

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

SPAIN

1 The implementation of European Directives

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

Directive 96/29/EURATOM, implemented:

- Decree 6 July 2001, over Health Radiological protection against ionizing radiation
- Decree 3 December 1999, over Nuclear and Radioactive Facilities

Directive 97/43/EURATOM, implemented:

- Decree 5 December 1997; Quality criteria in Nuclear Medicine
- Decree 17 July 1998, Quality criteria in Radiotherapy
- Decree 23 December 1999, Quality criteria in Medical X Ray
- Decree 13 July 2001, Justification of using ionizing radiation for radiological protection people in medical exposures

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

2 Justification principle

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

The justification principle is stated in the article 4º of the Decree over Health Radiological Protection against ionizing radiation (6 July 2001):

Justification, Optimisation and Dose Limitation for Practices. “All practices involving exposure to ionizing radiation must be justified in advance of being adopted. The Competent Authority, with the binding report of CSN, will decide the practice’s approval, depending its benefits in relation to the health detriment they may cause”.

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

The article 5° of the same Decree (2 July 2001) establishes as unjustified and forbidden: “The deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and the import, export and movement between Member States of such goods.”

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

The justification of the practices has to be approved by Competent Authority (the authority depends of the subject) with the binding report of the Nuclear Safety Council (CSN).

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?*

The optimisation principle is stated in the article 4° of the Decree over Health Radiological Protection against ionizing radiation (6 July 2001):

Justification, Optimisation and Dose Limitation for Practices. “The individual doses the number of exposed people and the probability of exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account. The sum of the doses from all practices shall no exceed the dose limits for exposed workers, apprentices and students and members of the public”.

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)?*

The national regulation give a description on the practical way to implement the optimisation principle in the article 4° of the Decree over Health Radiological Protection against ionizing radiation (6 July 2001).

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

It exist specific guidance in the Radiological protection Manuals of each Radiological protection services and in the procedures of developing these Manuals. Also, the CSN has Guides with establishing the contained of the Radiological protection Manuals

issues. For Nuclear Power Plants CSN released a guide (CSN 1.12) entitled “Practical implementation of the radiation protection optimisation at operating Nuclear Power Plants”

4 Dose limits

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

The Decree of 6 July 2001 establishes the dose limits for workers, pregnant women, training people and students, emergency exposures and public. The especial exposures have to have, each one, authorization of the CSN.

Dose limits for exposed workers:

- The limit on effective dose for exposed workers shall be 100 mSv in a consecutive five official years, subject to a maximum effective dose of 50 mSv in any single official year
- The limit on equivalent dose for the lens of the eye shall be 150 mSv in a official year
- The limit on equivalent dose for the skin shall be 500 mSv in an official year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed
- The limit on equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a official year

Pregnancy: it will be unlikely 1 mSv during at least the remainder of the pregnancy

Apprentices and Students: apprentices and students aged 18 years or over, the same dose limits that exposed workers.

Apprentices and Students: aged between 16 and 18 years the limits of effective dose shall be 6 mSv in an official year. Also:

- The limit on equivalent dose for the lens of the eye shall be 50 mSv in a official year
- The limit on equivalent dose for the skin shall be 150 mSv in an official year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed

- The limit on equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in an official year

Dose limits for members of the public: the limits for effective dose shall be 1 mSv in an official year. However, in special circumstances, the CSN can authorise a higher effective dose in a single year, if the average over 5 consecutive years does not exceed 1 mSv in an official year. Also:

- The limit on equivalent dose for the lens of the eye shall be 15 mSv in an official year
- The limit on equivalent dose for the skin shall be 50 mSv in an official year. This limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed

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

The dose limits to prevent deterministic health effects are less than:

- All body: 1 Gy
- Liver: 6 Gy
- Skin: 3 Gy
- Thyroids: 5 Gy
- Lens of the eye: 2 Gy
- Gonads: 3 Gy

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?*

The concept of dose constraints is mentioned in the article 6° of the Decree 6 July 2001, article 6° “Dose Constraints”. Dose constraints will be used, where appropriate, within context of optimization of radiological protection, taking account the recommendation of CSN. These dose constraints must be assessed and approved for CSN.

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?*

Dose constraints will be used on the appropriate procedures for the people who willingly helping and relieving to patients undergoing medical diagnosis or treatment, and exposure of volunteers participating in medical and biomedical research programmes. They should be implemented by licensees following health authority guidance.

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

There are not values for dose constraints, there are reference values. These reference values are included in the Radiological Protection Manuals in each Nuclear Power Plant and they have to be approved by CSN. There are reference values for workers and public in each Nuclear Power Plant. For Radioactive Facilities, there are only for industrial gammagraphy.

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

Above the reference values they have to undertake a specific action. The reference values and action are mandatory because they are established in an official document.

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

By the moment, nobody has exceeded reference values, but if it exceeds penalties can be applied.