the ANPA and the other organisations concerned. Provisionally, these values and conditions are established in Annex 1 to Decree No. 230/95, as amended by Annex 1 to Decree No. 241/00.

Another Prime Ministerial Decree (made under a similar procedure) is to establish the maximum dose limits for workers and the public. These dose limits are established, in the meantime, by Annexes III and IV to Decree No. 230/95, as amended by Annex 1 to Decree No. 241/00.

### a) *Protection of workers*

As provided by Decree No. 230/95, responsibility for the radiation protection of workers lies with the Ministry for Labour and Social Security (acting through the Labour Inspectorate) [Section 59], the local authorities of the National Health Service and the ANPA (see *infra*, Part II “Institutional Framework”).

Those entities, including the state, the regions, the provinces, the communes, public bodies, educational establishments and research laboratories, which, in the course of their work, expose workers to the hazards arising from ionising radiation, must comply with the provisions of Decree No. 230/95.

The general rules for the radiation protection of workers, like Presidential Decree No. 185/64, are based upon the Euratom basic standards. This source is expressly cited in particular in the provisions for the adoption of dose limits [Section 96] mentioned above.

Decree No. 230/95 also regulates work in mines where radioactive substances are present and, in particular, defines the obligations of employers in relation to the radiation protection of workers in the mining industry. The conditions governing the application of these provisions are set out in a Decree of the Minister for Industry, who is also responsible for inspection activities to ensure protection against ionising radiation risks.

In particular, specific provisions have been introduced as regards the protection of outside workers covered by 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. This involves, *inter alia*, the establishment for each worker of a personal radiation logbook with which he must be provided in compliance with the above Directive.

Finally, another very important innovation is the inclusion of provisions allowing the ALARA principle to be applied to the employer’s activities.

Besides incorporating the latest Euratom basic standards, Decree No. 241/00 also regulates the protection of workers exposed to natural sources of ionising radiation [Sections 10 *bis* et *seq*] as well as crew members of high altitude flights.

**b) *Protection of the public***

Decree No. 230/95 also contains provisions on the protection of the public against ionising radiation. The Ministry for Health is responsible for such protection and must, in particular, through its National Health Service, control all sources of ionising radiation to avoid any contamination of the public and of the general environment [Section 97]. Regional and provincial commissions have been set up to give their advice on radiation protection and related problems.

Dose limits and maximum permissible concentrations for the public are established in accordance with Section 96 of Decree No. 230/95, in compliance with applicable Community Directives.

Provisions of Decree No. 187/00 concern the protection of persons during medical exposure in compliance with Council Directive 43/97/Euratom of 3 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. These provisions repeal those provisions in Decree No. 230/95 [Sections 109 to 114] which implemented Directive 84/466/Euratom. The Ministry for Health must adopt the necessary measures to give full effect to Decree No. 187/00. Such measures will cover the conditions governing training of staff, the criteria for approval of radiological equipment, justification of certain exposures etc.

**c) *Protection of the environment***

The most important provisions of Decree No. 230/95 relating expressly to the environment are Sections 100 and 104. Decree No. 241/00 also requires that an optimum level of environmental protection be maintained, thereby ensuring that the exposure limits set out in the Euratom basic standards are observed.

In the event of an accident during an operation which involves radioactive substances, if the environment is affected, the operator must intervene to prevent the risk of subsequent contamination or injury to persons [Section 100 of Decree No. 230/95]. The Prefect of the Province and the local authorities of the National Health Service must be informed immediately.

Whereas Section 104 provides that the Ministry for the Environment is responsible for monitoring ambient radioactivity, the monitoring of foodstuffs and beverages is entrusted to the Ministry for Health, with overall technical co-ordination being ensured by the ANPA (see *infra*, Part II “Institutional Framework”). All monitoring is carried out by national and regional networks, the latter acting under Directives issued by the above-mentioned Ministries.

The activities of the ANPA are also governed by relevant directives from these Ministries, and by Section 35 of the Euratom Treaty. Its functions include the co-ordination and standardisation of measurements, the introduction of new measuring stations, etc.

The situation described above is one result of the referendum held on 18 April 1993 which abolished the powers of Local Health Units as regards the environment, entrusting these powers to the ANPA and to other relevant regional and provincial departments and organisations concerned.

## **7. Radioactive Waste Management**

Decree No. 230/95 regulates radioactive waste disposal in a more precise manner than Presidential Decree No. 185/64. In general, this waste must be managed in accordance with the rules of good practice and the instructions set out in the disposal licence [Section 102]; furthermore, any person producing, treating, handling, using, trading in or storing radioactive substances must conduct a whole series of assessments concerning the disposal of solid, liquid or gaseous radioactive waste in order to ensure that the limits and the other conditions governing disposal into the environment are observed [Section 103]. Except in cases covered by Chapter VII of the Decree (nuclear installations), radioactive waste disposal must be licensed by the authorities identified by regional legislation, while a decree of the Minister for the Environment, adopted in co-operation with the Ministers for Health & Industry and after consultations with the ANPA, determines the upper limits beyond which a licence is required. A prior licence must also be obtained from the Ministry for Industry to build and operate installations for the storage or disposal of radioactive waste [Section 33]. There are also specific requirements governing the disposal of waste intended to be eliminated or recycled in installations which are not subject to the licensing requirements in Decree No. 230/95 [Section 12 of Decree No. 241/00].

Decree No. 230/95 also implemented Council Directive 92/3/Euratom concerning transfers of waste. Circular No. 236 of the Ministry for Industry of 28 October 1994, adopted in order to implement this Directive into Italian legislation pending Decree No. 230/95, was basically transcribed into this Decree. Pursuant to that Directive, a prior licence is required for transfer, import, export and transit of radioactive waste [Section 32]. The procedure governing such licences is laid down in a Decree of the Minister for Industry.

At the international level, Italy ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 30 April 1984.

## **8. Non-Proliferation and Physical Protection**

Act No. 1860/62 provides that holders of special fissile materials must report them to the Ministry for Industry. Responsibility for controlling such materials, previously vested in the ENEA, now lies with the ANPA [Act No. 61/94] (see *infra*, Part II “Institutional Framework”). The Agency is required to verify compliance with the physical protection measures applicable to nuclear installations and substances.

In addition, a Ministerial Decree of 19 April 1979 set up an Interministerial Committee for the Physical Protection of Nuclear Installations and Substances. This Committee is responsible for laying down standards in relation to protective measures designed to prevent criminal acts against nuclear installations or substances. The Committee is also required to provide its opinion on the security plan each operator prepares in respect of his installation and, if necessary, to suggest changes.

At the international level, Italy ratified the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991. As regards non-proliferation, it may be noted that Italy is a Party to the Treaty on the Non-Proliferation of Nuclear Weapons, ratified on 2 May 1975 [Act

No. 131 of 24 April 1975] and has agreed to act in accordance with the Guidelines for Nuclear Transfers issued in 1978 by the International Atomic Energy Agency (IAEA). It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 1 February 1999.

## **9. Transport**

As regards safety and radiation protection, the transport of radioactive materials is governed by rules adopted by the competent authorities for the different types of transport, which take into account the Regulations for the Safe Transport of Radioactive Materials issued by the International Atomic Energy Agency (IAEA).

The transport of radioactive materials by rail is carried out in accordance with Legislative Decree No. 41 of 13 January 1999, which aims to implement Council Directive 96/49/EC and Commission Directive 96/87/EC on the transport of dangerous goods, including radioactive materials, by rail (Class VII). These provisions are based on the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID).

Transport by road is regulated by a Decree of 4 September 1996 adopted by the Minister for Transport and Navigation, amended by a Decree of 15 May 1997. These provisions were adopted with a view to implementing Council Directive 94/55/EC and Commission Directive 96/86/EC, and are based on the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). Furthermore, Circular No. 162 of 16 December 1996, as amended on 4 April 1997, establishes the technical requirements which apply. Lastly, Circular No. 244/F of 26 May 1997 updates licence procedures for transport by road of radioactive and fissile materials.

The maritime transport of radioactive materials is regulated by a Decree of 6 April 1995 of the Ministry for Transport and Navigation which allowed for the adoption of some of the standards laid down by the International Maritime Organisation (IMO). This Decree was adopted pursuant to Regulation No. 1008 of 9 May 1968.

The air transport of radioactive materials, originally regulated by a Ministry for Transport Circular of 1982, is now subject to the provisions of Circular No. 334096/30 of 3 December 1992. These provisions are based on the requirements set out in the International Civil Aviation Organisation Regulations. After defining its scope [Sections 1 to 5], the Circular describes the procedure to be followed for the transport of radioactive materials (consignor's and consignee's obligations) and designates the competent authorities (the Ministry for Industry, Commerce and Crafts, the Ministry for Transport and Navigation and the ANPA).

With regard to licences, the regulatory basis can be found in Act No. 1860/62, as modified by Presidential Decree No. 1704 of 30 December 1965, which requires a licence from the Minister for Industry in conjunction with the minister concerned, depending on the mode of transport. There is provision for certain exemptions in the Decree of 15 December 1970 (adopted in implementation of Act No. 1008/69 modifying Act No. 1860/62).

Presidential Decree No. 1704/65 provides for the adoption of a regulation concerning safety and radiation protection in the transport of radioactive materials. This regulation is adopted by decrees of the Minister for Transport and Navigation (following consultations with the ANPA) for the different modes of transport, in compliance with the Directives and Recommendations of the European Union and international agreements on the transport of dangerous goods [Section 21 of Decree No. 230/95].

## 10. Nuclear Third Party Liability

Act No. 1860/62 on the Peaceful Uses of Nuclear Energy regulates nuclear third party liability in Italy, and implements the provisions of the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, ratified by Italy on 17 September 1975, and of the 1963 Brussels Supplementary Convention, ratified on 3 February 1976.

Act No. 109 of 12 February 1974 authorised ratification of both Conventions and vested the government with the powers required to implement them by decree at national level. Consequently, a Presidential Decree of 1975 amended Section 1 (definitions) and Sections 15 to 24 (third party liability) of Act No. 1860/62 to bring them into line with the above-mentioned Conventions [Presidential Decree No. 519 of 10 May 1975]. Furthermore, on 14 and 28 June 1985, Italy ratified the 1982 Protocols amending the two above-mentioned Conventions [Act No. 131 of 5 March 1985]. The most recent development was the ratification on 31 July 1991 and implementation by Italy of the Joint Protocol of 1988 relating to the application of the Vienna Convention and the Paris Convention [Act No. 147 of 23 April 1991]. It is also relevant to note that Italy ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 21 July 1980.

Act No. 1860/62, as amended, provides for a system of absolute and exclusive liability for the operator of a nuclear installation in the event of any nuclear damage occurring in this installation or in connection with it [Sections 15 and 18]. When the operators of several installations are held liable for the same damage, they are jointly and severally liable for compensation [Section 17]. Nuclear operators are also liable in respect of damage caused by a combination of a nuclear incident and an incident other than a nuclear one, where the nuclear damage cannot be separated with certainty from the other damage.

Under Italian law, the maximum amount of liability of the operator of a nuclear installation for damage caused by a nuclear incident is fixed at 7 500 million Italian Lira (ITL) [Section 19]. If the amount of damage exceeds the limit of the operator's liability, thereby necessitating intervention by the state, the total amount of compensation available will not exceed the equivalent of 300 million SDRs, corresponding to the maximum limit of the Brussels Supplementary Convention to which Italy is a Party.

A Ministerial Decree of 16 February 1976 approved a model certificate of financial security for the transport of nuclear materials, based on the model certificate recommended by the Steering Committee of the OECD Nuclear Energy Agency (NEA) in accordance with the Paris Convention. Another Ministerial Decree of 1978 approved the general conditions of third party liability insurance policies for nuclear operators and for the transport of nuclear materials [Ministerial Decree of 3 March 1978]. Lastly, a later Decree [Ministerial Decree of 20 March 1979] implemented at national level the Steering Committee Decision of 27 October 1977 excluding certain categories of nuclear substances from the scope of the above Conventions. These three Decrees were adopted in implementation of the above-mentioned Presidential Decree of 1975.

## II. INSTITUTIONAL FRAMEWORK

Responsibility for the control of nuclear activities in Italy is shared amongst several ministries assisted by other bodies, such as the Interministerial Committee for Economic Planning (CIPE) and the National Environmental Protection Agency (ANPA). As regards the National Agency for New Technologies, Energy and the Environment (ENEA) and the National Electricity Company (ENEL), see the more recent developments under item 3(a) and (d) *infra*.

### 1. Regulatory and Supervisory Authorities

#### a) *Interministerial Committee for Economic Planning (CIPE)*

Act No. 933 of 11 August 1960 which originally created the National Committee for Nuclear Energy (*Comitato Nazionale per l'Energia Nucleare* – CNEN), now the ENEA, set up an Interministerial Committee responsible for defining the general policy of the CNEN. A Presidential Decree of 1968 transferred its powers to the CIPE [Presidential Decree No. 626 of 30 March 1968]. The CIPE is responsible, in particular, for establishing the national nuclear power programme, though some of its duties are for the moment irrelevant due to the moratorium on the Italian nuclear programme. This applies in particular to the CIPE's approval of the programme concerning nuclear power plant construction over a number of years, and to its approval with regard to the suitability of sites for such plants.

Act No. 282 of 25 August 1991, which established the ENEA, expressly provides that the ENEA shall follow the guidelines laid down by the CIPE [Section 1]. In addition, after being submitted to the Ministry for Industry, Commerce and Crafts and examined by an Interministerial Committee, the ENEA's three-year programme of work has to be approved formally by the CIPE. Lastly, the ENEA Board of Governors may be asked to resign in the event of repeated non-compliance with CIPE directives [Section 16].

The Committee also has decisive powers concerning the effective implementation of the National Energy Plan. Act No. 10 of 9 January 1991, which establishes the standards for the rational use of energy and for the development of renewable energy sources, provides that the CIPE shall adopt, at least once every three years, a series of guidelines on various subjects. The purpose is to co-ordinate the activities of the different public bodies involved, to promote the research and development of technology in the fields of production, recycling and use of renewable energy sources and to promote programmes to reduce energy consumption.

The CIPE meets under the chairmanship of the Prime Minister, and includes the Minister for the Budget and Economic Planning as Vice-Chairman, and the Ministers for Industry, Commerce and Crafts, Foreign Affairs, the Treasury, Finance, Public Works, Labour and Social Security, and Transport and Navigation. Other ministers may be called upon to take part in meetings of the Committee.

**b) *Prime Minister***

Pursuant to Decrees Nos. 230/95 and 241/00, the Prime Minister is empowered to adopt basic decrees such as those laying down the application thresholds of Decree No. 230, dose limits for workers and the public and the reference dose levels for nuclear emergencies.

*Department of Civil Protection*

This Department, which comes under the authority of the Prime Minister is entrusted, pursuant to Decrees Nos. 230/95 and 241/00, with a number of regulatory and administrative tasks in the fields of public protection and radiation emergencies, in conjunction with other competent ministries.

**c) *Minister for Industry, Commerce and Crafts***

Act No. 1860/62 on the Peaceful Uses of Nuclear Energy vests the Minister for Industry with the necessary powers to make regulations and issue the licences required in the nuclear field. The Minister is therefore the competent authority, in conjunction with the CIPE, for matters relating to nuclear power plants [Chapter II of Act No. 1860/92]. In addition, he authorises by decree the operation of installations for the production and use of nuclear energy for industrial purposes, as well as of plants for the processing and use of ores, source materials, special fissile materials, enriched uranium and radioactive materials [Section 6 of Act No. 1860/62; Act No. 1240/71, as amended by Act No. 84/82 and Act No. 282 of 25 August 1991].

In implementation of Legislative Decree No. 230/95 [Sections 15, 32, 34 to 36 and 55], the Minister for Industry, in agreement with the other Ministers concerned (Interior, Labour, Health and Environment) issues decrees laying down the levels of radioactivity and other conditions pursuant to which a license is required for different activities involving ionising radiation (including the mining industry, commercial operations and utilisation for industrial and research purposes), as well as the application procedures for licences. The same Minister authorises the above-mentioned activities, as well as the transfer of radioactive substances within the European Union, the operation of radioactive waste disposal sites, etc. Decree No. 241/00 extended the licensing powers of the Minister for Industry to other activities such as the addition of radioactive materials to consumer goods, export and import of such goods and transfer of materials subject to Directive 92/3/Euratom.

The Minister for Industry may also determine the amount and terms of the financial security covering the third party liability of the operator of a nuclear installation. He approves the general conditions of the insurance policy or other form of financial security by decree, in agreement with the Treasury Minister and after consultations with the Attorney General [Sections 19, 21 and 22 of Act No. 1860/62, as amended by Presidential Decree No. 519 of 10 May 1975].

**d) *Minister for Labour and Social Security***

The Minister for Labour and Social Security is generally responsible for the radiation protection of workers engaged in nuclear activities [Section 59 of Decree No. 230/95]. In agreement with the other ministers concerned, he establishes rules governing radiation protection and monitors their application through the controls of Health and Safety inspectors and through the competent bodies of the National Health Service in each region. He also sets out rules governing the qualifications of experts and of authorised doctors.

**e) *Minister for Health***

Responsibility for protecting public health against the hazards of ionising radiation lies with the Ministry for Health, the National Health Service and the ANPA, whose aim is to prevent, by inspections or otherwise, the possibility of radiation contamination of the population or of any part of the natural environment, foodstuffs and beverages [Section 97 of Decree No. 230/95]. Furthermore, the Minister submits proposals to the Prime Minister concerning dose limits for workers and for the public [Section 96].

The Minister for Health is also empowered to establish thresholds beneath which certain electrical equipments emitting radiation may be circulated [Section 98]. He may furthermore carry out controls on foodstuffs and beverages [Section 104].

The Higher Institute of Health and the Higher Institute for Labour Protection and Safety, as support organisations of the Ministry for Health, are consulted with regard to a number of decrees implementing Decrees Nos. 230/95 and 241/00 (dose limits, reference dose levels for emergencies, official approval of certain sources, etc.)

A standing commission has been created in the Ministry for Health, the essential task of which is to prepare information for the public in the event of a nuclear emergency.

With regard to radiation protection during medical exposure, Decree No. 187/00, which repeals Sections 109 to 114 of Decree No. 230/95, entrusts the Minister for Health with quasi-exclusive powers in relation to the training of personnel, criteria governing the authorisation of radiological equipment, justification of certain exposure, etc. Control over the implementation of Decree No. 187/00 is vested exclusively in the National Health Service.

**f) *Minister for the Environment***

Act No. 349 of 8 July 1986 set up the Ministry for the Environment which has since been involved in decision-making in collaboration with the other competent ministries. Although the Minister is not expressly given any functions in the nuclear field in Act No. 349/86, Section 2 provides, in a general manner, that the Minister for the Environment performs his functions with a view to ensuring protection of the soil, air and water. Moreover, the Minister, in agreement with the Minister for Health, proposes to the President of the Council the maximum concentration limits and maximum exposure doses with respect to chemical, physical or biological contamination [Section 2(14)]. With regard to the establishment of ceilings governing the exposure of workers, the Minister for Labour and Social Security must be consulted before the proposal is submitted to the Prime Minister. In addition, whenever construction of an installation capable of having an impact on the surrounding environment is being planned, the Minister for the Environment reports on the compatibility of the project with environmental protection requirements.

The Ministry for the Environment has taken over some of the powers of the Minister for Health, in particular, the monitoring of environmental radioactivity [Section 104 of Decree No. 230/95]. The Minister for the Environment is also competent to establish, in co-operation with the other ministries concerned, the derived reference dose levels which correspond to the dose levels established by the Prime Minister in relation to the planning of emergency interventions [Section 26 of Decree No. 241/00 which replaces Section 115 of Decree No. 230/95]. The Minister must be consulted during the drafting of certain implementing decrees for Decree No. 230/95, including those related to scope of application, declaration of practices and dose limits.

**g) *Minister for the Interior***

In accordance with Decree No. 230/95, the Minister for the Interior, who is generally responsible for public safety, assists with the drafting of regulations by other ministers in connection with the classification and licensing of commercial activities using nuclear and radioactive materials.

The same Decree provides that each nuclear installation must have an off-site emergency plan to ensure protection of the public against the harmful effects of a nuclear accident. Such plans consist of a series of co-ordinated measures to be taken by those responsible in the event of an incident at a nuclear installation which might put public safety at risk. The Minister for the Interior contributes to the establishment of the national radiological emergency plan [Section 121 of Decree No. 230/95], in conjunction with the Department of Civil Protection.

In addition, in accordance with Act No. 996 of 8 December 1970, the Ministry for the Interior and its services are responsible for taking the measures required to protect the public in the event of catastrophes.

As the authority associated with the Minister for the Interior in each region, the Prefect is competent to grant a clearance certificate for category B use of radioactive substances and appliances containing them, in industry and research. The Prefect is also responsible for preparing and updating the emergency plan in province over which he has authority (except the medical aspects) and for its application as part of the national emergency plan.

**h) *Minister for Transport and Navigation***

This Ministry, established by Act No. 537 of 24 December 1993, results from the merger of two former Ministries: the Ministry for Transport and the Ministry for the Merchant Navy. The duties carried out by these two Ministries have been transferred to the Ministry for Transport and Navigation. Thus, the latter Minister is, at present, the competent authority, in conjunction with the Minister for Industry, Commerce and Crafts, for granting licences for the transport of nuclear and radioactive materials by road, rail, air and sea [Section 5 of Act No. 1860/62, as amended by Presidential Decree No. 1704/65]. The Minister is also responsible for the adoption of regulations governing these different modes of transport [Section 21 of Decree No. 230/95].

**i) *Minister for Foreign Trade***

The import of ores, source materials and radioactive materials is subject to authorisation by the Minister for Foreign Trade when such authorisations are required by financial and currency regulations. Together with the Finance Minister, the Minister for Foreign Trade has laid down the rules for importing goods, establishing in particular which goods require an import licence, including radioisotopes and ionising radiation-emitting equipment [Section 4 of Act No. 1860/62 and Ministerial Decree of 30 October 1990 promulgating the list of goods requiring an import licence]. Legislative Decree No. 89 of 24 February 1997 established the list of dual use goods which are subject to licensing.

***j) Minister for Education***

Public institutions possessing radioactive materials for teaching or scientific research are required to report them to the Minister where the quantity of materials involved exceeds the prescribed levels [Section 3 of Act No. 1860/62, as amended by Section 1 of Presidential Decree No. 1704/65]. Pursuant to the amendments introduced following the adoption of Decree No. 241/00, practices involving the possession of such materials are also subject to prior notification.

The Minister is also involved in licensing the use of radioisotopes above certain quantities [Section 13, as amended by Section 3 of Presidential Decree No. 1704/65].

***k) Treasury Minister***

The Treasury Minister is required to approve the general conditions of the financial security for the third party liability of nuclear operators when such security is not in the form of an insurance policy. Furthermore, notice of summons in respect of actions for compensation of nuclear damage are submitted to the Minister who may, in all cases, intervene in the proceedings [Sections 22 and 25 of Act No. 1860/62, as amended by Section 2 of the Presidential Decree of 10 May 1975].

***l) Minister for Universities and for Scientific and Technical Research***

The above Minister is responsible for co-ordinating at national and international level all measures to promote the development of scientific and technical research. He is consulted by the Minister for Industry, Commerce and Crafts in connection with ENEA research and development programmes and its scientific, technical and industrial co-operation with international or foreign organisations [Section 1 of Legislative Decree No. 36 of 30 January 1999]. The Minister for Universities is also involved in determining the radiation protection qualifications of personnel in radiology and nuclear medicine [Section 7 of Decree No. 241/00].

***m) Minister for Foreign Affairs***

The above Minister is consulted by the Minister for Industry, Commerce and Crafts in connection with the activities of the ENEA in the field of international co-operation [Section 1 of Legislative Decree No. 36 of 30 January 1999].

***n) State Advocate General***

Presidential Decree No. 519 of 10 May 1975 provides that the opinion of the State Advocate General must be obtained before final approval may be given to the general conditions for insurance or other form of financial security decided on by the Minister for Industry, Commerce and Crafts in agreement with the Treasury Minister.

## 2. **Advisory Bodies**

### a) ***Interministerial Council for Consultation and Co-ordination***

This Interministerial Council was set up under the Ministry for Industry, Commerce and Crafts pursuant to Presidential Decree No. 185 of 1964 on Radiation Protection and was confirmed by Decree No. 230/95 [Section 8]. It meets under the chairmanship of the Director-General for Energy and Mining Resources and is composed of nine representatives of the ministries concerned and one representative of the ANPA. All members are appointed for four years by Decree of the Prime Minister, on the proposal of the Minister for Industry. The Council is responsible for co-ordinating, from the administrative point of view, the activities of the different government departments responsible for the application of Decree No. 230/95, by reviewing all the provisions concerning the peaceful uses of nuclear energy.

### b) ***Co-ordinating Committee for Radiation Protection of Workers and the Public***

This Committee was set up by Act No. 619/80, and includes representatives of the organisations mentioned in Section 1(e) above, as well as the National Research Council and the ANPA. The Committee is consulted by the Ministers for Health and the Environment on topics that fall within their competence.

### c) ***Regional and Provincial Commissions for Public Health Protection Against the Hazards of Ionising Radiation***

By Presidential Decree No. 185/64, a commission was set up in each region under the chairmanship of the Regional Director of Public Health to give its advice on questions relating to public health protection against the hazards of ionising radiation. The commissions are involved in the licensing procedures for the possession and use of radioactive sources and for radioactive waste disposal in connection with scientific, industrial and medical activities.

Decree No. 230/95 now provides for such technical advisory bodies to be established at regional and provincial levels under legislation adopted at those levels.

### d) ***Technical Commission for Nuclear Safety and Health Protection***

This Commission, set up by Decree No. 185/64, was confirmed by Decree No. 230/95 [Section 9]. It consists of 16 experts appointed by the ministries concerned, by the ENEA and by the ANPA. The chairperson is appointed from amongst these experts by decree of the Prime Minister. The Commission gives its advice on questions relating to the licensing of nuclear installations and radiation emergencies as provided for in Decree No. 230/95, as well as at the request of the government.

Decree No. 241 of 2000 [Section 10 *septies*] established a special section within this Commission to establish criteria and formulate proposals concerning the control of activities involving exposure to natural radioactivity.

### 3. Public and Semi-Public Agencies

#### a) *National Agency for New Technologies, Energy and the Environment (ENEA)*

Four important changes have been made within this body between 1960, the year in which the National Committee for Nuclear Energy (*Comitato Nazionale per l'Energia Nucleare – CNEN*) was set up [Act No. 933 of 1 August 1960], and 1999, the year of the latest re-structuring.

The first change, in 1971, gave the CNEN new powers, and in particular the task of undertaking, in collaboration with specialised companies, the construction of experimental facilities and the development of prototype reactors [Act No. 1240 of 15 December 1971].

The second change dates from Act No. 84 of 5 March 1982, which renamed and re-structured the CNEN. The acronym ENEA, which stands for National Committee for Research and Development of Nuclear and Alternative Energies (*Comitato Nazionale per la Ricerca e per lo Sviluppo dell'Energia Nucleare e delle Energie Alternative*), replaced the CNEN whose former duties were extended to include research into, and development of alternative energies. The ENEA, however, continues to perform the CNEN's statutory tasks, in particular, ensuring that nuclear energy and ionising radiation are used without causing any hazard.

Under the third reorganisation, dating from 1991, significant changes were made to the ENEA's duties [Act No. 282 of 25 August 1991]. While retaining its acronym, the ENEA is now called the National Agency for New Technologies, Energy and the Environment (*Ente per le nuove tecnologie, l'energia e l'ambiente*). The ENEA retains its technical and scientific responsibilities (special studies, research, experimental work, etc.) regarding nuclear activities, notably in the field of nuclear safety and radiation protection, while broadening its jurisdiction to include questions relating to the environment and to new technologies.

Lastly, Legislative Decree No. 36 of 30 January 1999, which repeals and replaces Act No. 282/91, further widens and modifies the scope of the Agency's activities. The new tasks assigned to the ENEA essentially involve research in the field of sustainable development, innovation in terms of the production of small and medium-sized businesses and in relation to transfer of technology to such businesses, in particular in the energy field. As a civil service body, the ENEA provides advanced technical support in the fields of energy, the environment and technological innovation.

#### i) *Legal status*

The ENEA is a body governed by public law which carries on its activities in accordance with the directives of the Interministerial Committee for Economic Planning (CIPE). It is placed under the authority of the Minister for Industry, Commerce and Crafts, and consults the Minister for Universities and for Scientific and Technological Research as regards R&D programmes, the Minister for the Environment in relation to projects which could affect the natural environment and the Minister for Foreign Affairs with regard to international activities [Decree No. 36/99, Section 1].

#### ii) *Responsibilities*

As regards new technologies, energy and the environment, the ENEA's duties are [Section 2]:

- to carry out and promote studies, research and development with respect to technological aspects;

- to carry out, promote and co-ordinate studies, research and experiments on the effects, including the economic and social consequences, of the development and use of technologies, and on the safety of nuclear installations and protection against ionising radiation;
- to co-operate in the scientific, technical and industrial fields, with the international bodies involved in the same sectors;
- to formulate and implement plans for the dissemination of know-how and research results to government departments;
- to train staff in technological subjects and disseminate the knowledge acquired;
- to give opinions to, and carry out technical controls on behalf of government, regional and local authorities.

To this end, the ENEA may conclude agreements with the competent ministries, the regions, the autonomous provinces of Trento and Bolzano, local authorities and certain local firms, as provided for by Act No. 142 of 8 June 1990. In addition, the ENEA was responsible, within three months of the entry into force of the Act, for setting up a consortium for the promotion of the rational use of energy and of renewable sources, and of businesses engaged in developing such technologies.

The control of nuclear safety, radiation protection, physical protection, etc. are the responsibility of the ANPA according to the Act [No. 61/94] establishing that Agency.

**b) *National Institute of Nuclear Physics (INFN)***

This Institute was set up under Act No. 1240 of 15 December 1971 as a public body with an autonomous budget, and is run in accordance with a Ministerial Decree of 1967. The CIPE supervises the programmes of the INFN which are communicated to it by the Minister for Education [Act No. 1240/71, Sections 25 and 26; Ministerial Decree of 26 July 1967].

**c) *National Health Service***

Act No. 833 of 23 December 1978 set up a National Health Service with responsibilities in the field of radiation protection. The Act determines and allocates between the state, the regions and local authorities, the various duties, structures and services aimed at promoting, maintaining and restoring the health of workers and the population.

The state maintains its powers concerning the health control of the production and use of nuclear energy and radioactive materials, while certain administrative functions are delegated to the regions concerning control, trade in and storage of radioactive materials, as well as environmental monitoring [Section 6(K) of Act No. 833/78].

Under Act No. 833/78, the Provincial Director of Public Health is no longer answerable to the Ministry for Health but to the regional authorities.

Decrees Nos. 230/95 and 241/00 entrusted various functions to the National Health Service, as well as to its regional structures.

**d) *Electricity Company (ENEL, s.p.a.)***

Act No. 1643 of 6 December 1962 nationalising the electricity industry in Italy set up a body governed by public law and possessing legal personality: the National Electricity Company (*Ente Nazionale per l'Energia Elettrica* – ENEL), responsible for all activities relating to the production, import, export, conversion, distribution and sale of electrical power. The ENEL accordingly managed and operated nuclear power plants in Italy and was also responsible for the power plant building programme. The ENEL therefore held a monopoly of national electricity [Act No. 1643/62].

Important changes occurred in Italy in the energy field during the 1990s. In the first place, Acts Nos. 9 and 10 of 9 January 1991 significantly reduced the ENEL's monopoly to leave more room for independent producers and local businesses. Then, the ENEL was transformed into a limited company (ENEL s.p.a.) which made it possible for private individuals to take out shares in the company [Act No. 359 of 8 August 1992].

Legislative Decree No. 79 of 16 March 1999, adopted in implementation of Directive 96/92/EC of the Parliament and of the Council of 19 December 1996 concerning common rules for the internal market in electricity, provided that ENEL be re-structured, through the establishment of several companies, one of which – the Company for the Management of Nuclear Installations (*Società per la Gestione degli Impianti Nucleari* – SOGIN) – would monitor the decommissioning of nuclear power plants. Following this, SOGIN set up a consortium with the company *Fabbricazioni Nucleari* and the ENEA in order to ensure the planning and co-ordination of the dismantling of research installations belonging to the ENEA and which are associated with the nuclear fuel cycle.

**e) *National Environmental Protection Agency (ANPA)***

In January 1994, the Italian Parliament implemented Decree No. 496 of 4 December 1993 providing for the creation of the National Environmental Protection Agency (*Agenzia Nazionale per la Protezione dell'Ambiente* – ANPA). This Decree became Act No. 61 of 21 January 1994.

The decision to create this Agency was a result of the referendum of 18 April 1993 which repealed the provisions giving Local Health Units responsibility for monitoring the environment. Since this issue was particularly sensitive, it was important to make a distinction as soon as possible between health questions and those relating to the environment as well as the corresponding roles of the different bodies in respect of these two questions.

The ANPA comes directly under the Minister for the Environment and is subject to controls by the Board of Auditors. Its powers relate to a series of technical and scientific activities of national interest. Its main role is to carry out public duties, such as providing technical and scientific back-up to the Ministry for the Environment and associated bodies with a view to protecting the environment, the collection and periodic dissemination of data on the state of the environment, the formulation of proposals and opinions for both central government and local authorities concerning quality standards for air, water, soil, etc. [Section 1(1) of Act No. 61/94]. In the nuclear field, the Agency is responsible for exercising control over activities relating to the peaceful uses of nuclear energy and over the effects of ionising radiation on the environment [Section 1(L)]. The Agency's functions are essentially radiation protection inspection, as well as formulating advice as to the legal, regulatory and administrative provisions affecting radiation protection of workers, the public and the environment [Decrees Nos. 230/95 and 241/00].

The ANPA also replaces the Nuclear Safety and Health Protection Directorate of the ENEA (ENEA-DISP) in respect of its powers of inspection and control described in Act No. 282 of 25 August 1991: its functions, staff, technical structures and equipment and financial resources are transferred to the ANPA [Section 1(5) of Act No. 61/94].

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## **I. GENERAL REGULATORY REGIME**

### **1. Introduction**

The starting point for discussion of Japan's nuclear legislation is the Atomic Energy Basic Law (the Basic Law) [No. 186, 19 December 1955]. The Basic Law states that its objectives are to secure energy resources for the future and to promote the research, development and use of nuclear energy for peaceful purposes [Chapter 1]. It goes on to establish a framework for the regulation of nuclear activities, specific aspects of which are to be dealt with in subsequent, separate Acts. The Basic Law created the Atomic Energy Commission (AEC) and the Nuclear Safety Commission (NSC) [Chapter 2]. Its provisions also deal in very broad terms with the mining of nuclear source materials [Chapter 4], control over nuclear fuel materials [Chapter 5], control over nuclear reactors [Chapter 6], protection from radiation hazards [Chapter 8] and compensation for damage caused by nuclear activities [Chapter 9]. These provisions, in effect, do no more than signal the state's intention to exercise regulatory powers in these areas by means of subsequent legislation. The most important of these later Acts are:

- the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Regulation Law) [No. 166, 10 June 1957], as amended;
- the Law concerning Prevention from Radiation Hazards due to Radioisotopes etc. (Prevention Law) [No. 167, 10 June 1957], as amended; and
- the Law on Compensation for Nuclear Damage [No. 147, 17 June 1961], as amended.

These laws will be discussed in more detail below.

Pursuant to the Government Reorganisation Basic Law [No. 103, 12 June 1998] and various laws related to the administrative reform of central government adopted in July 1999, the structure of the Japanese Government was re-organised on 1 January 2001. Before the re-organisation, responsibilities for the regulation of nuclear activities were vested in the Science and Technology Agency (STA) and the Ministry of International Trade and Industry (MITI) according to the type of activity involved. Following the re-organisation, the STA, which previously reported directly to the former Prime Minister's Office (now the Cabinet Office), merged with the Ministry of Education to become the Ministry of Education, Culture, Sports, Science and Technology (MEXT), while MITI became the Ministry of Economy, Trade and Industry (METI).

### **2. Mining Regime**

The Basic Law states that special provisions dealing with the mining of nuclear source material may be made by subsequent laws [Section 8]. It also states that the government may legislate to acquire all nuclear source material, to control all dealings with nuclear source material and to

encourage the development of nuclear source material by means of subsidies and other financial incentives [Sections 9-11]. The Power Reactor and Nuclear Fuel Development Corporation (PNC) withdrew from activities related to prospecting for nuclear source material in 1998 when it was reorganised as the Japan Nuclear Cycle Development Institute (JNC). Japanese mining law does not differentiate between uranium and other minerals.

### **3. Radioactive Substances, Nuclear Fuel and Equipment**

Activities involving radioactive substances are governed by the Prevention Law while activities connected with the nuclear fuel cycle come within the scope of the Regulation Law.

The principal purpose of the Prevention Law is radiation protection and to this end it regulates the use, sale, lease, disposal etc. of radioisotopes and ionising radiation-generating equipment. In general, any person wishing to use radioisotopes or ionising radiation-generating equipment must obtain a licence to do so from the Minister of Education, Culture, Sports, Science and Technology (MEXT) [Section 3]. The application must contain information about intended use, location, radiation safety measures to be observed, etc. The Minister may attach conditions to the licence [Section 8] and may suspend or cancel it if there is non-compliance with the law or any condition thereof. The sale of radioisotopes is subject to licensing conditions similar to those regarding their use [Section 4]. The use of sealed sources containing radioisotopes below a prescribed quantity is exempt from licensing requirements, but advance notification to the same Minister is necessary [Section 3]. The Prevention Law also contains criminal sanctions (fines and imprisonment) for non-compliance with its provisions [Chapter VII].

The purpose of the Regulation Law is to ensure the peaceful use of nuclear source material, nuclear fuel and nuclear reactors. It provides for a comprehensive licensing regime covering the following nuclear activities: refining nuclear source material, manufacture and use of nuclear fuel, construction, operation and decommissioning of reactors, storage and reprocessing of spent nuclear fuel, disposal of radioactive waste, and any other use of internationally-controlled material (that is, material subject to internationally agreed safeguards).

The Regulation Law requires that a person (other than a government-controlled entity) wishing to carry on a refining business must obtain the authorisation of the Minister of Economy, Trade and Industry (METI) [Section 3]. Applications for a licence must contain information on the planned design, proposed safety measures and the intended construction and refining methods for the facility. The advice of the Atomic Energy Commission and the Nuclear Safety Commission must be obtained by METI before the licence is granted [Section 4]. Licensees are required to keep records of their operations as prescribed by order of METI [Section 11].

Licensing requirements similar to those for refining activities apply to nuclear activities covered by the Regulation Law. The licensing authority differs depending on the nuclear activities involved. METI is responsible for the licensing of reactors used for electricity generation, including those at the research and development stage, and for uranium milling, refining of nuclear source material, the manufacture of nuclear fuel, reprocessing and storage of spent nuclear fuel, and disposal of radioactive waste, while MEXT is responsible for the licensing of research reactors, reactors not used for electricity generation, including those at the research and development stage, and facilities using nuclear fuel.

Until 1980, reprocessing of spent fuel could be carried on only by the Power Reactor and Nuclear Fuel Development Corporation (PNC) (now the Japan Nuclear Cycle Development Institute –

JNC) and the Japan Atomic Energy Research Institute (JAERI). However, an amendment to the Regulation Law, adopted on 20 June 1979, enabled the Prime Minister to authorise private companies to also carry out such activities. Since the re-organisation of the government in 2001, the power to grant such authorisations is vested in METI. The Regulation Law specifies certain conditions which must be met by such companies, and provides for government supervision and inspection of the construction of the reprocessing facility and during its operation and decommissioning [Sections 44-51].

#### **4. Nuclear Installations**

##### ***a) Licensing and inspection, including nuclear safety***

The Regulation Law governs the siting, construction and operation of nuclear facilities. Two Cabinet Orders establish the details of a comprehensive licensing system: the Ordinance implementing the Regulation Law [Cabinet Order No. 324, 21 November 1957] and the Ordinance for the Definition of Nuclear Fuel Material, Nuclear Source Material, Reactors and Radiation [Cabinet Order No. 325, 21 November 1957]. The Prevention Law is also relevant in relation to the safety aspects of nuclear facilities.

Responsibility for the establishment, operation and decommissioning of a nuclear facility depends on the type of facility involved [Regulation Law, Section 23]. METI is responsible for all commercial nuclear power facilities as part of the broader responsibility for all types of electricity generation under the Electricity Utility Industries Law [No. 170, 11 July 1964, as amended], as well as for reactors used for electricity generation, including those at the research and development stage, and nuclear fuel fabrication facilities, spent fuel reprocessing facilities and waste disposal facilities. The Minister of Education, Culture, Sports, Science and Technology (MEXT) is responsible for giving approval for the construction, operation and decommissioning of research reactors, reactors not used for electricity generation, including those at the research and development stage, and facilities using nuclear fuel. The Minister of Land, Infrastructure and Transport (MLIT) is responsible for nuclear-powered ships. At all stages of the licensing process, both the Atomic Energy Commission and the Nuclear Safety Commission are involved in advising the appropriate licensing authority.

The Environmental Impact Law [No. 81, 9 June 1997] establishes a general procedure for the environmental impact assessment of large scale projects which could have a significant impact on the environment, including the construction of a power plant.

The licensing procedure of reactors is divided into three main stages: approval of a particular site, the granting of a construction licence, and finally, approval to operate the installation. A construction licence for a reactor can only be granted if the Minister responsible is satisfied that the reactor will be used only for peaceful purposes, the construction is consistent with the national atomic energy development plan, the applicant has the necessary technical and financial resources, and the location, structure and equipment of the reactor all comply with safety requirements [Regulation Law, Section 24]. Before granting a licence, the relevant Minister must seek the views of both the AEC and the NSC on the proposal [Section 24-2]. Once the construction licence has been granted, no change in the design or construction method is allowed unless approval has been sought and obtained for the change from the minister [Sections 26 and 27]. Before the reactor can begin to operate, an inspection must be carried out which satisfies the Minister that the construction conforms to the approved design and methods and to all the relevant technical standards [Section 28]. The operator must also have an approved set of safety rules and procedures in place before operations may commence [Section 37].

The operator is subject to an annual inspection of the facility by the relevant ministry [Section 29] and must also provide an operating plan which conforms to the requirements set out for such plans in orders issued by the ministry [Section 30].

A licence may be revoked if the operator has failed to comply with the obligations pursuant to the Act, any applicable orders made under the Act or any licence condition [Section 33].

Several regulations made under the Regulation Law deal in detail with the various categories of reactor. The Regulations concerning the Installation and Operation of Reactors for Power Generation [MITI Order No. 77, 28 December 1978, as amended] cover application procedures for commercial reactor design and construction and for alteration of facilities, limits on access to controlled areas, storage of nuclear materials and waste and security measures. The construction and operation of research reactors are dealt with under the Regulations concerning Installation, Operation etc. of Nuclear Reactors in Use for Testing and Research Purposes [Prime Ministerial Order No. 83, 1957].

The Regulation Law also contains penalties for various activities related to the operation of nuclear reactors, for example, using nuclear fuel without a permit [Section 77], non-compliance with restrictions on the transfer of nuclear fuel, failure to lay down approved safety rules [Section 79] and failure to maintain records of internationally controlled material or to provide information on such material as required [Section 80]. Such penalties are applied to other nuclear activities, such as refining nuclear source material, the manufacture of nuclear fuel and storage and reprocessing of spent nuclear fuel, disposal of nuclear waste, etc.

In relation to nuclear safety, the Regulation Law was amended in order to strengthen the nuclear safety requirements within nuclear facilities [Law No. 157, 13 December 1999]. In this respect, periodic inspections of processing facilities, compulsory notification of their dismantling, and regular checks on the management and operational procedures of nuclear energy facilities are required to ensure compliance with safety regulations. The Law furthermore provides for the appointment of Inspectors for Safety Management of Nuclear Installations under MEXT and METI in order to carry out such inspections. Nuclear operators are also required to organise safety training for radiation workers.

Japan accepted the 1994 Convention on Nuclear Safety on 12 May 1995.

Finally, it should be noted that the Law on Compensation for Nuclear Damage [No. 147, 17 June 1961] prohibits the operation of a nuclear installation if the financial security for damage required by the law is not in place in respect of that installation.

## ***b) Emergency response***

The Special Law on Emergency Preparedness for Nuclear Disaster (hereinafter referred to as “the Special Law”) [No. 156, 17 December 1999] aims to enforce countermeasures in the event of a nuclear emergency. In this respect it modifies and complements the countermeasures against natural disasters described in the Basic Law for Disaster Countermeasures [No. 223, 15 November 1961].

Under the Special Law, the nuclear operator must take measures to prevent nuclear emergencies, prepare an Emergency Plan, in consultation with mayors and prefectural governors, and establish a Nuclear Emergency Prevention Organisation. This Organisation is responsible for taking necessary measures to prevent or mitigate nuclear emergencies.

The nuclear operator shall also appoint a Nuclear Emergency Prevention Manager who will be responsible for supervising the activities of this Organisation. The Manager shall inform the competent ministers, mayors and governors of municipalities and prefectures, promptly after such an event takes place and, upon the request of governors or mayors, the competent ministers shall dispatch their appropriate personnel.

The nuclear operator is also required to install and maintain equipment for measuring radiation doses and to provide special radiation protection clothes, emergency communication equipment, etc.

Relevant ministers are to establish Off-Site Centres, which shall take necessary measures in the event of an emergency situation, in each prefecture where a nuclear installation is located.

In the event of an emergency situation, the Prime Minister issues a Declaration of a Nuclear Emergency Situation, notifies the public in the area where urgent countermeasures must be adopted and gives evacuation instructions to the mayors and governors of relevant municipalities and prefectures.

The Special Law further provides that, in the event of an emergency situation, several structures will be established:

- Within the Cabinet Office, a Government Countermeasures Headquarters shall be created, and in emergency situations the Prime Minister, as a director of the Headquarters, may request the Director General of the Defence Agency to dispatch the Self-Defence Force. He may also request technical advice regarding the implementation of urgent countermeasures from the Nuclear Safety Commission.
- A Joint Council for Countermeasures in the event of Nuclear Emergency shall be set up within the Off-Site Centre in order to facilitate exchange of information and co-operation among the various organisations concerned.

The government, local authorities, relevant organisations and operators shall take urgent measures such as notifying information, evacuation, collecting information including radiation dose rate, rescuing victims, controlling emergency transportation, measuring exposure dose rate of residents, etc., within their respective fields of competence.

Lastly, in order to inform nuclear operators about emergency prevention measures and to collect information in the event of an emergency, MEXT and METI appoint specialists in nuclear emergency preparedness at each nuclear installation.

At the international level, Japan accepted the 1986 Conventions on Early Notification of a Nuclear Accident and on Assistance in the Case of a Nuclear Accident or Radiological Emergency respectively on 9 June 1987.

## **5. Trade in Nuclear Materials and Equipment**

While Japan imports nuclear fuels, materials and technology, it also has a highly developed nuclear industry and the corresponding potential to supply numerous nuclear and nuclear-related services and equipment.

Japan has a clearly-defined nuclear export policy based on assurance of peaceful uses and non-proliferation, including compliance with the London Club Guidelines, elaborated by the Nuclear Suppliers Group (London Club).

In 1962, the Atomic Energy Commission issued a policy statement to the effect that nuclear materials, reactor cores and units for the reprocessing of special nuclear materials, exported from Japan, be used solely for peaceful purposes, thus setting a fundamental principle for nuclear exports control, consistent with the principles of the Basic Law [Section 2].

The Regulation Law provides for control of nuclear material and equipment while the Prevention Law regulates the sale of radioactive materials and equipment.

The Regulation Law restricts the transfer, import and export of nuclear fuel to those who are engaged in refining, manufacturing or reprocessing such material, and to operators of nuclear facilities [Section 61]. These restrictions do not apply where the government receives or transfers nuclear fuel at the national level or in accordance with international arrangements.

The sale and import of radioisotopes for medical purposes are governed by the Medical Supplies Act [No. 145, 1960] and are subject to licensing requirements. Trade in medical X-ray apparatus is regulated by an Ordinance of the Ministry of Health, Labour and Welfare and is subject to notification, but not licensing, requirements.

The import and export of nuclear materials and equipment are also subject to the provisions of general trade law, namely the Foreign Exchange and Foreign Trade Control Law [No. 228, 1 December 1949, as amended] and its implementing orders and regulations which describe the procedures for obtaining import and export licences and approvals. METI is responsible for this Act and its implementing legislation. Nuclear material and equipment are classified as “exceptional items” which means that prior approval must be obtained for their export and importation. The Import Trade Control Order [Cabinet Order No. 414, 29 December 1949] and the Export Trade Control Order [Cabinet Order No. 378, 1 December 1949] contain the basic rules for import and export activities, while the procedures to be followed to obtain the necessary licence are set out in the Import Trade Control Regulations [Ordinance No. 77, 1949] and the Export Trade Control Regulations [Ordinance No. 64, 1 December 1949].

## **6. Radiation Protection**

Both the Prevention Law and the Regulation Law govern radiation protection issues.

The aim of the Prevention Law is to regulate the use, sale, lease, disposal or any other handling of radioisotopes and ionising radiation-generating equipment in order to prevent ionising radiation hazards and to secure public safety [Section 1]. Pursuant to this Law, applications must be made to the Minister of Education, Culture, Sports, Science and Technology for any activity connected with radioisotopes or ionising radiation-generating equipment. Granting of the licence depends on whether the site, structure and equipment proposed conform to the standards laid down by the Order of the Prime Minister [No. 56, 30 September 1960], and whether potential hazards from ionising radiation have been dealt with satisfactorily [Sections 6, 7 and 7-2]. The Prevention Law also sets out dose limits for exposure to ionising radiation. The limit is 50 mSv per year for workers whose work involves radiation activities, and 1 mSv per year for members of the public. In 1980, the Prevention Law was amended to introduce a system of inspection and approval of radioisotopic equipment and to prescribe compulsory training courses for radiation protection supervisors. The amendments also

established a training institution to conduct these courses. In 1995, further amendments established a system for leasing radioisotopes and simplified the licensing system for the use of radioisotopes with a lower risk of radiation hazard.

The Regulation Law deals with safety issues in relation to nuclear reactors and nuclear fuel. The licensing procedure involves scrutiny of safety measures and accident prevention at every stage. Detailed rules on these matters are contained in the Ordinance for the Enforcement of the Law Concerning Nuclear Source Materials, Nuclear Fuel Materials and Nuclear Reactors [Ordinance No. 324, 21 November 1957].

In addition to these laws, there are also the Regulations on the Prevention of Ionising Radiation Hazards [Ordinance of the Ministry of Labour, No. 41, 30 September 1972].

The Nuclear Safety Commission, which has a significant advisory role in the licensing process for nuclear installations, was established in 1978 to take over responsibility for safety issues formerly dealt with by the Atomic Energy Commission. It is responsible *inter alia* for protection against hazards resulting from the use of nuclear energy and radioactive fallout.

## **7. Radioactive Waste Management**

The legislation applicable to the management of waste resulting from nuclear reactor operations is the Regulation Law. In relation to waste resulting from the use of radioisotopes and ionising radiation-emitting equipment, the Prevention Law is applicable. Furthermore, a Law on Final Disposal of High Level Radioactive Waste [No. 117, 31 May 2000] governs the geological disposal of such waste.

Waste management policy is determined by the Atomic Energy Commission (basic policy) and the Nuclear Safety Commission (safety aspects), and that policy is implemented through the licensing system for nuclear activities. Pursuant to Chapter V-II of the Regulation Law, application may be made to METI for a licence to engage in nuclear waste disposal activities [Section 51-2]. The licence may authorise either the storage of waste or (in the case of low-level waste) its final disposal by underground burial. The licence application must include information about the type of waste and its properties, the location of the proposed storage or disposal facilities, a safety plan, an engineering plan and a management plan. The application must also establish that the project has adequate technical and financial resources. The site must conform to standards specified in the relevant Orders from the former Prime Minister's Office (now the Cabinet Office) and METI Ordinances. Once the licence has been granted, the operator of the waste management facility is subject to supervision and inspection by METI at regular intervals [Sections 51-8 to 51-10].

Regarding high level radioactive waste, a Nuclear Waste Management Organisation was established as a private law company pursuant to Law No. 117 of 2000 [Section 40]. This Organisation, which is supervised by METI, is entrusted with the task of implementing the final disposal of high-level radioactive waste. It is responsible for all steps involved in the disposal of radioactive waste, from the selection of the site and preliminary investigations to post-closure management of disposal facilities. The operators of nuclear power plants shall pay a specific fee, determined by the Ministry, to this Organisation every year. High-level waste originating from research and experimental reactors is not subject to an annual fee, but may be accepted by the Organisation for final disposal if this does not disrupt normal business activity.

In selecting the final disposal site, the Organisation shall follow a three-step procedure. First, it shall select a Preliminary Survey Site, following the results of a survey on geological disturbances caused by earthquakes or other natural phenomena [Section 6]. At that site, tests shall be carried out to determine the stability of the geological stratum, resulting in the choice of a Specific Survey Site [Section 7]. Finally, the Organisation shall select a site where the final disposal facilities are to be constructed [Section 8]. METI is to review the Final Disposal Plan upon selection of the Final Disposal Site by the Organisation, taking into account the opinions of the heads of local government where the site is located.

Should the Organisation encounter difficulties in continuing operations, METI shall take over its responsibility until appropriate measures, such as the transfer of its operations, shall be established by legislation.

The Prevention Law has a series of provisions dealing with the obligations of those responsible for the disposal of radioisotopes and material contaminated by radioisotopes [Sections 19-26]. Measures to prevent ionising radiation hazards must be taken, in accordance with the technical standards laid down by order of the former Prime Minister's Office and ordinance of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Failure to comply with these standards may result in the Minister ordering the suspension of the disposal activities. Records must be kept of disposal activities and of the results of monitoring radiation levels at waste storage and disposal facilities. Further provisions require that all waste disposal operators develop their own internal rules for the prevention of radiation hazards, that these rules be approved by MEXT, and that training and medical examinations be made available to all employees entering waste storage and disposal facilities.

As far as the dumping of radioactive waste at sea is concerned, Japan has been a Party to the 1972 London Convention on Prevention of Marine Pollution by the Dumping of Waste and Other Matters since 15 October 1980. Up until early 1994, the Convention permitted the dumping at sea of certain low-level radioactive waste. However, in 1993, Japan's Atomic Energy Commission decided to discontinue dumping at sea as a means of disposal and, since 20 February 1994, all Parties to the Convention have become bound by a 25-year ban on the dumping at sea of any radioactive waste.

## **8. Non-Proliferation and Physical Protection**

Japan has been a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons since 8 June 1976 and to the 1979 Convention on the Physical Protection of Nuclear Material since 28 October 1988. It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 8 July 1997.

Provisions regarding the peaceful use of nuclear materials are established in the Basic Law and the Regulation Law. The Basic Law states that research into, development and use of nuclear energy shall be limited to peaceful purposes and provides, *inter alia*, that import, export, possession etc. of nuclear fuel shall be subject to regulations for control purposes [Section 2]. The Regulation Law lays down detailed regulations for the different types of nuclear activities, including provisions for control of the use of internationally-controlled material [Chapter VI-II]. The Regulation Law specifies that such material includes nuclear source material, nuclear fuel, reactors and other material or equipment to which safeguards and other regulations are applied pursuant to the Safeguard Agreement concluded with the International Atomic Energy Agency (IAEA) and other agreements concluded with foreign governments or international organisations, pursuant to the Additional Protocol to the Safeguard Agreement, in relation to research, development and use of nuclear energy [Section 2].

The Ministry of Education, Culture, Sports, Science and Technology (MEXT) bears responsibility for the peaceful uses of nuclear energy. The Nuclear Safety Division within the Science and Technology Policy Bureau is in charge of safeguards. Chapter VII of the Regulation Law provides that inspectors appointed by METI, MEXT and the Ministry of Land, Infrastructure and Transport (MLIT) are to have access to the offices, facilities or places where nuclear fuel is located in order to carry out controls as required by this Law. If premises contain internationally-controlled material, persons appointed by the supplier state or IAEA inspectors also have inspection powers. Japan accepted to apply IAEA safeguards to nuclear material in conformity with its obligations under the Nuclear Non-Proliferation Treaty [Section 68]. On 16 June 1999, new provisions were added to the Regulation Law to incorporate the requirements of the Additional Protocol to the Safeguard Agreement, which Japan signed within the framework of the IAEA in 1998. The new provisions establish the obligation of persons who undertake specified activities, defined as the activities listed in Annex I of the Additional Protocol, to report to MEXT [Section 61-9(2)]. They furthermore provide that users of internationally controlled material are subject to regular inspection by that Minister to the extent necessary for the implementation of the Safeguard Agreement [Section 61-8(2)]. The Minister may designate one or more organisation(s) to conduct inspections under his control [Section 61-23(1)]. The new provisions of the Law allow the IAEA inspectors to enter the offices, facilities or premises of the users of internationally-controlled material and persons carrying out internationally specified activities to conduct complementary inspections in the presence of officials appointed by the Minister, within the limits established by the Additional Protocol [Section 68].

Chapter VI-II of the Regulation Law contains accounting provisions: users of nuclear fuel must keep records and must report any loss or theft. Failure to maintain records of internationally-controlled material or provide information on such material as required is punishable by a fine of up to Japanese yen (JPY) 200 000 [Section 80]. Criminal sanctions, carrying prison sentences, also apply to the unauthorised use of specified nuclear fuels [Chapter VIII].

The Regulation Law provides that people engaged in any of the nuclear activities to which it applies (refining, manufacture, reactor operation, reprocessing, waste disposal and use of nuclear fuel material) are responsible for establishing rules for the physical protection of specified nuclear materials in their establishments [see, for example, Sections 12-2 to 12-5]. These rules must conform to requirements specified in various ministerial orders. The orders are issued by different ministers, depending on the type of nuclear activity addressed. MEXT issues orders laying down a framework for physical protection in relation to research reactors which are not used for power generation and use of nuclear materials, while METI has a similar responsibility in relation to power reactors, refining, manufacture, reprocessing and waste disposal, and MLIT is responsible for nuclear ships.

The physical protection rules established by an operator of nuclear installations can only be modified with the approval of the minister responsible (who also has the power to order that certain modifications be made). The operator must appoint a physical protection supervisor to ensure compliance with the rules [Sections 12-3, 22-7, 51, 51-24 and 57-3].

## **9. Transport**

The administrative requirements and safety standards applicable to the transport of radioactive materials in Japan are set out in ordinances by METI, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Land, Infrastructure and Transport (MLIT), which incorporate the 1985 Edition of the IAEA Regulations for the Safe Transport of Radioactive Material into domestic law.

In order to prevent exposure to radiation and, in the case of fissile materials, to prevent criticality, during the transport of radioactive materials, different governmental agencies are responsible for the application of laws and ordinances for the different modes of transport, with classification of packages into different categories according to the specific radioactivity, form, characteristics and total radioactivity of the contained radioactive materials and the dose equivalent rate from the packages.

*Overland transport* (transport by rail and road) is governed by various regulations adopted by MEXT, METI and MLIT pursuant to the Regulation Law (for nuclear materials) and the Prevention Law (for radioisotopes). Such transport operations are supervised by MEXT, METI and MLIT to ensure that technical standards are met. The procedure is as follows:

- a) MEXT, METI and MLIT issue a certificate of package design approval after examination of the package's safety in terms of structure, material, manufacture, handling, maintenance control etc. MEXT issues orders laying down a framework for transport in relation to research reactors and use of nuclear materials, while METI has a similar responsibility in relation to commercial power reactors, refining, fabrication, reprocessing and waste disposal, and MLIT is responsible for reactors in operation on nuclear ships.
- b) MEXT, METI and MLIT, if they are satisfied that it has been manufactured in accordance with the approved design, and in light of inspections and tests in relation to material, dimensions, welding, pressure, heat conditions, shielding, etc., assign registration numbers to the individual packages and issue the applicant with a packaging approval certificate.
- c) Prior to each transport operation, the applicant also applies to MEXT, METI and MLIT to have the packages approved. Having confirmed that they are in conformity with (a) and (b) above, and that they meet standards regarding the appearance of the packages, surface dose equivalent rate and leakage, the certificate of confirmation is issued.
- d) Prior to each transport operation, the applicant furthermore applies to MLIT for approval of the method of transport. Upon confirmation that the mode of transport (method of loading of the packages on the vehicles, marking and labelling, loading limits, etc.) are in conformity with the technical standards, the Ministry issues a certificate of approval.
- e) Prior to each shipment, the applicant must formally notify the prefectural Public Safety Committee (PSC) of the specific transport plans. The PSC then gives guidance and instruction on safety issues, if necessary, and issues a permit for the transport operation.

Concerning *maritime transport*, basically the same procedure as applies to overland transport is followed, except that the competent bodies are MLIT and the Japan Coast Guard. The applicable legislation is the Ship Safety Law [No. 11, 15 March 1933], which has incorporated the provisions of the IAEA Regulations for the Safe Transport of Radioactive Materials concerning packages and the provisions of the International Maritime Organisation's (IMO) 1960 International Convention for the Safety of Life at Sea (SOLAS) concerning the structure and facilities of the ship. In the case of combined overland and maritime transport, packages are approved by MEXT, METI and MLIT on the basis of the Regulation Law (or the Prevention Law for radioisotopes). This approval procedure is sufficient to satisfy the conditions of the Ship Safety Law. Prior notification in the case of maritime transport is provided to the Head of the Regional Maritime Safety Headquarters of the MSA with jurisdiction over the port of departure of the ship.

In relation to *air transport*, the procedure outlined above with regard to overland transport is also followed; in this particular field the competent body is MLIT. The applicable legislation is the Civil Aeronautic Law [No. 231, 15 July 1953]. In the case of combined overland and air transport, packages are approved by MEXT, METI or MLIT on the basis of the Regulation Law (or the Prevention Law for radioisotopes), which is sufficient to satisfy the conditions of the Civil Aeronautic Law.

## 10. Nuclear Third Party Liability

Japan is not a Party to either the 1960 Paris Convention or the 1963 Vienna Convention on civil liability for nuclear damage. However, it has established a national regime dealing with compensation for nuclear damage which incorporates a number of the principles embodied in both Conventions. The four major legislative instruments to be considered in this context are the Law on Compensation for Nuclear Damage [No. 147, 17 June 1961, as amended], the Ordinance implementing the Law on Compensation for Nuclear Damage [Cabinet Order No. 44, 6 March 1962, as amended], the Law on Indemnity Agreements for Compensation for Nuclear Damage [No. 148, 17 June 1961, as amended] and the Ordinance implementing the Law on Indemnity Agreements for Compensation for Nuclear Damage [Cabinet Order No. 45, 6 March 1962, as amended].

The Compensation Law provides for the strict, exclusive and unlimited liability of the operator of a nuclear installation [Sections 3 and 4] in respect of nuclear damage resulting from the operation of his installation [Section 3(1)]. “Nuclear damage” is defined as any damage caused by the effects of the fission process of nuclear fuel material, or of the radiation from nuclear fuel material etc., or by the effects of the toxic nature of such material [Section 2]. The Compensation Law requires each installation to be insured for a prescribed amount (pursuant to the amendment of 28 April 1999 to the Compensation Law, JPY 60 billion for the operation of nuclear reactors) [Section 7] and prohibits the operation of the installation if the required financial security is not in place [Section 6].

In addition to the funds available from the operator’s insurance, the Law on Indemnity Agreements provides that the government may conclude an agreement with the operator according to which it will indemnify the operator for any amount payable as compensation which is not covered by the operator’s insurance. This indemnity is of particular importance in the event of nuclear damage resulting from earthquakes or volcanic eruptions as this type of damage is not covered by private liability insurance. The amount provided under the indemnity agreement is equal to the prescribed amount of the operator’s private insurance. The operator is required to pay an annual fee to the government in order to benefit from this indemnity arrangement [Sections 2, 4 and 6].

Finally, the Compensation Law also provides for the possibility of government aid where the cost of nuclear damage exceeds the amount of the operator’s financial capacity [Section 16(1)].

The legislative provisions dealing with indemnity agreements and with government aid will remain in force until 2009.

Jurisdiction to hear a claim for compensation for nuclear damage is determined by the ordinary rules of civil litigation. Under Section 724 of the Civil Code, the right to compensation for damage shall be extinguished if an action is not brought within three years from the date on which the person suffering damage had knowledge both of the damage and of the person liable for such damage. The right to compensation shall also be fully extinguished 20 years after the date on which a tort occurs.

The Compensation Law provides for the possibility of referring a claim to a Dispute Reconciliation Committee for Nuclear Damage Compensation, whose function would be to mediate in respect of disputes concerning compensation [Section 18].

Pursuant to a 1994 amendment of the Compensation Law [No. 85], nuclear damage which occurs due to the operation of a nuclear reactor (including fuel manufacture, spent fuel reprocessing, etc.) is outside the scope of the Product Liability Law. This distinction was required because the Compensation Law provides for the exclusive liability of the nuclear operator, whereas within the meaning of the Product Liability Law, not only the nuclear operator but also a supplier of a nuclear reactor or nuclear fuel material could be considered a “producer etc”.

## II. INSTITUTIONAL FRAMEWORK

### 1. Regulatory and Supervisory Authorities

Responsibility for the regulation of nuclear activities is vested in the Minister of Economy, Trade and Industry (METI), the Minister of Education, Culture, Sports, Science and Technology (MEXT) and the Minister of Land, Infrastructure and Transport (MLIT) according to the type of activity involved.

#### a) *Cabinet Office*

The Basic Law initially provided for the establishment of an Atomic Energy Commission (AEC), within the former Prime Minister’s Office (now the Cabinet Office), for the purpose of developing national policies on the research, development and use of nuclear energy [Section 4]. In 1978, the AEC’s responsibilities were divided and a Nuclear Safety Commission (NSC) was created, also within the former Prime Minister’s Office, to take over responsibility for the safety aspects of nuclear activities (for more details on the AEC and the NSC see *infra* under Section 2 “Advisory bodies”).

#### b) *Minister of Economy, Trade and Industry (METI)*

In January 2001, the former Ministry of International Trade and Industry (MITI) was reorganised and the Ministry of Economy, Trade and Industry (METI) was established pursuant to the Law for the Establishment of this Ministry [No. 99, 16 July 1999]. METI is responsible for securing a stable and efficient energy supply, and for the uses of nuclear energy, including policy making in this field and the development of nuclear technology. METI is also empowered to govern safety regulation and licensing of nuclear energy utilisation, namely milling and refining, nuclear fuel fabrication, nuclear power generation, reprocessing and storage of spent nuclear fuel, and disposal of radioactive waste.

### *The Agency of Natural Resources and Energy (ANRE)*

The Agency of Natural Resources and Energy (ANRE) is established within METI. Its tasks are to ensure a stable and efficient supply of energy (including from mineral resources), to promote appropriate uses of energy and to ensure industrial safety. It is headed by a director-general and is divided into the Director-General's Secretariat, the Energy Conservation and Renewable Energy Department, the Natural Resources and Fuel Department and the Electricity and Gas Industry Department. The Electricity and Gas Industry Department is divided into six Divisions, including the Nuclear Energy Policy Planning Division and the Nuclear Fuel Cycle Industry Division. The Nuclear Energy Policy Planning Division administers nuclear energy policy, nuclear energy technology development, and development, improvement and co-ordination of nuclear radioactive waste management. It also oversees the work of the Japan Nuclear Cycle Development Institute (JNC). The Nuclear Fuel Cycle Industry Division is responsible for ensuring a stable and efficient supply of nuclear materials, technology development for nuclear fuel materials, and nuclear facility siting.

The ANRE is assisted in its work by the Advisory Committee for Energy and the Electricity Utility Industry Council.

### *Agency for Nuclear and Industrial Safety (ANIS)*

During the reorganisation of the government in January 2001, an Agency for Nuclear and Industrial Safety (ANIS) was established as a special organisation within the ANRE. It is responsible for regulating both nuclear and industrial safety of nuclear activities. The drafting of safety regulations and the licensing of milling and refining, nuclear power reactors, nuclear fuel fabrication, reprocessing and storage of spent nuclear fuel, and disposal of radioactive waste are now carried out by ANIS.

ANIS is headed by a Director-General together with a Director-General for Nuclear and Industrial Safety Policy, three Deputy Director-Generals for Nuclear Power Safety, the Nuclear Fuel Cycle and Industrial Safety respectively, a Deputy Director-General for Safety Examination and seven Directors for Safety Examination. It consists of 14 Divisions, 9 of which are responsible for nuclear safety regulations and licensing, namely the Policy Planning and Co-ordination Division, Nuclear Safety Administration Division, Nuclear Power Licensing Division, Advanced Reactor and Fuel Regulation Division, Nuclear Fuel Cycle Regulation Division, Radioactive Waste Regulation Division, Nuclear Emergency Preparedness Division and Electric Power Safety Division.

The Policy Planning and Co-ordination Division provides administrative support to the ANIS and co-ordinates all functions of the Agency. The Nuclear Safety Administration Division has under its authority the Nuclear Safety Inspectors and the Nuclear Emergency Prevention Manager and it oversees their training. The Nuclear Power Licensing Division is responsible for the licensing of commercial nuclear power reactors. The Nuclear Power Inspection Division deals with the inspection of commercial nuclear power reactors and is responsible for their nuclear safety regulations and nuclear material protection. The Advanced Reactor and Fuel Regulation Division is in charge of the licensing of reactors at the stage of research and development used for electricity generation. The Nuclear Fuel Cycle Regulation Division is responsible for safety regulations governing refining, nuclear fuel fabrication, and spent fuel reprocessing and storage. The Radioactive Waste Regulation Division oversees the safety regulation of radioactive waste and the decommissioning of nuclear facilities. The Nuclear Emergency Preparedness Division is in charge of policy planning concerning nuclear disaster preparedness. Finally, the Electric Power Safety Division carries out inspections in relation to power generation and turbines of commercial nuclear power plants.

ANIS is assisted in its work by the Nuclear and Industrial Safety Sub-Committee and by the Advisory Committee for Natural Resources and Energy.

**c) *Minister of Land, Infrastructure and Transport (MLIT)***

During the reorganisation of the government in 2001, the Ministry of Transport, the Ministry of Construction, the Hokkaido Development Agency and the National Land Agency merged to become the Ministry of Land, Infrastructure and Transport (MLIT). It is responsible for all forms of transport of radioactive materials. In relation to transport by rail or road, the Regulation Law and the Prevention Law provide that this responsibility is shared with the Ministry of Education, Culture, Sports, Science and Technology. Both the Ship Safety Law [No. 11, 15 March 1933] regulating the transport of radioactive materials by sea and the Civil Aeronautics Law, 1952, regulating the transport of radioactive materials by air are administered by MLIT.

**d) *Minister of Education, Culture, Sports, Science and Technology (MEXT)***

In January 2001, the Science and Technology Agency (STA) merged with the Ministry of Education to become the Ministry of Education, Culture, Sports, Science and Technology (MEXT) pursuant to the Law for the Establishment of this Ministry [No. 96, 16 July 1999]. This Ministry is responsible for the science and technology aspects of nuclear energy, including policy making in this field, development of nuclear technologies, safety regulations governing research reactors, protection against radiation hazards, the use and transportation of nuclear materials, except those originating in nuclear fuel cycle facilities and nuclear power plants, the use, storage and transportation of radioisotopes and the peaceful uses of nuclear energy (safeguards). The Ministry is also responsible for nuclear third party liability.

The Ministry is comprised of a Secretariat, seven Bureaux and a Director-General for International Affairs. Nuclear regulations are administered by the Science and Technology Policy Bureau.

The *Science and Technology Policy Bureau* is divided into four Divisions: Policy, Research and Co-ordination, Infrastructure Policy and Nuclear Safety, and has two Directors (International Affairs and Planning). The Policy Division co-ordinates all the work of the Bureau and is responsible for the planning and co-ordination of science and technology policy. The Research and Co-ordination Division co-ordinates the budget for the promotion of science and technology and deals with collection, research and analysis of science and technology information inside and outside Japan. The Infrastructure Policy Division plans and co-ordinates the overall policy for the promotion of science and technology and deals with the education and training of nuclear researchers and technical experts. The Nuclear Safety Division is responsible for nuclear safety, including disaster prevention, radiation safety, monitoring of environmental radioactivity, safeguards and safety regulations governing the use of nuclear materials, research reactors and reactors not used for electricity generation at the research and development stage. The Nuclear Safety Division also provides administrative support to the Radiation Council. The Director for International Affairs is in charge of policy planning of international co-operation in the field of science and technology.

The *Research Promotion Bureau* is divided into eight Divisions, including the Quantum and Radiation Research Division which is responsible for the infrastructure supporting nuclear technology development, radiation use, and the use of radioisotopes. It is also responsible for the management of research reactors, decommissioning of reactors, disposal of radioisotope waste and the high energy

accelerator. It also oversees the work of the JAERI, the National Institute of Radiological Sciences and the High Energy Accelerator Research Organisation.

The *Research and Development Bureau* consists of seven Divisions, including the Research and Development Policy Division, the Atomic Energy Division and the Nuclear Fuel Cycle Research and Development Division. The Research and Development Policy Division co-ordinates all the work of the Bureau and deals with natural disaster prevention technology and nuclear facility siting. The Atomic Energy Division is responsible for the nuclear research policy and programmes including their budget. It is also responsible for policy making in relation to nuclear third party liability, international co-operation in the field of nuclear energy, peaceful uses of nuclear energy and the development of nuclear fusion science. The Division also oversees the work of the JNC and the JAERI. The Nuclear Fuel Cycle Research and Development Division is responsible for the research and development of fast breeder reactor and related nuclear fuel cycle technologies. This Division also oversees the work of the JNC.

## 2. Advisory Bodies

### a) *Atomic Energy Commission (AEC)*

The AEC was established by the Basic Law, with a view to developing policies on all matters related to the research, development and utilisation of atomic energy [Section 5]. The AEC operates under the terms of its own legislation, the Law for the Establishment of the Atomic Energy Commission (the “Establishment Law”) [No. 188, 19 December 1955].

Although its functions are advisory, it is a powerful body, which can make recommendations on its own initiative, through the Prime Minister, to other ministries and agencies involved in regulating the use of nuclear energy. These ministries and agencies are also obliged to consult with the AEC in the course of carrying out their own licensing and other regulatory activities.

The main task of the AEC is to consider and make recommendations on the following matters:

- policies on the utilisation of atomic energy;
- co-ordination between different government agencies involved in regulating nuclear activities;
- the content of regulations dealing with nuclear fuel and nuclear reactors (apart from safety issues);
- promotion of nuclear energy research;
- policies on training of professional and technical staff working in the field of nuclear energy;
- collection of data, preparation of statistics and research on the use of nuclear energy.

The AEC, which was placed under the auspices of the Cabinet Office during the reorganisation of the government in 2001, consists of a chairperson and four commissioners, who are appointed by

the Prime Minister for a period of three years. A commissioner's appointment may be renewed following approval by the Diet (Japanese Parliament).

**b) *Nuclear Safety Commission (NSC)***

The NSC came into existence in 1978 as a result of a decision that nuclear safety issues should no longer be dealt with by the AEC (which was also responsible for the promotion of nuclear energy), but by an independent body, so as to institute a clear separation of responsibility between the development and use of nuclear energy and nuclear safety and health protection. This separation was carried out by an amendment to the Atomic Energy Basic Law [No. 186, 19 December 1955] and the Law for the Establishment of the Atomic Energy Commission [No. 188, 19 December 1955].

In the wake of the Tokai-mura criticality accident in 1999, the Secretariat of the NSC was transferred on 1 April 2000 from the STA to the Prime Minister's Office (now the Cabinet Office), pursuant to a governmental decision stating that the NSC should strengthen its independence, enhance the secretariat and recruit experts on nuclear safety. Its functions are:

- to define regulatory policies for the safe utilisation of nuclear energy;
- to issue guidelines for the safety of nuclear fuel, source material and nuclear reactors;
- to issue guidelines on the prevention of ionising radiation hazards resulting from the use of nuclear energy and radioactive fallout;
- to make recommendations on any other aspects of radiation safety as it considers appropriate.

Licensing authorities are obliged to consult the NSC on safety and radiation protection issues in the course of their licensing procedures. The NSC must confirm subsequent regulation performed by the administrative authorities.

The NSC consists of a chairperson and four commissioners, appointed by the Prime Minister with the approval of both Houses of the Diet for a period of three years. A commissioner's term of office may be renewed following approval by the Diet.

A number of advisory committees are attached to the NSC to provide expert assistance to the Commission, the most important of these being the Committee on Examination of Reactor Safety and the Committee on Examination of Nuclear Fuel Safety. Other committees include the Special Committees on Nuclear Safety Standards, Nuclear Safety Research, Comprehensive Nuclear Safety, on Basic Prevention against Radiation Hazards, Investigation of Nuclear Accidents and Failures, and Nuclear Disasters.

**c) *Radiation Council***

The Radiation Council is a specialised body placed under the authority of MEXT which is governed by the Law concerning Technical Standards of Radiation Protection [No. 162, 21 May 1958].

The principal function of the Council is to establish technical standards for radiation protection and measurement of radioactivity levels [Section 5].

The Council has a maximum of 20 members, appointed by MEXT. Members are appointed on the basis of relevant specialist knowledge, and may be either from within or outside government agencies. They hold office (on a part-time basis) for a period of two years (unless they belong to government agencies) [Section 7].

The Nuclear Safety Division of MEXT provides administrative support to the Council.

**d) *Special Committee on Energy Policy***

This Committee of the House of Councillors was set up by the Diet in 1979 to study Japan's long-term energy policy and to submit proposals and draft legislation giving effect to these proposals to the government. The Committee is assisted in this task by specialists in the field.

The Committee is made up of 21 members of the Diet, appointed for a period of 6 years.

**e) *Other Advisory Bodies***

METI consults several committees for advice in the course of its procedures for the licensing of commercial nuclear power reactors. In particular, it seeks the advice of the Advisory Committee on Environmental Matters and some of the members of the Nuclear and Industrial Safety Sub-committee under the Advisory Committee for Natural Resources and Energy. METI also consults the Electric Power Development Committee of the Advisory Committee for Natural Resources and Energy, whose approval must be obtained before any application to build and operate a commercial reactor is granted.

**3. Public and Semi-Public Agencies**

**a) *Japan Atomic Energy Research Institute (JAERI)***

The Japan Atomic Energy Research Institute (JAERI) was established pursuant to the terms of the Basic Law. The Japan Atomic Energy Research Institute Law [No. 92, 4 May 1956] sets out the functions of the Institute and its structure.

**i) *Legal Status***

Law No. 92 of 1956 established the JAERI to carry out research on the comprehensive and efficient development of atomic energy along with the research necessary for development of nuclear powered ships, and thereby contribute to fostering research, development and use of atomic energy [Section 1]. MEXT supervises all the activities of the JAERI, in collaboration with MLIT regarding research on nuclear powered ships [Section 38(2)].

**ii) *Responsibilities***

The main responsibilities of the Institute are [Section 22]:

- to conduct both basic and applied research on nuclear energy, including research necessary for the development of nuclear powered ships;
- to design, construct and operate research reactors;
- to train research specialists and engineers in nuclear energy;
- to import, produce and distribute radioisotopes; and
- to collect data on nuclear energy and to disseminate the results of its own research work.

The JAERI's nuclear activities, with the exception of those related to nuclear powered ships, are carried out on the basis of the Basic Programme for Research, Development and Utilisation of Nuclear Energy, which was established by MEXT with the approval of the AEC and the NSC [Section 24(1)]. On the other hand, its activities related to nuclear powered ships are carried out on the basis of the Basic Programme on Research for the Development of Nuclear Powered Ships, which was established by MEXT and MLIT upon the advice of the AEC [Section 24(2)].

In 1985 the Japan Nuclear Ship Research and Development Agency merged with the Institute.

### *iii) Structure*

The JAERI is managed by a board of directors consisting of the president, two executive vice-presidents, eight executive directors and up to two auditors. The president and the auditors are appointed by MEXT with the consent of the AEC. The president appoints the other members of the board with the consent of MEXT. The president and vice-presidents are appointed for a term of four years, the executive directors and auditors for two years [Sections 10, 12 and 13].

### *iv) Financing*

The major part of the JAERI's funds is provided by the government. The Institute is required to prepare financial statements for the previous year as well as budgetary estimates and a programme of work for the following year for submission either to MEXT or to MLIT, depending on the activities involved [Sections 4, 26 and 28].

## ***b) Japan Nuclear Cycle Development Institute (JNC)***

### *i) Legal status*

Pursuant to the terms of the Basic Law, the Power Reactor and Nuclear Fuel Development Corporation (PNC) was established by Law No. 73 of 20 July 1967 before being reorganised as the Japan Nuclear Cycle Development Institute (JNC) by the Law introducing Partial Amendments to the Atomic Energy Basic Law and the Power Reactor and Nuclear Fuel Development Corporation Law [No. 62, 20 May 1998]. The JNC undertakes research and development necessary for establishing the nuclear fuel cycle.

The JNC is endowed with the status of a separate legal entity [Section 3] and is supervised by both MEXT and METI [Section 44]. When carrying out its activities, the JNC is required to receive approval from the competent Ministry [Section 24]. Furthermore, it is required to follow the Basic Policy established by those Ministries with the approval of the AEC [Section 27]. The Basic Policy describes the fundamental principles governing the management and activities of the JNC.

*ii) Responsibilities*

The main responsibilities of the Institute are [Section 24]:

- to develop the fast breeder reactor and conduct related research;
- to develop nuclear fuel for the fast breeder reactor and conduct related research;
- to develop technology for the reprocessing of nuclear fuel materials and conduct related research; and
- to develop technology for treatment and disposal of high-level radioactive waste.

The JNC's nuclear activities may only be carried out for peaceful purposes and they shall contribute to the promotion of the development and use of atomic energy [Section 1].

*iii) Structure*

The JNC is managed by a board of directors, consisting of the president, two executive vice-presidents, up to seven directors and up to two auditors. The president is appointed by the MEXT and METI with the consent of the AEC. The president appoints the other members of the board, with the consent of the above-mentioned Ministries. The president and the executive vice-presidents are appointed for a term of four years, and the directors and auditors for two years [Sections 11, 13 and 14].

Law No. 62 of 1998 created a management review board which consists of up to 15 members [Section 22]. This board provides an external evaluation of the management of the JNC.

*iv) Financing*

The JNC's funding is made up of contributions from the government and from private industry [Section 5]. The JNC is required to prepare financial statements for the previous year as well as budgetary estimates and a programme of work for the following year for submission to the MEXT and METI [Sections 29 and 31].

# LUXEMBOURG

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## **I. GENERAL REGULATORY REGIME**

### **1. Introduction**

In Luxembourg, regulation of nuclear energy is based on the Framework Act of 25 March 1963 on the Protection of the Public Against the Hazards of Ionising Radiation, which established general principles governing nuclear activities. These principles were expanded in detail in the Grand Ducal Regulations of 8 February 1967, which were subsequently repealed and replaced by the Grand Ducal Regulations on the Protection of the Public Against the Hazards of Ionising Radiation [Regulations of 29 December 1990], which were in turn repealed and replaced by Regulations bearing the same name [Regulations of 14 December 2000]. They apply to the production, manufacture, possession, sale, transit, transport, import, export, use for commercial, industrial, medical, scientific or other purposes, recycling and re-use of equipment or substances capable of emitting ionising radiation. They also apply to the treatment, handling, storage, elimination and disposal of radioactive substances or waste and to any other activity involving a risk arising from ionising radiation [Section 1.1].

The Minister of Health and his services assume prime responsibility for nuclear energy matters; other government departments have general advisory functions within their respective spheres of competence.

In Luxembourg there are neither public or semi-public bodies responsible for research and development projects in the field of the peaceful uses of nuclear energy, nor installations for the production of nuclear energy.

### **2. Mining Regime**

Luxembourg legislation has no special provisions relating to nuclear ores. Consequently, the ordinary law relating to mining applies; therefore operators of mineral deposits must obtain a prior concession from the government.

### **3. Radioactive Substances, Nuclear Fuel and Equipment**

In accordance with Section 2 of the Act of 25 March 1963 on the Protection of the Public Against the Hazards of Ionising Radiation, which refers to the application of special provisions with regard to the production, possession, use and marketing of nuclear equipment and substances, irrespective of the type of use, the relevant rules were established in further detail by the Grand Ducal Regulations of 14 December 2000.

The production and marketing of nuclear materials require a licence – which may be general or specific in form – issued for a fixed or indeterminate period by the Minister of Health or the Health

Directorate, depending on the type of materials concerned [2000 Regulations, Section 2.2]. A special licence is required for each product in respect of the possession, import, export and sale of irradiated medication or domestic products, as well as the use of X-ray equipment or of radioactive sources for industrial radiography or research [Section 10.2]. The import of nuclear substances for medical purposes must also be covered by a certificate from a pharmacist approved by the competent authority of the country of origin of the product; the use of such products is confined to members of the medical or veterinary professions approved for this purpose by the Minister of Health.

In addition, the Grand Ducal Regulations of 14 December 2000 prohibit the manufacture, import, sale or installation of fire or smoke detectors including radio-elements, or the activation or intentional addition of radioactive substances in foods and irradiated cosmetic products [Section 10.2].

With regard to the irradiation of food, the Grand Ducal Regulations of 17 July 2000 relating to Foods and Food Ingredients Treated with Ionising Radiation implement Directives 1999/2/EC and 1999/3/EC of the European Parliament and of the Council of 22 February 1999, into the law of Luxembourg, by setting out limitations concerning the foodstuffs and food ingredients which may be treated with ionising radiation.

#### **4. Nuclear Installations**

##### ***a) Licensing and inspection, including nuclear safety***

The provisions governing nuclear installations are contained in the Grand Ducal Regulations of 14 December 2000.

Nuclear installations are divided into four categories from I to IV according to the risks they present [Section 2.1].

Chapter 2 of the Regulations lays down separate licensing conditions for each category of installation, notably with relation to the technical information to be supplied, public information and participation in the licensing procedure, etc. A prior license from the competent authorities is nevertheless required for each of these categories. The authority competent to issue licences is the Government in Council for Category I installations, the Minister of Health for Category II installations and the Health Directorate of this Ministry for Category III and IV installations. However, licence applications for all classified installations, irrespective of category, are sent to the Labour and Mines Inspectorate for opinion.

The Government in Council (Category I), the Minister of Health (Category II) or the Health Directorate (Categories III and IV) lay down the conditions to which the granting of the licence is subject. Reasons are always given for any refusal to grant a licence.

The following information must be included with licensing applications [Section 2.6.1]:

- the applicant's name, occupation and address;
- the nature and purpose of the installation in question, the type and characteristics of the radiation emitted, the characteristics of the equipment used, etc.;

- the person responsible for physical control and the implementation of any measures required to ensure compliance with licensing conditions and any requirements laid down by the Regulations;
- the training in radiation protection of the staff responsible for receiving, producing, distributing, using, maintaining and supervising radioactive substances and equipment;
- a draft of the third party liability insurance contract covering nuclear activities;
- a plan of the installations and premises containing radioactive substances or equipment;
- a safety report describing the most serious incidents which could occur in the installation.

The Minister of Health may suspend or withdraw a licence in the event of failure to comply with the provisions of the Regulations of 14 December 2000 or the conditions attached to the licence [Section 2.15].

At the international level, Luxembourg ratified the 1994 Convention on Nuclear Safety on 7 April 1997.

#### ***b) Emergency response***

The Grand Ducal Regulations of 14 December 2000 impose a certain number of obligations on heads of installations in order to manage radiological emergency situations [Section 2.19.3]. They are obliged, in particular:

- to take any measure necessary to remedy any accident in their installation which may lead to radiological consequences for workers or the public;
- to establish an internal intervention plan to address different types of radiological emergency situation and to ensure that this plan can be activated at all times;
- to ensure that the personnel are familiar with this plan.

In the event of a radiological emergency, the head of the installation immediately notifies the accident to the Emergency Assistance Centre for Civil Protection and to the Radiation Protection Division of the Ministry of Health, evaluates the circumstances and the consequences of the situation, and assists in carrying out interventions. He is also required to take the necessary measures to limit the release of radiation and the exposure of workers or emergency staff.

Furthermore, there exists a national intervention plan which aims to notify, protect and assist the public in the event of a radiological emergency situation. This plan is administered by the Minister of the Interior and the Minister of Health. In the event of an emergency situation, these Ministers take the necessary measures to limit exposure of the public to radiation [Section 11.1.1].

Luxembourg ratified the 1986 Convention on Early Notification of a Nuclear Accident and acceded to the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency on 26 September 2000.

## **5. Trade in Nuclear Materials and Equipment**

Trade in nuclear materials and equipment is subject to the Act of 25 March 1963 [Section 2] which provides that rules governing the import, transport, sale, etc. of any equipment or substance capable of emitting ionising radiation shall be laid down by administrative regulation.

Thus, the Regulations of 14 December 2000 on the Protection of the Public Against the Hazards of Ionising Radiation provide that the import, export, transport, sale, etc. of radioactive substances are subject to prior licensing [Section 1.1].

The licensing procedure for the transit of radioactive substances is contained in two legislative instruments: the Grand Ducal Regulations of 31 July 1989 on the Transfer of Nuclear Materials, Equipment and Technology and on Physical Protection Conditions, and the above-mentioned Regulations of 14 December 2000.

The former of these two sets of Regulations was revised by the Ministerial Regulations of 3 February 1993, which repealed and replaced its first Annex containing definitions of nuclear materials, equipment and technology.

The latter Regulations list in Chapter 3 the conditions to be met for licensing. These provisions apply both to the transit and the transport of radioactive substances. Thus, transport and transit operations can only be carried out by persons or firms previously authorised to do so, either by the Minister of Health where the quantities correspond to those used in Category I and II installations, or by the Health Directorate if the quantities are used by Category III installations (see *supra* under Section 4 “Nuclear Installations”).

Licences may be limited to a single operation or considered valid for several operations. In the latter case, each operation must be notified in advance to the Radiation Protection Division of the Ministry of Health.

Applications must contain detailed information about the sender and the addressee, the origin of the substances in question, the qualifications of the staff involved, the nature and intensity of the radiation emitted, etc. Applicants must also produce a certificate from the insurer covering the nuclear risks involved in the operation to be carried out.

Furthermore, the Law on the Liberalisation of the Electricity Market of 23 May 2000 contains a provision which allows the government to reject contracts for the supply of electricity from countries outside the European Union where it is demonstrated that the electricity is generated by facilities whose technology is not state of the art, and which pose a direct or indirect threat to persons, or if the supplier fails to demonstrate a state-of-the-art waste management plan or concept.

## **6. Radiation Protection**

The Grand Ducal Regulations of 14 December 2000 constitute the basic text governing radiation protection in Luxembourg. These Regulations were adopted to implement Council Directive 96/29/Euratom of 13 May 1996 laying down basic standards for the health protection of the general public and workers against the dangers of ionising radiation.

Chapter 5 of the Regulations contains provisions relating to the dose limits for members of the public and workers, while Chapters 6 to 10 deal with the protection and safety of exposed workers, including outside workers, and of the public.

Generally speaking, the Radiation Protection Division of the Ministry of Health is the competent authority for the radiological protection of workers and the public.

The provisions relating to dose limits for the public and workers take into consideration the ALARA principle (As Low As Reasonably Achievable). Thus, the exposure of the public and workers to ionising radiation, where such exposure is controllable, must be kept as low as reasonably possible, as must the number of persons and workers exposed to such radiation [Section 5.1.1].

The overall dose limit for members of the public is set at 1 mSv per year. That for occupationally-exposed workers must not exceed 10 mSv per year. The Regulations also lay down dose limits for certain categories of persons, notably apprentices and students aged between 16 and 18 and pregnant women.

After having laid down dose limits, the Regulations of 2000 describe the operational rules to protect workers, outside workers, apprentices and students exposed to radiation [Chapters 6 to 8]. In particular, working areas are divided into “controlled areas” and “supervised areas” [Section 6.1] and workers are also placed in different categories [Section 6.2]. The Regulations also impose a certain number of obligations on heads of installations, including the implementation of radiological monitoring of workers and the workplace [described in Sections 6.5.1 and 6.5.2] and the medical supervision of workers [described in Chapter 9], the adoption of procedures regulating access to different areas, the information of workers on the risks associated with ionising radiation, training in the field of radiation protection of workers, etc. [Section 6.3].

With regard to the protection of “outside” (contract) workers [Chapter 7 of the Regulations], the Radiation Protection Division of the Health Directorate is responsible for ensuring that these workers enjoy the same protection as that afforded to workers employed on a permanent basis [Section 7.2]. In addition, the contracting company monitors, either directly or by contractual agreement with the operator, the radiological protection of its personnel, ensuring in particular that dose limits are respected, that workers are under medical supervision and that they dispose of the necessary training and information in the field of radiation protection [Section 7.3]. The head of the installation of an “identified area” in which outside workers are employed is responsible, either directly or through contractual agreements, for the operational aspects of their radiation protection depending on the type of area and the activities carried out [Section 7.4].

The Radiation Protection Division of the Health Directorate is responsible for monitoring the protection and safety of the general public. Its tasks include in particular [2000 Regulations, Section 10.1]:

- the regular monitoring of radioactivity in the air, water, soil and food chain, and the studying of measures to be taken and the co-ordination of emergency assistance in the event of an accident;
- the evaluation and monitoring of radiation doses received by occupationally exposed persons, by members of the public living in the neighbourhood of radioactive sources. The Radiation Protection Division is informed immediately of any accidental exposure or emergency situation;
- the setting up of a national dosimetry register;
- the monitoring and regular verification of the effectiveness of radiation protection measures and techniques at places of work where there is a risk of exposure to ionising radiation.

The Radiation Protection Division also regularly establishes estimates of the radiation dose to which the public is exposed.

When a danger to health exists, the Minister of Health is empowered to issue orders, after consultation with the medical inspector of the district concerned and the radiation protection expert answerable to the chief health medical officer, recommending the emergency measures to be taken. To remain valid, however, any such orders must be confirmed within three months by public administration Regulations [Act of 25 March 1963, Section 3].

Lastly, reference should be made to the provisions relating to the medical use of ionising radiation. In this respect, the Act of 10 August 1983 concerning the medical use of ionising radiation provides that the use of such radiation for diagnostic or therapeutic purposes shall be subject to conditions relating to the training of physicians and to standards for apparatus and equipment [Section 1].

In particular, the practice of general radiodiagnosis and radiotherapy is restricted to medical specialists having received appropriate training. The use of unsealed radioactive sources on humans is limited to physicians who have undergone specialised training in nuclear medicine and who have been approved by the Minister of Health. The conditions for such training are to be laid down in Grand Ducal regulations [Section 2].

The Act further requires prior licensing by the Minister of Health for any utilisation of apparatus and equipment used for radiodiagnosis, radiotherapy or nuclear medicine. The conditions for the possession and utilisation of such apparatus and equipment are laid down in specific regulations [Section 4].

More detailed provisions are contained in the Grand Ducal Regulations of 17 February 1987 concerning the Medical Use of Ionising Radiation, adopted in implementation of the Act of 10 August 1983. These Regulations are based directly on Council Directives 80/836/Euratom of 15 July 1980, 84/467/Euratom of 3 September 1984, and 84/466/Euratom of 3 September 1984.

The Regulations further specify the provisions of the Act of 10 August 1983 concerning radiodiagnosis [Chapter 1], radiotherapy [Chapter 2] and nuclear medicine [Chapter 3], essentially with respect to the training of physicians, the useful life of appliances, the distribution of radiological tasks among the different fields of medicine and their classification according to the appliances, isotope selection and the conditions to be observed during examinations and treatment by radiation.

They also contain provisions common to radiodiagnosis, nuclear medicine and radiotherapy, in particular with regard to the possession and use of appliances and facilities and the establishment of an individual radiological book for patients, in which the physician must note each radiological or therapeutic intervention, he carries out and the number of exposures [Chapter 4].

Annex I of the Regulations was repealed and replaced by the Grand Ducal Regulations of 13 May 1989 which amend the list of radiological interventions associated with different medical specialities, aside from radiation used for diagnostic purposes or electroradiology.

## **7. Radioactive Waste Management**

There is no special legislation in Luxembourg dealing with the management of radioactive waste. These activities are subject to the Regulations of 14 December 2000 on protection of the

population against the hazards of ionising radiation, the scope of which extends to the reprocessing, handling, storage, elimination and disposal of radioactive waste [Section 1.1].

Facilities for the processing, conditioning and storage of radioactive waste have been included in Category II [Section 2.1] and require prior licensing. Applications must be made to the competent authority, namely the Minister of Health. Licensing applications are transferred to the Labour and Mines Inspectorate for comments and are then sent to the mayor of the commune in which the facility is to be built, and to the mayors of communes within a radius of 300 metres from the source emitting ionising radiation. Licensing applications must be posted for a period of 15 days in the above-mentioned communes, following which an inquiry is carried out. Within 45 days, the relevant information, including any written comments received and the report setting out the results of the enquiry, must be sent to the Minister of Health who lays down the licensing conditions. Reasons must always be given for any refusal to grant a licence [Section 2.4].

Licensing applications for facilities dealing with radioactive waste must contain additional information as compared to those for other types of classified installations (for further details on the information which must be provided by all licence applicants, see *supra* under Section 4(a) “Nuclear Installations – Licensing and inspection, including nuclear safety”). First of all, a description must be given of the management, purification and disposal measures proposed and secondly, more detailed information, depending on whether the waste in question is liquid, solid or gaseous, has to be provided [Section 2.6.1].

## **8. Non-Proliferation and Physical Protection**

The physical protection rules in Luxembourg are contained in the Regulations of 31 July 1989 concerning Transfers of Nuclear Materials, Equipment and Technology and the Conditions of Physical Protection.

No one may transfer nuclear materials and equipment or nuclear technological data and derivatives to a non-nuclear weapon state, except for peaceful purposes [Section 1]. Annex 1 to the Regulations, which provides the definitions of nuclear materials, equipment and technological data, was repealed and replaced by the Ministerial Regulations of 3 February 1993 on Transfers of Nuclear Materials, Equipment and Technology.

These Regulations make a distinction between exports to a non-European Union country [Chapter I] and those to European Union countries [Chapter II]. In the first case, exports are subject to a prior licence from the Minister of Foreign Affairs and Foreign Trade. In the second case, exports can be made without restriction as long as a number of specified conditions applying to each of the substances concerned are fulfilled.

At international level, Luxembourg, as a Euratom Member State, ratified, on 6 September 1991, the 1979 Convention on the Physical Protection of Nuclear Material.

As regards non-proliferation, Luxembourg has, since 2 May 1975, been a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons. Furthermore, the safeguards system set up under the IAEA and the security control provided for under the 1957 Euratom Treaty are applied in Luxembourg. It also ratified the 1996 Comprehensive Test Ban Treaty on 26 May 1999.

## **9. Transport**

The International Regulations concerning the Carriage of Dangerous Goods by Rail (RID), the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the IATA Restricted Articles Regulations, and the IMO International Maritime Dangerous Goods Code, are applied in Luxembourg.

The international rules governing the transport of nuclear substances were harmonised in Luxembourg's legislation by the Grand Ducal Regulations of 14 December 2000, whose provisions apply to all modes of transport. Transport operations are subject to a licence, which may be general or specific, which is issued by the Minister of Health where the quantities correspond to those used in Category I and II installations, or by the Health Directorate if the quantities are used by Category III installations (see *supra* under Section 4 "Nuclear Installations") [2000 Regulations, Section 3.1].

Transport licence applications must specify the identity of the applicant and of the consignee, the origin and physical and chemical characteristics of the substances concerned, etc. The licensing order lays down the conditions attaching to the licence and the preventive measures which must be taken to protect the public and workers.

Lastly, under the Regulations of 27 March 1964 establishing the conditions of appointment and powers of the radiation protection expert to assist the chief health medical officer, this expert must give his opinion on the level of protection and safety before and after each transport operation of radioactive substances [Section 2].

## **10. Nuclear Third Party Liability**

There are no special rules in Luxembourg legislation governing nuclear third party liability. However, it is provided that cover against nuclear risk necessary for the operation of a nuclear installation in Categories I to III or for transport operations could be subject to specific conditions attached to the licence [Regulations of 14 December 2000, Sections 2.6.1 and 3.1].

## II. INSTITUTIONAL FRAMEWORK

### 1. Regulatory and Supervisory Authorities

#### a) *Minister of Health*

The Minister of Health is responsible for enforcing radiation protection legislation. For this purpose, he closely supervises nuclear activities through licensing procedures enabling him to intervene extensively in the production and use of nuclear energy.

Within the Ministry of Health, the Radiation Protection Division, which is part of the Health Directorate, gives effect to measures to protect individuals and ensure the safety of nuclear installations. More precisely, it is responsible for monitoring the exposure of the public and the environment to ionising radiation [Regulations of 14 December 2000].

#### b) *Minister of Labour*

The Minister of Labour exercises certain powers regarding the health and safety of workers in collaboration with the Minister of Health. The Labour and Mines Inspectorate, a sub-division of this Ministry, plays a particularly important role in nuclear activities.

This department co-operates with the Radiation Protection Division throughout the licensing procedure laid down for nuclear installations. Thus, its opinion is required when an application is submitted [2000 Regulations, Sections 2.3-2.5]. The Labour and Mines Inspectorate is kept informed of any decision of the Minister of Health to suspend or refuse a licence [Section 2.15] and of any accidental exposure of workers to ionising radiation [Section 5.1.8].

#### c) *Other ministerial powers*

The Ministers responsible for Social Security, the Interior, Transport, Foreign Affairs, Justice, the National Economy, and Agriculture each participate in their respective fields of competence in certain decisions affecting nuclear energy.

## 2. Advisory Bodies

### *Higher Health Council*

The Higher Health Council (*Conseil supérieur d'hygiène*) was set up in 1963 under the Minister of Health as an advisory body on all health questions [Ministerial Regulations of 18 April 1963, Section 1]. The Higher Council thus reports to the Minister on scientific and technical matters relating to health, and proposes measures which it deems appropriate [Section 2].

The Higher Health Council has a maximum of 30 members, most of whom sit as *ex officio* representatives of the Ministries of Health, Agriculture, Labour, Justice, and the Interior. The other members may be either nationals or foreigners. The Council may also ask national or foreign experts to attend its meetings in an advisory capacity [Section 3].

The chairperson, vice-chairperson and the secretary are appointed by the Minister of Health from among the members of the Council [Section 5].

The Executive Committee of the Higher Health Council consists of five members, namely the chairperson, the vice-chairperson and the secretary together with two other members nominated by the Council. The Executive Committee is responsible for day-to-day management and allocates work to the different sections of the Council. Meetings of the Council are called by the Executive Committee at the request of the Minister of Health except in emergencies when they may be called by the chairperson, or in his absence by the vice-chairperson [Section 6].

The Higher Health Council is divided into five sections, one of which deals with toxic and dangerous products. The Executive Committee can set up special sections where a particular question is not appropriate for any of the existing sections. Each section appoints its own chairperson and rapporteur [Section 7].

# NORWAY

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

Although at present there are no plans for nuclear power projects in Norway, it was one of the first countries to embark upon a nuclear research programme and to enact legislation governing nuclear activities.

As far back as 1938, an Act on the Use of X-rays and Radium, etc. was passed to establish rules governing the use of radioactive substances [Act No. 1 of 18 June 1938]. This legislation remained in force until it was repealed and replaced by Act No. 36 of 12 May 2000 on Radiation Protection and Use of Radiation, which entered into force on 1 July 2000. Regulations adopted pursuant to the 1938 Act continue to remain in force pending the adoption of new regulations.

The nuclear sector is also regulated by Act No. 28 of 12 May 1972, as amended, on Nuclear Energy Activities (the Nuclear Energy Activities Act). This Act establishes a licensing regime for nuclear installations, nuclear fuels and radioactive substances and sets out a third party liability regime for compensation of nuclear damage. In addition, there are the Regulations of 1 March 1983 on the Production, Import and Sale of Radioisotopes.

With respect to the authorities responsible for the different fields of nuclear activities, the 1972 Act, as amended, provided that the Norwegian Nuclear Energy Safety Authority (*Statens Atomtilsyn*), established by Royal Decree of 9 February 1973 under the aegis of the Ministry of Industry and Energy, was the supervisory authority for the licensing of nuclear materials [Section 10], and that the State Institute of Radiation Hygiene (*Statens Institutt for Strålehygiene – SIS*) established by Royal Decree of 25 September 1953 under the aegis of the Ministry of Health and Social Affairs was also responsible for radioactive substances. On 1 January 1993, the Nuclear Energy Safety Authority and the State Institute of Radiation Hygiene were merged into one single body, the Norwegian Radiation Protection Authority (*Statens Strålevern*), and were placed under the authority of the Ministry of Health and Social Affairs [Nuclear Energy Activities Act, as amended by the Act of 18 December 1992].

### 2. Mining Regime

Under the General Concessions Act on the Acquisition of Waterfalls, Mines and Other Real Estate, general prospecting activities may be carried out by the state, local authorities and Norwegian nationals and companies [Act No. 16 of 14 December 1917, Chapter II]. A mine may not be operated without authorisation from the Ministry of Trade and Industry; the state and local authorities are exempted from this requirement. While existing legislation contains no express provisions giving the state direct control over the ownership and distribution of products obtained from mining, the Ministry

of Trade and Industry, when granting mining concessions, enjoys wide powers to impose conditions it deems necessary in the public interest. In practice, uranium prospecting in Norway is almost entirely carried out by the state. There is at present no activity in this field.

### **3. Radioactive Substances, Nuclear Fuel and Equipment**

The Nuclear Energy Activities Act establishes the general regime governing nuclear fuels, radioactive products and nuclear substances. Pursuant to this Act, “nuclear fuels” mean fissionable materials in the form of uranium or plutonium metal, alloy or chemical compound; “radioactive products” mean other radioactive materials (including waste) which are produced or have become radioactive through exposure to ionising radiation incidental to the production or use of nuclear fuels; “nuclear substances” mean nuclear fuels, other than natural or depleted uranium, as well as radioactive products, with the exception of radioisotopes used for industrial, commercial, agricultural, medical or scientific purposes [Section 1(a), (b) and (c)].

The Act provides that it is unlawful to manufacture, own, store, handle, transport, sell or otherwise dispose of nuclear substances without a permit from the Ministry of Health and Social Affairs [Section 5(1) and (2)].

Permits may be granted for a limited or indefinite period and may cover one or more of the above activities involving nuclear substances [Section 5(2)]. The conditions subject to which permits are granted may be amended where necessary for safety reasons or to ensure that compensation will be provided [Section 8(2)].

The Ministry may make exceptions to the obligation to obtain a permit, provided that certain conditions are complied with [Section 5(1)]. A permit may be revoked if its requirements are being substantially or repeatedly disregarded or for safety reasons [Section 9].

The King may decide that any activities involving nuclear fuels or radioactive products other than nuclear substances should be subject to notification or licensing [Section 5(3)]. He may issue rules regarding the manufacture, handling, packaging, storage, etc. of nuclear fuels or radioactive materials [Section 6].

The manufacture of radioisotopes is subject to a permit issued by the Norwegian Radiation Protection Authority [Regulations of 1 March 1983, Section 2].

The Regulations of 1 June 1979 exempt radioisotopes produced for medical use by the Institute for Energy Technology (*Institutt for Energiteknikk* – IFE) from the above-mentioned procedure [Section 3(1)(c)].

### **4. Nuclear Installations**

Although no nuclear power plant has ever been established in Norway, there is a comprehensive legal framework for licensing the construction and operation of nuclear installations. This legal regime is laid down by the Nuclear Energy Activities Act and its relevant provisions are described below.

**a) *Licensing and inspection, including nuclear safety***

It is prohibited to construct, own or operate a nuclear installation without a licence [Section 4].

The competent authority in matters of licensing is the Ministry of Health and Social Affairs; the Norwegian Radiation Protection Authority advises the Ministry in connection with the safety aspects of nuclear installations and makes recommendations on licensing applications [Section 10]. However, the Minister of Petroleum and Energy is responsible for the licensing of nuclear power plants.

The licence for a nuclear installation covers both construction and operation. However, before the installation is put into operation, the operator concerned must fulfil certain requirements which require the approval of the Norwegian Radiation Protection Authority [Section 11]. The Authority exercises continuous supervision over all operations and ensures that all the conditions prescribed by the licence are being met [Section 13].

Licences are granted for a specific site and are, as a rule, limited in duration. A separate licence is required for the transfer of a nuclear installation to a new owner or operator [Section 4].

A licence is granted when [Section 11(2)]:

- the technical standards of the installation, the operating regulations, safety measures and accident emergency plans are satisfactory;
- the management and personnel of the installation have the necessary qualifications and clearly defined spheres of responsibility; and
- all the necessary authorisations have been obtained in accordance with other legislative provisions.

Concerning the inspection of nuclear installations, the Norwegian Radiation Protection Authority may, at any time, demand access to any such installation and its surrounding area [Section 14].

Norway ratified the 1994 Convention on Nuclear Safety on 29 September 1994.

At present, only one licensee has been granted permission to own and operate nuclear installations in Norway, namely the Institute for Energy Technology, which operates research reactors at Kjeller and Halden.

**b) *Emergency response***

The King may decide that municipal and county authorities in the area in which a nuclear installation is or will be situated must collaborate with the operator of that installation in respect of safety measures for protection of the public in that area. In accordance with rules to be issued by the King, a plan should be prepared for safety and relief measures in the event of an incident including, where necessary, compulsory evacuation [Section 49].

Where an incident has occurred within the national territory, the Ministry of Health and Social Affairs may order all persons who were in the danger area at the time of the incident to identify themselves to the Municipal Medical Officer or the police within a given time-limit and supply the

information necessary to register the damage. They must also undergo a medical examination when considered necessary by the health authorities [Section 50].

On 26 September 1986, Norway gave its consent to be bound by the provisions of the 1986 Convention on Early Notification of a Nuclear Accident.

## **5. Trade in Nuclear Materials and Equipment**

Nuclear trade in Norway is governed by several basic principles, namely nuclear non-proliferation (*i.e.* safeguards), nuclear safety, physical protection and radiation protection. These considerations are reflected in the legislation in force and such trade is subject to a licensing regime, pursuant to the legislation governing nuclear energy, radiation protection and export and import control. These three complimentary approaches mean that several authorities are involved in the licensing procedures for trade in nuclear materials and equipment.

### ***a) Trade governed by nuclear energy legislation***

The Nuclear Energy Activities Act covers trade in nuclear fuel products and radioactive substances (for an explanation of these terms, see *supra*, Section 3 “Radioactive Substances, Nuclear Fuel and Equipment”). The Act provides that it is unlawful to manufacture, own, store, sell, or otherwise hold or dispose of nuclear substances without a permit from the Ministry of Health and Social Affairs [Section 5(1)]. The permit may be granted for a limited or indefinite period, or on an individual basis, and may be restricted to a special authorisation for one of the above activities [Section 5(2)]. The granting of a permit to handle, own or sell radioactive substances is subject to such safety conditions as are deemed necessary [Section 8(1)]. Regulations on how to obtain a permit for possession, disposal and transportation of nuclear materials, are laid down in a Royal Decree of 12 May 2000, supplementing the Act of 1972. In addition, the Regulations for the Physical Protection of Nuclear Material, laid down by the Royal Decree of 2 November 1984, provide that persons responsible for nuclear materials must establish a system for physical protection of such materials during their storage and transport [Section 12]. The sender, in co-operation with the Norwegian Radiation Protection Authority and the recipient, must ensure in advance that during shipment the nuclear material will be subject at least to the minimum level of physical protection set out in Appendix 3 to the Regulations [Section 17].

### ***b) Trade governed by radiation protection legislation***

The Regulations of 1 March 1983 issued by the Ministry of Health and Social Affairs regulate the manufacture, import and sale of radioisotopes used for industrial, commercial, agricultural, medical or scientific purposes, in order to ensure radiation protection [Section 1].

The import and sale of radioisotopes require a permit from the Norwegian Radiation Protection Authority [Sections 3 and 4]. Generally, applications for such permits are made by those involved in such trade, but end-users may also apply. Permits are issued on a case-by-case basis, but may also be granted as a general permit covering several years. The main criteria applied in respect of the issue of a general permit aim to prove the necessity of such activity and the observance of the relevant radiation protection regulations. The Institute for Energy Technology has a general permit for the import and sale of all types of radioisotopes.

The Norwegian Radiation Protection Authority is empowered to issue detailed rules concerning registration and reporting of imports and sales of radioisotopes and such conditions are set out in a document of 20 June 1984 entitled “Conditions for Production, Import and Sale of Radioactive Material in Norway”. These conditions are general and concern, in particular, safety procedures, quality control and the requirements concerning reporting to the Authority.

**c) *Trade governed by export and import control legislation***

Act No. 32 of 6 June 1997 on Import and Export Control authorises the King to regulate the import or export of any article, and to establish such licensing regimes as may be appropriate for the article or product in question [Section 1]. The Act is general in its scope, and thus it applies equally to nuclear or radioactive materials of any kind.

Regulations issued to implement the two previous Acts of 13 December 1946 on import and export control are still in force. They authorise the Ministry of Foreign Affairs to establish a list of goods that require an import licence [Regulation No. 1596 of 1 November 1983] and a list of goods that can be exported without restriction [Regulation No. 52 of 10 January 1989]. At present these regulations do not specify licensing requirements for nuclear or radioactive materials.

In addition, Act No. 93 of 18 December 1987 on Control of Strategic Goods, Services and Technology sets out stringent measures governing export control for nuclear materials and equipment, and strategic or sensitive goods, services and technology. The Ministry of Foreign Affairs has established an export control regime to implement this Act. Through its Regulation No. 51 of 10 January 1989, it set out a list of goods requiring an export licence. Any nuclear material, technology or equipment that is strategic or may have a military use (dual-use or which may be converted to military use) is covered by this export control regime.

Finally, Regulation No. 157 of 10 March 1989, adopted pursuant to Act No. 93 of 18 December 1987, prohibits generally the export of heavy water from Norway [Section 1]. The Ministry of Foreign Affairs may, however, grant an export licence when the heavy water concerned is of insignificant quantity and will be used exclusively for medical, research or industrial purposes [Section 2]. Since 1980, Norway exports nuclear materials and equipment only to those countries where all nuclear activities are covered by the International Atomic Energy Agency safeguards.

## **6. Radiation Protection**

Legislation on radiation protection in Norway is made up of a series of laws and regulations, the most important of which is Act No. 36 of 12 May 2000 on Radiation Protection and Use of Radiation. The purpose of the Act is to protect human health from the harmful effects of radiation and to promote the protection of the environment. The Act applies to the manufacture, import, export, transport, transfer, possession, installation, and use of radiation sources as well as the handling and disposal of their waste. It also covers emergency planning and preparedness. More detailed administrative regulations will be adopted pursuant to this Act.

The Ministry of Health and Social Affairs is the competent authority in matters of radiation protection. Under its aegis, the Norwegian Radiation Protection Authority is responsible, *inter alia*, for ensuring that work involving ionising radiation is properly carried out. In this respect it co-ordinates its activities with the Labour Inspectorate [Royal Decree of 25 September 1953 and Royal Decree of 23 January 1976].

Regulations No. 1157 on Work Involving Exposure to Ionising Radiation, were issued on 14 June 1985 by the Ministry of Local Government and Labour in implementation of Act No. 4 of 4 February 1977 on the Protection of Workers and their Working Environment. They prescribe protective measures during work with ionising radiation and provide that employees may not be assigned to work involving radiation where the effective dose equivalent exceeds 50 millisieverts (mSv) over a period of 12 months; it is planned to lower the limit to 20 mSv. For adolescents between 16 and 18 years of age, the dose limit is set at 5 mSv for that same period [Section 4]. Pregnant women and children below the age of 16 may not be assigned to work which involves exposure to ionising radiation [Sections 4 and 6]. Other provisions of the Regulations provide for medical examinations, duties of employers, etc. The Regulations also apply to offshore petroleum activities in accordance with the Regulation on the Protection of Workers and their Working Environment in relation to Petroleum Activities.

Several regulations provide for radiation protection in a number of activities, in particular for industrial radiography, industrial gauges and well logging. Furthermore, the Regulations of 24 June 1977, adopted pursuant to Act No. 47 of 14 June 1974 on Approval of Health Personnel, deal with the use of ionising radiation in educational establishments and the approval procedure for radiographs.

The Royal Decree of 23 January 1976, issued pursuant to the 1938 Act, lays down detailed provisions on the supervision and use of installations, apparatus, materials and substances which release ionising and other radiation representing a hazard to health. The text specifies the authority competent in supervisory matters, namely the State Institute of Radiation Hygiene (now the Norwegian Radiation Protection Authority) [Section 1], as well as the type of devices concerned [Section 3] and the duties of the persons using them [Section 5].

The following are subject to supervision by the Norwegian Radiation Protection Authority:

- all installations, apparatus, materials and substances which produce ionising radiation and are used for medical, veterinary, scientific, industrial or other purposes;
- waste and discharges of substances which produce ionising radiation; and
- use of lasers, radar, microwaves and other electromagnetic radiation representing a danger to health.

Such equipment and materials cannot be sold or used without prior notification to the Authority, which may prohibit transactions or use before it has granted a licence to this effect. Furthermore, the Authority must be notified of new installations or extensions or major alterations to existing facilities; it must grant permission before they are used [Section 4].

Certain installations, facilities and other devices may be exempted from these obligations by the Minister of Defence [Section 3].

A Royal Decree of 2 November 1979 prescribes the qualifications required for using X-ray devices for medical purposes.

In November 1988, the State Institute of Radiation Hygiene (now the Norwegian Radiation Protection Authority) issued Guidelines on Radon Measurements in Dwellings, based on the results of large-scale surveys carried out in Norway and on conclusions reached by national experts and competent international organisations (International Commission on Radiological Protection, World Health Organisation). The Authority concluded that radon was the main source of collective exposure

to ionising radiation in the country and made recommendations on the permissible average yearly radon concentration, in existing and future dwellings. In the first case if the concentration is higher than 200 Bq/m<sup>3</sup> (becquerel), consideration should be given to lowering that level, and if higher than 800 Bq/m<sup>3</sup>, remedial action should be taken. A maximum level of 200 Bq/m<sup>3</sup> is recommended for future dwellings. Similar Guidelines on Radon Measurements for Building Grounds were also issued in November 1988.

## **7. Radioactive Waste Management**

The 1972 Act on Nuclear Energy Activities specifies that the Norwegian Radiation Protection Authority (NRPA) must exercise continuous supervision over the operation of nuclear installations, including the disposal of radioactive waste [Sections 11 and 13], while the 1983 Regulations on Production, Import and Sales of Radioisotopes provide that the NRPA prescribes the conditions governing radioactive waste disposal operations and issues the required permits [Sections 2 and 4].

At the international level, Norway ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 4 April 1974, and its 1996 Protocol on 16 December 1999, and the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 12 January 1998.

## **8. Non-Proliferation and Physical Protection**

The 1972 Act provides that the King may take the necessary measures to ensure that nuclear installations, equipment, fuel, radioactive products and other materials used for nuclear energy purposes, which are subject to international safeguards pursuant to agreements to which Norway is a party, are used only for non-explosive, peaceful purposes [Section 51]. The Act also specifies that persons engaged in activities in accordance with the Act have an obligation to preserve secrecy concerning confidential technical information acquired in the course of their work [Section 53].

As regards non-proliferation, Norway has been a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons since 5 March 1970 but has not adopted domestic legislation in this respect. It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 15 July 1999.

As regards physical protection, Norway ratified the 1979 Convention on the Physical Protection of Nuclear Material on 15 August 1985, although it had already enacted legislation on this subject. A Royal Decree of 2 November 1984, issued pursuant to the 1972 Act, lays down Regulations for the Physical Protection of Nuclear Material. These Regulations aim to establish conditions which will minimise the possibilities of theft of nuclear materials and sabotage of nuclear installations. They lay down detailed provisions concerning the obligations of nuclear operators and specify the powers of the competent authorities regarding physical protection [Section 1].

The Norwegian Radiation Protection Authority (NRPA) is the competent body for the physical protection of nuclear materials and is empowered to make rules in this respect.

If theft or sabotage is reported, the Ministry of Health and Social Affairs acts as the co-ordinating body for the steps to be taken by the Ministry of Justice and the Ministry of Foreign Affairs; the former Ministry is responsible for initiating the operations to counteract such theft or sabotage while the latter Ministry is in charge of notifying other countries in accordance with the Convention on the Physical Protection of Nuclear Materials [Annex II].

Persons responsible for nuclear materials and equipment (operators pursuant to the 1972 Act) must establish and maintain a system for physical protection of the equipment and materials during storage, processing and transport. They must prepare a safety report on physical protection for the approval of the Ministry of Health and Social Services. This report must take into account radiation protection aspects and criticality hazards and be kept up to date regarding any changes or any acquisition of nuclear materials requiring stricter safety measures [Section 12].

Operators must also appoint one or more persons to be responsible for the physical protection aspects of stored material or material being processed or shipped. They are responsible for ensuring that the physical protection system operates in accordance with the rules issued by the NRPA [Section 12].

The Regulations lay down specific requirements for protecting nuclear material in storage and for nuclear equipment, and it divides the materials into three Categories (I, II and III) according to their radioactivity and weight [Section 14 and Annex I]. The premises where they may be housed are also divided into three areas for surveillance purposes: restricted, protected and vital; access to these areas differs according to their classification and detailed instructions are provided for the setting up of protection and alarm systems for each type of area, aside from the general alarm system, directly connected to the police through a continuously manned guard centre [Section 15].

The Regulations also provide for the preparation of a contingency or emergency plan, which will also apply to transport, in consultation with the police. The plan must take into account the division of responsibility between the different bodies involved and must include the necessary protective equipment to be made available to the police. The safety report prepared by the operator must also include arrangements for effective action by personnel and the police in the event of theft or sabotage of nuclear material [Section 13].

Adoption of the Regulations gave rise to an amendment of the Penal Code [Section 152(a)] to include a provision dealing with unlawful possession, utilisation, transfer or distribution of plutonium or uranium, thereby endangering human life, health or property or the environment. Such acts are liable to a fine or a term of imprisonment of up to four years. Acts which may result in loss of human life or extensive damage to property are punishable by the penalty prescribed in Section 148 of the Penal Code, namely imprisonment ranging from two to twenty-one years, but not less than five years where death or serious injury has occurred.

The provisions on the physical protection of nuclear material during transport are discussed *infra* under Section 9 “Transport”.

## **9. Transport**

The basic framework for the rules governing the transport of nuclear fuels and certain radioactive materials is established in the 1972 Act on Nuclear Energy Activities; the transport of radioactive materials not covered by that Act falls within the scope of the 2000 Act on Radiation Protection and Use of Radiation.

The Norwegian Radiation Protection Authority (NRPA) is the competent authority for the transport of radioactive materials by road and rail. The Maritime Directorate of the Ministry of Foreign Affairs is the authority responsible for issuing regulations on the maritime transport of dangerous goods; regulation of the transport by air of radioactive materials is the responsibility of the Civil Aviation Administration [Act of 11 June 1993 on Civil Aviation, Section 9(1) and (4); this

assignment of authority was confirmed by the Ministry of Transport and Communication's decision of 25 March 1994].

The different modes of transport are regulated by provisions specific to each mode as summarised below. It should be noted that the international regulations applying to the different modes of transport of radioactive materials are based on the IAEA's Regulations for the Safe Transport of Radioactive Materials.

The Directorate for Fire and Explosion Prevention, as the competent authority for the transport of dangerous goods by road and rail in Norway, works in co-operation with the NRPA as regards Class 7 (radioactive) materials. The Regulations of 20 December 1996 on the Transport of Dangerous Goods by Road and Rail state that the International Regulations for Carriage of Dangerous Goods by Road (ADR) and Rail (RID) shall apply to both international and domestic transport of dangerous goods.

As regards maritime transport, the relevant provisions of the International Maritime Dangerous Goods Code issued by the International Maritime Organization (IMO) and the provisions of the International Convention for the Safety of Life at Sea (SOLAS) are applied in Norway pursuant to Regulations issued by the Maritime Directorate on 30 November 1979.

Pursuant to the Regulations of 15 May 1979 issued by the Civil Aviation Administration, air transport of radioactive materials is carried out in accordance with technical instructions governing safety for the air transport of dangerous goods of the International Civil Aviation Organisation (ICAO).

The Regulations on the Physical Protection of Nuclear Material of 12 November 1984 contain provisions establishing basic rules for physical protection of nuclear material during transport by road, rail, sea and air. These provisions apply in addition to the different regulations referred to above.

The physical protection of all shipments must be approved and authorised in advance by the NRPA. The licences specify the conditions applying to each particular shipment. The Authority may only grant a general permit for shipments of Categories II and III material, in which case no further notification is required for individual shipments [Section 17(c)].

Only authorised persons may carry out shipments and the operator and the authorities concerned must be cautious in dealing with information which could jeopardise physical protection [Section 17(a)].

Shipments of nuclear materials are subject to agreements being concluded prior to the shipment between the sender and the recipient, and the sender and the transport firm, respectively [Section 17(f)]. The operator must also ensure that the shipment remains as short a time as possible in transit, that as few reloadings as possible occur and that shipments do not take place at regular, known times [Section 17(a)].

The operator must establish an external transport executive body for the transport operation and inform the parties concerned accordingly; that body must maintain telephone or radio contact with the transport vehicle and/or the escort vehicle and based on the information received, give appropriate instructions relating to irregularities during the transport to the transport personnel, the police or the road authorities as the case may be [Section 17(e)].

The Regulations set out special provisions in connection with the transport of Category I material (with the highest fissile content) for different modes of transport. These are summarised below [Section 18].

As regards road transport, the transport vehicle must be constructed and equipped to resist attack, be equipped with a two-way communication system and be manned by at least two persons. The transport must also have a police escort and the position of the vehicle must be reported to the transport executive body several times an hour [Section 18(a)].

Transport by rail must be carried out in a freight train or a separate carriage in a passenger train [Section 18(b)]. The transport must have a police escort and the accompanying guard must be equipped with a two-way communication system.

The sea transport of Category I material must be carried out with a police escort and the consignment placed in a locked and sealed room or container.

Transport by air must take place in an especially selected aeroplane, with a police escort [Section 18(b)].

## **10. Nuclear Third Party Liability**

The regulations governing nuclear third party liability are set out in the Act of 12 May 1972 on Nuclear Energy Activities, as amended. This Act, which enabled Norway to ratify the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy (on 2 July 1973) and the 1963 Brussels Supplementary Convention (on 7 July 1973), applies the principles of the Paris Convention, including the strict liability of the operator, which is limited in amount and in time. The Act applies to nuclear damage caused by an incident occurring in Norway or in another country Party to the Paris Convention.

The Ministry of Health and Social Affairs may exempt from the provisions of the Act certain types of nuclear installation, nuclear fuel, radioactive products or substances which, in its opinion, constitute no significant hazard [Section 2(1)].

Liability under the Act is vested exclusively and strictly in the operator of a nuclear installation [Sections 20–28]. Therefore, claims for compensation for nuclear damage for which the operator is liable may not be brought against any person other than the operator himself, or his insurer or guarantor [Section 27].

The liability of an operator for one and the same nuclear incident is limited to 60 million Special Drawing Rights (SDR) [approximately 500 million Norwegian kroner (NOK)] [Section 30(1)]. However, the King may, if the size and nature of the installation or operation so warrant, lower that amount to SDR 5 million (approximately NOK 42 million).

To cover his liability, the operator of a nuclear installation must take out and maintain insurance or such other security as the Ministry of Health and Social Affairs authorises [Section 35(1) and (2)]. The Ministry may approve separate insurance or other security to cover liability for incidents occurring during transport [Section 35(3)].

Whenever a nuclear substance is transported to or from a foreign country, the operator liable under the Act must supply the carrier with a certificate of financial security for the carriage issued by or on behalf of the guarantor [Section 38(1)].

If claims for compensation against a nuclear operator cannot be satisfied by the maximum amount of that operator's liability, but are valid under the Act, the Act provides for the claims to be paid out of government funds up to a total amount of SDR 300 million [Section 40(1)].

A claim is extinguished if it is not acknowledged or if legal action is not instituted within ten years of the date of the nuclear incident [Section 34(1)]. If the incident is attributable to nuclear substances which have been stolen, lost or abandoned, the time limit for bringing claims is twenty years from the date of the theft, loss or abandonment [Section 34(2)].

Norwegian courts have jurisdiction to hear cases on the liability of an operator in respect of nuclear damage if the nuclear incident occurred wholly or partly on Norwegian territory, if it occurred on the high seas at a time when the substances in question were being carried between countries not party to the Paris Convention, or if the place of the incident cannot be determined with certainty and the installation of the operator liable is situated in Norway [Section 45(1)].

Lastly, Norway ratified the 1988 Joint Protocol relating to the Application of the Vienna Convention and the Paris Convention on 11 March 1991, and it ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 16 April 1975.

## **II. INSTITUTIONAL FRAMEWORK**

In Norway, responsibility for nuclear matters is vested mainly in the Ministry of Health and Social Affairs. The Ministry is assisted in its work by bodies which have advisory and supervisory authority.

Several other ministries also have certain responsibilities in the nuclear field when related activities are within their competence.

### **1. Regulatory and Supervisory Authorities**

#### **A. Ministerial Level**

##### **a) *Ministry of Health and Social Affairs***

The Ministry of Health and Social Affairs is the competent authority pursuant to the 1972 Act on Nuclear Energy Activities and the 1984 Regulations for the Physical Protection of Nuclear Material. The Ministry issues licences for nuclear installations.

The Ministry is also responsible for the protection of public health and is therefore competent to deal with questions of radiation protection [Act No. 36 of 2000 on Radiation Protection and Use of Radiation]. In this capacity, it is not only in charge of drafting legislation in this field but also of ensuring that work involving ionising radiation is properly carried out.

The Ministry performs its licensing and control functions and, to some extent, drafts regulations through the NRPA for which it has administrative responsibility [1972 Act on Nuclear Energy Activities, as amended by the Act of 18 December 1992].

**b) *Ministry of Trade and Industry***

The Ministry of Trade and Industry has general co-ordinating functions and deals with budgetary matters concerning research and development in the field of nuclear energy.

This Ministry also deals with matters concerning prospecting for deposits of uranium, thorium and other ores or minerals which may be of use for the exploitation of nuclear energy [1917 General Concessions Act on the Acquisition of Waterfalls, Mines and other Real Estate].

**c) *Ministry of Foreign Affairs***

The Ministry of Foreign Affairs is the competent authority under Act No. 32 of 6 June 1997 on Export and Import Control, and thus has responsibility under that legislation for export and import of nuclear materials. It is also responsible for the export control regime established by Regulation No. 51 of 10 January 1989, made pursuant to Act No. 93 of 18 December 1987 on Export Control for Strategic Goods, Services and Technology, which also applies to sensitive nuclear material. The Ministry of Foreign Affairs is also empowered to grant exceptional export licences for heavy water [Regulation No. 157 of 10 March 1989, adopted pursuant to Act No. 93 of 18 December 1987].

The Ministry is responsible for international relations and agreements in the nuclear field. It also co-ordinates Norwegian participation in this field in international organisations.

**d) *Other Ministries***

The Ministries of Justice, Agriculture, Transport and Communications, the Environment, Culture and Science, and Local Government and Labour may also be called upon to deal with legislative or administrative questions in the nuclear field.

**B. *Subsidiary Level***

**a) *The Norwegian Radiation Protection Authority (NRPA)***

The NRPA (*Statens Strålevern*), as explained earlier in this study, was established in 1993 through a merger of the Nuclear Energy Safety Authority and the State Institute of Radiation Hygiene. The NRPA is placed under the Ministry of Health and Social Affairs for administrative purposes and has taken over the responsibilities of both of these bodies.

The Authority advises the Ministry of Health and Social Affairs in its capacity as the highest specialised agency on questions of nuclear safety and is the supervisory authority in that field [1972 Act, Section 10].

The Authority may, on its own initiative, put into effect all the measures it deems necessary from a safety viewpoint and is responsible for ensuring that all rules and conditions connected with safety precautions are complied with. It is responsible for the licensing aspects of nuclear installations and must exercise continuous supervision over the construction and operation of such installations [1972 Act, Sections 11 and 13].

It is also empowered to license and control all equipment and apparatus emitting ionising radiation with regard to radiation protection and public health and may issue the necessary regulations for that purpose [Royal Decree of 23 January 1976]. In addition, it grants permits for the production, import and sale of radioisotopes, and issues conditions governing their production, storage, labelling and quality control, as well as conditions regarding disposal, radiation protection and facilities and equipment connected with such materials [Regulations of 1 March 1983 on the Production, Import and Sale of Radioisotopes, Sections 2-4].

Furthermore, the NRPA is responsible for research and educational activities in the fields of dosimetry, radiation hygiene and other related topics. The research work covers the following sectors: medical radiation physics, industrial radiation physics and medicine.

The NRPA has five departments: Nuclear Safety, Health Physics, Radiation Medicine, Environmental Protection and Administration and Information.

It is funded by the ordinary budget allocated to the Ministry of Health and Social Affairs and through project contracts with other ministries, *i.e.* the Ministry of Foreign Affairs and the Ministry of the Environment.

**b) *The Norwegian Nuclear Emergency Organisation***

Based on the Royal Decree of 26 June 1998 the government decided to establish the above Organisation made up of representatives of the following entities:

- the ministries involved;
- the Ministerial Co-ordination Committee;
- the Crisis Committee for Nuclear Accidents;
- the Advisors to the Crisis Committee for Nuclear Accidents;
- the Secretariat for the Crisis Committee;
- the regional emergency organisations.

The ministries are entirely responsible for emergency preparedness in their respective areas of competence. In order to deal effectively with the early phase of a nuclear accident, the ministries have transferred responsibility for remedial actions to the Crisis Committee for Nuclear Accidents.

The Ministerial Co-ordination Committee is responsible for ensuring co-operation and co-ordination between the different ministries and ensuring that the necessary resources are made available for this purpose. Its members are the Ministries of Health and Social Affairs, Justice, Defence, Foreign Affairs, Environment, Agriculture, Trade and Industry, Education, Research and Church Affairs, Transport and Communications and Fisheries. The Committee is headed by the Ministry of Health and Social Affairs.

The Crisis Committee for Nuclear Accidents is made up of representatives of the following institutions:

- Norwegian Radiation Protection Authority (NRPA);
- Directorate of Civil Defence and Emergency Planning;
- Norway Military Headquarters;
- Police Department of the Ministry of Justice;
- Norwegian Board of Health;
- Norwegian Food Control Authority.

It is headed by the NRPA representative.

The Committee is responsible for establishing and implementing remedial actions in the event of a nuclear accident or an impending nuclear accident representing a potential threat to Norway. It must organise the evacuation of the population if the situation represents a direct threat to health and life; provide shelter, administer stable iodine, block and secure contaminated areas; impose short-term restrictions on production and distribution of foodstuffs; and advise on the consumption of dairy products.

Wherever possible, the Committee must discuss its decisions with the Ministries before acting on them.

The Advisors to the Crisis Committee for Nuclear Accidents are representatives of 12 organisations and institutions with the expertise and competence required to organise emergency measures, regarding both the management of nuclear accident situations and the further development and maintenance of emergency preparedness. They are representatives from the Norwegian Defence Research Establishment, the Institute for Energy Technology, the Norwegian Meteorological Institute, the Geological Survey of Norway and the Norwegian Agricultural Inspection Service, etc. During accident situations, their tasks are:

- to submit and make available all information, data and measurements relevant to emergency situations, and to make forecasts for radioactive dispersion, fallout and radiation doses to the public;
- to advise on preventing or reducing the radiological and economic consequences of a nuclear accident in Norway.

The Secretariat for the Crisis Committee (the Nuclear Safety Department in the NRPA) is responsible, *inter alia*, for alerting the Nuclear Emergency Organisation and for warnings in a

emergency situation; it also organises a telephone watch so that the Organisation can be alerted at all times.

The regional emergency organisations are established under the direction of the Chief Administrative Officers in the Norwegian counties.

## **2. Public and Semi-Public Agencies**

### ***Institute for Energy Technology (IFE)***

#### *i) Legal Status*

The Institute for Energy Technology (*Institutt for Energiteknikk* – IFE) was set up by Royal Decree of 30 May 1947 as the Institute for Atomic Energy (*Institutt for Atomenergi* – IFA) and became an independent foundation in 1953. It reports to the Ministry of Petroleum and Energy. In 1980, its name was changed to its present one, in line with recent developments in its work and adapted to national goals, as specified by the authorities.

#### *ii) Responsibilities*

The Institute's mandate, as defined in 1980, is to conduct research and development, analyses, etc. within the field of energy, including nuclear research and other fields particularly suited to the Institute's competence.

The IFE is the national centre for nuclear research and development, and as such, it carries out work in nuclear safety, environmental protection, waste management and materials technology.

The IFE owns and operates the JEEP II reactor, a 2 MW, heavy water-cooled and moderated research reactor, as well as the 20 MW Halden Boiling Water Reactor which is used in an International Project, set up in 1958 under the auspices of the OECD Nuclear Energy Agency (OECD/NEA) for the purpose of carrying out a joint programme of research and experiments between national centres and nuclear power manufacturing industries from OECD Member countries in connection with the operation of a boiling water reactor.

IFE also produces and distributes radioisotopes; it has a gamma radiation plant in operation and arranges courses in data processing and isotope applications.

The activities of IFE are geographically divided between two sites, Kjeller, which is the main research centre, and Halden, where the OECD/NEA Halden Reactor Project is located.

The research and development activities are performed in the following sectors:

- energy and systems technology;
- petroleum technology;
- OECD/NEA Halden Reactor Project;

- materials technology;
- isotopes and chemistry;
- industrial chemistry;
- physics.

The Institute operates a waste treatment plant which processes radioactive waste from its own activities and from outside sources, as well as the Combined Storage and Disposal Facility for low and intermediate level waste in Haldalen.

*iii) Structure*

The Institute is managed by a board consisting of six members, one appointed by the government, one by the firm Norsk Hydro A/S and two by the Royal Council of Scientific and Industrial Research. The remaining two members are chosen by and from among the staff and are appointed by the government.

A managing director, appointed by the board, is entrusted with the day to day management of the Institute.

*iv) Financing*

The Institute's yearly expenditure is covered by grants from the Ministry of Trade and Industry and by income from research and development work undertaken on a contractual basis with other national and foreign firms and institutions.

In connection with the OECD/NEA Halden Reactor Project, the majority of the programmes are financed by contributions from the Parties and Associated Parties to the Halden Agreement.

# POLAND

## *Information Note*

The Atomic Law was adopted on 29 November 2000 and will enter into force on 1 January 2002, with the notable exception of Chapter 13 on the President of the National Atomic Energy Agency, which entered into force 14 days after publication. This new and comprehensive legislation, which replaces the former Atomic Energy Act of 10 April 1986, regulates all activities related to peaceful uses of nuclear energy and defines the role of the competent authority in the nuclear safety and radiation protection fields. It further identifies the operator's obligations and the principles of nuclear third party liability.

Taking into account the date of entry into force of this new Law and the number of implementing regulations currently under preparation, it was decided not to incorporate this legislation into the 2001 Update. Therefore, the chapter which appears in the 1999 Edition of this Study is based on the legislative framework existing at the end of 1999 which is still in force at the time of publication. Pending entry into force of the Atomic Law, the main provisions of this new Law are described in this Information Note.

As already set out in the 1986 Act, the new Law provides that any person carrying out activities involving exposure to ionising radiation such as manufacture, use, transport, conversion, storage, or disposal of nuclear materials, radioactive sources, radioactive waste and spent nuclear fuel, or construction, commissioning, operation and decommissioning of nuclear facilities, is required to obtain a licence issued by the President of the National Atomic Energy Agency (NAEA) [Sections 4, 5 and 37].

Any person conducting such activities shall be responsible for compliance with nuclear safety and radiation protection requirements, in particular through the appointment of a radiological protection inspector, [Section 7]. All such activities shall be carried out in compliance with the principles of justification, optimisation and limitation of dose [Sections 8 and 9].

With regard to the radiation protection of workers, the Law provides that the operator shall ensure health surveillance and personal protection of workers, in particular by providing them with dosimetric equipment [Section 26] and by organising periodic medical examinations [Sections 10 and 30]. Occupational exposure assessment of workers, classified in category A or B depending on the degree of risk, shall also be performed through individual dose measurements or dosimetric measurements in the workplace [Section 17]. Radiation workers are also required to possess the appropriate skills and qualifications and to complete preliminary and periodic training courses, organised by the operator, on nuclear safety and radiation protection [Section 11]. The operator shall also keep records of individual doses received by category A workers [Section 21]. The same radiation protection requirements apply to outside workers [Section 29].

The Law also governs exposure to ionising radiation for medical purposes, and provides that the Minister for Health shall establish the conditions governing the safety of such exposure by regulation [Section 15].

The NAEA President shall regularly assess public radiation exposure [Section 24] and, through the Centre for Radiation Emergencies established within the NAEA, monitors the national radiation situation [Section 72]. On the basis of such assessment, the President shall inform the public of the situation, in particular in relation to radioactive contamination levels, under normal circumstances and in radiation emergencies [Section 80]. In the event of an emergency, the operator shall organise the confinement of the emergency site and shall immediately notify the NAEA President and other relevant authorities [Section 83]. The Law empowers the operator, the region's governor or the Minister for the Interior, depending on the type of emergency (on-site, regional scale or national scale), to take actions aiming to eliminate the threat or its consequences [Section 84], including intervention measures [Section 89]. Such measures shall consist of temporary relocation, sheltering, stable iodine administration, and bans or restrictions on contaminated food and water consumption [Section 90]. Costs of intervention measures and those related to the elimination of radiation emergency consequences shall lie with the operator of the nuclear facility causing the emergency [Section 93].

Regarding nuclear facilities [Chapter 4], which are defined in the same manner as in the 1986 Atomic Energy Act, the obligation to ensure nuclear safety and radiological and physical protection during siting, design, construction, commissioning and test operation of a nuclear facility shall lie with the licensed investor; these responsibilities shall be exercised by the licensed operator during operation and decommissioning [Section 35]. Where nuclear safety is endangered, the NAEA President shall issue an order to decrease or halt the operation of the facility [Section 39].

A restricted area surrounding the nuclear facility site shall be established, detailed rules governing which shall be established by the Minister competent in environmental matters [Section 38].

The operator shall be responsible for the accountancy of nuclear materials, through inventories and inspections, and must also ensure the physical protection of nuclear materials during their manufacture, conversion, storage, use, transport, disposal and trade [Sections 40(1), 40(2) and 41]. Central nuclear material inventory records shall be kept by the NAEA President [Section 40(3)]. Inspection and accountancy of ionising radiation sources and radioactive sources shall also be carried out by the operator [Section 43].

With regard to radioactive waste and spent fuel management, the Law provides that the operator of the facility where the radioactive waste or spent fuel is stored shall be responsible for keeping appropriate inventories and ensuring their physical protection [Section 49]. During storage, adequate protection of the public and the environment shall be guaranteed [Section 50]. Radioactive waste and spent nuclear fuel management activities shall be performed by the Radioactive Waste Neutralisation Plant, a state-owned utility established under this Law [Section 56(1) and Chapter 14]. Such activities, with the exception of disposal of radioactive waste or spent fuel, or their transport to the disposal facility, may be conducted by another organisation which obtains a licence and meets nuclear safety and radiological protection requirements [Section 56(2)].

The Law provides that nuclear materials, ionising radiation sources, radioactive waste and spent nuclear fuel shall be prepared and transported in compliance with physical protection principles and with conditions and requirements imposed by other regulations [Sections 58 and 59].

Chapter 12 of the Law governs civil liability for nuclear damage. “Nuclear damage” is defined as damage to an individual, to property or to the environment, including the costs of recovery measures, loss of potential benefits and the costs of applied countermeasures or the damage caused by such countermeasures [Section 100(5)]. The Law provides for the exclusive liability of the operator of the nuclear installation where a nuclear accident takes place or to which it is related, with the exception of damage caused directly by war hostilities or military conflict [Section 101]. If an accident occurs in the course of transport, the operator remains liable, unless otherwise stipulated in a contract with the consignee [Section 101(2)]. The Law fixes the liability limit of the operator at 150 million Special Drawing Rights [Section 102] and requires that he obtain financial security. It furthermore establishes rules relating to the distribution of funds [Section 103]. Whereas personal injury claims are not subject to a prescription period, compensation claims for nuclear damage to property or the environment shall be extinguished ten years after the date of the nuclear accident or three years after the date upon which the person suffering nuclear damage had knowledge or should have had knowledge of the damage and of the identity of the person liable [Section 105].

The statute and functions of the NAEA President are described in Chapter 13 [Sections 109-113]. In addition, the NAEA President, the Chief Regulatory Inspector and regulatory inspectors are appointed as responsible bodies for carrying out activities of nuclear safety and radiological protection surveillance and inspection [Section 64(1)], and their responsibilities and powers in this respect, including the right to access transport vehicles and the nuclear facility site, are set out in Sections 64(4) and 66.

To ensure national nuclear safety and radiological protection, the costs of certain activities such as operation and decommissioning of nuclear research reactors, operation of accelerators, impact assessment of nuclear facilities, X-ray machines, etc. on the environment and human health and activities aiming to eliminate the consequences of radiation emergencies, may be partially reimbursed from the national budget in the form of a subsidy [Section 33].

Finally, Chapter 15 of the Law sets out penalties for breach of its provisions.

The Law provides that a series of regulations is to be adopted to regulate *inter alia*: licensing exemptions, licensing documentation, training conditions, radiation dose limits, methods and frequency of occupational and public exposure assessments, safe conditions governing radiation exposure for medical purposes, requirements for individual dose records and dosimetric equipment, a list of nuclear materials subject to accountancy and physical protection measures, radioactive waste classification, procedures for radioactive waste inventories, and conditions for radioactive waste and spent fuel storage.

# SLOVAK REPUBLIC

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

On 1 January 1993, the former Czechoslovakia was divided into the Slovak Republic and the Czech Republic. To ensure a smooth transition of legal regimes, it was agreed that all acts, regulations and decisions, *inter alia* in the field of nuclear energy and ionising radiation, would continue to apply until subsequent legislation was enacted, provided that such laws were consistent with the Constitution of the Slovak Republic.

On 1 April 1998, the National Council of the Slovak Republic (Slovak Parliament) adopted the Act on the Peaceful Uses of Nuclear Energy (and on alterations and amendments to Act No. 174/1968 Zb.<sup>1</sup> on State Supervision of Work Safety as amended by Act of the National Council of the Slovak Republic No. 256/1994 Z.z.)<sup>2</sup> [Act No. 130/1998 Z.z.] (hereinafter referred to as “the Act”). It came into force on 1 July 1998, providing a comprehensive framework for the regulation of nuclear activities in the Slovak Republic. The legislation provides for the adoption of implementing regulations, some of which have been promulgated, with others under preparation or still to be prepared. Until replaced by such implementing regulations, the regulations in force in the former Czechoslovakia remain applicable, provided that such regulations are consistent with the new Act.

In the former Czechoslovakia, the principal authority regulating nuclear activities was the Czechoslovak Atomic Energy Commission (*Ceskoslovenska Komisia pre atómovú energiu* – CSAEC). Its successor in the Slovak Republic is the Nuclear Regulatory Authority (*Úrad Jadrového Dozoru Slovenskej Republiky* – ÚJD) of the Slovak Republic. The responsibilities and tasks of the ÚJD are set out in Act No. 2/1993 Z.z., which specifies its independent status in nuclear safety matters.

The Slovak Republic is heavily dependent on external primary energy resources, importing more than 80% of its needs, particularly oil, gas and nuclear fuel from the Russian Federation. This makes the efficient generation of electrical power of crucial importance. The unit cost of electricity generated by nuclear power plants in the Slovak Republic is half that of electricity generated by its fossil power plants.

The Slovak Republic has two nuclear power stations located at Bohunice and Mochovce. At the Bohunice station there are four nuclear power plants in operation and one unit which has been decommissioned. Two are VVER 440 model V230 and two are 440 model V213 with a total installed capacity of 1 632 MWe. In September 1999, the government decided to shut down two units of Bohunice NPP in 2006 and 2008 respectively. At Mochovce power plant two units, each of which are VVER 440 model V213 with a capacity of 412 MWe each, were commissioned in 1998 and 2000 respectively. In 1999, nuclear energy represented 47% of total electricity generated in the Slovak Republic.

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1. Zb. (*Zbierka*), meaning from the collection of laws of the former Czechoslovakia.

2. Z.z. (*Zbierka zákonov*), meaning from the collection of laws of the Slovak Republic, commencing on 1 January 1993.

There are also three radioactive waste treatment facilities, an interim spent fuel storage facility and a radioactive waste disposal facility at Mochovce. A near-surface repository for low level and intermediate level waste was licensed and put into operation on a trial basis, and the construction of a disposal facility for high-level waste and spent fuel in deep geological formations is planned.

## **2. Mining Regime**

There has been no uranium mining in the Slovak Republic since 1990. There are, however, mining laws which formerly applied to the mining of uranium and which are still in force. These laws are as follows:

- a) Section 34(1)(b) of Act No. 44/1988 Zb. on Protection and Utilisation of Mineral Resources (the Mining Act), as amended by Act No. 498/1991 Zb.;
- b) Section 11 of Act No. 51/1988 Zb. on Mining Activities, Explosives and State Mining, as amended;
- c) Sections 5(c), 6(1) and 6(2)(e) and Annexes Nos. 9 and 10 to Decree of the Slovak Mines Inspectorate (*Slovensky bansky urad*) No. 89/1988 Zb. on Rational Utilisation of Exclusive Deposits, on Permits for and Registration of Mining Activities, as amended by Decree of the Slovak Mines Inspectorate No. 16/1992 Zb.

## **3. Radioactive Substances and Equipment**

Section 9(1) of the Act defines “nuclear materials” as comprising the following “source materials”: natural uranium, depleted uranium, thorium and any of these materials in the form of metal, alloy, chemical compounds or concentrates and materials containing one or more of the aforementioned substances in a minimum quantity of 0.005 kg; and the following “special fissionable materials”: plutonium 239, 241, uranium 233, uranium enriched in 235 or 233 isotopes and materials containing one or more of the aforementioned isotopes in a minimum quantity of 0.005 gramme.

The Act exempts from the definition of “nuclear materials” uranium and thorium ore during mining and processing [Section 9(2)].

Nuclear materials may only be procured and used on the basis of a permit issued by the ÚJD [Section 10(1)]. The permit may be issued for a specific period of time, up to a maximum of ten years [Section 10(2)].

Conditions which applicants for a licence must fulfil and general requirements governing the issue of an authorisation (in respect of nuclear materials and equipment, nuclear installations, radioactive waste and spent fuel and training of nuclear installation employees) are set out in Sections 5 and 6 of the Act. Section 7 provides that a decision shall be made by the ÚJD.

An authorisation is terminated upon expiry of its period of validity, by a decision of the ÚJD to withdraw the authorisation, by the holder of the authorisation being struck off the commercial register, or, in the case of a natural person, by the death or declaration of death of that person [Section 8(1)]. An authorisation may be withdrawn or restricted by the ÚJD if: the holder of the authorisation ceases to meet the conditions under which it is issued or in some significant way threatens the life or health of

persons or causes damage to the environment; or where the ÚJD subsequently ascertains that the authorisation was issued on the basis of incorrect or incomplete information [Section 8(2)].

If a person has procured or is using nuclear materials and does not observe the obligations arising out of the permit and, further, does not remedy the breach within the period stipulated by the ÚJD, the ÚJD may require the nuclear materials to be transferred, at the expense of the person concerned, to another person who has an authorisation [Section 10(5)]. In the case of nuclear materials in respect of which the owner is not known or which were procured in violation of this Act, the ÚJD is required to order the holder of an authorisation to manage such materials, with reimbursement of the consequent expenses being made in accordance with Section 17(10) of the Act [Section 10(6)].

Pursuant to Section 12(1), legal and natural persons who produce, process, store or procure nuclear materials are obliged to:

- a) keep accounting and operational records of these materials and submit reports of the accounting records to the ÚJD;
- b) appoint an employee with special qualifications, and his deputy, to keep accounting and operational records of control of nuclear materials, and notify the ÚJD of their names;
- c) notify the relevant police authorities, the Ministry of Health and the ÚJD, without delay, of any loss or misappropriation of nuclear materials;
- d) inform the ÚJD of any interference with equipment under surveillance by the ÚJD or an international organisation under an international safeguards agreement, and of any accident which led to or could have led to violation of the integrity of nuclear material; and
- e) enable access, in the presence of inspectors from the ÚJD, of inspectors from international organisations under an international safeguards agreement governing nuclear substances, and to provide them with the necessary support during their inspections.

Details of the requirements for accounting and operational records, and for the control and notification of incidents relating to nuclear materials, were established by Decree No. 198/1999 on Accounting for and Control of Nuclear Materials of 26 July 1999 which repealed Regulations No. 28/1977 Zb. of 12 April 1977 of the Czechoslovak Atomic Energy Commission, as amended by Decree No. 100/1989 Zb. This Decree provides details governing accounting and operating records, including records of nuclear materials, operating records, accounting reports, special reports and advance notifications [Sections 2-7] and relating to inspections carried out by the ÚJD [Section 8].

The ÚJD plays a central role in the regulation of nuclear materials and its powers in relation to nuclear materials are, *inter alia*, set out in Chapter 6 of the Act. In particular, the ÚJD is empowered to issue permits for the procurement and use of nuclear materials, the management of spent fuel and radioactive waste, the import or export of nuclear materials and equipment, and the transportation of nuclear materials [Section 31(b)]. It performs state supervision of nuclear materials and equipment and of the arrangements in place for their physical protection [Section 32(1)].

#### 4. Nuclear Installations

##### a) *Licensing and inspection, including nuclear safety*

##### i) *Licensing*

Under Section 13(1) of the Act “nuclear installation” means:

- a) installations and facilities incorporating a nuclear reactor utilising a controlled fission chain reaction;
- b) installations and facilities for the production, treatment and storage of nuclear materials;
- c) installations and facilities for the disposal of spent nuclear fuel;
- d) installations and facilities for the processing, conditioning, storage and disposal of radioactive waste.

The general rule under the Act is that any use of nuclear energy requires an authorisation issued by the ÚJD [Section 4(1)]. In particular, the ÚJD is responsible for issuing authorisations for the siting, design, construction, importation, commissioning, operation and reconstruction of nuclear installations and their decommissioning; the design, planning, construction, manufacture, importation, assembly, testing, maintenance, repair and reconstruction of selected equipment; and the professional training of nuclear installation employees at specialised institutions.

The general conditions governing applicants for licences, the manner in which applications should be made and the issue of the ÚJD’s decision in respect of a licence are set out in Sections 5, 6 and 7 of the Act (see Section 3 “Radioactive Substances and Equipment” *supra*).

Construction licences for nuclear installations are dealt with separately in Section 14 of the Act. First, the construction of nuclear installations is governed by the Construction Act [Act No. 50/1976 Zb.], unless otherwise stipulated in the Act [Section 14(1)]. The construction of a nuclear installation may only be carried out by a holder of an authorisation (referred to as the “builder”) on the basis of a permit granted by the ÚJD [Section 14(2)]. The ÚJD decides on whether to issue a permit on the basis of a written application from the builder supported by the following documents: safety analysis report; design specifications; provisional plan for the management of radioactive waste and, if appropriate, of spent nuclear fuel; conceptual plan for decommissioning of the nuclear installation; classification of selected equipment by safety classes; preliminary physical protection plan; quality assurance programme for construction; preliminary on-site emergency plan; proposal of limits and conditions for safe operation; preliminary programme for pre-operational inspection of the nuclear installation; and preliminary radiation monitoring programme of the environment in the vicinity of the nuclear installation.

As a condition to granting a permit for construction, the ÚJD may require the fulfilment of specific nuclear safety requirements [Section 14(5)]. Following the issue of a statement of intent by the ÚJD regarding a permit for the construction of a nuclear installation, there is a requirement for evaluation of the proposal by the Ministry of Environment under Act No. 127/1994 Z.z. on Environmental Impact Assessment [Section 14(6)].

In addition to the provisions governing construction in the Act itself, there are also detailed regulations to be observed, which, at the moment, are those issued by the former Czechoslovakian authorities [Regulation No. 2/1978 Zb. on the Assurance of Nuclear Safety in Designing, Approving and Constructing a Nuclear Power Installation; Regulation No. 4/1979 Zb. on the General Criteria for the Assurance of Nuclear Safety in Siting and Constructing a Nuclear Power Installation; and Regulation No. 378/1992 Zb. of the Slovak Commission of the Environment].

To commission and operate a nuclear installation, the holder of an authorisation (“operator”) pursuant to Section 4 must obtain a permit from the ÚJD [Section 15(1)]. In order to obtain a permit to commission a nuclear installation, the operator is required to submit an application supplemented by the safety documentation stipulated in Section 15(2) of the Act. This safety documentation falls into two categories: that submitted for approval and that submitted for review. A permit to operate a nuclear installation is issued by the ÚJD on submission of an application supplemented by a report evaluating the commissioning stages of the nuclear installation [Section 15(3)]. The permit for commissioning or operating a nuclear installation may be made conditional upon fulfilment of requirements relating to nuclear safety [Section 15(4)]. The operator must adhere to the assessed or approved documentation submitted under Section 15(2), which may only be deviated from with the prior permission of the ÚJD [Section 15(5)].

As with construction of a nuclear installation, in addition to the provisions of the Act there are also detailed regulations to be observed with respect to the commissioning and operation of a nuclear installation. The regulations presently in force derive from the former Czechoslovakia [Regulation No. 6/1980 Zb. on the Assurance of Nuclear Safety in the Commissioning and Operation of Nuclear Power Installations].

The ÚJD may extend the validity of a permit issued for the operation of a nuclear installation, depending on the current state of the installation and on the basis of supplementary safety documentation [Section 16(1)].

## *ii) Inspection*

The ÚJD is empowered under the Act to perform state supervision of: nuclear safety at nuclear installations; management of radioactive waste and spent nuclear fuel; nuclear materials, special materials and equipment; physical protection of nuclear installations; and emergency planning.

In carrying out state supervision, the ÚJD is required under the Act to:

- a) conduct inspections of workplaces, operations and facilities at nuclear installations, to determine if duties are being fulfilled, and whether operating limits and conditions and quality assurance systems are being adhered to;
- b) determine whether obligations arising out of international agreements relating to nuclear safety and management of nuclear materials and radioactive waste (including spent fuel) are being fulfilled;
- c) investigate accidents, incidents and selected malfunctions at their place of occurrence;
- d) verify the conduct of obligatory reviews, surveys, operational checks and tests on selected equipment at nuclear installations;

- e) order corrective actions for deficiencies affecting nuclear safety;
- f) assess nuclear safety at nuclear installations independently of their operator; and
- g) inspect the content and practices of emergency plans.

There is an obligation on the part of the holders of authorisations, or other persons responsible for nuclear materials, to submit all materials, documentation, information and expert analyses required for state supervision. They must also co-operate with the ÚJD, as required for it to carry out state supervision, and apply the results of its findings in their activities [Section 33(1)]. The ÚJD is required to make reports to the Government and the relevant public service bodies, on deficiencies identified and the measures taken to remedy them [Section 33(3)].

Inspectors appointed by the ÚJD must have the required qualifications and have passed an inspector's examination [Section 34(2)]. During the performance of state-governed inspection, they are required to prove their identity using the identification card issued by the ÚJD [Section 34(3)].

Under the Act an inspector is authorised:

- a) to have access at any time to facilities and areas in nuclear installations and to areas in which nuclear materials, special materials and equipment are located, or radioactive waste management is being conducted; to carry out reviews and control actions; to require the submission of relevant evidence and documentation, information and explanations; to ensure that employees have the appropriate professional qualifications, and in particular, that the selected employees are familiar with regulations; to control the implementation of conditions for the performance of work; to identify the status, causes and consequences of operating events; to check the status of emergency planning;
- b) following discussion of identified deficiencies with the operator, to give binding orders for the necessary steps to eliminate such deficiencies; and
- c) to confiscate the certificate of a particular professional qualification if the relevant employee has flagrantly or repeatedly violated operating procedures or is unsuitable as regards the particular professional qualification.

As a means of enforcement, the ÚJD is empowered to impose various penalties for violations under the Act [Section 36]. These include the power to impose a further penalty of up to double the amount of the initial penalty on a person who has not remedied the deficiencies for which the initial penalty was imposed within the given period [Section 36(6)]. A penalty may be imposed within a year of the date that the ÚJD identified the breach, but no later than three years from the day when the breach took place [Section 36(7)]. The imposition of a penalty on a holder of an authorisation does not impinge upon the criminal responsibility of the holder's employees [Section 36(9)]. Penalties are to be paid into the State Fund for Decommissioning of Nuclear Power Plants and Management of Spent Nuclear Fuel and Radioactive Waste [Section 36(10)].

### iii) *Decommissioning*

Under the Act, the operator is made responsible for the decommissioning of a nuclear installation (which for the purposes of Section 19 does not include a radioactive waste or spent nuclear fuel repository) and must ensure that the financial means are available for this purpose [Section 19(2)].

Act No. 254/1994 Z.z. of 25 August 1994 and Decree No. 14/1995 Z.z. establish a State Fund for the decommissioning of nuclear power plants and the management of spent fuel and radioactive waste arising from their decommissioning. The Fund, which is established as a separate legal entity, is managed by the Ministry of Economy which appoints the Fund's Director. The Ministry has also set-up a Steering Committee made up of seven members, experts in the fields of nuclear energy, health, environmental protection, economy and public administration to provide advice on the distribution of funds.

The operator must submit an updated conceptual plan for decommissioning, together with an environmental impact statement (pursuant to Act No. 127/1994 Z.z. on Environmental Impact Assessment) [Section 19(3)]. Decommissioning may only commence on the basis of a permit from the ÚJD, the issuance of which is conditional upon an application from the operator supported by documentation on nuclear safety during decommissioning. Where the nuclear installation is decommissioned in several steps, a permit from the ÚJD is required for each step [Section 19(4)].

The safety documentation for the decommissioning of nuclear installations is governed by Regulation No. 246/1999, which entered into force on 1 October 1999.

#### iv) *Nuclear Safety*

Nuclear safety and quality assurance are dealt with in Chapter 4 of the Act. "Nuclear safety" is defined as the status and ability of a nuclear installation and its staff to prevent the uncontrolled development of a fission chain reaction or the inadmissible release of radioactive substances or ionising radiation into the workplace or into the environment and to limit the consequences of accidents and emergency situations [Section 20(1)]. The operator is responsible for nuclear safety and must ensure that there are adequate financial and human resources to meet this responsibility [Section 20(2)].

During the construction and commissioning of a nuclear installation and throughout its operating life, the builder and operator must perform a comprehensive and systematic evaluation of nuclear safety and take steps to eliminate any deficiencies identified. The frequency and scope of the evaluations are to be set out in regulations issued by the ÚJD [Section 20(6)]. The operator must ensure that exposure of employees and other persons to ionising radiation caused by the operation of a nuclear installation is kept below the set limits and at the lowest reasonably achievable level [Section 20(7)].

In addition to governing the safety aspects of radioactive waste management (see Section 7 "Radioactive Waste Management" *infra*), Regulation No. 190/2000 Z.z. establishes requirements governing the safe handling, processing, storage and transport of radioactive waste and the safe handling, storage and reprocessing of spent nuclear fuel.

The Act contains detailed provisions governing the professional qualifications of employees at nuclear installations [Section 21]. The Act gives ÚJD inspectors the power to confiscate certificates of professional qualification if there are grounds for doing so [Section 34].

Regarding quality assurance, the operator must set up an appropriate organisational structure, procedures and sources to define and adhere to quality assurance requirements for nuclear installations and activities [Section 22(1)].

In addition to the Act, there are many decrees which regulate safety in the design, siting, construction, commissioning and operation of nuclear facilities [Regulations No. 2/1978 Zb., No. 4/1979 Zb. and No. 6/1980 Zb.], which regulate the quality assurance of classified equipment of nuclear installations [Regulation No. 436/1990 Zb.], which regulate evaluation of special professional abilities of selected personnel from nuclear installations [Regulation No. 187/1999 Z.z.], which ensure nuclear safety in the course of radioactive waste management [Regulation No. 190/2000 Z.z.] and, finally, which ensure safety during the testing of devices for nuclear materials transport and disposal [Regulation No. 8/1981 Zb.].

Regulation No. 9/1985 Zb. governs the assurance of nuclear safety at nuclear research installations.

The Slovak Republic ratified the 1994 Convention on Nuclear Safety on 7 March 1995.

#### ***b) Emergency Response***

The emergency response system is governed by the Act and its implementing Regulations, in particular Decree No. 245/1999 Z.z. on Emergency Planning in the Event of a Nuclear Incident or Accident of 6 September 1999 and Regulation No. 31/2000 Z.z. on Events Occurring in Nuclear Installations of 20 January 2000.

Under the terms of the Act, an “event at a nuclear installation” means an event in which there is a risk to, or an infringement of, nuclear safety at the nuclear installation during its commissioning, operation or decommissioning [Section 24(1)].

Events at nuclear installations are divided into:

- a) a malfunction causing an infringement of nuclear safety requirements, or identification of deficiencies which could have led to the occurrence of an accident or emergency situation;
- b) an incident which caused minor damage to a nuclear installation or harm to the health of employees, which led however to an automatic shutdown, or enforced shutdown for maintenance, infringement of limits and conditions, release of radioactive materials or contamination or irradiation of employees;
- c) an accident in which the nuclear installation was seriously damaged or there was, or might have been, serious harm to health due to the impact of ionising radiation or release of radioactive materials into the environment [Section 24(2) of the Act; Section 2 of Regulation No. 31/2000 Z.z.].

An operator is obliged to take preventive and corrective measures in a timely manner and eliminate without delay all situations which could pose a threat to nuclear safety or to human life or health; to give notification of events to the ÚJD, and, in the case of accidents or emergency situations, also to the Ministry of the Interior; identify the causes of such events and take corrective action based on the identified causes; to take steps in the operation of the nuclear installation to prevent their recurrence; and to inform the public of the occurrence of incidents and accidents.

In the event of a hazard arising, or if serious circumstances arise which are of significance for nuclear safety, physical protection or emergency readiness, the ÚJD may order the holder of an

authorisation to take certain steps, including a reduction in output or shutdown of a nuclear installation or cessation of its construction, to cease using nuclear material or to cease radioactive waste management [Section 35 of the Act].

Under the Act, the ÚJD is required to identify the causes and circumstances of accidents, emergency situations and serious malfunctions. This does not detract from the specific regulations which govern the investigation of exceptional incidents [Section 24(6)].

“Emergency planning”, as defined in the Act, means a set of measures to identify and bring under control accidents at nuclear installations and to identify and bring under control releases of radioactive substances into the environment during the use and transportation of nuclear materials or radioactive waste [Section 25(1)]. An emergency plan consists of a set of technical and organisational measures required to bring events under control or to mitigate their consequences [Section 25(2)]. Emergency plans fall into the following categories:

- a) emergency plans for nuclear installations (referred to as “on-site emergency plans”) which consist of planned measures to be taken on-site, linked to a plan for the protection of the public;
- b) plans for protection of the public which establish measures to protect public health and property and the environment in the hazard area, also linked to the on-site emergency plan;
- c) emergency transport procedures in relation to the transportation of nuclear materials or radioactive waste (see Section 9 “Transport” *infra*).

The operator is responsible for preparation of an on-site emergency plan [Section 25(5)], which must be submitted to the ÚJD for approval and to the Ministry of Internal Affairs for consideration six months prior to the planned commencement of commissioning of a nuclear installation [Section 25(9)]. The local authorities are responsible for the plan for protection of the public within regions, districts and communities, with the Ministry of the Interior being responsible for co-ordination [Section 25(6)]. The Ministry of the Interior is responsible for civil defence during radiological accidents and for assistance in the event of a nuclear accident or radiological emergency [Act No. 42/1994 Z.z. on Civil Protection].

Prior to the commissioning of a nuclear installation, emergency plans must be practised, and during the operation of nuclear installations certain parts of emergency plans must be practised and evaluated at set intervals [Section 25(14)].

There is a general obligation on the part of operators and state authorities to make available to the ÚJD data required to evaluate accidents and to forecast their development. The data might consist of technological data from the nuclear installation, radiation monitoring data, meteorological data and other data as requested by the ÚJD [Section 25(18)].

Details on the content of on- and off-site emergency plans [Sections 3 and 5] and emergency transport procedures [Section 20] are set out in Decree No. 245/1999 Z.z. There are three emergency levels (alert, site area emergency and general emergency) [Section 4] which call for different measures to be taken at each level [Sections 14-16]. Measures include notification of authorities, public warnings, public protection measures, such as recommendations to shelter indoors or evacuation and monitoring of the radiological situation.

The Slovak Republic succeeded to the 1986 Convention on Early Notification of a Nuclear Accident and to the 1986 Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency on 10 February 1993.

## **5. Trade in Nuclear Materials and Equipment**

The Act expressly precludes the issue of an authorisation to a foreign importer of nuclear installations, selected equipment or services. The receiver of such equipment or services must be the holder of an authorisation under Section 4(2) (which can only be granted to a legal person with its registered head office in the Slovak Republic or to a natural person with permanent or long term residence in the country [Section 5(1) and (2)] or the holder of a licence or permit issued in accordance with specific regulations [Section 4(4)]). In respect of the latter, a permit from the ÚJD is required for the import or export of nuclear materials or equipment under specific regulations [Section 10]. Such specific regulations include two Decrees, namely the Decree of the Federal Ministry of Foreign Trade No. 50/1992 Zb., which implements Act No. 547/1990 Zb. on the Management of Special Substances and their Control, and the Decree of the Economics Ministry No. 15/1998 Z.z. on Conditions for the Issuance of an Official Permit for the Import and Export of Goods and Services. Act No. 547/1990 Zb. specifies that the Ministry of the Economy is the authority with jurisdiction to issue export-import licences for nuclear materials and other sensitive items subject to the approval of the ÚJD. The accounting and control aspects of such trade are dealt with by Decrees Nos. 50/1992 Zb. and 505/1992 Zb.

## **6. Radiation Protection**

Act No. 272/1994 Z.z. on Protection of Human Health and Act No. 290/1996 Z.z. on the Safety of the Health of the Population lay down the requirements for radiation protection based on the International Commission for Radiological Protection (ICRP) recommendations and IAEA standards in this area. In implementation of these Acts a Governmental Decree on Radiation Protection was adopted in December 2000. This Decree, which has not yet entered into force, will replace Regulation No. 65/1972 Zb. of the Czechoslovak Ministry of Health governing the radiation protection of workers, the public and the environment against ionising radiation sources. As a matter of general principle, the main objective for radiation protection is to keep the radiological consequences related to the use of ionising radiation as low as reasonably achievable (ALARA).

Radiation protection is also addressed in the Act, first, in the statement of general principles applicable to the peaceful use of nuclear energy [Section 3(3)] and, secondly, in relation to the safe operation of nuclear installations (see Section 4(a)(iv) *supra* “Nuclear Installations – Nuclear Safety”). In respect of the latter, the operator must ensure that exposure of employees and other persons to ionising radiation caused by the operation of a nuclear installation is kept below the set limits during all operational states and activities, and at the lowest reasonably achievable level [Section 20(7)]. Implementing Decree No. 187/1999 Z.z. on the Qualifications of Personnel of Nuclear Installations of 21 July 1999 lays down the requirements concerning the professional qualifications of personnel of such installations.

Generally, however, the Ministry of Health is the regulatory authority responsible for radiation protection at nuclear installations, medical installations and other workplaces where ionising radiation is used. Workplaces are supervised by the Institute for Hygiene and Epidemiology (under the Ministry of Health), managed by the Chief Hygienist, with the ÚJD also involved at nuclear installations as part of its responsibility for nuclear safety.

The Slovak Republic succeeded to the 1960 Convention concerning the Protection of Workers against Ionising Radiation on 1 January 1993.

## **7. Radioactive Waste Management**

Under the Act, the safe disposal of radioactive waste, including the disposal of spent fuel, is the responsibility of a legal person appointed or entrusted for this purpose by the Ministry of the Economy on the terms established in the Act and by specific regulations. A radioactive waste repository may only be sited on land owned by the State [Section 17(12)]. With respect to radioactive waste management, the ÚJD is responsible for supervising radioactive waste originating from nuclear installations and for repositories for all types of radioactive waste [Sections 17 and 18]. The Ministry of Health is designated as the responsible authority for supervising radioactive waste originating from all other sources until their treatment and transportation for final disposal [Act No. 290/1996 Z.z.].

Regulation No. 190/2000 Z.z. lays down the basic technical and organisational requirements for ensuring nuclear safety and the prevention of releases of radioactivity into the environment in the course of radioactive waste management. It also sets out mandatory radioactive waste management procedures for authorities, organisations and their staff involved in the design, commissioning, operation or decommissioning of nuclear installations, including the basic safety requirements for all steps of radioactive waste management, such as collection, segregation, storage, treatment, conditioning and finally, the disposal of radioactive waste.

“Radioactive waste” is defined under the Act as non-useable materials in gaseous, liquid or solid form which may not be released into the environment because of the content of radionuclides in them or because of contamination by radionuclides [Section 17(1)]. Pending the entry into force of the new Decree on Radiation Protection of December 2000, the levels of radionuclides which cause materials to be defined as waste are laid down in Decree No. 65/1972 Zb. on the Protection of Workers, the Public and the Environment against Ionising Radiation. “Spent nuclear fuel” means irradiated nuclear fuel withdrawn from a nuclear reactor [Section 18(1)].

The generator of radioactive waste shall manage its waste in such a manner that its quantity and activity are kept to the lowest reasonably achievable level [Section 17(13)].

Authorisations for the management of radioactive waste and spent nuclear fuel are issued by the ÚJD [Section 4(2)(d)]. “Radioactive waste management” means the collection, segregation, storage, treatment, conditioning, handling, transportation and disposal of radioactive waste from nuclear installations and conditioning for transportation and disposal of institutional radioactive waste [Section 17(2)]. “Management of spent nuclear fuel” means storage, reprocessing, handling, transportation and disposal of spent nuclear fuel in a spent nuclear fuel repository [Section 18(2)]. “Storage of radioactive waste or spent nuclear fuel” means their temporary emplacement in sites, facilities or equipment that enable them to be isolated and monitored and the environment to be protected [Section 2(b)]. “Disposal of radioactive waste or spent nuclear fuel” means their permanent emplacement in a radioactive waste or spent nuclear fuel repository [Section 2(c)].

The generator of radioactive waste is responsible for the safe management of the waste from its generation until it is transferred to a radioactive waste repository, unless the ÚJD specifies otherwise [Section 17(6)]. Similarly, the producer of spent nuclear fuel is responsible for its management until its transfer to a spent nuclear fuel repository [Section 18(3)]. A “radioactive waste or spent nuclear fuel repository” means a site, facility or equipment on the surface or underground used for disposal of

radioactive waste or spent nuclear fuel, which enable them to be isolated and monitored and the environment to be protected [Section 2(d)].

The provisions applying to the management of radioactive waste apply also to the management of spent nuclear fuel [Section 18(4)]. Requirements for radioactive waste and spent fuel management are set out in further detail in Regulation No. 190/2000 Z.z.

The costs associated with the management of radioactive waste and spent nuclear fuel, including monitoring of repositories after they have been sealed and the relevant research and development, are to be reimbursed by the originator of the waste [Section 17(8)]. Where the generator is not known or is not capable of managing the waste, the ÚJD is required to appoint someone with a radioactive waste management authorisation. In its decision the ÚJD must define the scope of management and the method of reimbursement of costs [Section 17(9)]. The costs of management where the generator is not known are to be reimbursed by the State Fund for Decommissioning of Nuclear Power Plants and Management of Spent Nuclear Fuel and Radioactive Waste. A generator who is subsequently identified must reimburse the costs arising from the management to the Fund [Section 17(10)].

The Fund is regulated under Act No. 254/1994 Z.z. on the State Fund for Decommissioning Nuclear Power Plants and Management of Spent Nuclear Fuel and Radioactive Waste [see also Regulation No. 14/1995 Z.z.] (for details on the management of the Fund, see Section 4(a)(iii) *supra* in relation to “Nuclear Installations – Decommissioning”). The Fund is financed by several means, including contributions by nuclear power plant operators, bank and state funding and other sources.

Importation of radioactive waste into the Slovak Republic is prohibited, except for the return of radioactive waste which arose during reprocessing and conditioning of radioactive materials exported for this purpose, provided the re-importation of this waste has received a permit in advance from the ÚJD [Section 17(14)].

The Slovak Republic ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 6 October 1998.

## **8. Non-Proliferation and Physical Protection**

The Slovak Republic succeeded to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 1 January 1993 and to the 1979 Convention on the Physical Protection of Nuclear Material on 10 February 1993. It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 3 March 1998. The ÚJD is the official contact point for international bodies dealing with non-proliferation regimes such as the Nuclear Suppliers Group or the Zangger Committee.

For details of the system of accountancy and monitoring of nuclear materials, see *supra* Section 3 “Radioactive Substances and Equipment”.

Physical protection of nuclear installations and nuclear materials is dealt with in Section 23 of the Act. “Physical protection of nuclear installations or nuclear materials” means a system of technical and organisational measures, the aim of which is to prevent unauthorised activities with nuclear installations or nuclear materials, especially their misuse or intentional damage [Section 23(1)]. The operator is responsible for the physical protection of a nuclear installation [Section 23(2)].

A consignor or carrier when nuclear materials are being transported, and legal or natural persons who use nuclear materials, are responsible for the provision of physical protection of the nuclear materials during these activities [Section 23(4)].

In cases of unauthorised access to a nuclear installation or unauthorised handling of nuclear materials, assistance shall be rendered within the limits of their competence by the Police and the Railway Police at the request of the builder, operator, carrier or consignor or user of the nuclear materials [Section 23(6)]. When unauthorised actions have been perpetrated with nuclear installations or nuclear materials, or there is a threat of such actions, the operator, consignor or user of the nuclear materials is required to take the necessary measures and notify the relevant department of the Police and the ÚJD without delay [Section 23(7)].

The provisions of Section 23 also apply to the physical protection of radioactive waste during its management [Section 17(15)].

In addition to the detailed provisions in the Act, Regulation No. 186/1999 Z.z. establishing Requirements for the Physical Protection of Nuclear Facilities, Nuclear Materials and Radioactive Waste, sets out criteria to categorise nuclear facilities, nuclear materials and radioactive waste as well as other areas and provides for various and differentiated requirements according to their categorisation. The issue of a permit is also required to enter into protected areas.

## **9. Transport**

Road, rail, water and air transport of radioactive materials, radioactive waste and spent nuclear fuel are governed by both the Act and by Decree No. 284/1999 Z.z. of 13 October 1999, which is based on the IAEA Safety Standards Series No. ST-1 – Regulations for the Safe Transport of Radioactive Material (1996 Edition).

Nuclear materials may only be transported on the basis of a transportation permit issued by the ÚJD to the consignor or carrier [Section 11(1) of the Act]. The scope and content of the documentation required to obtain a permit for such transport is established in Sections 3 and 4 of the Decree. Transportation of nuclear material may only be carried out in transport equipment of types approved by the ÚJD [Section 11(2) of the Act]. Each transportation of nuclear material requires a separate permit, although for transportation of nuclear material of the same type by the same carrier, a permit may be issued for a longer period of time, for a maximum of one year [Section 11(3)]. The same provisions in the Act apply to the transportation of radioactive waste [Section 17(16)] and spent nuclear fuel [Section 18(4)].

For the obligations of the consignor or carrier when nuclear materials are being transported, see Section 8 “Non-Proliferation and Physical Protection” *supra*. Legal and natural persons who take part in the transportation of nuclear materials must observe the physical protection requirements set by the consignor [Section 23(5) of the Act; Section 6 of the Decree].

There are specific provisions in the Act dealing with accidents during transportation of nuclear material, radioactive waste or spent nuclear fuel. Thus, a transport accident is defined as an exceptional event which causes harm to health, gives rise to a threat to the health of persons due to the impact of ionising radiation, or causes damage to property as a result of a release of radioactive substances into the environment [Section 24(3)]. The consignor must notify the ÚJD, the Ministry of the Interior and the Ministry of Transport, Post and Telecommunications of the transport accident, and must also inform the public [Section 24(5)].

As part of the emergency planning requirements under the Act, the carrier is required to draw up emergency transport procedures on the basis of obligatory principles from the consignor [Section 25(7)]. These emergency transport procedures must be submitted by the carrier for consideration by the ÚJD and the public service bodies affected two months prior to the transportation taking place [Section 25(11)]. The emergency transport procedures are to be approved by the Ministry of Transport, Post and Telecommunications [Section 25(12)(c)]. Nuclear materials and radioactive waste may not be transported without approved emergency transport procedures [Section 25(14)]. Details on the emergency planning procedure are provided in Decree No. 245/1999 Z.z. on Emergency Planning in the Event of a Nuclear Incident or Accident of 6 September 1999.

## 10. Nuclear Third Party Liability

Compensation for nuclear damage is covered by general regulations on liability for damage, *e.g.* Sections 415 to 450 of the Civil Code [Act No. 40/1964 Zb., as amended], except as otherwise stipulated in the act or an international agreement to which the Slovak Republic is bound [Section 26(2)]. In fact, the Act contains very detailed provisions on third party liability for nuclear damage, which largely reflect the provisions of the 1963 Vienna Convention on Civil Liability for Nuclear Damage. The Slovak Republic acceded to the Vienna Convention and the 1988 Joint Protocol on the Application of the Vienna Convention and the Paris Convention on 7 March 1995.

“Nuclear damage” is defined as [Section 26(1) of the Act] detriment to property, loss of life or harm to health caused by an “emergency situation” [as defined in Section 24(2)(c)] or by a “transport accident” [as defined by Section 24(3)]. It is also damage that has arisen through the expenditure of costs on measures necessary to avert or reduce irradiation or to restore the environment to its previous or an equivalent state, should such measures have been instigated as a result of a nuclear incident [Section 26(3)]. If damage was caused jointly by a nuclear incident and another event not dependent on the nuclear incident, the nuclear damage shall be that part of the damage which was not demonstrably caused by the other event. The operator has the burden of proving the scope of the damage which cannot be categorised as nuclear damage [Section 26(4)].

Liability for nuclear damage caused by a nuclear incident is channelled to the operator [Section 27(1)]. Liability for nuclear damage caused during the transportation of nuclear materials or radioactive waste rests with the carrier who applied for recognition as operator of a nuclear installation and, with the consent of the operator concerned, was recognised by the ÚJD as the operator [Section 27(2)]. If an operator operates a number of installations located on a territory for which a common internal emergency plan has been approved, they will be taken as a single nuclear installation for the purposes of liability for nuclear damage. More than one nuclear installation on one site, where the operators are different holders of authorisations, may not, however, be taken as a single installation, even if these installations are technically linked together [Section 27(3)].

The operator’s limit of liability for nuclear damage is 2 billion Slovak crowns (SKK) [Section 28(1)], which does not include interest or costs [Section 28(2)].

Under the Vienna Convention, which has force of law in the Slovak Republic [Section 26(2)], liability for nuclear damage is strict. In meeting claims for compensation for nuclear damage, an operator should proceed as follows:

**Group I:** Justified claims made within 12 months of the occurrence of the nuclear incident shall be met within 60 days of the date the claim was made. Seventy per cent of the limit of liability specified in Section 28 of the Act may be used to meet claims for compensation for damage

which fall within this group. If the damage compensation claims exceed the sum that may be utilised for this Group, compensation claims for damage to health and compensation for cases of death shall be met in full and other claims proportionately.

**Group II:** Other claims made between 12 and 36 months after the occurrence of a nuclear incident shall be met within 60 days of the claim, and include claims which were met proportionately in Group I.

**Group III:** When a period of 36 months has elapsed since the occurrence of a nuclear incident, individual claims for compensation for nuclear damage are to be met within 90 days of the claim, but only until the sum specified in Section 28 is exhausted. These include claims which were met proportionately in Groups I and II.

The operator must ensure that the liability for nuclear damage is covered by insurance or some other form of financial cover [Section 30(1)], which must be in place for the duration of operation of the nuclear installation and at least ten years after a nuclear incident [Section 30(2)]. There is an exemption from nuclear damage liability cover for nuclear incidents caused by small amounts of nuclear materials which are assumed not to be capable of giving rise to nuclear damage [Section 30(3)].

## II. INSTITUTIONAL FRAMEWORK

### 1. Regulatory and Supervisory Authorities

#### a) *Nuclear Regulatory Authority (ÚJD)*

The Nuclear Regulatory Authority (*Úrad Jadrového Dozoru – ÚJD*) of the Slovak Republic is the successor to the former Czechoslovak Atomic Energy Commission. It was established on 1 January 1993 and its powers are based on Act No. 2/1993 Z.z. The ÚJD acts as an independent state regulatory body which reports directly to the Government and is directed by a chairperson appointed by the Government.

Besides its Chairperson, the ÚJD comprises a small secretariat and two departments, one for assessment and inspection activities and one for safety policy assessment and international co-operation. The Inspection Activities Department is headed by the Chief Inspector and based at Trnava, near the Bohunice nuclear power plant, while the Safety Policy and International Co-operation Department is headed by the Vice Chairman and is located at the Bratislava headquarters. There are also two inspection units located at the nuclear power plant sites. In 1995, the ÚJD established an Information Centre in order to provide information on its activities to the public and the media.

The ÚJD is responsible for regulation and supervision of the use of nuclear energy. Its regulatory powers cover the following areas:

- safety of nuclear installations;
- radioactive waste management, *i.e.* supervision of radioactive waste originating from nuclear installations and repositories for all types of radioactive waste;
- safeguards and control over nuclear and dual-use materials;
- quality assurance programmes;
- transportation of nuclear material;
- early notification of nuclear accidents;
- international agreements and obligations in the field of nuclear safety and nuclear materials.

Details of the tasks of the ÚJD relating to each of these areas are set out in Chapter 6 of the Act. Of particular importance is the inspection function of the ÚJD [see Section 4(b) “Nuclear Installations – Inspection” *supra*].

**b) *Ministry of Health***

The Regional Radiation Protection Body under the Ministry is responsible for radiation protection and for the control of radiation protection measures inside nuclear installations and off-site [Act No. 272/1994 Z.z.]. It is also designated as the responsible authority for supervising radioactive waste from non-nuclear installations until its treatment and transportation for final disposal. The Institute for Hygiene and Epidemiology is responsible for providing technical support in the regulation and supervision of radiation protection.

**c) *Ministry of the Environment***

This Ministry has control over the Regional Environmental Offices which issue licences for the siting, construction, operation and decommissioning of nuclear facilities, on the basis of approval by the ÚJD, the Ministry of the Environment and other organisations, and operate the online environmental radiation monitoring network. The Ministry is responsible for environmental impact assessments: Act No. 127/1994 Z.z. requires it to evaluate all proposals for the construction of or technical changes to nuclear installations, which might have an adverse effect on the environment.

The Minister of the Environment also chairs the Government Commission for Radiological Emergencies.

**d) *Ministry of the Interior***

The Ministry is responsible for fire protection, support of physical protection of nuclear materials and nuclear installations in emergency situations, civil defence during radiological accidents

and assistance in the event of a nuclear accident or radiological emergency [Act No. 42/1994 Z.z. on Civil Protection]. In the event of incidents or accidents, the Ministry must be informed by the operator [Section 24(4)].

*e) Ministry of Economy*

The Ministry is responsible for promoting and developing a nuclear power programme and for preparing related legislation. It also issues export and import licences for nuclear materials, nuclear-related or dual-use material, equipment and technology, subject to the agreement of the ÚJD.

Under the Act the Ministry appoints the legal person responsible for the safe disposal of radioactive waste [Section 17(12)].

*f) National Office for Occupational Safety*

The responsibilities of the Office are set out in Act No. 95/2000 Z.z. on Work Inspection. The Office is established under the aegis of the Ministry of Labour, Social Affairs and the Family which is responsible for matters of industrial safety.

## **2. Public and Semi-Public Agencies**

### *Nuclear Power Plant Research Institute*

The Nuclear Power Plant Research Institute (*Vyskumny Ustav Jadrovych Elektrarni Trnava a.s. – VUJE*) undertakes research and development in the field of nuclear safety. The Institute also conducts training for the employees of the nuclear power plants at Trnava.

The final training of operating personnel at the Mochovce plant is also carried out with a full-scale simulator which is located on-site.

# SPAIN

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## I. GENERAL REGULATORY REGIME

### 1. Introduction

After the end of World War II, Spain was aware that nuclear electricity production would play an important role in meeting its energy needs, and therefore adopted legislation providing for State ownership of all radioactive ores on the national territory. A public body, entitled *Junta de Energía Nuclear* (Nuclear Energy Commission) was set up for this purpose by a Decree-Law of 22 October 1951, with full powers over nuclear matters. At the same time, Spain extended its legislation in the field of atomic energy and in particular, on 29 April 1964, adopted the Nuclear Energy Act [Act No. 25/1964]. This is a framework Act, allowing the introduction and development of a general programme of action in the nuclear field. Pursuant to this Act and until the governmental reorganisation of 2000, the Ministry of Industry, whose functions are now assumed by the Ministry of Economy, was responsible for granting licences and permits for nuclear and radioactive installations and activities. The provisions of the Act governing licensing and civil liability were then completed by Regulations in 1969 and 1972.

Since the early 1970s or so, the Spanish authorities have been amending the previous legal and institutional regime. The nuclear sector was reorganised by separating research from industrial and commercial activities of nuclear energy. The *Junta de Energía Nuclear*, which in 1986 became the Research Centre for Energy, the Environment and Technology (*Centro de Investigaciones Energeticas, Medioambientales y Tecnológicas* – CIEMAT), was given responsibility for research and development [Act No. 13 of 14 April 1986], whereas the Nuclear Safety Council (*Consejo de Seguridad Nuclear*) was entrusted with tasks relating to nuclear safety control and radiation protection [Act No. 15 of 22 April 1980, as last amended by Royal Decree No. 1339 of 31 July 1999]. The National Uranium Enterprise (*Empresa Nacional del Uranio S.A.* – ENUSA) was given responsibility for industrial activities in the nuclear fuel cycle, except for radioactive waste management, which was to be dealt with by the National Enterprise for Radioactive Waste Management (*Empresa Nacional de Residuos Radioactivos S.A.* – ENRESA) [Decree No. 2967 of 7 December 1979; Decrees of 1984, 1985 and 1996].

Act No. 40 of 30 December 1994 relating to the re-organisation of the country's electricity industry confirmed the suspension of certain nuclear power plant construction projects (Lemoniz, Valdecaballeros and Unit 2 at Trillo) and recognised the right of the owners of these projects to receive compensation for the losses that they sustained. Decree No. 2202 of 28 December 1995 implemented this Act and established a mechanism for indemnifying investors affected by the moratorium.

On 27 November 1997, Parliament adopted Act No. 54 governing the Electricity Sector in Spain. This Act, which replaces Act No. 40/1994, regulates all activities related to the distribution of electrical energy, in particular, its production, transport, distribution and commercialisation, and international and community-wide trade in this field. The Act sets out the principle of free enterprise in respect of the production and distribution of electrical energy. These activities must, from now on,

be pursued in a manner which guarantees access to electrical energy to all interested consumers on the national territory. Certain provisions of this Act amend the provisions of the 1964 Nuclear Energy Act.

## **2. Mining Regime**

Previously, Spain had had a system whereby the *Junta de Energía Nuclear* held exclusive mining rights [Decree-Law of 22 October 1951, Sections 3 and 4], whilst prospecting activities remained unrestricted.

Since the adoption of the Act of 17 July 1958, referred to as the Freedom of Mining Act, radioactive ore prospecting and mining activities may be carried out by any private person. This legislation is confirmed by Royal Decree No. 1464 of 17 September 1999 on Activities Comprising the Front End of the Nuclear Fuel Cycle, which liberalises the activities concerned.

Individuals and firms wishing to prospect for and mine radioactive ores must now apply to the Ministry of Economy for a prospection licence and a mining concession. The applications are accompanied by a report drawn up by ENUSA and are governed by the general law on mining. ENUSA is responsible for supervising these activities and may submit proposals for any suitable measures to the Ministry of Economy. The Ministry keeps a record of the quantities of radioactive ores mined.

These rules do not apply to ENUSA, which has taken over the mining activities formerly carried out by the *Junta de Energía Nuclear*. ENUSA may purchase from private individuals an annual quota of radioactive ores fixed by the Minister of Economy. Ores are classified under two categories, depending on whether or not the uranium is combined with another mineral.

## **3. Radioactive Substances, Nuclear Fuel and Equipment**

Under Section 22 of the Nuclear Energy Act of 29 April 1964, private companies are allowed to produce and market nuclear material and equipment.

Since, in theory, the *Junta de Energía Nuclear* was not empowered under its own rules to carry out nuclear industrial and marketing activities, a company was set up in 1971 [Decree No. 3322 of 23 December 1971] for this purpose: the National Uranium Enterprise (ENUSA). This is a public company which, among other things, is responsible for producing and constituting emergency stockpiles of nuclear substances.

In relation to the front end of the nuclear fuel cycle, the provisions of Royal Decree No. 2967 of 7 December 1979, as amended, were substantially amended by Royal Decree No. 1464 of 17 September 1999 which liberalised the sector in general.

Pursuant to this Royal Decree, ENUSA is an authorised company to carry out activities in the front end of the nuclear fuel cycle. The operators of nuclear installations shall ensure the enriched uranium supply for a period of five years and store the fresh nuclear fuel elements at their installations two months prior to refuelling. The operators shall also jointly constitute a stock of enriched uranium up to the amount prescribed in the Ministerial Order issued pursuant to Royal Decree No. 1464/1999 on 17 April 2000.

The Minister of Economy authorises the manufacture of nuclear or radioactive components after examining a report drawn up by the Nuclear Safety Council [Act No. 15 of 22 April 1980, as amended, Section 3].

#### **4. Nuclear Installations**

##### ***a) Licensing and inspection, including nuclear safety***

In Spain, there is no state monopoly for the production of nuclear electricity, and private industrial concerns (notably electricity-producing companies) may also become nuclear operators. The first legal instrument governing the operation of nuclear facilities appeared in 1963 as a Decree regulating industry in general [Decree No. 157 of 26 January 1963]. However, it was not until 29 April 1964, when the Nuclear Energy Act was adopted, that special regulations concerning nuclear installations were issued. Decree No. 2072 of 27 July 1968 establishing a Licensing System for Industries Producing and Using Nuclear Power was superseded by Decree No. 2869 of 21 July 1972 concerning the approval of the Regulations on Nuclear and Radioactive Installations, which was in turn repealed by Decree No. 1836 of 3 December 1999.

The licensing procedure is now governed by Act No. 15 of 22 April 1980 setting up a Nuclear Safety Council, as amended by Act No. 14 of 4 May 1999, and Royal Decree No. 1836/1999.

“Nuclear installations” means nuclear power plants, nuclear reactors, facilities for manufacturing nuclear substances and for processing or reprocessing nuclear fuel, and storage facilities.

The licensing procedure for nuclear installations includes separate licences:

- a preliminary (site) licence;
- a construction licence;
- an operating licence;
- a dismantling licence; and
- a declaration of shutdown.

The application for a preliminary licence must provide the reasons justifying the purpose of the installation, list its general characteristics, provide a detailed description of the site selected and its environment and explain the financial aspects of the project. The application for a construction licence must include a series of documents, in particular: a general design of the installation; the procurement programme for components and materials; the analysis of the electricity market in the area affected, and the preliminary safety analysis report. The contents of this report are based on those reports which are developed in the country of origin of the main supplier and must include a reference plant against which the safety assessment is performed. Finally, the operating licence is divided into two parts. The applicant must first obtain a provisional operating licence, and then a final licence. The application must include a final safety study, the operating rules and the technical specifications of the nuclear testing programme. Operators of storage facilities may request and obtain preliminary and construction licences in one step.

As a general rule, the various types of licence required for nuclear installations are issued by the Minister of Economy. Prior to issuing the preliminary licence for site approval, public hearings are held in the province where the site is to be located. The Minister also consults the state and local authorities concerned, as well as the autonomous communities affected by the project, whose opinions are forwarded to the Nuclear Safety Council. The latter draws up a report for the Minister of Economy who makes the decision. Construction, operating and dismantling licences are granted by the Minister in the light of a favourable opinion and a technical report prepared by the Council.

Other licences and permits are granted by the Director-General for Energy Policy and Mines. Apart from such licences, nuclear installations have to obtain other licences and permits from governmental or local authorities. Such authorities may not however refuse to grant a licence on grounds of nuclear safety or radiation protection, as the Nuclear Safety Council alone is qualified to judge these criteria [Act No. 15/1980, as amended, Section 3].

Radioactive installations are divided into three categories, and only those in the Category I, *i.e.* installations related to the nuclear fuel cycle, are subject to the same procedure as for nuclear installations. The other two categories, which comprise in particular radioactive installations for scientific, medical, agricultural, commercial or industrial purposes, are governed by a simplified procedure, which contains nevertheless sufficiently stringent radiological protection provisions to ensure that safety conditions prevail. To this end, Decree No. 1836/1999 implements Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, and other European Union standards.

The Minister of Economy is responsible for issuing licences for Category I radioactive installations; the second and third categories receive their licences from the Directorate-General for Energy Policy and Mines, or in certain cases, this task has been entrusted to the authorities of the autonomous communities.

The Nuclear Safety Council has taken over responsibility for the safety of nuclear installations from the *Junta de Energía Nuclear*. Together with the competent authorities, it contributes to the development of nuclear legislation on the subject and in particular, proposes criteria concerning emergency and physical protection plans for nuclear facilities. The inspectors of the Nuclear Safety Council monitor the safety and radiation protection of nuclear installations. The inspection work commences with the construction and assembling of the installation and continues throughout the normal operating period.

At the international level, Spain ratified the 1994 Convention on Nuclear Safety on 4 July 1995.

#### ***b) Protection of the environment against radiation effects***

Environmental impact studies are becoming increasingly widespread in the industrialised countries, and Spain has, for many years, included various provisions concerning environmental protection in its legislation. Examples include the Order of the Ministry of Industry of 18 October 1976 concerning projects for new activities capable of contaminating the atmosphere and the extension of existing activities, together with the Act of 2 August 1985.

The relevant administrative procedure was completed and strengthened by Royal Decree-Law No. 1302 of 28 June 1986 on Environmental Impact Studies and Royal Decree No. 1131 of 30 September 1988, based on Council Directive 85/337/EEC of 27 June 1985 on the Assessment of

the Effects of Certain Public and Private Projects on the Environment. This legislation was amended by Royal Decree-Law No. 9 of 6 October 2000 implementing Council Directive 97/11/EC of 3 March 1997.

The Royal Decree-Law provides for the preparation of studies assessing the environmental impact of certain planned installations and activities [Section 1]. The installations and activities for which studies are now required are listed in Annex I to the Decree-Law: this list includes nuclear power plants and reactors (except for nuclear reactors the thermal capacity of which does not exceed 1 kW) and installations for production or enrichment of nuclear fuel, treatment of spent fuel or high level radioactive waste, reprocessing of spent fuel, final disposal of spent fuel or radioactive waste, and storage of spent nuclear fuel or radioactive waste for a period of more than ten years at a site different from the production site.

The Authority responsible for issuing the environmental impact statement is the Ministry of the Environment, after consultation of the Nuclear Safety Council and the autonomous community on the territory where the installation will be sited.

Autonomous communities may provide for a compulsory environmental impact study for projects which are not envisaged by the national legislation. Under such circumstances, a simplified procedure applies to the study.

In the case of a project likely to affect the environment of another European Union Member State, the applicable procedure is set out in the 1991 Convention on Environmental Impact Assessment in a Transboundary Context, ratified by Spain on 1 September 1992.

Requirements governing environmental impact studies have not been substantially modified since Decree-Law No. 1302/1986 [Section 2]; a study must include the following information:

- a general description of the project and foreseeable requirements in relation to the use of the soil and other natural resources, an estimate of the type and quantities of waste and effluent produced in the course of operations or by the work concerned;
- an estimate of the foreseeable direct and indirect effects of the project on the population, fauna, flora, soil, air, water, climate, etc.;
- the measures envisaged for reducing or eliminating adverse effects on the environment;
- the environmental monitoring programme;
- a description of alternative options;
- justification of reasons which lead to the solution chosen.

Studies are submitted to the competent authority within the context of the licensing procedure for the project in question, namely, the Ministry of Economy. In parallel with the procedure for informing the public [Section 3] and before adopting the administrative resolution for the construction of the installation or licensing of the activity concerned, the Ministry forwards the file to the Ministry of the Environment so that it can draw up the Environmental Impact Statement [Section 4] which is a public document. If there is a difference of opinion between this Ministry and the Ministry of Economy, the decision lies with the Council of Ministers.

**c) *Emergency response***

An Order of 29 March 1989 approves the Basic Nuclear Emergency Plan (*Plan Básico de Emergencia Nuclear – PLABEN*) together with the text of the Plan itself. This Basic Emergency Plan contains the instructions to be complied with when nuclear emergency plans are established at province level in accordance with the radiological criteria laid down by the Nuclear Safety Council in the event that an area is affected by an accident originating in a nuclear power plant. A State Decree of 1992 set out the characteristics of the emergency plan, entitled Basic Intervention Plan.

On the basis of a prior report by the Nuclear Safety Council and the National Civil Protection Commission, the Minister of the Interior makes any amendments required to the Basic Nuclear Emergency Plan.

A governmental representative of a province where a nuclear power plant is located is designated as the Director of the Province Plan. He is responsible for declaring emergency situations, deciding on the appropriate measures to be taken, informing the public and determining the protection measures required [Section 2(1)]. At the same time, local groups are set up to deal with the emergency and co-ordinate operations.

The Basic Nuclear Emergency Plan is supplemented by Annexes which set out the different intervention levels, area limits, protection measures and transmission plans as well as a glossary of the terms contained in the Plan.

Spain ratified the 1986 Convention on Early Notification of a Nuclear Accident as well as the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency on 13 September 1989.

## **5. Trade in Nuclear Materials and Equipment**

**a) *General provisions***

Restrictions on the export of nuclear materials and equipment which are sensitive from the viewpoint of the non-proliferation of nuclear weapons, are not integrated into Spain's nuclear legislation but are included in the general legislation on international trade. Furthermore, following Spain's membership of the European Union, the Community provisions concerning trade in nuclear items contained in both nuclear regulations and in general regulations are applicable.

Nuclear materials, installations and equipment constitute one of the categories of dual-use items subject to export restrictions pursuant to specific legislation.

This legislation includes Council Regulation (EC) No. 2889/2000 of 22 December 2000 amending Regulation (EC) No. 1334/2000 with regard to intra-Community transfers and exports of dual-use items and technology as far as EU legislation is concerned and Royal Decree No. 491 of 27 March 1998 containing Regulations on Foreign Trade of Defence and Dual Use Materials, and the Ministerial Order of 30 June 1998 which establishes the procedure to be followed.

Under this legislation, trade in nuclear materials, installations and equipment requires specific licences issued by the State Secretary of Trade within the Ministry of Economy, on the advice of an

Interministerial Committee on Defence and Dual Use Items Trade. The exporters of such items shall be recorded in a special register.

**b) Patents**

Provisions relating to patents, trademarks and inventions in the field of nuclear energy were included in the framework Nuclear Energy Act No. 25 of 29 April 1964, as amended by Act No. 25 of 20 June 1968.

Patent applications are filed in accordance with the normal procedure laid down by Spanish legislation on industrial property [Section 81]. This legislation is in line with the principles established in the European treaties and legislation, as well as in other international instruments ratified by Spain.

Patents are issued by the Industrial Property Registration Office, following examination of a report by CIEMAT.

On the basis of this report, the Ministry of Economy may grant exemption from the requirement to provide evidence of implementation and operation required by the law on industrial property, to any patent owner who has submitted a request to this effect to the Industrial Property Registration Office.

**6. Radiation Protection**

Radiation protection was mentioned for the first time in Spanish legislation in 1959. The Order of 22 December 1959 contains standards for protection against ionising radiation. Legislation on radiation protection has since been considerably expanded and the original Order has been amended and supplemented [Orders of 10 January 1962 and 9 March 1971]. General provisions concerning protection against ionising radiation were similarly included in Act No. 25 on Nuclear Energy of 29 April 1964.

Royal Decree No. 2519 of 12 August 1982 approved the Regulations on Protection against Ionising Radiation, adopted in pursuance of Act No. 25/1964 on Nuclear Energy. This Decree was amended in part by Royal Decree No. 1753 of 25 November 1987 in order to introduce European legal provisions on radiological protection, in particular Council Directives 80/836/Euratom of 15 July 1980 and 84/467/Euratom of 3 September 1984 laying down the basic standards for the protection of the public and workers against the dangers of ionising radiation.

In 1992, a Regulation on Protection against Ionising Radiation [Royal Decree No. 53 of 24 January 1992] consolidated in a single instrument the regulations existing in this field, notably Decrees No. 2519/1982 and 1753/1987 mentioned above and now repealed.

These Regulations contain detailed administrative and technical provisions applicable to nuclear and radioactive installations and to the use of radiation-emitting equipment. These standards comply with the international radiation and nuclear safety regulations, in particular the recommendations of the International Atomic Energy Agency (IAEA), OECD Nuclear Energy Agency (NEA), International Labour Organisation (ILO) and World Health Organisation (WHO). They lay down the fundamental radiation protection measures applicable to persons exposed at work and to members of the public taken individually and collectively [Sections 5-14]; they contain provisions concerning medical supervision [Sections 40-46], radioactive waste [Sections 53-59], and the inspection of installations and activities representing a potential danger of exposure to radiation [Sections 60-63].

Various penalties are envisaged in the event of breach of the Regulations [Section 64]. The Regulations are supplemented by Annexes which contain definitions of radiological, biological and medical terms and by tables setting out radiation exposure limits.

The authorities responsible for ensuring implementation of the Regulations are the Minister of Economy, the Minister of Health and the Nuclear Safety Council, without prejudice to the special duties of other ministries or national agencies.

More recently, Royal Decree No. 413 of 21 March 1997 on the Operational Protection of Workers Employed by Outside Companies and Exposed to the Risk of Ionising Radiation during their Activities in Controlled Areas, was adopted. This Decree was established to implement Council Directive 90/641/Euratom, and to ensure that this protective regime would apply to all workers carrying out activities in controlled areas. A Resolution of 16 July 1997, published on 4 October 1997, was adopted by the Nuclear Safety Council in implementation of this Decree. This Resolution establishes a register of outside companies.

Radiation protection is a matter for the Nuclear Safety Council. In particular, the latter is responsible for radiation protection controls both within and around atomic facilities [Act No. 15 of 22 April 1980, as amended, Section 2]. In addition, the Directorate-General for Civil Protection, answerable to the Minister of the Interior, organises radioactivity warning networks which take the action required when any abnormal increase in radioactivity is recorded [Decree No. 53 of 10 January 1963].

The basic measures for the radiation protection of persons undergoing medical examination or treatment are contained in Royal Decree No. 1132 of 14 September 1990 which implements Council Directive 84/466/Euratom on this matter into Spanish legislation. The fundamental principle (the ALARA principle) is that all exposure to radiation for medical purposes must be kept as low as reasonably achievable [Section 1]. Furthermore, all radiodiagnostic, radiotherapy and nuclear medicine facilities must be recorded in the national inventory which is kept by the Ministry for Health and Consumers to avoid unnecessary proliferation of such equipment [Section 6], in accordance with the provisions of the above Directive.

Royal Decree No. 1891 of 30 December 1991 relates to the use of X-ray equipment for the purposes of medical diagnosis. The Decree lays down the rules enabling government authorities to monitor the proper functioning of such appliances. It also takes account of Council Directive 80/836/Euratom, amended by Council Directives 84/467/Euratom, and 84/466/Euratom, referred to above. The Decree provides for a register of firms authorised to sell and maintain X-ray equipment for medical use and for a register of the equipment installed. It also sets out requirements relating to third party liability insurance, and to the qualifications and training of personnel operating the equipment.

Decree No. 2071 of 22 December 1995 was enacted in order to establish procedures for implementing the two above-mentioned Decrees of 1990 and 1991, respectively. It sets out the criteria for quality control within the medical sector so as to avoid excessive exposures to both patients and workers. The verification of doses administered to patients is to be carried out according to the technical criteria set forth in Annex I to the Decree, while the levels of radiation at places of work and other places accessible to the public must comply with standards set out in Annex II.

## 7. Radioactive Waste Management

Under the Nuclear Energy Act of 29 April 1964, operators of nuclear and radioactive installations are required to ensure that they possess the equipment necessary to store, handle and transport radioactive waste resulting from the operation of such installations [Section 38]. Sections 2 and 57 of this Act were amended by the fourth additional provision of Act No. 54 of 27 November 1997 in relation to the definition of radioactive waste. "Radioactive waste" means any material or product for which no future use is planned, and which contains or is contaminated by radionuclides whose concentration or level of activity exceeds the limits laid down by the Ministry of Economy.

Royal Decree No. 53 of 24 January 1992 on Protection against Ionising Radiation contains a number of provisions concerning radioactive waste.

In particular, it provides that installations whose activities are likely to produce significant quantities of radioactive waste must be equipped with adequate facilities for storage, treatment and disposal of such waste. In addition, radioactive waste disposal requires an administrative permit and any operation of this type must be undertaken in compliance with the terms of the permit.

Royal Decree No. 1899 of 1 August 1984 amends Royal Decree No. 2967 of 7 December 1979 on the Organisation of Activities Forming Part of the Nuclear Fuel Cycle, under which ENUSA was made responsible for the management of spent fuel, whereas the *Junta de Energía Nuclear* was entrusted with the permanent storage of radioactive waste. However, certain aspects, such as the storage of radioactive waste resulting from different fuel cycle processes and the dismantling of nuclear and radioactive installations, were not taken into account.

Decree No. 1899/1984 thus authorises the National Enterprise for Radioactive Waste (ENRESA, created by Royal Decree No. 1522 of 4 July 1984, modified on 1 March 1996) to carry out the whole range of radioactive waste management activities. Moreover, companies producing nuclear energy and the operators of nuclear and radioactive installations may now call on the services of ENRESA to ensure the permanent storage, handling and transport of their radioactive waste.

To finance the activities of ENRESA relating to the storage of spent fuel and radioactive waste produced by nuclear power plants and their decommissioning, a fund financed by a percentage of the price paid for electricity was created. Services provided by ENRESA to other installations are dealt with in contractual arrangements which also represent a source of funding. The Minister of Economy approves the economic and contractual conditions of such services.

Under Royal Decree No. 1522 of 4 July 1984, ENRESA is responsible in particular for selecting sites for the construction and operation of storage facilities for radioactive waste. But in as much as the resulting work inevitably affects the areas selected, an Order of 30 December 1988 adopted in pursuance of the above-mentioned Decree No. 1522/1984, and a supplementary Order of 1 December 1989 authorise ENRESA, within the context of its work, to provide financial assistance to the municipal councils of the communes on whose territory nuclear installations which store radioactive waste or spent fuel are located.

With respect to the financing of radioactive waste management operations, Decree No. 404 of 1 March 1996 establishes a Monitoring and Control Committee (*Comitato de Seguimiento y Control*) to take charge of the fund allocated to the management of such waste. The Committee, which reports to the Ministry of Economy, is composed of a Commissioner of Accounts for State Administration, a Director-General of the Treasury and Financial Policy and a Director-General for Energy Policy and Mines.

The management fund, which is constituted under the terms of the 1994 Law on the National Electricity System amended in 1997, will be utilised in the manner set forth in the General Plan on Radioactive Waste.

Spain ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 11 May 1999. It is also a Party to the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, ratified on 31 July 1974, and its 1996 Protocol, ratified on 24 March 1999.

## **8. Non-Proliferation and Physical Protection**

The provisions on nuclear security contained in Nuclear Energy Act No. 25 of 29 April 1964 and in Decree No. 1836 of 3 December 1999 are quite brief.

The Ministry of Economy is kept informed of operations involving nuclear material, and keeps a register in which to record the movements of such material [Act No. 25/1964, Section 23].

Any loss, abandonment or theft of nuclear substances must be notified to the competent authorities as soon as possible [Section 40]. Offences are punishable by criminal or administrative penalties, depending on the seriousness of the offence, either by the competent department of the Ministry of Economy, the Minister himself or by the Council of Ministers when secret information relating to nuclear energy has been divulged [Sections 87 and 91].

Royal Decree No. 58 of 3 February 1995 establishes a national system for the physical protection of nuclear installations and material. It covers the handling, use and transport of nuclear material and lays down a series of requirements for licensees. These activities are subject to licensing by the Ministry of Economy after consultation with the Ministry of the Interior and the Nuclear Safety Council.

At the international level, Spain has ratified the following international instruments:

- the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 5 November 1987;
- the 1996 Comprehensive Nuclear Test Ban Treaty, on 31 July 1998;
- the 1979 Convention on Physical Protection, on 6 September 1991.

## **9. Transport**

The Act on Nuclear Energy of 29 April 1964, in particular in Chapter VI, contains specific provisions on the transport of radioactive materials in general. Subsequent Decrees have completed the provisions of this Act [as amended by Act No. 25 of 20 June 1968], in respect of certain modes of transport, *e.g.* road, rail or air, to bring Spanish legislation into line with the international agreements ratified by Spain. The other transport modes – inland waterways and sea – are still governed by the original provisions of the 1964 Act.

As far as the transport of radioactive materials by *road* is concerned, Spain acceded, on 22 November 1972, to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Following this accession, several pieces of legislation were passed, including

a 1973 Decree [Decree No. 2674 of 19 October 1973, as amended], implementing the ADR and determining the competent authorities. Ministerial orders have completed this legislation to bring the 1973 Decree up to date and to provide persons involved in international transport with the necessary information on the procedures and formalities to be observed.

In order to meet the special needs of Spanish road transport, two Decrees were promulgated in 1976 [Decrees No. 1754 of 6 February 1976 and No. 2101 of 10 August 1976], implementing the national regulations for the transport by road of dangerous goods which contain the provisions laid down by the ADR. Decree No. 1754/1976 was first amended by Decree No. 1999 of 29 June 1976 to take account of the amendments made in November 1977 to the ADR following the revised 1973 edition of the IAEA Regulations for the Safe Transport of Radioactive Materials, then by Decree No. 1723 of 20 June 1984.

A Regulation was adopted on 31 January 1997 in order to implement into national law the amendments made in 1993 to the Regulation on the International Transport of Dangerous Goods by Road, which is an Annex to the 1980 Convention on International Road Transport. Transport by road of dangerous goods is also governed by Royal Decree No. 2115 of 22 October 1998.

As regards *rail transport*, on 19 November 1974, Spain ratified the International Convention concerning the Carriage of Goods by Rail (CIM) and thus applies within its territory its Annex I: the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID). Decree No. 2115/1998 also contains provisions related to the carriage of dangerous goods by rail.

As for *air transport*, Royal Decree No. 1749 of 1 August 1984 brought up to date by Ministerial Order of 28 December 1990, approved the national Regulations on the Safe Transport of Dangerous Goods by Air. These Regulations, together with the detailed technical instructions accompanying them, are based on the 1981 revised version of the Dangerous Goods Annex of the Chicago Convention on International Civil Aviation. Radioactive substances are contained in Class 7 of the classification of dangerous goods under the Regulations. Given that the provisions of the Chicago Convention are directly applicable in Spain, there are no national regulations in this field. A similar situation exists in relation to *maritime transport* which is governed by codes and regulations of the International Maritime Organisation.

Responsibility for the transport of radioactive materials is shared by the Ministry of Economy and the Ministry of Public Works. The Ministry of Economy is responsible for issuing licences for the transport of nuclear substances, in the light of a report submitted by the Nuclear Safety Council.

The Ministry of Economy is also responsible for issuing approval certificates and for licensing shipments of radioactive materials involving foreign undertakings [Act No. 25/1964, Section 22]. Further conditions may also be imposed by other government departments, including the Ministry of Trade. The carriers of radioactive substances or concentrates must report their activities to the Ministry of Economy, which keeps *ad hoc* records of all the information received [Section 23].

Regulations No. 2519/1982 on Protection against Ionising Radiation, as amended, provide in a supplementary section that any transport of radioactive material which is not governed by specific regulations shall be subject to the provisions of these Regulations, supplemented by the technical radiation protection standards contained in the latest edition of the IAEA Transport Regulations.

The Minister of Public Works has general responsibility for all transport [Decree No. 1558/1977, Section 11].

The Nuclear Safety Council is responsible for monitoring and enforcing safety and radiation protection requirements in the field of transport. To this effect, it helps the competent authorities to draw up criteria relating to emergency plans [Act No. 15 of 22 April 1980, as amended, Section 2].

## **10. Nuclear Third Party Liability**

The framework Act on Nuclear Energy laid the foundations for the rules governing nuclear third party liability [Act No. 25 of 29 April 1964, Chapters VII-X]. It was supplemented by an implementing Decree No. 2177 of 22 July 1967 approving the Regulations on Cover for Nuclear Damage Risks, which was itself amended by Decree No. 742 of 28 March 1968 and then by Decree No. 2864 of 7 November 1968. This Decree is now almost completely repealed by the general legislation on insurance and the 1999 Regulations on Nuclear and Radioactive Installations [Royal Decree No. 1836 of 3 December 1999], which eliminate the liability coverage obligation for second and third category nuclear installations.

The basic general principle of Act No. 25/1964 is that the operator of a nuclear or radioactive installation is objectively liable for all nuclear damage up to the maximum amount of his liability [Section 45]. However, persons using or storing radioactive materials or equipment which, according to the national standards in force, are incapable of emitting radiation representing a serious hazard, are excluded from the scope of the nuclear liability regime [Decree No. 2177/1967, Section 1].

As to the amount of liability, Section 57 of Act No. 25/1964 provides that the amount of the nuclear operator's liability should be reviewed if necessary to ensure that it is not lower than the amount established by the international conventions ratified by Spain and referred to below. Under this provision, the previous amount of 850 million Spanish pesetas (ESP) was raised to ESP 25 billion (which corresponds to approximately 150 million Special Drawing Rights) as from 1994 [Act No. 40 of 30 December 1994 on the Reorganisation of the National Electricity System]. Furthermore, a Regulation was adopted on 25 April 1997 to confirm that the two units of Almaraz NPP should be considered as one single nuclear installation. As a result of this, the two units are covered by the same insurance policy and the operator is liable for damage caused to third parties as if it were one single installation.

However, in respect of the transport of nuclear substances and low risk installations, for which the Nuclear Safety Council judges the risk to be lesser to that in respect of nuclear installations, the Ministry of Economy may set a lower ceiling of liability, which may not in any case be less than ESP 1 billion. The legislation also provides that these liability amounts may be raised by the government, upon the proposal of the above-mentioned Ministry, either to implement Spain's international obligations or to take account of inflation, thereby effectively ensuring the same amount of financial cover.

At international level, Spain ratified the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy on 31 October 1961 and the 1963 Brussels Supplementary Convention on 27 July 1966. It also ratified the 1971 Convention Relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 21 May 1974.

## II. INSTITUTIONAL FRAMEWORK

Nuclear activities are carried out in Spain under the control of various ministries, each being responsible for the area assigned to it under Spanish law. It should be noted, however, that the Ministry of Economy clearly plays a major role since it is generally responsible for enforcing existing nuclear legislation.

When the *Junta de Energía Nuclear* was set up in 1951 [Decree-Law of 22 October 1951], it was the first specialised body with full powers over nuclear matters [Section 7]. Since then, as already explained, the *Junta* has been replaced by the Research Centre for Energy, the Environment and Technology (CIEMAT) [Act No. 13 of 14 April 1986]. The Nuclear Safety Council, the National Uranium Enterprise (ENUSA) and the National Enterprise for Radioactive Waste (ENRESA) also play an important role in the nuclear field.

### 1. Regulatory and Supervisory Authorities

#### a) *Ministry of Economy*

The Ministry of Economy which has assumed the activities of the former Minister of Industry and Energy in the field of nuclear energy since May 2000, controls the application of nuclear legislation, except for those responsibilities which are expressly assigned to other ministries [Act No. 25 of 29 April 1964, Section 3].

The National Enterprise for Radioactive Waste (ENRESA) is also under the direct supervision of the Ministry of Economy, through CIEMAT which holds the majority of the capital of ENRESA, the remainder being held by the State Company of Industrial Participation (SEPI), a public undertaking.

As far as the Nuclear Safety Council is concerned, the Minister of Economy submits proposals to the government regarding the appointment of the Council's Secretary-General. Appointments are then submitted to Parliament for approval [Act No. 15 of 22 April 1980, as amended, Section 5].

As already stated, the Minister of Economy may intervene in ENUSA's activities; however, since the entry into force of Royal Decree No. 1464 of 17 September 1999, a major liberalisation of the activities comprising the front end of the nuclear fuel cycle has taken place.

It is also recalled that the Minister of Economy has the power to grant licences for constructing and operating nuclear installations and Category I radioactive installations and the Directorate-General for Energy Policy and Mines of this Ministry is the competent body for all other licences such as those for the transport of radioactive substances and the manufacture of nuclear components, after consultations with the competent authorities, including the Nuclear Safety Council [Act No. 25/1980, as amended, Section 3].

### *Directorate-General for Energy Policy and Mines*

The Directorate-General for Energy Policy and Mines of the Ministry of Economy, which is composed of a number of Sub-directorates, including the Sub-directorate of Nuclear Energy, assumes the previous responsibilities of the former Directorate-General for Energy within the Ministry of Industry and Energy. It is responsible for planning, co-ordinating and implementing Spanish electro-nuclear development, with the help of the competent bodies. It is also responsible for official procedures relating to administrative licences and, after receiving an opinion from the Nuclear Safety Council, it issues the necessary licences other than those for nuclear installations and Category I radioactive installations, subject to those powers which are attributed to the autonomous communities [Section 3].

#### **b) *Ministry of the Interior***

The Ministry of the Interior is the supervisory authority for the Directorate-General for Civil Protection.

The Directorate-General for Civil Protection is responsible for setting up an emergency warning network in the event of an increase in radioactivity on Spanish territory, especially in areas where nuclear facilities are located [Decree No. 53 of 10 January 1963].

The Minister of the Interior is responsible for drawing up and amending the basic nuclear emergency plan in consultation with the Nuclear Safety Council and the National Civil Protection Commission [Order of 29 March 1989].

The Ministry of the Interior also plays an important role in relation to the physical protection of nuclear materials. In co-operation with the Ministry of Economy, it is responsible for monitoring the transport of nuclear materials, and it issues reports during the procedure for issuing licences required for international trade and for possession or transport of nuclear materials.

#### **c) *Ministry of Finance***

The Ministry of Finance takes decisions regarding the financing of expenditure to be met by the state under national nuclear legislation and international nuclear conventions [Act No. 25/1964, Section 68]. The Ministry, through its Directorate-General for Insurance, approves the financial security to cover nuclear risks [Section 56] and is responsible for supervising the insurance companies which are active in the nuclear sector.

### *Directorate-General for Insurance*

The Directorate-General for Insurance is responsible for the Insurance Compensation Consortium (*Consortio de Compensación de Seguros*), whose task is to share in covering nuclear risks should insurance companies be unable to meet the entire cost [Decree No. 2177 of 22 July 1967]. It undertakes reinsurance in accordance with directives of the Minister of Finance. The Consortium is a member of the Executive Committee of the Nuclear Insurance Pools.

A special Nuclear Risks Department has been set up under the Consortium for the purpose of insurance compensation. It is financially independent and is managed by a government committee

chaired by the Director-General of Insurance. The committee meets either in plenary Session or in the form of a standing committee.

An appeal against the decisions of the Department may be made before the Insurance Compensation Consortium, with the possibility of a further appeal before the Insurance Arbitration Court.

The plenary committee is responsible for applying the measures adopted for covering nuclear risks. It authorises reinsurance and pays compensation in excess of ESP 1 million. The sale of assets of the Department and its expenditure must be approved by the Committee.

The Standing Committee is responsible for claims of less than ESP 1 million.

**d) *Ministry of Science and Technology***

CIEMAT and other research and training centres, which were previously under the supervision of the former Ministry of Industry and Energy, are now placed under the supervision of the Ministry of Science and Technology which was set up in May 2000.

**2. *Public and Semi-Public Agencies***

**a) *Nuclear Safety Council***

In accordance with the guidelines of the National Energy Plan and the Resolution on Nuclear Energy adopted on 28 July 1979 by the Spanish Parliament, the Nuclear Safety Council was set up under Act No. 15 of 22 April 1980. Its tasks, as set out in this Act, were re-defined and broadened by Act No. 14 of 4 May 1999.

It is generally responsible for the regulation and supervision of nuclear installations. In this context, it therefore takes over the tasks previously carried out by the *Junta de Energía Nuclear* under the Nuclear Energy Act of 29 April 1964.

**i) *Legal status***

Act No. 15/1980, as amended, provides that the Nuclear Safety Council is independent of government administration [Section 1]. Royal Decree No. 1157 of 30 April 1982, adopted pursuant to the 1980 Act, defines the Statute of the Council. It provides that the Council is a body governed by public law and that it enjoys legal personality and administrative and financial autonomy [Section 1].

The Statute of the Council was partly amended by Royal Decree No. 643 of 2 June 1989. This Decree provides for a reorganisation of the Council's work and amends Article 41 of its Statute concerning the Technical Directorate. It sets up several Sub-Directorates under its responsibility: the Sub-Directorates for nuclear power plants, for radioactive and nuclear fuel cycle installations, for radiation protection, for analysis and evaluation and lastly, for siting and co-operation programmes at national and international level [Article 41(3)(a)-(e)]. Royal Decree No. 2209 of 28 December 1995 introduced a further amendment to the Statute of the Council. This Decree, which entered into force on 13 January 1996, in fact completely restructures the Technical Directorate into several general

sub-divisions, each relating to a specific subject such as nuclear reactor control, control of the nuclear fuel cycle, radiation protection, etc. Furthermore, several existing sub-divisions were disbanded.

*ii) Responsibilities*

The Nuclear Safety Council is intended to be an independent body with exclusive jurisdiction in the field of safety and radiation protection [Act No. 15/1980, as amended, 3<sup>rd</sup> supplementary provision]. Nevertheless, it may delegate powers to the autonomous communities in accordance with procedures laid down by the Council itself [Royal Decree No. 1157/1982, Section 1].

The Council maintains contacts with similar bodies abroad [Act No. 15/1980, as amended, Section 2(l)] and advises the Spanish Government on the commitments it has entered into with other states or international organisations in the field of nuclear safety and protection against ionising radiation [Section 2(n)].

The Council has very extensive powers in its field of jurisdiction:

- In regulatory matters, the Council co-operates with the government to draw up or review rules concerning nuclear safety and radiation protection [Section 2(a)]. In collaboration with the competent authorities, it draws up and approves the criteria relating to the siting of nuclear and radioactive installations, emergency plans, physical protection of nuclear and radioactive installations as well as those used in relation to the transport of nuclear substances and radioactive materials [Section 2(a) and (f)].
- Pursuant to its administrative powers, the Council submits reports on the issuing of licences required for nuclear and radioactive installations, the transport of nuclear substances or radioactive materials, the manufacture of nuclear or radioactive components, and uranium mining, to the Ministry of Economy before the latter takes any decisions in this respect [Section 2(b)]. In the case of site licences, the Nuclear Safety Council examines beforehand the reports prepared either by the autonomous communities or the pre-autonomous bodies, or failing this, by the provinces concerned [Section 3(3)]. The opinions given by the Nuclear Safety Council must be followed when they are against the applications being granted. Any conditions contained in favourable opinions must also be complied with.
- In the field of radiation protection, the Council has the power to supervise, by carrying out inspections, nuclear or radioactive installations and transport and component manufacturing plants, to ensure that the safety requirements are complied with [Section 2(c)]. Where it notes that there is a safety risk, it has the right either to suspend the activities of the enterprises concerned or to propose to the Ministry of Economy that it should revoke the licence already granted. These measures may be accompanied by penalties [Section 2(e)]. Courts and administrative bodies may consult the Council on matters concerning nuclear safety and radiation protection [Section 2(l)].
- The Council also controls the means to ensure radiation protection of workers, the public and the environment. It checks on irradiation levels in the area surrounding nuclear and radioactive installations and in the areas through which nuclear or radioactive materials are transported. It monitors the cumulative doses received by persons exposed to radiation in the course of their work, and grants or renews the necessary licences [Sections 2(g) and (h)]. The Council is kept informed of incidents caused by radiation and gives its opinion on the steps to be taken.

- The Council is also responsible for informing the public of its administrative activities and of matters relating to radiation protection and nuclear safety [Section 2(m)]. It reports annually to the Senate and the Chamber of Deputies on its activities [Section 11].
- The Council carries out studies, assessments and inspections in relation to radioactive waste management [Section 2(k)].

### *iii) Structure*

The Nuclear Safety Council consists of a chairperson and a board composed of four members assisted by a General Secretariat.

The chairperson and the board members are appointed by the Government for a period of six years, which is renewable, after consultation with the Minister of Economy and following a favourable opinion of at least three-fifths of the members of the competent committee of the chamber of deputies [Section 5(2)].

The chairperson and members are selected in the light of their expertise in nuclear safety and radiation protection [Section 5(1)]. One of the four members is appointed vice-chairperson by the board on a proposal from the chairperson, and replaces the latter in his absence.

The Secretary-General of the Nuclear Safety Council is appointed by the government on a proposal from the Minister of Economy [Section 5(3)]. He takes part in the Council's meetings in an advisory capacity [Section 4(3)].

The Council meets at least once a fortnight in regular session. Extraordinary sessions may be convened by the chairperson or at the request of a member of the board [Royal Decree No. 1157/1982, Section 45].

The Nuclear Safety Council recruits the necessary qualified staff and may, for the performance of specific tasks or for a set period of not more than one year, call upon persons outside the Council, both Spanish and foreign [Act No. 15/1980, as amended, Section 8].

### *iv) Financing*

The Council's funds come from appropriations from the general state budget and from the Council's own resources. Other resources may also be allocated in some cases [Act No. 15/1980, as amended, Section 9; Royal Decree No. 1157/1982, Section 3].

The Nuclear Safety Council obtains its own funds through the levy of a special charge for services rendered, which has been established especially for this purpose [Act No. 15/1980, as amended, Section 10]. This charge is based on studies carried out by the Council in respect of the issue of licences, and on inspections relating to nuclear and radioactive installations, the transport of nuclear or radioactive substances, the manufacture of nuclear or radioactive components and type-approval of radioactive equipment [Section 10(3)].

A charge is also levied on the issue or renewal of licences for operational staff in nuclear and radioactive facilities [Section 10(4)]. The charge, usually paid to the competent collecting centre, is

payable by persons who have applied for the said licences and permits. The entire proceeds are used to cover the cost of the services rendered by the Council on behalf of third parties.

**b) *Research Centre for Energy, the Environment and Technology (CIEMAT)***

Under Act No. 13 of 14 April 1986 on the development and general co-ordination of scientific and technical research, the *Junta de Energía Nuclear* was replaced by the Research Centre for Energy, the Environment and Technology (CIEMAT).

The *Junta de Energía Nuclear* was set up in 1951 in the expectation of growing nuclear power applications in Spain. This body, which was to be given major technical, financial and staff resources, had been envisaged as an instrument for promoting nuclear industrial development and, to this end, had been given broad powers in this field.

Subsequently, because of the growth in nuclear activities connected with the need to meet energy requirements, and the corresponding increase in regulations to meet legitimate safety concerns, the government decided to split up the complex structures of the *Junta* into separate bodies in the nuclear field. As a result, the *Junta de Energía Nuclear* remained responsible for the tasks connected with promotion and research relating to the peaceful uses of nuclear energy, whilst those connected with the industrial aspects of the nuclear fuel cycle were entrusted to ENUSA [Decree No. 2967 of 7 December 1979] and those relating to radioactive waste management and storage to ENRESA. Similarly, regulatory and supervisory duties for nuclear installations were transferred to the Nuclear Safety Council [Act No. 15 of 22 April 1980, as amended].

At the moment, CIEMAT, which has many activities outside the nuclear field, has taken over some of the tasks formerly carried out by the *Junta de Energía Nuclear*. Its responsibilities mainly include the promotion and development of fundamental and applied research activities, as well as the development of technology in the energy field.

*i) Legal status*

CIEMAT is a public body directly answerable to the Ministry of Science and Technology.

*ii) Responsibilities*

CIEMAT is a research centre, an advisory agency and a representative body at national and international level in the industrial sphere. It also intervenes in nuclear emergencies in co-operation with the Nuclear Safety Council and ENRESA.

*Nuclear research and development*

CIEMAT has fundamental research laboratories and pilot plants in which – in agreement with the government departments concerned – it carries out fundamental and applied research. Possessing all the services required to perform its nuclear tasks, it gives technical assistance to ENUSA in the field of scientific research relating to the successive phases of the nuclear fuel cycle. It also gives advice and offers technical assistance in its sphere of competence to ENRESA, and to private industry. CIEMAT helps promote and develop nuclear energy by subsidising other Spanish research centres.

### *An advisory role*

Broadly speaking, when matters within its jurisdiction are being studied and put into practice, CIEMAT is represented on joint advisory committees when these are not within the jurisdiction of other departments or public entities.

### *A representative role*

Within its jurisdiction, CIEMAT alone maintains official relations with corresponding foreign nuclear bodies with which it collaborates on the implementation of technical and scientific nuclear programmes.

### *Residual responsibilities in the industrial field*

Following the reorganisation of the nuclear sector, the tasks of the former *Junta de Energía Nuclear*, notably in the fields of the nuclear fuel cycle, radioactive waste, nuclear installations and radiation protection, were transferred to ENUSA, ENRESA and the Nuclear Safety Council. CIEMAT may, however, offer technical assistance in fields within its jurisdiction.

### *iii) Structure*

CIEMAT is administered by its chairperson, who is a representative of the Ministry of Science and Technology. A governing board and a director-general are appointed by the government.

Pursuant to its statute and upon approval of the government, CIEMAT is empowered to set up all the services, divisions, sections or work centres required for its operation.

### *iv) Financing*

Contributions to the CIEMAT budget are made from both external and internal sources.

External income is received through regular and one-off grants from the general state budget, and from moneys from autonomous bodies, received through the government. Legal and natural persons, both Spanish and foreign, may contribute funds through gifts or subsidies. Lastly, other financial resources may be allocated to CIEMAT under contract or by judicial decision.

CIEMAT generates its own income through sales, payment for services rendered on behalf of third parties, and income from CIEMAT's shares in national and international enterprises.

In carrying out its tasks, CIEMAT may conduct all the financial transactions required for its operation. It is a shareholder in the National Uranium Enterprise and in the National Enterprise for Radioactive Waste.

*c) National Uranium Enterprise (ENUSA)*

The National Uranium Enterprise (ENUSA) was set up by Decree No. 3322 of 23 December 1971 for the general purpose of assuming responsibility for the various stages of the nuclear fuel cycle, with the technical co-operation of CIEMAT.

Decree No. 2967 of 7 December 1979, amended by a Decree of 1 August 1984 implementing the guidelines of the national energy plan, widened ENUSA's scope in the nuclear fuel cycle by redefining its tasks to make them more independent of those of the former *Junta de Energía Nuclear* [Section 5(1)]. The growth in the nuclear industry had made it necessary to transfer responsibilities from the *Junta de Energía Nuclear* to a unit which would efficiently secure uranium supplies for nuclear facilities.

*i) Legal status*

ENUSA's statute was modified by Royal Decree No. 1464 of 17 September 1999. ENUSA is now a state enterprise in the form of a limited liability company.

*ii) Responsibilities*

ENUSA is responsible for the general supervision of the implementation of the national uranium exploration and prospecting plan [Decree No. 2967/1979, Section 5(1)]. It has direct responsibility for the following tasks [Section 2]:

- prospecting and mining radioactive deposits with a view to processing ore into uranium and thorium concentrates;
- converting uranium concentrates into uranium hexafluoride;
- uranium enrichment;
- manufacturing nuclear fuel and reprocessing irradiated fuel.

The research and development activities relating to the various stages in the nuclear fuel cycle are undertaken with the technical assistance of CIEMAT.

Uranium supplies to nuclear power plants and uranium enrichment and the conversion of uranium concentrates into uranium hexafluoride are guaranteed by ENUSA.

*iii) Financing*

The State Company of Industrial Participation (SEPI) has a majority shareholding in ENUSA, with CIEMAT holding the remainder of the shares.

*d) National Enterprise for Radioactive Waste (ENRESA)*

Given the development of nuclear energy applications and the growing use of radioactive materials and the waste arising therefrom, Spain needed a body responsible for the overall management of radioactive waste, a task previously carried out in part by the former *Junta* and by ENUSA, as described above.

The National Enterprise for Radioactive Waste (ENRESA) was thus created on 22 November 1984 in pursuance of Royal Decree No. 1522 of 4 July 1984, supplemented by an Order of 30 December 1988, and has been given overall responsibility for the management of radioactive waste [Decree No. 1522/1984, Section 1].

*i) Legal status*

ENRESA is a state enterprise in the form of a limited liability company.

*ii) Responsibilities*

ENRESA is directly responsible for the following [Decree No. 1522/1984, Section 2]:

- the treatment and conditioning of radioactive waste;
- the siting, construction and operation of storage facilities (both temporary and permanent) for low, medium and high-level radioactive waste;
- the carrying out of all activities associated with the final shutdown of nuclear and radioactive installations;
- establishing procedures for the collecting, transfer and transport of radioactive residues;
- the final treatment of wastes resulting from the extraction and manufacture of ore concentrates;
- the carrying out of the technical, economic and financial studies necessary to determine the various costs associated with the management of radioactive waste, to help formulate an appropriate economic policy.

Decree No. 1522/1984 was modified by Royal Decree No. 404 of 1 March 1996, revising the tasks to be carried out by ENRESA.

ENRESA is also responsible for drawing up a permanent inventory of all radioactive waste storage facilities. This inventory will be maintained even after closure of the installation concerned [Decree No. 1522/1984, Section 6].

In the event of a nuclear emergency, ENRESA may be required to support the civil protection services [Section 2(e)].

Each year, ENRESA is to report to the Minister of Economy on its activities and also to submit a general plan for radioactive waste management including a review and cost analysis of technical solutions [Section 4].

ENRESA receives technical assistance and technological support from CIEMAT within its fields of competence.

*iii) Financing*

ENRESA's capital is constituted by CIEMAT and SEPI, an industrial public undertaking. Its activities are financed by a fund composed of a percentage of electricity prices and remuneration received from its contractual arrangements.

*e) National Energy Commission*

The Commission on the National Electric System, established by Law No. 40 of 30 December 1994, was replaced by a National Energy Commission pursuant to Act No. 34 of 7 October 1998.

This new Commission exercises quite a wide range of powers, although its priority sectors remain the energy and fossil fuel markets. As an advisory body, the Commission is required to participate in the legislative procedure in the energy field, and in the licensing procedure for energy installations.

The Commission is a public body under the aegis of the Ministry for Economy. It is administered by a governing board made up of a chairperson and eight members. Its members are selected from amongst eminent figures, whose positions are confirmed by royal decree adopted on a proposal of the Minister of Economy.

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