

Synthesis of reflections and conclusions of the SFRP-IRPA seminar on the reasonableness in the practical implementation of the ALARA principle

Thierry SCHNEIDER, Jean-François LECOMTE, Caroline SCHIEBER, Sylvain ANDRESZ, Valérie CHAMBRETTE, Bernard LE GUEN, Ludovic VAILLANT

Context and Objective

For almost two years, the International Radiological Protection Association (IRPA) has been engaged in reflection on the implementation of the radiological protection system and its evolution. In this context, the French Society for Radiological Protection (SFRP) proposed to organize a seminar on the practical implementation of the optimisation approach held in Paris last February.

The principle of optimisation of radiological protection, known as ALARA (as low as reasonably achievable), is now the corner stone of the radiological protection system as defined by the International Commission on Radiological Protection (ICRP) in its Publication 103. In practice, its implementation is based on the search for a level of protection judged to be "reasonable" for a given exposure situation, taking into account economic and societal factors. The demonstration that exposures are as low as reasonably achievable is sometimes not sufficiently objectified and rarely made visible. Beyond the development of procedures such as multi-criteria analysis or cost-benefit analysis based on the adoption of monetary reference values of the person-sievert, the experience of implementing the optimisation principle shows that the "search for reasonableness" and the associated negotiating processes could be further discussed and shared at the national and international level with the various stakeholders.

The objective of this workshop was to initiate a discussion on the foundations of the optimisation principle and to share experience feedback on its implementation in three areas: the nuclear sector (particularly for occupational exposures), the medical sector and some existing exposure situations (exposure to radon, management of radium contaminated sites and management of post-accident situations).

The following paragraphs summarize the discussions and conclusions of the workshop. The oral presentations given to initiate the discussions are available on the SFRP website¹.

The principle of optimisation and the issues associated with its implementation

Introduced in the 1970s in ICRP Publications 22 and 26, the optimisation principle was initially based on the use of a cost-benefit analysis to judge the "reasonable" nature of protection actions: "... *a reduction in collective dose can be compared directly with the detriment or cost of achieving this reduction.*" (ICRP Pub. 22, §18). This led to the adoption of reference monetary values of the person-sievert, particularly in the nuclear industry, for occupational exposures, but also for the management of public exposures.

Since cost-benefit analysis doesn't capture the various factors involved in the decision-making process, multi-criteria approaches were developed and the model of risk tolerability was adopted in the Recommendations of ICRP in the early 1990s (Publication 60). This model, applicable to practices (now the planned exposure situations), determines areas in which the exposure situation is deemed to be

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tolerable or unacceptable depending on the level of individual exposure and the efforts granted in order to achieve a level of risk reasonably "acceptable". In this context, stakeholder involvement has gradually emerged as a key issue in the decision-making processes.

In order to judge the reasonableness of an exposure situation, ICRP further described the optimisation approach in its Publication 101 by introducing a set of criteria, taking into account economic, ethical and societal considerations and promoting the stakeholder involvement process for implementing the evaluation and decision-making processes. Publication 103, by confirming the optimisation principle as being the cornerstone of the radiological protection system, has also strengthened the role of stakeholder involvement in the search for "reasonableness".

More recently, the ICRP's reflections on the ethical foundations of the radiological protection system (document currently under consultation on the ICRP website) led to the conclusion that *"applying the principles of radiological protection (justification, optimisation and limitation) is a permanent quest for decisions that do more good than harm (beneficence/non-maleficence), that avoid unnecessary risk (prudence), that establish a fair distribution of exposures (justice) and treat people with respect (dignity)"*. The optimisation principle is seen, on the one hand, as *"a principle of action, which allows the practical implementation of prudence"*. On the other hand, *"it also allows the introduction of equity, or fairness in the distribution of exposures among people exposed which refers directly to the ethical value of justice. Ultimately, taking into consideration the particular circumstances in which people are exposed as well as their concerns and expectations, the principle of optimisation respects people and treats them with dignity"*. Finally, it is interesting to note that the glossary of this document proposes a definition of *"Reasonableness"*: *"To make rational, informed and impartial decisions that respect other views, goals, and conflicting interests"*.

In this context, IRPA launched a survey among the radiation protection societies in 2016 to gather views on the practical implementation of the radiological protection system. The results of this survey were presented for the first time at the International Congress of Radiation Protection in Cape Town in May 2016. The survey shows that the system is sometimes (even often?) complex and difficult to explain to non-specialists. It also appeared that it is not always easy to identify the reasons behind the adoption of a decision on protective measures. This calls for a greater visibility of the decision-making processes on the notion of "reasonable". Finally, a permanent question was reported: "How low is low enough?".

ALARA in the nuclear sector

In the nuclear sector, there has been a significant reduction of the occupational collective dose as well as a decrease of individual exposures since ICRP Publication 60. These results are mainly due to a structured implementation of the ALARA principle, the use of individual dose constraints in the optimisation process and a large contribution of feedback experience analysis to guide protection actions. However, it has to be stressed that while the mean individual occupational dose is rather low, there is a variable dose distribution depending on the specialty of the workers, which requires particular vigilance in the implementation of the optimisation process. In this sector, the use of cost-benefit analysis has been developed in the 1980s and 1990s as a decision-aiding tool for the selection of protection actions, especially when major investments have to be considered, usually associated with multi-criteria analysis for the final decision.

However, in an economic environment evolving to more difficulties, the continuation of the implementation of the ALARA approach for occupational exposures raises questions, such as:

- What are the optimisation margins for occupational exposures in normal operation of installations?
- How to implement a holistic / multi-risk and graded approach?
- What criteria should be used in assessing the reasonableness of protection investments, taking equity consideration into account?
- How to take into account potential risk transfer between workers (from different specialties) or between public and workers (when managing effluents for example)?

These various questions show that the search for "reasonableness" is still under discussion. In particular, it appears that the point of view of operators and regulators may vary on this topic and it would be necessary to reinforce the dialogue between these actors in order to set and share the evaluation criteria used in the implementation of the optimisation process.

The specific issue of the management of radioactive discharges was also raised by the workshop participants: in most situations, it seems that the objectives of the implemented processes refer more to minimization than to optimisation. Furthermore, it appears also complex to take into account the political and environmental considerations adopted at both national and international levels. In this field, what is usually required in the use of the "best available technologies" and the question of the link between this approach and the search for "reasonableness" can be raised.

Finally, the participants agreed that education and training as well as awareness-raising amongst stakeholders and the dissemination of the radiological protection culture must be strengthened in order to allow both effective protection and informed participation of the various stakeholders in the assessment and decision-making processes concerning protection measures in the nuclear sector.

ALARA in the medical sector

In the medical sector, the primary goal of healthcare professionals is to improve the quality of diagnostic and medical treatment. However, it can be noted that the ICRP Publication 105, published in 2007, reinforced the need to implement optimisation of radiological protection for both patients and staff. In this Publication, and the followings dedicated to specific use of radiations in the medical field, ICRP reminds that for patient exposures, the expression 'as low as reasonably achievable' (ALARA) is only part of the concept of optimisation and that the entire concept implies, more precisely, keeping patient exposure to the minimum necessary to achieve the required medical objective (diagnostic or therapeutic). That means that in some cases, patient doses need to be increased for the clinical outcome.

In practice, the approach to reduce or maintain individual doses as low as reasonably achievable is more often applied in diagnostic/interventional radiology than in radiotherapy or nuclear medicine. There is often a focus on the justification of the medical act, sometimes confounded with optimisation.

The implementation of optimisation is a shared responsibility, involving not only the health professionals using radiations (surgeon, clinicians, radiologists...), the medical physicists or the radiographers, but also hospital managers who can play a key role to in setting the necessary organisation facilitating the implementation of the optimisation process taking into account budgetary constraints, and the equipment manufacturers.

The participants of the workshop underlined a difference in behaviour and/or radiological protection culture between, on the one hand, "prescribing" doctors, generally not very aware of radiological protection issues and, on the other hand, specialist doctors involved in diagnostic or therapeutic acts,

more aware/trained in radiological protection. Concerning health workers who work directly with patients, they are sometimes unaware of / trained to radiological protection.

With regard to patients, it has been noticed that their direct involvement in the optimisation process is not so easy, due notably to their lack of knowledge regarding radiological protection issues. In some few cases, patients are represented by patient associations, but generally focused on protection against medical incidents. However, the obligation laid down in the new European Directive to inform patients about the dose received should help to raise their awareness, the main concern being then to avoid raising fear of radiations. For this purpose, the development of the information and the dissemination of the radiological protection culture with patients, health professionals and families is a key issue. The participants noticed that, for health professionals, the sharing of experience through the implementation of internal audits, are considered as effective vectors for spreading radiological protection culture.

Among the remaining questions to be further studied, the participants of the workshop highlighted the challenges facing new technologies. While some of them, notably in diagnostic/interventional radiology, allow a reduction of patient/staff doses, others, in particular in radiotherapy, may give rise to new types of incidents/accidents. For all these new technologies, there is a need to involve the relevant stakeholders (from manufacturers to end-users) to better control these technologies in a view to optimise protection and avoid incidents. The reinforcement of radiological protection education and training in Medicine should also contribute to enhance progress in the implementation of optimisation of radiological protection for both patients and staff.

It can be noticed that, as in the nuclear sector, the coordination with regulators was highlighted as necessary to assess the implementation of ALARA.

Lastly, in relation to the forthcoming Publication of the ICRP on the ethical foundation of the radiological protection system, the participants initiated reflections on the links between some principles and procedures associated with the medical use of radiations (informed consent, justification, inequity in patient dose distributions, etc.) and some ethical considerations (beneficence/non maleficence, prudence, justice, dignity). These should be further developed in the future.

ALARA in existing exposure situations

Concerning existing exposure situations, it was first stressed that these situations were characterized by the fact that there was little or no control or capacity to intervene on the source, that there was a need to characterize the exposure situation before deciding to act and that there was an ability to intervene on the transfer routes and on the exposure pathways and habits. Moreover, for these situations, the persons directly exposed often play a key role in the implementation of protection actions and sometimes in the decision-making processes.

Very often, the approach put more emphasis on quality of life than on exposure levels (especially in the case of radon exposure and post-accident management). Similarly, the important role of ethical and societal considerations in the management of these situations was emphasized.

In this context where exposures already exist before any decision on protection action is taken, the optimisation approach is an iterative and generally long process aimed at gradually improving the situation. There is an acknowledgment that reaching zero risk is generally not achievable (for example, for environmental decontamination programmes after an accident or reduction of radon concentration

in dwellings). The question then arises: what exposure level or contamination level is considered reasonable or sufficiently low? Here again the question arises of the competition between optimisation and minimisation approaches.

The practical implementation of the optimisation approach depends largely on the prevailing circumstances and the local context. During the workshop, two issues were particularly discussed for the implementation of the optimisation approach in these situations: the role of the reference level and the importance of the stakeholder involvement process with the associated development of the radiological protection culture.

Role of reference level:

The choice of the values adopted for the reference levels constitutes a real challenge. There is a need for guidelines and proposed values to define this reference level (very often, a focus on 1 mSv/year is adopted for public exposure in these situations). However, the reference level is very often considered by the various stakeholders as a limit value. Moreover, in setting these levels, there is the need not to treat individuals as "second zone" people and the reference to normal or planned exposure situations seems to be inevitable. Since then, it seems important to promote the establishment of a deliberative process and to increase transparency in the choice of values and selection of protection actions. While it is not central in setting the reference levels, health risk calculation is a sensitive issue that needs to be addressed in a comprehensible manner and avoiding the use of conservative exposure assessments that may induce bias in the dialogue with stakeholders.

Stakeholder involvement and radiological protection culture:

The experiences discussed during the workshop show that members of the public have difficulty in understanding the radiological protection system, the meaning of reference levels, and more generally the health risks associated with low-dose exposures. This reinforces the need to develop the radiological protection culture among the different stakeholders with a focus on actions and the specific context at the local level. In this perspective, local professionals, such as health professionals, education staff, construction professionals..., have a key role to play. Finally, the importance of developing the conditions for social trust, in particular through enhanced transparency of decision-making processes and stakeholder involvement, was stressed.

As for the other sectors and perhaps more significantly, the multi-risk approach seems to be predominant in existing exposure situations, with the need for developing a graded approach tailored to each specific context. In this context, if putting radiological exposure situations into perspective with other risks seems to be useful to better cope with the specific situation, it has been stressed the need to use it with precaution. The question of the transfer of risk between workers of different specialities or between the public and workers or between different populations or between generations is to be considered in these exposure situations, but remains to be further addressed and was not really dealt with in the experiences presented during the workshop.

Conclusions / perspectives

This workshop is a first step in the reflection on the implementation of the principle of optimisation. Besides addressing specific exposure situations (such as radioactive waste management, public exposure associated with discharges of nuclear installations or hospitals, emergency exposures, ALARA in non-ionising radiation...), the perspectives identified for the different exposure situations are as follows:

- Continue the analysis of the criteria adopted to assess the reasonableness of the protection

- actions;
- Share feedback experience on the identification of the characteristics of each exposure situation, the risk assessment approaches, the decision-making processes, etc.;
- Initiate a reflection on the implementation and the role of ethical and societal considerations for the various exposure situations;
- Analyse the modalities for the practical implementation of a "graded approach";
- Further analyse the component and the role of the radiological protection culture as well as the modalities for its development among the stakeholders;
- Deepen the feedback experience and draw recommendations on the organisation of dialogue in the identification of the reasonable level of protection between the different stakeholders (authorities, operators, experts, public, patients, workers, etc.).

References

- Workshop presentations:
<http://www.sfrp.asso.fr/manifestations/manifestations/irpa-workshop-on-reasonableness-in-the-implementation-on-the-alara-principle-.html,9,38,0,0,2823>
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- ICRP, 2013. Radiological Protection in Paediatric Diagnostic and Interventional Radiology , ICRP Publication 121. Ann. ICRP 42 (2).
- ICRP, 2017. Draft Report for Consultation: Ethical Foundations of the System of Radiological Protection: <http://www.icrp.org/page.asp?id=348>
- European Commission: COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

Participants for SFRP-IRPA seminar on the reasonableness in the practical implementation of the ALARA principle: 23-24 February, 2017

Name	First name	Organism
ALLISY	Pénélope	EUTERP, EFOMP and IPEM
ANDRESZ	Sylvain	SFRP (France)
BAR-DEROMA	Raquel	ISRP (Israël)
BILLARAND	Yann	SFRP (France)
BRYANT	Pete	SRP (UK)
CANTONE	Marie-Claire	AIRP (Italy) & IRPA
CHAMBRETTE	Valérie	SFRP (France)
CHO	Kunwoo	KARP (Korea) & ICRP
COATES	Roger	SRP (UK) & IRPA
COLE	Pete	SRP (UK)
CROFT	John	SRP (UK)
CZARWINSKI	Renate	FS (Germany-Swiss)
GALLEGO	Edouardo	SEPR (Spain) & IRPA & ICRP
HARDEMAN	Frank	ABR (Germany)
HOMMA	Toshimitsu	ICRP
JANSSEN-PINKSE	Linda	NVS (Netherlands)
KAI	Michiaki	JHPS (Japan) & ICRP
LAZO	Edward	OECD Nuclear Energy Agency
LE GUEN	Bernard	SFRP (France) & IRPA
LECOMTE	Jean-François	SFRP (France) & ICRP
LEIJEN	Carolien	NVS (Netherlands)
LOCHARD	Jacques	ICRP
MUNDLER	Olivier	SFMN (France)
MURITH	Christophe	FS (Germany-Swiss)
SCHIEBER	Caroline	SFRP (France)
SCHNEIDER	Thierry	SFRP (France)
SHAH	Bikina	World Nuclear Association
VAILLANT	Ludovic	SFRP (France)
VAN DEVENTER	Tahera Emilie	WHO
VANO	Eliseo	SEPR (Spain) & ICRP
VERMEERSCH	Fernand	European ALARA Network
VUILLEZ	Jean-Philippe	SFMN (France)



IRPA workshop on reasonableness in the implementation of the ALARA principle



23-24 February, 2017

**Conservatoire National des Arts et
Métiers (CNAM), Paris**



Context

The principle of optimisation of radiation protection, also known as ALARA is the cornerstone of the radiological protection system. In practice, its implementation is to search for a given exposure situation, what is the reasonable level of protection taking into account economic and societal factors.

The demonstration that actual exposures are ALARA is in many cases not sufficient, objectified or made visible. In some cases, the use of cost-benefit analysis associated with the use of reference monetary values of person-sievert remains confidential, even if it is in some cases used to guide investment decisions in the nuclear industry.

Rather than trying to develop tools or to adopt numerical values, experience shows that the quest for reasonableness would benefit to be further discussed and shared, both at the national and international levels, with the various stakeholders. In particular, the implementation of the optimisation process should take into consideration more explicitly societal and ethical considerations.

The proposed workshop aims to review the current practices in implementing ALARA and particularly to question the respective roles of decision-aiding techniques and stakeholders in establishing reasonable levels of protection. The aim is also to initiate a reflection on ethical and societal values that underpin the concept of reasonableness.

Programme

Thursday, 23 February 2017 (Morning)	Time
• Welcome and Registration : Salon d'honneur (room 37-1-50) • Welcoming address Thierry Schneider (President of French Society for Radiological Protection)	08:30 - 09:00 09:00 - 09:10
Plenary session (1/3) - Salon d'honneur (room 37-1-50)	
• Introduction of the workshop Thierry Schneider (SFRP) • Feedback from IRPA consultation of affiliated societies Roger Coates (IRPA) • Considerations on the concept of reasonableness in the ICRP system and ethical issues Kunwoo Cho (KARP)	09:10 - 09:30 09:30 - 09:50 09:50 - 10:10
Discussion	10:10 - 10:30
Coffee break	10:30 - 11:00
Plenary session (2/3) - Salon d'honneur (room 37-1-50)	
• Methodologies for the implementation of the ALARA principle: ALARA in practice Fernand Vermeersch & Caroline Schieber (European ALARA Network) • Implementing ALARA in the nuclear sector Bernard Le Guen (SFRP & IRPA) • Implementing ALARA in the medical sector Eliseo Vañó (SEPR)	11:00 - 11:20 11:20 - 11:40 11:40 - 12:00
Discussion	12:00 - 12:30
Lunch	12:30 - 13:30

Reasonableness in the implementation of the ALARA principle

Thursday, 23 February 2017 (Afternoon)		Time
Plenary session (3/3) - Salon d'honneur (room 37-1-50)		
Implementing ALARA in existing exposure situations (radon and legacy sites) Christophe Murith (FS)		13:30 - 13:50
Implementing ALARA in existing exposure situations (post-accidental situation) Michiaki Kai (JHPS)		13:50 - 14:10
Approaches addressing the integration of different risks Pete Bryant (SRP)		14:10 - 14:30
Discussion		14:30 - 15:00
Coffee break		15:00 - 15:30
Working group session		
- Working group N°1 on implementing ALARA in the nuclear sector Chair: Eduardo Gallego (SEPR & IRPA) Secretariat: Ludovic Vaillant (SFRP) - Working group N°2 on implementing ALARA in the medical sector Chair: Marie-Claire Cantone (AIRP & IRPA) Secretariat: Caroline Schieber (SFRP) - Working group N°3 on implementing ALARA in existing exposure situations Chair: Jean-François Lecomte (SFRP) Secretariat: Sylvain Andresz (SFRP)		15:30 - 17:00
Visit of the Conservatoire National des Arts et Métiers Museum (optional)		17:30 - 19:00
Dinner (Procope Restaurant)		20:00 - 22:00

Friday, 24 February 2017 (Morning)		Time
Working group session and preparation of the report		
- Working group N°1 on implementing ALARA in the nuclear sector Chair: Eduardo Gallego (SEPR & IRPA) Secretariat: Ludovic Vaillant (SFRP) - Working group N°2 on implementing ALARA in the medical sector Chair: Marie-Claire Cantone (AIRP & IRPA) Secretariat: Caroline Schieber (SFRP) - Working group N°3 on implementing ALARA in existing exposure situations Chair: Jean-François Lecomte (SFRP) Secretariat: Sylvain Andresz (SFRP)		09:00 – 10:30
Coffee break		10:30 - 11:00
Plenary session- Salon d'honneur (room 37-1-50)		
Report of the working groups and general discussion		11:00 - 13:00
Closure of the workshop		13:00 - 13:15



Programme committee – corresponding members

- Marie Claire Cantone (AIRP & IRPA – Italy)
- Kunwoo Cho (KARP – Korea)
- Chris Clement (ICRP & IRPA)
- Roger Coates (IRPA)
- John Croft (SRP – UK)
- Eduardo Gallego (SEPR & IRPA – Spain)
- Klaus Henrichs (FS & IRPA – Germany)
- Michiaki Kai (JHPS – Japan)
- Ted Lazo (CRPPH-NEA)
- Bernard Le Guen (SFRP & IRPA - France)
- Jacques Lochard (ICRP)
- Christophe Murith (FS – Switzerland – Germany)
- Thierry Schneider (SFRP – France)
- Fernand Vermeersch (European ALARA Network)

Organising committee (SFRP-France)

Thierry Schneider
Bernard Le Guen
Catherine Luccioni

Jean-François Lecomte
Valerie Chambrette

