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

ITALY

1 The implementation of European Directives

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

Decreto Legislativo 17.3.1995 n. 230, Decreto Legislativo 26.5.2000 n. 187 (for E.D. 97/43); Decreto Legislativo 26.5.2000 n. 241 (for E.D. 96/29); Decreto legislativo 9.5.2001 n. 257

2 Justification principle

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

Art. 2: New types or new categories of practices, causing exposures to ionising radiation, before their adoption, should be justified by their economical and social advantages compared to their likely health detriment.

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

Art. 98: The adding of radioactive materials is absolutely forbidden for products used for:

- Hygiene and make up;
- Domestic and personal tools;
- Toys;
- Food and drinks;
- Lightening devices.

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

The Health Department (Ministero della Salute)

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?*

Art. 2, comma 4: Each practice should be carried out according to procedures suitable to maintain exposures as low as reasonably achievable, economical and social factors taken into account.

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)?*

No, ALARA principle is applied during the licensing analysis case by case.

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

We usually refer to literature such as NRPB or NBS or IAEA publications.

4 Dose limits

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

0 ≤ no radiological concern ≤ 10 μSv/year* &
1 man.Sv/year**10 μSv/year ≤ members of the public ≤ 1 mSv/year

(or not exposed workers)1 mSv/year ≤ exposed category B worker ≤ 6 mSv/year6 mSv/year ≤ exposed category A worker ≤ 20 mSv/year20 mSv overexposure

* *effective doses per year*** collective dose per year*

For pregnant women: 1 mSv for the whole period of pregnancy

As for post-accidental intervention limits, rules are provided but they are rather complicated to be summarized in a questionnaire

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

Any dose overcoming 20 mSv is considered as an accident; you prevent accidents with safety systems and procedures. Accident prevention is considered during the safety analysis prior to the license of the practice.

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.*

Dose constraints are considered during the analysis prior to the license of the practice, in order to ensure the application of the ALARA principle. Dose constraint is defined at the *art. 4, comma 4b*: constraint is the value of a radiation protection quantity, stated for particular conditions in order to apply the optimisation principle.

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?*

Many public administrations are involved in the licensing of a practice. All of them can give advise or prescriptions on dose constraints.

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?*

If a dose constraint is exceeded, the qualified expert must report his own evaluations and an analysis of the causes. During an inspection, the fact is considered in order to ascertain if there are responsibilities.