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NUCLEAR LEGISLATION IN OECD COUNTRIES

Regulatory and Institutional Framework for Nuclear Activities

Luxembourg

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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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
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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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LUXEMBOURG

This chapter was last revised in 2001 and is correct as of that date.

The NEA Secretariat is currently revising this chapter in close consultation with the national authorities and plans to issue a new version in the near future.

LUXEMBOURG

I. GENERAL REGULATORY REGIME	5
1. Introduction	5
2. Mining Regime.....	5
3. Radioactive Substances, Nuclear Fuel and Equipment	3
4. Nuclear Installations.....	6
<i>a) Licensing and inspection, including nuclear safety</i>	6
<i>b) Emergency response</i>	7
5. Trade in Nuclear Materials and Equipment.....	8
6. Radiation Protection	9
7. Radioactive Waste Management	11
8. Non-Proliferation and Physical Protection	11
9. Transport	12
10. Nuclear Third Party Liability	12
II. INSTITUTIONAL FRAMEWORK.....	13
1. Regulatory and Supervisory Authorities	13
<i>a) Minister of Health</i>	13
<i>b) Minister of Labour</i>	13
<i>c) Other ministerial powers</i>	13
2. Advisory Bodies	14
<i>Higher Health Council</i>	14

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 These principles were expanded in detail in the Grand Ducal Regulations of 8 February 1967, which were subsequently repealed and replaced by the Grand Ducal Regulations on the Protection of the Public Against the Hazards of Ionising Radiation [Regulations of 29 December 1990], which were in turn repealed and replaced by Regulations bearing the same name [Regulations of 14 December 2000].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].