## **ANNEXES**

ANNEX I

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EXPLANATORY MATERIAL ON THE 1990 RECOMMENDATIONS OF THE

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

#### EXPLANATORY MATERIAL ON THE 1990 RECOMMENDATIONS OF THE ICRP

(1) The ICRP Recommendations are intended to be of help to regulatory and advisory agencies in establishing national regulations and practices and to management bodies and their professional staff in carrying out their own operations. They deal only with ionizing radiation and with the protection of man, in the belief that the protection standards which are adequate to this purpose can ensure the protection of other living species although not necessarily of specific individuals of those species. The Commission emphasizes that ionizing radiation is only one of several existing sources of risk; it needs to be treated with care rather than fear and its risks should be kept in perspective with other risks. Radiological protection cannot be conducted on the basis of scientific considerations alone. All those concerned have to make value judgments about the relative importance of different kinds of risk and about the balancing of risks and benefits.

#### Quantities used in Radiological Protection

The Commission uses macroscopic dosumetric quantities which are justified empirically by the observation that the gross amount of energy deposited in a given mass of material coordinates fairly well with the resulting biological effects. In so doing it is recognized that microdosimetric quantities based on the statistical distribution of events in a small volume of material, corresponding to the dimensions of biological entities affected by radiation such as the nucleus of the cell or its molecular DNA, may eventually be considered more appropriate. The principal dosimetric quantities in radiological protection are the mean absorbed dose in a tissue or organ,  $D_p$  namely the average energy absorbed per unit mass of the irradiated tissue or organ; the equivalent dose in a tissue or organ,  $H_p$  formed by weighting the mean absorbed dose by a radiation weighting factor,  $w_R$  depending on the type and energy of radiation incident upon the body or from sources within the body; and the effective dose, E, formed by weighting the equivalent doses in the different tissues and organs by the weighting factors,  $w_T$  for these tissues and organs and summing over all tissues. It is given by the expression

$$E = \sum_{T} w_{T} \cdot H_{T}$$

The time integral of the effective-dose rate following an intake of a radionuclide is called the committed effective dose,  $E(\tau)$ , where  $\tau$  is the integration time (in years) following the intake. This time is usually assumed as 50 years for adults and from age of intake to age 70 years for children. The unit of absorbed dose is the gray (Gy), and the unit of both equivalent and effective dose is the sievert (Sv). The values of the radiation and tissue weighting factors are given in Tables 1 and 2.

#### Table 1 Radiation weighting factors

Type and energy range <sup>2</sup> Photons, all energies		Radiation weighting factor, W,		
		1		
Electrons and muon	is, all energies?	1		
Neutrons, energy	<10 keV	5		
	10 keV to 100 keV	10		
	>100 keV to 2 MeV	20		
	>2 MeV to 20 MeV	10		
	> 20 MeV	5		
Protons, other than recoil protons, energy >2MeV		5		
Alpha particles, fission fragments, heavy nuclei		20		

All values relate to the radiation incident on the body or, for internal sources, emitted from the source

The choice of values for other radiations is discussed in Annex A

Excluding Auger electrons emitted from nuclei bound to DNA

Table 2 Tissue weighting factors \*

Tissue or organ	Tissue weighting factor, W <sub>1</sub>
Gonads	0 20
Bone marrow (red)	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Bladder	0.05
Breast	0.05
Liver	0.05
Oesophagus	0 05
Thyroid	0 05
Skin	0 01
Bone surface	0 01
Remainder	0 05 *

The values have been developed from a reference population of equal numbers of both sexes and a wide range of ages. In the definition of effective dose they apply to workers, to the whole population and to either sex.

For purposes of calculation, the remainder is composed of the following additional tissues and organs, adrenals, brain, upper large intestine, small intestine, kidney, muscle, pancreas, spleen, thymus and uterus. The list includes organs which are likely to be selectively irradiated. Some organs in the list are known to be susceptible to cancer induction. If other tissues and organs subsequently become identified as having a significant risk of induced cancer they will then be included either with a specific  $W_{\gamma}$  or in this additional list constituting the remainder. The latter may also include other tissues or organs selectively irradiated.

In those exceptional cases in which a single one of the remainder tissues or organs receives an equivalent dose in excess of the highest dose in any of the twelve organs for which a weighing factor is specified, a weighing factor of 0.025 should be applied to that tissue or organ and a weighing factor of 0.025 to the average dose in the rest of the remainder as defined above

- (3) Other useful quantities are the collective equivalent dose in a given tissue or organ and the collective effective dose, which are the products, respectively, of the mean equivalent dose or the mean effective dose in a group and the number of individuals in the group. With some reservations, the collective effective dose can be thought of as representing the total consequences of the exposure of a population or group.
- (4) The Commission uses "dose" as a generic term that can apply to any of the relevant dosimetric quantities, and uses "exposure" in a generic sense to mean the process of being exposed to radiation or radioactive material. The significance of an exposure is determined by the resulting doses.

#### Biological Effects of Radiation Exposure

- (5) Ionizing radiation can cause both deterministic and stochastic effects in irradiated tissues. Radiological protection aims at avoiding deterministic effects by setting dose limits below their thresholds. Stochastic effects are believed to occur, albeit with low frequency, even at the lowest doses and therefore are taken into account over all the range of doses.
- Deterministic effects result from the killing of cells which, if the dose is large enough, causes sufficient cell loss to impair the function of the tissue. The probability of causing such harm will be zero at small doses, but above some level of dose (the threshold for clinical effects) the probability will increase steeply to unity (100%). Above the threshold, the seventy of the harm will increase with dose. Thresholds for these effects are often at doses of a few Gy or dose rates of a fraction of a Gy per year.
- (7) An important observation in children exposed in utero during the first 8-15 weeks of pregnancy, at Hiroshima and Nagasaki, is a downward shift in the distribution of IQ with increasing dose which can result, after higher doses, in an increase in the probability of severe mental retardation. The effect is presumed to be deterministic with a shift in IQ which is proportional to dose with a coefficient of about 30 IQ points per sievert and an apparent threshold which is determined by the minimum detectable shift in IQ that can be clinically identified. This limit of detection is about 3 IQ points which, therefore, corresponds to a dose threshold of about 100 mSv.
- (8) Stochastic effects may result when an irradiated cell is modified rather than killed. Modified somatic cells may subsequently, after a prolonged delay, develop into a cancer. There are repair and defence mechanisms that make this a very improbable outcome. Nevertheless, the probability of a cancer resulting from radiation increases with increments of dose, probably with no threshold. The seventy of the cancer is not affected by the dose. If the damage occurs in a cell

whose function is to transmit genetic information to later generations, any resulting effects, which may be of many different kinds and severity, are expressed in the progeny of the exposed person. This type of stochastic effect is called "hereditary".

- (9) The Commission has estimated the probability of a fatal cancer by relying mainly on studies of the Japanese survivors of the atomic bombs and their assessment by bodies such as UNSCEAR and BEIR. These committees have estimated the lifetime cancer risk by considering the accumulated data to 1985, new dose estimates made in 1986, and the projection of risk to lifetime by a multiplicative or modified multiplicative model, for high dose, high dose rate exposure. The Commission has concluded, after reviewing the available experimental information on dose-response relationships and the influence of dose and dose rate, that the most probable response is linear quadratic in form for low LET radiation. The linear coefficient at low doses or low dose rates is obtained from the high dose, high dose rate estimates of risk by dividing by a DDREF (dose and dose rate effectiveness factor) of 2. The nominal fatal cancer probabilities for a working population and for a general population, which differ somewhat because of the greater sensitivity of young people, are given in Table 3.
- 15 (10) The estimates of the dose-response relationship for severe hereditary effects are also based on the assessments
  16 of UNSCEAR and BEIR of experimental data on genetic effects in animals. Evidence suggests that the estimated effects
  17 are not less than the corresponding effects in man. For low dose and dose rates, the probability coefficient for severe
  18 hereditary effects in all generations (resulting about equally from dominant and X-linked mutations and from multifactorial
  19 diseases weighted for severity) are given for both a working population and a general population in
- 20 Table 3.

(11) The Commission uses the term detriment to represent the combination of the probability of occurrence of a harmful health effect and a judgment of the severity of that effect. The many aspects of detriment make it undesirable to select a single quantity to represent the detriment and the Commission has therefore adopted a multi-dimensional concept. The principal components of detriment are the following stochastic quantities: the probability of attributable fatal cancer, the weighted probability of severe hereditary effects and the length of life lost if the harm occurs. The values of this total aggregated detriment at low dose for both a working population and a general population are also given in Table 3.

Lable 3.	Nominal	probability	coefficients	Jor	stochastic	effects

Exposed population	Detriment (10°2Sv-1)°				
	Fatal Cancer b	Non-fatal cancer	Severe hereditary effects	Total	
Adult workers	4.0	0.8	0.8	5.6	
Whole population	5.0	1.0	1.3	7.3	

<sup>\*</sup> Rounded values

(12) The Commission has also assessed the distribution of the detriment in organs and tissues by considering first the fatal cancer probability in each of them, multiplying by an appropriate factor for non-fatal cancer (which is determined by the severity (lethality factor) for that cancer), adding in the probability of severe hereditary effects and adjusting for the relative length of life lost. This distribution of aggregate detriment among organs is represented, after appropriate rounding, by the tissue weighing factors,  $w_T$  given in Table 2.

#### The Conceptual Framework of Radiological Protection

#### Principles of the System of Protection

(13) A system of radiological protection should aim to do more good than harm, should call for protection arrangements that maximize the net benefit, and should aim to limit the inequity that may arise from a conflict of interest between individuals and society as a whole.

b For fatal cancer, the detriment coefficient is equal to the probability coefficient.

- (14) Some human activities increase the overall exposure to radiation. The Commission calls these activities "practices". Other human activities can decrease the overall exposure by influencing the existing causes of exposure. The Commission describes these activities as "intervention".
- (15) The Commission uses a division into three types of exposure: occupational exposure, which is the exposure incurred at work, and principally as a result of work; medical exposure, which is principally the exposure of persons as part of their diagnosis or treatment; and public exposure, which comprises all other exposures.
- (16) In practices and intervention, it will often be virtually certain that exposures will occur and their magnitude will be predictable, albeit with some degree of error. Sometimes, however, there will be a potential for exposure, but no certainty that it will occur. The Commission calls such exposures "potential exposures".

#### Potential Exposures

Potential exposures are those that could result from equipment failures, design or operating errors, or from changed conditions such as environmental changes occurring after the disposal of radioactive waste, changes in the way in which equipment or the environment is used. The possibility of such events can be foreseen and their probability of occurrence estimated, but they cannot be predicted in detail nor with certainty. The means for controlling potential exposures involve primarily the design of plant, equipment and operating procedures such as to limit the probability of occurrence of events that could lead to such unplanned exposures and to restrict the magnitude of exposures that could result if the events were to occur. The degree to which the risk should be limited can be determined by an optimization analysis that aims to find the design and operating options that will keep the risk as far below the risk constraints as is reasonably achievable. The criterion for judging whether the risk is as low as reasonably achievable is that any expenditure for further reducing the risk should be commensurate with the reduction in radiation risk that results from that expenditure. In other words, the objective is to limit the risk, where "risk" is broadly defined as the probability of an individual being exposed multiplied by the probability that the exposure will give rise to a deleterious health effect.

A spectrum of accidents may occur, and the total potential risk to an individual or to society is comprised of a summation of risks over the entire spectrum, taking into account the probability of occurrence and the consequences of each class of accidents. Thus, there is a probability distribution of risk which incorporates the probability of events and factors that could affect the exposure of individuals. For example, the factors generally considered when assessing the consequences of a release of radioactive substances to the atmosphere are the weather conditions and the wind direction Such probability distributions of risk form the basis for accident risk criteria, which could be a single number, a set of numbers, or a curve.

Taking individual risk of death as an example, the risk criterion could incorporate the probability of an accident occurring, the probability of a person being exposed and the probability of death resulting from the exposure. There could also be advantages in using a criterion curve which shows a varying level of tolerable risk, depending on the probability and magnitude of an accident. Factors such as greater aversion to large accidents could be taken into account, as could different degrees of concern for death occurring soon after an exposure or very much later.

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Particular problems may arise if the optimization for potential exposures is not independent of optimization for normal situations. For example, the optimization of the radiological protection for the normal operation of, a nuclear site may indicate that it is advantageous to trap and store on site short-lived gaseous fission products; however, this would concentrate them which could result in higher occupational exposures than if the gaseous fission products were released continuously as routine discharges. Other problems exist; for example, when considering the potential societal impact of accidents, how much weight should be given to factors such as anxiety, social disruptions and environmental effects? There is also a problem in defining risk. The magnitude of individual exposures in a potential exposure situation depends on the circumstances, and the so-called risk is really a probability distribution of risk, which raises the question of which percentile of the distribution to select for comparison with any pre-established risk criterion. If the uncertainties which are inherent in risk calculations are taken into account, the result could be a family of probability distribution curves which further complicates the problem. Further work is needed on such questions and problems before the control of potential exposures can be fully integrated into a comprehensive system of radiobiological protection that includes the control of both normal and potential exposures.

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#### The system of protection in practices

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(17)The system of radiological protection recommended by the Commission for proposed and continuing practices is based on the following general principles.

25 26 27 (a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice )

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(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedures should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit any inequity that could result from the inherent economic and social judgments. (The optimization of protection.)

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The exposure of individuals resulting from the combination of all the relevant practices should be subject (c) to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring

that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in normal circumstances. Not all sources are susceptible to control by action at the source and it is necessary to specify the sources to be included as relevant before setting a dose limit. (Individual dose and risk limits.)

In order to establish the link between the dose limit for individuals and the controls to be exercised on a given source, it is necessary to restrain the maximum dose to individuals that may result from that source to a fraction of the dose limit. Such individuals could then be exposed to other sources, presently existing or expected to arise in the future, without their cumulative dose exceeding the dose limit. Moreover, the principle of optimization of protection requires that the optimization procedure be constrained by a restriction on the dose to individuals in order to limit the inequity between individuals that might result from an uneven distribution of benefits and detriments within the exposed group. In order to satisfy the above two requirements, the Commission has introduced the concept of "Dose Constraint". A dose constraint is expressed in terms of individual dose but is applied to a single source and used as a ceiling on the levels of individual dose that can be considered when optimizing the protection for that source. In order to satisfy the above-mentioned requirements, the dose constraint has to be set at an appropriate fraction of the dose limit, taking into account possible exposures from present and future sources other than the one under consideration. Analogous considerations apply when the assessment and control of potential exposures is concerned, for which the Commission has introduced the parallel concept of "Risk Constraint".

The application of the above-mentioned principles to practices implies that the assessment, planning and control actions must address both normal operation and the potential of exposure from accidents.

#### The system of protection in intervention

(18) The system of radiological protection recommended by the Commission for intervention is based on the following general principles.

(a) The proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention.

 (b) The form, scale, and duration of the intervention should be optimized so that the net benefit of the reduction of dose; i.e., the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, is maximized.

Dose limits do not apply in the case of intervention. Principles (a) and (b) can lead to intervention levels which give guidance to the situations in which intervention is appropriate. There will be some level of projected dose above which, because of serious deterministic effects, intervention will almost always be justified.

(19) Any system of protection should include an overall assessment of its effectiveness in practice. This should be based on the distribution of doses achieved and on an appraisal of the steps taken to limit the probability of potential exposures. It is important that the basic principles be treated as a coherent system. No one part should be taken in isolation.

#### Types of exposures

Occupational exposure is that incurred by workers while at work, as a result of situations which can be considered as being under the responsibility of the operating management. With this definition, occupational exposure would include the exposure of workers due to artificial radiation sources and radioactive materials in a practice. Exposure to natural sources should also be considered as part of occupational exposure when it is controllable by the operating management and the levels of exposure are identified by the authorities as requiring regulatory control. Situations of this kind may include work in buildings and installations where the levels in the workplace are significantly above the normal ambient levels in the surrounding area due either to the presence of radon and its decay products or to the handling of naturally radioactive materials, and may also include occupational flying in jet aircraft. Controls on occupational exposure can be applied to all points of the network linking the source with the exposed individual, namely, at the source, in the environment (along the exposure pathways) and at the level of the individual.

Medical exposure is that incurred by individuals as part of their diagnosis or treatment as patients, or that incurred knowingly and willingly by individuals, other than medical and paramedical personnel, who visit or help in the comfort and support of patients exposed to radiation in diagnosis or treatment. Exposures incurred by medical and paramedical personnel are part of occupational exposure. The exposure of volunteers for purposes of biomedical research is also classified as medical exposure. Controls on medical exposure can also be applied to all points of the aforementioned network, although they are applied primarily to the source and, in some cases, to the individuals.

Public exposure encompasses all exposures incurred by persons other than occupational and medical exposures. Public exposure can result from practices and artificial sources, as well as from natural sources. It also includes the exposure of individuals to stray radiation from the diagnosis and medical treatment of other persons. Controls on public exposure are applied primarily at the level of the source and sometimes on the exposure pathways in the environment. The application of controls to the individuals can only be done in rare, special cases.

#### Application of the System of Protection to Practices

#### Justification of Practices

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According to the Commission, the decision to introduce a new practice should be made on the basis of a process of justification which initially involves a review of the benefits and radiation detriments associated with the practice. The practice is considered as justified when the balance between benefits and radiation detriments is positive, that is, when a positive net benefit can result from the introduction of the practice.

Analogously, the justification of an existing practice may need to be reviewed when substantial changes are made to the protection system or conditions in the practice, or when new alternative practices are proposed. The continuation of the practice is justified if it results in a positive net benefit; otherwise, the discontinuation of the practice should be considered or action should be taken to decrease the detriment to the point that there is once again a positive net benefit. The process of justification should address all aspects relevant to radiation protection, including the detriment associated with normal and potential exposures, the trade-off between occupational and public exposure, and the costs of protection.

However, radiation protection considerations are only one of the elements of judgment to be included in the decision-making process leading to the overall justification of the practice. Other factors are relevant to this process, including non-radiological detriments and social and political considerations.

The level of responsibility involved in the justification decision (by society, political authorities, regulatory authorities, management bodies, or radiation protection specialists) depends on the size and complexity of the practice and the associated problems. For example, the decision about the justification of a nuclear power programme is the responsibility of the national political authorities and society, the justification of a medical mass screening operation is decided by national medical authorities, and the justification of an individual medical procedure with radiation is the responsibility of the concerned medical practitioner.

In the case of medical exposures, the justification process should be first applied to broadly defined practices. However, each diagnostic or therapeutic procedure is subject to a separate decision, so that there is an opportunity to apply a further, case-by-case, justification for each procedure. This will not be necessary for simple diagnostic procedures but may be important for complex investigations and for therapy.

#### Optimization of protection

Once a practice is justified, the design and operating objectives that guarantee the best use of resources in reducing the radiation risks to individuals and to populations should be sought. This is the process of optimization. The main factors playing a role in the process of optimization are the collective and individual health detriments and the costs associated with different protection options. For the purposes of the optimization analysis, the health detriments can be adequately represented by the individual and collective effective doses.

The detriments which could result from potential exposures should also be considered. However, because these potential detriments can not be expressed in terms of dose, the trade-offs between normal and potential exposures require a separate treatment in the optimization process. Guidance on this matter is still being developed.

The process of optimization usually ends up in the selection from available protection options of the option that offers the best balance between factors such as collective and individual dose reductions, commitment of resources, and preferences between different kinds of detriment. The broad aim is to ensure that magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures which are not certain to be received, are all kept as low as reasonably achievable, economic and social factors being taken into account. The optimized option can be characterized by numerical values of design and operating parameters such as dose to the critical group, ambient radiation levels, activity concentrations, ventilation flows, and effluent discharge rates. These values should be compared with any pre-established constraints and any option having a value exceeding a constraint should be rejected. The next best option which satisfies the constraints should then be considered.

Conceptually, the optimization principle leads to case-by-case assessments. However, there are situations where a standardized approach is possible for common, routine protection measures. A standardized approach to optimization could be appropriate, for example, for the design of mass-produced equipment or for planning repetitive operations or standard medical procedures. Such a standardized approach can be further refined if necessary by a case-by-case optimization analysis, taking into account the specific circumstances.

In some situations, attempts to reduce one type of exposure may result in an increase in another type of exposure. Optimization of protection for a given practice may therefore involve trade-offs between the different types of exposure. For example, measures for to reducing public exposure from the discharge of radioactive effluents to the environment could result in increased occupational exposure due to additional requirements for waste processing and storage. Trade-offs between potential exposure, occupational exposure and public exposure could occur, for example, in the implementation of some nuclear safety requirements such as in-service inspection. Such inspection could decrease the likelihood of potential exposures by reducing the probability of an accident, but increase the exposure of workers due to inspection activities in high radiation fields. Trade-offs could also arise when deciding between waste management options that involve either present or future exposures.

#### Dose Constraints

The Commission recommends the use of constraints as part of the process of optimization and also to ensure that individual dose limits are not exceeded due to exposure of a given individual to more than one controlled source. Dose constraints are conceptually different from dose limits: the limits are absolute in nature and can only be exceeded in exceptional circumstances, whereas constraints are more in the nature of levels of good practice which are intended to ensure that individuals do not receive unnecessarily high doses from any particular source. Constraints operate in two ways: first, to provide criteria for the maximum exposure to be envisaged when designing a new plant or when planning a work programme. The second use of constraints is to act as a means of triggering investigations into the circumstances surrounding the exposure of individuals from the viewpoint of whether doses are as low as reasonably achievable. On the other hand, compliance with this constraint does not necessarily indicate that the protection is optimal.

#### Dose Constraints for Occupational Exposure

The first step in establishing dose constraints is to determine the presently existing dose distributions, identify the worker groups receiving the higher doses, and determining the reasons for the higher doses. The objective is to determine what levels of individual dose are 'reasonably achievable' in given circumstances, not just what levels are 'technically achievable'. A level at the upper end of the distribution of reasonably achievable doses would be a sensible choice for the dose constraint, bearing in mind that the maximum value of occupational constraint recommended by the Commission is 20mSv per year.

It is recommended that dose constraints be established for broad sectors of occupations, recognizing that there may be some categories of workers for whom separate dose constraints would be appropriate. For example most of the higher doses within the occupation of nursing are received by radiotherapy nurses. The only useful way of applying constraints to nursing is to set appropriate constraints for such specialized nurses and lower constraints for other nursing activities. In general, constraints should be based on the results of generic optimization studies taking into account the exposures incurred in well managed operations.

The protection in some occupations is already at an optimum level and dose constraints are therefore likely to be of little value. If constraints are nevertheless used, they should be set at the levels determined by an optimization analysis even if such levels are significantly higher than the doses achieved in practice. This is to prevent ratcheting of standards to become more restrictive than is necessary or desirable.

Large organizations, such as many of those in the nuclear industry have the necessary infrastructure to set siteand use-specific constraints, indeed a number effectively do this. Such constraints should be established by management in consultation with worker representatives and safety committees. For smaller organizations, the qualified expert can provide appropriate advice.

Since the definition of types of occupation for which constraints are established is often not very precise, it would generally not be appropriate to consider constraints in the same regulatory sense as dose limits. Rather, constraints are more in the nature of investigation levels.

#### Dose Constraints for Public Exposure

Dose constraints for the public generally relate to overall exposure pathways, arising from the current and future operation of a controlled source, where a 'controlled source' is the totality of all sources and practices at a single location, such as all the sources at a hospital, all reactor units at a nuclear power site, an industrial site using several sources or a vehicle transporting radioactive sources. The exposures of concern include those due to controlled discharges and external irradiation from the site of the controlled source, and the exposure pathways include those expected to arise in the future that can be influenced by current control procedures. Exposures arising from past discharges from the site are not included because they cannot be influenced by on-site control procedures. Any other exposures arising from past operations, where the source of the exposure is currently on the site, are included because they can be influenced by current procedures. For example, radioactively contaminated material resulting from past operations, but currently stored on site, is unlikely to irradiate the public as long as it remains under on-site control.

One means of implementing the dose constraints for a controlled source is by setting authorized levels for a site. In circumstances where an authorization does not cover all pathways arising from operations at a site, such as when liquid and gaseous discharges are authorized separately, the exposures from all pathways should be taken into account when setting authorized levels for any individual pathways. Other factors to consider include the levels of exposure achieved elsewhere for similar operations and exposures from past discharges. It is therefore entirely reasonable if authorizations are set at levels which imply lower doses to members of the public than indicated by the relevant dose constraint.

The IAEA has recommended dose constraints from 0.1 to 0.5 mSv per year, the exact value depending on the location and nature of the controlled source. These constraint values allow for contributions to individual dose from the global distribution of radionuclides released from practices, from contributions from other sources in the region, and for possible future practices which are unknown at present, and are appropriate for application to controlled sources from which most of the exposed individuals receive a benefit and where the operation is considered to benefit society as a whole (e.g. electricity generation). It is recommended that lower dose constraints be set for controlled sources which either provide little benefit to the most exposed individuals or which are not considered to significantly benefit society as a whole (e.g. public exposure from radon spas or tourist caves). Since the doses to be compared with dose constraints include only those

that can be altered by changes in the control of the source, compliance with a dose constraint is generally demonstrated by calculating the exposure of members of the public from the measured discharges and from any direct irradiation from the controlled source. Assessment of compliance by direct measurements of environmental contamination or individual dose is generally not appropriate because such measurements would usually include contributions from other controlled sources, from past discharges and from natural background radiation, all of which can be very difficult to distinguish from the contribution from the controlled source in question.

Since the application of dose constraints can influence the operational control of a source, estimates of doses to the public should be realistic (as opposed to over- or under-estimations), otherwise operational decisions could be taken which result in smaller doses to members of the public, but with higher costs and possibly higher doses to workers than would be truly optimum. Realism is required at all stages of the dose assessment, when estimating discharges and levels of direct irradiation, when modelling exposure pathways and when making assumptions concerning the location, habits and characteristics of the exposed individuals. It is also important to understand the uncertainties inherent in the models and assumptions used.

 The dose to be estimated for comparison with a dose constraint for the public is generally the average dose to the critical group, where a critical group is representative of those members of the public who receive the highest doses from a particular controlled source.

#### Methods for Justification and Optimization

Several methods are available for justification and optimization analyses. They range from relatively simple analytical techniques such as cost-benefit analysis, where all the relevant parameters can be treated quantitatively, up to complex decision-aiding methods such as multi-attribute analysis, where a broad spectrum of factors, not all hable to quantification, are to be integrated into the assessment

In many cases optimization of protection does not require specific analytical tools, but can be carried out largely on the basis of common sense and good professional judgment. This is often the case in the planning of individual operations in an installation, and in the establishment of diagnostic or therapeutic procedures involving radiation

As said before, actual and potential exposures need to be treated separately in a justification or optimization analysis. In order to integrate them into a unified treatment, it is necessary to extend the concept of detriment to include the probability of occurrence of the situation giving rise to the detriment. Techniques for achieving this are still being developed. Nevertheless, the integration of actual and potential exposures is possible for those situations where the individual and collective doses will be small even if the event occurs. In other words, if a dose will not be in excess of the dose limit and its probability of occurrence is relatively high, it is adequate to consider the product of the expected dose and its probability as it were a dose that was certain to occur. The conventional procedures of justification and optimization can then be applied.

### Individual Dose and Risk Limitations

Individual dose limits are needed for occupational and public exposures both to impose a limit on the choice of dose constraints and to provide a guarantee against errors of judgment when optimizing protection, especially in view of the fact that the detriments and benefits are generally not distributed equally among the persons involved. The concept of dose limit is that the limit should be set such that continued exposure at a dose just above the limit would be widely regarded as unacceptable. Continued exposure just below the dose limit would be just tolerable, while acceptable doses would be those that occur when the protection has been optimized.

Different considerations apply in the case of medical exposure. In effect, medical exposures are meant to provide a direct benefit to the exposed individuals and, therefore, the distributions of detriment and benefit are accrued by the same individual. If the medical practice is justified and the protection optimized, the dose in the patient will not be higher than what is required to achieve the desired medical objective. Any further application of individual limits could be to the patient's detriment. For these reasons, the Commission recommends that dose limits not be applied to medical

exposures. For these same reasons, the dose received by persons from medical exposures should not be considered when examining compliance with the dose limits for occupational and public exposures.

#### Dose Limits for Occupational Exposure

In the past, the Commission has used the attributable probability of death or severe hereditary disorders as the basis for judging the consequences of an exposure. This quantity is still a major factor, but is no longer regarded as sufficient to describe the health detriment. Other factors have now been considered, including the length of life lost if the attributable death occurs, and the incidence of non-fatal cancers and hereditary disorders weighted for their severity relative to fatal cancer. With these considerations and with appropriate subjective assumptions regarding tolerability, the Commission has chosen as the basis for the definition of the dose limits for workers an effective dose of 1 Sv received moderately uniformly over a working lifetime of about 50 years. However, it would be inappropriate to use a lifetime dose limit in practical radiation protection and, therefore the Commission recommends that the dose limit be fixed on an annual basis, with some flexibility to accommodate transient operational requirements. The resulting dose limit system is an effective dose of 20 mSv per year, averaged over 5 years (100 mSv in 5 years) with the further provision that the effective dose must not exceed 50 mSv in any single year. The limits apply to the sum of all relevant doses from external exposure in the relevant periods and the committed doses from intakes of radionuclides during the same periods.

The occupational dose limits are meant to be applied to all occupational exposures including those resulting from minor mishaps in operation and minor unplanned events or incidents. This is an extension of the previous concept of dose limits and adds further stringency to the protection requirements recommended by the Commission. With respect to the relationship between the dose limit and the dose constraints for workers, the annual limit of 20 mSv is to be seen as a ceiling on the range of dose constraints that could be chosen for a given worker or group of workers in a given practice.

The Commission recognizes that, for some practices, it may be difficult to apply the increased stringency of protection requirements immediately to some equipment and operations that already exist. In these cases, regulatory bodies may need to consider transitional arrangements including interim higher dose limits to allow time for implementing the new requirements.

The level of protection provided by the system of protection for workers is adequate to guarantee the protection of the unborn child of a pregnant worker until pregnancy is recognized, and, therefore, the Commission does not recommend any special occupational dose limit for women. However, when pregnancy has been declared, supplementary restrictions should be applied so as to limit the dose to the surface of the woman's abdomen to 2 mSv for the remainder of the pregnancy, and to limit intakes of radionuclides to about 1/20 of the ALI. These restrictions are intended to provide the conceptus with a standard of protection broadly comparable with that for members of the general public.

#### Dose Limitation in Medical Exposure

The Commission recommends that no individual dose limits be applied during medical exposures, but that dose constraints be used when optimizing protection during the establishment of diagnostic and therapeutic protocols. In this field, however, constraints are to be seen as closer in concept to reference or investigation levels than to regulatory limits that must not be exceeded. The importance of constraints is that they will cause an investigation to be carried out if average doses for a particular medical procedure are consistently higher than the specific constraint established for that procedure. Such a situation should trigger an investigation, which could result in modifications to the procedure unless clinical factors justify the continuation of the original procedure. In other words, constraints in medical exposure should be applied with flexibility, to allow higher doses where indicated by sound clinical judgment.

#### Dose limits for public exposure

The control of public exposure in normal situations is generally exercised by the applying controls at the source rather than in the environment or on the individuals. Control is achieved almost entirely by the procedures of constrained optimization rather then by the use of dose limits, because the dose limits are rarely limiting in practice. Nevertheless, the Commission considers it appropriate to continue to recommend dose limits for public exposure so as to provide a limit on the choice of source-related dose constraint.

The dose limit for members of the public is set at a value that is considered to be just short of unacceptable for continued exposure resulting from practices which are a matter of choice. Such practices include the operation of installations such as mines and waste disposal sites which could expose the public to naturally occurring radiation and radionuclides. On the other hand, the exposure to naturally occurring radiation and radionuclides in dwellings and the open air, and to radioactive materials (natural or artificial) already present in the environment, is not a matter of choice and can only be influenced by intervention. Doses from these sources are, therefore, outside the scope of dose limits for public exposure

In addition to doses from normal operation, transient increases in dose resulting from variations in effectiveness of control procedures should also be subject to the dose limits. Some flexibility might be required in order to allow for such variations, which the Commission has provided by allowing for effective doses greater than 1 mSv in some years provided that the average over 5 years does not exceed 1 mSv per year.

#### Individual Risk Limitation in Potential Exposures

The principle of individual dose limits may be extended to potential exposures by specifying a risk limit which takes into account not only the probability of a detrimental health affect occurring as a result of an exposure, but also the probability of occurrence of the situation giving rise to the exposure. This would result in an overall individual probability of harm, for which a restriction corresponding to the dose limit for normal operating conditions could be expressed in the form of a risk limit for all the potential scenarios and event sequences that could affect an individual. This risk limit should be of the same order of magnitude as the health risk implied by the dose limit for normal exposures.

This use of the overall radiation risk is a good starting point for use in limiting potential exposures, but it is not sufficient. Potential scenarios or event sequences may be characterized by probabilities of occurrence and levels of dose, including doses above the dose limit for normal exposures and even above the threshold for deterministic effects. This suggests that an overall risk limit would be of limited use and should be supplemented by specific source-related risk constraints for the various potential scenarios and event sequences associated with any particular source. No detailed guidance has been provided yet by the Commission on this matter and work is being carried out to develop criteria for setting risk limits and constraints.

### Application of the System of Protection to Intervention

 The system of protection applied to practices can be adapted to "intervention" situations; that is, to situations where a source of exposure is not under control, not planned in advance, and already in place. The exposure of people in such situations can only be influenced by intervention. These situations, which may be linked to the existence of natural radiation sources or to radioactive contamination resulting from a nuclear or radiological accident, expose mainly members of the public, but may also include occupational exposure during some radiological emergencies. In all cases, the same basic principles of intervention apply, namely the justification of interventions and the optimization of the nature, scale and duration of the intervention measures.

The concept of individual dose limits as defined for practices does not apply to interventions. When an intervention is considered justified and its features are optimized, the resulting guidance for initiating intervention is normally in the form of a reference level called an intervention or action level. Intervention levels are generally expressed in terms of individual dose or a derived quantity such as ambient radiation or contamination level, or activity per unit mass of foodstuffs. Intervention or action levels should generally be set by the regulatory authorities or by an operating organization, usually as a result of an optimization analysis.

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Optimization of intervention measures involves a balance between the benefits of the intervention (in terms of radiological detriment averted), its costs (economic as well as social) and its non-radiological risks. All these factors depend on local circumstances and it is therefore not possible to define quantitative intervention or action levels for rigid application in all cases. Nevertheless, because some actions may be needed urgently, such as in the aftermath of a nuclear accident, it is often appropriate to prepare guidance in advance. For example, "generic" intervention levels may be derived, based on generic accident scenarios, which can serve as criteria for action in the early stages of an emergency before sufficient information becomes available for a fuller assessment of the situation and the optimization of the intervention measures.

# Long Standing Existing Situations

Many situations which can be dealt with by intervention are of long standing and, therefore, do not call for urgent action. Most typical of such situations is the natural exposure of people in dwellings where high concentrations of radon and its decay products can be found. Large numbers of people are exposed and the resulting individual and collective doses are higher than from almost any other source; even higher in some cases than would be permitted for occupational exposure. The only way to reduce the risk to the exposed people is to modify the dwellings or the behaviour of the occupants. The choice of action level for this kind of intervention is very complex, depending not only on the level of exposure but also on the economic and social implications of any action. The justification and optimization analyses may well lead in some cases to an action level corresponding to a dose numerically higher than the dose limit for public exposure from practices. This is a further confirmation of the inappropriateness of applying the dose limits for practices to interventions.

Another example of a long standing situation to be dealt with by intervention is the presence in the environment of long-lived radioactive residues from previous events such as early mining operations or luminizing with radium compounds. These residues can affect the exposure of people in agricultural areas where residues have been dumped and, in some cases in residential building areas where such residues have been used as land-fill material.

In these situations intervention may vary greatly in complexity and scale. The need for and the extent of remedial actions have to be judged by balancing the benefit of reducing exposures that would occur in the absence of intervention against the detriment resulting from the remedial work, including that due to exposure of workers involved in the remedial actions. No general solutions are available, and each case must be assessed on its own ments by using the methods of optimization of protection. Again, the optimization process may lead to an action level which would permit some members of the public to receive doses greater than the dose limit for public exposure from practices. However, any occupational exposure incurred in an intervention and its associated waste management activities should be controlled in accordance with the Commission's recommendations for practices

#### Post-Accident Situations

Accidents and other radiological emergencies are considered as potential events which could lead to potential exposures in a practice, and the limitation of their likelihood and the mitigation of possible consequences are dealt with primarily in the design and operation of practices. However, when an accident occurs, the resulting contamination of the environment and continuing exposure of people constitutes an existing situation that can only be affected by intervention. Justification of the intervention and optimization of the features of the intervention apply fully to this situation. The justification process should generally identify a range of possible corrective actions which vary in scale and duration and correspond to varying levels of obtainable benefit in terms of reduction of dose to the exposed people. The optimization analysis of this range of available options leads to an optimized value of the individual dose that can be averted and this value, called the intervention level, is used to trigger the corresponding protective measure. The intervention levels resulting from optimization are primarily expressed in terms of averted individual dose, but in practice it is usually necessary to derive from them operational intervention levels in terms of quantities that can be more easily assessed or measured such as projected individual dose, gamma exposure rate, or activity concentrations in the environment or in foodstuffs.

A particular case of intervention in a post-accident situation concerns the exposure of workers during urgent emergency or remedial actions. When the intervention is justified and considered necessary, the doses to such workers may well exceed the dose limits for occupational exposure in practices. Nevertheless, substantial efforts should be made to keep the doses below the relevant threshold for deterministic effects, except in the case of life-saving actions when doses in excess of the threshold may be unavoidable.