

SFRP-IRPA workshops
on the reasonableness in the practical implementation of the ALARA principle

Summary

1. Introduction

Two workshops were organised at the initiative of SFRP within the framework of the IRPA on the practical implementation of the principle of optimisation of radiological protection (i.e. ALARA principle). This initiative was launched following a request from the IRPA related to the evolution of the radiological protection system. The two workshops were held in Paris in February 2017 and October 2018 respectively. They each gathered about thirty participants from several countries and international organisations (IRPA, ICRP, NEA, WHO, EAN).

The objective of the 1st workshop was to share feedback experience of the current ALARA approach in different sectors (nuclear, medical, radon, contaminated sites, post-accident situations) and more specifically to challenge the role of the tools helping the decision-making process, the stakeholder involvement as well as the ethical and societal values that allow for a reasonable end to the optimisation process.

In the nuclear sector, the collective doses of workers have been significantly reduced since the implementation of ICRP 60 (1990), but vigilance is still necessary to cope with the disparities in the distribution of individual doses as well as with a more difficult economic situation. Vis-à-vis the public, there is a tendency to minimisation of the impact (discharges) instead of optimisation of radiological protection, in a context of increasing societal and environmental considerations.

In the medical sector, the primary objective of exposure is the quality of diagnosis or treatment and it should be achievable by further optimising exposures of patients, and in some cases of health professionals. Emphasis is placed on the justification of the medical act with a shared responsibility of the prescriber and the practitioner. The continuous evolution of technologies on the one hand, and the involvement of patients and stakeholders on the other hand, remain key challenges.

In situations involving radium (contaminated sites) or radon, or in post-accident situations, the control of exposure is made rather on the pathway than on the source, the individual behaviours may affect the level of exposure and the quality of life may be more at stake than the dose. The result of the optimisation process depends on the actual situation, and taking into account societal and ethical considerations is crucial.

In all sectors, the optimisation remains a challenge. Experience shows that it is implemented through a deliberative process to achieve a reasonable compromise with all informed parties. A summary of this 1st seminar was published in the journal "Radioprotection" [1].

After this first round, there was a wish to go further. A second workshop was organised on October 2018 in Paris, focused on practical cases. Three series of cases studies were presented, respectively related to the same sectors explored during the first workshop:

nuclear industry, medical practices and existing exposure situations. They intend to illustrate how the search for reasonableness can be done involving stakeholders.

2. Case-studies in the 3 sectors: nuclear, medical and existing exposure situations

In the nuclear sector, the French operator EDF and one of its subcontractors Comex/ONET presented together the building of an efficient relationship between them, with strong interfaces. This has led to a continuous reduction of the radiological exposure received for the replacement of the heating system of pressurizer in the French Nuclear Power Plants (NPPs). In this sector, dialogue and engagement are often formalised within contracts, written procedures and ALARA programmes that engage the hierarchy from bottom to top. This was also illustrated in the Spanish presentation related to the mobilisation of all concerned personnel to improve dosimetric performances in the NPP of Cofrentes. The third case-study was related to the UK experience in the implementation in the UK nuclear sector of the ALARP concept (As Low As Reasonably Practicable) developed more generally for all hazards. It showed, with several examples, how non-prescriptive regulation can set the tone in the quest for reasonableness and how, in some cases, conservatism may lead to the minimisation of the exposure instead of adaptation of optimised solutions. Finally, it also called for improving the dialogue and understanding of radiation risk between operators and regulators.

In the medical sector, two successful collaborative processes to optimise doses due to medical imaging were presented. The first was related to a dedicated team of multi-disciplinary experts traveling from hospital to hospital in the Province of Quebec (Canada) to outreach radiological protection (RP) culture also lead to global dosimetric improvement. The second one showed how in Greece, thanks to the involvement of the whole staff in the CT department of the public hospital of Konstantopoulos, a more accurate strategy was elaborated for effectively improving the implementation of the optimisation process. The questions on how to assess the involvement of individual (e.g. practitioners) in ALARA and how to ensure the sustainability of such involvement remain however unsolved. Also in the medical field, where dose reduction is achieved with the help of concrete tools and technique, an algorithm to optimise image in aortic CT angiography by balancing the noise and the exposure was presented by the Italian representatives. It was reported that emulation between manufacturers drives the design of devices contributing to reduce exposure.

In existing exposure situations, ethical and societal considerations are the most at stake because local stakeholders (i.e. members of the public, professionals, health authorities etc.), generally not aware of radioactivity and radiological protection, are the key stakeholders and even decision-makers in the optimisation process. In such situations, this process is done on a case-by-case basis, depending on the circumstances. The first case-study was about the radium action plan to manage the radiological legacy of the Swiss watch industry. Traces of radium were found in dwellings of former employees working at home. The selection of the reference level was a key point to determine the magnitude of the remediation, with the regulatory authority successfully taking the lead. The training of remediation workers was also crucial. The second case-study was related to the challenges in the Czech Republic to reach a better matching between the radon national action plan and the energy saving policy in order to achieve a better indoor air quality in dwellings and

buildings with public interest. Within the third case-study, the Belgian RP authorities presented their approach to setting a reasonable criterion for the management of drinking water, making a better compromise between protection of consumer and cost, and ensuring societal confidence in the control of water. For these different situations, four key questions that shape the dialogue between RP experts and the local stakeholders could be identified:

- The numerical values (of exposure) and their meaning(s);
- The importance of economic factors;
- The ownership of both the responsibilities and the leadership in the process; and
- The link of the radiation protection initiatives with the overall quality of life, taking into account societal and ethical considerations.

A specific case-study related to non-ionizing radiation (NIR) showed the difficulties in implementing the optimisation principle in a context of diversity of NIR sources, uncertainty about their effects, high sensitivity of some people to radiation and controversy around leukaemia clusters.

3. Discussion about reasonableness

Three working groups (WGs) were formed to further investigate the issue of implementing optimisation process with the involvement of stakeholders. At the end of the discussion, the three of them were in agreement with the conclusions of the first workshop and the following additional points were emphasized.

3.1. In nuclear sector

The WG on the nuclear sector advocated a holistic approach to optimising hazards as a whole, not just the dose, in a process of continuous improvement. Such approach should find a balance between the different hazards, by relying on multi-expertise teams (experts on conventional, environmental and radiological risks). The focus on the radiological risk may indeed lead, in some cases, to inequities in protection by focusing on the risk of radiation compared to other hazards. Adequate guidelines are needed for the evaluation and the management of the risk in a multi-hazards context.

For the protection of workers, the proof of the application of ALARA is based on the implementation of good practices agreed at the international level. A cost-benefit analysis and the use of multi-criteria tools can help present a reasoned argument, in particular at low doses, for why further reduction in dose is not ALARA. The application of ALARA also includes the need for established teams of experts, procedures and meetings as well as the development of a RP culture at all levels. All types of personnel should be involved: hierarchy, inside and outside-workers, and also authorities... Education and training is needed, even for the regulator. Feedback experience, from both the operator and the subcontractors is useful. Sharing responsibilities between the operator and the subcontractors is not obvious and a clear partnership should be established. The commitment of the operator is essential. The concept of “intelligent customer” introduced by the IAEA can be useful: the operator has responsibilities in embedding RP culture throughout the whole subcontracting chain. ALARA should also be implemented using a graded approach commensurate with the level of the risk.

Public perception of radiation risk and nuclear power is more critical since Fukushima. For public exposure, proving that there is no risk can be very expensive. Such consideration is important when setting dose criteria for public exposure. They also can depend on the context (country, exposure situation). Authorities require the application of the best available techniques (BAT) at all stages. This has resulted in a systematic minimisation of the sources, discharges and waste beyond ALARA, while NPPs are already designed and operated in order to produce extremely low releases, which can be considered as ALARA. In some cases, the good balance between public protection and worker's protection may require trade-off (e.g. when the reactor containment needs to be vented to provide better working conditions inside).

3.2. In medical sector

In the medical sector, according to the corresponding WG, the key elements to achieve reasonableness are education, training and development of RP culture. It is not always easy, however, to involve the patient. Work with patient associations may be useful. The concept ALADA (As Low As Diagnostically Achievable) in the use of the equipment (search of the optimised image) was encouraged until a proper balance between a cost-benefit analysis and the quality management system demonstrates that new equipment is needed. Occupational exposures in medical sector are generally low except for some practices (e.g. interventional surgery or radio-pharmacy). In some cases, the application of the dose limit to the lens of the eye may be a challenge. Multidisciplinary and equitable approaches were also recommended. A focus on medical ethics has also been emphasized for medical training.

Several suggestions were also made to IRPA in order to improve the dissemination of knowledge:

- Creation of a dedicated page on the IRPA website with links with the websites of other organisations (WHO, IAEA/RPOP, IOMP, ICRP/C3);
- Translation and promotion of guidelines;
- Elaboration and dissemination of pedagogic leaflets notably for patients;
- Promotion of specific physician's training;
- Making of lectures in medical conferences presenting case-studies;
- Making articles in scientific journals showing efforts and improvements...

3.3. In existing exposure situations

As pointed out by the corresponding WG, the scope of existing exposure situations is diverse and some are controversial situations (e.g. contaminated sites). Whatever the case, the WG emphasized the need to reach a kind of acceptance of the situation by the public and hence the importance of organising the dialogue. There is in most of the cases an underlying fear of radiation by the public. That fear is generally stronger toward anthropogenic sources (including radium used for its radioactive purpose) than toward natural ones (e.g. radon).

Messages should be clear and straightforward. The situation may evolve and that should be explained to better anticipate the evolution. The role of authorities is crucial to establish or restore confidence. Sometimes an empowerment of the stakeholders is needed, i.e. provide them sufficient skills to be able to take informed decisions. It is particularly needed when

people are involved in their own protection (self-help protection), e.g. against radon exposure or in post-accident situations. For the last ones, information and preparation in “peace time” can be helpful when the crisis arises.

In case of pollution, there is no “acceptable” level of radiation: from the point of view of members of the public, the radioactivity is unwelcomed and should be deleted. However, zero risk does not exist and the total clean-up of the site is often unfeasible. The quantitative approach is favoured by experts, while sometimes the public better understands qualitative or comparative arguments. Experience shows that it may be preferable to organise a deliberation reaching an agreement on what is reasonable. Comparison with other risks may be helpful but it can also be tricky. For instance, when the situation is controversial, such comparison may be seen as a banalisation of the radiological risk.

Thresholds are often wrongly seen as a border between safe and dangerous. The value of 1 mSv/y is used as reference level in many cases for public exposure while it is the low end of the range recommended by ICRP for existing exposure situations (1-20 mSv/y). Such value is a reference level but in practice it is rather used as an action level. It is expressed in effective dose while that concept is not meant to reflect individual risk.

In existing exposure situations, what is at stake is to achieve or recover a good quality of life. The optimisation principle may then be called ALAQA (As Low As Qualitatively Achievable). It can be achieved using a flexible approach. Authorities should be clear about what the ground rules are: what they will do or will not do, what resources are available and how they will be allocated. It was finally pointed out that in this approach the question of who pays is crucial.

3.4. Other considerations

The workshop discussions were focussed around the different sectors - nuclear, medical and existing exposures as above. Whilst it is clear that there are real lessons for each individual sector, none the less there are several important common themes emerging which are worthy of further interest.

There are particular similarities between the occupational (including nuclear) exposure and medical exposure situations. Here the employees are broadly knowledgeable about radiation, and the key aspects of the ALARA process are very strongly aligned with the key attributes of a (radiation) safety culture, and as such are likely to be more embedded within the organisation:

- Engaging with all parties involved in the exposure;
- Appropriate education and training;
- Maintaining a work environment allowing openness and challenge;
- Learning and sharing from experiences;
- Strong commitment of the management;
- An integrated management system to provide a framework for consideration of ALARA.

In addition there is a recognition of the need to focus on the higher exposure situations (on both individual and collective dose considerations), where necessary giving specific focussed attention to these key areas (e.g. major engineering interventions in a nuclear facility, CT and therapy doses in medical exposure).

On the other hand, where 'the public' is central to the ALARA processes the dynamics can be very different, in particular when the presence of the radioactive source is disturbing or controversial. In such cases, the principal interested parties are unlikely to have a good understanding of radiation (at least at the start of any process), and often the situations take place in a 'high stress' environment with a lack of trust between the parties. There needs to be much more focus on the **process** of working together, including moving towards an enhanced and shared understanding of radiation risk and radiation environment, within the context of other risks and concerns associated with the situation. There is a growing experience of stakeholder engagement which can serve to successfully address these challenges. Indeed, in some situations where longer term ongoing action is necessary, there is evidence that working together to develop a 'societal RP culture' can be very helpful.

However, in some public exposure situations, including for example environmental discharge considerations, there is evidence of an emphasis on minimisation rather than true optimisation. There is concern that the concept of 'reasonableness' has been lost or not considered helpful in the decision-making process, with a reluctance to give any meaningful weight to economic factors and an over-emphasis on 'as low as' rather than 'reasonable'.

The workshops have shown a growing recognition of the need to consider wider 'value for money' considerations for society. The need for a debate, including how to ensure a balance between the ethical values of dignity (ensuring stakeholder engagement), prudence (ensuring appropriate safety) and beneficence (broadly interpreted as ensuring best use of resources for society) is becoming recognised. It is interesting to note that previous considerations of Cost Benefit Analysis, with an 'alpha value' defining the monetary value of a manSv, were aimed to address this factor. Whilst CBA can still play a role, experience has shown that it is not usually a dominant input to the overall judgement of what is 'reasonable'. Delivering a broader approach including the objective of reasonable value for money is still a challenge.

There is a wide acceptance that optimisation of exposure is a **process** requiring judgement, and that there is no single formula leading to an outcome. There are some proposals suggesting that there should be minimum thresholds, below which there would be no requirement for consideration of optimisation. This approach is not currently widely supported, with most believing that we should always be trying to be 'reasonable', and indeed be seen to be 'reasonable'. However, there is a widespread concern over what seems like a trend to delivering 'ever lower doses'. There needs to be a wider acceptance from all interested parties that there should be a focus on the higher doses, whilst ensuring a proportionate consideration of less significant exposures. For the lower occupational and medical exposures this should focus on developing and supporting an effective safety culture across all hazards. For public exposures there is no substitute for careful and empathetic engagement with all relevant stakeholders, but which also recognises the need for appropriate allocation of society's resources.

4. Conclusions / perspectives

The second workshop confirmed the conclusion of the first one on the basis of practical case-studies: in all sectors, the optimisation remains a challenge and experience shows that it is implemented through a deliberative process to achieve a reasonable compromise with all informed parties. Each case is a particular case.

In the light of the reflections carried out within the three WGs, it seems possible to interpret the "R" of the acronym ALARA, i.e. the term *reasonable*, in a more dedicated way according to the situation. In the nuclear sector, where reasonableness is notably a matter of good balance between the protection against several hazards, R may be H as Holistically. In the medical sector, where the capability to carry out the good image for a proper diagnosis is still a challenge for the optimisation of patient exposure, the R of ALARA may be D as diagnostically. In existing exposure situations such as radon exposure, legacy sites or post-accident situations, the R may be Q as Qualitatively in order to illustrate the importance to maintain or recover a decent quality of life for all individuals in the prevailing circumstances. However, whilst such interpretations may be helpful in some specific situations, they cannot replace the concept of *reasonableness* which is the common driving factor in all situations.

It emerges from the reflexions during the two workshops that, in complement of the use of classical tools such as cost-benefit analysis, the implementation of the optimisation principle implies a clear identification of the challenges to be met to achieve the best protection in the prevailing circumstances. These challenges may be specific to a type of exposure situations and in some cases to a given situation. The process should also well identify the relevant stakeholders and decision-makers to be involved in the optimisation process, and determine how they will be involved. A proactive process including development of awareness, empowerment and/or training may be needed. This reflexion deserves to be further developed.

The summary of the two workshops is intended to be disseminated throughout IRPA societies. It is planned to write a new article in the journal of the French society (SFRP) "Radioprotection" and to present an oral communication at the IRPA 15 congress in Seoul in 2020. In addition, a workshop on the issue of reasonableness gathering the main international organisations in charge of radiological protection (ICRP, IAEA, WHO, NEA...) is envisaged in Paris in the next months.

Reference

[1] T. Schneider, J.-F. Lecomte, C. Schieber, S. Andresz, V. Chambrette, B. Le Guen and L. Vaillant, Synthesis of reflections and conclusions of the SFRP-IRPA workshop on the reasonableness in the practical implementation of the ALARA principle, *Radioprotection* (2017), 52 (4), 259-263.