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

IRELAND

1 The implementation of European Directives

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

Euratom 96/29 is enacted in Irish legislation by the Radiological Protection Act, 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) in May 2000.

Euratom 97/43 is enacted in Irish legislation by the European Communities (Medical Ionising Radiation Protection) Regulations 2002 (S.I. No. 478 of 2002) in October 2002. An amendment to this SI is currently being drafted.

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?*

S.I. No. 125 of 2000

Part 3 JUSTIFICATION, OPTIMISATION AND DOSE LIMITATION

Justification

8. (1) No practice shall be licensed under this Order unless-

(a) it falls within a class or type of practice carried on immediately before the commencement of this Order, or

(b) it falls within a class or type of practice which has been approved in writing by the Institute (which the Institute is hereby empowered to do) as being justified by its economic, social or other benefits in relation to the health detriment it may cause.

S.I. No. 478 of 2002

7.1. Medical exposure referred to in regulation 4.1 shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefit it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation

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

S.I No. 125 of 2000

Licensing of Practices

4. (1) Subject to Article 5, a practice to which this Order applies shall not be carried on save under and in accordance with a licence issued by the Institute.

(2) Such a licence shall not be granted in respect of the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics and the import and export of such goods.

S.I. No. 478 of 2002

18.1. The conduct of fluoroscopy examinations without an image intensification or equivalent techniques are prohibited.

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

S.I. No.125 of 2000

Article 8 (1) b empowers the Radiological Protection Institute of Ireland to approve the justification of practices.

S.I. No 478 of 2002

7.11. A prescriber shall state in writing on each individual prescription his or her reason for requesting the particular procedure and the practitioner shall make arrangements to satisfy himself or herself that the procedure as prescribed is justified.

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?*

S.I. No. 125 of 2000

9. (1) The undertaking shall ensure that all exposures, including those to the population as a whole, from practices and work activities under its control, are kept as low as reasonably achievable, taking into account economic and social factors, except for –

(a) The case of medical exposures other than radiotherapeutic procedures, which exposures shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors, and

(b) The case of medical exposure of individuals for radiotherapeutic purposes, in which exposures of target volumes shall be individually planned, taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

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)?*

S.I. No. 125 of 2000

9. (2) For the purpose of identifying the protective measures needed to restrict exposures to ionising radiation, the undertaking shall, before commencing a practice, make an assessment acceptable to the Institute of the risks of exposure to ionising radiation arising from the practice or from reasonably foreseeable accidents resulting from the practice for workers and members of the public who may be affected.

(3) The undertaking shall, in respect of a work activity, make an assessment acceptable to the Institute of the risks of exposure to ionising radiation arising from the work activity to any workers or members of the public for the purposes of identifying the protective measures needed to restrict exposure to ionising radiation.

(4) Where, in the opinion of the Institute, the assessment provided by the undertaking in accordance with paragraph (2) or (3) is insufficient or inadequate, the Institute may, by notice in writing sent to the undertaking at the address specified in its application under Article 6 in the case of a practice, or at the address given in its notification under

Article 7, in the case of a work activity require that undertaking to furnish the Institute with such additional information as it specifies in the notice.

(5) The undertaking shall, where appropriate, use dose constraints in restricting exposure to ionising radiation pursuant to paragraph (1).

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

The RPII has a guidance note on Dose Constraints for the design of new facilities using sources of ionising radiation. This guidance note is currently being revised to take account of Radiotherapy facilities.

4 Dose limits

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

Schedule 2 to S.I. No. 125 of 2000

Dose Limits for Exposed Workers

1. (1) The limit on effective dose for an exposed worker shall be 20 mSv in a period of 12 months.

(2)Without prejudice to subparagraph (1) -

(a) The limit on equivalent dose for the lens of the eye of such a worker shall be 150 mSv in a period of 12 months,

(b) the limit on equivalent dose for the skin of such a worker shall be 500 mSv in a period of 12 months; this limit shall apply to the dose averaged over any area of 1 cm^2, regardless of the area exposed,

(c) The limit on equivalent dose for the hands, forearms, feet and ankles of such a worker shall be 500 mSv in a period of 12 months.

(3) Notwithstanding subparagraphs (1) and (2), as soon as a pregnant exposed worker informs the undertaking of her condition, the equivalent dose to the child to be born shall be limited to 1 mSv for the remainder of the pregnancy.

Dose Limits for Apprentices and Students

2. (1) The dose limits for an apprentice or student aged 18 years or over who, in the course of his or her studies, is obliged to use sources shall be the same as the dose limits for an exposed worker specified in paragraph 1 of this Schedule.

(2) The limit of effective dose for an apprentice or student aged 16 years or more but less than 18 years who, in the course of his or her studies, is obliged to use sources shall be 6 mSv in a period of 12 months.

(3) Without prejudice to subparagraph (2) -

(a) The limit on equivalent dose for the lens of the eye of an apprentice or student referred to in that subparagraph shall be 50 mSv in a period of 12 months.

(b) The limit on equivalent dose for the skin of such an apprentice or student shall be 150 mSv in a period of 12 months; this limit shall apply to the dose averaged over any area of 1 cm^2 regardless of the area exposed,

(c) The limit on equivalent dose for the hands, forearms, feet and ankles of such an apprentice or student shall be 150 mSv in a period of 12 months.

(4) The dose limits for an apprentice or student to whom subparagraphs (1) and (2) do not apply shall be the same as the dose limits for members of the public specified in paragraph 3.

Dose Limits for Members of the Public

3. (1) The limit on effective dose for a member of the public shall be 1 mSv in a period of 12 months.

(2) Without prejudice to subparagraph (1) -

(a) The limit on equivalent dose for the lens of the eye shall be 15 mSv in a period of 12 months.

(b) The limit on equivalent dose for the skin shall be 50 mSv in a period of 12 months averaged over any 1 cm^2 of skin, regardless of the area exposed.

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

I assume that you are referring to intervention dose limits?

Intervention Principles

36. (1) This Article applies to interventions in cases of radiological emergencies or in cases of lasting exposure resulting from the after effects of a radiological emergency or a past or old work practice or work activity.

(2) The implementation and extent of any intervention shall be considered in conformity with the following principles -

(a) Intervention shall be undertaken only if the reduction in detriment due to radiation is sufficient to justify the harm and costs, including social costs, of the intervention,

(b) The form, scale and duration of the intervention shall be optimised so that the benefits of the reduction in health detriment less the detriment associated with the intervention, will be maximised,

(c) Dose limits specified in Schedule 2 shall not apply to intervention,

(d) Such intervention levels as are determined by the Institute from time to time shall be regarded as indications as to the situations in which intervention is appropriate, and

(e) In cases of long term exposure to which Article 40 applies, the dose limits specified in Schedule 2 should normally be appropriate for workers involved in interventions.

(3) Where the intervention is necessary in respect of a particular radiological emergency, the undertaking shall comply with the provisions of subparagraphs (b) to (e) of paragraph (2) after consultation with the Institute on the intervention measures considered appropriate and in accordance with any guidance given to it by the Institute in relation to that matter.

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.*

S.I. No. 125 of 2000

9 (5) The undertaking shall, where appropriate, use dose constraints in restricting exposure to ionising radiation pursuant to paragraph (1).

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 are set out by the RPII for the protection of occupationally exposed workers and all others, including members of the public, from the hazards associated with the use of sources of ionising radiation.

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

In general the dose constraint is source related. However, for applications where there may be many sources in close proximity e.g. along a corridor in X-ray department within a large hospital, the design dose constraint should be applied to the predominant source in conjunction with a risk assessment being performed of all the combined sources.

The Dose Constraints are given in terms of the Time Averaged Dose Rate (TADR) over a 2000 hour working year:

Exposed worker: 1.0 mSv/yr
All others: 0.3 mSv/yr

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

For existing licensees it is a condition of their licence that all new facilities, including redevelopments, must be designed to meet the dose constraints. The Radiological Protection (Amendment Act) 2002 (S.I. No. 3 of 2002) makes it a prosecutable offence if a licensee fails to comply with any condition of their licence.

For new licensees the RPII requires a shielding assessment to be submitted in support of a licence application which demonstrates that the new facility has been designed so that the dose constraints will be met. Failure to demonstrate to the RPII's satisfaction that the design dose constraints will be met will result in a licence not being issued.

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

Dose constraints are intended for use during the design stage of any new building or redevelopment work and are used as a tool for optimisation purposes. The undertaking is required to demonstrate to the Institute's satisfaction that the new facility has been suitably designed to ensure that the necessary dose constraints for exposed workers and members of the public will be met. All dose calculations must be based upon worse case/maximum workload assumptions. However, once the facility is in routine operation the undertaking is legally required to ensure that none of the dose limits, as defined in S.I. No. 125 of 2000, rather than the dose constraints, are exceeded.