Approximation of European Union Legislation on Medical Exposure in Slovak Republic

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Medical exposures constitutes the major source of exposure from artificial sources of ionizing radiation of European Union population (90-95%). The use of ionizing radiation has enabled great progress to be made in many aspects of medicine.

Slovak legislation in force on health protection of individuals against dangers from ionizing radiation in relation to the medical exposures is as follows:

- The Act No. 272/1994 Coll. of National Council of the Slovak Republic on people health protection,
- The Act No. 470/2000 Coll. amendment of the Act No. 272/1994 on people health protection,
- The Regulation of the Ministry of Health of SR No. 12/2001 Coll. about the requirements for the radiation protection.

Whereas the Slovak legislation in force about the radiation protection is not completely in accordance with European legislation and whereas the detailed medical exposure requirements are not included in this legislation, a new legislation on radiation protection has been prepared.

The health protection of persons against dangerous effects of ionizing radiation in relation to the use of radiation sources in medicine include following regulations:

- Regulation of Slovak Government on the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation,
- Regulation of Slovak Government on health protection on individuals against the dangers of ionizing radiation in relation to medical exposure.

Radiation protection and medical exposure

The regulation of Slovak Government on the basic safety standards for the protection of the health of workers and the general public against the dangers arising from the ionizing radiation lays down basic requirements for the protection of the workers administering the medical exposure; exposure limits of workers and members of public; health and safety requirements for installations; licensees, registrations and notifications; requirements for monitoring, practices in emergency situations, radioactive waste managements and radioactive effluents in environment, etc.

The regulation of Slovak Government on health protection on individuals against the dangers of ionizing radiation in relation to medical exposure set out radiation protection requirements for medical use of radiation sources. This regulation is for the first time defining the term "medical exposure".

The medical exposure in regulation is defined as:

a) the exposure of patients as part of their own medical diagnosis or treatment,
b) the exposure of individuals as part of occupational health surveillance,
c) the exposure of individuals as part of health screening programmes,
d) the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
e) the exposure of individuals as part of medico-legal procedures,
f) the exposure of individuals knowingly and willingly helping, other than as part of their occupation, in the support and comfort of individuals undergoing medical exposure.

Basic requirements for medical exposure

The regulation of Slovak Government is in more detail defining the basic radiation protection requirements – justification and optimization in relation to the medical exposure. Regulation set up diagnostic reference levels for standard procedures and standard patients in a diagnostic radiology and nuclear medicine and set the limits for the exposure of individuals voluntarily participating in medical or biomedical research programmes depending on their age (effective dose 1 mSv per year, in exception circumstances effective dose 10 mSv within 10 years).

The regulation also for the first time defined special conditions for release of patients from hospitals with administered radionuclide following a iodine-131 therapy and a maximal activity of I-131 in an out-patient body. Maximal activity of I-131 in the patient body before releasing him from hospital is determined

to 400 MBq.

Medical doctor, or other health professional, who is practicing the medical exposure has clinical responsibility for any medical exposure.

Education and training of medical staff in radiation protection

The regulation defines special requirements for an education and training of medical physics experts in the radiation protection. Each owner of an radiological installation for the radiotherapy and the nuclear medicine must employ at least one medical physics expert. Criteria for the minimal staffing levels for the qualified medical physics experts in hospitals and other health facilities are also defined.

The minimal staffing levels requirements for the qualified medical physics experts in hospitals and other health facilities are following:

Radiotherapy	**Minimal staffing levels of qualified medical physicists**
Linnear accelerator	0,88
Equipments for external gamma radiotherapy (Co-60, Cs-137)	0,34
Therapeutic X-Ray	0,07
Equipments for brachytherapy with afterloading systems	0,42
X-Ray simulator for radiotherapy	0,05
Planning system for external radiotherapy	0,38
Planning system for brachytherapy	0,08
Plannig of external therapy – 100 new patients per year	0,27
Plannig of brachytherapy - 100 new patients per year	0,22
Nuclear medicine	
Gamma camera	0,13
Equipment for in-vitro diagnostic, RIA	0,08
Computerized analytical equipment	0,23
PET - camera	0,70
Cyklotron – generation of radiopharmacs	0,62
Whole body detector	0,20
1000 diagnostic examinations per year	0,06
Plannig of therapy with radionuclides - 100 new patients per year	0,10
Diagnostic radiology	
Diagnostic X-Ray	0,05
Film-processing developer	0,05
Radiation protection of workers	
100 monitored workers	0,38

The syllabus and extension of the basic radiation protection education and training for prescribers, practitioners and other medical staff are also defined in this regulation. Employer is responsible for the education and training of the medical staff in the radiation protection.

Quality assurance and quality control in medical exposure

In accordance with the Regulation of Slovak Government on health protection on individuals against the dangers of ionizing radiation in relation to medical exposure each owner of the radiological installation is obligatory to prepare quality program for the medical exposure. The quality program for the medical exposures should contain:

a) specification of used radiological equipments,
b) responsibility of medical staff for the quality assurance and the radiation protection,
c) criteria for acceptability of the radiological equipments,
d) frequency of stability tests of the radiological equipments,
e) record about measurements of radiation exposure of patients,
f) standard diagnostic or therapeutic procedures.

The regulation is defining also detailed requirements for acceptability of the radiological installations

and the minimal frequency for the stability tests of the radiological equipments as follows:

Radiological equipment	Minimal frequency for stability tests
Diagnostic radiology	
X-Ray equipment for classic radiography	1 x per year
X-Ray equipment for fluoroscopy	1 x per year
X-Ray equipment for mammography	2 x per year
X-Ray equipment for DSA	2 x per year
X-Ray equipment for computer tomography	2 x per year
X-Ray equipment for intraoral dental radioghraphy	1 x per year
X-Ray equipment for panoramatic dental examination	1 x per year
Digital X-Ray equipment	1 x per year
Mobile X-Ray equipment for radiography or fluoroscopy	1 x per year
X-Ray equipment for skelet densitometry	1 x within 3 years
Shielding barriers and installations	1 x within 3 years
Radiotherapy	
Therapeutic X-Ray installation	2 x per year
Equipment for external gamma radiotherapy (Co-60, Cs-137)	2 x per year
Equipment for brachytherapy with afterloading systems	2 x per year
Linnear accelerator for radiotherapy	2 x per year
X-Ray simulator for radiotherapy	2 x per year
3D plannig system	1 x per year
Shielding barriers and installations	1 x within 2 years
Nuclear medicine	
Dosecalibrator	2 x per year
Gamma camera - SPECT	2 x per year
Gamma camera - PET	2 x per year
Detector for in-vivo dosimetry	1 x per year
Plannar scintilation gamma camera	2 x per year
Shielding barriers and installations	1 x within 2 years
Dosimetric monitors	1 x within 2 years

The specific protection requirements were established for a pregnant woman and her unborn child, for the examination of children and patients in the interventional radiology, considering high doses.

Conclusion

The Regulation of Slovak Government on health protection on individuals against the dangers of the ionizing radiation in relation to medical exposure is planned to be in force from the 1. January 2006.