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Reflections on the Radiation Protection System

The present publication contains an article on the tolerability of low individual exposures. The reflections are made in the light of a possible future evolution of the ICRP recommendations. The issue will be addressed at the next scientific meeting of the Belgian Society for Radiation Protection, planned for 8th December 2023.

A second article summarises the principle of optimisation of the radiation protection. It is published in follow-up of a scientific meeting on ALARA in June 2022.

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Reflections on the Radiation Protection System

CONTENT

Reflections on the tolerability of low doses

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Abstract

The paper reflects on different issues with regard to the tolerability of low levels of exposure. These include the fundamental differences between occupational and public exposures, the control of discharges of effluent to the environment and the interpretation of the dose criterion for exemption and clearance and its ethical basis. It is advocated to reconsider the third principle of the radiation protection system, introducing a single "level of tolerability" of individual exposures, across all exposure situations and categories of exposure. The application of dose limits is regarded a mere regulatory instrument, to be applied to any occupational exposures, rather not to public exposures. The further use of a dose criterion of the order of 1 mSv/y in a range of situations is discussed in the light of ethics, in particular the principles of Beneficence (Justification) and Dignity.

Keywords: principles, ethics, dose limitation, exposure situations, exemption, clearance

Preamble

This paper does not address the still ongoing discussion on the health risk at low doses. The author remains convinced that the application of the paradigm of a linear response of stochastic radiation effects with dose, without threshold, remains the only way to build a simple, robust, and cautious system of protection. The present discussion on low doses is approached from the ethical point of view, on the basis of ICRP Publication 138 [1], and offers a new way of looking into dose limits for public exposures, and into very low doses such as may result from the application of the concepts of exemption and clearance. The aim is to simplify the general ICRP recommendations and to make these more coherent with the international basic safety standards [2] with regard to the definition of exposure situations.

This reformulation of the general principles of the radiation protection system may resolve the old problem with the perception of dose limits for stochastic effects, in particular the limit applicable to members of the public. Indeed any limit is generally understood to point at an unbearable risk, that should not be exceeded in any circumstances. It will be seen as the borderline between “safe” and “unsafe”. Of course the wording in the radiation protection system developed over a long time-span by ICRP is much more subtle than everyday language. Radiation protection experts will most likely fail to convey their more proper understanding to laymen, however. Such confusion is detrimental in emergency exposure situations, as well as in a number of existing exposure situations. The main focus of the paper is nevertheless on planned exposure situations, in particular on public exposures resulting from practices, but has implications in all exposure situations.

Tolerability

Quoting from Publication 138 [1]: “(64) The concept of tolerability is present from the early publications of the Commission (ICRP, 1959). In Publication 60, a conceptual framework was introduced which allows one to determine the degree of tolerability of an exposure (or of the associated radiation risk), and thus, depending on the category of exposure (public or occupational), to distinguish between unacceptable and tolerable levels of exposure (ICRP, 1991)”.

Publication 60 [3] in addition introduced the concept of "acceptable level":

> *"(150) The Commission has found it useful to use three words to indicate the degree of tolerability of an exposure (or risk). They are necessarily subjective in character and must be interpreted in relation to the type and source of the exposure under consideration. The first word is "unacceptable", which is used to indicate that the exposure would, in the Commission's view, not be acceptable on any reasonable basis in the normal operation of any practice of which the use was a matter of choice. ... Exposures that are not unacceptable are then subdivided into those that are "tolerable", meaning that they are not welcome but can reasonably be tolerated, and "acceptable", meaning that they can be accepted without further improvement i.e. <u>when the protection has been optimised</u>. In this framework, a dose limit represents a selected boundary in the region between "unacceptable" and "tolerable" for ... the control of practices."*

So already at an early stage the concept of tolerability was linked to that of "dose limits", hence to the third fundamental principle of radiation protection.

Fundamental principles of radiation protection

The present radiological protection system encompasses three fundamental principles to achieve its objectives [1]:

- "The principle of **justification**, which states that any decision that alters the exposure situation should do more good than harm. This means that by introducing a new radiation source in planned exposure situations, … one should achieve sufficient benefit to offset any costs or negative consequences. …
- The principle of **optimisation**, which stipulates that all exposures should be kept as low as reasonably achievable, taking into account economic and societal factors. It is a source-related process, aimed at achieving the best level of protection under the prevailing circumstances … . This principle is the cornerstone of the system of protection. Furthermore, in order to avoid inequitable distributions of individual exposures, the

Commission recommends restricting doses to individuals and nonhuman biota from a particular source.

- The principle of **limitation**, which declares that individual exposures should not exceed the dose limits recommended by the Commission. It applies only to planned exposure situations, other than medical exposure of patients or exposure of non-human biota."

The above formulation of the third principle in Publication 138 is not convincing, one might say it is rather tautological. It offers no ethical basis for the limitation of exposures. A more profound statement on the concept of tolerability is made only later in the text, in the already quoted paragraph (64), that continues as:

> *"... and thus, depending on the category of exposure (public or occupational), to distinguish between unacceptable and tolerable levels of exposure (ICRP, 1991). In Publication 103, tolerability is referred to specifically in each type of exposure situation, taking into account not only the radiation risk associated with exposure (and the related value of non-maleficence), but also the practicality of reducing or preventing the exposure (prudence and beneficence), the benefits from the exposure situation to individuals and society (beneficence and justice), and other societal criteria (justice and dignity) (ICRP, 2007a)."*

Prevailing circumstances

As stated above, ICRP considers the concept of tolerability to depend on the type of exposure situation, i.e. the same "prevailing circumstances" introduced in the principle of Optimisation. In order to understand this, one needs to look into ICRP's further discussion of two roles of "Protection criteria" [1] :

> *"(54) <u>First</u>, radiological protection criteria aim to reduce inequities in the distribution of individual exposures in situations where some individuals could be subject to much more exposure than others. This restriction of individual exposures is done through the use of dose constraints that apply to planned exposure situations [and] reference levels that apply to existing and emergency exposure situations ... . Dose constraints [and] reference levels ... are integral parts of the*

optimisation process, and thus must be chosen depending on the prevailing circumstances by those responsible for protection."

"(55) The second role of protection criteria is to ensure that exposures do not exceed the values beyond which the associated risk is considered as not tolerable given a particular context. This is ensured through the application of dose limits recommended by the Commission for the protection of workers and the public in planned exposure situations. As with dose constraints and reference levels, dose limits are tools to restrict individual exposure in order to ensure fairness in the distribution of risks across the exposed group of individuals."

In my view it is superfluous to put dose limits (par. 55) in the same basket as dose constraints (par. 54). While constraints relate to specific circumstances, , the concept of tolerability does not, hence there is an opportunity for a unified approach, not depending on any circumstances.

Equal rights

ICRP further argues [1]:

"(56) Thus, through the protection criteria, the system of radiological protection aims to ensure that the distribution of individual exposures meets two principles of distributive justice. First, the principle of equity reflects the personal circumstances in which individuals are involved. It is the role of dose constraints and reference levels to reduce the range of exposure to individuals subject to the same exposure situation. Secondly, the principle of equal rights guarantees equal treatment for all individuals belonging to the same category of exposure in planned exposure situations. It is the role of dose limits to ensure that all members of the public, and all occupationally exposed workers, do not exceed the level of risk deemed tolerable by society and recognised in law."

It is not quite clear from the above quotes what might be the fundamental distinction between constraints and dose limits, except that the latter is more readily transposed in law. In my view legal enforcement is not within the remit of ICRP but of international standards and national legislation. The current radiation protection system is sound, and its voluntary implementation by stakeholders would ensure adequate protection. Still, even with a sound and clear system of protection, radiation protection also needs to be regulated [4]. Annual dose limits are in fact nothing but a regulatory tool for the enforcement of a level of tolerability.

Dose limits

Of course, the translation of any level of tolerability into dose limits needs to be put in context. In medical exposures, single individuals are at stake and the tolerability of their exposure is put in balance to the medical benefit of the examination or treatment. This is generally considered a matter of Justification, the first principle, applied at three levels down to the individual exposure. Indeed no dose limits are set on medical exposures. For occupational exposures, while the exposure of workers results from their work, they also derive a benefit, not from exposure but from their employment. A ceiling on tolerable exposures could correspond to a level of risk beyond which this benefit would not justify the exposure.

For public exposures there is no similar benefit. This argument, together with other characteristics of public exposure [5], prompted the dose limit for public exposures to be much lower than for occupational exposures, initially by an order of magnitude, then further down to the round figure of 1 mSv per year [6].

In my view, this rationale for lower dose limits for public exposures mixes up the concepts of “justification of exposures” and “justification of practices”: a practice that gives rise to significant exposures to a large number of people, without corresponding benefit, would indeed not be justified. For example, the optimised control of releases of radioactive substances to the environment actually gives rise to very low doses to members of the public. This confirms the merit of setting discharge limits, as part of the discharge authorisation and licensing of e.g. a nuclear installation. The process protecting members of the public is driven by the principles of Justification and Optimisation, not by dose limits.

It may be concluded that dose limits for public exposures are superfluous. The absence of dose limits for members of the public removes any obstacle to setting the same level of tolerability, as a boundary between exposures that are "tolerable" and "unacceptable", for public exposures as for occupational exposures, and to applying the concept indistinctly in all exposure situations. In this way one solves, or avoids, quite a few recurrent problems resulting from the perception that, if there is a dose limit, then it applies across all exposure situations: it is almost impossible to apply a dose limit of 1 mSv/y to natural radiation sources; in an emergency exposure situation any intervention to reach this level would not be achieved at a reasonable cost and would cause un unjustifiable burden to the individual, including risks much higher than the risk of radiation exposure.

Fairness

Looking back in the quoted paragraph (54), the concept of Justice is principally defined as "fairness in the distribution of advantages and disadvantages among groups of people" (distributive justice) [1]. Equity is the quality of being fair and impartial. It is the role of reference levels and dose constraints to reduce the range of individual exposures, for individuals subject to the same exposure situation.

For workers, dose constraints ensure that there is an equitable distribution of the risk among workforces. The idea of distributive justice in occupational exposures is clear: the optimisation of protection measures may favour an option conferring high doses to some individuals (e.g. itinerant specialists) while reducing the overall collective dose. This option may be the right choice if the overall reduction is significant, but for the individuals with the highest exposures it may not be sufficient that the dose limit is complied with, it may be fair to set a constraint well below the limit.

Similarly, in the management of an emergency exposure situation it is appropriate to set a reference level so as to ensure that no one is left out. This reference level should be part of emergency preparedness, and set a benchmark for the actual decision making in the event of an emergency. In an existing exposure situation a reference level gives priority to measures that reduce the exposure of the most affected individuals.

In public exposures resulting from a regulated practice however, the distribution of the "disadvantage" of radiation exposure among the affected population does not really matter. From a health perspective, at doses well below 1 mSv/y there is no point arguing why one individual is more exposed than another one. One may then wonder whether "distributive justice" is truly an issue.

In my view the ethical basis for keeping exposures down to a very low level of dose is not a matter Justice, of equity or inequity. A constraint may, for example, prompt a reduction of discharges of radioactive effluent, but the shape of the distribution remains very much the same. Hence constraints on public exposures may define generic expectation values in optimisation, they may reflect fairness to the population in relation to the benefit for the operator[1], but they are not a matter of equity within the affected population group.

Quiescence

The level of 1 mSv/y has nevertheless proven to be a useful threshold for other purposes. It is also the boundary for categorising workers as "exposed worker" [7]. Workers who are not classified as "exposed workers" bear no personal responsibility for their exposure (apart from not entering controlled areas). In contrast "exposed workers" ought to be informed of radiation risks, receive adequate training in the operation of radiation sources and in radiation protection, their exposures is assessed (either individually or on the basis of workplace monitoring) etc. Exposed workers are meant to be in charge of their own protection, by keeping a distance to the source while standing in its proximity for the shortest time possible, by manipulating sources safely etc. None of these protection measures are legally required for "non-exposed" workers, even though nothing precludes an enterprise to extend certain measures, e.g. information and training, also to this category.

Broadly speaking however, "non-exposed" workers are dealt with in the same way as members of the public, who are not expected to adjust their behaviour to the situation either, at least in a planned exposure situation. This status of comfort, of serenity, is for now labelled as "quiescence", pending a possible better term translating the French "quiétude" (restfulness).

[1] and for the population as a whole, considering the production of electricity or of radioisotopes for nuclear medicine.

Inversely, with regard to members of the public, a planned exposure situation in which environmental levels of exposure would be so high that in order to keep exposures below 1 mSv/y they would be instructed to adjust their behaviour (not eating certain food, avoiding certain areas etc.), would definitely not be acceptable. An existing exposure situation where members of the public are exposed above 1 mSv/y is not sustainable, and continued efforts should be made over long time scales, both by the government and by the affected population, to reduce exposures down to 1 mSv/y in the long run. Hence, both in planned and existing exposure situations the value of 1 mSv/y relates to whether exposed individuals take part in their own protection. It does not relate to the concept of tolerability.

In this new perspective it is meaningful to refer to natural radiation sources in setting the dose criterion: people rarely bother about these (with the albeit infrequent exception of exposure to indoor radon). In the old scheme a similar argument was used for setting the dose limit for public exposures. Nonetheless it was admitted that:

> *"(35) ... the presence of doses from natural sources does not justify the dose from controllable sources" [3]*. One may note that in the above sentence the verb "justify" is used in its everyday meaning, there is actually no "justification" in the very specific sense of the first principle of radiation protection.

Dignity

So far, we have concluded that current dose limits for members of the public neither reflect the concept of Tolerability, nor the principle of (distributive) Justice. In my view the management of public exposures as a separate category is a matter of Dignity. The principle of Dignity is highlighted in paragraph (60) of ICRP Publication 138 only in the sense that it promotes the autonomy of individuals in facing radioactivity in their daily lives, that they have "*an equal right to accept or refuse the risk" [1]*. I feel that it is also contrary to human dignity to impose on individuals to adjust their behaviour, except in particular crisis situations[2]. People should be in a position to enjoy life, not worrying about environmental threats, they should feel comforted in ignoring such risks in their daily business. They should be restful, about their exposure situation.

It goes without saying that restfulness, or quiescence, is a matter of trust. It does not result from merely being told that doses are very low: this needs to be explained, and one needs to trust the provider of the information. The argument of quiescence should indeed not be distorted from its purpose. It does not mean that people should be discouraged to question any low exposures: they may legitimately question any practices, and in particular any discharges of radioactive effluent, however small, from nuclear installations; their rights as stakeholders should not be dismissed. At this level of exposure, however, one may argue that the health risk is of concern essentially on a collective basis, not in terms of risk to any specific individual. Hence, the argument should not be read as a return to utilitarianism, i.e. to preserve overall well-being of people and the common good, within the framework of consequential ethics. The principle of "equal rights" underlying the current focus on protecting the individual is further supported, but should be put in the context of justification, rather than of tolerability of exposures.

Solidarity

The utilitarian approach, prevailing decades ago in radiation protection, was top-down: radiation protection experts, as well as regulators, would conclude on grounds of cost-benefit optimisation what is the best or the most reasonable option for society. Today this attitude is no longer advocated, even though quantitative optimisation offers useful benchmarks. The voluntary acceptance of individual exposures is a matter of Solidarity[3]: the individual comes to the

[2] In a crisis situation a government may need to pass laws or make strong recommendations that pertain to private life. This was the case with the Covid-pandemic, but one should remember that many restrictions were imposed in order to reduce the risk of infecting other people and to safeguard the fundamental right to health care, with hospitals operating above their normal capacity in terms of beds, nursing staff and equipment.

[3] Parenthesis: the idea of solidarity in matters of public health inevitably also brings to mind the Covid-pandemic : it gave rise to a comforting demonstration of solidarity, at least in the first wave of the spread of infection; later, part of the population started pleading for less restrictions, and infringed those in place; subsequently a similar attitude emerged with regard to the vaccination campaign. In both cases individuals looked essentially at their own well-being, and

conclusion, being well informed and receiving adequate response to whatever question may arise, that excessive concern for reducing individual exposures may be detrimental to other parts of society, even to mankind. The striking example is that of exposures resulting from slightly contaminated food originating from regions adjacent to the site of a nuclear accident. Consumers can no doubt refuse to purchase such food, as long as there is plenty of other similar food available, but in doing so impede local farmers to rebuild a sustainable activity, thereby destroying rural communities. If consumers are aware of both the relatively small health risk involved in food consumption, once maximum permitted levels of radioactivity are strictly controlled, and the importance of the adverse societal consequences, then one could hope for their responsible attitude when confronted with this situation.

Exemption and clearance

In the chapter on "Fairness" it was questioned whether at very low doses dose constraints truly relate to the concept of distributive justice. This chapter expands the argument to the very, very low doses that may result from the application of the concepts of exemption and clearance. Doses are not only extremely low, but in addition one should consider that doses are assessed through hypothetical exposure scenarios. In most scenarios it is not even possible to identify which actual individuals would be concerned. The scenarios introduce broad categories of people with specific occupations, living conditions or habits, but it is not demonstrated that these features would apply to any single individual. The *a priori* application of distributive justice among hypothetical individuals seems rather meaningless.

In the early nineties, in dealing with exemption and clearance, discussions focused on the concept of "triviality of risks" in every-day life. This resulted in a dose criterion "in the range of 10 to 100 μSv/y" [8], soon reformulated into "of the order of 10 μSv in a year" [9], allowing for a hypothetical exposure of an individual to several exempted practices. Such caution eventually proved not to

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at the hypothetical risk from the vaccine itself, disregarding the consequences of individual choices on the development of the pandemic. One might qualify this attitude as selfishness, the opposite of solidarity, but I think the most important factor in this process was disinformation, enhanced by the social media.

be warranted, but the round figure of 10 µSv/y remained in place. For a while, this threshold was regarded, even within ICRP [10], as a lower boundary in the optimisation of protection. This extension was conceptually wrong: there is no reason why exposures below the threshold should be dismissed, and if there are reasonable means of avoiding or reducing any such exposures then these ought to be implemented. The rationale for judging what is reasonable includes the principle of Optimisation, looking into collective dose or whatever more relevant quantity, but also into other societal values, for instance the principle of sustainable development.

Exemption

It was quite straightforward to apply the dose criterion for exempting practices from regulatory control (as part of the advocated "graded approach"). On different grounds (safety, occupational exposures, radioactive effluent …), most practices would never be exempted. Hence all that was left were "practices" involving consumer goods incorporating radioactive substances, including very small sources e.g. for calibration, and some unintended radiation generators. The exposure scenarios should realistically relate to their use, not only in normal, safe operation but including possible misuse, accidental spillage etc. It is worth noting that in scenarios for which a probability of occurrence is set, it was judged inappropriate to allow exposures to exceed 1 mSv/y [11], however small the probability. This approach was confirmed in the international standards [2]; in the Euratom standards [7] it was in addition specified that the 10 µSv/y criterion applies only to members of the public, for workers it was sufficient that they "should not be classified as exposed workers" (i.e., exceed 1 mSv/y).

Practical experience has shown that the problem with admitting consumer goods is not with the doses, but with the justification of this type of products compared to similar ones without radioactive substances. Some types of consumer goods were placed on the market a long time ago, but they either disappeared when proven inefficient (lightning rods) or by technological developments (smoke detectors). A major concern is the collection and disposal of disused sources.

In international standards [2], long lists of nuclide-specific exemption values were published, based on generic scenarios. They may have proven useful occasionally. Even though the application of the values to specific consumer goods would appear straightforward, there was a lively discussion on their meaning. At stake were not the handful of consumer goods, but the occurrence of low activity concentrations in the environment, and in materials arising from the dismantling of nuclear installations (or otherwise removed from a controlled area). In those contexts, the choice of the dose criterion and of the resulting values, i. e. clearance levels, had much larger economic implications. This prompted an unsuccessful attempt to achieve universal "scope defining levels" [12] [13][14], de facto excluding low levels of radioactivity from the scope of the radiation protection system.

Clearance

There is nothing in the radiation protection system that would prevent materials being released from regulatory control even though this would result in individual doses that are liable to exceed 10 µSv/y. If doses remain below 1 mSv/y and if the release of materials is shown to be justified, then the concept of clearance is in full respect of the basic principles, and fundamental ethics, of radiation protection.

This flexibility is well illustrated in relation to the release of secondary NORM materials: in view of the ubiquity of such materials in the earth's crust, it would not be helpful to impose a criterion of 10 µSv/y [15]. In the same way, the trade in building materials with relatively high natural radionuclide concentrations is governed by the criterion of 1 mSv/y [7]. On the other hand, for human-made radionuclides there was a great deal of consensus that any, however low, activity concentration value for clearance would save a significant amount of valuable materials for recycling or reuse while allowing the dismantling of nuclear installations at a reasonable cost. The prospect of saving resources should be a crucial element in the justification of clearance policies, along with avoiding the engineered disposal of waste materials that are not but slightly contaminated. The urgent need for clearance levels explains why consensus on the criterion of 10 µSv/y emerged so soon.

The dose criterion for exemption and clearance are not an expression of the tolerability of exposures. The dose criterion is merely a benchmark. It offers a unified basis for managing broad radionuclide vectors. The question of justification should be addressed very carefully, specifically for each category of radionuclides, and holistically. The issue is not only whether the release of a batch of materials is justified, but whether the overall strategy of cleaning, dismantling, sorting, possibly mixing, measurement and eventually release is justified, and whether the entire chain is adequate for this purpose.

As a result of these reflections, we concluded earlier [16] that:

- Criteria for clearance relate to the concept of justification (non-maleficence), rather than to any consideration of tolerability of exposures; "triviality" of exposure is not in itself a necessary requirement.
- If dosimetric criteria are preferred for clearance, these can range from 10 µSv to 1 mSv per year, depending on the exposure situation. The criterion of 1 mSv already applies to NORM materials.
- Criteria other than dosimetric ones may be equally important, such as not to spread contamination (enhancing background levels).

Post-accidental situations

While we have exemption values for consumer goods and clearance levels for application in planned exposure situations, similar considerations apply to exposures in post-accidental existing exposure situations. We already looked into the consumption of contaminated food under the heading "Solidarity". The Fukushima accident prompted a lot of questions on the application of international transport regulations, that still need to be resolved. There is still no guidance nor nuclide-specific (surface) activity concentration values that can be applied after an emergency. A more pragmatic approach to clearance as outlined above may allow to address the issue of post-accidental residual levels of contamination of commodities and means of transport.

Transparency and accountability

This chapter should not be concluded without pointing to further developments in the philosophy of clearance. The dream of having "scope-defining levels" arose from the prevailing idea that neither exempted consumer goods nor cleared materials should be subject to any form of regulatory supervision. This idea is obsolete. The regulator remains accountable for the consequences of its exemption and clearance policy. The processes leading to decisions in this area need to be documented in full transparency. The metal scrap market, including dealers and the recycling industry or steel works, cannot function without some documentation ensuring traceability of the material to its origins; this holds in particular in international trade [17]. Transparency and accountability are important pillars of Operational Justice [1].

Exposure situations

The introduction of exposure situations was one of the main novelties in the radiation protection system introduced by Publication 103 [18][19]. In particular, the definition of "existing exposure situations" has allowed to give proper attention to the management of exposures to natural radiation sources and of exposures in case of post-accidental environmental contamination. Unfortunately, the definition was soon broadened from "an exposure situation that already exists" to situations in which only the source of exposure is present already. The pre-existence of a source is a relevant feature in the sense that the introduction of the source does not demand a formal justification. An existing source of exposure may nevertheless result in a new exposure situation, by introducing or modifying exposure pathways.

In the international standards [2] the ICRP definition was kept, but it was concluded that while the source may not be amenable to change, the pathways of exposure may be affected by planned human activities. Whenever these activities result in an increase of exposures that may be of concern, they may need to be regulated. Hence the case of "regulated practices within an existing exposure situation" [7]. The most striking examples are the exposure of aircrew, whose exposure is due to cosmic radiation but much more evidently results from flying at high altitude and latitude, and the exposure to radon at work. Occupational exposures include all exposures incurred at work, and principally as a result of work. In ordinary workplaces, offices, radon exposure results from where one works, the office being located in a radon prone area, rather than as a result of work. Still, under general (ILO) rules on occupational exposures the employer is responsible for health and safety at work. Hence high radon concentrations should reasonably be considered the responsibility of the employer; even more so because radon concentrations can effectively be reduced through adequate remediation. Thus it was decided in international standards [2] that the occupational dose limit would apply to, or include radon at work.

These developments once more emphasise the need for a common level of "tolerability" not only across all categories of exposure, but also all exposure situations. It then no longer matters whether a worker is merely exposed "at work" (e.g. from natural radiation sources) or as a result of working with radiation sources.

One may object that the above analysis ignores the fact that dose limits apply to the sum of all exposures, from different sources, and that expanding the concept of tolerability across exposure situations runs into trouble. In fact there is already a precedent: in the Euratom Basic Safety Standards the occupational dose limit applies to the sum of all exposures, both from operations with man-made radionuclides, i.e. from practices, and from exposure to radon at work. It is up to regulators however, and not a matter of basic principles, how to enforce the requirements, amongst other by establishing dose limits. With regard to members of the public adding up doses from different practices is almost never an issue, apart from the obvious case of different practices, or different undertakings, on the same site. Hence there never was a need to partition the dose limit in smaller fractions, nor was it straightforward to allocate such fractions to different sources. Anyway, in the new approach setting a level of quiescence, such a level is closer to the concept of a source-related dose constraint than to a limit.

Conclusions

The notion of "tolerability" of individual exposures is an essential part of the radiation protection system. Experience has shown that dose limits are useful in occupational exposures, not only in planned exposure situations but also in existing exposure situations. Numerical guidance by ICRP on the level of tolerability of individual exposures across all exposure situations and categories of exposure ought to be consistent with the prevailing occupational dose limits. It is appropriate to set the level of tolerability in terms of dose rather than annual dose rate. This overall level of tolerability may hence be set at 100 mSv, corresponding to the dose limit for to workers integrated over 5 years. This level was also set earlier as an upper boundary to the range of reference levels in emergency exposure situations [18].

In contrast to such a broad understanding of the borderline between tolerable and unacceptable exposures, the levels at which exposures are qualified as "acceptable" depends on the prevailing circumstances, in particular the type of exposure situation and the category of exposed persons. With regard to public exposures it is therefore still advocated that these be kept well below the overall level of tolerability, but on the other hand that the current public exposure limits be discarded. Instead the notion of "quiescence" ought to be further developed, on grounds of the ethical value of Dignity. It is believed that a suitable level for this purpose may still be around 1 mSv/y.

For the sake of clarity, being aware that the argument may easily be misunderstood, I offer a possible rewording of the third principle (limitation of doses):

> *In order to avoid inequitable distributions of individual exposures, the Commission recommends restricting doses to individuals and non-human biota from a particular source. In addition, it ought to be ensured that exposures do not exceed the values beyond which the associated risk is considered as not tolerable. Exposures ought to be below thresholds for tissue effects, and below a level causing a serious stochastic risk. For the latter purpose the Commission recommends a common value of 100 mSv effective dose in all exposure situations and all categories of exposure. The time frame over which this exposure is incurred depends on circumstances. For the protection of workers in planned exposure situations the current dose limits recommended by the Commission ought to be applied. For members of the public it is no longer recommended to apply dose limits. However, planned exposure situations should not rely on members of the public adjusting their behaviour in order to avoid exposures. It is believed that individual members of the public may remain restful when doses are below 1 mSv/y. This level seems adequate in planned exposure situations, and in post-accidental exposure situations a reduction of exposures, in the long run, down to this level should be pursued.*

The concept of quiescence also prevails in the analysis of the ethical basis for exemption and clearance, together with the prime principle of justification, applied to the overall management of contaminated materials arising from controlled areas for instance at the time of dismantling a nuclear installation. The historical dose criterion of around 10 µSv/y may still be applied as a benchmark for justification purposes, but a nuclide-specific approach to justification is recommended. The dose criterion should never be linked to any notion of tolerability, and the term "trivial exposures" should no longer be used.

As a whole, the author is convinced that decisions in radiation protection should always be explained in terms of ethical principles and values, referring to Publication 138 [1] as the basis of the current radiation protection system. The key principles of Tolerability and of Dignity ought to be developed further to sustain the system, complemented by other societal values, Solidarity in particular. The first principle of the system of protection, Justification, ought to keep its prominent position. Many radiation protection experts feel uncomfortable with the fact that Justification brings into play matters beyond the stricter remit of protection against ionizing radiation, but one cannot avoid economic considerations nor other societal principles and values, in particular the principle of sustainable development. The main principles and their ethical basis need to be spelled out in plane language, bearing in mind the nuances of similar words in different languages, and the confusion that may arise from mixing up jargon and everyday language (as is the case for instance with "justification".

The conceptual changes that are proposed in this paper will cause no relaxation of current good radiation protection practice, but hopefully will contribute to a better understanding of the philosophy, better regulation, and a more straightforward and coherent communication.

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Optimisation of protection,

the cornerstone of radiation protection

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Abstract

In this paper, an overview of the application of the optimisation principle in radiation protection and in safety and well-being as a whole is provided. It illustrates how the optimisation principle, including the concept of reasonability, is almost de-facto embedded in the holistic all-hazard approach in prevention and protection for the worker, the public and the patient involving a multi-disciplinary approach.

Keywords: optimisation, ALARA

Introduction

It is important to remind the benefits and the risks of the application of ionizing radiation. The discovery of X-rays by Wilhelm Röntgen at the end of 1895 and radioactivity a year later by Becquerel opened new opportunities for scientific research, and for technical and medical applications of ionizing radiation. The discoveries opened opportunities to further explore and understand the structure and nature of matter, to improve materials, to generate energy, to diagnose, understand and treat diseases.

The use of ionizing radiation has also a downside: the deleterious effects of ionizing radiation rapidly became apparent under the form of deterministic and stochastic health effects.

It became clear, already in the early days, that there was a need to manage the risks associated with the use of ionizing radiation, in order to ensure a benefit from its use.

Basic principles of radiation protection

In 1928 ICRP took on the task to develop recommendations on the subject. These evolved over the years, based on the expanding scientific knowledge and the knowledge gathered by other organisations on the health effects. The recommendations resulted in the three basic principles of radiation protection, , formulated on the basis of the linear no-threshold dose-effect relationship model. These recommendations, recalled in ICRP publication 103 (2007) [1], are the foundation of the Basic Safety Standards (Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards IAEA GSR part 3), adapted and translated worldwide into national regulations.

The principles of radiation protection are:

- Justification: show that there is more benefit than harm in using the ionizing radiation
- Optimisation: keep doses as low as reasonably achievable taking into account economical and societal factors

- Dose limits: keep stochastic effects tolerable and avoid deterministic effects.

Optimisation

Respecting the dose limits assures that the probability of stochastic effects occurring is deemed to be tolerable. The optimisation process strives to further reduce the risk to an acceptable level given the economic and societal factors, or as we further will develop, taking into account the prevailing circumstances.

The wording to address optimisation has evolved over the years, as represented in the table below. We see an evolution from "reduce to the lowest possible level" to "as low as reasonably achievable, economic and societal factors being taken into account." Today, ALARA and "the optimisation principle" are synonymous [2].

The optimisation process is a decision-aiding tool, and aims at an acceptable level of exposure that takes into account the prevailing circumstances. Based on the description given in ICRP 101b (2006) [3] and ICRP 103 (2007) [1], the following elements can be identified:

- Exposure situation: Planned, Existing and Emergency,
- Economical factors: Value for money of the protection means, or the efficiency of the radiation protection measures,
- Societal factors: Value for society, the use of resources, based on good governance, optimal use of societal resources,
- Other risks: Industrial risks, overall well-being,
- Technical elements: Conditions, preconditions that affect the implementation of the radiation protection measures,
- Processes and procedures: The radiation protection measures can be influenced by specific processes and procedures,
- Judgements: Dialogue with the stakeholders and their involvement.

The question that arises immediately is: what is a reasonable, acceptable level of risk, how safe is safe enough?

It is important that the ALARA process is performed in a structured way in a deliberative process. The ALARA process presented in 1991 [4] was further developed to a methodology in the European ALARA practical guidebook [2]. The process involves evaluating and selecting radiation protection actions to reduce the magnitude of the individual exposure, the number of people exposed and the likelihood of potential exposure of workers, public and patients to a level as low as reasonably achievable.

The comprehensive deliberative process, the all-hazard approach and the attention to the involvement of the stakeholders involve different steps (Figure 1).

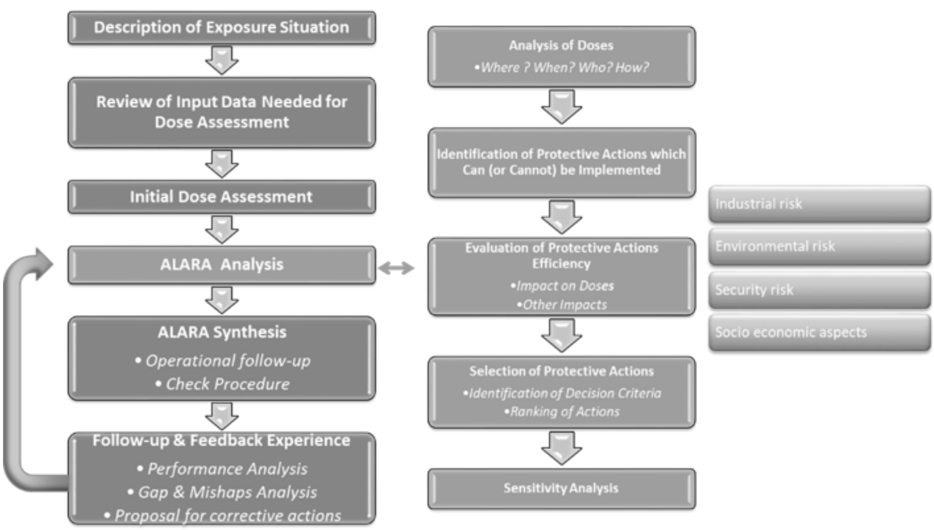


Figure 1: Steps in the ALARA process.

The process starts with the definition of the problem, leading to a first dose evaluation before optimisation. This is followed by a detailed analysis to identify protective actions to further reduce collective and individual dose.

In the process we clearly identify the factors that influence the final selection of radiation protection actions and evaluate them with regard to their impact.

The structured process enables the evaluation of the effectiveness of the radiation protection measures and of the key factors that determine the decision. This structured approach makes the process transparent for the different key users and stakeholders. The process can benefit from a Cost Benefit Analysis to evaluate the value-for-money aspect (cost efficiency) or can use other quantitative techniques such as multi-attribute utility analysis, which accommodates value for society (good governance, optimal use of societal resources, ethics).

ALARA Culture

The optimisation process can be fully successful only if it is embedded in overall safety culture, of which radiation safety culture and ALARA culture are a subset. The following elements are identified as components of a good safety culture:

- Engaging with all parties involved in the activity,
- Appropriate education and training,
- An environment that supports a questioning attitude, openness, and challenge,
- Learning from experience and sharing it,
- Strong commitment from the leadership,
- Integration of the above commitments into a clear management system.

Elements of the ALARA culture are clearly attitude and behaviour, risk awareness and the involvement of stakeholders.

To illustrate this, to the left of Figure 2 an example of the stakeholders involved in a planned exposure situation is sketched, and to the right the graphic extends to a broader set of stakeholders identified by the EAN working group on ALARA culture [5], each having their specific contribution to the practical implementation of optimisation.

An important element in establishing safety culture and in engaging an effective deliberative process is education and training. A good understanding of the risk,

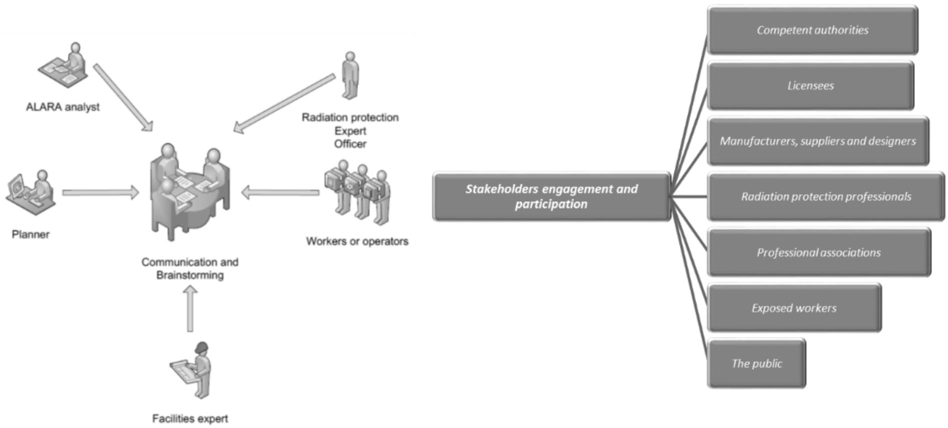


Figure 2: Stakeholders' engagement

and risk awareness are necessary, addressing the science upon which is based the risk assessment and the risk perception by stakeholders.

Dialogue is essential in the process and must be based on the clear representation of the elements used to select protection measures, to achieve an acceptable risk level and to determine the residual risk.

Reasonableness

The question remains on what is reasonable or acceptable. This has been explored by ICRP in its publication 138 (2018) [6] on the ethical basis of the radiation protection system. It defines the pursuit of reasonableness as "the permanent quest depending on the prevailing circumstances in order to act on knowledge and experience, to do more good than harm (beneficence/non-maleficence), avoid unnecessary risk , establish a fair distribution of exposures, and to treat people with respect ." The question of reasonableness was also further explored by IRPA [7] an NEA/CRPPH [8].

IRPA defined principal factors that underpin reasonableness; they identify the following elements contributing to the decision:

- Judgement,
- Proportionality,
- Stakeholder engagement,
- Holistic approach,
- Avoid over-conservatism,
- Optimal use of societal resources,
- Radiation safety culture,
- Auditability: transparency.

In the summary report “Optimisation: Rethinking the Art of Reasonable” [8] NEA/CRPPH came to a conclusion in line with the current recommendation in ICRP103(2007), with emphasis on the multidisciplinary, multi-dimensional nature of the complex circumstances to consider. The radiological risk is considered as a part of the overall risk vector.

The elements identified by IRPA [7] are intrinsically embedded in the ALARA process developed earlier based on the process described in the practical guidebook [2]. The “art” of ALARA remains in applying this and reach a situation-based judgement call, taking into account the knowledge of the risks and the prevailing circumstances. The structured approach makes clear how the different elements are considered to arrive at the acceptable level making the process auditable for all the stakeholders and makes them aware of the decision drivers.

Benefits of the optimisation principle

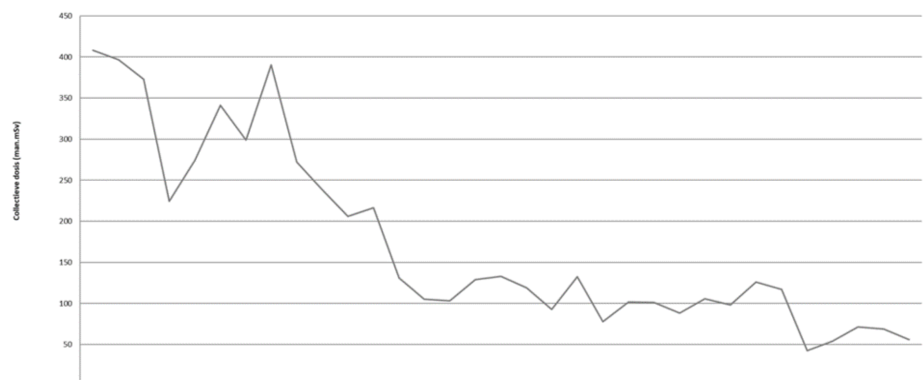
What are, and what were, the benefits of introducing and using the optimisation approach?

In fact, the optimisation approach can be seen as a reference framework, a state of mind and attitude that:

- allows an individual and/or an organisation to act in a responsible way to manage risks and giving safety the needed priority,

- is inclusive of exposed individuals’ and stakeholders’ views and experience,
- is characterized by risk awareness, balanced judgement of risk and benefits, and the capability to develop and use required skills and tools for risk assessment and management,
- is realized through transdisciplinary education and training tailored at each level,
- is supported by management commitment and by a management system,
- supports feedback from the field and continuous improvement.

Did the implementation of optimisation lead to a reduction of exposure to ionising radiation of the worker, the public and the patients?



	89	90	91	92	93	94	95	96	97	98	99
Dosis (man.mSv)	408,0	396,6	372,8	224,5	274,0	341,2	298,7	390,2	271,9	238,4	205,8

	00	01	02	03	04	05	06	07	08	09	10
Dosis (man.mSv)	216,7	131,1	105,3	103,4	129,0	132,9	118,9	92,8	132,3	77,7	101,6

	11	12	13	14	15	16	17	18	19	20	21
Dosis (man.mSv)	101,4	88,3	105,8	98,4	126,1	116,9	42,5	54,2	71,63	68,97	56,08

Figure 3: Evolution of the collective dose as a function of time (1989-2021) at the SCK CEN research centre, Belgium

We can get an idea by analysing the feedback by different organisations that report on occupational exposure and/or optimisation such as UNSCEAR, ISOE, EAN, ISEMIR, EMAN, EFOMP, … When focusing on the three-year rolling average collective dose per reactor for all operating reactors included in ISOE by reactor type from 1992-2018 [9]; it can be seen that on average for all types of reactors (except the PHWR) the collective dose shows a downward trend, and that there is a link with the optimisation process in the management of doses in these reactors.

Also UNSCEAR reports that “the average annual effective dose for exposed workers decreased in the period 2000-2014” [10].

A similar influence of the introduction of the ALARA process in a research centre is illustrated in Figure 3 by the collective dose as a function of time. A clear downward trend is visible. The optimisation at this research centre is supported by an ALARA process and an ALARA committee that analyses past experiences and evaluates new operations.

In the medical field we see a further growing awareness and effort towards optimisation for exposed workers and for patients. As an example, the Nuclear Safety Authority FANC in Belgium concludes after analysing the dose results that, although there is an increase in medical imagery, there is a reduction of dose to the patients.

Exposures of workers in conventional radiology, both radio diagnostics and radiotherapy, are generally well controlled. There are, however, areas of medical practice where we see an increase of interventional techniques, in which very high exposures are incurred. Ensuring that sufficient attention is paid to the control and reduction of such exposures requires continued efforts in post-graduate education and in awareness raising of the medical professionals involved. The participation of medical physicists in the implementation of optimisation programmes in interventional radiology is strongly recommended.

Conclusion

Does the optimisation approach benefit to the management of occupational exposures? We can answer this positively when we look at individual and collective occupational dose reductions achieved in the different fields involving the use of ionising radiation.

The optimisation approach promotes a forward-looking risk-aware attitude that supports safety and safety culture as a whole, the use of a structured approach provides transparency to the stakeholders on the implemented protection measures and on the acceptable risk level. The optimisation approach promotes a balanced judgement on the risks and the benefits allowing an optimal us of the resources. Optimisation is a cornerstone of protection and radiation protection.

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