Survey on the implementation of the "justification", "optimisation" and "limitation of doses" radiological principles in national regulations in Europe

SERBIA

1 The implementation of European Directives

1. *Since when have the European Directives 96/29 and 97/43 been implemented in your country?*

Not implemented.

2. *If they are not implemented, is it expected and when?*

IAEA BSS No. 115 and ICRP 60 are implemented in the Law on Protection of Ionizing Radiation, Official Gazette FRY, No. 46/96 and regulations issued from 1997 until 1999 (also Official Gazettes No. 45/97, 32/98, 9/99)

2 Justification principle

1. *What is the exact wording of the justification principle in the Law?*

Law on Protection of Ionizing Radiation, Official Gazette FRY, No. 46/96, **article 4**:

"System of measures for ionizing radiation protection is based on:

1) **Justification** of using ionizing radiation sources;
2) Optimization;
3) Effective and equivalent dose limits.

Applying of an ionizing radiation source deems as justified if yield positive net-benefit."

Justification is repeating in Regulation Concerning the Limits of Exposure to Ionizing Radiation, Official Gazette FRY, No. 32/98, article 10.

2. *Which practices are explicitly named as unjustified or forbidden?*

Explicitly named as **forbidden** are:

- The Law, No. 46/96
  - Article 17: systematic x-ray screening persons younger than 16; systematic mammography screening;
  - Article 20: installing radioactive lighting rods;
  - Article 21: import of radioactive waste and reprocessing, storage and repository radioactive waste of outside origin.

- Regulation Concerning the Limits of Exposure to Ionizing Radiation, Official Gazette FRY, No. 32/98:
  - Article 17: "It is not allowed adding radioactive material in food, toys, jewelries, cosmetic and other goods of common using, as well as activation of them."

3. *Which regulatory body(ies) is (are) responsible to determine if a practice is justified or not?*

Responsible regulatory body to determine if a practice is justified or not is **Ministry of Science and Environmental Protection**.

Very specific issue is justification principle in medical applications. Regulation of Application of the Ionizing Radiation Sources in Medicine and Basic Provisions, Official Gazette, FRY, No. 32/98, defines responsibilities in particular medical application.

3 Optimisation principle

1. *Could you give is the exact wording (citation) of the optimisation principle (ALARA) as defined in the Law or national regulation?*

Law on Protection of Ionizing Radiation, Official Gazette FRY, No. 46/96, **article 4**:

"System of measures for ionizing radiation protection is based on:

1) Justification of using ionizing radiation sources;
2) **Optimization**;
3) Effective and equivalent dose limits.

[…] System of measures for ionizing radiation protection has to provide as low exposing as possible according to social and economic factors."

2. *Does the national regulation give a description on the practical way to implement the optimisation principle (e.g. need to perform dose prediction and to establish dose objectives, need to perform real-time dose follow-up, need to write feedback experience report, etc)?*

Yes.

Regulation Concerning the Limits of Exposure to Ionizing Radiation, Official Gazette FRY, No. 32/98, article 19:

- Preliminary estimation of dose and risk;
- Classification of working areas;
- Categorization of workers (A & B);
- Appliance of adequate control measures and dosimetry measurements (individual and working monitoring);
- Keeping records.

3. *Does it exist a specific guidance to help operators / end-users in implementing the optimisation principle?*

No, it does not. Above mentioned article 19 in second paragraph explains that owner/user provides RP measures in cooperation with authorized institutions.

4 Dose limits

1. *Can you provide us with present regulatory dose limits established to reduce the probability of occurrence of stochastic effects?*

See Annex: Comment of Regulation Concerning the Limits of Exposure to Ionizing Radiation, Official Gazette FRY, No. 32/98

These comments were performed at the aim to analyze compliance of Regulation with BSS and ICRP 60 Recommendations at the August 2005 meeting between IAEA consultant and group of Serbian experts. We agree with conclusions written in EOM Report that:

"The regulations summarized in Appendices B and C were compared against the IAEA Basic Safety Standards. The following assessment resulted:

- Regulation 32/98 (Appendice B) is in **general** in agreement with the BSS. Some provisions could be streamlined but in general it was concluded that this regulation forms a suitable basis for the activities within the VIND Programme;
- Regulation 9/99 (*) (Appendice C) represents substantial problems."

*(*) **Regulation Concerning the Limits of Radioactive Contamination No .9/99** is interesting here as contains limits for occupational exposing via inhalation and ingestion. So, new regulations will be established very soon after adoption new law, more or less different from the old ones.*

Briefly, public and occupational dose limits are separated in the Regulation; permanent and interim workers – not explicitly, only in definition of A and B categories; pregnant women – special attention for them as patients (**) and not permitted special exposure for women in reproductive period (Regulation, article 25). (***)

(**) Regulation of Application of the Ionizing Radiation Sources in Medicine and Basic Provisions, Official Gazette, FRY, No. 32/98:

a) Article 29: diagnostic procedure in abdomen region of woman in reproductive period is allowed in first 10 days of monthly period, except in special cases of vital indication;

b) Articles 33 and 34: special attention for patient in nuclear medicine in the case of pregnancy or breastfeeding.

(***) Not big attention for pregnant women occupational exposed because in practice pregnant woman usually does not work during pregnancy with ionizing sources!

2. *What are the legal dose limits to prevent public and workers from deterministic health effects?*

There is article 4 - equivalent dose limits (skin, extremities, eye lens) for public and workers. From my point of view, these limits prevent deterministic health effects for workers, but for public (article 9) – not. All limits aimed at prevent deterministic effects but more important reduce probability of occurrence of stochastic effects (if the second is satisfied – the first is too, undoubtedly).

5 Dose constraints

1. *Here again, could you give is the exact wording (citation) of the Law or regulations where the concept of dose constraint is mentioned.*

In the Regulation (which comments are attached) – Regulations concerning the limits of exposure to ionizing radiation, Official Gazette, No. 32/98, in article 2 there are 39 definitions.

35th is the same as definition of investigation level in BSS. There is nothing about authorities responsible for putting such levels in various applications.

2. *In which domain (e.g. public dose, occupational dose, patient dose, etc) and by whom (regulatory body, operators, etc) are dose constraints implemented in your country?*

The domain of implementation could be each practice related to public, occupational exposing or patients. Maybe the right description is lawyer formulation: we do not have dose constraints *de jure*, but we have them *de facto*.

Some rules are followed as good practice, not as legal duties.

a) Designing shielding of particular sources is done to ensure impact to the most exposed individual in category of population < 0.3 mSv/year;
b) Designing shielding is done to ensure impact to the most occupational exposed individual as low as reasonable achievable (usually much lower than annual effective dose limits).

Regarding patients:

In the Regulation of Application of the Ionizing Radiation Sources in Medicine and Basic Provisions, Official Gazette, FRY, No. 32/98:

Article 17:

"Value of surface entrance dose at the patients' skin for each radiography procedure must not be more than 20% of references levels given in Tables from 1 to 4 which are printed in this regulation and represent its component." (Tables refer to typical adults for conventional radiography, CT, mammography and fluoroscopy.)

Article 36, paragraph 3rd:

"Radiopharmaceutical activity must not be higher than values given in Table 6 which is printed in this regulation and represent its component." (Table 6, as well as above mentioned 1-4 are prescribed from BSS, No. 115)

Checking compliance practice with the reference levels in Regulation were done voluntary in few cases: measuring entrance surface dose with TLD (our Institute Lab) and with KAP meter (another authorized institution in Serbia - Department Protection, INS Vinca).

External individual monitoring

Practical criteria in the Laboratory for personal dosimetry in the Institute of Occupational and Radiological Health is to ask users for written information if estimated dose Hp(10) exceeded 4 mSv for read-out result. Also, recommendation is to investigate causes if Hp(10) twice

higher than usual value for the same period for very low doses (or in any case when RPO find unreasonable result).

3. *What are the corresponding values and rationales behind these values?*

4. *What is(are) the status(es) of dose constraint(s)?*

5. *What is effectively done if a constraint is exceeded?*

EOM Report – August 2005 – Appendix B

Comments of

Regulation concerning the limits of exposure to ionizing radiation (32/98)

Article 1: Scope

Regulations give limits for exposure to ionizing radiation limits for occupationally exposed persons and the public.

Article 2: Definitions

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Article 3: Dose limits for occupational exposure

Effective dose limit is 20 mSv annually as average over a five year period with the additional limitation that 50 mSv are not exceeded in any year. Doses have to be determined according to ICRP 60.

Article 4: Equivalent dose limits

Limits on organ doses (eye lens 150 mSv annually, skin 500 mSv annually, extremities 500 mSv).

Article 5 and 6: Dose limits for exposure during education

Effective dose limits for persons of age below 18 years of age: 6 mSv annually plus further restrictions on organ doses (equivalent to category B workers, see below)

Article 7: Dose limits for population

Verification of compliance with dose limits for public has to consider critical group.

Article 8: Effective dose limits for population

Effective dose limit for practices is 1 mSv per annum to be determined according to ICRP 60. In case of emergencies higher limits are permissible but 5 mSv in five years must not be exceeded.

Article 9: Equivalent dose limits

Limits on organ doses (eye lens 15 mSv annually, skin 50 mSv annually, extremities 50 mSv).

Article 10: Justification

All practices have to be justified

Article 11: Optimization

Doses have to be kept as low as reasonably achievable, economic and social factors taken into account.

Article 12: Exemptions

Limits do not apply to

1. Patients during medical treatment with ionizing sources,
2. Persons assisting patients during medical procedures,
3. Voluntaries in medical research,
4. Exposures in emergencies,
5. Exposure to natural radioactivity except in cases where this exposure is occupational.

Article 13: Intervention in emergencies

Procedures for intervention in cases of emergency have to be justified.

Article 14: Optimization of intervention

Type and duration of intervention have to be optimized to achieve a maximum benefit.

Article 15: Intervention level

Intervention levels for acute and chronically exposure are given in Appendix 2 (given for absorbed dose in two days and for equivalent dose rate for chronical exposure).

Article 16: Intervention level for chronical exposure to radon in dwelling

Average annual radon concentration of 200 Bq/m^3 in new buildings, of 400 Bq/m^3 in existing buildings and of 1000 Bq/m^3 at work places defined as intervention levels.

Article 17: Use of radioactive material

It is prohibited to add radioactive material to foodstuff, toys, jewels and other articles of common use.

Article 18: Occupational exposure

Persons below the age of 16 must not be occupationally exposed. Work in controlled zones is prohibited for persons below the age of 18.

Article 19: Measures to limit exposures to occupationally exposed workers

The following measures have to be undertaken:

1. Before exposure estimation of radiation risk is required.

2. Work places have to be classified in radiation zones based on estimation of annual dose and of probability of higher doses.
3. Occupationally exposed workers have to be categorized.
4. Using adequate control measures for persons and work places.
5. Worker health surveillance.

Responsibility for these measures is with the user of ionizing radiation in cooperation with the authorized institutions.

Article 20: Radiation zones

Requirements for radiation zones:

1. Zones in which ionizing radiation is used must be marked with standardized signs.
2. Type of ionizing sources must be indicated.
3. Working procedures must be clearly indicated.
4. Dosimetry control of working area.

In addition, entrances into controlled zones must be controlled and only authorized person may be allowed to enter.

Article 21: Categorization of workers

Occupationally exposed persons are categorized in categories A and B. Category A are workers in controlled zones and which can receive an effective dose over 6 mSv per annum or equivalent doses above three tens above prescribed equivalent dose limits. Category B workers are occupationally exposed workers in supervised zones or only working temporary in controlled zones.

Article 22: Measures for limitation of occupational exposure in special circumstances

Occupational exposures above prescribed limits are only permissible in specific situations in normal operation conditions if no possibilities for alternative procedures exists. For such situations, special limits must be authorized.

Article 23: Special exposures

Exposures according to Article 22 may be authorized only for Category A workers and consideration has to be given to their age and health state. Authorization of higher limits may only be done for a maximum period of five years.

Article 24: Special exposures

For each specially authorized exposure it is necessary to obtain an estimation of doses from an authorized institution for measurements and for health care according to this law.

Exposures must be justified and persons involved must be informed about risks associated with these doses and about the measures undertaken during specially authorized exposures.

Article 25: Special exposures

Specially authorized exposures must not be permitted for

1. Persons who received higher effective or organ doses than the prescribed limits within the last 12 months,
2. Persons who because of irregular conditions received an effective dose which is was five times higher than the prescribed limits,
3. Women in reproductive period.

Article 26: Special exposures

For Category A workers exposure must not exceed 50 mSv in any year and must not exceed an average of 20 mSv over ten consecutive years. Conditions under which special exposures are authorized must be analyzed when the dose accumulated since the start of the extended averaging period exceeds 100 mSv.

Article 27: Recording of special exposures

Information about special exposures must be recorded and added to doses of normal exposures.

Article 28: Special exposures

Persons for which special exposures are authorized are to be excluded from regular work tasks upon requirement from authorized persons from health care.

Article 29 and 30: Occupational exposure to natural radiation sources

Regulations for miners and aircrews.

Article 31: Emergencies

In the case of emergencies workers involved in intervention can be exposed above prescribed limits only in the following cases:

1. To save lives or to prevent heavy injuries,
2. To prevent over-exposing a large number of people,
3. To prevent accidents of catastrophic dimensions.

Persons involved in interventions must agree to this, must have an appropriate training and must be informed about health risks.

Article 32: Emergencies

In cases of Article 31 the measures must assure that doses of persons involved in the intervention have to be less than twice the annual dose limits. Doses for persons who are involved in saving lives must be lower than ten times the annual effective dose limits. Persons saving lives may be allowed to be exposed to higher levels if the benefit of the intervention is higher than the risk to these persons.

Article 33: Emergencies

People involved in interventions following emergencies have to be medically examined after finishing their activities and must be informed about measured doses and estimated risks.

Article 34: Estimation of occupational exposure

Estimation of exposure has to consider external and internal exposure using the methodology given in Appendix III of this regulation.

Article 35: External dosimetry

External exposure for Category A workers is measured with personal TLD dosimetry monthly.

Article 36: External dosimetry

External exposure for Category A workers is estimated using results of personal TLD dosimetry and adequate measurements in working area, working conditions and model results. The period for TLD dosimetry must not exceed three months.

Article 37: External dosimetry

If in controlled zones exposure estimates exceed 25 mSv per day electronic personal dosimeters with direct readings have to be used. Persons responsible for radiation protection must distribute recorded results.

Article 38: Internal dosimetry

For assessment of internal exposure of occupationally exposed persons direct measurements of whole-body activity or activity in target organ (thyroid, lung) and calculation of equivalent dose are performed. Alternatively, measurements of specific of radionuclides in biological samples are performed and the committed effective dose is calculated.

Article 39: Internal dosimetry

The control period for occupationally exposed workers handling unsealed sources is defined based on biological properties of the radionuclides. Concerning exposure to tritium,

measurements of tritium in 24 hours urine samples once a week are required. Concerning exposure to iodine-131 measurement of specific activity in 24 hours urine samples once a week are required and, if necessary, thyroid activity has to be determined. Concerning exposure to long-lived gamma emitters, measurements within six months have to be performed. For radionuclides not specified in this article, the authorized institution define the program and periods for dosimetry based on the properties of the radionuclides.

Article 40: Internal dosimetry

Internal exposure of persons working with unsealed sources are estimated by calculating the committed effected dose using the results from Article 38 and 39 of this regulation.

Article 41: Radiation control

Radiation control of work places and the environment includes:

1. Measurement of dose rate and indication of the type of radiation,
2. Airborne concentration of radionuclides and surface activity concentration measurements with indication of the physical and chemical characteristics of the radionuclides,
3. Results from measurements from Numbers 1 and 2 are recorded and used for the assessment of individual exposures.

Article 42: Effective Dose

Compliance with dose limits is assessed by calculating the effective dose according to the formula given in Schedule II-12 (a) of the BSS:

$$E_T = H_p(d) + \sum_j e(g)_{j,ing} I_{j,ing} + \sum_j e(g)_{j,inh} I_{j,inh}$$

<u>Appendices</u>

Appendix I:

Definition of dosimetric quantities, quality and tissue weighting factors etc.

Appendix II:

Intervention levels (see Article 15).

Appendix III:

Methodologies for assessment of radiation exposures (occupational, medical patients and the public) focusing on medical applications and uses of sealed sources in industry.

Appendix IV:

Dose factors for inhalation and ingestion (identical to BSS).