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

THE UNITED KINGDOM

1 The implementation of European Directives

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

Directive 97/43

In the United Kingdom European Council Directive 97/43/Euratom was implemented in 1999 and 2000:

- the Ionising Radiations (Medical Exposure) Regulations 2000;
- the Ionising Radiations (Medical Exposure)Regulations (Northern Ireland) 2000;
- regulation 32 of the Ionising Radiations Regulations 1999.

Directive 96/29

In the United Kingdom no single legal instrument gives effect to European Council Directive 96/29/Euratom but several Acts and Regulations together, plus administrative arrangements, achieve implementation. The main implementing legislation came into effect in 1999 and 2000.

The principal pieces of legislation are:

- the Ionising Radiations Regulations 1999 (IRR99) and Approved Code of Practice;
- the Ionising Radiations Regulations (Northern Ireland) 2000;
- the Radiation (Emergency Preparedness and Public Information) Regulations 2001;
- the Justification of Practices Involving Ionising Radiation Regulations 2004;
- the Nuclear Installations Act 1965;
- the Medicines Act 1968;
- the Medicines (Administration of Radioactive Substances) Regulations 1968 and associated Regulations and Orders;
- the Radioactive Substances Act 1993 and associated Regulations and Orders;
- the Food Safety Act 1990;
- the Environment Act 1995;
- the Food and Environment Protection Act 1985;
- the Air Navigation Order 2000.

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

N/A

2 Justification principle

The justification aspects of the European Council Directive 96/29/Euratom were implemented by the Department of Environment, Food and Rural Affairs's Justification of Practices Involving Ionising Radiation Regulations 2004.

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

Justification of new classes or types of practice

4. (1) A class or type of practice is "new" for the purposes of these Regulations if no practice in that class or type was carried out in the United Kingdom before 13th May 2000, and neither has the class or type of practice been found to be justified.

(2) In these Regulations, "justified" in relation a class or type of practice means justified by its economic, social or other benefits in relation to the health detriment it may cause.

(3) A "justification decision" for the purposes of these Regulations is a decision which -

(a) is made by the Justifying Authority in the form specified in regulation 14, and which determines whether a class or type of practice is justified; and

(b) in regulation 5(3) or 7, or for the purpose of determining whether a class or type of practice has been justified for the purpose of regulation 4(5), applies to the part of the United Kingdom in which it is proposed that the practice in question be carried out.

(4) A class or type of practice is "found to be justified" for the purposes of these Regulations if a justification decision has been made determining that it is justified.

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

Addition of radioactive substances to personal ornaments, toys or cosmetics

20. (1) No person shall -

(a) knowingly or recklessly add any radioactive substance in the production of personal ornaments or toys; or

(b) knowingly or recklessly import or export any personal ornament, toy or cosmetic to which any radioactive substance has been added in its production.

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

Justifying Authority

6. (1) In these Regulations, "the Justifying Authority" means such of the following persons as may exercise a function under these Regulations -

(a) the Secretary of State;

(b) the Scottish Ministers;

(c) a Northern Ireland department;

(d) the National Assembly for Wales.

Consultation

18. (1) Before making a justification decision, a determination under regulation 12 or serving a contravention notice under regulation 22, the Justifying Authority or Secretary of State (as the case may be) -

(a) shall consult -

(i) the Health and Safety Executive;

(ii) the Food Standards Agency;

(iii) the National Radiological Protection Board; and

(iv) where the class or type of practice involves a radioactive substance, the Environment Agency, the Scottish Environment Protection Agency and the Department of the Environment for Northern Ireland;

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 Ionising Radiations Regulations 1999

Regulation 8

(1) Every radiation employer shall, in relation to any work with ionising radiation that he undertakes, take all necessary steps to restrict so far as is reasonably practicable the extent to which his employees and other persons are exposed to ionising radiation.

(2) Without prejudice to the generality of paragraph (1), a radiation employer shall-

(a) so far as reasonably practicable achieve the restriction of exposure to ionising radiation required under that paragraph by means of engineering controls and design features and in addition by the provision and use of safety features and warning devices; and

(b) in addition to sub-paragraph (a) above, provide such systems of work as will, so far as is reasonably practicable, restrict the exposure to ionising radiation of employees and other persons; and

(c) in addition to sub-paragraphs (a) and (b) above, where it is reasonably practicable to further restrict exposure to ionising radiation by means of personal protective equipment, provide employees or other persons with adequate and suitable personal protective equipment (including respiratory protective equipment) unless the use of personal protective equipment of a particular kind is not appropriate having regard to the nature of the work or the circumstances of the particular case.

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 Ionising Radiations Regulations 1999 Approved code of practice* states:

Dose sharing should not be used as a primary means of keeping exposures below the dose limits. Rather, the radiation employer should give priority to improving engineering controls and adopting other means of restricting exposure, including changing the methods of work. However, if a choice has to be made between restricting doses to individuals and restricting doses to a group of persons, priority should be given to keeping individual doses as far below dose limits as reasonably practicable.

Radiation employers should take particular steps to restrict the exposure of any employees who would not normally be exposed to ionising radiation in the course of their work. The dose control measures should make it unlikely that such persons would receive an effective dose greater than 1 millisievert per year or an equivalent dose which exceeds that specified as a dose limit for any other person in The Ionising Radiations Regulations 1999: Schedule 4.

* In the UK, a Code of Practice approved by the Health and Safety Commission, with the consent of the Secretary of State, has a special legal status. It gives practical advice on how to comply with the law and an employer who follows the advice will be doing enough to comply with the law (in respect of those specific matters on which the Code gives advice). Employers may use alternative methods to comply with the law but, in that case, if they are prosecuted they will need to show that those other methods achieved the necessary compliance.

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

Further guidance is available in addition to the Approved Code of Practice mentioned in 2. This includes advice to accompany the legal requirement for optimisation in 1. above.

Both the Approved Code of Practice and guidance are published (together with the regulations in Work with ionising radiation HSC Approved Code of Practice (ACOP) and guidance in support of IRR99. ISBN 0 7176 1746 7 reference L121 HSE Books.

4 Dose limits

1. *Can you provide us with present regulatory dose limits established to reduce the probability of occurrence of stochastic effects?*
2. *What are the legal dose limits to prevent public and workers from deterministic health effects?*

The limit on effective dose, in the Ionising Radiations Regulations 1999, for any employee aged 18 years of age or above is 20 mSv in any calendar year. However, the Regulations recognise that there may be some cases where, because of the special nature of the work undertaken by an employee, it may not be practicable to comply with this annual dose limit. This situation may arise where there are skilled tasks that need to be undertaken by key specialist staff, including foreign nationals. Where the employer can demonstrate that this is the case, the employer may apply the special dose limit of 100 mSv in five years (and no more than 50 mSv in any single year) to a named employee. The choice of the five-year dose limit for any particular employee is subject to a number of preconditions (set out in Part 2 of Schedule 4 of the Regulations). These include:

- consultation with the radiation protection adviser (qualified expert) and with the affected employee(s) (and any appointed safety representatives);
- provision of information to the affected employee(s) and the approved dosimetry service; and
- giving prior notice to the Health and Safety Executive (HSE), which may (subject to appeal) over-ride the employer's decision and require the employer to revert to annual dose limitation for that employee.

Further conditions are imposed once the five-year dose limit has been applied to an employee, including:

- investigation of any suspected exposures exceeding 20 mSv in a calendar year and notify HSE (to check that the five-year dose limit will still be met);
- need to review whether five-year dose limit if still appropriate at least once every five years;
- restrictions on reversion to an annual dose limit for that employee; and
- recording and retention of the reasons for the five-year dose limit.

Ionising Radiations Regulations 1999: Regulation 11:Schedule 4

Part I Classes of persons to whom dose limits apply

Employees of 18 years of age or above

1 For the purposes of regulation 11(1), the limit on effective dose for any employee of 18 years or above shall be 20 mSv in any calendar year.

2 Without prejudice to paragraph 1 -

(a) the limit on equivalent dose for the lens of the eye shall be 150 mSv in a calendar year;

(b) the limit on equivalent dose for the skin shall be 500 mSv in a calendar year as applied 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 shall be 500 mSv in a calendar year.

Trainees aged under 18 years

3 For the purposes of regulation 11(1), the limit on effective dose for any trainee under 18 years of age shall be 6 mSv in any calendar year.

4 Without prejudice to paragraph 3 -

(a) the limit on equivalent dose for the lens of the eye shall be 50 mSv in a calendar year;

(b) the limit on equivalent dose for the skin shall be 150 mSv in a calendar year as applied 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 shall be 150 mSv in a calendar year.

Women of reproductive capacity

5 Without prejudice to paragraphs 1 and 3, the limit on equivalent dose for the abdomen of a woman of reproductive capacity who is at work, being the equivalent dose from external radiation resulting from exposure to ionising radiation averaged throughout the abdomen, shall be 13 mSv in any consecutive period of three months.

Other persons

6 Subject to paragraph 7, for the purposes of regulation 11(1) the limit on effective dose for any person other than an employee or trainee, including any person below the age of 16, shall be 1 mSv in any calendar year.

7 Paragraph 6 shall not apply in relation to any person (not being a comforter or carer) who may be exposed to ionising radiation resulting from the medical exposure of another and in such a case the limit on effective dose for any such person shall be 5 mSv in any period of 5 consecutive calendar years.

8 Without prejudice to paragraphs 6 and 7 -

(a) the limit on equivalent dose for the lens of the eye shall be 15 mSv in any calendar year;

(b) the limit on equivalent dose for the skin shall be 50 mSv in any calendar year averaged over any 1 cm^2 area regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles shall be 50 mSv in a calendar year.

Part II

9 For the purposes of regulation 11(2), the limit on effective dose for employees of 18 years or above shall be 100 mSv in any period of five consecutive calendar years subject to a maximum effective dose of 50 mSv in any single calendar year.

10 Without prejudice to paragraph 9 -

(a) the limit on equivalent dose for the lens of the eye shall be 150 mSv in a calendar year;

(b) the limit on equivalent dose for the skin shall be 500 mSv in a calendar year as applied 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 shall be 500 mSv in a calendar year.

11 Without prejudice to paragraph 9, the limit on equivalent dose for the abdomen of a woman of reproductive capacity who is at work, being the equivalent dose from external radiation resulting from exposure to ionising radiation averaged throughout the abdomen, shall be 13 mSv in any consecutive period of three months.

12 The employer shall ensure that any employee in respect of whom regulation 11(2) applies is not exposed to ionising radiation to an extent that any dose limit specified in paragraphs 9 to 11 is exceeded.

13 An employer shall not put into effect a system of dose limitation in pursuance of regulation 11(2) unless -

(a) the radiation protection adviser and any employees who are affected have been consulted;

(b) any employees affected and the approved dosimetry service have been informed in writing of the decision and of the reasons for that decision; and

(c) notice has been given to the Executive at least 28 days (or such shorter period as the Executive may allow) before the decision is put into effect giving the reasons for the decision.

14 Where there is reasonable cause to believe that any employee has been exposed to an effective dose greater than 20 mSv in any calendar year, the employer shall, as soon as is practicable -

(a) undertake an investigation into the circumstances of the exposure for the purpose of determining whether the dose limit referred to in paragraph 9 is likely to be complied with; and

(b) notify the Executive of that suspected exposure.

15 An employer shall review the decision to put into effect a system of dose limitation pursuant to regulation 11(2) at appropriate intervals and in any event not less than once every five years.

16 Where as a result of a review undertaken pursuant to paragraph 15 an employer proposes to revert to a system of annual dose limitation pursuant to regulation 11(1), the provisions of paragraph 13 shall apply as if the reference in that paragraph to regulation 11(2) was a reference to regulation 11(1).

17 Where an employer puts into effect a system of dose limitation in pursuance of regulation 11(2), he shall record the reasons for that decision and shall ensure that the record is preserved for a period of 50 years from the date of its making.

18 In any case where -

(a) the dose limits specified in paragraph 9 are being applied by a radiation employer in respect of an employee; and

(b) the Executive is not satisfied that it is impracticable for that employee to be subject to the dose limit specified in paragraph 1 of Part I of this schedule,

the Executive may require the employer to apply the dose limit specified in paragraph 1 of Part I with effect from such time as the Executive may consider appropriate having regard to the interests of the employee concerned.

19 In any case where, as a result of a review undertaken pursuant to paragraph 15, an employer proposes to revert to an annual dose limitation pursuant to regulation 11(2), the Executive may require the employer to defer the implementation of that decision to such time as the Executive may consider appropriate having regard to the interests of the employee concerned.

20 Any person who is aggrieved by the decision of the Executive taken pursuant to paragraphs 18 or 19 may appeal to the Secretary of State.

21 Sub-sections (2) to (6) of section 44 of the 1974 Act shall apply for the purposes of paragraph 20 as they apply to an appeal under section 44(1) of that Act.

22 The Health and Safety Licensing Appeals (Hearings Procedure) Rules 1974,[(a)] as respects England and Wales, and the Health and Safety Licensing Appeals (Hearing Procedure) (Scotland) Rules 1974[(b)], as respects Scotland, shall apply to an appeal under paragraph 20 as they apply to an appeal under sub-section (1) of the said section 44, but with the modification that references to a licensing authority are to be read as references to the Executive.

(a) SI 1974/2040.

(b) SI 1974/2068.

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.*

Ionising Radiations Regulations 1999
Regulation 8.3
Where it is appropriate to do so at the planning stage of radiation protection, dose constraints shall be used 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?*

HSE has encouraged plant operators in the nuclear industry to use the concept of dose constraints on a number of occasions where plant modifications or new projects have been introduced. This has been captured in their documentation. In these instances a dose constraint is a tool to be used to help employers reduce exposure during the planning stage i.e. if a new job is being started then the employer should have the design intent (constraint) in his mind. As work progresses then assuming that all the engineered and management controls are in place this would be the dose constraint against which progress would be monitored.

The Ionising Radiations Regulations 1999 Approved code of practice states that It should always be appropriate to use dose constraints in restricting exposure for comforters and carers.

'Comforters and carers' are defined as 'individuals who (other than as part of their occupation) knowingly and willingly incur an exposure to ionising radiation in the support and comfort of another person who is undergoing, or who has undergone, a medical exposure'. That is, they will normally be relatives or friends of the patient; they are not health-care employees.

They may include members of the public who, for example:

(a) visit patients in hospital after those patients have been administered with radiopharmaceuticals (most notably for therapeutic purposes) or have undergone brachytherapy;
(b) offer support for those patients at home after they have been discharged from hospital; or
(c) (in some cases) offer support to a young child or disabled person while that child or person receives a diagnostic X-ray examination;

and are likely to receive 1 millisievert or more in a year resulting from direct radiation or contamination during the comfort and support they offer.

As comforters and carers are not subject to dose limits, the dose constraint is important as a means of helping to plan general arrangements for restricting any unnecessary exposure of such people.

3. *What are the corresponding values and rationales behind these values?*
4. *What is(are) the status(es) of dose constraint(s)?*

Dose constraints are triggered levels, chosen by operators

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

This is dependent on the reasons for the constraint being exceeded – for example in some cases the radiation employer may decide it is acceptable for doses to exceed the constraint where other health and safety risks have to be taken into account.