Nuclear Legislation in OECD and NEA Countries

Regulatory and Institutional Framework for Nuclear Activities

Luxembourg

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NUCLEAR ENERGY AGENCY

Luxembourg

I. General Regulatory Framework

1. General

In Luxembourg, the regulation of nuclear energy is based on the Framework Act of 25 March 1963 concerning the Protection of the Population against the Dangers arising from Ionising Radiation. This act laid down the general principles of nuclear regulation which were subsequently reaffirmed and defined further in the Grand-Ducal Regulation of 8 February 1967 [repealed and replaced by the Grand-Ducal Regulation concerning the Protection of the Population against the Dangers arising from Ionising Radiation (Regulation of 29 December 1990), Regulation of 14 December 2000 and subsequently amended by Grand-Ducal Regulation of 21 July 2006]. This legislation applies to the production, manufacture, possession, sale, transit, transport, import, export, use for commercial, industrial, medical, scientific or other purposes. This includes recycling or re-use of apparatus or substances capable of emitting ionising radiation. It also applies to the processing, handling, temporary or permanent storage, and disposal of radioactive substances or waste and to any other activity involving a risk arising from ionising radiation (Section 1.1).

The Ministry of Health is responsible for the most part for issues relating to nuclear safety. There are other competent government departments, each within its jurisdiction, who play an advisory role.

There are no public or semi-public bodies in Luxembourg responsible for research and development relating to the peaceful uses of nuclear energy, nor are there installations for producing nuclear energy.

2. Mining

There are no specific provisions in the laws of Luxembourg relating to nuclear ores. Consequently, the ordinary law on mining applies and anyone wishing to exploit a mine must obtain a prior concession from the Government.

3. Radioactive substances, nuclear fuel and equipment

Section 2 of the Act of 25 March 1963 concerning the Protection of the Public against the Dangers arising from Ionising Radiation provides for the implementation of special provisions relating to the production, possession, use and marketing of nuclear equipment and substances irrespective of the use to which they are put. The rules governing such operations are laid down in greater detail in the Grand-Ducal Regulation of 14 December 2000, as amended.

A licence is required for the production and marketing of nuclear materials. This licence may be general or specific and is issued for a period which may be definite or indefinite by the Minister of Health or the Director of Health depending on the type of materials in question (2000 Regulation, as amended, Section 2.2). A special licence is required for the possession, import, export and sale of any irradiated medicines or domestic products as well as for the use of X-ray machines or radioactive sources for industrial radiography purposes or research (Section 10.2). In addition, imports of nuclear substances for medical uses need a certificate from a pharmacist accredited by the competent authority of the product's country of origin; the use of such substances is reserved to members of the medical or veterinary profession who have received accreditation from the Minister of Health.

In addition, the Grand-Ducal Regulation of 14 December 2000 prohibits the manufacture, import, sale and installation of fire or smoke detectors incorporating radioelements as well as the activation or intentional addition of radioactive substances in the production of foodstuffs or cosmetic products that have been treated with radiation (Section 10.2).

As far as the irradiation of foodstuffs is concerned, the Grand-Ducal Regulation of 17 July 2000 concerning Foods and Food Ingredients treated with Ionising Radiation transposes into Luxembourg law Directives 1999/2/EC and 1999/3/EC of the European Parliament and of the Council of 22 February 1999 and contains an exhaustive list of the foods and food ingredients which may be treated with ionising radiation.

4. Nuclear installations

a) Licensing and inspection, including nuclear safety

The rules governing nuclear installations are contained in the Grand-Ducal Regulation of 14 December 2000.

Such installations are classified in four different categories depending on the risks they present (Section 2.1).

Chapter 2 of the regulation lays down the specific licensing conditions for each category of installation, notably with regard to the technical information to be provided, the information and participation of the public in the licensing procedure etc. A prior authorisation from the competent authorities is, however, required for each of these categories. The authority responsible for granting licences is the Government in Council for Category I installations, the Minister of Health for Category II, and the Health Directorate of this Ministry for installations in Categories III and IV. However, applications for licences for all classified installations, irrespective of the category to which they belong, are forwarded to the Labour and Mines Inspectorate for opinion.

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

Various items of information must be attached to the licensing application (Section 2.6.1), namely:

- the name, occupation and residence of the applicant;
- the nature and purpose of the installation, the type and characteristics of the radiation emitted, the characteristics of the apparatus used etc.;
- the person in charge of the physical control and of the implementation of the measures required to comply with the licensing conditions and with the provisions of the regulation;
- the radiation protection qualifications of the staff responsible for receiving, producing, distributing, using and maintaining or monitoring the radioactive substances and apparatus;
- the proposed third party liability insurance contract covering nuclear activities;
- a written undertaking from the supplier of the radioactive source to take it back once it is no longer being used;
- a plan of the installations and premises containing the radioactive substances or apparatus;
- 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 non-compliance with the provisions of the Regulation of 14 December 2000 or with the licensing conditions (Section 2.15).

At international level, Luxembourg ratified, on 7 April 1997, the 1994 Nuclear Safety Convention.

b) Emergency measures

The Grand-Ducal Regulation of 14 December 2000, as amended, imposes a number of obligations on the head of the installation aimed at managing radiological emergencies (Section 2.19.3). In particular, he is obliged:

- to take all necessary measures to deal with any accident in his installation which could give rise to radiological consequences for workers or the public;
- to prepare an internal intervention plan in order to cope with different types of radiological emergencies and to ensure that this plan can be implemented at any time;
- to ensure that the staff is familiar with this plan.

In the event of a radiological emergency, the head of the installation should immediately notify the accident to the Central Civil Protection Emergency Assistance Unit and to the Radiation Protection Division of the Ministry of Health, evaluate the circumstances and consequences of the situation and help with the emergency intervention measures. He should also take steps to reduce the emission of radiation and the exposure of workers and intervention staff.

A national emergency plan has also been drawn up with a view to warning, protecting and assisting the public in the event of a radiological emergency, the implementation of which is the responsibility of the Interior Minister and of the Minister of Health. In the event of an emergency, these Ministers take the necessary steps to limit public exposure (Section 11.1.1).

On 28 July 2000, Luxembourg ratified the 1986 Convention on Early Notification of a Nuclear Accident and on the same date adhered to the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. On 28 March 1984, Luxembourg ratified the Agreement between the Government of the Grand-Duchy of Luxembourg and the Government of the French Republic on the exchange of information in the event of an incident or accident which could have radiological consequences. Also on 27 April 2006, the Agreement between the Government of the Grand-Duchy of Luxembourg and the Government of the Kingdom of Belgium on the exchange of information in the event of an incident or accident which could have radiological consequences.

5. Trade in nuclear materials and equipment

Trade in nuclear materials and equipment is regulated by the Act of 25 March 1963 (Section 2) according to which the conditions for the import, transport, sale etc. of equipment or substances capable of emitting ionising radiation shall be laid down by administrative regulation.

Thus, the Regulation of 14 December 2000 on the Protection of the Population against the Dangers arising from Ionising Radiation makes the import, export, transport, transit, sale etc. of radioactive substances subject to prior authorisation (Section 1.1).

The licensing procedure for the transit of radioactive substances is laid down in two texts: the Grand-Ducal Regulation of 31 July 1989 on the transfer of nuclear materials, equipment and technology and on the physical protection conditions as well as the above-mentioned Regulation of 14 December 2000.

The first of these two regulations was amended by the Ministerial Regulation of 3 February 1993 which repealed and replaced its Annex 1 containing the definitions of nuclear materials, equipment and technology.

Chapter 3 of the second regulation lists the conditions to be met in order to obtain a licence. Thus, transport and transit operations can only be carried out by persons or firms which have received prior authorisation to do so either by the Minister of Health, in the case of transport, or the Director of Health in the case of transit.

Licences may be limited to a single operation or considered valid for several operations.

Licence applications must contain detailed information about the sender and the addressee, as well as the origin of the substances in question, the qualifications of the staff involved, the nature and intensity of the radiation emitted etc. It should be noted that applicants are also obliged to submit a certificate from an insurer covering the nuclear risks linked to the operation to be carried out.

Furthermore, the Act on the Liberalisation of the Electricity Market of 23 May 2000 contains a provision which enables the Government to refuse contracts to supply electricity from countries outside the European Union if it is shown that the electricity produced comes from installations which are not up-to-date in terms of technological knowledge and which constitute a direct or indirect danger to persons. This also applies in a case where the supplier omits to detail a waste management plan or approach which reflects the latest technical expertise.

6. Radiation protection

The Grand-Ducal Regulation of 14 December 2000 is the basic text with regard to radiation protection in Luxembourg. It was adopted in application of Directive 96/29/Euratom of the Council 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.

Chapter 5 of the Regulation contains provisions relating to dose limits for exposure to radiation for the public and workers, while Chapters 6 to 10 contain provisions for the protection and safety of exposed workers, including external workers, and of the general public.

Generally speaking, the Radiation Protection Division of the Ministry of Health is the regulatory body with regard to radiation protection for workers and the public, including exposure for medical purposes.

The provisions relating to dose limits for the public and workers take account of the ALARA principle (as low as reasonably achievable). Thus, the exposure of workers and the general public to ionising radiation in the case of controllable exposure must be as low as reasonably possible while the number of persons and workers exposed must also be kept as low as reasonably possible (Section 5.1.1).

The overall dose limit for members of the public is fixed at 1 mSv a year. For workers whose occupation involves exposure, radiation must not exceed 10 mSv a year. The regulation also lays down dose limits for certain categories of persons, in particular apprentices and students aged between 16 and 18 and pregnant women.

After having laid down the dose limits, the 2000 Regulation establishes operational rules for the protection of workers, external workers, apprentices and students exposed to radiation (Chapters 6 to 8). "Controlled areas" and "supervised areas" are delimited for work purposes (Section 6.1) and a classification is made of workers (Section 6.2). The regulation also imposes a number of obligations on the head of the installation such as the setting up of radiological monitoring for workers and work premises (detailed in Sections 6.5.1 and 6.5.2) and the medical supervision of workers (detailed in Chapter 9), the establishment of procedures regulating access

to the different areas, the information of workers about the risks related to ionising radiation, training in radiation protection for workers etc. (Section 6.3).

With regard to the protection of external workers (Chapter 7 of the regulation), the Radiation Protection Division of the Health Directorate ensures that such workers have the same protection as permanent workers (Section 7.2). In addition, the external enterprise ensures, either directly or through contractual agreements with the operator, the radiation protection of its workers and in particular compliance with dose limits and medical supervision, providing them with the necessary training and information with regard to radiation protection (Section 7.3). The head of the installation in which external workers operate within a specified area is responsible, either directly or through contractual agreements, for the operational aspects of their radiation protection which depend on the nature of the area involved and of the work (Section 7.4).

As far as the protection and safety of the general public is concerned, the Radiation Protection Division of the Health Directorate is responsible for the monitoring. This includes, in particular (Regulation of 2000, Section 10.1):

- regularly measuring radioactivity in the air, water, earth and food chain, studying the steps to be taken and co-ordinating emergency measures in the event of an accident;
- measuring and monitoring the radiation doses received by persons exposed at work and by members of the public living in the neighbourhood of radioactive sources; the Radiation Protection Division is informed without delay of any accidental exposure or emergency situation;
- setting up a national dosimetry register;
- monitoring and periodically checking the effectiveness of the radiation protection arrangements and techniques used on work premises in which there is a risk of exposure to ionising radiation.

In addition, the Radiation Protection Division makes regular estimates of the doses to which the general public is exposed.

If there is a risk to health, the Minister of Health, in consultation with the medical inspector of the constituency concerned and the radiation protection expert working under the medical director of health, has the authority to promulgate orders recommending the appropriate emergency measures to be taken. Such orders must nevertheless be confirmed within three months by a government administration regulation otherwise they lapse (Act of 25 March 1963, Section 3).

Lastly, note should be taken of the provisions relating to the medical use of ionising radiation. The Act of 10 August 1983 governing this matter provides that the use of ionising radiation for diagnostic or therapeutic purposes is subject to conditions relating to the training of doctors and the standards to be met by the apparatus and facilities involved (Section 1).

In particular, only specialist medical personnel who have received appropriate training are authorised to practice general radiodiagnosis and radiotherapy. The use of unsealed radioactive sources on patients is restricted to doctors with special training in nuclear medicine and who have been accredited by the Minister of Health. The conditions of such training are to be detailed in a Grand-Ducal Regulation (Section 2).

The act also provides that the Minister of Health must give prior authorisation for any use of apparatus or facilities in connection with radiodiagnosis, radiotherapy or nuclear medicine. The conditions for possessing and using apparatus and facilities are laid down in specific regulations (Section 4).

More detailed provisions are contained in the Grand-Ducal Regulation of 16 March 2001 on the health protection of persons exposed for medical purposes against the dangers of ionising radiation. This regulation is based directly on Directives 80/836/Euratom of the Council of 15 July 1980, 84/467/Euratom of the Council of 3 September 1984, and 97/43/Euratom of the Council of 30 June 1997.

The regulation gives further details concerning the provisions of the Act of 10 August 1983 relating to radiodiagnosis, radiotherapy and nuclear medicine, with regard to the principles of justification, optimisation and liability (Chapter 1), procedures (Chapter 2), the training of medical specialists (Chapter 3), quality assurance of the equipment and the particular conditions applying to special practices (Chapter 4).

7. Radioactive waste management

There are no specific regulations in Luxembourg dealing with radioactive waste management activities. Such activities are subject to the Regulation of 14 December 2000 concerning the Protection of the Population against the Dangers arising from Ionising Radiation, the scope of which covers operations relating to the reprocessing, handling, temporary or permanent storage, and disposal of radioactive waste (Section 1.1).

Installations for the processing, conditioning and storage of radioactive waste have been classified in Category II (Section 2.1) and require a licence. Applications are made to the competent authority, namely the Minister of Health. Application files are forwarded to the Labour and Mines Inspectorate for opinion and then sent to the mayor of the *commune* in which the installation is to be built, as well as to the mayors of the *communes* within 300 metres of the source emitting ionising radiation. Applications for licences are posted for a period of 15 days in the above-mentioned *communes*, after which an inquiry is held. The file, including any written comments received and the record of the inquiry proceedings must be sent to the Minister of Health within 45 days, after which he lays down the licensing conditions. Reasons must always be given for any refusal to grant a licence (Section 2.4).

Licensing applications for installations in which radioactive waste is kept must contain information in addition to that needed for other types of classified installations [for further details about the information to be supplied by all applicants, see Section 4(a) above "nuclear installations – licensing and inspection, including nuclear safety"]. The information required is first of all a description of the measures proposed for the management, treatment and disposal of the waste, and then more detailed information depending on whether the waste is in liquid, solid or gaseous form (Section 2.6.1).

At the international level, on 21 June 2001, Luxembourg ratified the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

8. Non-proliferation and physical protection

In Luxembourg, the provisions relating to physical protection are based on the Regulation of 31 July 1989 on the transfer of nuclear materials, equipment and technology and on physical protection conditions.

No one may transfer nuclear materials or equipment, or nuclear technological data or derived information, to a non-nuclear weapon country except for peaceful purposes (Section 1). Annex I of the regulation, containing definitions of nuclear materials, equipment and technological data, was repealed and replaced by the Ministerial Regulation of 3 February 1993 on the transfer of nuclear materials, equipment and technology.

The regulation makes a distinction between exporting to a non-EU Member State (Chapter I) and exporting to another European Union country (Chapter II). In the first case, exports require prior authorisation from the Minister of Foreign Affairs and Foreign Trade. In the second, exports

can be made without restriction subject to compliance with a series of conditions laid down for each of the substances concerned.

At the international level, on 11 April 1985, Luxembourg ratified the 1980 Convention on Physical Protection of Nuclear Material.

With regard to non-proliferation, Luxembourg has been party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons since 2 May 1975. In addition, the IAEA system of safeguards and the security control provided for in the 1957 Euratom Treaty apply in Luxembourg which also ratified, on 26 May 1999, the 1996 Comprehensive Nuclear Test-Ban Treaty.

9. Transport

The regulations concerning the international carriage of dangerous goods by rail (RID), the European Agreement concerning the international carriage of dangerous goods by road (ADR), the IATA Regulations on the transport of dangerous goods and the IMO International Maritime Dangerous Goods Code are all applicable in Luxembourg.

International standards relating to the transport of nuclear substances have been harmonised in domestic legislation by the Grand-Ducal Regulation of 14 December 2000. Transport is regulated irrespective of the mode of transport used. Transport operations require a licence, which may be general or specific, to be issued by the Minister of Health (2000 Regulation Sections 3.1 and 3.3).

Applications for a transport licence must indicate the identity of the applicant and of the addressee, the origin and physical and chemical characteristics of the substances concerned, etc. The order authorising the transport establishes the licensing conditions and the preventive measures to be taken in order to protect the public and workers.

10. Nuclear third party liability

Luxembourg legislation contains no special rules as to nuclear third party liability. It is specified that conditions may be included in the licensing decision as to the insurance against nuclear risks which the operator of a Category I, II or III nuclear installation is required to take out, or the insurance required for transport operations (Regulation of 14 December 2000, Sections 2.6.1 and 3.4).

II. General Institutional Framework

1. Regulatory and supervisory authorities

a) Minister of Health

It is the responsibility of the Minister of Health to enforce the regulations adopted in the field of radiation protection. To this end, he exercises strict control over nuclear activities by means of licensing mechanisms which enable him to intervene to a very large extent in the production and use of nuclear energy.

Within the Ministry of Health, the Radiation Protection Division of the Health Directorate is responsible for applying the measures aimed at protecting the public and ensuring the safety of nuclear installations. More particularly, it monitors the exposure of the public and environment to ionising radiation (Regulation of 14 December 2000).

b) Minister of Labour

The Minister of Labour, in collaboration with the Minister of Health, exercises certain powers in the field of the health and safety of workers. The Labour and Mines Inspectorate, an internal department of the Ministry, plays a particularly important role with regard to nuclear activities.

The Inspectorate is involved, alongside the Radiation Protection Division, throughout the licensing procedure for nuclear installations. Its opinion is solicited when the applicant submits the licensing request (2000 Regulation, Sections 2.3 to 2.5). The Inspectorate is kept informed of any decision by the Health Minister to suspend or refuse a licence (Section 2.1.5) and of any accidental exposure of workers to ionising radiation (Section 5.1.8).

c) Other Ministers competent

The Ministers of Social Security, the Interior, Transport, Foreign Affairs, Justice, the National Economy and Agriculture participate, each in their own sphere of competence, in a number of decisions taken in the field of nuclear energy.

2. Advisory bodies

Higher Health Council

The Higher Health Council was created in 1963, under the responsibility of the Minister of Health, as an advisory body for all health questions (Ministerial Regulation of 18 April 1963, Section 1). It is responsible for informing the Minister of Health about scientific and technical developments affecting health and for proposing any measures it deems necessary (Section 2).

The Higher Health Council is made up of a maximum of 30 persons, most of whom are *ex officio* members representing the Ministries of Health, Agriculture, Labour, Justice and the Interior. The remaining members may be Luxembourg nationals or foreigners. The Council may also call upon Luxembourg or foreign experts to take part in its meetings in an advisory capacity (Section 3).

The Chairman, Vice-Chairman and Secretary are appointed by the Minister of Health from among the members of the Council (Section 5).

The Executive Bureau of the Council comprises five members, namely the Chairman, the Vice-Chairman and the Secretary of the Council along with two other members appointed by the Council. The Bureau deals with the management of current issues and allocates tasks among the different sections constituted within the Council. Council meetings are convened by the Bureau at the request of the Minister of Health except in emergencies, when a meeting may be convened by the Chairman or, in his absence, the Vice-Chairman (Section 6).

The Higher Council is divided into five sections and one of these deals with toxic and dangerous products. The Bureau may create special sections when a given topic selected for consideration does not fall within the competence of one of the existing five. Each section appoints its own Chairman and rapporteur (Section 7).

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The OECD is a unique forum where the governments of 30 democracies work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD member countries are: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities takes part in the work of the OECD.

OECD Publishing disseminates widely the results of the Organisation's statistics gathering and research on economic, social and environmental issues, as well as the conventions, guidelines and standards agreed by its members.

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full member. NEA membership today consists of 28 OECD member countries: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

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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