LAW ON PROTECTION AGAINST IONISING RADIATION AND NUCLEAR SAFETY IN SLOVENIA

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Introduction

The existing legislation related to nuclear and radiation safety in Slovenia was introduced in 80's. The necessity for the new law is based on the new radiation safety standards (ICRP 60) and the intention of Slovenia to harmonise the legislation with the European Union. The harmonisation means adoption of the basic safety standards and other relevant directives and regulations of Euratom. The nuclear safety section of this law is based on the legally binding international conventions ratified by Slovenia. The general approach is similar to that of some members of Nuclear Energy Agency (OECD). The guidelines of the law were set by the Ministry of the Environment and Spatial Planning, Nuclear Safety Administration, and Ministry of Health.

The expert group of the Ministry of Environment and Spatial Planning and the Ministry of Health together with the representatives of the users of the ionising sources and representatives of the nuclear sector, prepared the draft of the subject law. The emphasis in this paper is given to main topics and solutions related to the control of the occupationally exposed workers, radiation safety, licensing, nuclear and waste safety, and radiation protection of people and patients.

General legislation

Nuclear legislation of the Republic of Slovenia has began twenty five years ago and covers the use of radiation sources and nuclear energy. The original features of this legislation were derived from international recommendations or regulations. For example, radiation protection standards were derived from ICRP recommendations and IAEA basic standards. Requirements for nuclear safety and liability of a nuclear operator were based on adopted international conventions.

Slovenia used to be a part of federal state of Yugoslavia and nuclear legislation was found in the Act on Radiation Protection and Safe Use of Nuclear Energy issued in 1984, its first version was from 1976. In late eighties ten executive regulations were put in place on radiation protection, four on nuclear installations, some more related to other activities and standardization, and a few decrees. Act on Liability for Nuclear Damage was issued in 1978. The former Republic of Slovenia issued also its own regulations on protection against ionizing radiation and nuclear safety and on nuclear liability. There were two agreements set between the former state and IAEA to obtain Agency assistance and to implement safety standards for construction of research reactor in Ljubljana (1961) and nuclear power plant in Krško (1976).

The regulatory basis in new independent Republic of Slovenia has been provided by Act of Constitution in 1991, which specifies the regulations and agreements to be maintained from the former regulatory system. Some segments of the old legislation system were not coherent and excessively prescribing. The need for revision is due to adoption of the overall legislation changes, to the new radiation safety standards and international conventions, and due to approaching the European Union.

The validity of the new Law on Radiation and Nuclear Safety is scheduled for the year 2002. The draft of this Law covers: basic rules and conditions for radiation practices, protection of people against ionizing radiation, radiation and nuclear safety of the installations, radioactive waste, spent fuel, and transport, non-proliferation and physical protection, environmental and operational monitoring, intervention and remedial

measures, expenses of source user and public expenses, compensation of nuclear installation due to limitation in use of the surrounding space, state report on radiation and nuclear safety, and penalties.

The new Law corresponds to previous acts introducing the Convention on nuclear safety (1996) and Joint convention on the safety of spent fuel and radioactive waste management (1999), and to other acts related to environmental protection, construction and mining, transport of dangerous goods, civil defence, and to internal affairs.

Guiding principles

The new Law is guided by the following main principles:

- implementation of all appropriate and reasonable measures of the state in executing this law to prevent a possible health detriment and radioactive contamination of the environment,
- justification of new methods or practices causing exposure to ionizing radiation,
- optimization of exposures of the practices to the level as low as reasonably achievable, economic and social factors being taken into account,
- the dose limits for total doses caused by all relevant practices and exposures due to natural sources,
- peaceful use of nuclear materials and technologies, according to international conventions,
- prime responsibility of source user or the operator for protection against radiation and for nuclear and radiation safety,
- liability of the source user and the operator,
- causer pays for remedial measures necessary to ensure radiation protection
- emergency preparedness of the nuclear installation or radiation facility licencee,
- state's subsidiary measures in case of unknown or unclear polluters, and
- openness to the public.

Reporting to the authorities

The Law requires reporting to authorities by an application before start with the practice that can increase exposure of individuals, such as production, processing, use, storage, transport, export, import, disposal, other handling or possessing of radioactive materials. The practices which should also be reported are related to operation or maintenance of electrical equipment emitting ionizing radiation and containing components having voltage more than 5 kV, and other practices if defined by the government. The reporting is performed by notification to the authorities. There are exemptions foreseen in the reporting. In executive regulations, the government will define exemption levels, and also clearance levels of radioactivity to be used as basis for release from regulatory control. Sources of minor importance will only be registered.

The authorities are Ministry of Environment and Spatial Planning, and Ministry of Health in case of medical or veterinary practices. They maintain the registers of practices, nuclear materials and radioactive sources. The radioactive sources are registered based on the notification to the competent authority.

In some cases the reporting is performed already by application for licence. Such exemptions are import, export or transit of radioactive materials or waste, multiple use of radioactive sources, and siting of the nuclear or radiation facilities.

Classification of installations

Classification of installations is based on environmental aspect and is related to site permit and construction licence procedure. The law defines nuclear installations, radiation facilities, and less important facilities related to a radiation practice.

Nuclear installations are nuclear power plant, critical or sub-critical reactor, research reactor, nuclear fuel fabrication, enrichment or reprocessing facility, spent fuel storage or repository, temporary storage or final repository of low or medium active waste, radioactive waste treatment or incineration facilities. Siting of nuclear installations correspond to the state's spatial planning rules and prescribed safety analysis of the location and report on to environmental impact.

Radiation facilities are defined as:

- radiation facility having a risk that the dose of the public may exceed the dose limit,
- facility with open radioactive source(s) having a risk of release to environment which may cause the dose exceeding the dose limit for individuals of the public,
- facility with the practice having releases to environment in a year in excees of ten times exempted activity levels,
- installation for mining, processing or enrichment of nuclear oar materials,
- depository of nuclear mineral oar or related hydrometalurgic tailings

Less important radiation facilities are buildings with radioactive source(s), having a risk, that doses of individuals or workers inside them, exceed the dose limits.

Licencing

Authorization, as defined by Directive 96/29/Euratom, is adopted in the Law as licence or permit. The licence for practice in case of nuclear installation or radiation facility is understood as operation licence.

Application for licence for new classes or types of practices or use of new radioactive source or new procedure should include report on justification of these practices.

The prior permit of Ministry for Environment is required for:

- operation and decommissioning of radiation or nuclear installations,
- the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods,
- the use of X-ray sets or radioactive sources and the use of accelerators with exception of electron microscopes, in other than medical or veterinary practices,
- disposal, processing or reuse of radioactive materials or contaminated materials, originating from the practice or usage of radioactive source if these materials are not previously authorized to be released from regulatory control,
- production or development equipment or means related to nuclear technology,
- import, export or transit of nuclear and radioactive materials,
- maintenance, calibration or similar work with radioactive sources, if not already included above.

Ministry of Health is competent to licence the use of radioactive sources or the practices in medical or veterinary field, as they are specified by the Directive 96/29/Euratom, and the control of, or other work with radioactive sources.

The licence for radioactive sources is based on the permit for the practice and written confirmation that the source is registered. In case of nuclear installations and radiation facilities the operating licence includes the licence for radioactive source or nuclear material.

The siting of nuclear installation shall be included in the general spatial plan of the state. For this, a special safety analysis of the site is required. In a case, that site permit is necessary to provide an agreement on conditions of environmental protection for nuclear or radiation facility, it includes radiation and nuclear safety requirements, defines contents of project documentation, levels of radiation in the environment, and limited use of the territory.

Location and construction permit for nuclear installations and radiation facilities correspond to Environmental Law and to Act on Buildings Construction.

For obtaining the construction licence, it is required to submit the Safety Report, specifications for safe operation, and the programmes for physical safety, organization, emergency planning, training, quality assurance, monitoring, test operation, radiation protection and assessment of protection of workers against radiation.

Permits are required also for start of operation or closure of nuclear installation, beginning or ending of decommissioning of nuclear installations or radiation facilities, closure of mining or depository facilities of nuclear mineral oar tailings. Before operation, the test operation permit is forseen for new nuclear installations or radiation facilities. Application for operation licence should include updated Safety Report and the opinion of authorized technical organization.

For the radiation facilities with medical or veterinary practice, the procedure requires only practice licence and source licence, and report on assessment of protection of exposed workers, to permit the operation.

The permit for practice and the operation licence are issued for a fixed period of time. These licences can be changed by the Ministry in the case when:

- nuclear or radiation safety conditions are changed
- there are reasons for protection of environment, human life or health in public interest
- significant decrease of nuclear or radiation safety due to external or natural phenomena

Radiation and nuclear safety

Operation of nuclear power plant is regulated on the basis of Convention on Nuclear Safety. The Law requires implementation of operating experience and corrective action programs, financial and human resources management, qualification of personnel, quality assurance, reporting, operational and environmental monitoring, emergency preparedness and evaluations of radiation and nuclear safety.

Periodic safety reviews for overall assessment of radiation or nuclear safety should be performed by the operators as defined by executive regulations.

A specialized radiation protection unit, authorized to perform radiation protection tasks and provide specific advice is required for nuclear installations and radiation facilities. For other practices, it is required to have a person responsible for radiation protection.

Changes or modification of the facilities and operating procedures should be classified according to the importance for nuclear or radiation safety. According to this the operator should evaluate and, as appropriate, notify the authorities, report, or should obtain the permit to perform the changes.

Ministry of Environment, as a result of their oversight activities, may stop the operation of nuclear installation or radiation facility in he following cases:

- if radiation or nuclear safety conditions are not fulfilled within reasonably defined time frame, required by the inspector,
- if the licencee does not provide, within due time, a revised assessment of radiation protection of the workers.
- if the licencee starts with maintenance activity or implements technical changes, important from a radiation or a nuclear safety aspect, without prior approval.

Revocation of licences for a practice is possible in the following cases:

- if radiation safety requirements, as a result of the oversight activities, are not fulfilled in a reasonable time frame
- assessment of protection of exposed workers is not provided to the authorities or if the practice is conducted without approved assessment for more than six months.

Radioactive waste and spent fuel

It is required that the owner of radioactive waste or spent fuel should assure:

- storage and handling of the waste or spent fuel in accordance with current regulation,
- avoiding imposing burdens of waste or spent fuel removal on future generations as much as possible, and
- should minimize radioactive waste production.

Radioactive waste and spent fuel disposal is under responsibility of the state. The financing is assured by dedicated public fund. The costs for waste management rely on those who generate or possess the waste. The state is responsible to cover these expenses if the origin of the waste is not known.

The government establishes public agency to manage radioactive waste and spent fuel storage, treatment before removal, and final deposition. The producers may also temporary store or process the waste or spent fuel at the source, if they have the licence. Collection, transport and temporary storage of the waste before removal is a matter of a public service. The agency prepares national programmes for radioactive waste and spent fuel management.

Protection of individuals

General obligations related to the practice

The licencee should justify and prove that each new practice has benefits in relation to the health detriment, should justify already permitted practice in case of new important evidence about it's benefit or detriment, should optimize the exposures as low as reasonably achievable, economic and social factors being taken into account, should use dose constraints in optimization of the practice, should assure that doses of workers, apprentices, students and individuals from the population are within prescribed dose limits.

Protection of exposed workers

The undertaking should provide protection of exposed workers, students and practioneers by:

- prior evaluation of the risk and optimization of radiation protection in all working conditions
- classification of workplaces regarding the expected annual doses and to probability of potential exposures
- classification of workers into categories
- training
- informing the personnel about technical, medical and administrative procedures related to all aspects of use of radioactive source
- informing about the risk for health of workers and early declaration of pregnancy
- monitoring of workplace and personal dosimetry
- regular checking of emergency guidelines and effectiveness of protective equipment
- regular calibration, checking and use of measuring instruments
- medical surveillance of exposed workers

These requirements should be fulfilled by the employer if there exist a possibility for the workers to exceed annual dose limits for members of the public.

The undertaking is responsible for arrangements for the radiological protection and to consult the qualified expert or the approved radiation protection service in case of assessment and implementation of these arrangements.

The Law explicitly defines the outside workers in accordance with the Directive 90/641/Euratom and gives the bases for the implementation of the Directive for these workers by controlling the outside undertakings as well as the operators.

In some cases the individuals are specifically protected: a worker who refuses specially authorized exposures exceeding the dose limits; a pregnant or lactating woman relocated to a new job, should be given an equal position; a person under 18 years of age should not became an exposed worker.

The Law has provisions to define responsibilities within the radiation practice, and to recognize approved medical practitioners, occupational health services, and qualified experts. It defines also basic rules for dosimetric services, central dose register, and dose information exchange.

Medical exposure

In accordance with the Directive 97/43/Euratom the improved concept of the medical exposure is elaborated. The medical practice exposure is regulated in a way requiring specific written protocols, programmes and assessments, and by introducing optimization and evaluation of the exposures based on the exposures register information.

Exposure due to natural radiation sources

The competent authority should assure protection of individuals and monitoring of increased exposures due to natural radiation sources, or in case of some work activities. The protection of air crew and related actions should be required from the employer if there is a probability to exceed the dose limits.

Institutional framework and competent authorities

The Parliament approves state's spatial plan with siting of nuclear installations. The Minister of Environment and Spatial Planning may initiate this procedure.

The Government establishes advisory committees, and is competent to issue executive regulations or decrees, and to finance education programmes for authorized expert, development studies, independent expertises, and international collaboration in the field of radiation protection and nuclear safety.

The Ministry of Environment and Spatial Planning is competent authority in the field of nuclear and radiation safety, except medical or veterinary practices. The Ministry also approves qualified experts for radiation and nuclear safety and qualified technical organizations. The Ministry of Health is competent authority for protection of professionally exposed workers and individuals from the public, for medical and veterinary exposures, for the licencing of the related practices or radiation facilities with insignificant influence to the environment, for approval of dosimetric services, qualified experts or technical organizations, and for licences of radiation protection staff in the installations. Both ministries have dedicated units to perform licencing and administration procedures or to concur in some cases.

The two advisory bodies to advise the ministries, and to support decision of inspectorates or governmental administration are:

- Committee for topics related to radiation and nuclear safety, physical protection of nuclear materials, radioactivity in the environment and remedial measures after radiological incidents,
- Committee for topics related to protection of individuals against ionizing radiation, medical and veterinary use of radiation sources.

The Minister of Internal Affairs is competent for approval of physical protection plans and for non proliferation control.

It is the responsibility of the Ministers of Environment, Health, Internal Affairs, and of Civil Defence to issue executive regulations or concurrence, as appropriate.