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

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1. Introduction

Ten years after the issuing of the European Basic Safety Standards for the protection of the health of workers and the general public from the dangers arising from ionizing radiation (the so-called EURATOM Directive 96/29 [1]), the European ALARA Network has considered that it would be useful to make a specific survey in order to evaluate the dissemination of the justification, limitation, and optimisation principles through Europe. A questionnaire was thus prepared by the EAN Newsletter Editorial Board and sent to all EAN (18 countries) and RECAN (22 countries) national contact persons.

Such a survey was first undertaken in 2001 and its results were published in the ALARA Newsletter issue no9 [2]. However, at that time, it was mainly limited to EAN Member countries. Since then, the enlargement of the EU has led to several new implementations of both European Directives 96/29 and 97/43 that were directly inspired by ICRP 60 Recommendations (the latter, which comes into force at the same date, lays down principles for the protection of individuals in relation to medical exposures). In addition, the questionnaire was sent to some non-Member States which are using the IAEA Basic Safety Standards for Radiation Protection [1996] that are also based on the Recommendations made by ICRP in 1990.

The answers to the questionnaire received from about 25 countries are presented and discussed in this paper.

2. Implementation of European Directives 96/29 and 97/43

The survey shows that all 25 EU countries have partially or fully implemented into national regulations both European Directives 96/29 and 97/43. However, in some countries (e.g. Sweden, Estonia, Slovak Republic, Ireland, etc) certain requirements will be implemented in 2006/2007: they concern very specific topics such as the protection of individuals from the danger of ionizing radiations from Naturally Occurring Radioactive Materials (NORM) or, the protection of aircraft crews or, the establishment of reference levels of exposures for some medical devices. But in a more general sense and as far as the well known three fundamental principles of radiological protection are concerned (i.e. justification of practices and interventions, limitation of individual doses and, optimisation of individual and collective exposures ALARA), the survey has confirmed that they are now adopted everywhere in the European Union. In non EU-member countries, the radiological protection legislation is fully in compliance with the European Directives, even if these countries are not obliged to enact them into their national regulations (e.g. Switzerland, Norway). This is also the case for the two acceding countries Romania and Bulgaria (see **Table 1**).

In Croatia (candidate country to the EU), both Directives were enacted in a Law promulgated this year (due to be adopted when the questionnaire was sent). In Macedonia (candidate country), a complete implementation is expected by the end of May 2007.

In Armenia, the process of implementation of the European legislation has just started, but, at that time, ICRP and IAEA recommendations are partially implemented for non-nuclear sources in the industrial and medical sectors. Regulations on radiation protection in Kazakhstan, in Georgia, and in Serbia explicitly refer to IAEA BSS [4] and/or ICRP 60 [5].

3. Principle of Justification

The concept of justification (of a practice) has been one of the key principles of radiation protection established by the International Commission on Radiological Protection for many decades. The principle is quite simple in

essence as it means that any practice involving exposures to radiation should not be adopted (licensed) unless it produces sufficient benefit to the exposed individuals or the society to offset the detriment it causes, and that any intervention with the purpose to reduce pre-existing doses also should do more good than harm.

All the responding countries have introduced the principle of justification into their regulations and the differences from one country to another are very small.

It can be indicated that most of the countries state explicitly what has to be put in the balance in order to demonstrate that a practice is justified or not. It is obvious that all considerations - health aspects, social, economical, environmental, scientific, etc. advantages and disadvantages - must enter into account but they are not always all cited in the regulations.

The table hereunder summarizes the exact wording of the justification principle in the national regulations. It can be pointed out that only two countries (Lithuania and Macedonia) underline specifically the environmental aspects, only one the scientific interest (France) and only two (France again, and Belgium) the health benefit that may overweigh disadvantages - which refer in these two cases to the risk or health effects instead of to the health detriment in the other countries - that may be introduced by the acceptance of the practice (i.e the licensing process).

Medical procedures shall also in all countries show a sufficient net benefit weighting the total potential diagnostic or therapeutic benefit it produces, including the direct health benefits to an individual an the benefits to society, against the detriment that the exposure might cause, taking into account the efficacy,

	Which aspects (advantages and disadvantages) have to be taken into account in relation to the health detriment that a practice may cause to be declared by the competent authority as justified ?					
Country	Health	Social	Economical	Environmental	Scientific	"other", "all", or not specifically mentioned
BSS		√	√			√
Armenia		√	√			√
Belgium	√					√
Croatia		√	√			
Czech Republic						√
Denmark						√
Estonia		√	√			√
France	√	√	√		√	
Georgia						√
Germany		√	√			√
Greece		√	√			√
Italy		√	√			
Ireland		√	√			√
Kazakhstan						√
Latvia						√
Lithuania		√	√	√		√
Macedonia		√	√	√		√
Norway						√
Serbia						√
Slovak Republic						√
Spain						√
Sweden						√
United Kingdom		√	√			√

No country has established a complete list of unjustified practices. In Germany and in Norway, there is even no practice explicitly cited as "unjustified" or "forbidden" by Law (however, there is an unofficial list drafted in Germany). Most of the national regulations mention that the addition of radioactive substances to **foodstuff** (food and drinks), **personal ornaments**, **jewellery**[1], **toys** or **cosmetics** (hygiene and beauty products) is forbidden as well as their importation or exportation if any radioactive substance has been added in their production.

Several other forbidden practices or activities are mentioned in a few number of national regulations (which does not mean that they are not forbidden in other countries):

- The addition of radioactive substances to materials that can be put into contact with food or water used for human consumption (e.g. France),
- The addition of radioactive substances to building materials (e.g. France),
- The addition of radioactive substances to animal feed[2] (e.g. Latvia)
- The treatment of medicines with ionising radiation (e.g. Belgium, Croatia), sterilisation of medicines being allowed under certain conditions (e.g. Belgium),
- The use of radioactive substances for lightning rods (e.g. Belgium, Croatia, Serbia, Italy),
- The use of radioactive substances for research purposes (in agriculture, zoo-techniques, and entomology) outside specific authorized locations (e.g. Belgium),
- The use of devices with sources of ionising radiation for shoes sale (e.g. Belgium),
- The fluoroscopy examinations without an image intensification or equivalent techniques (e.g. Ireland),
- The systematic X-ray screening of young people under 16 (e.g. Serbia),
- The systematic mammography screening (e.g. Serbia),
- etc

The competent bodies who are in charge of delivering the authorisation of a practice (licensing) that may lead to public or occupational exposures are almost everywhere the Ministry of Health and the independent regulatory authority in charge of the Radiological Protection and/or Nuclear Safety, in a binomial association or, one or the other, alone. (see table hereafter).

Country	**Which regulatory body(ies) is(are) responsible for determining if a practice is justified or not?**
Armenia	The Armenian Nuclear Regulatory Authority in consultation with The Ethical Committee of the Ministry of Health
Belgium	The Federal Agency – AFCN - in consultation with a Scientific Counsel of experts and/or The Health Council and/or The Council for Prevention and Protection at the Workplace
Croatia	The Ministry of Health and State Office for Radiation Protection
Czech Republic	The State Office for Nuclear Safety or - for medical practices - The Department of Health with an approval provided by The State Office for Nuclear Safety
Denmark	The Danish National Institute for Radiation Hygiene – NIRH
Estonia	The Estonian Ministry of the Environment - within the limits of its competence - through The Environmental Inspectorate and The Estonian Radiation Protection Centre
France	The Nuclear Safety Agency – DGSNR
Georgia	The Nuclear and radiation Safety Service of The Ministry of Environment Protection & natural Resources
Germany	The Ministry of Environment, Nature Conservation and Nuclear Safety in co-operation with competent authorities of Länder (regions)
Greece	The Greek Atomic Energy Commission - EEAE - and The Committee of the Ministry of Health for medical practices

(…)

[1] Tolerance levels (in terms of dose and dose rates) do exist in Belgium for the addition of radioactive substances for making precious and semi-precious stones and pearls.

[2] It is not clear that the generic word "foodstuff" always includes animal feed.

Country	**Which regulatory body(ies) is(are) responsible to determine if a practice is justified or not?**
Ireland	The Radiological Protection Institute of Ireland – RPII
Italy	The Ministry of Health
Kazakhstan	State sanitary & epidemiological services
Latvia	The Radiation Safety Centre
Lithuania	The Radiation Protection Centre
Macedonia	The Radiation Safety Directorate of Republic of Macedonia
Norway	The Norwegian Radiation Protection Authority – NRPA
Serbia	The Ministry of Science and Environmental Protection
Slovak Republic	The Public Health Authority
Spain	A competent authority - depending on the practice to be licensed - with the binding report of The Nuclear Safety Council – CSN
Sweden	The Swedish Radiation Protection Authority – SSI
United Kingdom	The Secretary of State / The Scottish Ministers / a Northern Ireland department, or The National Assembly for Wales) in consultation with The Health & Safety Executive - HSE, The Foods Standard Agency - FSA, The National Radiological Protection Board (now The Health Protection Agency - HPA) and/or - in specific cases only - The Environment Agency/The Scottish Environment Protection Agency/the Department of the Environment of Northern Ireland

4. Principle of Optimisation

The "principle of optimisation" which states that individual and collective ***radiation exposures must be kept as low as reasonably achievable (ALARA) social and economical factors being taken into account***, is considered as being of central importance in the control of occupational exposure, especially at workplace. It is now included within all European regulations with almost the same wording.

Germany is still an exception in that domain, where the application of the *minimization principle* (avoidance of unnecessary radiation exposures) seems to remain valid, at least officially: in Germany, it is mandatory "to avoid each unnecessary radiation exposure or contamination" and to "keep radiation exposures or contamination of humans and environment as small underneath the limit values as possible". But, the fact that it has to be done on "a case-by-case basis with considerations to the conditions of science and technology" can be interpreted as an application of the ALARA principle (taking into account other decision-making parameters).

In the medical sector, the implementation of the Directive 97/43 led to a real harmonization of the whole system of protection. Basically, the concept of optimization is now applicable in the medical field with some adjustments in wordings, which depend on the domain of application (radiotherapy, radio-diagnostic, etc). As an example, the Irish regulation stipulates that:

- for medical exposure of individuals for radio-therapeutic purposes, *exposures of target volumes shall be individually planned, taking into account that dose to non-target volumes and tissues shall be ALARA and consistent with the intended radio-therapeutic purpose of the exposure,*

- for medical exposures other than therapeutic procedures, *exposures shall be kept ALARA consistent with obtaining the required diagnostic information, taking into account economic and social factors.*

Diagnostic reference levels for medical examinations are prescribed by Competent Authorities in several countries (e.g. France, Greece). In the medical installations, a periodic prediction of doses and fields of radiation at the workplace is even mandatory in France. This could help to size the effort of protection and to design the needs to perform an adapted dose follow-up of workers in the medical sector.

Most of the European regulations (Armenia, Belgium, Croatia, Estonia, France, Greece, Ireland, Latvia, Serbia, Spain, Slovak Republic, Sweden, UK, etc) propose also practical ways to implement properly the optimisation principle (i.e. - how to perform dose prediction?, - how to set up dose objectives?, - how to perform real-time dose follow-up?, what must be catch in a feedback experience report?, etc). However, the form it takes differs

considerably from one country to another: it can just be a short paragraph within the regulation or, it can be ensured through the publications of big Codes of Practices (e.g. UK)

Other regulations (e.g. Greece, Ireland) enounce that the principle of optimisation shall apply to all practices by laying down general or specific dose constraints (see hereafter) for practices and/or sources.

A few number of countries are using an official value of the acceptable cost of protection, the so-called value of the man.Sv (Czech Republic, Slovak Republic, Kazakhstan).

It is quite uncommon that the regulatory body issues specific additional guidance, aiming at helping operators and end-users to implement the optimisation principle in a practical way. Some national authorities (Armenia, Latvia, Lithuania, Spain, Norway, UK) have published such documents - in mother language - for medical applications, operations in nuclear power plants, and/or specific industrial activities (e.g. industrial gammagraphy).

5. Dose Constraints

The concept of dose constraints, emphasized in the ICRP Publication 60, is currently seen as supporting the optimisation process. This concept will probably be re-emphasized and clarified by ICRP within its next set of recommendations. The questionnaire (see annex) tried to evaluate to what extent the concept was spread in national regulations. The fact that "dose constraint" means a different thing in different contexts has led to heterogeneous answers.

In an occupational exposure context, it is generally considered that constraints should be defined for the purpose of providing an upper bound on the process of optimisation of protection and should therefore be used prospectively. Thus, this level must be understood as the upper value, which shall not be exceeded in normal circumstances of operation, and below which optimization has to be undertaken.

A few countries have introduced the values of occupational dose constraints into their regulations such as Ireland, Belgium, Slovak Republic, and Greece. Most of the European regulations give the possibility to the national regulatory body to set up dose constraints. More often, it is the duty of operators to determine occupational dose constraints. In that case, the constraints are negotiated with and submitted for approval to the national regulatory body, which will often derive from them investigation levels.

In a public exposure context, the dose constraint is rather expressed as a fraction of the regulatory individual dose limit, and attached to a single source of exposures or pathway (e.g. the releases from a nuclear installation). In that case, it is used to guarantee that an individual who would be exposed to several sources, will always receive a total dose below the individual dose limit. This concept is the most frequently used in Europe but the values vary from 10 μSv/y (Greece) to 300 μSv/y. without any understandable rationale!

A third meaning of the "dose constraint" deals with those persons who are not subject to dose limits, e.g. individuals who knowingly and willingly incur an exposure to radiation in the support or comfort of a patient. As they are not health-care employees but could receive doses higher than 1 mSv/y, dose constraints are established for restricting any unnecessary exposure of such people.

Because it is a very rich and complex issue, it has been very difficult to summarize in this paper all answers that have been received from more than 20 countries. **Table 2** does not synthesize all the information received but it shows the huge diversity in the interpretation and uses of the concept of dose constraint within Europe. The whole content of the answers will be quite soon accessible and downloadable from the EAN website (see the conclusion).

6. Limitation of exposures

Today, the regulatory individual limits in terms of public and occupational annual effective doses are very similar everywhere in Europe i.e. 1 mSv/y for general members of the public, and 20 mSv/y for workers. The set of existing limits for minor students, category B workers (6 mSv/y), pregnant women (1 mSv to foetus) are also likely the same through Europe (see **Table 3**). The questionnaire was also addressing dose limits established to guarantee that no deterministic effects will appear after an irradiation or a contamination. There is neither

discrepancy between countries in that domain.

However, small differences can still be observed: the period of reference can be a calendar year, or 12 consecutive months. To be more flexible, several countries have also - or only - adopted a reference period of 5 calendar years (i.e. 5 mSv/5 years for the general public, and 100 mSv/5 years for workers, sometimes with the possibility to observe a higher occupational effective dose - ≤ 50 mSv - one particular year).

Some more original complementary figures can be pointed out in Germany for workers (400 mSv/occupational life) and in Kazakhstan for the general public (70 mSv/70 years).

In the course of unusual/exceptional circumstances or operations - the questionnaire excluded the emergency situations – higher effective doses could be received by workers, with a preliminary authorisation of the competent regulatory body. Here, differences between countries are more obvious, but the occurrence of such an event is very seldom.

7. Conclusion

This new EAN survey shows that a large majority of European countries have now adopted a common framework and compatible regulations as far as radiological risk management in normal circumstances is concerned, even if small differences remain.

The justification principle is systematically included into regulations but, the practices which are definitively unjustified by Law are not often clearly cited, nor are the criteria to be used to justify a continuation of an existing practice, the use of radiation exposures for diagnostic or therapeutic purposes, or an intervention after a radiological accident.

The maximum individual doses for public and, the occupational dose limits are similar everywhere; the small differences that can be observed (e.g. on the reference period taken into account, the way to manage exceptional cases, etc) are not especially significant but could still, potentially, lead to unjustified and time-consuming administrative difficulties, especially in the context of a labour market which is more and more open to a free circulation of goods and workers. A total harmonisation of these dose limits would, therefore, be beneficial.

Nuances of style in the wordings of the optimisation principle (ALARA) exist, but the overall meaning appears consistent. The survey shows clearly that a few countries have explicitly adopted the concept of occupational *dose constraint,* which was especially emphasized by ICRP Publication 60 as an upper bound to support prospectively the optimisation process. It would be of great clarification and help that the different meanings and uses of the concept of dose constraint will be addressed by ICRP within its next set of recommendations. It should probably help a lot towards a greater harmonisation between international regulations in the field of optimisation of radiological protection in the industrial and medical sectors.

The European ALARA Network will publish on its website all questionnaires sent by the national contact persons. Their update will be performed regularly thanks to comments and corrections that EAN will receive on its forum (http://lists.eu-alara.net/mailman/listinfo/ean.forum)*,

***The electronic address to be used for sending comments and corrections is: ean.forum@lists.eu-alara.net**

5.2 Table 1. Status of the Basic Safety Standards in the Regulations of European Countries (March 2006)

Countries	Date of National Laws & Regulations that implement BSS
EC MEMBER STATES	
Austria	10 December **2004** (96/29 & 97/43)
Belgium	20 July **2001** (96/29 & 97/43)
Cyprus	**2002** (96/29 & 97/43)
Czech Republic	12 July **2002** (96/29 & 97/43)
Denmark	31 October 1997 (96/29) 1998-**2000** several Orders (97/43)
Estonia	16 May 1997 (96/29) 1 May **2004** (97/43) to be completed in 2006/2007
Finland	before May **2000** (96/29 & 97/43)
France	28 March 2001 - Order 31 March **2003** - Decree (96/29 & 97/43)
Germany	20 July 2001 (96/29) 24 June **2002** (97/43)
Greece	6 March **2001** (96/29 & 97/43)
Hungary	2000 (96/29) 3 October **2001** (97/43)
Ireland	11 May 2000 (96/29) October **2002** (97/43)
Italy	26 May 2000 (96/29 & 97/43 partially) revised 9 May **2001**
Latvia	5 March 2002 (97/43) 9 April **2002** (96/29)
Lithuania	24 December 1997 revised 21 December **2001** (96/29 & 97/43)
Luxemburg	14 December 2000 (96/29) 6 Juin **2001** (97/43)
Malta	**2003** (96/29)
Poland	28 May 2002 (96/29) 12 March **2004** (97/43)
Portugal	17 July 2002 (96/29) 8 August **2002** (97/43)
Slovak Republic	2000-2001 (96/29 & 97/43, both partially) full implementation expected in June 2006
Slovenia	11 July **2002** (96/29)
Spain	6 July 2001 (96/29) 13 July **2001** (97/43)
Sweden	1998-2000 (96/29, partially) -**2002** (97/43) (complements in 2006: NORMs, aircraft crews)
The Netherlands	16 July **2001** (96/29 & 97/43)
United Kingdom	3 December 1999 (96/29 & 97/43) 13 April **2000** (97/43)
NON EC MEMBER STATES	
Bulgaria	In compliance with EC Directive(s) 24 August 2004 (~ 96/29) &? (~97/43)
Croatia	In compliance with EC Directives (5 March 1999) Definite implementation expected in 2006
Georgia	Regulation refers to IAEA BSS Compliance with EC Directives in progress
Kazakhstan	Regulation refers to IAEA BSS
Macedonia	Regulation refers to IAEA BSS Compliance with EC Directives in progress (expected end of May 2007)
Norway	In compliance with EC Directives 12 May 2000 & 1 February 2001
Romania	In compliance with EC Directives 28 December 2001(~ 96/29) 14 March 2002 (~ 97/43)
Serbia	Draft Law complying with IAEA BSS
Switzerland	In compliance with EC Directives 22 June 1994 (ORaP) revised 1999-2001 20 January 1998 (medical sector) 15 November 2001 (sealed sources in medicine)

Table 2. Examples of use of the concept of dose constraint in national regulations of European countries

Country	Dose constraint for occupational exposures	Dose constraint for public exposures
Armenia	Defined by the operators, and approved by authorities.	0,25 mSv from the releases of a nuclear power plant.
Belgium	Can be imposed by the Agency in the framework of optimisation for every source, practice or task. Set by the Agency in consultation with operators [e.g. 10 mSv/y in NPPs]. Investigation levels, derived from dose constraints, are used to trigger retrospective investigations or inspections.	Is a fraction of the dose limit of the effective public dose limit related to the exposure due to the discharges/releases from the installation only. In the medical field, dose constraints are set out by the Federal Agency in consultation with a Qualified Expert in medical radiation physics.
Croatia	Can be set by the regulatory body.	0,3 mSv from any source within an authorised practice
Czech Republic	Regulations allow authorities to lay down dose constraints, based on feedback experience (best practices). A collective effective dose constraint (4 man.Sv/y.GWe) is set out by authorities, only for NPPs; A lower bound for optimisation also exist: 1 mSv/y	0.25 mSv/y (from total releases at a workplace where radiation activities are performed: 0.2 mSv in the atmosphere + 0.05 mSv in watercourses as an average for the appropriate critical group of the public). For patient doses, guidance levels (diagnostic reference levels) are fixed by regulations. A lower bound for optimisation also exist: 0.05 mSv/y
Denmark	Can be used to force optimisation. For example, in specific uses of ionising radiations, they can be set by the National Board of Health in the planning phase of operations.	Do exist for X-ray examinations, examinations using radioactive isotopes, bio-medical research. (the values are based on best practices) For operation and decommissioning of nuclear facilities, is a reference dose to members of the public - critical group - fixed in the operating license. Limits of releases are derived from the following: 0.05 mSv for each facility, and 0.1 mSv from all facilities.
France	Defined by the operators, agreed by authorities. The authority has also set investigation levels, derived from dose constraints, established in consultation with operators (e.g. NPP).	Required in the medical sector, especially for medico-legal procedures, and medical research, Also required for people helping and relieving patients during their diagnosis and treatment. 0.25 mSv/y (for the licensing of the decommissioning of one nuclear facilities)
Georgia	Do exist for radon exposures	Do exist for radon exposures
Germany		0.3 mSv/y + other constraints for equivalent doses (from releases during planning, operation, decommissioning, dismantling of one plant) [it has the same status as a dose limit]
Greece	*For all approved practices or activities, EEAE shall lay down general dose constraints for the protection of the public and workers. For each source, the radiation protection officer shall lay down a specific dose constraint at the planning stage (with the approval of EEAE).*	
	Specific dose constraints are chosen by operators (with the approval of EEAE)	0.01 mSv/y (due to all releases from any source)

(…) see next page

Ireland	*Dose constraints, generally source-related (or based on a risk assessment study), are set out by RPII for public and occupational exposures. [for existing licensees, it is a condition of their license that all new facilities, including redevelopments, must be designed to meet the dose constraints; demonstration of the constraints respect is required for new licensees]*	
	1 mSv/y (exposed worker)	0.3 mSv/y (all other people)
Italy	*Dose constraints are considered during the analysis prior to the license of a practice in order to ensure the application of the ALARA principle*	
Kazakhstan	*Lower bounds for optimisation (0.01 mSv/y and 1 man.Sv/y) do exist but, not upper bounds.*	
Lithuania	Set by operators	Dose constraints are not applicable for patient exposures (recommended exposure guidance levels shall be followed). 0.2 mSv/y (for the licensing of the operation and decommissioning of one nuclear facilities)
Norway		Radiation shielding and other safety equipments must be designed so as to prevent irradiation of members of the general public to more than 0.25 mSv/y
Romania		0.3 mSv/y (for the licensing of the decommissioning of one nuclear facilities)
Serbia	Investigation criteria do exist (but they are not fixed by Law).	Sources must be shielded so that the most exposed individuals won't receive a dose exceeding 0.3 mSv/y In the medical sector (conventional radiography, mammography, CT, fluoroscopy, etc) 25% (value of surface entrance dose) of the reference levels fixed by regulations.
Slovak Republic	*Fixed by the Public Health Authority, dose constraints can be both source or job-related. They are considered as values above which the radiation protection should not have been properly optimized.*	
Spain	*Reference values of doses exist. If they are exceeded, CSN would trigger specific actions, and penalties could be applied.*	
	In NPP reference values do exist both for public and workers doses (approved by CSN). Do exist for industrial gammagraphy as well.	Will be used for people helping and relieving patients during their diagnosis and treatment, and for medical and bio-medical research programmes.
Sweden	*In the process of planning a practice or in a single case, SSI has the right to establish a dose constraint, by which is meant an exposure restriction to individuals from a given source*	
		Doses received by people helping and relieving patients discharged from hospital after treatment and their relatives are constrained in the range of 1 to 15 mSv/y and, for other members of the public at 0.3 mSv/y. Radiation shielding of a therapy room must be designed with a dose constraint of 0.1 mSv/y for any member of the general public. The effective dose to an individual of one year of releases of radioactive substances to air and water from all activities in the same geographically delimited area shall not exceed 0.1 mSv. (No specific requirement below 0.01 mSv/y)
United Kingdom	HSE has encouraged plant operators in the nuclear industry to use the concept of dose constraints (plant modifications, new projects, etc)	Used for comforters and carers who are likely to receive 1 mSv or more in a year resulting from direct radiation or contamination during the comfort and support they offer to a patient.

Table 3. Individual Public and Occupational Dose Limits in Europe (September 2006)

Countries	Members of Public	"Workers A" and Major Students	"Workers B" and Minor Students	Pregnant Women and Foetus	Workers in exceptional circumstances (excluding emergency situations)
EC EURATOM DIRECTIVE 96/29	1 / year	100 / 5 years & 50 / year	6 / year	1 (fœtus)	-
Austria	1 / year	100 / 5 years & 50 / year	6/ year	1 (fœtus)	
Belgium	1 / year	20 / 12 rolling months	6 / year	1 (fœtus) - whole pregnancy No work in contaminated area	
Czech Republic	1 / year 5 / 5 years*	100 / 5 years & 50 / year	6 / year	1 (fœtus) **	50 / year ("specific circumstances") 500 / 5 years ("unusual events")
Denmark	1 / year	20 / year	6 / year	1 (fœtus) **	-
Estonia	1 / year	100 / 5 years & 50 / year	6 / year	1 (fœtus)	-
Finland	1 / year	100 / 5 years & 50 / year	6 / year	1 (fœtus)	-
France	1 / year	20 / 12 rolling months	6 / 12 roll. months	1 (fœtus) **	40 / operation ("exceptional circumstances", needs authorization)
Germany	1 / year 0.3 / site	20 / year & 400 / lifetime	6 / year	1 (fœtus) **	-
Greece	1 / year	20 / year	6 / year	1 (fœtus) **	Needs authorization 100 / 5 years & 20 / year
Hungary	1 / year	100 / 5 years & 50 / year	6 / year		50 / year (maximum 5 years & specific conditions)
Ireland	1 / 12 rolling months	20 / 12 rolling months	6 / 12 roll. months	1 (fœtus) **	-
Italy	1 / year	20 / year	6 / year	1 – whole pregnancy	20
Latvia	1 / year	20 / year	6 / year	1 / year	Needs special authorization 100 / 5 years & 20 / year
Lithuania	1 / year 5 / 5 years*	100 / 5 years & 50 / year	6 / year	1 (fœtus) **	-
The Netherlands	1 / year 0.1 / source	20 / year	6 / year	unlikely > 1 (woman)**	100 / operation
Slovak Republic	*1 / year*	*100 / 5 years & 50 / year*	*6 / year*	*1 (fœtus)*	-
Slovenia	*1 / year*				
Spain	1 / year 5 / 5 years	100 / 5 years & 50 / year	6 / year	1 (fœtus) & unlikely >1 (woman) **	Case by case (needs CSN approval)
Sweden	1 / year	100 / 5 years & 50 / year	6 / year	1 (fœtus)	Case by case (needs SSI approval)
UK	1 / year	20 / year	6 / year	1 (fœtus) & 13/3 months (abdom. eq. dose) ***	100 / 5 years & 50 / year
International BSS (1994)	1 / year	100 / 5 years & 50 / year	6 / year	-	200 / 10 years & 50 / year (review when over 100) or 50 / year renewable 5 times
Armenia	*5 / 5 years &* *5 / year*	*100 / 5 years & 50 / year*	*¼ of dose limit for cat. A workers*	-	-
Bulgaria		100 / 5 years & 50 / year			
Croatia	*1 / year*	*100 / 5 years & 50 / year*		*1 – whole pregnancy*	
Georgia	*5 / 5 years &* *5 / year*	*100 / 5 years & 50 / year*	*25 / 5 years* *12,5 / year*	-	-
Kazakhstan	5 / 5 years 5 / year & 70 / 70 years	100 / 5 years & 50 / year 1000 / 50 years	-		
Macedonia	*1 / year*	*100 / 5 years & 50 / year*	-	*Not allowed to work*	-
Norway	1 / year	20 / year	6 / year	1 (fœtus) **	100 / 5 years & 50 / year Needs NRPA approval
Poland	*1 /year*	*100 / 5 years & 50 / year*	*6 / year*	*1 (fœtus)*	
Romania	1 / year & 5 / 5 years	20 / year	6 / year	1 (fœtus)	Case by case (needs CNCAN app.)
Serbia	1 / year	100 / 5 years & 50 / year	6 / year		Case by case (needs authorization) Cat. A: 200 / 10 years & 50 / year
Switzerland	1 / year	20 / year	5 / year	2 (abdomen surface) & 1 when incorporated	100 / 5 years & 50 / year

Underlined: situation in 2001 (not updated); * in specific cases; ** for the remainder pregnancy period; *** for women of reproductive capacity;

References

[1] EURATOM 1996/29 • Laying Down Basic Safety Standards for the Protection of the Health of Workers and the General Public from the Dangers Arising from Ionizing Radiation. Council Directive 96/29 Euratom of May 13, 1996. Official Journal of the European Communities, Vol. 39, No. L 159, June 29, 1996

[2] EUROPEAN ALARA NETWORK. • Justification, Optimisation and Dose Limits, the Recent Evolution of National Regulations in the European Countries (as of January 2001). P. Crouail, P. Shaw, C. Lefaure, in- EUROPEAN ALARA Newsletter No 9, March, 2001. (http://www.eu-alara.net/)

[3] EURATOM 1997/43 • Laying down measures on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Council Directive 97/43/Euratom of June 30, 1997. Official Journal of the European Communities No. L180, July 9, 1997.

[4] IAEA • Basic Safety Standard for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No 115. 1996.

[5] ICRP • 1990 Recommendations of the International Commission on Radiological Protection, 60 - Annals of the ICRP, Volume 21/ Nos 1-3, 1991.

ANNEX

EAN QUESTIONNAIRE SENT TO EAN & RECAN NATIONAL CONTACT PERSONS

1 IMPLEMENTATION OF EUROPEAN DIRECTIVES

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

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

2 JUSTIFICATION PRINCIPLE

2.1 What is the exact wording of the justification principle in the Law?

2.2 Which practices are explicitly named as unjustified or forbidden?

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

3 OPTIMISATION PRINCIPLE

3.1 Could you give is the exact wording (citation) of the optimisation principle (ALARA) as defined in the Law or national regulation?

3.2 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)?

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

4 LIMITATION OF EXPOSURES

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

4.1.1 public dose limits
4.1.2 occupational dose limits,
4.1.3 interim workers dose limits,
4.1.4 pregnant women dose limits,
4.1.5 post-accidental intervention dose limits,
4.1.6 life dose limit (if any)
4.1.7 other dose limit (if any)

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

5. DOSE CONSTRAINTS

5.1 Here again, could you give is the exact wording (citation) of the Law or regulations where the concept of dose constraint is mentioned.

5.3 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?

5.4 *What are the corresponding values and rationales behind these values*

5.5 What is(are) the status(es) of dose constraint(s)?

5.6 What is effectively done if a constraint is exceeded?