# AN APPROACH TO CONTROLLING RADIATION EXPOSURES OF PROBABILITIES LESS THAN ONE

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#### 1. INTRODUCTION

The radiation protection system recommended by the International Commission on Radiological Protection (ICRP) [1] has been incorporated into many national and international regulations, including the IAEA/ILO/WHO/OECD-NEA<sup>(b)</sup> "Basic Safety Standards for Radiation Protection" (BSS) [2]. The system, however, is intended only for application to the preplanned control<sup>(c)</sup> of exposures which are expected to occur with certainty as a result of practices involving radiation sources. Such exposures, resulting from the so-called 'normal' operation of the sources, are therefore assumed to occur with a probability of unity. They are usually called 'normal' exposures, although sometimes they should be more properly referred to as exposures resulting from planned occurrences of events concerning radiation sources.

Rather different are those situations in which there is only a potential for radiation exposure, i.e. the probability that the exposure actually occurs is less than one. These situations are usually called 'accidental', not meaning that they necessarily arise from accidents but that exposures may or may not occur as a result of probabilistic events concerning a radiation source. The exposures that may potentially arise from such situations have frequently been called 'probabilistic' exposures. The ICRP system cannot be applied in its current form to the control of either the magnitude or the probability of occurrence of 'probabilistic' exposures and a much needed international consensus on a coherent and consistent system of control seems to be lacking.

<sup>(</sup>a) Mr. Ahmed and Mr. Gonzalez were Scientific Secretary and Chairman respectively of the IAEA Advisory Group on the Application of the Principles of Radiation Protection to Sources Potentially Causing Radiation Exposure. This paper, however, expresses the authors' personal opinions and should not be interpreted as indicating the Advisory Group's position on the subject.

<sup>(</sup>b) International Atomic Energy Agency/International Labour Organization/World Health Organization/Nuclear Energy Agency of the Organization for Economic Co-operation and Development.

<sup>(</sup>c) The term control is used to mean the act or fact of exercising restraint, rather than checking, testing or verifying.

The IAEA has a project to develop guidelines for a unified approach to the application of radiation protection principles to both radiation exposures occurring with certainty and exposures which are not certain to occur, and a consultative document has already been prepared [3]. The present paper briefly summarizes some aspects of the progress made towards this unified approach to radiation safety.

## 2. STATUS QUO

#### 2.1 TERMINOLOGY AND SOME CONCEPTUAL PROBLEMS

When dealing with probabilistic situations, some concepts, such as risk, uncertainty and probability, are used with different connotations by different authors. Consideration of radiation exposures cannot escape this problem and the imprecise usage of the term radiation 'risk' is a good example. The IAEA had adopted [2] the ICRP usage of the concept of risk as the probability of harm resulting from a given radiation dose [4] and precisely defined risk in the TAEA Radiation Protection Glossary [5] as "the probability that a given individual will incur any given deleterious stochastic effect as a result of radiation exposure". However, the IAEA's Nuclear Safety Standards (NUSS) [6] subsequently used the term risk "in the general sense of a combination of probability and consequences of an event", i.e. in a sense of a mathematical expectation of harm rather than a probability of harm. However, in the limited area of radioactive waste disposal, both the ICRP and the OECD/NEA have used the term 'risk' to mean the product of the probability of exposure and the probability that the dose received will produce serious health effects [7] [8], i.e. as a probability of harm resulting from convolution of two stochastic phenomena. Risk has also been used in the literature in its imprecise colloquial meaning, and also as the equivalent of consequences.

The concept of probability itself is also being used with different connotations, either based on the classical frequentistic interpretation or in the more modern subjective formulation. This in turn has had an effect on the interpretation of the meaning of uncertainty.

Many of the current conceptual problems which appear when dealing with 'normal' and 'probabilistic' exposures are linked to the imprecise use of terminology.

# 2.2. SCENARIOS OF EXPOSURE

Effectively all radiation sources may cause 'normal' exposures and have a potential to deliver 'probabilistic' exposures. As a simple example showing the coexistence of both exposure scenarios, consider a radiation generator enclosed in a radiotherapy room fitted with an interlocked entry system. On the one hand, people will be exposed to the radiation that penetrates the shielding during normal operation. On the other hand, if the interlock fails, then someone might enter the radiotherapy room when the generator is operating and thus receive an unplanned exposure.

More sophisticated examples of normal and probabilistic scenarios of exposure can be given for nuclear installations. The relative importance of each scenario may naturally differ enormously for different sources and installations but in principle both modes should always be considered. The coexistence of both types of exposures seems to indicate that a unified approach for the radiation safety of the source is needed in order to ensure coherence and consistency in the safety objectives.

# 2.3. CURRENT PRINCIPLES OF RADIATION PROTECTION

The current system of radiation protection is intended for planning radiation protection for 'normal' exposures. It includes two types of requirements: (i) the individual related requirement of the limitation of individual doses; and (ii) the source related requirements of justification of practices and optimization of protection.

Individual dose limits have traditionally been recommended by ICRP and were incorporated in the BSSs. They apply to the combined exposure due to all sources, excluding that due to natural background radiation and the medical exposure of patients. For members of the public the ICRP recommends a dose limit of 1 mSv for exposures committed in any single year [9]. Taking into account the currently used hypothesis of a linear non-threshold dose-response relationship with a risk factor of approximately  $10^{-2}$  per sievert, an individual dose limit of 1 mSv per annum implies a constraint of less than about  $10^{-5}$  year-1 on the risk incurred by the individual.

Since individuals may be subject to exposures due to several sources, in order to ensure compliance with individual dose limits, both the ICRP [4] and IAEA [10] have suggested the setting of dose upper bounds to be assigned to particular sources of exposures. Although specific dose upper bounds have not yet been recommended, it is assumed that they should be established by national authorities and applied to exposures resulting from the normal operation of a radiation source or installation whenever the exposures are assumed to occur with certainty. De facto dose upper bounds used by national authorities suggest that the constraint imposed in practice on individual risk due to a single radiation source is of the order of 10-6 per annum.

Optimization of protection, however, requires that the radiation protection applied to a source of exposure must be optimized in order that all doses be kept as low as reasonably achievable, economic and social factors being taken into account (ALARA). The application of the optimization requirement implies in practice that the actual risk incurred is much lower than the corresponding upper bound. Optimization requires an evaluation of the various possible options for protection and a judgement of their different features against preference criteria. The features to which these criteria apply include the achievements in protection, such as reductions of doses and favourable changes in their distribution in time and level of dose, and the efforts, such as costs and difficulties, required in achieving such protection. Since some of these criteria may be in conflict with others, evaluation for other than the

simplest prob'ems will require some kind of decision aiding technique to differentiate between alternative options from the point of view of radiation protection. One particular technique recommended by the ICRP is cost-benefit analysis [11], but it has been emphasized that this is only one way of quantifying some of the inputs to the optimization decisions. Other techniques, such as multiattribute analysis, are also being investigated by the ICRP.

Finally, the requirement of justification of practices provides that no practice shall be adopted unless its introduction yields a positive net benefit. A practice, such as the generation of electrical energy by nuclear fission or the radiosterilization of medical products, means the sum of all processes, industrial operations and actions associated with that activity which produces the benefit. The net benefit should be determined by assessing both benefits and efforts, including the possible harm due to radiation, resulting from the introduction of the practice.

#### 2.4. CONTRASTING SAFETY PRINCIPLES

In contrast to the common international approach for controlling 'normal' exposures, there seems to be a lack of unified procedures for controlling the likelihood of 'probabilistic' exposures. There are, however, implicit procedures for the assessment and control of 'accidental' situations at some installations, notably nuclear reactors. They have been developed in parallel with, and to some extent separately from, the principles of radiation protection. It is therefore not surprising that in practice different principles are applied to exposures presumed to be certain and to potential exposures.

An example of these contrasting approaches is given by the treatment of the safety of nuclear reactors. The study of nuclear reactor safety developed from that of conventional safety and initially inherited the essentially deterministic concepts of that discipline. Engineering safety standards were set either as a result of experiments and tests or more subjectively using engineering judgement. A concept of 'maximum credible accident'- then called 'design basis accident'- was developed by means of such a deterministic approach and engineering safety features were designed to cope with this accident in an attempt to ensure absolute safety. Time and experience showed, however, that there remained some probability of accidents occurring and not being coped with by the safety related engineering systems. As a result, the nuclear accident scenarios - including beyond design basis accidents - their causes, probabilities and consequences, began to be studied by the more comprehensive technique of probabilistic safety assessment (PSA). In order to evaluate the results of PSA, it was found necessary to establish comparison criteria in the form of probabilistic safety criteria (PSC). One useful form of PSC is that of a limit on individual risk, which can be derived from the radiation protection principles, but this has not been the sole approach used. Rather, limits for 'societal' risk, expressed in terms of relationships between probability and number of people affected, have also been used as PSC. In any case, there has been a marked contrast between these various principles of nuclear safety and the radiation protection principles. These in turn lead to a situation in which the overall safety objectives cannot be easily formulated and create a real conflict, particularly in situations in which a trade-off is unavoidable. For instance, in some cases an increase in the protection against exposures presumed to be certain may lead to a reduction in the safety measures for potential exposures, and vice versa; a typical example of this is the trade-off between occupational protection requirements and operational safety requirements such as maintenance and inspection.

For other sources the principles have also been in conflict. Procedures for assessment and control relating to waste disposal also started to evolve separately but have now been tackled by extending and developing the ICRP Basic Recommendations to deal with the particular problems of wastes [7][8]. In the uses of radioisotopes and radiation sources there is a contrast between the many standards and criteria used for normal operations and the few, if any, standards for preventing accidental exposures.

#### SUGGESTED APPROACH FOR A UNIFIED POLICY

There follows a brief summary of the suggested approach for a unified safety policy.

## 3.1. USAGE OF SOME RELEVANT CONCEPTS

It is suggested to use the concept of <u>probability</u> as a number between 0 and 1 assigned to the likelihood of the actual occurrence of an event, a radiation exposure due to the event, or a radiation effect due to the exposure. The number must be interpreted as a measure of the degree of belief that the event, exposure or effect will occur rather than as a measure of the actual frequency of occurrence. It must comply with the rules of coherence as follows: (i) the complement of an event with probability p should be assigned a probability (1-p); (ii) events which may occur at a greater frequency should be assigned a greater probability; and (iii) if event <u>a</u> is more probable than <u>b</u>, and <u>b</u> is more probable than <u>c</u>, then <u>a</u> must be more probable than <u>c</u>. This definition encompasses the usual frequentistic definition of probability but does not require statistical information, and is particularly tailored to be used for controlling 'probabilistic' exposures.

However, it is recommended that <u>risk</u> be defined as the probability that a serious detrimental health effect will occur to an individual exposed to either 'normal' or 'probabilistic' exposures. Risk is, therefore, the product of the probability of an event occurring <u>and</u> the probability of radiation exposure occurring given the event <u>and</u> the probability of harm given the exposure, because each one of these probabilities is assumed not to influence the others. For normal operation the probability of both the event and the 'normal' exposure occurring is assumed to be unity and the definition matches the usual meaning of risk for radiation protection purposes.

#### 3.2. ASSUMING A RISK-DOSE RELATIONSHIP

When considering probabilistic exposures, the possibility of doses exceeding the linear (stochastic) region of the dose-response relationship and entering the 'non-stochastic' region must be taken into account. Figure 1 presents the extremely simplified scheme suggested for the relationship between the probability of suffering a severe harmful effect as a result of a radiation dose versus the incurred dose. At levels up to a fraction of a sievert only stochastic effects are assumed to occur, including fatal cancers in the irradiated individual and severe genetic effects in the succeeding generations of descendants; the risk factor being of the order of one in a hundred per sievert. For doses that exceed O.1 Sv, say, delivered in a short period of time, non-stochastic effects may occur and at doses higher than about 5-10 Sv also delivered in a short period of time, practically all irradiated individuals will suffer an acute radiation syndrome and eventually die. As a simplified but practical approximation, therefore, the risk-dose relationship is assumed to be linear with a slope of  $10^{-2}$  Sv<sup>-1</sup> in the low dose region and to approach asymptotically a probability of unity for doses higher than about 5-10 Sv.

## 3.3. SOURCE CHARACTERIZATION

Radiation sources should be characterized from a safety point of view according to their potential for delivering harm. For normal exposures the relevant quantity characterizing the individual risk is the individual dose assumed to occur with certainty. For the low doses expected in normal operation, the probability of harm for the individual is assumed to be proportional to the incremental dose received and the collective dose is a measure of the total expected harm. For 'normal' exposures, therefore, individual and collective doses are the quantities which characterize the safety of the source.

For 'probabilistic' exposures, however, there can be identified a probability of individual harm, or risk, and a probability distribution of consequences. These quantities characterize the safety of the source in this case. The mathematical expectation of harm is not a good indicator of the safety of the source owing to the large uncertainties associated with low probability-high consequence events.

## 4. LIMITATION OF INDIVIDUAL RISK AS A BASIS FOR A UNIFIED APPROACH

Probabilistic events could be brought under a unified system of control in a way which is consistent with the current system of dose limitation. A possible method of incorporating accident situations into a risk based system would be to define a total individual risk limit for the combined sum of 'normal' and 'probabilistic' exposures. However, this approach has two disadvantages: firstly, it could be construed to imply an allowable trade off of risk between normal and accident situations; secondly, such a method would involve changing the current system of dose limitation for 'normal' exposures.

The simplest method would be to define separate risk limits for 'probabilistic' exposures and to retain the current dose limits for 'normal' exposures. In the context of radioactive waste disposal the ICRP recommended for members of the public an annual risk limit of  $10^{-5}$  to deal with probabilistic events [8], which is of the same magnitude as that implied by the dose limit for normal situations. The ICRP proposal aims to achieve compatibility with the current system of dose limitation and thereafter to improve safety by reducing doses below this limit by optimization. Thus, for consistency, it is suggested that the proposal be extended to the control of individual risk from 'probabilistic' exposures in general. This limit would apply to the individual risk in the most highly exposed critical group and would encompass all sources of probabilistic exposure.

In addition to the individual risk limit, there need to be alloted risk upper bounds in order to constrain the individual risk due to a single source. The risk upper bound should be apportioned from the risk limit. The apportionment may be different according to circumstances; thus a smaller fraction may be chosen for waste disposal than for nuclear power plants because of our uncertain knowledge about the variety of sources to which a future individual may be exposed. A risk upper bound is to be used in the design and regulation of a particular facility in the same manner as dose upper bounds are currently used.

Compliance with a risk limit or with a risk upper bound, either for a source or even for a single scenario, can also be shown by means of a criterion curve, which allows the use of dose distributions or doses and probabilities directly without the need to convert them to risks. An example of such a criterion curve is shown in Fig. 2 for an annual risk limit of  $10^{-5}$ . The shape of the curve is derived from the dose-effect relationship of Fig. 1. Every point on the curve represents the same risk, that is 10-5 in a year. The curve starts at the point where the probability is one and the dose is about  $10^{-3}$  Sv, where the risk is then  $10^{-5}$ . Doses below  $10^{-3}$  Sv correspond to a risk of less than  $10^{-5}$ and therefore automatically comply with the risk limit. The first part of the curve is a straight line of slope 45°; it represents the region of doses up to about 1 Sv where the risk due to a given dose is assumed to be proportional to that dose. Thus a dose of 10-2 Sv occurring with a probability of  $10^{-1}$  confers the same risk as a dose of 1 Sv occurring with a probability of  $10^{-3}$ . From doses of 10 Sv or greater, from which death is certain to occur, the risk no longer depends on the dose but only on the probability. Since the risk limit is assumed to be  $10^{-5}$  in a year, the criterion curve is then horizontal at an annual probability of  $10^{-5}$ . In the short region between 1 Sv and 10 Sv the two straight parts of the curve are joined by some smooth path whose exact shape is irrelevant. If the probability distribution (given that its integral is normalized to one) or - in the simplified case of discrete doses - the number pair of the annual dose and the annual probability of that dose falls everywhere below the criterion curve, then compliance with the risk limit has been shown.

However, assuming arbitrarily simultaneous risks from ten different sources or scenarios, then the risk upper bound per source would be  $10^{-6}$ 

and the corresponding criterion curve of the same type of the described earlier will be that shown in Fig. 3. If the risk upper bound refers to the source, then the sum over all scenarios has to be used for the dose distribution; if, however, the risk upper bound has already been apportioned to a single scenario, then the dose distribution of that scenario is to be entered into the diagram with the criterion curve.

A basic conceptual policy question remains, however. This question is whether the certain occurrence of a dose with a given probability of causing death should be considered equivalent to the potential occurrence with this same numerical probability of a fatal dose. In other words, the question is whether the risk due to the certain occurrence of a dose with a given probability of causing death is equal to the risk due to a dose which has this same numerical probability of occurring and which would certainly be fatal. Quantitatively, the risks in the two cases are the same and, therefore, for risk limitation purposes the two situations have been assumed to be identical. This assumption is basic to the unified approach for limiting individual risk.

## 5. OPTIMIZATION OF RADIATION SAFETY

It seems reasonable to consider on the idea of a limit on individual risk as an essential requirement for a unified approach to radiation safety in general and, particularly, to the control of probabilistic exposures. However, the limit on individual risk should be viewed as a necessary but not sufficient condition for ensuring the appropriateness of the level of safety of a radiation source. The question remains for the responsible authorities whether that level should be improved further by taking into account, for instance, that a high number of individuals incurring an acceptably low probability of harm may still represent an unacceptably high expectation of harm. For exposures resulting from normal operation the basic requirement is that the radiation protection applied to the source must be optimized. Similarly, for accident situations the full assessment of the consequences must take into consideration the number of people affected and the level of harm to them, and the costs of and efforts required for improved safety. This aspect is sufficiently close to the ideas involved in the optimization of protection.

# 6. LIMITS ON SOCIETAL RISK OR JUSTIFICATION?

As indicated before, societal risk limits have been proposed and utilized for many aspects of radiation safety, for instance in relation to the probability and consequences of reactor accidents. Societal risk limits do not follow directly from the principles of protection developed by the ICRP, whose extension to probabilistic exposures has been suggested before. Conceptually, however, societal risk limits may have a logical connection with the ICRP principle of justification. This logical connection has still to be explored.

## 7. SUMMARY

The problems in dealing consistently and coherently with normal exposures assumed to occur with certainty and potential exposures of a

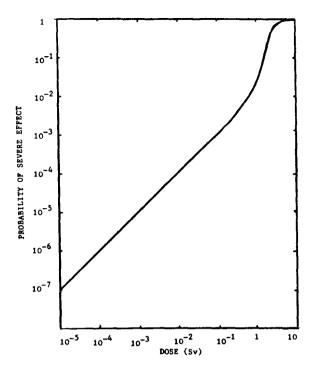


Fig.1: INDIVIDUAL PROBABILITY OF SEVERE HARMFUL EFFECT VERSUS RADIATION DOSE

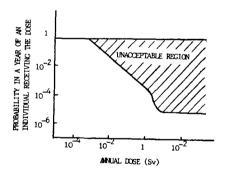


Fig. 3: CRITERION CURVE CORRESPONDING TO AN ANNUAL RISK CONSTRAINT OF 10<sup>-5</sup>FROM ALL EVENTS

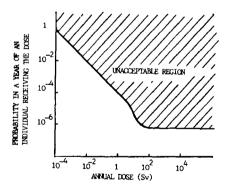


Fig. 3: CRITERION CURVE CORRESPONDING TO AN ANNUAL RISK CONSTRAINT OF 10 FROM ALL EVENTS

probabilistic nature have been explored. An IAEA project has suggested how a start might be made to work towards such a unified approach to radiation safety and has proposed the use of a risk based system. The paper briefly summarizes some aspects of the proposal.

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