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

GERMANY

1 Implementation of European Directives

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

- ED 96/29: German Radiation Protection Ordinance (StrlSchV) of 20.07.2001 (Federal Law Gazette I, page 1714) officially amended on 22.04.2002 (Federal Law Gazette I, page 1459), last amended on 18.06.2002 (Federal Law Gazette I, page 1869)

- ED 97/43: German Guideline on "Radiation protection in medicine" of 24.06.2002

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

Not applicable

2 Justification principle

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

Article 4, Justification

(1) New types of activities that would fall under Paragraph 2, Section 1, No. 1, which could ledad to radiation exposure or contamination of persons and the environment, must be justified under consideration of their economic, social or other use in relation to the health impairment possibly outgoing from them. The justification of existing types of practices can be examined, as soon as substantial new findings are present on the use or the effects of the practice.

(2) Medical radiation exposures in the context of medicine, dentistry or medical research must furnish a sufficient use, whereby its overall potential at diagnostic or therapeutic use, including the direct health use for the individual and the use for the society is to be weighed, in relation to the damage of the individual possibly caused by the radiation exposure.

(3) Which types of practices are not justified in accordance with the paragraphs 1 and 2 is determined by separate statutory order according to § 12 exp. 1 sentence 1 No. 1 of the atomic law.

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

Chapter 1, §12, para (1), subpara (1), No. 1 of the German Atomic Energy Act.

Chapter 1 General

§12 Enabling provisions (protective measures))

(1) To achieve the purposes referred to in § 1, it is provided by statutory ordinance

1. which precautions and supervisory measures, including the justification required under Article 6, paras (1) and (2) of Council Directive 6/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (Official Journal of the EC No. L 159, page 1) and Article 3 of Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/EURATOM (Official Journal of the EC No. L 180, page 22), must be taken in order to protect individuals and the general public with regard to the handling of and transactions with radioactive substances, the erection, operation and possession of installations of the kind referred to in § 7 and § 11, para. (1), subpara. 2, as well as the handling of and transactions in installations, equipment and devices of the kind referred to in § 11, para. (1), subpara. 3, and also with regard to the appropriated addition or activation of material, against ionizing radiation of natural origin when carrying out such work.

In other words, the Atomic Energy Act leaves it to the Federal Ministry on Environment to establish regulations regarding non-justified practices. There is, in fact, a draft version of an ordinance determining non-justified practices and the BfS was involved in researching this subject. However, it was concluded that the technical content should be included in the next revision of the Radiation Protection Ordinance rather than as an ordinance.

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

For the time being, the Federal Ministry of Environment, Nature Conservation and Nuclear Safety in cooperation with the competent authorities of individual states decide whether or not a practice is justified on a case-to-case basis.

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?*

§ 6 Avoidance of unnecessary radiation exposure and dose reduction:

(1) Who plans or exercises a practice according to § 2 exp. 1 No. 1, is obligated, to avoid each unnecessary radiation exposure or contamination from humans and environment to.

(2) Who plans or exercises a practice according to § 2 exp. 1 No. 1, is obligated, to keep as small each radiation exposure or contamination of humans and environment considering the conditions of science and technology and with consideration of all circumstances of the individual case also underneath the limit values as possible.

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, optimisation in general and in particular the items in brackets might be addressed under the specific conditions during licensing processes or as feedback from inspections.

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

No

4 Dose limits

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

Occupational: 20 mSv/a (max 50 mSv/a), not more than 100 mSv within 5 years; persons under 18 years 1 mSv/a, as an exception 6 mSv/a

Public: 1 mSv/a, 0.3 mSv/site

Exceptional cases (assistance after accidents): 100 mSv once a year, 250 mSv once in a lifetime

In medical diagnosis, diagnostic reference values have to be used:

§81 (2) Investigation of humans have to be based on diagnostic reference values. An excess of the diagnostic reference values is to be justified in writing. The Federal Office for radiation protection provides and publishes the diagnostic reference values. In therapy, irradiation planning by medical physicists is required: 3) Before the application of radioactive substances or ionizing radiation for treatment at humans, an expert physician and a medical physics expert must specify an irradiation plan for the patient in writing (acc. § 82). The dose in the treatment volume is to be specified with each person who can be treated after the requirements of the medical science individually; the dose outside of the treatment volume is to be kept so low, as this is possible with consideration of the treatment purpose.

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

	Public	Workers	Post
Accidental			
Eye	15 mSv	150 mSv	150 mSv
Skin	50 mSv	500 mSv	500 mSv
Gonads, uterus, marrow (red)	0.3 mSv	50 mSv	50 mSv
Thyroid	1.8 mSv	300 mSv	150 mSv
Surface of bones	1.8 mSv	300 mSv	300 mSv
Colon, lung, stomach, bleb, thorax, liver, gullet	0.9 mSv	150 mSv	150 mSv

For workers under the age of 18 the same limits are valid as for the public, as an exception 45 mSv for the eye and 150 mSv for the skin.

For an unborn child, exposed due to the occupation of the mother, the limit is 1 mSv for external and internal exposure to ionizing radiation, beginning with the first notice of pregnancy up to its end.

In exceptional cases (assistance after accidents) the limits are 300 mSv for the eye and 1 Sv for the skin (§ 59).

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 is not mentioned in the regulation, however, when regulating discharges during normal operation, source-related constraints are given (see next question) which have the legal status of dose limits.

In cases of accidental discharges these values are higher.

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?*

§ 47 Limitation of releases of radioactive substances
(1) For the planning, the establishment, the operation, the decommissioning, the safe inclusion and the dismantling of plants the following limit values apply for radiation exposure of individuals of the population in the calendar year due to the release of radioactive substances with air or water from these plants:

1. Effective dose 0.3 mSv
2. Organ dose for gonads, uterus, marrow (red) 0.3 mSv
3. Organ dose for large intestine, lung, stomach, blister, chest, liver, esophagus, thyroid, other organs or fabrics in accordance with annex VI part of C No. 2 footnote 1, so far not mentioned under No. 2: .0, 9 mSv
4. Organ dose for bone surface, skin: 1.8 mSv.

It is to be ensured that radioactive substances are not released uncontrolled into the environment.

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

The constraints for the public mentioned in 1. are source-related.

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

The constraints for the public mentioned in 1 have the same legal status like dose limits.

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