Observation

IMPLEMENTATION OF THE EU COUNCIL DIRECTIVE 96/29/EURATOM IN INDUSTRY*

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Received in June 2005
Accepted in January 2006

The 1996 EU Council Directive 96/29/EURATOM defines a series of specific requirements related to the safe use of radiation sources and to public and occupational exposure. The implementation of these requirements is seen in comprehensive radiation protection measures undertaken at user site and in regulatory practice.
The implementation of the 96/29/EURATOM in the last years in Slovenia led to a comprehensive two-step process of authorisation of practices involving ionising radiation. The process is based on the assessment of risk associated with a practice involving radiation and a source. One of the steps includes either a registration or a permit issued by the regulatory authority to use a specific radiation source. The authorisation process has been described in detail in Slovene legislation. The 96/29/EURATOM also includes reporting intention to carry out a practice involving radiation, which is a new tool in Slovene legislation. The implementation of the 96/29/EURATOM has improved overall radiation protection in industry was improved thanks to well-defined requirements such as classification areas for control.

KEY WORDS: *controlled area, European Union, radiation protection, radiation sources, supervised area*

The EU Council Directive 96/29/EURATOM of 1996 defines a series of specific requirements related to the safe use of radiation sources and to public and occupational exposure to these sources (1). The requirements are based on recommendations issued by the International Commission on Radiation Protection (ICRP) in its Publication 60 (2). They are being implemented in industry through comprehensive radiation protection measures at user site, as well as through a variety of regulatory measures.

COUNCIL DIRECTIVE 96/29/EURATOM

The European Union published the first radiation protection directive in 1959 in order to standardise the protection of workers and public in the European Community. This directive was revised six times between 1959 and 1984, when the Directive 84/467/ was adopted. The reason for the last revision were the recommendations published by the ICRP in 1990, based on new scientific knowledge (2).

The 96/29/EURATOM Directive became effective in 2000. In 2002 *Lefaure and Croüail* published an analysis of its implementation in the European countries (3), showing that national regulations were much behind the schedule (3). The analysis also showed that the principles of justification, optimisation and dose limitations were translated in a consistent manner.

A probable cause of this delay in the harmonisation lies in the fact that national radiation protection

*Preliminary report presented at the 6th Symposium of the Croatian Radiation Protection Association with international participation, Stubičke Toplice, Croatia, 18-20 April 2005

systems were to be harmonised not only for normal operational procedures, but also for incidents or accidents. In other words, harmonisation was very complex. The analysis of the use of ionising radiation showed an exceptional diversity in practice as well as in the physical properties of the sources (4). An effective system of regulatory control should be able to include all these considerations (5). The Directive also introduces basic changes in radiation protection; for example it has cancelled the classification of about 800 radionuclides in four groups according to radiotoxicity.

In 2002, Slovenia enacted the Ionising Radiation Protection and Nuclear Safety Act (the 2002 Act) (6). It is harmonised with the EU basic safety standards, particularly with the 96/29/EURATOM Directive. The instruments to implement the 96/29/EURATOM Directive in the 2002 Act and subsequent regulations could be divided in new instruments and updated old instruments.

The most important new instruments are reporting intention to carry out a practice involving radiation, authorisation of such practice; classification and definition of a supervised and controlled area; radiation protection of apprentices; preparation of a written document about an evaluation of the protection of exposed workers; the concept of qualified experts; and the concept of clearance levels.

Instruments which were known to the Slovenian legislation before the 2002 Act include radiation protection of apprentices, students, breastfeeding and pregnant women, dose limits for general public and workers, and classification of workers. The updated instruments meant in some cases more severe radiation protection measures such as the lowering of the annual dose limit for workers from 50 mSv to 20 mSv and in other cases more relaxed measurers such as reducing health surveillance of workers from one to every three years.

IMPLEMENTATION OF THE 96/29/EURATOM DIRECTIVE IN INDUSTRY

Beside the Nuclear Power Plant Krško, the inventory of a few hundred radiation sources used in Slovenia (6) includes radioisotopes and X-ray machines used in industrial radiography, level gauges, thickness gauges, moisture gauges and density gauges. The 96/29/EURATOM Directive is implemented in Slovenia through radiation protection measures which affect the practice of users. The basic changes are related to the system of reporting intention to carry out a radiation practice or to use a radiation source and to the classification of the working environment.

System of reporting intention

Reporting intention is a new legislative instrument related to the use of radioactive sources. It means notifying the competent ministry about the intention to carry out a practice involving radiation or using a radiation source. The purpose of the reporting system is to enable an efficient licensing procedure based on data submitted in the reporting document. Table 1 gives the basic data required for reporting a practice to a regulatory authority.

Table 1 *Basic data required for reporting intent to carry out a radiation practice to a regulatory authority (6)*

Notification parameters
1. Name of the company
2. Headquarters of the company
3. Name and the address of a person representing the person who carries out a practice involving radiation
4. Information about the practice involving radiation and the radiation source used
5. Location of a practice
6. Details of the commencement
7. Duration of the carrying out of the practice involving radiation, or the time of import, purchase, sale, letting, export, removal or decommissioning of a radiation source

A person who is obliged to notify the regulatory authority:

- produces, processes, uses, stores, transports, imports, exports or disposes radioactive substances, or possesses or handles them in any way,
- produces, imports, maintains or carries out a practice using an apparatus or equipment which itself or due to its constituent parts emits ionising radiation resulting from operating at a voltage greater than 5 kV, or
- carries out a practice defined by the government as a practice involving radiation, for the performance of which it is necessary to obtain a permit.

According to the 2002 Act, authorisation is a two-step procedure based on the assessment of the risk associated with a practice and a source. The authorisation to carry out a practice involving radiation is the first step. The second step involves either a registration of use of a radiation source or a request

for a permit to use a radiation source. The registration is associated with a practice involving a lower radiation risk than a practice for which a permit is required. In addition, regulations based on the 2002 Act limit the validity of the permit to three years since the beginning of a practice. The necessity for stringent control also lies in the fact that no specific lifetime period of an older source is given in technical specifications.

In practice the system of reporting simplifies the communication between the regulatory authority and a user to a great extent and hence the licensing procedure.

Classification of a working area

The classification of working areas is a new instrument which is based on the risk associated with the use of a specific source. The 96/29/EURATOM Directive requires that all workplaces with a possibility of exposure to ionising radiation in the excess of 1 mSv per year or an equivalent dose which is 1/10 of the established dose limits for the eye lenses, skin and extremities should be categorised as *supervised* or *controlled areas*. No operational quantities are given in the 96/29/EURATOM Directive. Slovene legislation gives a detailed definition of a controlled area applicable for the industry (see Table 2).

Table 2 *Definition of controlled and supervised areas*

Controlled area
Annual occupational effective dose >6 mSv
Annual equivalent dose for lens of the eye >45 mSv
Annual equivalent dose for the skin, palm of hand, hand or forearm >150 mSv
Average dose rate in 8 hours ≥3 μSv h^{-1}
Instantaneous dose rate ≥60 μSv h^{-1}
Significant risk associated to a spread of a contamination exist
Supervised area
Average dose rate in 8 hours >0.5 μSv h^{-1} and <3 μSv h^{-1}
Instantaneous dose rate >3 micro Sv h^{-1} and <60 μSv h^{-1}
Restriction of an area is not required, but monitoring is necessary

The classification of an area in industry is a complex task requiring help of a qualified expert. Moreover, once a workplace is classified as a controlled or supervised area, additional, more stringent measures of radiation protection should be introduced in the controlled areas. Some are administrative such as instructions for the use of a radiation source, but some are demanding for a user such as strict control of the entrance and exit from the controlled area.

CONCLUSION

The harmonisation of Slovene legislation with the Council Directive 96/29/EURATOM has introduced new concepts in the national regulatory framework such as reporting and has updated some of the old concepts such as dose limits. The implementation of these new regulations is based on the risk-informed analysis of technical specifications of a particular source or practice, as well as on radiation protection. The analysis requires a higher level of knowledge on either the regulatory and industrial user side. The implementation of new and updated old instruments will lead to a more effective inspection and control of radiation sources and practices.

REFERENCES

1. The Council of the European Union. 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 Danger Arising from Ionising Radiation. Official Journal 1996;L159:1-114.
2. International Commission on Radiological Protection (ICRP). 1990 Recommendations of the International Commission on Radiological Protection. Annals ICRP 1991;21:1-215.
3. Lefaure C, Croüail P. Implementation of the basic safety standards in the regulations of European countries. In: 3rd ISOE European Workshop on Occupational Exposure Management at NPPs; 17-19 April 2002; Portorož, Slovenia. Fontenay-aux-Roses: CEPN; 2003. p. 35-46.
4. International Atomic Energy Agency (IAEA). Categorisation of sources IAEA-TECDOC-1344. Vienna: IAEA; 2003.
5. Janžekovič H, Križman M, Vokal B, Petrovič Z. Categorisation of practices and sources - a key issue in licensing process. In: 11th International Congress of the International Radiation Protection Association; 23-28 May 2004; Madrid, Spain [on CD-rom]. Madrid: IRPA; 2004.
6. Ionising Radiation Protection and Nuclear Safety Act. [consolidated text, displayed 17 January 2006]. Official Gazette 2004;102. Available at http://www.sigov.si/ursjv/en/med_pog/zvisjv-ang.pdf

Sažetak

PROVEDBA DIREKTIVE 96/29/EURATOM U INDUSTRIJI

Europska direktiva 96/29/EURATOM iz 1996. definirala je niz posebnih zahtjeva vezanih uz sigurnu primjenu izvora radijacije te uz izloženost opće i profesionalne populacije. Primjena ovih zahtjeva, zasnovanih na preporukama Međunarodnog odbora za zaštitu od zračenja (ICRP), vidljiva je na opsežnim mjerama zaštite na mjestu uporabe izvora te u djelovanju regulacijskih tijela.
U radu se raspravlja o provedbi ove direktive u posljednje vrijeme u Sloveniji, polazeći od inspekcijskih postupaka, koji obuhvaćaju nadzor industrijske radiografije, industrijskih baždarnih mjera, kao i od iskustava s detektorima dima. Također se raspravlja o teškoćama vezanim uz sigurnu primjenu radijacijskih izvora i rok trajanja primjene koji preporučuje proizvođač.

KLJUČNE RIJEČI: *Europska Unija, izvori radijacije, kontrolirano područje, područje pod nadzorom, zaštita od zračenja*

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